This publication was approved by the Correctional Managed Care Pharmacy & Therapeutics Committee that includes representatives from the Texas Department of Criminal Justice Health Services Division, the University of Texas Medical Branch Correctional Managed Care, and the Texas Tech University Health Sciences Center Office of Correctional Managed Health Care.

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<tr>
<td>Almonte, Alina</td>
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<tr>
<td>Abraham, Johns</td>
<td>409-747-2780</td>
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<tr>
<td>Dalehite, Celeste</td>
<td>409-747-2777</td>
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<td>Morris, Joyce*</td>
<td>409-880-0381</td>
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<tr>
<td>Phan, Sonja</td>
<td>409-747-2783</td>
</tr>
<tr>
<td>Ruiz, Karen</td>
<td>409-747-2779</td>
</tr>
<tr>
<td>Thomas, Alex</td>
<td>409-747-2778</td>
</tr>
</tbody>
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UNIT RESTRICTION LIST FOR FLOOR STOCK PURPOSES

**Dialysis Units:** GC, E2, HP

**Female Units:** BB, GC, GR, GV, HB, HT, LC, LJ, LM, LT, MV, N1, N2, SV, WM, XQ

**HCV Centers of Excellence:** BX, GC, J3, ST, WM

**Hospice:** JA, MI, GC-RMF

**Hospital Galveston:** No P-list restrictions. All medications administered from stock.

**Infirmaries:** AH, 0B, B2, CY, J3, MI, ML, P1, P2, R3, ST, TL, TO

**Intake Facilities:** DU, ND, NE, NF, NH, SAJP facilities, State Jails

**Phototherapy Center:** E2-RMF

**Psychiatric Inpatient Units:** BC-PAMIO, J4, JM, SV

**Regional Medical Facilities:** BC, E2-RMF, GC-RMF, HP, JA, JM, RB

**SAFP Facilities:** BB, E2, GV, J1, JT, KY, LT, SO, SY, XQ

**State Jails:** AJ, BH, BJ, BL, BX, CL, FB, HF, HJ, HM, LJ, LN, LT, RL, RZ, TI, WI, WM, WR

**Therapeutic Diversion Program Facilities:** AH, MI

**Transient Facilities:** 0B, BC, DA, DU, E2, EA, FE, GR, GV, HV, ML, ND, N1, N3, N4, N5, N6, NE, NF, NH, RB, TH, WY, State Jails

**Wheelchair Units:** BA, BJ, BY, DU, GL, LM, N6, Regional Medical Facilities, Infirmaries

**Wound Care Units:** BC, E2-RMF, GC-RMF, JA, J3, JM, RB

SAFP = Substance Abuse Felony Punishment
CONVERSIONS AND CALCULATIONS

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<th>WEIGHT MEASURE</th>
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<tr>
<td>1 kg (kilogram) = 1000 gm (grams)</td>
<td>METRIC=APOTHECARY</td>
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<td>1 gm = 1000 mg (milligrams)</td>
<td>1 mL (milliliter) = 1 cc</td>
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<tr>
<td>1 mg = 1000 mcg or µg (micrograms)</td>
<td>30 mL = 1 oz</td>
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<tr>
<td><strong>METRIC=APOTHECARY</strong></td>
<td>15 mL = 1/2 oz</td>
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<tr>
<td>60 mg or 65 mg = 1 gr (grain)</td>
<td>15 mL = 1 tablespoon (tbsp.)</td>
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<tr>
<td>125 mg = 2 gr</td>
<td>5 mL = 1 teaspoon (tsp.)</td>
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<tr>
<td>200 mg = 3 gr</td>
<td>2.5 mL = 1/2 tsp.</td>
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<tr>
<td>300 mg or 325 mg = 5 gr</td>
<td>960 mL = 1 quart</td>
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<td>600 mg or 650 mg = 10 gr</td>
<td><strong>1 L (liter) = 1000 mL (milliliters)</strong></td>
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<td>0.4 mg or 400 mcg = 1/150 gr</td>
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<td>0.6 mg 600 mcg = 1/100 gr</td>
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<td>15 gm = ½ oz</td>
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<td>30 gm = 1 oz</td>
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<td>60 gm = 2 oz</td>
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<td>240 gm = 8 oz = 1/2 lb</td>
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<tr>
<td>480 gm = 16 oz = 1 lb</td>
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<td>1 kg = 2.2 lb (pounds)</td>
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To convert from grams to milligrams multiply by 1000, milligrams to grams ÷ by 1000
To convert from kilograms to pounds multiply by 2.2, pound to kilograms ÷ by 2.2
To convert from grains to milligrams multiply by 60, milligrams to grains ÷ by 60

Formula for Calculating the Volume of a Solution Needed to Give a Certain Dose:
Solution Available: A mg / B mL, Dosage Necessary is C mg /? mL
Formula: C x B then divide by A
Example: Solution available is 100 mg / 5 mL. Dose ordered is 60 mg. What volume (mL) should be administered?  60 X 5 = 300 divided by 100 = 3 mL

Formula for Calculating Drip Rate of IV Fluids:
\[
\text{total volume} = \frac{\text{mL/hr}}{\text{total hours}} \quad \text{Example:}\quad \frac{1000 \text{ mL}}{8 \text{ hr}} = 125 \text{ mL/hr}
\]

Formula for Calculating Drops (gtts) Per Minute (min): \(\text{mL/hr} \times \text{gtts/mL} = \text{gtts/min}\)
Example: \(\frac{125 \text{ mL/hr} \times 10 \text{ gtts/mL}}{60 \text{ min}} = \frac{125 \times 10}{60} = 1250 \text{ or 21 gtts/min}\)
OVERVIEW
The rising cost of health care in the Texas prisons prompted the 73rd Texas Legislature to enact Senate Bill 378 that established the Texas Correctional Managed Health Care program (CMHC). The Texas CMHC program represents a legislatively established partnership between the Texas Department of Criminal Justice (TDCJ), the Texas Tech University Health Sciences Center (TTUHSC) and the University of Texas Medical Branch at Galveston (UTMB). TTUHSC manages the care of the western 20% of the state and UTMB the remaining 80%. The partnership is governed by the Correctional Managed Health Care Committee (CMHCC) and is responsible for providing comprehensive health care services to all adult offenders incarcerated in Texas state prisons and state jails.

The mission of the CMHC program is to develop a statewide managed health care network to address three key goals:
- providing TDCJ offenders with timely access to care consistent with correctional standards;
- maintaining a quality of care that meets accepted standards of care; and,
- managing the costs of delivering comprehensive health care services to a growing and aging offender population.

These goals can only be realized by promoting communication between the unit level primary care providers, specialty physicians, and tertiary, referral hospitals.

UNIT LEVEL HEALTH CARE
Each prison in the state has a local, primary health care program. It consists of a team of physicians, physician assistants, advanced practice registered nurses, dentists, nurses and assistants. These primary care providers (PCP) are responsible for providing care at the unit level. Health care services including medical, dental and mental health are available at each unit.

All offenders have access to health care services. Each facility within TDCJ has written procedures which describe the process for offenders to gain access to the care needed to meet their medical, dental and mental health needs.

Under the correctional health care program, offenders are provided with those health care services determined to be medically necessary. Consideration of medical necessity involves determinations that the service(s) to be provided are:
- appropriate and necessary for the symptoms, diagnosis or treatment of the medical condition;
- provided for the diagnosis or direct care and treatment of the medical condition;
- within standards of good medical practice within the organized medical community;
- not primarily for convenience; and,
- the most appropriate provision or level of service which can be safely provided.
UTILIZATION REVIEW
Referrals made by PCP for certain types of care (e.g., specialty clinics, procedures, surgery) require prior authorization through the utilization review process. Utilization management and review is a physician-driven system for making individual evaluations as to medical necessity. The review process entails consulting national accepted standards of care and comparing the individual circumstances of each case. Determinations made through the utilization management and review process may be appealed by the referring provider for additional review and decision in accordance with established procedures.

If the referral is appropriate, an appointment is scheduled and the unit is informed. If a referral is redirected or deferred, an explanation and a recommended treatment alternative are given. Specialty telephone consultation may also be coordinated by the UR Nurses. For immediate or emergent admission, the unit physician should call the UR Nurse at 1-800-605-8165 (FAX 409-762-2765) for expedited approval.

SECURITY
The goals of the unit level health facility and TDCJ are (1) to provide excellent, cost effective, and timely access to care and (2) to maintain complete security (65th Texas Legislature).

CMC FORMULARY & DISEASE MANAGEMENT GUIDELINES
A standard statewide formulary is maintained by the Pharmacy and Therapeutics Committee and updated as needed and at least annually. This committee meets regularly to review the use of drugs within the health care system, evaluate agents on the Formulary and consider changes to the available medications. All medications prescribed for offenders must be listed in the Formulary, unless specific medical necessity exists for authorizing a non-formulary medication. In such circumstances, a request for non-formulary approval will be processed and evaluated. Non-formulary determinations may be appealed by the referring provider for additional review and decision in accordance with established procedures.

In addition to the Formulary, the Pharmacy and Therapeutics Committee develops and maintains disease management guidelines that outline recommended treatment approaches for management of a variety of illnesses and chronic diseases. These guidelines are reviewed regularly and updated as necessary. Disease management guidelines focus on disease-based drug therapy and outline a recommended therapeutic approach to specific diseases. They are typically developed for high risk, high volume, or problem prone diseases encountered in the patient population. The goal is to improve patient outcomes and provide consistent, cost-effective care, which is based on national guidelines, current medical literature, and has been tailored to meet the specific needs of the patient population served. Disease management guidelines are not meant to replace sound clinical judgment nor are they intended to strictly apply to all patients.

DISCHARGE PLANNING & CONTINUITY OF CARE
All patients will be switched to a CMC Formulary medication (if appropriate) at the time of discharge from subspecialty clinics and hospitals. A copy of the CMC Formulary is located at Hospital Galveston.

Non-formulary approval at the unit level is obtained by completing an electronic non-formulary request form and forwarding it to the assigned clinical pharmacist for a consultation. If the unit
provider disagrees with the clinical pharmacist’s recommendation, approval may be requested from the Regional Medical Director. Non-formulary procedures for UTMB clinic/discharge patients can be found under subsection NON-FORMULARY APPROVAL PROCESS FOR DISCHARGE/CLINIC PATIENTS.

OVERVIEW OF HOSPITAL GALVESTON PROCESS

Offenders transferring from Hospital Galveston (HG) to Texas Department of Criminal Justice (TDCJ) units will have all active medication orders entered into the Pearl EHR/PRS system by the Hospital Galveston Pharmacist (Pharmacy Policy 10-50). Orders must be entered and will be filled for critical medications prior to the patient’s departure. This will be done for all patients being discharged from the inpatient setting.

Medications will not be routinely entered into the Pearl EHR/PRS system for outpatients. However, the HG practitioner may fax orders to the HG Pharmacy for any medication that is considered critical and that must be started immediately prior to the patient’s return to his or her unit of assignment. Orders must be written on the TDCJ Discharge Prescription Fax Form and must specify drug, strength, route, frequency, KOP status and duration.

The Hospital Galveston pharmacy will dispense a 10-day supply of critical medications with no refills. Formulary medications will be supplied from facility unit stock. The HG pharmacists should use their professional judgment when determining if a medication is critical and should be sent with the patient.

The CMC Pharmacy and Therapeutics Committee will maintain the list of medications that have been deemed as critical. The list of critical medications is not inclusive. Critical medications are defined as:

- Anti-infectives – formulary and non-formulary agents
- Anti-platelets (e.g., clopidogrel, prasugrel, ticagrelor)
- Immunosuppressants – formulary and non-formulary agents
- Ophthalmic preparations – formulary and non-formulary agents
- Otic preparations – formulary and non-formulary agents
- Respiratory oral inhalers – formulary and non-formulary agents
- Sublingual nitroglycerin
- Non-formulary medications

All UTMB-CMC unit staff must be aware that the Pearl EHR or PRS must be checked when a patient is received from Hospital Galveston to check for critical discharge medication orders. Patients transported to the unit from HG should have a 10-day supply of critical medications sent with them upon discharge for continuity of patient care.
HG PHYSICIANS-ORDERING OF MEDICATION
All discharge medication orders must be included in the discharge plan. Medication orders will be reviewed in EPIC for correct drug, strength, route, regimen, duration and type and frequency of any special monitoring. It is an option to email the clinical pharmacist for HG at utmbcmc.pharmacyHG@utmb.edu for an advanced approval for non-formulary medications that will need to be continued at the unit level.

DISPENSING OF MEDICATION FROM HOSPITAL GALVESTON
The Hospital Galveston pharmacist will enter orders for ALL medications ordered in EPIC or written on the TDCJ discharge prescription fax form (TDCJ-HG clinic/outpatient medication orders) to assure continuity of care and dispense a 10-day supply of critical medications only. The unit provider will be responsible for continuing the orders beyond the 10 days.

- Hospital Galveston pharmacists will screen all medication orders for appropriateness.
- Any orders active on the Pearl EHR/PRS system prior to entering discharge medications MUST BE VERIFIED with the discharging provider if there is not an indication to “discontinue previous meds” in the patient’s discharge orders.
- The Therapeutic Interchange Policy may be used by the HG pharmacy to substitute a formulary medication for a non-formulary medication that has been deemed interchangeable by the CMC P&T committee. Practitioners may override a therapeutic interchange by noting on the medication drug order “do not interchange.”
- Orders will be entered for 10 days with no refill if needed for 10 days.
- The HG Pharmacy will type the number of days actually ordered by the HG physician in the special instructions field (e.g., take 1 tablet twice daily for 6 months HG Dr. Smith)
- All critical medications will be written as KOP except controlled substances, injectables, medications that require refrigeration, TPN and tiotropium since it has a needle piercing mechanism.
- The computer system will automatically append “HG” followed by the prescriber’s name in the special instructions field of the order (e.g., take 1 tablet twice daily for 30 days HG Dr. Smith).
- The HG Pharmacy will provide a 10-day supply of critical medications. One package/container will be sent for items that come in a package such as eye drops and inhalers.
- The HG Pharmacy will not dispense a medication that is not deemed critical.
- The HG Pharmacy will not dispense controlled substances.
- The HG Pharmacy will not dispense TPN. See policy 10-45 for details on TPN ordering process.
- Medications will be blister packed if possible and labeled with the patient label generated by the computer system.
- The HG Pharmacy will place filled orders in bags for distribution to patients.

NON-FORMULARY APPROVAL PROCESS FOR DISCHARGE/CLINIC PATIENTS
It is an option to email the clinical pharmacist for HG at utmbcmc.pharmacyHG@utmb.edu for an advanced approval for non-formulary medications that will need to be continued at the unit level.
NON-FORMULARY APPROVAL PROCESS/UNIT LEVEL
The unit practitioner is responsible for evaluating the patient and determining if the medication needs to be continued beyond 10 days. If the HG physician obtained advanced approval for a non-formulary medication, a copy of the approval will be sent to the TDCJ facility. If an approval was not obtained, the TDCJ facility will submit a non-formulary request using the usual procedure.

MEDICATION NOT RECEIVED FROM HOSPITAL GALVESTON
If the patient arrives at the unit without non-formulary medications, unit personnel should re-enter the non-formulary medication for 10 days with no refills into the system & TYPE “HG-SEND” in the SPECIAL INSTRUCTIONS field. This will trigger the CMC pharmacist to allow an automatic 10-day approval of the non-formulary medication and the order will be sent. This will also give providers additional time to assess the patient and request non-formulary approval for the continuation of therapy if needed.

If a patient arrives at the unit without critical formulary medications, floor stock may be used or the order may be re-entered into PRS if not available in stock to be dispensed from the CMC Pharmacy.

In an urgent situation when the medication is not immediately available and there is no acceptable formulary substitute, the provider should follow the medication procurement after hours process (Pharmacy Policy 10-40).

PAROLE AND DISCHARGE PATIENTS
If a patient is to directly discharge from HG, the HG pharmacist will dispense the appropriate medications per Pharmacy Policy 25-10.

SUMMARY
This guide outlines the mission of the CMHC program and provides an overview of unit level care, utilization review and the Formulary. Compliance with the CMC Formulary is necessary to provide cost-effective care. Non-formulary medications will be approved as needed and the CMC Formulary will be continually updated by the Pharmacy and Therapeutics Committee with the goal of providing appropriate medical care.
MEDICATION PROCUREMENT AFTER HOURS
(§10.40)

PURPOSE: To define guidelines for units to contact a pharmacist to obtain medications or drug information during hours that the UTMB CMC Pharmacy is closed.

POLICY: Units must obtain authorization to purchase medications from an outside pharmacy from a UTMB CMC pharmacist during business hours or the On-call UTMB CMC Pharmacist after hours. Facilities may also contact the on-call pharmacist after hours to obtain drug information.

PROCEDURE:
I. Contacting the Pharmacy
   A. Units should call the Pharmacy during normal business hours from 6:00 am to 6:00 pm Monday through Friday.
   B. Units should call the On-Call Pharmacist when the Pharmacy is closed by calling 936-436-2093.

II. Procuring Medication from an Outside Pharmacy
   A. Unit personnel should contact the prescriber or the facility’s on-call provider to see if another medication may be substituted from stock.
   B. If substitution is not possible, contact a Pharmacy representative as outlined above in section I.
      1. Authorization from a pharmacist is required to purchase medication from an outside pharmacy.
      2. Unit personnel must provide the pharmacist with the information listed below:
         a. Facility name
         b. Facility contact person and telephone number
         c. Prescriber
         d. Patient name, number, date of birth and allergies
         e. Medication requested including strength, dosage form, quantity, and directions for use.
         f. Indication (diagnosis) for medication
         g. Rationale for urgent need
         h. Texas Tech Unit - Source of purchase (i.e., outside pharmacy) including company name, contact person and telephone number
3. The pharmacist will review the request and provide an alternative recommendation if applicable. If a formulary alternative is not available and the need is urgent as determined by a practitioner, the Pharmacist will authorize a purchase from an outside pharmacy.

4. Contract Pharmacy Available - UTMB Sector
   a. Pharmacist
      i. The Pharmacist will contact the approved outside pharmacy and verify that the medication is in stock.
      ii. If the medication is available in stock, the Pharmacist will provide the pharmacy with the billing information.
      iii. The Pharmacist will notify the unit that the medication is available and the location of the pharmacy.
      iv. The Pharmacist will approve a 5-day supply or up to a 7-day supply of medication for holiday weekends. One package (e.g., eye drop, inhaler, bottle) may be approved for medications that come in unbreakable packaging.
   b. Unit Personnel
      i. Unit personnel will call in or take a written prescription to the pharmacy and pick up the medication.
      ii. Unit personnel will email a copy of the receipt to the Pharmacy on the next business day. The email should be sent attention “Pharmacy Accounting Department” to utmbcmc.pharmacy@utmb.edu.

5. Contract Pharmacy Not Available – Texas Tech Sectors
   a. Unit personnel will call in or take a written prescription to the pharmacy and pick up the medication. The Pharmacist will approve a 5-day supply or up to a 7-day supply of medication for holiday weekends. One package (e.g., eye drop, inhaler, bottle) may be approved for medications that come in unbreakable packaging.
   b. Unit personnel will have to secure payment for the medication(s).
   c. Unit personnel will email a copy of the receipt to the Pharmacy on the next business day. The email should be sent attention “Pharmacy Accounting Department” to utmbcmc.pharmacy@utmb.edu.
   d. The Pharmacy will submit the receipt and request reimbursement.

C. The Pharmacist authorizing the purchase will provide the UTMB CMC Pharmacy with the purchasing information and reason for approval by completing the required authorization form and submitting the form on the next business day to the Pharmacy Accounting Department. If a Texas Tech Sector facility, the Pharmacist will also notify the Chief of Managed Health Care Pharmacy Services.

D. In most instances, the UTMB CMC Pharmacy will not be able to supply medication on the same day or after hours, since there is usually no way to ship the medication to the facility.
PURPOSE: The Pharmacy and Therapeutics Committee will develop and monitor the statewide formulary, drug use policies, treatment guidelines, and drug control measures used by facilities to ensure that safe, efficacious and cost effective therapies are used.

POLICY: The Pharmacy and Therapeutics (P&T) Committee will meet regularly to develop and maintain the statewide drug formulary, drug use policies, and disease management guidelines. The Committee will establish policy regarding the evaluation, selection, procurement, distribution, control, use, and other matters related to medications within the health care system. The Committee further serves to support educational efforts directed toward the health care staff on matters related to drugs and drug use. All new and/or revised policies and procedures that have been approved by the P&T Committee and the University Medical Directors will require final approval by the TDCJ Director of Health Services.

PROCEDURE:

I. The P&T Committee is a joint workgroup. Membership is multi-disciplinary and includes the following:
   A. TDCJ Director of Health Services Division or designee
   B. TDCJ Director of Office of Public Health or designee
   C. University Medical Directors or designees
   D. Texas Tech Regional Medical Directors or designees
   E. Texas Tech Regional Medical Facility Director or designee
   F. UTMB Chief Medical Officer or designee
   G. UTMB Regional Medical Directors or designees
   H. University Directors of Pharmacy or designees
   I. University Assistant Directors of Pharmacy or designees
   J. Appointed Members - The TDCJ Director of Health Services and each University Medical Director may appoint additional representatives to the Committee:
      1. Psychiatry
      2. Dental
      3. Nursing
   K. Other Appointments
      1. The Committee may add ex-officio, non-voting, representatives as deemed appropriate.
      2. The Committee may appoint working subcommittees to review and provide recommendations regarding a specific topic such as policies, medication delivery process or disease management guidelines.
      3. At a minimum, appointments must be reviewed when the current chairperson’s term expires.
L. Committee Officers
   1. Chairperson
      a. The Chair shall be appointed by the Joint Medical Director’s Committee from the P&T Committee membership for a period not to exceed 2 years.
      b. Individuals may serve no more than two (2) consecutive terms as chairperson.
      c. The Chairperson shall serve as the Committee nonpartisan facilitator and will vote only when it is necessary to break a tie.
   2. Secretary - The Secretary shall be the Director of Pharmacy or designee.

II. Meeting
   A. The Committee shall meet bimonthly on the second Thursday of each month from 9:30 AM until 12:00 PM.
   B. Subcommittees will meet prior to the Committee-at-Large from 8:30 AM until 9:30 AM.
   C. Individual meetings may be held at other times agreed to by the Committee.

III. Meeting Informational Materials
   A. Agenda - The agenda will be defined by the Chairperson and Secretary. Agenda items may also be added by Committee vote.
   B. Meeting Information
      1. The Secretary will be responsible for coordinating the preparation of information for Committee deliberations to include minutes, monthly reports, medication use evaluations, policies, and other reports.
      2. Meeting materials will be provided to members at least 3 days prior to each meeting to allow ample time for review.
      3. Deliberations, discussions, and actions of the Committee will be disseminated in the form of minutes to members.
      4. Committee decisions will be communicated to health care staff in the Pill Pass Newsletter, by email, and will be published on the Pharmacy’s homepage.
      5. Meeting materials and minutes should not be distributed and should be kept confidential in accordance with Vernon’s Annotated Civil Statutes, Health & Safety Code, Chapters 161.032 and 161.033.

IV. Voting
   A. A quorum must be reached to vote on actions before the Committee. A quorum is defined as seven voting members or their designees by proxy. Voting members will notify the Chair and Secretary if a proxy is used.
   B. Only members may vote on actions in front of the Committee. Ex-officio members and guests may not vote.
   C. Members must disclose all conflicts of interest prior to voting on an action before the Committee.
      1. Receipt of research funding, consulting fees or other funds from a manufacturer or vendor of a product under review for formulary inclusion or exclusion
      2. Income, honorarium for speaking, or gift from a manufacturer or vendor of a product under review for formulary inclusion or exclusion
3. Financial interests (stocks, shares, investments, etc.) in a company or manufacturer of a product under review for formulary inclusion or exclusion

V. Function and Scope
   A. To serve in the evaluative, educational, policy development, maintenance, and review capacity in all matters pertaining to the use of drugs (including but not limited to, investigational drugs, treatment protocols, disease management guidelines, patient education materials, health care management, and the use of non-formulary medication).
   B. To develop and maintain the drug formulary.
   C. To develop and maintain the disease management guidelines.
   D. To establish and maintain drug use policies, procedures, and programs that help ensure medications are safe, efficacious and cost-effective.
   E. To ensure policies support and meet accreditation standards.
   F. To establish or plan suitable educational programs for the organization’s professional staff on matters related to drugs or drug use.
   G. To implement performance improvement activities related to prescribing, distribution, administration, and use of medications such as medication error reporting, adverse effect monitoring, and review of drug utilization and prescribing patterns.
   H. To establish a listing of medications that may be kept in stock.
   I. To initiate and direct medication use evaluation studies, review the results of such activities, and make appropriate recommendations to optimize drug use.
   J. To advise the pharmacy department in the implementation of effective drug distribution and control procedures.
   K. To disseminate information on its actions and approved recommendations to all organizational health care staff.
   L. To develop and/or review all patient education materials related to medication use.

VI. Formulary Maintenance
   A. The selection of items to be included in the Formulary shall be based on the following:
      1. Objective evaluation of a medication’s relative therapeutic merits based on the medical literature, safety, and cost.
      2. Duplication of the same basic drug type, drug entity, or drug products will be avoided.
      3. Generic equivalents will be utilized whenever possible.
   B. A tier-system will be used and includes the following categories:
      1. Formulary Agents – Medications listed in the CMC Formulary that may be prescribed for any patient at any facility.
      2. Restricted Agents – Medications that may be prescribed at specific facilities only. Restrictions will be noted under individual medications in the CMC Formulary. All other uses require non-formulary approval.
      3. Clinic Use Only Agents – Medications that may only be administered to patients one dose at a time while they are in clinic. They may not be prescribed to patients as individual orders to be dispensed by the Pharmacy.
4. Prior Authorization Agents – Medications that may be prescribed if specific clinical criteria are met. The prior authorization criteria must be met and included in the special instructions field of the medication order. All other uses require non-formulary approval.

5. Non-formulary Agents – Medications not included in the CMC Formulary. Approval must be obtained prior to their use (Pharmacy P&P 05-10).

VII. Policy Development
A. The Correctional Managed Care Pharmacy Policy and Procedure Manual will be reviewed on an annual basis. A proportionate amount of policies will be reviewed every other meeting.
B. Policies and procedures may be reviewed and/or revised more frequently as deemed necessary by the Pharmacy and Therapeutics Committee.
C. All new and/or revised policies and procedures that have been approved by the Pharmacy and Therapeutics Committee and the University Medical Directors will require final approval by the TDCJ Director of Health Services.
POLICIES REGARDING REPRESENTATIVES OF PHARMACEUTICAL SUPPLIES AND RELATED COMPANIES
(§70.05)

PURPOSE: To define guidelines for pharmaceutical manufacturer and related supply representatives within Correctional Managed Care (CMC) facilities.

POLICY

Healthcare staff and practitioners shall interact with vendors in a manner that meets ethical standards, protects patient confidentiality, does not interfere with the process of patient care, and encourages the appropriate, efficient and cost effective use of equipment, supplies, and pharmaceuticals within CMC facilities.

Industry Vendors who conduct business with CMC must do so in accordance with policy and procedure. Healthcare personnel must monitor industry vendors to ensure that they comply with these guidelines. Healthcare personnel must immediately report noncompliant vendors.

All personnel of the company which employs an industry vendor who violates any of the aforementioned policies may be denied access to CMC for a period of time determined by the CMC Pharmacy and Therapeutics Committee.

DEFINITION:
Industry Vendor - Means any sales representative or account executive and includes, but is not limited to, any sales representative, pharmaceutical representative, or equipment or device manufacturer representative.

PROCEDURES:

I. Healthcare staff and practitioners shall interact with vendors in a manner that meets ethical standards, protects patient confidentiality, does not interfere with the process of patient care, and encourages the appropriate, efficient and cost effective use of equipment, supplies, and pharmaceuticals within CMC facilities.
   A. Only medications or devices approved by the Pharmacy and Therapeutics Committee may be used within facilities.
   B. Product samples may not be left by vendor representatives on facilities or at the Pharmacy (P&P 70-10).
   C. Industry vendors are not permitted to bring drug samples, large bulky items, boxes, detailing materials, food or other related items on to facilities.

II. Industry Vendors who conduct business with CMC must do so in accordance with policy and procedure. Healthcare personnel must monitor industry vendors to ensure that they comply with these guidelines. Healthcare personnel must immediately report noncompliant vendors.

III. All personnel of the company which employs an industry vendor who violates any of the aforementioned policies may be denied access to CMC for a period of time determined by the CMC Pharmacy and Therapeutics Committee.

IV. Industry vendor contact- All contact with CMC practitioners by pharmaceutical representatives must be in compliance with PhRMA (Pharmaceutical Research and Manufacturers of America) Code and OIG (Office of Inspector General Compliance
Program Guidance for Pharmaceutical Manufacturers) guidelines.

V. Industry vendor appointments
A. Industry vendors must have an appointment prior to arrival at facilities, the Pharmacy or the Medical Warehouse.
B. Industry vendors must sign in and obtain a visitor badge.
C. Visits are for the scheduled appointment only and do not provide authorization to visit other areas or meet with other staff.

VI. Industry vendor access
A. Industry vendors may not have access to Protected Health Information (PHI) unless a business associate contract specifically delineates such access or patient authorization has been obtained.
B. Each agency reserves the right to limit the number of industry vendors that any single company has visiting a facility.
C. Industry vendors are not permitted inside facilities without permission from the agency Medical Directors or their designee (see VII for designees). Industry vendors shall be accompanied by authorized personnel at all times.
D. Industry vendors are prohibited from entering patient care areas for promotional purposes.
E. Industry vendors shall not attend programs or meetings in which specific patients are discussed or when quality assurance or risk management issues are presented.
F. Security
1. Industry vendors must observe all security precautions on a facility being visited.
2. Security precautions may vary depending on the facility.
3. Representatives must have a driver’s license with picture identification to enter a facility.

VII. Educational Activities
A. Exhibits by pharmaceutical representatives in association with continuing medical education (CME) programs must meet Standards to Ensure the Separation of Promotion from Education within the CME Activities of ACCME (Accreditation Council for Continuing Medical Education) standards.
B. Industry vendors who desire to provide educational material to facility-based healthcare personnel must contact the Regional or Chief Medical Officer (UTMB sector), Director of Mental Health Services or the Dental Director. The Regional or Senior Medical Director, Director of Mental Health Services, or Dental Director will review all material for the accuracy and appropriateness of its content and will then make decisions about the proper forum for making the information available.
C. Industry vendors who desire to provide educational meetings with facility-based healthcare personnel must contact the Regional or Chief Medical Officer (UTMB sector) Director of Mental Health Services or Dental Director. The Regional or Chief Medical Officer, Director of Mental Health Services or Dental Director will review the meeting agenda and all material for the accuracy and appropriateness of its contents and will then make decisions about the proper forum for making the information available.
D. All decisions concerning educational needs, objectives, content, methods, evaluation and speaker are made free of a commercial interest.
E. The lecturer must explicitly disclose all of his or her related financial
relationships to the audience at the beginning of the educational activity. If an individual has no relevant financial relationship, the learners should be informed that no relevant financial relationship exists.

F. Attendees in the audience are not compensated or otherwise materially rewarded for attendance (e.g., through payment of travel expenses, lodging, honoraria, or personal expenses).

G. No gifts of any type are distributed to attendees or participants before, during, or after the meeting or lecture.

H. The content or format of an educational activity or its related materials must promote improvements of quality in health care and not a specific proprietary business purpose of a commercial interest.

VIII. Formulary Inquiries
A. Industry vendors should contact the Assistant Director of Pharmacy Clinical Programs regarding actions of the Pharmacy and Therapeutics Committee including information on the formulary status of new medications.

B. Industry vendors may not contact members of the Pharmacy and Therapeutics Committee regarding actions of the Committee, to influence the decision making process, or to influence the approval process of medications.

C. Industry vendors may not request an addition to the Formulary or a formulary review.

IX. Gifts and Travel
A. UTMB CMC personnel may not accept any form of personal gift from industry or its representatives.

B. See applicable employer policy.
CRUSHING OF MEDICATIONS

§35.05

PURPOSE: To define guidelines for the crushing of medications for administration to patients.

POLICY: A practitioner's order is required to crush an individual patient's medication(s).

PROCEDURE:

I. Only medical personnel may initiate an order to crush medication.
   A. A RN, in case of an emergency, may make a decision to allow a single dose of medication to be crushed. Proper documentation in the chart is required when the crushed medication is administered.
   B. A practitioner may order a medication to be crushed for a patient with proper justification documented in the patient's medical record.

II. Some medications cannot or should not be crushed (Attachment A: Tables 1 and 2).
   A. Medications not suitable for crushing include:
      1. Medications surrounded by a protective coating (e.g., enteric-coated).
      2. Medications formulated to provide delayed or continuous release of active ingredients. Many dosage forms can be identified by abbreviations such as TR (timed release), SA (sustained action), SR (sustained release), ER (extended release), CR (controlled release), LA (long acting), and XL or XR (extended release).
      3. Medications designed to be absorbed in the mouth or to have a local healing effect (e.g., lozenges, sublingual nitroglycerin).
      4. Medications that have an unpleasant taste (e.g., ibuprofen).
      5. Medications that may produce mucosal or gastrointestinal tract irritation (e.g., alendronate).
      6. Medications that meet National Institute for Occupational Safety and Health (NIOSH) hazardous drug criteria.
   B. A physician or dentist may override all precautions and order all or any medication to be crushed for administration with the exception of items included in Table 1 of Attachment A (This is not an all-inclusive list).
   C. The Facility Medical Director may append Policy §35-05 and proclaim that specific medications should be crushed for all patients at the facility except those medications listed in Table 1 of Attachment A (This is not an all-inclusive list). Written documentation must be maintained and renewed at least annually.
   D. If uncertain that a medication may be crushed, refer to medication package insert, drug reference or contact Pharmacy.

III. When medications are crushed for administration, care should be taken in selecting the substance to which the medication is added in order to prevent possible chemical alteration of the prescribed medication.

IV. Crushed medication should be administered as soon as possible once it has been crushed and added to another substance.
## Table 1: Solid Dosage Forms that Cannot be Crushed, Opened, or Chewed

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>DOSAGE</th>
<th>COMMENTS/REASON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alendronate (Fosamax®)</td>
<td>Tablet</td>
<td>Mucous Membrane Irritant</td>
</tr>
<tr>
<td>Aspirin (Ecotrin®, Enseals®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Aspirin/Dipyridamole (Aggrenox®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Bisacodyl (Dulcolax®, Correctol®)</td>
<td>Tablet¹</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Carbamazepine (Tegretol XR®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Chemotherapeutic agents</td>
<td>Oral</td>
<td>See Pharmacy Policies 40-10 and 75-30</td>
</tr>
<tr>
<td>Clotrimazole (Mycelex® Troches)</td>
<td>Troches²</td>
<td>Troche</td>
</tr>
<tr>
<td>Darifenacin (Enablex®)</td>
<td>Capsule</td>
<td>75% Increase Bioavailability</td>
</tr>
<tr>
<td>Desvenlafaxine (Pristiq®, Khedezla)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Didanosine EC (Videx® EC)</td>
<td>Capsule</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Diltiazem (Diacor® XR, Cardizem CD®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Divalproex Sodium (Depakote®, Depakote ER®)</td>
<td>Tablet</td>
<td>Enteric Coated, Extended Release, NIOSH</td>
</tr>
<tr>
<td>Erythromycin (E-Mycin®, Ery-Tab®, E.E.S.®, Eryc®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Felodipine (Plendil®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Ferrous Sulfate (Fosol®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Finasteride (Proscar®, Propcia®)</td>
<td>Tablet</td>
<td>Entier Coated, Teratogenic, NIOSH Medication</td>
</tr>
<tr>
<td>Guaiifenesin (Mucinex®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Guanfacine ER (Intuniv®)</td>
<td>Tablet</td>
<td>Slow Release</td>
</tr>
<tr>
<td>Hyoscyamine (Symax-SR®, Levbid®)</td>
<td>Capsule, Sustained Release, Extended Release</td>
<td></td>
</tr>
<tr>
<td>Isosorbide (Isordil SR®)</td>
<td>Tablet</td>
<td>Slow Release</td>
</tr>
<tr>
<td>Levomilnacipran (Fetzima®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Lithium Carbonate (Lithobid®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Lopinavir/ritonavir 200mg/50mg (Kaletra®)</td>
<td>Tablet</td>
<td>Film Coated</td>
</tr>
<tr>
<td>Mescalamin (Asacol®, Lialda®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Methylphenidate (Ritalin® SR, Concerta®, Metadate® ER, Methylin® ER)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Morphone Sulfate (MS Contin®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Mycophenolate (CellCept®, Myfortic®)</td>
<td>Capsule, Mucous Membrane Irritant, Teratogenic,</td>
<td></td>
</tr>
<tr>
<td>Niacin (Niaspan®)</td>
<td>Tablet</td>
<td>Enteric Coated Tablet, NIOSH Medication</td>
</tr>
<tr>
<td>Nifedipine (Adalat CC®, Procardia XL®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Nitroglycerin (Nitrostat® SL)</td>
<td>Tablet</td>
<td>4 Sublingual</td>
</tr>
<tr>
<td>Oxybutynin ( Ditropan® XL)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Paliperidone (Invega®)</td>
<td>Tablet</td>
<td>Extended Release, NIOSH Medication</td>
</tr>
<tr>
<td>PRODUCT</td>
<td>DOSAGE</td>
<td>COMMENTS/REASON</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>----------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>Pantoprazole (Protonix®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Pentoxifylline (Trental®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Phenytoin (Dilantin Kapseals®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Potassium Chloride/Gluconate (Klor-Con®, Klor-Con® M, K-Tab®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Ranolazine (Ranexa®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Ritonavir (Norvir®)</td>
<td>Tablet</td>
<td>Decreased Bioavailability</td>
</tr>
<tr>
<td>Sevelamer carbonate (Renvela®)</td>
<td>Tablet</td>
<td>Tablets expand when exposed to liquid</td>
</tr>
<tr>
<td>Sulfasalazine (Azulidine® EN-tabs®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Tamsulosin (Flomax®)</td>
<td>Capsule</td>
<td>Slow Release</td>
</tr>
<tr>
<td>Theophylline (Uniphy®, Theochron®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Valproic Acid (Depakene®)</td>
<td>Capsule</td>
<td>Slow Release, Mucous Membrane Irritant, NIOSH Medication</td>
</tr>
<tr>
<td>Venlafaxine (Effexor XR®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
</tbody>
</table>

The recommendations are specific to the drug product listed by proprietary name. Other immediate release forms of the drugs listed may be available and can be crushed, opened or chewed. (1) Antacids or milk may prematurely dissolve the coating of the tablets. (2) Troches are made to slowly dissolve in the mouth. (3) Tablet may be split, but do not chew or crush (4) Tablet is made to disintegrate under the tongue.
Table 2: Solid Dosage Forms that Should not be Crushed, Opened or Chewed

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>DOSAGE</th>
<th>COMMENTS/REASON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir (Ziagen®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Ambisentan (Letairis®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Amphetamine/Dextroamphetamine (Adderall XR®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Atomoxetine (Strattera®)</td>
<td>Capsule</td>
<td>Ocular Irritant</td>
</tr>
<tr>
<td>Azathioprine (Imuran®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Cabergoline (Dostinex®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Carbamazepine (Equetrol®, Carbatrol®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Clonazepam (Klonopin®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Colchicine (Colcrys®)</td>
<td>Capsule</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Cyclosporine (Neoral®)</td>
<td>Capsule</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Dextroamphetamine (Dexedrine Spansule®)</td>
<td>Capsule</td>
<td>Slow Release</td>
</tr>
<tr>
<td>Divalproex Sodium (Depakote Sprinkles®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Docusate Calcium/Sodium (Surfak®, Colace®)</td>
<td>Capsule</td>
<td>Liquid Filled, Bad Taste</td>
</tr>
<tr>
<td>Dronedarone (Multaq®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Duloxetine (Cymbalta®)</td>
<td>Capsule</td>
<td>Enteric-Coated Pellets</td>
</tr>
<tr>
<td>Etapecar (Baraclude®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Isosorbid Mononitrate (Imdur®)</td>
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<td>Extended Release</td>
</tr>
<tr>
<td>Lansoprazole (Prevacid®)</td>
<td>Capsule</td>
<td>Mucous Membrane, Irritant, Liquid Filled</td>
</tr>
<tr>
<td>Lenvadismide (Revlidimid®)</td>
<td>Capsule</td>
<td>Teratogenic Potential</td>
</tr>
<tr>
<td>Levetiracetam (Keppra®)</td>
<td>Tablet</td>
<td>Bitter Taste</td>
</tr>
<tr>
<td>Lisinapetametale (Vyanse®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Medroxyprogesterone acetate (Provera®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Methimazole (Tapazole®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Methylenphedate (Metadate CD®, Ritalin LA®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Metoprolol Succinate (Toprol XL®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Moxapro (Cytotec®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Nevaripine (Viramune®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Nifedipine (Procardia®)</td>
<td>Capsule</td>
<td>Liquid Filled</td>
</tr>
<tr>
<td>Omeprazole (Pralose®)</td>
<td>Capsule</td>
<td>Delayed Release</td>
</tr>
<tr>
<td>Oxcarbazepine (Trileptal®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Pancrelipase (Creon®)</td>
<td>Capsule</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Paroxetine (Paxil®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Phenytoin (Dilantin®)</td>
<td>Tablet</td>
<td>NIOSH Medication</td>
</tr>
<tr>
<td>Pirxicam (Feldene®)</td>
<td>Capsule</td>
<td>Mucous Membrane, Irritant</td>
</tr>
</tbody>
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These dosage forms may be crushed or opened at the physician’s discretion. (1) Capsule may be opened and the contents taken without crushing or chewing. Soft food such as applesauce or pudding may facilitate administration. (2) Contents of capsule may be removed for administration; incomplete recovery of content may result in decreased dosage being administered. (3) Capsule may be opened and the contents may be mixed in applesauce or apple juice to facilitate administration. (4) If unable to swallow, tablet may be dispersed in a glass of water, stir well and drink immediately. Glass should be rinsed with water several times and each rinse completely swallowed to ensure entire dose is taken. (5) Tablet may be split, but do not chew or crush. (6) Administration of liquid from within capsule may result in partial sublingual absorption.
NON-FORMULARY APPROVAL PROCESS

Medication order is written for non-formulary medication
(Note: Do not enter order into computer until medication has been approved)

Obtain non-formulary approval from assigned clinical pharmacist. Contact clinical pharmacist via TDCJ mainframe email:
1. From main computer screen type EMS, then enter.
2. Type "4.4", then enter
3. A list of E-Forms appears. Tab down and select the E-Form "HS_NF_REQ" Nonformulary consult.
4. Fill in all requested information.
5. Press F3 key to route EMAIL to appropriate clinical pharmacist.
6. Tab down & type EMAIL address.
7. Press enter to return to command line. Then type "S" to send.

Retrieve e-mail notification of non-formulary approval or deferral.
1. From main computer screen type EMS
2. Type "2" for kwickread at the enter command line
3. Press enter key to scroll through messages
4. Type "p" to print at the enter command prompt
5. Retain a copy of the email for your records

Approval Obtained?
- Yes
- No

Prescribing clinician agrees with pharmacist?
- Yes
- No

Forward copy of email notification of non-formulary approval or deferral to:
- Regional Medical Director
- Director of Mental Health Services
- Unit, clinical pharmacist
- CMC Pharmacy e-mail EPOTP04

Clinician writes order for Formulary medication or determines the patient does not need medication at this time.

Approval obtained from:
- Regional Medical Director
- Director of Mental Health Services
- Prescribing clinician
- Pharmacist

Enter order for non-formulary medication into the computer (email message ID# should be included in the special instructions field of the order)

Retrieve e-mail and scan a copy into the patient’s medical record.

Regional Medical Director or Director of Mental Health Services forwards e-mail approval to unit, clinical pharmacist, and CMC Pharmacy (CMC Pharmacy e-mail EPOTP04)

Refer to P&P 05-10 for complete details
MEDICATION STATUS

Listings of brand name products are for reference only. The least expensive generic equivalent will be utilized whenever possible. Use outside specific restrictions or prior authorization criteria requires non-formulary approval. Medications are classified into different statuses for use and management purposes. The different medication statuses are listed below.

1. **Formulary Agents** – Medications listed in the CMC Formulary that may be prescribed for any patient at any facility.

2. **Restricted Agents** – Medications that may be prescribed at specific facilities only (e.g., dialysis unit). Restrictions are noted under individual medications in the alphabetical listing by generic name in the CMC Formulary. All other uses require non-formulary approval. Restricted agents are designated in the EHR and PRS with an exclamation point (!) after the medication name.

3. **Clinic Use Only Agents** – Medications that may only be administered to patients one dose at a time while they are in clinic. They may not be prescribed to patients as individual orders to be dispensed by the Pharmacy or issued KOP by facility staff.

4. **Prior Authorization Agents** – Medications that may be prescribed if specific clinical criteria are met (see table on next page or alphabetical listing by generic name for drug-specific criteria). The prior authorization criteria must be met and included in the special instructions field of the medication order. All other uses require non-formulary approval. Prior authorization agents are designated in the EHR and PRS with an asterisk (*) after the medication name.

5. **Non-formulary Agents** – Medications not included in the CMC Formulary. Approval must be obtained from a clinical pharmacist prior to their use (see P&P 05-10 for complete details). Non-formulary agents are designated in the EHR and PRS with a pound sign (#) after the medication name.

KOP ELIGIBILITY

The KOP (Keep-On-Person) eligibility of medications is determined by the Pharmacy and Therapeutics Committee (P&P 50-05). Medications that meet any of the criteria listed below are generally excluded from the KOP program:

1. Potential for abuse or misuse (e.g., controlled substances)
2. Injectable medications (e.g., insulin)
3. Risk in overdose (e.g., antidepressants)
4. Close monitoring is required (e.g., TB medications, warfarin)
5. Caustic or harmful agents (e.g., podofilox)
6. Cost
7. Orders for half (½) tablets not split by the Pharmacy
8. Medications that require refrigeration
9. Clinic use only items (e.g., local anesthetics, nebulizer solutions)
10. Psychotropic medications (including antidepressants, antipsychotics and Lithium)
11. Medications that may be used as weapons (e.g., cans of enteral nutrition, medications in glass containers, Spiriva-has piercing needles in device)
12. Medications ordered DOT
13. Oral chemotherapy medications

Medications that are not allowed KOP because of cost only will be allowed KOP at designated 8-hour units (Refer to Attachment A of P&P 50-05 for a list of 8-hour units).
### USE CRITERIA FOR PRIOR AUTHORIZATION AND RESTRICTED AGENTS

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<td>Absorbase (Eucerin®)</td>
<td>RMF or Dialysis</td>
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<td>Acetaminophen/Codeine (Tylenol 3®)</td>
<td>Restricted to 10 days. Minimum of 30 days between orders without non-formulary approval.</td>
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<tr>
<td>Adenosine (Adenocard®) injection</td>
<td>EMS or RMF</td>
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<tr>
<td>Albumin, Human (Plasbumin-25®)</td>
<td>RMF for paracentesis</td>
</tr>
<tr>
<td>Albuterol (Ventolin®) nebulizer solution</td>
<td>KOP USE template-issued Nebulizer Machine.</td>
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<tr>
<td>Albuterol (Ventolin®) metered dose inhaler</td>
<td>90mcg/actuation</td>
</tr>
<tr>
<td>Alteplase (Cathflo Activase®)</td>
<td>Dialysis for catheter restoration</td>
</tr>
<tr>
<td>Amiodarone (Cordarone®) injection</td>
<td>EMS or RMF</td>
</tr>
<tr>
<td>Amiodarone (Nexterone®)</td>
<td>RMF</td>
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| Atomoxetine (Strattera®)                     | TJJD only. Prior authorization criteria must be met and include: **ADHD plus**  
  - Treatment failure on adequate dose and trial of both formulary stimulants  
  - Intolerance to both formulary stimulants  
  - Contraindication to both formulary stimulants  
  - Significant history of substance abuse  
  - Co-morbid anxiety disorder  |
| Azithromycin (Zithromax®)                    | HIV+ dosed 1200 milligrams q week for MAC primary prophylaxis when CD4 < 50  
  - Gonorrhea (GC)  
    - 1200 mg x 1 dose in combination with ceftriaxone 250 mg IM x 1 dose  
  - Pregnant patients  
    - Treatment of chlamydia dosed 1200 milligrams x 1 dose  |
| Baclofen (Lioresal®)                         | Spinal cord injury  
  - Multiple Sclerosis  
  - Muscular dystrophy  
  - Spastic hemiplegia  
  - Amyotrophic lateral sclerosis  
  - Cerebral palsy  |
| Benztrapine 1mg/ml 2ml SDV                    | Restricted to Psychiatric inpatient facilities  
  - Patients with acute dystonia who fail to respond to diphenhydramine injection  |
| Birth control (Low-Ogestrel®, Pirmella®, Zovia®) | Females                                     |
| Cefazidine (Fortaz®, Tazicef®)               | RMF (inpatient use only) or TJJD patient        |
| Ceftriaxone (Rochephin®)                     | 250 mg – 250 mg IM x 1 dose for GC (gonorrhea) in combination with azithromycin 1200 mg x 1 dose  
  - 1 gram – RMF (inpatient use only),  |

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### Prior Authorization Agent / Restricted Agent

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<th>Prior Authorization Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
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<td>Chlordiazepoxide (Librium®)</td>
<td>Infirmary unit (inpatient use only), and TJJD</td>
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<tr>
<td>Ciprofloxacin eye drop (Ciloxan®)</td>
<td>Restricted to detoxification</td>
</tr>
<tr>
<td>Ciprofloxacin tablet (Cipro®)</td>
<td>Post-cataract surgery or ocular procedure</td>
</tr>
<tr>
<td>Clonidine (Catapres®)</td>
<td>RMF (inpatient use only)</td>
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<tr>
<td>Clonidine (Catapres®)</td>
<td>Hypertensive emergency</td>
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<tr>
<td>Clonidine (Catapres®)</td>
<td>Management of opioid withdrawal</td>
</tr>
<tr>
<td>Clonidine (Catapres®)</td>
<td>Intake to taper</td>
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<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Intolerant or allergic to aspirin and needs cardioprotection or prevention</td>
</tr>
<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Failed aspirin therapy (Event while on aspirin such as MI, stroke, TIA)</td>
</tr>
<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Acute coronary syndromes (e.g., MI, unstable angina, or PCI with or without stent placement) and treatment is in combination with aspirin</td>
</tr>
<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Brachytherapy</td>
</tr>
<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Intermittent claudication and failed trial or remained symptomatic while on aspirin plus dipyridamole</td>
</tr>
<tr>
<td>Clopidogrel (Plavix®)</td>
<td>Dialysis vascular graft</td>
</tr>
<tr>
<td>Collagenase (Santyl®)</td>
<td>Wound care facility</td>
</tr>
<tr>
<td>Dextrose 10% Water 1000 mL (D10W)</td>
<td>Restricted to Beto, Estelle, Michael, Montford and Young facilities for use until TPN is available.</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Spinal Cord Injury</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Muscular Dystrophy</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Spastic Hemiplegia</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Amyotrophic Lateral Sclerosis</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Cerebral Palsy</td>
</tr>
<tr>
<td>Elvitegravir – Cobicistat – Emtricitabine –</td>
<td>Patient on Genvoya or Stribild at intake</td>
</tr>
<tr>
<td>Tenofovir (Genvoya®)</td>
<td>EMS and TJJD emergency boxes and patients at TJJD halfway houses</td>
</tr>
<tr>
<td>Epinephrine (Epipen®)</td>
<td>Dialysis</td>
</tr>
<tr>
<td>Epoetin Alfa (Epogen®)</td>
<td>Dialysis</td>
</tr>
<tr>
<td>Estrogens (Premarin®)</td>
<td>Females</td>
</tr>
<tr>
<td>Fluconazole (Diflucan®)</td>
<td>150 mg – single dose for vaginal candidiasis</td>
</tr>
<tr>
<td>Fluconazole (Diflucan®)</td>
<td>100 mg &amp; 200 mg – HIV-positive patients, for treatment or prevention of opportunistic infections</td>
</tr>
<tr>
<td>Flumazenil (Romazicon®)</td>
<td>Emergency use only</td>
</tr>
<tr>
<td>Glucose Tolerance test (Glucola®)</td>
<td>Diagnostic use in females</td>
</tr>
<tr>
<td>Heparin</td>
<td>1,000 U/mL – 30 mL; Dialysis</td>
</tr>
<tr>
<td>Prior Authorization Agent / Restricted Agent</td>
<td>Criteria (Should be typed in Special Instructions)</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Hepatitis A Vaccine (Havrix®)**           | Patient is not immune (P&P B-14.07) plus one of the following:  
|                                            | • HIV  
|                                            | • Chronic hepatitis C  
|                                            | • Chronic hepatitis B  
|                                            | • ESLD |
| **Hepatitis B vaccine (Engerix B®)**        | Patient is not immune (P&P B-14.07) plus one of the following:  
|                                            | • Chronic hepatitis C  
|                                            | • HIV  
|                                            | • Post-exposure prophylaxis  
|                                            | • Job assignment that includes the handling of medical waste |
|                                            | • ESLD  
|                                            | • ≤ 19 years old without documentation of series completion (labwork not required) |
| **Hepatitis B Vaccine, Dialysis formulation**| Patient is not immune (P&P B-14.07) plus patient is on dialysis |
| **Human Papillomavirus Vaccine – HPV**      | Females ages 9 through 26 with no previous vaccination. |
| **Hydroxyzine Pamoate (Vistaril®)**         | Restricted to TJJD |
| **Imipramine (Tofranil®)**                  | TJJD for enuresis |
| **Ipratropium bromide (Atrovent®) nebulizer solution** | KOP USE template-Issued Nebulizer Machine. |
| **Iron sucrose (Venofer®)**                 | Dialysis |
| **Isosorbide Dinitrate (Isordil®)**         | Heart failure |
| **Labetalol injection**                     | EMS use only for treatment of HTN emergencies per protocol |
| **Lidocaine**                               | • 2% jelly – emergency use only  
|                                            | • 5% ointment – OB/GYN services at GC or GV  
|                                            | • 0.4%/DSW 500 mL bag – restricted to EMS |
| **Lisdexamfetamine (Vyvanse®)**             | TJJD only. Prior authorization criteria must be met and include:  
|                                            | • Failed treatment with Methylphenidate and Adderall. |
| **Lorazepam (Ativan®)**                     | Injection  
|                                            | • Treatment of acute seizures uncontrolled by other measures.  
<p>|                                            | • Short-term treatment of agitation at inpatient psychiatric facilities. |
| <strong>Medroxyprogesterone (Provera®, Depo-Provera®)</strong> | Females |</p>
<table>
<thead>
<tr>
<th>Prior Authorization Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal Vaccine (Menactra®, Menomune®)</td>
<td>Anatomic or functional asplenic patients who have no history of prior immunization or require a booster (every 5 years)</td>
</tr>
<tr>
<td>Meropenem (Merrem®)</td>
<td>RMF (inpatient use only)</td>
</tr>
<tr>
<td>Methocarbamol (Robaxin®)</td>
<td>One 7 day supply/injury; min. 30 days between orders</td>
</tr>
<tr>
<td>Miconazole vaginal suppositories (Monistat®)</td>
<td>Females</td>
</tr>
</tbody>
</table>
| MMR Vaccine (M-M-R®-II) | • ≤19 years old without documentation of series completion  
• Born after 1956 & did not attend public school in Texas  
• Immigrants that have not completed the series |
| Morphine sulfate (MS Contin®) | • Elixir and extended release tablets – RMF inpatient or Hospice (may not exceed 10 day supply)  
• Injection – one time orders for pain associated with acute trauma or severe medical condition |
| Multivitamin | • HIV-positive + CD4 count < 100 + not on enteral feeding |
| Nephro-Vite® | Dialysis |
| Nitroglycerin topical oint (Nitrobid®) | Clinic use only for short term relief of angina |
| Onodansetron (Zofran®) | HCV Treatment |
| Paricalcitol (Zemplar®) | Dialysis |
| Penicillin G Benzathine (Bicillin LA®) | Syphilis |
| Petrolatum (Vaseline®) | Phototherapy at E2 |
| Phenytoin (Dilantin®) | • Oral suspension restricted to RMFs  
• Injection restricted to Emergency Medical Services (EMS) |
| Polio Vaccine (Ipol®) | Patients under 19 years old |
| Potassium Chloride injection | Infirmary or RMF |
| Prenatal vitamins | Pregnancy |
| Rilpivirine (Edurant®) | Patient on Edurant, Complera, or Odefsey at intake. |
| Sevelamer (Renvela®) | • Chronic kidney disease  
• Dialysis |
| Surgical lubricant (Surgilube®) 4.25 oz tube | RMF |
| Terbutaline injections (Brethine®) | Female patients at CYMF (GC) and Crain (GV) |
| Tdap (Boostrix®) | • Pregnancy  
• Td booster indicated and not previously vaccinated with Tdap |
<p>| Tiotropium 18mcg (Spiriva®) | • Inadequate response to ipratropium 2 puffs |</p>
<table>
<thead>
<tr>
<th>Prior Authorization Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulipristal (Ella®)</td>
<td>Female unit/patient for emergency contraception</td>
</tr>
</tbody>
</table>
| Varicella Vaccine (Varivax®)                | ≤ 19 years old without documentation of previous disease or immunization (labwork not required)  
|                                              | Post-exposure prophylaxis with approval from Office of Public Health  
|                                              | HIV positive patients without documented immunity and CD4 count > 200 |
IV SOLUTION ADMIXTURE SYSTEMS

There are two admixture systems available for use. Advantages of the admixture systems include reduced risk for contamination, elimination of needles in the preparation of IV admixtures, reduced chance for errors, and greater convenience. Disadvantages include increased storage space requirements, decreased dosing flexibility, and not all antibiotics may be used with the systems.

The Mini-Bag Plus Admixture System is designed to be used with single dose powdered medications that are contained in standard 20 mm vials and need reconstitution prior to admixture with an IV solution. The Vial-Mate Adaptor is designed to connect a powdered drug contained in a standard 20 mm vial to a 250 mL IV solution bag. The Vial-Mate Adaptor should be reserved for use with medications that cannot be used with the Mini-Bag Plus Admixture System (i.e., the drug needs to be prepared in a 250 mL bag).

System | Antibiotics That May Be Used With System
--- | ---
Mini-Bag Plus Admixture System
* Mini-Bag Plus 0.9% NaCl 100 mL bag
* Mini-Bag Plus DSW 100 mL bag | Ampicillin (NS only)
Cefazolin
Ceftazidime**
Ceftriaxone**
Meropenem**
Nafcillin
Oxacillin*
Penicillin G Potassium

Mini-Bag Vial-Mate Adaptor | Doxycycline*
Erythromycin Lactobionate*
Vancomycin

NS=normal saline
*Non-formulary approval required
**Restricted to Regional Medical Facilities; otherwise non-formulary approval required.

Antibiotics that cannot be used with the admixture systems include amphotericin, clindamycin, gentamicin, sulfamethoxazole/trimethoprim, and tobramycin.

In addition, clindamycin 900 mg in 50 mL D5 and metronidazole 500 mg in 100 mL NS are available in premixed bags.
The disease management guidelines (DMGs) were developed by the CMC Pharmacy and Therapeutics Committee through review of the medical literature, review of national treatment guidelines, and evaluation of population-specific treatment data. The goal was to develop tools that would assist practitioners in making treatment decisions regarding commonly encountered disease states found within the health care system that would result in improved outcomes and consistent and cost-effective care. Complimentary written patient education leaflets in English and Spanish are also available for providers and nursing staff. The DMGs should not replace sound clinical judgment nor are they intended to strictly apply to all patients. The DMGs are reviewed and/or revised every five years or when new national treatment guidelines, landmark clinical studies, and/or new drug entities become available, whichever is sooner.

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<td>Pain, Mild to Moderate</td>
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<td>Pain, Neuropathic</td>
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<td>Thyroid Disorders</td>
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<td>Tinea Pedis</td>
<td>281</td>
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<td>Warfarin</td>
<td>282-293</td>
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<tr>
<td>Wound Care</td>
<td>294-306</td>
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</tbody>
</table>

Disease Management Guidelines for Youth

The youth psychiatric disease management guidelines were prepared by the Youth Services Pharmacy and Therapeutics Committee.

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<th>Disease Management Guideline</th>
<th>Page</th>
</tr>
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<td>Asthma, Adults and Adolescents (see adult listing)</td>
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<td>Seizures, Acute</td>
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<td>Seizures, Chronic</td>
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</table>
Anemia in Pre-Dialysis Chronic Renal Failure

Erythropoietin Dosing and Monitoring

Starting Dose

- Consider starting erythropoietin therapy with 5,000 to 10,000 units subcutaneously once weekly after careful consideration of the risks versus benefit of treatment.
- Note: It may take 2 to 6 weeks to see a significant change in Hgb after dose adjustments. Dose increases should not be made more frequently than once a month.

Pretherapy Evaluation

- Anemia with Hgb < 10 g/dL:
  - Consider initiating erythropoietin stimulating agent (ESA) treatment only when the hematocrit level is less than 30% and the following considerations apply:
    - The rate of hematocrit decline indicates the likelihood of requiring a red blood cell transfusion; and
    - Reducing the risk of alloimmunization and/or other red blood cell-transfusion-related risks is a goal.
- Transferrin saturation ≥ 20% (transferrin saturation = serum iron/iron binding capacity)
- Serum ferritin ≥ 100 ng/mL
- Supplement iron if transferrin saturation < 20% or ferritin < 100 ng/mL.
- Note: Nearly all patients will eventually require iron supplementation.
- Evaluate BP for adequate control.

Check Hgb at 2 weeks

Maintenance Dose

- Titrate dose as needed to maintain Hgb sufficient to:
  - Not exceed 11 g/dL; or
  - Not increase Hgb > 2 g/dL during ANY 4-week period.
- If the hematocrit level exceeds 40%, reduce or interrupt the dose of ESA and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions.
- Dosage adjustments should generally not exceed 25%.
- When initiating or adjusting therapy, monitor hematocrit levels at least every two weeks and sulfate, then monitor at least monthly.
- For patients who do not respond adequately over a 12-week escalation period, increasing the ESA dose further is unlikely to improve response and may increase risks. Refer to Table 1.
- Maintenance doses should be individualized to maintain lowest ESA dose possible to reduce the need for transfusions.
- Follow monitoring parameters in Table 2 on page 2.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee; 
Approved July 2009; Revised 7/2011; Reviewed 1/2012, 05/2016.
Table 1: Possible Causes for Lack of Response or Loss of Response

1. Iron deficiency – supplement if transferrin saturation (Tsat) < 20%
2. Underlying infectious, inflammatory, or malignant processes
3. Occult blood loss
4. Underlying hematologic diseases (e.g. thalassemia, refractory anemia or other myelodysplastic disorders)
5. Vitamin deficiencies (folic acid, vitamin B12)
6. Hemolytic
7. Aluminum intoxication
8. Osteitis fibrosa cystica
9. Pure Red Cell Aplasia (PRCA) or anti-erythropoietin antibody-associated anemia (test for presence of antibodies to erythropoietin)

Table 2: Monitoring Parameters

<table>
<thead>
<tr>
<th>Baseline Parameters</th>
<th>Follow-Up Parameters</th>
</tr>
</thead>
</table>
| Hgb, Hct, and platelets
| CMP (including BUN, uric acid, Cr, Phos and K)
| Transferrin saturation and serum ferritin
| Blood pressure
| High every 4 weeks with maintenance therapy
| High 4 weeks after any dose adjustment
| Hgb and platelets regularly
| Transferrin saturation and serum ferritin every 1-3 months. Supplement iron if transferrin saturation < 20% or ferritin >100 ng/mL
| Blood pressure monthly (MUST remain adequately controlled to continue therapy)
| CMP regularly (including BUN, uric acid, Cr, Phos, and K)

Table 3: Contraindications

1. Uncontrolled hypertension
2. Known hypersensitivity to mammalian cell-derived products
3. Known hypersensitivity to albumin (Human)

Table 4: Warnings

The ESA labels now warn:
In controlled trials with CKD patients, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL. No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.

ESA labels now recommend:
For patients with CKD, consider starting ESA treatment when the hemoglobin level is less than 10 g/dL. This advice does not define how far below 10 g/dL is appropriate for an individual to initiate. This advice also does not recommend that the goal is to achieve a hemoglobin of 10 g/dL or a hemoglobin above 10 g/dL. Individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions. Adjust dosing as appropriate.
Patient Presents to Medical Department with Chest Pain

Clinical Assessment
Chest Pain Is Substernal
Chest Pain Radiates
Patient Is Experiencing Nausea, Shortness of Breath, Diaphoresis, or Palpitations
Patient Has Cardiac Risk Factors
(If Patient has Diabetes Mellitus observe for nausea as chest pain may be masked)
Consider other life threatening causes of chest pain, like aneurysm, pneumonia, pneumothorax, or pulmonary embolism.

While Obtaining EKG:
1. Nitroglycerin SL up to 3 doses as tolerated by blood pressure if necessary
2. Chew Aspirin 325 mg
3. Administer Oxygen

EKG Q-T Changes?
- ST elevation or depression
- Significant Q-waves
- Inverted T-waves
- Changes from previous EKG’s
- NTG SL X 3 Ineffective?
- Positive Troponin Level/ other Cardiac Enzyme Levels?

If CAD equivalent OR 2 or more cardiac risk factors* present, repeat EKG in 2 hours, maintain in observation for 6 hours, and repeat troponin level.
If less than 2 cardiac risk factors and atypical presentation of chest pain that is not suspected to be cardiac in origin, then ascertain and treat etiology.

Changes in parameters?
- Yes
- No

Transfer to nearest Emergency Room
- Call 911 and follow unit protocol
- For UTMB, if ambulance is not immediately available call 911
- Start Normal Saline Intravenous Infusion
- Consider Morphine Sulfate Intravenous if pain is not relieved after 3 doses of sublingual nitroglycerin

Discharge from Medical Department
- Follow up next morning with provider with instructions to return prn for chest pain

Changes in parameters?
- Yes
- No

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved February 2001; Revised 1/07, 1/15; Revised 4/03, 3/08, 5/11, 7/11.

*Calculate Cardiac Risk Factors:
Positive Cardiac Risk Factors:
- Family history premature CHD (CHD in first degree male relative <55 or female relative <65);
- Age ≥45 Males, ≥55 Females;
- HTN ≥140/90 mm Hg or on an antihypertensive medication;
- Smoker within the last 2 years;
- HDL < 40 mg/dl.

Negative Cardiac Risk Factors:
- HDL ≥60 mg/dl (subtract 1 risk factor).

Positive Troponin Level/ other Cardiac Enzyme Levels?
ANXIETY and PANIC DISORDER

1. Rule out medical cause for presentation

2. Presence of panic attacks?
   - Yes
   - No

3. Treat modifying causes
   - Yes
   - No

4. Meets DSM-5 criteria for Anxiety Disorder?
   - Yes
   - No

5. Meets DSM-5 criteria for Panic Disorder?
   - Yes
   - No

6. Observe baseline BPRS
   - Yes
   - No

7. Psychotherapy should be initial treatment of choice and should be continued throughout treatment, even if drug therapy is started
   - Yes
   - No

8. Initiate formulary SSRI antidepressant
   - Start at lower end of dosing range and titrate gradually upward to decrease potential for activating side effects
   - Continue for 4-6 weeks at a therapeutic dose and assess response

9. Meets DSM-5 criteria for Anxiety Disorder?
   - Yes
   - No

10. Meets DSM-5 criteria for Panic Disorder?
    - Yes
    - No

11. Treat underlying causes
    - Yes
    - No

12. Presence of panic attacks?
    - Yes
    - No

13. Adequate response per BPRS?
    - Yes
    - No

14. Continue therapy for 8-12 months, reassessing as needed by unit mental health provider
    - Yes
    - No

15. After 12-18 months, consider tapering and discontinuing pharmacotherapy
    - Yes
    - No

16. If compliance < 80%, counsel on medication compliance
    - Yes
    - No

17. Re-evaluate diagnostic checklist for medication
    - Yes
    - No

18. Increase dose of current agent to maximum tolerated dose for 4-6 weeks
    - Yes
    - No

19. If trial at max tolerated dose is partially effective, consider continuing this dose and reassessing response in another 4-6 weeks
    - Yes
    - No

20. If trial at max tolerated dose is ineffective, switch to another formulary agent (Table 1), or consider pharmacotherapy consult
    - Yes
    - No

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved 1/99, revised 5/02, 2/03, 4/03, 9/05, 7/08, 7/11, 9/11, 3/14, 5/17, 5/18
Table 1: Formulary Antidepressants

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Daily Dosage (Range)</th>
<th>Therapeutic Range</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram 20mg, 40mg tablet</td>
<td>Celexa® 20 mg (20 - 40 mg)</td>
<td>N/A</td>
<td>• Emergence of suicidal ideation or behavior</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fluoxetine 20mg capsule</td>
<td>Prozac® 20 mg (20 - 60 mg)</td>
<td>N/A</td>
<td>• Emergence of suicidal ideation or behavior</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sertraline 50mg, 100mg tablet</td>
<td>Zoloft® 50 mg (50 - 200 mg)</td>
<td>N/A</td>
<td>• Emergence of suicidal ideation or behavior</td>
<td></td>
</tr>
</tbody>
</table>

**Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)**

| Venlafaxine XR 75 - 375mg capsule | Effexor XR® 75 mg (75 - 225 mg) | N/A | • Emergence of suicidal ideation or behavior |
| Duloxetine 30, 60 mg capsules | Cymbalta® 30 - 60 mg (300 - 120 mg) | N/A | • Emergence of suicidal ideation or behavior |

**Other**

| Trazodone 50mg, 100mg tablet | Desyrel® 100 - 150 mg (300 - 600 mg) | N/A | • Emergence of suicidal ideation or behavior |

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**BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician**

The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by caregivers. It should be utilized at baseline and at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

**Instructions for Use and Scoring:**

Each item is rated on a seven-point scale (°not present to 7 (extremely severe)). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared from one evaluation to the next to measure response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.

---

**Note:**

- Risk factors for (Q)TQ prolongation include age > 65 years old, use of other concomitant (Q)TQ prolonging medications, baseline hypokalemia or hypomagnesemia, or pre-existing cardiovascular impairment.
- Fluoxetine has also been associated with (Q)TQ prolongation. EKG monitoring is encouraged if risk factors for (Q)TQ prolongation are present.
- Generally not recommended as first-line or second-line therapy for treatment of anxiety or panic disorder.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not assessed</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>ANXIETY</td>
<td>Worry, fear, over-concern for present or future, anxiety</td>
</tr>
<tr>
<td>2</td>
<td>CONCEPTUAL DISORGANIZATION</td>
<td>Thought processes confused, disconnected, disorganized, disoriented.</td>
</tr>
<tr>
<td>3</td>
<td>SEMIOTIC COGNITION</td>
<td>Orientation for present or future, anxiety</td>
</tr>
<tr>
<td>4</td>
<td>MENTAL RETARDATION</td>
<td>Slowed, weakened movements or speech, reduced body tone</td>
</tr>
<tr>
<td>5</td>
<td>MANNERISMS AND POSTURING</td>
<td>Peculiar, bizarre, unusual motor behavior (not including tic).</td>
</tr>
<tr>
<td>6</td>
<td>GRANDIOSITY</td>
<td>Exaggerated self-opinion, arrogance, conviction of unusual power or abilities</td>
</tr>
<tr>
<td>7</td>
<td>DEPRESSIVE MOOD</td>
<td>Sorrow, sadness, despondency, pessimism</td>
</tr>
<tr>
<td>8</td>
<td>HOSTILITY</td>
<td>Animosity, contempt, belligerence, dislike for others</td>
</tr>
<tr>
<td>9</td>
<td>SUSPICIOSITY</td>
<td>Mistrust, belief others harboring malicious or discriminatory intent</td>
</tr>
<tr>
<td>10</td>
<td>HALLUCINATORY BEHAVIOR</td>
<td>Perceptions without normal external stimulus correspondence</td>
</tr>
<tr>
<td>11</td>
<td>MOTOR RETARDATION</td>
<td>Slowed, weakened movements or speech, reduced body tone</td>
</tr>
<tr>
<td>12</td>
<td>UNUSUAL THOUGHT CONTENT</td>
<td>Unusual, odd, strange, bizarre thought content</td>
</tr>
<tr>
<td>13</td>
<td>BLUNTED AFFECT</td>
<td>Reduced emotional tone, reduction in formal intensity of feelings, flatness</td>
</tr>
<tr>
<td>14</td>
<td>EXCITEMENT</td>
<td>Heightened emotional tone, agitation, increased reactivity</td>
</tr>
<tr>
<td>15</td>
<td>DELUSIONS</td>
<td>False beliefs regarding person, place, or thing</td>
</tr>
<tr>
<td>16</td>
<td>ELEVATED MOOD</td>
<td>Pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>17</td>
<td>SUICIDALITY</td>
<td>Expressed desire, intent, or actions to harm or kill self</td>
</tr>
<tr>
<td>18</td>
<td>BIZARRE BEHAVIOR</td>
<td>Reports of behaviors which are odd, unusual, or psychotically criminal, not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>19</td>
<td>SELF-NEGLECT</td>
<td>Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td>20</td>
<td>DISTRACTIBILITY</td>
<td>Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distraction is rated when the individual shows a change in the focus of attention characterized by a pause in speech or a marked shift in gaze. Individual's attention may be drawn to noise in adjoining room, books on a shelf, interviewer's clothing, etc.</td>
</tr>
</tbody>
</table>
Asthma – Acute: Unit Level Management

Initial Assessment:
1) Determine degree of symptoms (dyspnea, wheezing, chest tightness, cough), duration of exacerbation, response to self treatment, and medications used for current exacerbation, and estimate of number of previous exacerbations.
2) Examine patient for degree of distress. Listen to chest for breath sounds and note symmetry and depth of respiration.
3) Use of accessory muscles or suprasternal retractions suggests severe exacerbation.
4) Measure pulse and respiratory rate.
5) Measure peak expiratory flow (PEF) and compare with personal best.
6) Obtain oxygen (O2) saturation.

FEV1 or PEF ≥ 50% (Mild-to-Moderate)
- Oxygen to achieve SaO2 ≥ 90%
- Inhaled SABA by nebulizer or MDI with valved holding chamber, up to 3 doses in first hour
- Oral systemic corticosteroids if no immediate response or if patient recently used oral systemic corticosteroids

Moderate Exacerbation
PEF 50-69% predicted/personal best
- Physical exam: moderate symptoms
- Inhaled SABA every 60 minutes
- Oral systemic corticosteroids
- Continue treatment 1-3 hours, provided there is improvement

Good Response
PEF ≥ 70%
- Response sustained 60 minutes after last treatment
- No distress
- Physical exam: normal

Incomplete Response
PEF 50-69%
- Mild-to-moderate symptoms
- Review or follow unit procedures.

Impending or Actual Respiratory Arrest
- Transfer to higher level of care.
- Intravenous corticosteroids
- Respiratory support
- Oxygen to achieve SaO2 ≥ 90%
- High-dose inhaled SABA and ipratropium
- Intravenous corticosteroids
- Intubation

Severe Exacerbation
PEF < 50%
- Physical exam: severe symptoms at rest, accessory muscle use, chest retraction
- History: high-risk patient
- History: poor response after initial treatment
- Oxygen
- Nebulized SABA + ipratropium, hourly or continuously
- Oral systemic corticosteroids

Post Response
PEF < 50%
- Increase SABA to maximum dose
- Intravenous corticosteroids
- Respiratory support
- Oxygen to achieve SaO2 ≥ 90%
- High-dose inhaled SABA and ipratropium
- Intubation
- Transfer to higher level of care.

Poor Response
PEF < 30%
- PCO2 ≥ 45 mm Hg
- Physical exam: symptoms severe, drowsiness, confusion
- Intravenous corticosteroids
- Respiratory support
- Oxygen to achieve SaO2 ≥ 90%
- High-dose inhaled SABA and ipratropium
- Intubation
- Transfer to higher level of care.
- Intravenous corticosteroids
- Respiratory support
- Oxygen to achieve SaO2 ≥ 90%
- High-dose inhaled SABA and ipratropium
- Intubation
- Transfer to higher level of care.
- Intravenous corticosteroids
- Respiratory support
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- High-dose inhaled SABA and ipratropium
- Intubation
- Transfer to higher level of care.
- Intravenous corticosteroids
- Respiratory support
- Oxygen to achieve SaO2 ≥ 90%
- High-dose inhaled SABA and ipratropium
- Intubation
- Transfer to higher level of care.

Exacerbations and poor control should prompt patient to strictly adhere to treatment plan.

SABA: Short-acting beta agonist (e.g., albuterol), ICS=Inhaled Corticosteroid.

Table 1: Risk Factors for Death from Asthma*

Asthma History
• Previous severe exacerbation (e.g., intubation or ICU admission for asthma)
• Two or more hospitalizations for asthma in the past year
• Hospitalization or emergency room visit for asthma in the past month
• Using >2 canisters of albuterol per month
• Difficulty perceiving asthma symptoms or severity of exacerbations
• Other risk factors: lack of a written asthma action plan

Social History
• Current drug use
• Major psychosocial problems

Co-morbidities
• Cardiovascular disease
• Other chronic lung disease
• Chronic psychiatric disease

*Adapted from National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma, Expert Panel Report 3

Table 2: Dosages of Drugs for Asthma Exacerbations

<table>
<thead>
<tr>
<th>Medication</th>
<th>Adult Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol nebulizer Solution (0.083%, 2.5mg/3ml)</td>
<td>2.5-5mg every 20 minutes for 3 doses, then 2.5-10mg every 1-4 hours as needed, or 10-15mg/hour continuously</td>
<td>Use large volume nebulizers for continuous administration. May mix with ipratropium nebulizer solution.</td>
</tr>
<tr>
<td>Albuterol MDI (90mcg/puff)</td>
<td>6-8 puffs every 20 minutes up to 4 hours, then every 4-8 hours as needed.</td>
<td>In mild-to-moderate exacerbations, MDI plus valved holding chamber is as effective as nebulized therapy with appropriate administration technique and coaching by trained personnel.</td>
</tr>
<tr>
<td>Ipratropium bromide nebulizer solution (0.25mg/ml)</td>
<td>0.5mg every 20 minutes for 3 doses, then as needed.</td>
<td>May mix in same nebulizer with albuterol. Should not be used as first-line therapy; should be added to SABA therapy for severe exacerbations.</td>
</tr>
<tr>
<td>Ipratropium bromide MDI (18mcg/puff)</td>
<td>6 puffs every 20 minutes as needed up to 3 hours</td>
<td></td>
</tr>
<tr>
<td>Ipratropium with albuterol nebulizer solution (each 5ml vial contains 0.5mg ipratropium bromide and 2.5mg albuterol)</td>
<td>3 ml every 20 minutes for 3 doses, then as needed</td>
<td>May be used for up to 3 hours in the initial management of severe exacerbations.</td>
</tr>
<tr>
<td>Prednisone (5mg, 10mg, and 20mg tablets)</td>
<td>40-80mg/day in 1 or 2 divided doses until PEF reaches 70% of predicted or personal best</td>
<td>For outpatient &quot;boost,&quot; use 40-60mg in single or 2 divided doses for total of 3 to 10 days.</td>
</tr>
</tbody>
</table>

Notes:
• There is no known advantage for higher doses of corticosteroids in severe asthma exacerbations, nor is there any advantage for intravenous administration over oral therapy provided gastrointestinal time or absorption is not impaired.
• The total course of systemic corticosteroids for an asthma exacerbation requiring an emergency department visit or hospitalization may last from 3 to 10 days. For corticosteroid courses of less than 1 week, there is no need to taper. For slightly longer courses (e.g., up to 10 days), there is probably no need to taper, especially if patients are concurrently taking inhaled corticosteroids (ICS).
• ICSs can be started at any point in the treatment of an asthma exacerbation.

Adapted from National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma, Expert Panel Report 3
I. Treatment Goals
   A. Correction of significant hypoxemia, in moderate or severe exacerbations, by administering supplemental oxygen.
   B. Rapid reversal of airflow obstruction which is best achieved by repetitive or continuous administration of a short-acting beta-agonist (SABA) (e.g., albuterol) and early in the course of treatment; administration of systemic corticosteroids to patients who have moderate to severe exacerbations or to patients who fail to respond promptly and completely to SABA treatment.
   C. Reduction of the likelihood of relapse of the exacerbation or future recurrence of severe airflow obstruction by intensifying therapy. Often, a short course of systemic corticosteroids is useful.

II. Classifying Asthma Severity
   (Adapted from National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma, Expert Panel Report 3)

<table>
<thead>
<tr>
<th>Symptoms and Signs</th>
<th>Initial PEF (or FEV1)</th>
<th>Clinical Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Dyspnea only with activity</td>
<td>PEF ≥ 70 percent predicted or personal best</td>
</tr>
<tr>
<td>Moderate</td>
<td>Dyspnea interferes with or limits usual activity</td>
<td>PEF 50-69 percent predicted or personal best</td>
</tr>
<tr>
<td>Severe</td>
<td>Dyspnea at rest; interferes with conversation</td>
<td>PEF &lt; 50 percent predicted or personal best</td>
</tr>
</tbody>
</table>

Subset: Life threatening
   Too dyspneic to speak; perspiring | PEF < 25 percent predicted or personal best | Requires ED/hospitalization; possible ICU; minimal or no relief from frequent inhaled SABA; intravenous corticosteroids |

Key: ED, emergency department; FEV1, forced expiratory volume in 1 second; ICU, intensive care unit; PEF, peak expiratory flow; SABA, short-acting beta2-agonist

III. Monitoring
   A. Serial Measurements of Lung Function - FEV1 or PEF appear to be more useful in categorizing the severity of the exacerbation, assessing treatment response, and predicting the need for hospitalization. Repeated measurements of PEF or FEV1 at 1 hour and beyond are useful as isolated assessments in determining who will require hospitalization and who is likely to have sufficient response to allow continued treatment in the emergency room.
   B. Pulse oximetry is indicated for patients in severe distress or have FEV1 or PEF < 40 percent of predicted, to assess the adequacy of arterial oxygen saturation.
   C. Signs and Symptoms – All patients presenting with a reported asthma exacerbation should be evaluated based on at least vital signs and an overall physical assessment (e.g., ability to breathe well enough to talk). The presence of drowsiness in a patient is a useful predictor of impending respiratory failure and reason to consider transfer to a higher level of care.
IV. Therapy
A. Oxygen is recommended for most patients. Administer supplemental oxygen (by nasal cannulae or mask, whichever is better tolerated) to maintain an \( \text{SaO}_2 > 90 \% \) (> 95% in pregnant women and in patients with coexistent heart disease). Monitor \( \text{SaO}_2 \) until a clear response to bronchodilator therapy has occurred.

B. Short-acting beta-agonists (e.g., albuterol) are recommended for all patients. The repetitive or continuous administration of SABAs is the most effective treatment for reversing airflow obstruction. Nebulizer therapy may be preferred for patients who are unable to cooperate effectively in using a metered dose inhaler (MDI) because of their age, agitation, or severity of the exacerbation. The onset of action is less than 5 minutes; repetitive administration produces incremental bronchodilation. In about 60-70 percent of patients, response to the initial three doses of therapy will be sufficient to discharge them, and most patients will have a significant response after the first dose. The duration of action of bronchodilation from SABAs in severe asthma exacerbations is not precisely known, but duration can be significantly shorter than that observed in stable asthma.

C. Ipratropium—Adding multiple high doses of ipratropium bromide (0.5mg nebulizer solution or 8 puffs by MDI in adults) to a selective SABA produces additional bronchodilation, resulting in fewer hospitalizations.

D. Oral corticosteroids are recommended for most patients. Give systemic corticosteroids to patients who have moderate or severe exacerbations and patients who do not respond completely to initial SABA therapy. These medications speed the resolution of airflow obstruction and reduce the relapse rate and may reduce hospitalizations. Patients given systemic corticosteroids should continue oral systemic corticosteroids for 3–10 days. The need for further corticosteroid therapy should be assessed at a follow up visit. For corticosteroid courses of less than 1 week, there is no need to taper the dose. For 10-day courses, there remains no need to taper especially if patients are concurrently taking inhaled corticosteroids.

E. Inhaled corticosteroids (ICS) should be considered at discharge in addition to oral corticosteroids. Long-term ICS therapy reduces exacerbations in patients who have persistent asthma. Patients already taking ICS should continue it following discharge.

V. Patient Education
A. Advise patient to keep follow up appointments
B. Review medications (e.g., dosing, purpose, side effects) and proper inhaler technique
C. Advise patient on when to seek medical care if asthma worsens
D. Review asthma triggers
E. Review or develop a written plan for managing either relapse of the exacerbation or recurrent symptoms
1. Obtain thorough history and perform physical exam
2. Review history of symptoms witnessed or addressed by healthcare staff
3. Document peak expiratory flow. Spirometry is suggested when available.
4. Consider transferring the patient to a 24 hour unit if the patient has a history of intubation.
5. Assess the patient’s knowledge and skills for self-management
6. Classify asthma severity to select the most appropriate therapy by assessing impairment & risk

### Components of Severity

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic</td>
<td>Intermittent</td>
</tr>
<tr>
<td>Nighttime</td>
<td>&lt; 2 times/month</td>
</tr>
<tr>
<td>Exacerbation</td>
<td>&lt; 2 days/week</td>
</tr>
<tr>
<td>Exacerbation with normal activity</td>
<td>None</td>
</tr>
<tr>
<td>Long function</td>
<td>Normal FEV₁ between exacerbations</td>
</tr>
<tr>
<td>Risk</td>
<td>Exacerbations requiring oral systemic corticosteroids</td>
</tr>
</tbody>
</table>

### Treatment

#### Long-Term Control Medication (see table 9 for alternatives)

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 3 or STEP 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Low dose inhaled corticosteroid</td>
<td>Medium dose ICS</td>
<td>High-dose ICS + LABA*</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Inhaled ICS 1 puff BID</td>
<td>Budesonide 2 puffs BID</td>
<td>Budesonide high dose 4 puffs BID plus Plen*</td>
</tr>
<tr>
<td>*Non-formulary approval required.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Quick Relief Medication

Short-acting Beta2-agonist as needed for symptoms for all patients for all steps of therapy

Albuterol HFA 2 puffs QID prn

*SABA=short-acting beta2-agonist, LABA=long-acting beta2-agonist, ICS=inhaled corticosteroid, EIB=exercise induced bronchospasm

**Non-formulary approval required.

Evaluate response to therapy in 2-6 weeks or as clinically indicated.

Go to page 2 box # 4
Assess the patient to determine if asthma is well controlled (based on the most severe symptoms during the previous 2-4 weeks and by spirometry or peak flow measures).

**Well Controlled**
- Symptoms: ≤ 2 days/week
- Nighttime awakenings: ≤ 2 times/week
- Limitations of activities: None
- Need for quick relief inhaler: ≤ 2 days/week
- FEV₁ or Peak Flow: >80% predicted/personal best
- Exacerbations requiring oral corticosteroids: 0-1/year

**Not Well Controlled**
- Symptoms: > 2 days/week
- Nighttime awakenings: 1-3 times/week
- Limitations of activities: Some
- Need for quick relief inhaler: > 2 days/week
- FEV₁ or Peak Flow: 60%-80% predicted/personal best
- Exacerbations requiring oral corticosteroids: ≥ 2/year

**Very Poorly Controlled**
- Symptoms: Throughout the day
- Nighttime awakenings: ≥ 4 times/week
- Limitations of activities: Extremely limited
- Need for quick relief inhaler: several times per day
- FEV₁ or Peak Flow: < 60% predicted/personal best
- Exacerbations requiring oral corticosteroids: ≥ 2/year

Exacerbations and poor control should prompt review of treatment plan.

- Continue current regimen.
- Follow up with peak flow to assess control.
- Consider step down if well controlled for at least 3 months.
- Once stable, follow up at least every 12 months.
- Obtain peak flow at each visit.
- Review medication technique, adherence, environmental control, and assess side effects during each visit.
- Review asthma action plan & revise as needed during each visit.
- Consider spirometry every 1-2 years.

- Before stepping up therapy, review adherence to medication, inhaler technique, environmental control, comorbid conditions and assess side effects.
- Obtain peak flow.
- Step up 1 step.
- Review asthma action plan & revise as needed.
- Consider Respiratory Care referral.
- Follow up in 2-6 weeks or as clinically indicated.

- Before stepping up therapy, review adherence to medication, inhaler technique, environmental control, comorbid conditions and assess side effects.
- Obtain peak flow.
- Consider short course oral systemic corticosteroids.
- Step up 1-2 steps.
- Review asthma action plan & revise as needed.
- Consider Respiratory Care or Specialty Care referral.
- Follow up in 2 weeks or as clinically indicated.

- Before stepping up therapy, review adherence to medication, inhaler technique, environmental control, comorbid conditions and assess side effects.
- Obtain peak flow.
- Consider short course oral systemic corticosteroids.
- Step up 1-2 steps.
- Review asthma action plan & revise as needed.
- Consider Specialty referral.
- Follow up in 2 weeks or as clinically indicated.

Asthma well controlled? Yes
- Go to box # 6

Asthma well controlled? No
- Before stepping up therapy, review adherence to medication, inhaler technique, environmental control, comorbid conditions and assess side effects.
- Obtain peak flow.
- Step up 1 step.
- Review asthma action plan & revise as needed.
- Consider Respiratory Care or Specialty Care referral.
- Follow up in 2-6 weeks or as clinically indicated.

- Before stepping up therapy, review adherence to medication, inhaler technique, environmental control, comorbid conditions and assess side effects.
- Obtain peak flow.
- Consider short course oral systemic corticosteroids.
- Step up 1-2 steps.
- Review asthma action plan & revise as needed.
- Consider Respiratory Care referral or Specialty Care referral.
- Follow up in 2 weeks or as clinically indicated.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. September 1996. Reviewed 3/05. Revised 4/98, 1/99, 4/02, 4/03, 10/03, 7/09, 1/10, 1/13, 1/15. Revised to include children 11/06.
I. Definition: Asthma is a chronic disorder of the airways that is complex and characterized by variable and recurring symptoms (e.g., cough, wheezing, shortness of breath, chest tightness, and sputum production), airflow obstruction, bronchial hyperresponsiveness and underlying inflammation. In some patients, airflow obstruction may be only partially reversible and permanent structural changes in the airways may occur. Structural changes are associated with progressive loss of lung function overtime that is not prevented or fully reversible by current therapies. The interaction of these features determines severity and response to treatment.

II. Diagnosis is based on the following:
A. History
   1. Family history of asthma, allergy, sinusitis, rhinitis, eczema or nasal polyps
   2. Age of onset and diagnosis
   3. Recurrent symptoms such as wheeze, cough, chest tightness, shortness of breath, or difficulty breathing
   4. Pattern of symptoms
      a. Perennial, seasonal or both
      b. Continual, episodic, or both
   5. Precipitating factors that cause symptoms to occur or worsen
      a. Exercise
      b. Allergen (e.g., mold, pollen, dust mites, animal fur)
      c. Irritant (e.g., smoke, chemicals)
      d. Viral infection
      e. Changes in weather
      f. Menstrual cycles
      g. Strong emotional expression (e.g., stress, laughing or crying hard)
      h. Drugs (e.g., aspirin, NSAIDS, or beta-blockers)
   6. Symptoms occur or worsen at night and awaken the patient
   7. History of exacerbations
      a. Usual prodromal signs and symptoms
      b. Rapidity of onset, duration & frequency
      c. Severity (e.g., need for hospitalization) and life-threatening exacerbations (e.g., intubation)
      d. Number and severity of exacerbations in last year
      e. Usual management of exacerbations
   8. Comorbid conditions that may aggravate asthma (e.g., rhinitis, GERD, obesity, obstructive sleep apnea)
B. Physical exam focusing on the upper respiratory tract, chest, and skin
   1. Hyper-expansion of the chest
   2. Wheezing during normal breathing or prolonged forced exhalation. Usually high pitched whistling sounds when breathing out
   3. Increased nasal secretion, mucosal swelling, and/or nasal polyps.
   4. Atopic dermatitis, eczema, or any other manifestations of an allergic skin condition.

   Note: Physical examination in patients with asthma is often normal. Lack of wheezing or normal chest examination does not exclude asthma.
C. Airflow obstruction is at least partially reversible
   1. Spirometry is used to demonstrate obstruction and assess reversibility.
   2. Considered reversible if either an increase in FEV₁ of ≥12 percent from baseline or by an increase of ≥10 percent of predicted FEV₁ after inhalation of a short-acting bronchodilator
   3. Spirometry typically measures the maximal volume of air forcibly exhaled from the point of maximal inhalation (FVC) and the volume of air exhaled during the first second of this maneuver (FEV₁).
D. Exclusion of other diagnoses
   1. Adults – COPD, heart failure, pulmonary embolism, mechanical obstruction such as tumor, vocal cord dysfunction, cough secondary to medications such as ACE inhibitors, or pulmonary infiltration.
   2. Children – Vocal cord dysfunction, bronchiectasis, cystic fibrosis, congenital heart disease, alpha-1-antitrypsin deficiency, inhaled foreign body, chronic upper airway cough syndrome
### III. Classification of severity

A. Classify asthma severity to select the most appropriate therapy by assessing **impairment** and **risk**.

#### Table 1: Impairment and Risk

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency of symptoms</td>
<td>Likelihood of exacerbation</td>
</tr>
<tr>
<td>Functional limitations</td>
<td>Progressive loss of lung function</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>Exacerbations requiring oral corticosteroids</td>
</tr>
<tr>
<td>Need for short-acting beta agonist for quick relief of symptoms</td>
<td>Two or more emergency room visits or hospitalizations for asthma in last year</td>
</tr>
<tr>
<td>School/work days missed</td>
<td>History of intubation or ICU admission especially in last 5 years</td>
</tr>
<tr>
<td>Ability to engage in normal daily activities</td>
<td>Patients report that they feel in danger or frightened by their asthma</td>
</tr>
<tr>
<td>Long function measured by spirometry</td>
<td>Psychological factors (e.g., depression, stress)</td>
</tr>
<tr>
<td></td>
<td>Severe airflow obstruction by spirometry</td>
</tr>
<tr>
<td></td>
<td>Abilities and beliefs about taking medications</td>
</tr>
</tbody>
</table>

B. Level of severity is determined by assessment of both impairment and risk. Assess impairment by patient’s recall of previous 2–4 weeks and spirometry. Assign severity to the most severe category in which any feature occurs.

C. Respiratory Care may be consulted to assist with asthma classification and patient education.

#### Table 2: Classification of Asthma Severity for Patients who are NOT Currently Taking Long-term Control Medications*

<table>
<thead>
<tr>
<th>Components of Severity</th>
<th>Intermittent</th>
<th>Persistent Mild</th>
<th>Persistent Moderate</th>
<th>Persistent Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impairment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week but not daily</td>
<td>Daily</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>≤ 2 times/week</td>
<td>&gt; 5 times/week</td>
<td>&gt; 1 times/week but not nightly</td>
<td>≥ 5 times/week</td>
</tr>
<tr>
<td>SABA for symptom control (not prevention of EIB)</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week but not &gt; 1 time/day</td>
<td>Daily</td>
<td>Several times per day</td>
</tr>
<tr>
<td>Long function</td>
<td>Normal FEV&lt;sub&gt;1&lt;/sub&gt;/FVC</td>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; ≤ 80% predicted</td>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; &gt; 80% predicted</td>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; ≥ 80% predicted</td>
</tr>
<tr>
<td>Risk</td>
<td>Exacerbations requiring oral systemic corticosteroids</td>
<td>0 times</td>
<td>&gt; 2 times</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step for Initiating Treatment</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4 or 5 (consider short course oral corticosteroids to gain control)</th>
</tr>
</thead>
</table>

Evaluates level of asthma control and step up or step down therapy as needed.

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*Adapted from Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma
SABA=short-acting beta<sub>2</sub>-agonist, EIB=exercise induced bronchospasm

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D. Once asthma is well controlled, classify asthma severity by the lowest level of treatment required to maintain control.

Table 3: Classification of Asthma Severity*  

<table>
<thead>
<tr>
<th></th>
<th>Interim</th>
<th>Persistent Mild</th>
<th>Persistent Moderate</th>
<th>Persistent Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest level of treatment required to maintain control</td>
<td>Step 1</td>
<td>Step 2</td>
<td>Step 3 - 4</td>
<td>Step 5 - 6</td>
</tr>
</tbody>
</table>

*Adapted from Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma

IV. Assessing asthma control
A. Level of control is based on the most severe impairment or risk category.
1. Impairment is assessed based on the patient’s recall of events during the previous 2-4 weeks and by spirometry or peak flow measures.
2. Risk is assessed based on events over the last year.
B. Patients who have asthma that is well controlled at the time of a clinical assessment must be monitored over time and treatment should be adjusted accordingly, since asthma can vary in intensity over time.
C. Depending on level of asthma control, the patients is assigned to one of six treatment steps.
D. Therapy is stepped up or stepped down based on how well asthma is controlled and level of severity assessed for both impairment and risk.
E. Any exacerbation should prompt review of maintenance treatment.

F. Note: For treatment purposes, patients who had ≥2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have not-well-controlled asthma, even in the absence of impairment levels consistent with not-well-controlled asthma.

Table 4: Assessing Asthma Control and Adjusting Therapy*  

<table>
<thead>
<tr>
<th>Component of Severity</th>
<th>Well Controlled</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Impairment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>≤ 2 times/month</td>
<td>3-4 times/week</td>
<td>&gt; 4 times/month</td>
</tr>
<tr>
<td>SABA for symptom control (not prevention EIB)</td>
<td>≤ 2 days/week</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>None</td>
<td>Some limitations</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>FEV1 or peak flow</td>
<td>&gt; 80% predicted/personal best</td>
<td>60-80% predicted/personal best</td>
<td>&lt; 60% predicted/personal best</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Risk</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Exacerbations</td>
<td>0-1/year</td>
<td>&gt; 2/year</td>
<td>Not correlated to level of control but should be evaluated in assessment of therapy</td>
</tr>
<tr>
<td>Treatment-related adverse effects</td>
<td>Consider severity &amp; interval since last exacerbation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Recommended Action**:  
• Maintain current treatment step
• Follow-up every 6-12 months as needed
• Consider step down if well controlled for at least 3 months
• Step up 1 step and reassess in 2-4 weeks or as clinically indicated
• Consider short course of oral systemic corticosteroids
• Step up 2 steps
• Reevaluate in 2 weeks or as clinically indicated

*Adapted from Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma

SABA=short-acting beta2-agonist, EIB=exercise induced bronchospasm

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V. Treatment Principles
A. Gain control of asthma as soon as possible.
B. Evaluate causes of poor control before stepping up therapy and increasing doses or adding long-term control medications.
   1. Poor patient inhaler technique
   2. Poor medication adherence
   3. Adverse effects to medications
   4. Exposure to environmental triggers
   5. Comorbidities that may aggravate asthma (e.g., rhinitis, GERD, obesity, obstructive sleep apnea)
C. Goals of therapy are to achieve asthma control by reducing impairment and risk
   1. Reduce impairment
      a. Prevent symptoms
      b. Require infrequent use of quick relief medications (≤ 2 days per week)
      c. Maintain normal activity level
      d. Maintain normal or near normal lung function
   2. Reduce risk
      a. Prevent exacerbations and minimize need for emergency department visits and hospitalizations
      b. Provide optimal treatment with minimal or no adverse effects
      c. Prevent progressive loss of lung function

VI. Treatment
A. Non-pharmacologic
   1. Avoidance of environmental triggers such as allergens or tobacco smoke.
   2. Physical activity should be encouraged because of its general health benefits. Provide advice about exercise-induced bronchoconstriction (EIB).
   3. Weight reduction if obese.
   4. Possibility of occupational asthma should be considered and sensitizers should be removed if possible.
   5. Avoidance of medications that may worsen asthma (e.g., aspirin, NSAIDS, or nonselective beta-blockers). However, use of these medications aren’t absolutely contraindicated unless there is a history of previous reactions to them.
B. Pharmacologic
   1. Annual influenza vaccination for the following patients
      a. Mild persistent to severe persistent asthma (i.e., requires chronic medication)
      b. History of hospitalization or emergency treatment for asthma
   2. Consider treatment of comorbid conditions that aggravate asthma especially if asthma is poorly controlled.
   3. Stepwise approach to therapy
      a. Therapy is determined by asthma severity for initiating therapy and the level of asthma control for adjusting therapy
      b. Six treatment steps. Stepped up or down based on how well asthma is controlled
         i. Step up
            • Optimize dose of long-term control medication but evaluate causes of poor control first
            • Complete resistance to inhaled corticosteroid is rare so consider trial of higher dose
            • Use sustained step up for at least 2-3 months if asthma poorly controlled
            • Use short-term step up for 1-2 weeks (e.g., with viral infection or allergen)
         ii. Step down
            • Consider step down after good control is maintained for at least 3 months
            • Goal is to find the minimum effective dose that controls symptoms & prevents exacerbations
            • Complete cessation of inhaled corticosteroids is not advised in adults
Two major categories of medications

a. Quick relief medications
   i. Used to provide prompt relief of symptoms
   ii. Will not provide long-term asthma control and is prescribed for as needed use
   iii. Short-acting beta₂-agonist such as albuterol is preferred
   iv. If used > 2 days per week (except for exercise-induced asthma), the patient may need to start or increase long-term control medications

b. Long-term control medications
   i. Taken daily over a long period of time to maintain control of symptoms
   ii. Not effective on an as needed (i.e., PRN) basis
   iii. Should not be prescribed without a quick relief medication.
   iv. Used to reduce inflammation, relax airway muscles, & improve symptoms & lung function
   v. Types
      • Inhaled corticosteroid (ICS) such as betamethasone
      • Most potent and effective
      • May cause systemic adverse effects at high doses
      • Long-acting beta₂-agonist (LABA) such as salmeterol
      • Not used alone and must be used in combination with ICS
      • When long-term control combination therapy is warranted, preferred combination is ICS plus LABA
      • Leukotriene receptor antagonist (LTRA) such as montelukast
      • Do NOT use LTRA plus LABA as a substitute for combination therapy with ICS plus LABA
      • Oral corticosteroid (OCS) such as prednisone
      • Not recommended as a long-term control medication except at Step 6 of treatment due to potential for systemic side effects
      • Generally reserved as short course for moderate to severe exacerbations to gain prompt control

Table 6: Quick Relief Medications

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type of Medication</th>
<th>Adult Dose</th>
<th>Child ≤ 12 Dose</th>
<th>Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol (Proventil HFA®) 90 mcg/puff</td>
<td>Quick relief Short-acting beta₂-agonist</td>
<td>Quick relief: 2 puffs qid prn (up to 2 puffs every 4 hrs.)</td>
<td>Exacerbation: 4-8 puffs every 20 min for 3 doses then every 1-4 hours prn</td>
<td>Tachycardia, tremor, headache</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prednisone (Deltasone®) 5 mg/10 mg tablets</td>
<td>Quick relief – used short-term for establishing control when initiating therapy or during moderate to severe exacerbations Oral corticosteroid</td>
<td>40-80 mg/day x 5-10 days</td>
<td>1-2 mg/kg/day maximum 60 mg/day x 5-10 days</td>
<td>Hyperglycemia, increased appetite, fluid retention, weight gain, facial flushing, mood alteration, hypertension, ulcer</td>
</tr>
<tr>
<td>Drug</td>
<td>Type of Medication</td>
<td>Adult Dose</td>
<td>Child ≤ 11 Dose</td>
<td>Adverse Effects</td>
</tr>
<tr>
<td>------------------------------</td>
<td>------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Beclomethasone HFA</td>
<td>ICS</td>
<td>Low dose: 80mcg-240mcg • 160mcg = 1 puff bid</td>
<td>Low dose: 80-160mcg • 160mcg = 1 puff bid</td>
<td>Cough, dysphoria, oral thrush</td>
</tr>
<tr>
<td>(Qvar®)</td>
<td></td>
<td>Medium dose: &gt;240mcg-400mcg • 320mcg = 2 puffs bid • 480mcg = 3 puffs bid</td>
<td>Medium dose: &gt;160-320mcg • 320mcg = 2 puffs bid</td>
<td>Systemic adverse effects may occur at high doses (see oral corticosteroids below for list)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High dose: &gt;400mcg • 640mcg = 4 puffs bid</td>
<td>High dose: &gt;320mcg • 480mcg = 3 puffs bid</td>
<td></td>
</tr>
<tr>
<td>Fluticasone HFA</td>
<td>ICS</td>
<td>Low dose: 88-264mcg • 88mcg = 1 puff (44mcg inhaler) bid</td>
<td>Low dose: 88-176mcg • 88mcg = 1 puff (44mcg inhaler) bid</td>
<td>Cough, dysphoria, oral thrush</td>
</tr>
<tr>
<td>(Flovent®)</td>
<td></td>
<td>Medium dose: &gt;264-400mcg • 440mcg = 2 puffs (110mcg inhaler) bid</td>
<td>Medium dose: &gt;176-352mcg • 220mcg = 1 puff (110mcg inhaler) bid</td>
<td>Systemic adverse effects may occur at high doses (see oral corticosteroids below for list)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High dose: &gt;440mcg • 880mcg = 2 puffs (220mcg inhaler) bid</td>
<td>High dose: &gt;352mcg • 440mcg = 1 puff (220mcg inhaler) bid</td>
<td></td>
</tr>
<tr>
<td>Salmeterol/Fluticasone HFA</td>
<td>LABA</td>
<td>1 puff bid</td>
<td>1 puff bid</td>
<td>Tachycardia, tinnitus, hypokalemia, QT prolongation, diminished bronchoprotective effect may occur within 1 week</td>
</tr>
<tr>
<td>(Serevent®/Nasonex®)</td>
<td></td>
<td>Notes:</td>
<td>Notes:</td>
<td>Uncommon, severe, life-threatening or fatal exacerbation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Must be used in combination with ICS</td>
<td>Must be used in combination with ICS</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Do NOT wash mouthpiece</td>
<td>Do NOT wash mouthpiece</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Child ≥ 4 years</td>
<td>Child ≥ 4 years</td>
<td></td>
</tr>
<tr>
<td>Montaluk/formoterol HFA</td>
<td>Combination</td>
<td>Medium dose: 100/5mcg (100mcg inhaler) bid</td>
<td>Not approved for use in children ≤ 11 years</td>
<td>See adverse effects for ICS and LABA</td>
</tr>
<tr>
<td>(Dulera®)</td>
<td>ICS &amp; LABA</td>
<td>Maximum 4 inhalations</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>High dose: 200/5mcg (200mcg inhaler) BID</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ICS=inhaled corticosteroid, LABA=long-acting beta2-agonist, LTRA=leukotriene receptor antagonist, OCS=oral corticosteroid
Table 8: Long-term Control Medications - Oral

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type of Medication</th>
<th>Adult Dose</th>
<th>Child ≤ 11 Dose</th>
<th>Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Montelukast (Singulair®)</td>
<td>LTRA</td>
<td>≥ 15 years - Adult: 10mg orally once daily in the evening</td>
<td>6-14 years: 5mg chewable once daily in the evening</td>
<td>None usually: Headache, cough, upper respiratory infection, pharyngitis, abdominal pain</td>
</tr>
<tr>
<td>Prednisone (Deltasone®)</td>
<td>OCS</td>
<td>5-60mg daily or every other day</td>
<td>0.25-2mg/kg daily or every other day</td>
<td>Short-term: Hyperglycemia, increased appetite, fluid retention, weight gain, facial flushing, mental alteration, hyper tension, ulcer Long-term: adrenal suppression, dermal thinning, hypertension, diabetes, Cushing’s syndrome, cataracts, muscle weakness, osteoporosis, immunosuppression</td>
</tr>
</tbody>
</table>

ICS=inhaled corticosteroid, LABA=long-acting beta2-agonist, LTRA=leukotriene receptor antagonist, OCS=oral corticosteroid

5. Factors that cause non-adherence
   a. Medication Usage
      i. Difficulties using inhalers
      ii. Complex regimens
      iii. Adverse effects
   b. Non-Medication Factors
      i. Misunderstanding or lack of information
      ii. Poor communication
      iii. Fears about adverse effects
      iv. Inappropriate expectations
      v. Underestimation of severity
      vi. Attitudes about health
      vii. Cultural factors
### Table 9: Stepwise Approach to Managing Asthma Long-term

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
<th>Step 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent Asthma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quick Relief Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• SABA is needed for symptoms for all patients for all stages of therapy. Intensity of treatment depends on severity of symptoms: up to 4 treatments every 20 minutes is included. Short courses of oral systemic corticosteroids may be needed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Caution: Use of SABA &gt; 2 days/week for symptom relief (not to prevent EIB) generally indicates inadequate control and the need to step up treatment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preferred Treatment</strong></td>
<td><strong>SABA as needed</strong></td>
<td><strong>Low dose ICS Beclomethasone HFA</strong></td>
<td><strong>Medium dose ICS Beclomethasone HFA</strong></td>
<td><strong>High dose ICS + LABA</strong></td>
<td><strong>High dose ICS + LABA</strong> + OCS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Fluticasone* HFA Plus Salmeterol* Plus Prednisone</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Consider specialty referral</td>
</tr>
<tr>
<td><strong>Alternative Treatment</strong></td>
<td><em><em>LTRA</em> Montelukast</em>*</td>
<td><strong>Low dose ICS + LABA</strong> Beclomethasone HFA Plus Salmeterol* Or Medium dose ICS + LTRA* Beclomethasone HFA Plus Montelukast**</td>
<td><strong>Medium dose ICS + LABA</strong> Combination inhaled corticosteroid/Formoterol* 250/6mcg Or <strong>Medium dose ICS + LTRA</strong> Beclomethasone HFA Plus Montelukast**</td>
<td><strong>High dose ICS + LABA</strong> Fluticasone HFA Plus Salmeterol* Or <strong>Combination inhaled corticosteroid/Formoterol</strong> 500/9mcg Plus Prednisone</td>
<td><strong>High dose ICS + LABA</strong> + OCS Combination inhaled corticosteroid/Formoterol* 500/9mcg Plus Prednisone</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Consider specialty referral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Consider specialty referral</td>
</tr>
</tbody>
</table>

*Non-formulary medication
SABA=short-acting beta2 agonist, LABA=long-acting beta2 agonist, ICS=inhaled corticosteroid, OCS=oral corticosteroid, LTRA=leukotriene receptor antagonist, EIB=exercise induced bronchospasm
VII. Follow-Up
A. Patients with a diagnosis of asthma should be seen based on acuity and clinical judgment, but duration between visits may not exceed 12 months.
B. Consider the following for frequency of follow-up visits
1. Follow-up at 2-6 week intervals when initiating therapy or if asthma is not well controlled therapy
2. Follow-up at 2 week intervals of asthma is very poorly controlled
3. Follow-up at 3 month intervals when stepping down therapy
C. Assess asthma classification severity (Table 3) and asthma control (Table 4) during each chronic care visit.
   1. Daytime and nighttime signs and symptoms of asthma
   2. Inability or difficulty performing normal activities due to asthma symptoms
   3. Pulmonary function
      a. Peak flow reading should be obtained at every chronic care visit. Consider more frequent peak flow monitoring for patients who
         i. Have moderate persistent and severe persistent asthma
         ii. Have a history of severe exacerbations (e.g., required intubation)
         iii. Poorly perceive airflow obstruction or worsening asthma
         iv. Have poorly controlled asthma
      b. Consider obtaining spirometry every 1-2 years.
   4. Exacerbations since last visit
   5. Frequency of use of quick relief medication - Monitor use of short-acting beta2-agonist at each chronic care visit as a measure of disease control. Asthma is not adequately controlled if the patient is using more than 2 times per week.
D. Review medication inhaler technique, adherence, and assess side effects during each chronic care visit.
E. Reinforce education
   1. Review asthma action plan and revise as needed
   2. Proper inhaler technique
   3. Importance of adherence with long-term control medications

VIII. Referrals
A. Consider respiratory care referral for a patient
   1. To assist with asthma classification and patient education
   2. If the patient is not well controlled or is very poorly controlled
B. Consider specialty referral for a patient that
   1. Requires Step 5 care or higher and isn’t meeting goals of therapy
   2. Persistent uncontrolled asthma or frequent exacerbations
   3. Risk factors for asthma-related death
      a. Had a life-threatening or near-fatal exacerbation (e.g., ICU admission or mechanical ventilation)
   4. Anaphylaxis or confirmed food allergy with asthma
   5. Other conditions that complicate asthma or its diagnosis

IX. Peak Flow Monitoring
A. The patient’s personal best peak flow should be used as the reference value
B. Personal best peak flow number is the highest peak flow number achieved over a 2-week period when asthma is well controlled.
C. Steps
   1. Move indicator to the bottom of the numbered scale
   2. Patient should be standing
   3. Patient should take a deep breath, filling their lungs completely
   4. Mouthpiece should be placed in mouth and lips should be closed around it. The tongue should not be placed inside the hole.
   5. Patient should exhale as hard and fast as possible in a single breath.
D. Interpretation of results
   1. Green Zone – 80% of personal best number signals control
   2. Yellow Zone – 50% to < 80% of personal best number signals caution
   3. Red Zone – less than 50% of personal best number signals a medical alert
Patient Education

Teach patients how to manage their asthma.

I. Basic facts about the disease
   A. What is asthma
   B. Consequences of poor control
   C. What to expect during an asthma exacerbation

II. Use of medication
   A. Difference between quick relief and long-term control medications and when to use them
   B. Proper inhaler technique (technique varies between inhalers)
   C. Importance of adherence for control

III. Self-monitoring to assess level of asthma control and recognize signs of worsening asthma based on symptoms.

IV. Use of a written asthma action plan
   A. How to adjust medications in response to worsening asthma
   B. When to seek medical care if symptoms fail to respond to quick relief medication

V. Avoidance of environmental triggers that worsen asthma
Priming HFA inhaler:
1. Shake the inhaler well
2. Prime the inhaler before using for the first time by releasing 4 test sprays into the air away from face
3. Repeat the above priming procedure before using only if the inhaler has not been used for more than 2 weeks.

Cleaning HFA inhaler:
1. Remove medication canister. Never get the canister wet.
2. Clean the plastic mouthpiece by running warm water through the top to the bottom for 30 seconds at least once a week.
3. Shake to remove excess water, then air dry thoroughly (such as overnight).

Instructions for taking a dose from your HFA inhaler:

Read the steps below before using your inhaler. If you have any questions, ask your provider.
1. Take the cap off the mouthpiece of the inhaler (plastic actuator) and shake the inhaler well before each spray.
2. Hold the inhaler upright with the mouthpiece down (see Figure 2). Breathe out through your mouth and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close your lips around it.
3. Push the top of the canister all the way down while you breathe in deeply and slowly through your mouth (see Figure 3). Right after the spray comes out, take your finger off the canister. After you have breathed in all the way, take the inhaler out of your mouth and close your mouth.
4. Hold your breath as long as you can, up to 10 seconds, to allow the drug to reach deeply into your lungs. Then breathe normally.
5. If your provider has prescribed more sprays, wait 1 minute between sprays. Shake the inhaler again and repeat steps 2 through 4.
6. Put the cap back on the mouthpiece after every time you use the inhaler, and make sure it snaps firmly into place.

Important points:
1. Do not use the inhaler after the expiration date, which is on the outside packaging.
2. This technique does not work with dry powder capsule inhalers. It is important to close the mouth tightly around the mouthpiece of the inhaler and to inhale rapidly when using a dry powder inhaler.
<table>
<thead>
<tr>
<th>Long-term Control Medicines</th>
<th>How to Take</th>
<th>Other Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quick Relief Medicine</th>
<th>How to Take</th>
<th>Other Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Take only if needed and in the yellow and red zones or before exercise.</td>
</tr>
</tbody>
</table>

### Special instructions when I feel ______ good, ______ not good, and ______ awful.

#### Green Zone
- **I feel good**
  - No cough, wheeze, chest tightness, or shortness of breath during the day or night
  - Can do usual activities.
  - **PREVENT asthma symptoms everyday**
    - Take my long-term control medicines every day.
    - Before exercise, take ___ puffs of _______.
    - Avoid known triggers when possible.

#### Yellow Zone
- **I do not feel good**
  - Cough, wheeze, chest tightness, shortness of breath, or
  - Waking at night due to asthma symptoms, or
  - Can do some, but not all, usual activities.
  - **CAUTION:** I should continue taking my long-term control asthma medicines every day AND
    - Take ____ puffs of quick relief medicine.
    - If you still do not feel good within 20-30 minutes, you should take ___ puffs. If you do not feel better within one hour, go to the Red Zone. If you do feel better,
      - Continue using quick-relief medicine every 4 hours as needed for 24 hours.
      - Increase ______.
      - Drop a sick call request.

#### Red Zone
- **I feel awful**
  - Very short of breath, or
  - Quick relief medicine has not helped, or
  - Cannot sleep because of trouble breathing, or
  - Cannot do usual activities because of trouble breathing
  - **MEDICAL ALERT! Get help!**
    - Take quick relief medicine _______ puffs every ______ minutes
    - Get help immediately if you are having difficulty walking or talking due to shortness of breath or lips or fingernails are gray or blue.
    - Increase ______.
BENZODIAZEPINE DISCONTINUATION

Intake screening identifies patient on benzodiazepine (BZD):
Provider completes assessment of BZD dependence, comorbid conditions, and risk for complicated withdrawal (see Table 1): Risk factors for complicated benzodiazepine withdrawal (BZW) present?

No

Risk Factors Present
One or more risk factors identified from Table 1 requires gradual discontinuation.
Start equivalent dose of chlordiazepoxide (see Table 3) and administer DOT to avoid BZW symptoms (see Table 2).
Transfer patient to a 24-hour medical facility.

Yes

Risk Factors Present
Three or more risk factors identified:

No

Begin gradual discontinuation and tapering of chlordiazepoxide. Continue the full dose equivalent for 5 days, then taper the total daily dose by 25% every 5 days until discontinued. The total daily dose should be divided and administered every 12 hours.
Monitor patient using the BZW Assessment Form every 12 hours.
Consider collaboration with Mental Health Services for conversion and taper schedule.

Yes

Three or more risk factors identified:

No

Less than 3 risk factors identified:

Yes

Signs/symptoms of BZW (Table 2) or sedation?

No

Continue taper and monitoring plan.

Yes

Consider modification of dose to alleviate symptoms.
Consider transfer to an inpatient facility.

Consider modification of dose to alleviate symptoms.
Consider transfer to an inpatient facility.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved January 2000. Revised 8/03, 1/10, 5/12, 2014.

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**Table 2 – Signs and Symptoms of BZW**

The likelihood and severity of withdrawal symptoms is a function of drug, dose, and duration of exposure.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Example Taper Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>1 mg lorazepam = 10 mg chlordiazepoxide, therefore 8 mg lorazepam = 80 mg chlordiazepoxide</td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
</tr>
<tr>
<td>Agitation</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
</tr>
<tr>
<td>Convulsions</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure lability</td>
<td>1 mg lorazepam = 10 mg chlordiazepoxide, therefore 8 mg lorazepam = 80 mg chlordiazepoxide</td>
</tr>
<tr>
<td>Tremor</td>
<td></td>
</tr>
<tr>
<td>Delirium</td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td></td>
</tr>
<tr>
<td>Hallucinations</td>
<td>1 mg lorazepam = 10 mg chlordiazepoxide, therefore 8 mg lorazepam = 80 mg chlordiazepoxide</td>
</tr>
<tr>
<td>Perspiration</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3 – BZD Equivalents (Estimates) & Withdrawal Data**

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Approx. Equivalent Dose (mg)</th>
<th>FDA Adult Max Daily Dose (mg/day)</th>
<th>Elimination Half Life (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolamb</td>
<td>Xanax</td>
<td>0.5</td>
<td>4</td>
<td>12-13</td>
</tr>
<tr>
<td>Chloridiazepoxide</td>
<td>Librium</td>
<td>10</td>
<td>100</td>
<td>15-40</td>
</tr>
<tr>
<td>Clonazepame</td>
<td>Klonopin</td>
<td>0.25</td>
<td>20</td>
<td>18-48</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Valium</td>
<td>5</td>
<td>40</td>
<td>20-80</td>
</tr>
<tr>
<td>Estazolamb</td>
<td>ProLux</td>
<td>0.5</td>
<td>2</td>
<td>10-24</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>Dalmane</td>
<td>15</td>
<td>80</td>
<td>40-100</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>Ativan</td>
<td>1</td>
<td>10</td>
<td>10-20</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>Serax</td>
<td>15</td>
<td>120</td>
<td>10-20</td>
</tr>
<tr>
<td>Quazepam</td>
<td>Doral</td>
<td>5</td>
<td>15</td>
<td>30-100</td>
</tr>
<tr>
<td>Temazepam</td>
<td>Restoril</td>
<td>7.5</td>
<td>50</td>
<td>10-40</td>
</tr>
<tr>
<td>Triazolam</td>
<td>Halcion</td>
<td>0.25</td>
<td>0.25</td>
<td>2-3</td>
</tr>
</tbody>
</table>

*Approximate equivalent doses may vary by source.

**Table 4 – Risk Factors for Complicated BZW**

- Long duration of daily BZD use (>4 weeks)
- Higher dosing frequency (>1.25 x FDA approved daily maximum)
- Use of BZD with short half-life
- Comorbid medical conditions exacerbated by adrenergic state (i.e. COPD, DM, HTN, CAD, and history of CVA)
- History of seizure disorder
- History of complicated BZD or alcohol withdrawal
- Concurrent dependence to benzodiazepines, opioids, or alcohol
- Comorbid psychiatric illness
- History of complicated BZD or alcohol withdrawal
- Concomitant dependence to barbiturates, opioids, or alcohol
<table>
<thead>
<tr>
<th>Benzodiazepine Withdrawal</th>
<th>Name: __________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>(BZW) Assessment Form Page 1</td>
<td>TDCJ # _________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Initials of Staff Assessing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Perspiration</th>
<th>0</th>
<th>no sweating</th>
<th>1</th>
<th>palms moist</th>
<th>2</th>
<th>palms/forehead moist</th>
<th>3</th>
<th>sweat beads on face</th>
<th>4</th>
<th>drenching sweat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tremor</td>
<td>0</td>
<td>none</td>
<td>1</td>
<td>none</td>
<td>2</td>
<td>mild visible tremor</td>
<td>3</td>
<td>moderate</td>
<td>arms out</td>
<td>4</td>
</tr>
<tr>
<td>Restlessness/Agitation</td>
<td>0</td>
<td>none</td>
<td>1</td>
<td>uneasy</td>
<td>2</td>
<td>restless</td>
<td>3</td>
<td>purposeless activity</td>
<td>4</td>
<td>purposeless to sit</td>
</tr>
<tr>
<td>Level of Consciousness</td>
<td>0</td>
<td>unimpaired</td>
<td>1</td>
<td>alert obeys commands</td>
<td>2</td>
<td>combined responses to speech</td>
<td>3</td>
<td>sporadic</td>
<td>responses to pain</td>
<td>4</td>
</tr>
</tbody>
</table>
Benzodiazepine Withdrawal (BZW)           Name ___________________________________
Data Collection Form Page 2                           TDCJ # ______________________

**Nausea or Vomiting**
- 0 none
- 1 mild
- 2 moderate
- 3 severe
- 4 very severe

**Baseline (Admission)**
- Blood Pressure
- Pulse
- Temperature
- Respirations

**Pearls**
- Monitor BZW Observation parameters based on setting guidelines
- Baseline (on admission) vital sign observation: those assessed prior to initiating tapering regimen
- Hyperthermia: any temperature exceeding 99.5 degrees F or 37.5 degrees C
- Tachycardia: heart rate > 90 BPM or an increase of ≥ 20 BPM from baseline heart rate on admission
- Blood pressure lability: change in systolic or diastolic of 20mm Hg from baseline on admission
- Severe a/v, blood pressure-pulse lability, hyperthermia, restlessness, tremor, perspiration, or agitation will require provider oversight and may indicate need for dose/titration adjustment.
BIPOLAR DEPRESSION

1. Rule out medical causes for presentation.

2. Is patient currently depressed?
   - Yes
   - No

3. History of at least 1 hypomanic or manic episode?
   - Yes
   - No

4. Re-evaluate diagnosis

Fellow Major Depressive Disorder Pathway

Maximize mood stabilizer
Add anti-depressant (sertraline, citalopram, etc.)
Continue for 4-6 weeks
Go to Box #11

Yes

No

1. Initiate antipsychotic per psychotic symptom
2. Taper antipsychotic upon resolution of psychotic symptoms
3. If psychotic symptoms continue, reassess diagnosis of bipolar disorder

Adequate response per clinical status and BPRS?
- Yes
- No

Monitor medication adherence & evaluate with BPRS

Continue maintenance treatment and reassess as clinically indicated

The use of antidepressants in patients with bipolar disorder is controversial and not recommended unless the patient is also receiving a therapeutic dose of a mood stabilizer.

*The use of antidepressants in patients with bipolar disorder is controversial and not recommended unless the patient is also receiving a therapeutic dose of a mood stabilizer.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee
Approved 1/99, revised 5/02, 2/03, 4/03, 9/05, 5/09, 7/09, 5/12, 1/15

*The use of antidepressants in patients with bipolar disorder is controversial and not recommended unless the patient is also receiving a therapeutic dose of a mood stabilizer.
I. Lithium
A. Cardiac – obtain ECG at baseline if patient is > 40 or has pre-existing heart disease
B. Metabolic
1. Obtain electrolytes, BUN, SCr, TSH, and T4 at baseline.
2. Repeat every 6 – 12 months.
C. Trough Serum Drug Levels
1. Obtain 5 – 10 days after lithium initiation.
2. Monitor every 2 – 6 months once patient and levels are stabilized.
3. Monitor weekly if patient begins to destabilize.
4. Levels should be drawn 5–10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase/decrease lithium renal clearance (e.g., ACE inhibitors, calcium-channel blockers, diuretics, NSAIDs, SSRIs, theophylline), or if there is a change in renal function.
5. Therapeutic Range: 0.6–1.2 mmol/L for maintenance, 0.8 – 1.2 mmol/L for acute stabilization. Determine by serum trough level in the morning, 10 – 12 hours after last dose.

II. Divalproex
A. Hematologic
1. CBC with differential – obtain at baseline, then monthly for first 2 months, then every 6 months thereafter.
2. Platelets – obtain at baseline, then every 6 – 12 months thereafter.
B. Chemistry – obtain LFTs at baseline, then monthly for first 2 months, then yearly thereafter. If LFTs are elevated on repeat testing, consider obtaining ammonia level and monitor for cognitive dysfunction.
C. Serum Drug Level
1. Obtain 1–3 weeks following initiation, change in dose, addition of other CNS agents to the patient’s regimen, or observed signs/symptoms of toxicity. Then obtain every 6 – 12 months thereafter.
2. Therapeutic Range: 50 – 125 mcg/mL, dose not to exceed 60 mg/kg/day.
3. Standard draw time is 12 hours after the last dose.

III. Lamotrigine (Requires Nonformulary Approval for use)
A. Dosing
1. Monotherapy (No concurrent enzyme-inducing or enzyme-inhibiting medications)
   a. 25 mg/day for 2 weeks, then 50 mg/day for 2 weeks, then 100 mg/day for 1 week; thereafter, daily dose may be increased to 200 mg/day.
2. Adjunctive therapy in patient receiving enzyme-inducing medications (e.g., carbamazepine, phenytoin, ritonavir, topiramate, valproate)
   a. 50 mg/day for 2 weeks, then 100 mg/day (in divided doses) for 2 weeks, followed by 200 mg/day (in divided doses) for 1 week, followed by 300 mg/day (in divided doses) for 1 week. May increase to 400 mg/day (in divided doses) during week 7 and thereafter.
   b. NOTE: if enzyme-inducing medication is discontinued, the daily dose of lamotrigine will need to be decreased in 100 mg increments at weekly intervals until daily dosage of 200 mg is attained.
3. Adjunctive therapy in patients receiving enzyme-inhibiting medications (e.g., valproate, sertraline)
   a. 25 mg every other day for 2 weeks, followed by 25 mg/day for 2 weeks, followed by 50 mg/day for 1 week, followed by 100 mg/day.
   b. NOTE: if enzyme-inhibiting medication is discontinued, increase daily lamotrigine dose in 50 mg increments at weekly intervals until daily dosage of 200 mg is attained.
B. Physical Findings
1. Rash
   a. Lamotrigine therapy should be discontinued at the first sign of a rash. If the cause of the rash has been clearly identified as not drug-related then lamotrigine does not need to be discontinued.
   b. Dosing schedule should be strictly followed to decrease risk of rash.
   c. Majority of rash cases occur within the first 8 weeks of therapy.
2. Hypersensitivity Reaction
   a. Fever and lymphadenopathy without rash. Hypersensitivity may progress to multisystem failure/dysfunction.
   b. Lamotrigine should be discontinued if other causes for hypersensitivity are ruled out.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Starting At Trough Serum Levels of:</th>
<th>Signs/symptoms of toxicity (dose-related)</th>
<th>Signs/symptoms of toxicity (NOT dose-related)</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium</td>
<td>Initially 900 - 1200 mg daily in 1 to 3 divided doses.</td>
<td>Hypersensitivity to lithium</td>
<td>1 - 1.2 mmol/L</td>
<td>Lithium toxicity can be FATAL</td>
<td>Acidosis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Due to stay between 0.6 mEq/L and 1.2 mEq/L. It is advised to not order doses &gt; 1200 mg daily.</td>
<td>Severe cardiovascular or renal disease</td>
<td></td>
<td></td>
<td>Apathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe debilitation</td>
<td></td>
<td></td>
<td>Coarsening hand tremor that spreads to other parts of body while patient sitting still</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dilution</td>
<td></td>
<td></td>
<td>Confusion / Drowsiness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sodium depletion</td>
<td></td>
<td></td>
<td>Dysarthria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pregnancy</td>
<td></td>
<td></td>
<td>Diarrhea, nausea, vomiting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category D</td>
<td></td>
<td></td>
<td>Giddiness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hyperkalemia</td>
<td></td>
<td></td>
<td>Acute:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hypoalbuminemia</td>
<td></td>
<td></td>
<td>Somnolence</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Thrombocytopenia</td>
<td></td>
<td></td>
<td>Heart block</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prolongation of bleeding time</td>
<td></td>
<td></td>
<td>Changes in mental status</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatotoxicity</td>
<td></td>
<td></td>
<td>Thrombocytopenia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pancreatitis - DO NOT RECHALLENGE</td>
<td></td>
<td></td>
<td>Prolongation of bleeding time</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hypersensitivity to VPA</td>
<td></td>
<td></td>
<td>Hepatotoxicity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatic dysfunction</td>
<td></td>
<td></td>
<td>Severe or fatal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Urticaria</td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td></td>
</tr>
<tr>
<td>Divalproex</td>
<td>20mg/kg/day, given in divided doses.</td>
<td>Hypersensitivity to VPA</td>
<td>100 - 125 mcg/mL</td>
<td>Toxic Epidermal Necrolysis</td>
<td>Polycystic ovarian syndrome (PCOS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Due to stay between 50 mcg/mL and 125 mcg/mL. It is not recommended to exceed 60mg/kg/day.</td>
<td>Hepatic dysfunction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**BIPOLAR DEPRESSION**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Starting At Trough Serum Levels of:</th>
<th>Signs/symptoms of toxicity (dose-related)</th>
<th>Signs/symptoms of toxicity (NOT dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamotrigine</td>
<td>25 – 400 mg/day</td>
<td>• Hypersensitivity to Lamotrigine</td>
<td>• Rash (maculopapular and erythematous)</td>
<td>• Fever</td>
<td>• Toxic Epidermal Necrolysis</td>
</tr>
<tr>
<td></td>
<td>(Dosing depends on concomitant medication due to significant drug interactions)</td>
<td>• Pregnancy Category C</td>
<td>• Tourette’s Syndrome</td>
<td>• Lymphocytopenia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Blood dyscrasias</td>
<td>• Multisystem dysfunction</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Stevens-Johnson Syndrome</td>
<td>• Toxic Epidermal Necrolysis</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: SSRI Antidepressants**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Initial Dose (Dose Range)</th>
<th>Significant Drug Interactions</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citalopram</td>
<td>20mg, 40mg tablet</td>
<td>• QTc prolonging agents</td>
<td>• Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>(20 – 40)</td>
<td>• Serotonergic agents</td>
<td>• EKG for citalopram if risk factors for QTc prolongation are pre</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>20mg capsule</td>
<td>• Agents that may increase citalopram levels</td>
<td>• If QTc is &gt; 450msec for males or &gt; 470msec for females, do not initiate citalopram. If pt is on citalopram and QTc is &gt; 480msec, consider alternative treatment.</td>
</tr>
<tr>
<td></td>
<td>(20 – 60)</td>
<td>• Serotonergic agents</td>
<td></td>
</tr>
<tr>
<td>Sertraline</td>
<td>20mg, 40mg tablet</td>
<td>• Agents that may increase fluoxetine levels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(50 – 200)</td>
<td>• Serotonergic agents</td>
<td></td>
</tr>
</tbody>
</table>

**BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician**

**Background:** The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed an antipsychotic.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

**Instructions for Use and Scoring:** Each item is rated on a seven-point scale (1=mild present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SOMATIC CONCERN</td>
<td>Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>2.</td>
<td>ANXIETY</td>
<td>Worry, fear, over-concern for present or future, uneasiness.</td>
</tr>
<tr>
<td>3.</td>
<td>EMOTIONAL WITHDRAWAL</td>
<td>Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>4.</td>
<td>CONCEPTUAL DISORGANIZATION</td>
<td>Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>5.</td>
<td>IMPULSIVENESS</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>MOTOR HYPERACTIVITY</td>
<td>Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td>7.</td>
<td>MANNERISMS AND POSTURING</td>
<td>Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>8.</td>
<td>GRANDIOSITY</td>
<td>Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td>9.</td>
<td>DEPRESSIVE MOOD</td>
<td>Sorrows, sadness, despondency, pessimism.</td>
</tr>
<tr>
<td>10.</td>
<td>HOSTILITY</td>
<td>Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td>11.</td>
<td>SUSPICIOUSNESS</td>
<td>Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td>12.</td>
<td>HALLUCINATORY BEHAVIOR</td>
<td>Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>13.</td>
<td>MOTOR RETARDATION</td>
<td>Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td>14.</td>
<td>UNCOOPERATIVENESS</td>
<td>Resistance, guardedness, rejection of authority.</td>
</tr>
<tr>
<td>15.</td>
<td>UNUSUAL THOUGHT CONTENT</td>
<td>Unusual, odd, strange, bizarre thought content.</td>
</tr>
<tr>
<td>16.</td>
<td>BLUNTED AFFECT</td>
<td>Reduced emotional tone, reduction in normal intensity of feelings, flatness.</td>
</tr>
<tr>
<td>17.</td>
<td>EXCITEMENT</td>
<td>Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td>18.</td>
<td>DISORIENTATION</td>
<td>Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td>19.</td>
<td>ELEVATED MOOD</td>
<td>A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>20.</td>
<td>SUICIDALITY</td>
<td>Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td>21.</td>
<td>BIZARRE BEHAVIOR</td>
<td>Reports of behaviors which are odd, unusual, or psychologically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>22.</td>
<td>SELF-NEGLECT</td>
<td>Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td>23.</td>
<td>DISTRACTIBILITY</td>
<td>Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.</td>
</tr>
</tbody>
</table>
BIPOLAR DISORDER: MANIA

1. Rule out medical causes for presentation.

2. Meet criteria for Manic or Hypomanic Episode as defined in DSM-5?
   - No
   - Yes
      - Re-evaluate diagnosis and treat underlying causes.

3. Is patient currently on an antidepressant?
   - No
   - Yes
      - Consider antidepressant discontinuation or tapering dose.

4. Is patient currently on a mood stabilizer or antipsychotic?*
   - No
   - Yes
      - Rule out medical causes for presentation.

5. Maximum mood stabilizer dose per serum level:
   - Lithium 0.6 – 1.2 mmol/L,
   - Divalproex 50 – 125 mcg/mL,
   -Continue for 4 – 6 weeks.
   - Maximize dose of antipsychotic, continue for 4 – 6 weeks.

6. Initiate treatment with mood stabilizer or antipsychotic, titrate to therapeutic levellnes (see box 7). Continue for 4 – 6 weeks.

7. Continue current therapy.

8. Discontinue current therapy and switch to the alternative mood stabilizer or antipsychotic for 4 – 6 weeks at therapeutic doses.

9. Adequate response per clinical status and BPRS?
   - Yes
   - No
      - Assess compliance.

10. Consider combination therapy:
    - Lithium plus Divalproex or
    - Lithium or Divalproex plus Risperidone.

11. Consider continuation therapy:
    - Lithium plus Divalproex
    - Lithium or Divalproex plus Risperidone.

12. Antipsychotic agents may be preferred in patients with significant psychotic features. If psychotic symptoms persist, reassess diagnosis of bipolar disorder.

13. Adequate response per clinical status and BPRS?
   - Yes
   - No
      - Re-evaluate diagnosis.


15. Consider use of combination therapy with lithium, divalproex, carbamazepine, or risperidone.

16. Adequate response per clinical status and BPRS?
   - Yes
   - No

17. Continue current therapy.

18. Assess compliance.


*Antipsychotic agents may be preferred in patients with significant psychotic features. If psychotic symptoms persist, reassess diagnosis of bipolar disorder.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 1/99; revised 3/02, 3/03; reviewed 4/03, 4/05.
I. Lithium
   A. Cardiac – obtain ECG at baseline if patient is > 40 or has pre-existing heart disease
   B. Metabolic
      1. Obtain electrolytes, BUN, SCr, TSH, and T4 at baseline.
      2. Repeat every 6 – 12 months.
   C. Trough Serum Drug Levels
      1. Obtain 5 – 10 days after lithium initiation.
      2. Monitor every 2 – 6 months once patient and levels are stabilized.
      3. Monitor weekly if patient begins to destabilize.
      4. Levels should be drawn 5-10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase/decrease lithium renal clearance (e.g., ACE inhibitors, calcium-channel blockers, diuretics, NSAIDs, SSRIs, theophylline), or if there is a change in renal function.
      5. Therapeutic Range: 0.6 – 1.2 mmol/L for maintenance, 0.8 – 1.2 mmol/L for acute stabilization. Determine by serum trough level in the morning, 10 – 12 hours after last dose.

II. Divalproex
   A. Hematologic
      1. CBC with differential – obtain at baseline, then monthly for first 2 months, then every 6 months thereafter.
      2. Platelets – obtain at baseline, then every 6 – 12 months thereafter.
   B. Chemistry
      1. Obtain LFTs at baseline, then monthly for first 2 months, then yearly thereafter.
      2. If LFTs are elevated on repeat testing, consider obtaining ammonia level and monitor for cognitive dysfunction.
   C. Serum Drug Level
      1. Obtain 1-3 weeks following initiation, change in dose, addition of other CNS agents to the patient’s regimen, or observed signs/symptoms of toxicity. Then obtain every 6 – 12 months thereafter.
      2. Therapeutic Range: 50 – 125 mcg/mL, dose not to exceed 60 mg/kg/day.
      3. Standard draw time is 12 hours after the last dose.

III. Carbamazepine
   A. Cardiac – obtain ECG at baseline if patient is > 40 or has pre-existing heart disease
   B. Hematologic
      1. CBC with differential – obtain baseline, then monthly for first 2 months, then every 6 months thereafter
      2. Platelets – obtain at baseline, then every 6 months thereafter
   C. Hepatic – obtain LFTs at baseline then yearly thereafter
   D. Metabolic – obtain serum sodium at baseline, 3 months, then annually.
   E. Serum Drug Level
      1. Initial level should be drawn within first 7 – 10 days of therapy.
      2. Obtain every 4 weeks while titrating to therapeutic levels, then every 6 months.
      3. Therapeutic Range: 4-12 mcg/mL.
      4. Onset of auto-induction occurs in about 3 days from first dose, with maximum effect at about 30 days.
      5. Draw serum trough levels just prior to the next dose.
   F. Genetic testing – recommended for people with Asian ancestry
      1. Serious skin reactions (e.g., Steven Johnson Syndrome) are more common in people with the HLA-B 1502 variant, a mutation found primarily in Asians. Reactions have been fatal.
      2. Carbamazepine should not be prescribed for patients with Asian ancestry unless no other reasonable alternative exists. If so, patients must undergo genetic testing for the mutation before being prescribed carbamazepine.
      3. Providers must obtain approval from their Regional Medical Director prior to ordering the test.
      4. The risk versus benefits of carbamazepine therapy should be weighed in patients that test positive, and discussed with the Regional Medical Director prior to initiating therapy.
      5. Carbamazepine therapy may be continued in intake Asian patients or Asian patients already taking the medication for > 3 months if they have not experienced adverse effects.

Recommended Laboratory Monitoring
<table>
<thead>
<tr>
<th>Medications</th>
<th>Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Starting At Trough Serum Levels of:</th>
<th>Signs/symptoms of toxicity (dose-related)</th>
<th>Signs/symptoms of toxicity (NOT dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses.</td>
<td>• Hypersensitivity to lithium • Severe cardiovascular or renal disease • Severe debilitation • Dehydration • Sodium depletion • Pregnancy Category D</td>
<td>&gt; 1 - 1.2 mmol/L Patients who are sensitive to lithium may manifest toxicity at serum levels &lt; 1 mmol/L Note: A rise in white blood cell count is to be expected</td>
<td>Lithium toxicity can be FATAL</td>
<td>Acute: • Apathy • Coarsening hand tremor that spreads to other parts of body while patient sitting still • Confusion / Drowsiness • Dysarthria • Diaphoresis, nausea, vomiting • Goldblum</td>
<td>Acute To Severe: • Blurred vision • Deep tendon reflexes increased • Muscle rigidity / fasciculations • Mild anorexia • Profound lethargy • Tinnitus • Vertical nystagmus • Vomiting</td>
</tr>
</tbody>
</table>

| Divalproex: 20mg/kg/day, given in divided doses | • Hypersensitivity to VPA • Hepatic dysfunction • Urate acidosis • Pregnancy Category D | > 100-125 mcg/mL | Acute: • Sedation • Heart block • Sleep coma • Hyperammonemia • Lethargy • Vomiting • Changes in mental status • Thrombocytopenia • Prolongation of bleeding time | Pancreatitis - DO NOT RECHALLENGE | Hyperammonemic encephalopathy | Hepatotoxicity, severe or fatal | Stevens-Johnson Syndrome | Toxic Epidermal Necrolysis | Polycystic ovarian syndrome (PCOS) |

| VPA: Initially 20 mg/kg/day, increased by 20 mg/kg/day up to 60 mg/kg/day | | | | Not applicable | | | | |
### Carbamazepine

**Drug:** Carbamazepine 600 - 1600 mg, given in divided doses

**Dose to stay between:** 4 mcg/mL and 12 mcg/mL

**Contraindications:**
- Hypersensitivity to carbamazepine or TCAs
- Bone marrow depression
- In combination with or within 14 days of MAOIs
- Pregnancy Category D

**Toxicity Seen Starting At Trough Serum Levels of:**

<table>
<thead>
<tr>
<th>Signs/symptoms of toxicity (dose-related)</th>
<th>Signs/symptoms of toxicity (NOT dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal reflex response</td>
<td>Arrhythmias</td>
</tr>
<tr>
<td>Autonina</td>
<td>Blood cell dyscrasias</td>
</tr>
<tr>
<td>Agitation / confusion</td>
<td>Chest pain</td>
</tr>
<tr>
<td>Anxiety / dizziness</td>
<td>CSF</td>
</tr>
<tr>
<td>Blurred vision / diplopia / nystagmus</td>
<td>Nausea / vomiting</td>
</tr>
<tr>
<td>Cardiac dehysthias</td>
<td>Photosensitivity</td>
</tr>
<tr>
<td>Coma</td>
<td>SIADH (Syndrome of Inappropriate ADH secretion)</td>
</tr>
<tr>
<td>Convulsions</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td>Disorientation</td>
<td>Toxic epidermal necrolysis</td>
</tr>
<tr>
<td>Extreme lethargy or drowsiness</td>
<td></td>
</tr>
<tr>
<td>Flushing</td>
<td></td>
</tr>
<tr>
<td>Glycosuria</td>
<td></td>
</tr>
<tr>
<td>Involuntary muscle movements</td>
<td></td>
</tr>
<tr>
<td>Nausea / vomiting</td>
<td></td>
</tr>
<tr>
<td>Nystagmus</td>
<td></td>
</tr>
<tr>
<td>Opisthotonos</td>
<td></td>
</tr>
<tr>
<td>Tics or tremors</td>
<td></td>
</tr>
<tr>
<td>Urinary retention</td>
<td></td>
</tr>
</tbody>
</table>

#### Antipsychotic Monitoring Parameters

Table 2: Metabolic and Endocrine Monitoring Guidelines

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Q 6 Months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, Height-BMI</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Complete Metabolic Panel</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td>As clinically indicated</td>
<td></td>
</tr>
<tr>
<td>EKG†</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolactin†</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Providers should consider obtaining any of the laboratories listed above more frequently if clinically indicated.

1. Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease or the patient is > 40 years old.

2. Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunctions:
   - Routine screening for hyperprolactinemia is not recommended unless symptoms are present
   - The normal range of prolactin is 10-20 mcg/L in males and 10-25 mcg/L in females
   - Symptoms typically do not appear until levels reach 60-100 mcg/L
   - Patients should be referred to medical to rule out other etiologies of hyperprolactinemia

#### Additional Monitoring Parameters for Specific Agents

- Ziprasidone (Geodon®) - EKG at baseline then annually or as clinically indicated
- Quetiapine (Seroquel®) - Ophthalmic exam checking for cataracts every 6 months
Table 3: Outcome and Adverse Effect Monitoring

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIMS (Abnormal Involuntary Movement Scale)</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td>Mental Status Exam</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td>BPRS (Brief Psychiatric Rating Scale)</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medication is started, changed or discontinued</td>
</tr>
</tbody>
</table>

Table 4: Atypical Antipsychotics Approved for Bipolar Mania - Dosages and Adverse Effects

<table>
<thead>
<tr>
<th>Agent</th>
<th>Formulary Status</th>
<th>Traditional Equivalents (approx. mg)</th>
<th>Dose Range (mg/day)</th>
<th>Weight Gain</th>
<th>EPS</th>
<th>Sedation</th>
<th>Anticholinergic</th>
<th>Orthostasis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole (Abilify®)</td>
<td>NF</td>
<td>7.5</td>
<td>10 – 30</td>
<td>0/+</td>
<td>0/+</td>
<td>+</td>
<td>0/+</td>
<td>0/+</td>
</tr>
<tr>
<td>Asenapine (Saphris®)</td>
<td>NF</td>
<td>5</td>
<td>5 – 20</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa®)</td>
<td>NF</td>
<td>5</td>
<td>5 – 20</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Quetiapine (Seroquel®)</td>
<td>NF</td>
<td>12.5</td>
<td>500 – 800</td>
<td>++</td>
<td>0/+</td>
<td>++</td>
<td>++</td>
<td>0/+</td>
</tr>
<tr>
<td>Risperidone (Risperdal®)</td>
<td>F</td>
<td>2</td>
<td>0.5 – 6</td>
<td>0/+</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Ziprasidone (Geodon®)</td>
<td>NF</td>
<td>60</td>
<td>120 – 160</td>
<td>0/+</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>

1 dose-dependent

BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician

Background: The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed an antipsychotic.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring: Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.

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Brief Psychiatric Rating Scale (BPRS)

Enter the score for the term that best describes the patient’s condition.

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score

1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.
2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness
3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.
4. CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.
5. IMPULSIVENESS
6. MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.
7. MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).
8. GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.
9. DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.
10. HOSTILITY - Animosity, contempt, belligerence, disdain for others.
11. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.
12. HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.
13. MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.
14. UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.
15. UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.
16. BLUNTED AFFECT - Reduced emotional tone, reduction in formal intensity of feelings, flatness.
17. EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.
18. DISORIENTATION - Confusion or lack of proper association for person, place or time.
19. ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.
20. SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.
21. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.
22. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.
23. DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual's attention may be drawn to noise in adjoining room, books on a shelf, interviewer's clothing, etc.
ABNORMAL INVOLUNTARY MOVEMENT SCALE

Complete examination procedure outlined in the instructions before making rating. Rate highest severity observed. Movements occurring upon activation rate one less than those occurring spontaneously. 

<table>
<thead>
<tr>
<th></th>
<th>Muscles of facial expression</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>e.g. movements of forehead, eyebrows, preorbital area, cheeks, include frowning, blinding, smiling, grimacing</td>
</tr>
<tr>
<td></td>
<td>Lips and perioral area</td>
</tr>
<tr>
<td>2</td>
<td>e.g. puckering, pouting, smacking</td>
</tr>
<tr>
<td></td>
<td>Jaw</td>
</tr>
<tr>
<td>3</td>
<td>e.g. biting, clenching, chewing, mouth opening, lateral movement</td>
</tr>
<tr>
<td></td>
<td>Tongue</td>
</tr>
<tr>
<td>4</td>
<td>Rate only increase in movement both in and out of mouth, not inability to sustain movement</td>
</tr>
<tr>
<td></td>
<td>Upper (arms, wrists, hands, fingers)</td>
</tr>
<tr>
<td>5</td>
<td>Include chronic movements (i.e. rapid, objectively purposeless, irregular, spontaneous); athetoid movements (i.e. slow, irregular, complex, serpentine). DO NOT include tremor (i.e. repetitive, regular, rhythmic).</td>
</tr>
<tr>
<td></td>
<td>Lower (legs, knees, ankles, toes)</td>
</tr>
<tr>
<td>6</td>
<td>e.g. lateral knee movement, foot tapping, heel dropping, foot squirming, inversion, and eversion of foot</td>
</tr>
<tr>
<td></td>
<td>Neck, shoulders, hips</td>
</tr>
<tr>
<td>7</td>
<td>e.g. rocking, twisting, squirming, pelvic gyrations</td>
</tr>
<tr>
<td></td>
<td>Severity of abnormal movements</td>
</tr>
<tr>
<td>8</td>
<td>Incapacitation due to abnormal movements</td>
</tr>
<tr>
<td>9</td>
<td>Patient's awareness of abnormal movements</td>
</tr>
<tr>
<td>10</td>
<td>Rate only patient's report</td>
</tr>
<tr>
<td></td>
<td>No awareness=0  Aware, no distress=1  Aware, mild distress=2  Aware, moderate distress=3  Aware, severe distress=4</td>
</tr>
<tr>
<td></td>
<td>Current problems with teeth &amp;/or dentures?</td>
</tr>
<tr>
<td>11</td>
<td>No=0  Yes=1</td>
</tr>
<tr>
<td></td>
<td>Does patient usually wear dentures?</td>
</tr>
<tr>
<td>12</td>
<td>No=0  Yes=1</td>
</tr>
<tr>
<td></td>
<td>COMMENTS:</td>
</tr>
</tbody>
</table>
CATHETER RESTORATION FOR HEMODIALYSIS PATIENTS
This protocol pertains to registered nurses who have received training and been validated in the procedure.

1. **Assessment of occlusion**
   1. Rule out mechanical obstruction
   2. Attempt to aspirate blood
   3. Attempt to flush the catheter with 5-10 mL of normal saline (0.9% Sodium Chloride)

2. **Is catheter occluded?**
   - No: Continue catheter use
   - Yes: Notify provider and obtain order for Cathflo®

3. **Explain procedure to patient.**

**PREPARATION OF CATHFLO® (ALTEPLASE, TPA) SOLUTION**

<table>
<thead>
<tr>
<th>ACTION</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Wash hands thoroughly. Put on PPE.</td>
<td>Hand washing protects the patient and health care staff from cross contamination. PPE is worn for health care staff protection.</td>
</tr>
<tr>
<td>2. Aseptically withdraw 2.2 mL of Sterile Water for injection, USP.</td>
<td>Do not use Bacteriostatic Water for injection.</td>
</tr>
<tr>
<td>3. Inject the 2.2 mL of Sterile Water for injection into the Cathflo® vial. The diluent stream should be directed into the powder.</td>
<td>Slight foaming may occur.</td>
</tr>
<tr>
<td>4. Let the vial stand undisturbed until foaming dissipates.</td>
<td>Allows large bubbles to dissipate prior to administration.</td>
</tr>
<tr>
<td>5. Mix by gently swirling the vial until the contents are completely dissolved. Complete dissolution should occur within 3 minutes. DO NOT SHAKE.</td>
<td>The reconstituted solution is colorless to pale yellow transparent solution. The final concentration is 1mg/1mL. pH is approximately 7.3.</td>
</tr>
<tr>
<td>6. Inspect the reconstituted solution prior to administration for foreign matter or discoloration. If any seen, discard the vial. DO NOT USE.</td>
<td>Should be reconstituted immediately prior to use or used within 8 hours after being reconstituted and stored at 2-30 °C or 36-86 °F.</td>
</tr>
<tr>
<td>7. No other medications should be added to the solution containing Cathflo®.</td>
<td></td>
</tr>
</tbody>
</table>

The protocol does not replace sound clinical judgment nor is it intended to strictly apply to all patients.

### ACTION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Inspect the reconstituted solution prior to administration for foreign matter or discoloration.</td>
</tr>
<tr>
<td>2.</td>
<td>Aseptically withdraw the reconstituted solution from the vial.</td>
</tr>
<tr>
<td>3.</td>
<td>Wash hands thoroughly. Put on PPE.</td>
</tr>
<tr>
<td>4.</td>
<td>Slowly instill the appropriate dose of Cathflo into the occluded catheter.</td>
</tr>
<tr>
<td>5.</td>
<td>Assess catheter function by attempting to aspirate blood after 60 minutes of catheter dwell time.</td>
</tr>
<tr>
<td>6.</td>
<td>Wait an additional 60 minutes for a total of 120 minutes dwell time. Assess catheter function by attempting to aspirate blood.</td>
</tr>
<tr>
<td>7.</td>
<td>A second dose of Cathflo® may be given upon the receipt of a provider order for a second dose if catheter function is not restored. Repeat the procedure beginning with Step 1 under PREPARATION OF CATHFLO® (ALTEPLASE, TPA) SOLUTION in box 6 on page 1.</td>
</tr>
<tr>
<td>8.</td>
<td>If successful, remove 4 to 5 mL of blood with a syringe to remove Cathflo® and residual clot. Then gently flush the catheter with 10 to 12 mL of normal saline (0.9% Sodium Chloride).</td>
</tr>
</tbody>
</table>

### NOTES

- If any seen, discard the vial. **DO NOT USE.**
- Dose to be determined by the provider. The usual dose is 2mg (2mL) for patients ≥30 kg.
- Hand washing protects the patient and health care staff from cross contamination. PPE is worn for health care staff protection.
- Excessive pressure should be avoided when instilled into the catheter, because excessive force could cause rupture of the catheter or expulsion of the clot into circulation.
- Vigorous suction should not be applied during attempts to assess catheter function, because of the risk of damage or collapse.
- An order must be obtained from the provider to administer a second dose.

### ACTION

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>Provider should be notified and a decision made regarding catheter viability. Referral of patient to a higher level of care should be considered.</td>
</tr>
</tbody>
</table>

---

A. Types of catheter occlusions
1. Intraluminal occlusion – Occlusion occurs within the catheter lumen
2. Fibrin sheath occlusion – Occlusion occurs as a layer around the outside of the catheter
3. Fibrin tail occlusion – Occlusion occurs over the tip of the catheter
4. Mural occlusion – Occlusion occurs as an extension from the wall of the blood vessel to the catheter

B. Contributing factors – The changes listed below lead to vasoconstriction, platelet aggregation, and activation of the clotting cascade resulting in thrombus formation.
1. Changes in blood flow – venous stasis
2. Changes in coagulability
3. Changes in vessel wall – trauma to the vessel

C. Signs & symptoms of thrombotic occlusion
1. May develop without symptoms
2. Sluggish flow may be seen as thrombus develops
3. Pump alarms may sound frequently as thrombus progresses
4. It may be possible to infuse fluid in some instances, but fluid withdrawal is impaired

D. Rationale for fibrinolytic therapy - Low dose fibrinolysis with alteplase can lyse clot and re-establish flow in occluded catheter resulting in catheter salvage. Catheter salvage is preferred over replacement for the following reasons:
1. Limit interruption of hemodialysis
2. Reduce risk of trauma and complication to patient
3. Preserve site for future access
4. Reduce cost (e.g., avoid transportation cost & hospitalization)

E. Treatment Goals
1. Re-establish flow in catheter
2. Resume hemodialysis
3. Avoid catheter replacement

F. Treatment – Cathflo® (Alteplase, TPA)
1. Availability – 2mg single dose vial
2. Storage - Refrigerate vial (2-8 °C, 36-46 °F) and protect from light
3. Stability of reconstituted solution – Reconstituted solution must be used within 8 hours if stored at 2-30 °C or 36-86 °F. Any unused solution should be discarded.
4. Usual Dose is 2mg (2mL) for patients ≥ 30 kg. A second dose may be given after 120 minutes if catheter function is not restored.
5. Adverse Effects
   a. Infection (e.g., sepsis)
   b. Bleeding (e.g., from site, gastrointestinal)
   c. Venous thrombosis
   d. Allergic reactions have not been reported. If occurs, notify provider and manage appropriately.
ACUTE EXACERBATION COPD

Patient presents with signs & symptoms of acute COPD exacerbation (Box 3)

1. Nebulized albuterol with or without ipratropium as needed. May repeat every 20 minutes x 2.

2. Prednisone 40mg/day for 5 days

3. Antibiotic Amoxicillin 1000mg bid x 10 days or Levofloxacin 500mg qd x 10 days

Follow up with unit provider in 3 days or sooner if clinically indicated

• Discharge patient when clinically stable
• Nebulized albuterol with or without ipratropium as needed up to 3 days or restart regular treatment with MDD* as tolerated
• Prednisone 40mg/day for 5 days
• Follow up with unit provider in 3 days or sooner if clinically indicated
• Go to Box # 17

Characteristics of a Severe Exacerbation
• Marked increase in symptom intensity
• Severe underlying COPD
• Onset of new physical signs (e.g. cyanosis, peripheral edema)
• No response to initial therapy
• Significant comorbidities (e.g., pneumonia, newly occurring arrhythmia, heart failure, diabetes, renal or hepatic failure)
• Patient is confused, lethargic, or comatose
• Older age (>65)

1. Does the patient have characteristics of a severe exacerbation? (Box 6)

2. Does the patient have risk factors for more severe infection? (frequent exacerbations defined as 2 or more in last year, antibiotic within last 3 months, or severe COPD)

3. Assess severity of signs & symptoms
4. Obtain oxygen saturation
5. Administer oxygen therapy

6. Stabilize
7. Does patient have characteristics of a severe exacerbation? (Box 6)

8. Patient responding?

9. Consider transfer to a higher level of care if the patient has severe dyspnea and did not respond adequately to initial therapy

10. Does the patient have risk factors for more severe infection? (Hospitilization defined as 2 or more in last year, antibiotic within last 3 months, or severe COPD)

11. Continue treatment and monitor the patient closely

12. Does the patient have risk factors for more severe infection? (frequent exacerbations defined as 2 or more in last year, antibiotic within last 3 months, or severe COPD)

13. Continue treatment and monitor the patient closely

14. Discharge patient when clinically stable

• Nebulized albuterol with or without ipratropium as needed up to 3 days or restart regular treatment with MDD* as tolerated
• Prednisone 40mg/day for 5 days
• Follow up with unit provider in 3 days or sooner if clinically indicated

15. Continue treatment and monitor the patient closely

• Nebulized albuterol with or without ipratropium as needed up to 3 days or restart regular treatment with MDD* as tolerated
• Prednisone 40mg/day for 5 days
• Follow up with unit provider in 3 days or sooner if clinically indicated

16. Go to page 2 box # 17

*MDI = Metered Dose Inhaler

17. Characteristics of a Severe Exacerbation

18. Go to page 2 box # 17

19. Transfer to a higher level of care if the patient has severe dyspnea and did not respond adequately to initial therapy
83
I. Definition of acute exacerbation
   • “An acute event characterized by a worsening of the patient’s respiratory symptoms (dyspnea, cough, sputum production) that is beyond normal day-to-day variations and leads to a change in medication.” (GOLD 2015 Guidelines)
   • COPD exacerbations are important events because of the following:
     ▪ Negatively impact quality of life
     ▪ May take several weeks for symptom improvement and lung function to recover
     ▪ Accelerate rate of lung function decline
     ▪ Associated with significant mortality, particularly if results in hospitalization

II. Risk factors for COPD exacerbation
A. Bacterial and viral infections
B. Environmental conditions
C. Lack of compliance with long-term oxygen therapy
D. Risk factors for relapse:
   1. Low pretreatment FEV1 (severe baseline COPD: FEV1/FVC <0.7, FEV1 <50)
   2. Need to increase bronchodilator or corticosteroid
   3. History of exacerbations (>5 in the last 2 years)
   4. Prior antibiotic treatment
   5. Presence of comorbid conditions (heart failure, coronary artery disease, chronic renal or liver failure)

III. Diagnosis
A. Medical History
   1. Severity of COPD based on degree of airflow limitation
   2. Duration of worsening or new symptoms
   3. Number of previous episodes (total/hospitalizations)
   4. Comorbidities
   5. Present treatment regimen
   6. Previous use of mechanical ventilation
B. Physical Exam (Signs of Severity)
   1. Use of accessory respiratory muscles
   2. Paradoxical chest wall movements
   3. Worsening or new onset central cyanosis
   4. Development of peripheral edema
   5. Hemodynamic instability
   6. Deteriorated mental status
C. Diagnostic Procedures
   1. Pulse oximetry to track and/or adjust supplemental oxygen therapy
   2. Chest x-ray to exclude alternative diagnosis (e.g., pneumonia, PE, or fluid overload from HF)
   3. ECG to aid in detecting coexisting cardiac condition
   4. Blood tests – CBC (may identify polycythemia, anemia, or leukocytosis), serum electrolytes, renal and liver function
   5. Sputum culture – consider if patient has severe underlying COPD, frequent exacerbations or had recent antibiotic use (within past 3 months) or patient does not respond to initial antibiotic therapy
### Table 1. Symptoms of COPD Exacerbation

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Cardiac</th>
<th>Musculoskeletal</th>
<th>Psychiatric</th>
<th>Pulmonary</th>
<th>Systemic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chest tightness</td>
<td>Decreased exercise tolerance</td>
<td>Confusion</td>
<td>Change in volume, color, or tenacity of the sputum</td>
<td>Fatigue</td>
</tr>
<tr>
<td></td>
<td>Tachycardia</td>
<td></td>
<td>Depression</td>
<td>Cough</td>
<td>Fever</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Insomnia or sleepiness</td>
<td>Dyspnea</td>
<td>Malaise</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tachypnea</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Wheezing</td>
<td></td>
</tr>
</tbody>
</table>

### IV. Risk factors for more severe infections (with P. aeruginosa, K. pneumonia, beta-lactamase producing bacteria) that require broader-spectrum antibiotics

A. Older age (>65 years old)
B. Comorbid cardiac diseases
C. Severe underlying COPD (FEV1 <50% predicted, FEV1/FVC<0.7)
D. Frequent exacerbations (2 or more/ year)
E. Antimicrobial therapy in the past 3 months
F. Chronic use of oral steroids (doses above 10 mg daily and used for longer than 3 weeks)

### Table 2. American Thoracic Society/European Respiratory Society Operational Classification of Severity

<table>
<thead>
<tr>
<th>Classification</th>
<th>Clinical History/Physical Findings</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| **Level I**    | - Mild-moderate chronic COPD by history  
                 - Hemodynamically stable (SBP > 90mmHg) | - Generally may be treated as an outpatient |
| **Level II**   | - Moderate-severe chronic COPD by history  
                 - Presence of comorbidities (e.g., heart failure, arrhythmias, pneumonia)  
                 - Hemodynamically stable (SBP > 90mmHg)  
                 - Use of accessory respiratory muscles, tachypnea, and persistent symptoms after initial therapy is likely | - Requires hospitalization |
| **Level III**  | - Severe chronic COPD by history  
                 - Presence of comorbidities (e.g., heart failure, arrhythmias)  
                 - Hemodynamically unstable (SBP < 90mmHg)  
                 - Use of accessory respiratory muscles, tachypnea, and persistent symptoms after initial therapy is likely | - Requires hospitalization and may lead to respiratory failure and ICU level care |
V. Treatment

A. More than 80% of exacerbations can be managed on an outpatient basis with pharmacologic therapy including bronchodilators, corticosteroids and antibiotics.

B. Supplemental oxygen should be titrated to improve hypoxemia with a target saturation of 88-92%.

C. Nebulizer treatment may be more convenient for sicker patients but a systematic review found no significant differences in FEV1 between metered dose inhalers and nebulizers.

D. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015 guidelines recommend a dose of prednisone 40mg daily for 5 days although it is noted that there is insufficient data to provide firm conclusions on the optimal duration of corticosteroid therapy for an acute COPD exacerbation.

1. Corticosteroids shorten recovery time, improve lung function and arterial hypoxemia, reduce the risk of early relapse, treatment failure and length of hospital stay.

E. Antibiotics should be given to patients that meet the below criteria:

1. Have three cardinal symptoms - increase in dyspnea, sputum volume, and sputum purulence

2. Have two of the cardinal symptoms if increased sputum purulence is one of the two symptoms

F. Sputum cultures are recommended if the patient has a history of frequent exacerbations (> 2/year), does not respond to initial antibiotic therapy, has severe airflow limitation, and/or exacerbations requiring mechanical ventilation.

Table 3. Treatment

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Dose</th>
<th>Therapy side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchodilators</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short acting inhaled beta2-agonist</td>
<td>Formulary: nebulized albuterol 2.5 mg q1-4 hrs Headache, nausea, palpitation, tremor, vomiting</td>
<td></td>
</tr>
<tr>
<td>With or without</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short acting anticholinergic</td>
<td>Formulary: 500 mcg nebulized ipratropium q 4hrs Dry mouth, tremor, urinary retention</td>
<td></td>
</tr>
<tr>
<td>Systemic corticosteroid</td>
<td>Prednisone 40mg by mouth daily for 5 days GI bleed, heart burn, hyperglycemia, infections, mood swing, myopathy</td>
<td></td>
</tr>
<tr>
<td>Narrow spectrum antibiotics* (target H. influenza, M. catarrhalis, S. pneumonia)</td>
<td>Formulary:</td>
<td>Rash, diarrheas, yeast vaginitis, increased risk of antibiotic resistance</td>
</tr>
<tr>
<td>• Amoxicillin 1000mg by mouth BID x 10 days</td>
<td></td>
<td>Minocycline: Tooth discoloration</td>
</tr>
<tr>
<td>• Minocycline 100 mg by mouth BID x 10 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broad spectrum antibiotics for resistant pathogens</td>
<td>Non-formulary:</td>
<td></td>
</tr>
<tr>
<td>• Augmentin 875mg by mouth BID x 10 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Levofoxacin 500mg by mouth QID x 10 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxygen therapy</td>
<td>Target saturation is 88-92% in most acutely ill patients</td>
<td></td>
</tr>
</tbody>
</table>

* Counsel patients to complete the prescribed course of antibiotic even if they begin to feel better to avoid treatment failure and antibiotic resistance.
VII. Refer to Chronic COPD Disease Management Guideline

A. Reassessment of inhaler technique
B. Education regarding the role of maintenance regimen
C. Influenza and pneumococcal vaccines
D. Encourage patient to maintain physical activity

VIII. Prognosis

A. The long-term prognosis following hospitalization for a COPD exacerbation is poor with a five-year mortality rate of about 50%.
B. Factors independently associated with poor outcome include:
   1. Older age
   2. Lower body mass index
   3. Comorbidities (e.g., cardiovascular disease or lung cancer)
   4. Previous hospitalizations for COPD exacerbation
   5. Clinical severity of index exacerbation and need for long-term oxygen therapy at Discharge
   6. Worsening lung function
   7. Lower exercise capacity
   8. Lower lung density and thickened bronchial walls

<table>
<thead>
<tr>
<th>Table 4. Follow up after initial treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responds to initial treatment</td>
</tr>
<tr>
<td>Rufast bronchodilator MDI prn if tolerated</td>
</tr>
<tr>
<td>o Restart maintenance therapy</td>
</tr>
<tr>
<td>o Finish the courses of oral steroid and antibiotic(s) if applicable</td>
</tr>
<tr>
<td>o Restart maintenance therapy</td>
</tr>
</tbody>
</table>
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Assess Symptom.

Consider COPD in any patient over 40 years old who has dyspnea, chronic cough or sputum production, and a history of exposure to risk factors for the disease (See Box A). For acute respiratory symptoms beyond normal day-to-day variation, see acute COPD (DMG).

Assess Risk of Exacerbations. The risk of exacerbations may be assessed by one of three methods:

1. Use spirometry to determine the GOLD grade of airflow (See Box B)
   - Low risk: FEV1 ≥ 80% predicted
   - High risk: FEV1 < 80% predicted

2. Assess the number of exacerbations within the past 12 months
   - Low risk: ≤ 1 exacerbation per year
   - High risk: ≥ 2 exacerbations per year

3. Determine whether the patient has had one or more hospitalizations in the previous year
   - Low risk: no hospitalization for exacerbation
   - High risk: ≥ 1 with hospitalization

Note: If these three ways of assessing risk do not result in the same level of risk, determine the risk by the method indicating the highest risk.

Assess Comorbidities. The below comorbidities may influence mortality and hospitalizations and should be looked for routinely and treated appropriately.

- Cardiovascular diseases
- Osteoporosis
- Depression and anxiety
- Skeletal muscle dysfunction
- Metabolic syndrome
- Lung cancer

Determine COPD Stage through combined assessment of symptoms, spirometry and risk of exacerbations in the above boxes.

Box B. Classification of Severity of Airflow Limitation

<table>
<thead>
<tr>
<th>GOLD</th>
<th>Description</th>
<th>FEV1 Prediction</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1</td>
<td>Mild</td>
<td>≥ 80% predicted</td>
</tr>
<tr>
<td>GOLD 2</td>
<td>Moderate</td>
<td>50% ≤ FEV1 &lt; 80% predicted</td>
</tr>
<tr>
<td>GOLD 3</td>
<td>Severe</td>
<td>30% ≤ FEV1 &lt; 50% predicted</td>
</tr>
<tr>
<td>GOLD 4</td>
<td>Very Severe</td>
<td>FEV1 &lt; 30% predicted</td>
</tr>
</tbody>
</table>

Prepared By: The Correctional Managed Care Pharmacy & Therapeutic Committee, September 1996, Revised 8/98, 12/98, 6/02, 6/03, 10/03, 11/06, 1/10, 7/12, 11/15. Reviewed 3/05, 1/09.
CHRONIC COPD

10

Patient Education - Proper use of inhaler and risk factor avoidance.
Recommended Treatment:
SA beta₂ - agonist: Albuterol HFA 2 puffs PRN up to QID (1 inhaler will last 30-90 days based on patient use)
Alternative:
SA anticholinergic: Ipratropium HFA 2 puffs PRN up to QID (1 inhaler will last 30-90 days based on patient use)
Follow Up - within 90 days
Go to Page 3, box 16

11

Patient Education - Proper use of inhaler and risk factor avoidance.
Recommended Treatment:
SA beta₂ - agonist: Albuterol HFA 2 puffs PRN up to QID (1 inhaler will last 30-90 days based on patient use)
LA anticholinergic:
Ipratropium HFA 2 puffs QID (1 inhaler will last 25 days)
Alternative:
SA beta₂ - agonist (above)
LA anticholinergic:
Ipratropium HFA 2 puffs QID (1 inhaler will last 30 days)
Follow Up - within 90 days
Go to Page 3, box 17

*Tiotropium is a Prior Authorization Agent. Prior authorization criteria must be met and noted in the special instructions field of the order. Criteria include the following:
1. Patient did not respond to Ipratropium 2 puffs QID
2. Moderate COPD
3. Severe COPD
4. Very Severe COPD

CAUTION: Tiotropium HFA 2 puffs NONKOP The device contains 2 piercing needles.

Note: Regular treatment with ICS in COPD patients with FEV₁ < 80% of predicted value, symptoms, lung function, quality of life, and reduces the frequency of exacerbations. ICS may increase risk of pneumonia. Withdrawal from treatment may also lead to exacerbations in some patients. Consider specialty referral for Severe and Very Severe COPD.
GOLD 1: Mild
Continued from Page 2, Box 12

GOLD 2: Moderate
Continued from Page 2, Box 13

GOLD 3: Severe
Continued from Page 2, Box 14

GOLD 4: Very Severe
Continued from Page 2, Box 15

Symptoms Controlled?

Yes

• Continue regimen
• Reinforce patient education
• Follow up at least every 12 months
• Consider RT referral for spirometry based on symptoms or at least every 2 years.

No

• Continue regimen
• Reinforce patient education
• Follow up at least every 12 months
• Consider RT referral for spirometry based on symptoms or at least every 2 years.

Symptoms Controlled?

Yes

• Continue regimen
• Reinforce patient education
• Follow up at least every 6 months
• Consider RT referral for spirometry based on symptoms or at least annually.

No

• Continue regimen
• Reinforce patient education
• Follow up at least every 3 months
• RT referral for spirometry based on symptoms or at least annually.

Symptoms Controlled?

Yes

• Refer to Specialist
• Reinforce patient education
• Proper use of inhaler and technique, importance of scheduled dosing of anticholinergics and corticosteroid inhalers, and risk factor avoidance.
• Continue LA anticholinergic
• Step Up therapy:
  • Maximum beclomethasone dosage to 4 puffs BID
  • Discontinue LA beta-agonist and beclomethasone and consider initiation of Combination Inhaled Corticosteroid/Long Acting Bronchodilator (non-formulary approval required). Dulera® 100/5 mcg 2 puffs bid for 30 days. May titrate up Dulera® to 200/5 mcg 2 puffs bid.

No

• Refer to Specialist
• Reinforce patient education
• Proper use of inhaler and technique, importance of scheduled dosing of anticholinergics and corticosteroid inhalers, and risk factor avoidance.
• Continue LA anticholinergic
• Step Up therapy:
  • Maximum beclomethasone dosage to 4 puffs BID
  • Discontinue LA beta-agonist and beclomethasone and consider initiation of Combination Inhaled Corticosteroid/Long Acting Bronchodilator (non-formulary approval required). Dulera® 100/5 mcg 2 puffs bid for 30 days. May titrate up Dulera® to 200/5 mcg 2 puffs bid.

90
Below are general instructions for HFA inhaler use. Please refer to the specific inhaler package insert for complete directions as instructions may vary.

**Priming HFA inhaler:**
1. Shake the inhaler well
2. Prime the inhaler before using for the first time by releasing 4 test sprays into the air away from face.
3. Repeat the above priming procedure before using only if the inhaler has not been used for more than 2 weeks.

**Cleaning HFA inhaler:**
1. Remove medication canister. Never get the canister wet.
2. Clean the plastic mouthpiece by running warm water through the top to the bottom for 30 seconds at least once a week.
3. Shake to remove excess water, then air dry thoroughly (such as overnight).

**Instructions for taking a dose from your HFA inhaler:**

Read the steps below before using your inhaler. If you have any questions, ask your provider.

1. Take the cap off the mouthpiece of the inhaler (plastic actuator) and shake the inhaler well before each spray.
2. Hold the inhaler upright with the mouthpiece down (see Figure 2). Breathe out through your mouth and push as much air from your lungs as you can. Put the mouthpiece in your mouth and close your lips around it.
3. Push the top of the canister all the way down while you breathe in deeply and slowly through your mouth (see Figure 3). Right after the spray comes out, take your finger off the canister. After you have breathed in all the way, take the inhaler out of your mouth and close your mouth.
4. Hold your breath as long as you can, up to 10 seconds, to allow the drug to reach deeply into your lungs. Then breathe normally.
5. If your provider has prescribed more sprays, wait 1 minute between sprays. Shake the inhaler again and repeat steps 2 through 4.
6. Put the cap back on the mouthpiece after every time you use the inhaler, and make sure it snaps firmly into place.

**Important points:**
1. Do not use the inhaler after the expiration date, which is on the outside packaging.
2. This technique does not work with dry powder capsule inhalers. It is important to close the mouth tightly around the mouthpiece of the inhaler and to inhale rapidly when using a dry powder inhaler.

---

**Figure 1: Inhaler Use**

Below are general instructions for HFA inhaler use. Please refer to the specific inhaler package insert for complete directions as instructions may vary.

**Priming HFA inhaler:**
1. Shake the inhaler well
2. Prime the inhaler before using for the first time by releasing 4 test sprays into the air away from face.
3. Repeat the above priming procedure before using only if the inhaler has not been used for more than 2 weeks.

**Cleaning HFA inhaler:**
1. Remove medication canister. Never get the canister wet.
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5. If your provider has prescribed more sprays, wait 1 minute between sprays. Shake the inhaler again and repeat steps 2 through 4.
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**Important points:**
1. Do not use the inhaler after the expiration date, which is on the outside packaging.
2. This technique does not work with dry powder capsule inhalers. It is important to close the mouth tightly around the mouthpiece of the inhaler and to inhale rapidly when using a dry powder inhaler.
**Inhaler parts:**
1. Dust cap
2. Mouthpiece
3. Base
4. Piercing Button
5. Center chamber
6. Air intake vents

**Figure 2: Inhaler Technique Tiotropium**

1. Open the inhaler cap by pressing the green piercing button and pulling upwards and then open the mouthpiece.
2. Place 1 capsule in the center chamber.
3. Close the mouthpiece. You will hear a click when it is firmly closed.
4. Hold the inhaler with the mouthpiece upwards and press the piercing button in once. This makes a hole in the capsule and allows the medication inside the capsule to be released.
5. Breath out completely away from the device.
6. Raise the inhaler to your mouth in a horizontal position and close your lips tightly around the mouthpiece. **Do not** block the air vents. Keep your head in an upright position and breathe in slowly and deeply at a rate sufficient to hear the capsule vibrate. Hold your breath as long as is comfortable.
7. **To get your full daily dose, you must again, breath out completely (Picture 5) and for a second time, breath in (Picture 6) from the same capsule. **Do not** press the green piercing button again.
8. After taking your daily dose, open the mouthpiece and turn the inhaler upside down to discard the capsule, without touching it.
9. Close the mouthpiece and inhaler cap for storage.

**Notes:**
Do not store capsules in the inhaler
Do not open capsule package until you are ready to use the inhaler
1. **Open your Diskus.** Hold the Diskus in your left hand and place the thumb of your right hand in the thumb grip. Push the thumb grip away from you as far as it will go until the mouthpiece shows and snaps into place. (Picture A)

2. **Slide the lever until you hear it click.** Hold the Diskus in a level, flat position with the mouthpiece towards you. Slide the lever away from mouthpiece as far as it will go until it clicks. The number on the counter will count down by 1. The Diskus is now ready for use. (Picture B)

3. **Inhale your medication.** Before you breath in your dose, breathe out as long as you can while you hold the Diskus level and away from your mouth. **Do not** breathe into the mouthpiece. Put the mouthpiece to your lips. Breathe in quickly and deeply through the Diskus. **Do not** breathe in through your nose. Remove the Diskus from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable for you. Breathe out slowly as long as you can. (Pictures C and D)

4. **Close the Diskus.** Place your thumb in the thumb grip and slide it back towards you as far as it will go. Make sure the Diskus clicks shut and you cannot see the mouthpiece. The Diskus is now ready for your next scheduled dose in about 12 hours. (Picture E)

**Important Notes:** To avoid accidentally wasting a dose:
- **Do not** close the Diskus
- **Do not** tilt the Diskus
- **Do not** move the lever on the Diskus
I. Definitions (adapted from the 2015 GOLD guidelines)
A. Chronic obstructive pulmonary disease (COPD) is a “disease state characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lungs to noxious particles or gases.”
B. Exacerbation of COPD is “an acute event characterized by a worsening of the patient’s respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication. The most common causes appear to be respiratory tract infections (viral or bacterial).”

II. Diagnosis
A. Consider diagnosis if patient has symptoms consistent with COPD and/or risk factors associated with the disease
1. Chronic cough: may be intermittent and may be unproductive
2. Chronic sputum production: any pattern of chronic sputum production may indicate COPD
3. Dyspnea that is: progressive (worse over time), persistent, and worse with exercise
4. History of exposure to risk factors: tobacco smoke, smoke from home cooking and heating fuels, and occupational dusts and chemicals
5. Family history of COPD
B. Diagnosis is confirmed by spirometry:
1. Post Bronchodilator FEV₁ <80% of predicted value
2. FEV₁/FVC < 70% (post bronchodilator)
C. Peak flow - low Peak flow is consistent with COPD but has less specificity
D. Chest X-ray - It is seldom diagnostic unless obvious bullous disease is seen but may be used to exclude other diagnoses.
E. Alpha-1 antitrypsin deficiency screening - Consider in patient that develops COPD at young age (<45 years) or has family history.

III. Classification

<table>
<thead>
<tr>
<th>COPD Stage</th>
<th>Spirometry</th>
<th>Exacerbations per year</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>GOLD 1: Mild</td>
<td>FEV₁ ≥ 80% predicted</td>
<td>≤ 1 per year and no hospitalization</td>
<td>Intermittent productive cough</td>
</tr>
<tr>
<td>GOLD 2: Moderate</td>
<td>50% ≤ FEV₁ &lt; 80% predicted</td>
<td>≤ 1 per year and no hospitalization</td>
<td>Chronic, productive cough</td>
</tr>
<tr>
<td>GOLD 3: Severe</td>
<td>30% ≤ FEV₁ &lt; 50% predicted</td>
<td>≥ 2 per year or ≥ 1 with hospitalization</td>
<td>Chronic, productive cough</td>
</tr>
<tr>
<td>GOLD 4: Very Severe</td>
<td>FEV₁ &lt; 30% predicted</td>
<td>≥ 2 per year or ≥ 1 with hospitalization</td>
<td>Chronic, productive cough</td>
</tr>
</tbody>
</table>
IV. Patient Evaluation
   A. Obtain thorough medical history
      1. Risk factors (smoking, occupational or environment exposures)
      2. Past medical history of respiratory problems such as asthma, allergies, infections, etc.
      3. Family history of respiratory disease
      4. History of symptom development and impact on activities and function
      5. History of exacerbations/hospitalizations
      6. Presence of co-morbidities such as cardiovascular disease, osteoporosis, depression and anxiety, skeletal muscle dysfunction, metabolic syndrome, diabetes, GERD, infections and malignancies (lung cancer)
      7. Past and current treatments

B. Physical Exam: Rarely diagnostic but important

V. Goals of therapy
   A. Prevent disease progression
   B. Relieve symptoms
   C. Improve exercise tolerance
   D. Prevent complications
   E. Prevent exacerbations
   F. Reduce mortality
   G. Prevent or minimize adverse effects of therapy

VI. Treatment
   A. Non-pharmacologic Treatment
      1. Risk factor avoidance (e.g., smoking cessation)
      2. Exercise
      3. Oxygen
         - Consider if patient has stage 4 COPD with chronic respiratory failure:
            • PaO$_2$ < 7.3 kPa (55 mmHg) or SaO$_2$ < 88% with or without hypoxemia or PaCO$_2$ between 7.3 kPa and 8 kPa (60 mmHg)
            • SaO$_2$ 88% if has evidence of pulmonary hypertension, peripheral edema suggesting heart failure or polycythemia (HCT > 55%).
   B. Pharmacological Treatment
      - Approach to therapy is stepwise depending on disease severity.
      1. Bronchodilators: Mainstay of therapy for COPD. Short-acting Beta$_2$-agonists are used as needed or on a regular basis to prevent or reduce symptoms. Anticholinergics are used daily. Long-acting inhaled bronchodilators are more effective at producing sustained symptom relief than short-acting bronchodilators. Combining bronchodilators of different pharmacological classes may improve efficacy and decrease the risk of side effects compared to increasing the dose of a single bronchodilator.
      2. Glucocorticosteroids: In COPD patients with FEV$_1$ < 60% predicted, regular use of inhaled corticosteroids has been shown to improve symptoms, lung function, quality of life, and reduce the frequency of exacerbations. There is an increased risk of pneumonia with inhaled corticosteroids therapy. Withdrawal from treatment with ICS may lead to exacerbations in some patients. Regular treatment with inhaled corticosteroids improves symptoms and reduces the frequency of exacerbations in COPD but does not modify the occurrence of long-term decline in pulmonary function or the rate of mortality in COPD patients.
      3. Vaccinations:
         a. Influenza vaccination can reduce serious illness and deaths in COPD patients and is recommended per Infection Control Policy B-14.07.
         b. Pneumococcal polysaccharide vaccine is recommended for COPD patients (See Infection Control Policy B-14.07).

VII. Follow Up
   A. Inquire about changes in symptoms at each visit including cough and sputum, breathlessness, fatigue, activity limitation, and sleep disturbances
   B. Review current treatment including medication dosages, adherence, inhaler technique, effectiveness of the current regimen at controlling symptoms, and adverse effects
   C. Evaluate the frequency, severity, and likely cause of exacerbations
   D. Monitor comorbidities which can potentially complicate management of COPD
<table>
<thead>
<tr>
<th>Regimen</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Very Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommended</strong></td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
</tr>
<tr>
<td><strong>Alternative</strong></td>
<td>SA anticholinergic as needed: Formulary: Ipratropium bromide HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
<td>SA beta₂-agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed</td>
</tr>
</tbody>
</table>

Note: Regular treatment with ICS in COPD patients with FEV₁ <60%, improves symptoms, lung function, quality of life, and reduces the frequency of exacerbations. ICS may increase risk of pneumonia. Withdrawal from treatment may also lead to exacerbations in some patients. Consider specialty referral for Severe and Very Severe COPD.
CHECKLIST FOR SECONDARY PREVENTION OF CORONARY ARTERY DISEASE*

DISEASE STATE MANAGEMENT

ACHIEVED?  GOAL

Yes  No
Blood pressure goal achieved?
< 140/90 mm Hg  or  < 130/80 mm Hg if patient has chronic kidney disease and
albuminuria.

Yes  No
Lipids already evaluated with the Hyperlipidemia algorithm
• Age ≤ 75 years and on atorvastatin
• Age >75 years OR is not a candidate for atorvastatin
then the patient is on pravastatin.

Yes  No
Diabetes goal achieved?
• HbA1C < 7%

Yes  No
Exhibiting heart failure symptoms or is diagnosed
with heart failure?

LIFESTYLE MODIFICATIONS***

ACHIEVED?  GOAL

Yes  No
Smoking cessation achieved?

Yes  No
Weight management achieved?
• BMI: 18.5 to 24.9 kg/m²
• Waist circumference: < 40 inches in men
  < 35 inches in women

Yes  No
Physical activity achieved?
• Minimum of 30 minutes 5 days per week

Yes  No
Diet for health initiated (or other diet as clinically indicated)?
• Encourage low salt and low fat

Yes  No
Dental evaluation annually?

*Patients covered by this guideline include those with established coronary and other atherosclerotic vascular
disease, including peripheral arterial disease, atherosclerotic aortic disease, and carotid artery disease. The
treatment of a patient whose only manifestation of cardiovascular risk is diabetes is not covered by this guideline.
**Non-HDL-C = Total cholesterol – HDL cholesterol.
***If Lifestyle Modifications are not met, then initiate treatment, perform education, or refer as appropriate.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, Approved May 2008
Revised 9/09, 05/2012, 05/2016.
<table>
<thead>
<tr>
<th>MEDICATION MANAGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>INITIATED?</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
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<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
</table>

1. Contraindications to antiplatelet therapy include allergies and significant bleeding risk.
2. Contraindications to warfarin include allergies and significant bleeding risk.
3. Contraindications to ACE inhibitor therapy include allergies and certain renal abnormalities.
4. Contraindications to β-blocker therapy include allergies and certain heart rhythm abnormalities.
5. Contraindications to aldosterone blockade include allergies, renal dysfunction, and hyperkalemia (K >5.0mEq/L).
6. Contraindications to influenza vaccine include egg allergy.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, Approved May 2008. Revised 9/09, 05/2012, 05/2016.
MAJOR DEPRESSIVE DISORDER (MDD)

1. Rule out medical causes for presentation

2. Does the patient meet DSM-5 criteria for Major Depressive Disorder?
   - Yes
   - No

3. Obtain baseline BPRS
   - Yes
   - No

4. Does the patient have concomitant psychotic symptoms?
   - Yes
   - No

5. Initiate formulary SSRI antidepressant
   - Continue for 4-6 weeks at a therapeutic dose* (Table 1)

6. Adequate response per BPRS?
   - Yes
   - No

7. Assess compliance
   - Yes
   - No

8. If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication
   - Yes
   - No

9. If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication
   - Yes
   - No

10. Assess compliance
    - Yes
    - No

11. Adequate response per BPRS?
    - Yes
    - No

12. If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication
    - Yes
    - No

13. If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication
    - Yes
    - No

14. Remission
    - Yes
    - No

15. Continuous treatment for 6-9 months
   - Yes
   - No

16. First episode?
    - Yes
    - No

17. Reassess annually for compliance and continued need for medication

Medical causes for depression may include endocrine, infectious, or neurologic disorders, vitamin deficiencies, fibromyalgia, etc.

Prepared By: The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved 1/99, revised 5/02, 2/03, 4/03, 11/05, 5/07, 1/11, 9/11, 3/13, 7/16, 5/17, 5/18

*Antidepressant trial of adequate dose/duration is 4-6 weeks at FDA approved maximum dosage or maximum tolerated dose with a minimum of 80% adherence.
Table 1: Formulary Antidepressants

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Daily Dosage (Range)</th>
<th>Therapeutic Range (ng/mL)</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram</td>
<td>Celexa® 20 mg</td>
<td>(20 – 40 mg)</td>
<td>N/A</td>
<td>Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine</td>
<td>Prozac® 20 mg</td>
<td>(20 – 60 mg)</td>
<td>N/A</td>
<td>Fluoxetine has also been associated with QTc prolongation. EKG monitoring is encouraged if risk factors for QTc prolongation are present.</td>
</tr>
<tr>
<td></td>
<td>Sertraline</td>
<td>Zoloft® 50 mg</td>
<td>(50 – 200 mg)</td>
<td>N/A</td>
<td>Serotonin Norepinephrine Reuptake Inhibitor (SNRI)</td>
</tr>
<tr>
<td></td>
<td>Venlafaxine XR</td>
<td>Effexor XR® 75 mg</td>
<td>(150 – 300 mg)</td>
<td>N/A</td>
<td>Duloxetine</td>
</tr>
<tr>
<td></td>
<td>Duloxetine</td>
<td>Cymbalta® 30, 60 mg</td>
<td>30 – 60 mg</td>
<td>60 – 120 mg</td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td>Trazodone</td>
<td>Desyrel® 100 mg</td>
<td>(300 – 600 mg)</td>
<td>N/A</td>
<td>Other</td>
</tr>
</tbody>
</table>

Risk factors for QTc prolongation include age > 65 years old, use of other concomitant QTc prolonging medications, baseline hypokalemia or hypomagnesemia, or pre-existing cardiovascular impairment.

Venlafaxine functions as an SNRI at doses ≥ 150 mg/day. Titration to such doses may offer enhanced efficacy in the treatment of MDD when compared to lower doses, at which this agent functions more like an SSRI.

Generally not recommended as first line or second line therapy for treatment of depression.

BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician

The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment interventions who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual's behavior over the previous 2-3 days should also be considered and can be reported by the patient's caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 25 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.
Instructions for Use and Scoring:
Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.

Brief Psychiatric Rating Scale (BPRS)
Patient Name ______________________  Patient Number __________  Date_______________
Facility ______________  Practitioner _______________

Enter the score for the term that best describes the patient’s condition.

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

<table>
<thead>
<tr>
<th>Score</th>
<th>1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness.</td>
</tr>
<tr>
<td></td>
<td>3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td></td>
<td>4. CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td></td>
<td>5. IMPULSIVENESS</td>
</tr>
<tr>
<td></td>
<td>6. MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td></td>
<td>7. MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td></td>
<td>8. GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td></td>
<td>9. DEPRESSIVE MOOD - Sorrow, sadness, despondency, passim.</td>
</tr>
<tr>
<td></td>
<td>10. HOSTILITY - Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td></td>
<td>11. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminative intent.</td>
</tr>
<tr>
<td></td>
<td>12. HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td></td>
<td>13. MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td></td>
<td>14. UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.</td>
</tr>
<tr>
<td></td>
<td>15. UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.</td>
</tr>
<tr>
<td></td>
<td>16. BLUNTED AFFECT - Reduced emotional tone, reduction in formal intensity of feelings, flatness.</td>
</tr>
<tr>
<td></td>
<td>17. EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td></td>
<td>18. DISORIENTATION - Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td></td>
<td>19. ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathologic mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td></td>
<td>20. SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td></td>
<td>21. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychologically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td></td>
<td>22. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life-threatening.</td>
</tr>
<tr>
<td></td>
<td>23. DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.</td>
</tr>
</tbody>
</table>

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TYPE 1 DIABETES MELLITUS

- Institute lifestyle modification & provide individual education with specific patient goals: weight loss (10% above ideal body weight), exercise plan (150 minutes/week), diet for health (DFH).
- Order complete metabolic panel (CMP), microalbumin, thyroid function, lipid panel and A1C.
- Initiate aspirin and statins if indicated (Table 6 and 7) and if there are no contraindications to therapy (Table 1).
- If blood pressure is >140/90, or if the patient has albuminuria, consider starting ACE-inhibitor (Ibosert 2.5 mg up to 40 mg QD) (see HTN DMG).
- Evaluate for target organ damage and co-morbidities – conduct baseline foot and eye exam.
- Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.

1. Are AM and PM FS at goal (Table A.)?

The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.

2. • Begin intensive insulin regimen. Initiate insulin based on 0.5u/kg/day for Total Daily Dose (TDD).
   • Use NPH for basal insulin requirement, which is 66% TDD. Administer 2/3 of NPH dose in AM and 1/3 in PM.
   • Remaining 33% of TDD is administered as Regular insulin divided equally before breakfast and supper.
   • Order fingersticks (FS) twice a day.
   • Follow up in 2 weeks.

3. • Return to clinic every month until stable, then follow up in Chronic Care Clinic.
   • Obtain A1C* every 3 months. Once A1C is at goal for 6 months (baselines consecutively drawn) and FS are stable, check A1C every 6 months.
   • Obtain CMP and lipid panel annually.
   • Order microalbumin annually if patient is not on an ACEI or ARB (angiotensin receptor blocker).
   • Conduct foot & eye exam annually.

4. Is patient experiencing hypoglycemia ≥ twice a week? (FS <70 mg/dL)?

- Yes
- No

5. • Return to clinic every month until stable, then follow up in Chronic Care Clinic.
   • Obtain A1C* every 3 months. Once A1C is at goal for 6 months (baselines consecutively drawn) and FS are stable, check A1C every 6 months.
   • Obtain CMP and lipid panel annually.
   • Order microalbumin annually if patient is not on an ACEI or ARB (angiotensin receptor blocker).
   • Conduct foot & eye exam annually.

6. • Use Flexiglucometer and check blood glucose at least twice a day before breakfast and before bed.
   • Initiate insulin sliding scale for severe hypoglycemia.
   • Monitor for hypoglycemia.
   • Is patient experiencing hypoglycemia ≥ twice a week? (FS <70 mg/dL)?
   - Yes
   - No

7. • Return to clinic every month until stable, then follow up in Chronic Care Clinic.
   • Obtain A1C* every 3 months. Once A1C is at goal for 6 months (baselines consecutively drawn) and FS are stable, check A1C every 6 months.
   • Obtain CMP and lipid panel annually.
   • Order microalbumin annually if patient is not on an ACEI or ARB (angiotensin receptor blocker).
   • Conduct foot & eye exam annually.

Table A.

<table>
<thead>
<tr>
<th>Glycemic Control Index</th>
<th>Ideal</th>
<th>Goal</th>
<th>Consider action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Blood Glucose (AM FS)</td>
<td>80-120 mg/dL</td>
<td>90-130 mg/dL</td>
<td>&lt;80 mg/dL or &gt;140 mg/dL</td>
</tr>
<tr>
<td>Postprandial Blood Glucose (PM FS)</td>
<td>100-140 mg/dL</td>
<td>&lt;180 mg/dL</td>
<td>&lt;100 mg/dL or &gt;180 mg/dL</td>
</tr>
<tr>
<td>A1C*</td>
<td>&lt;7%</td>
<td>&lt;7%</td>
<td>&gt;7%</td>
</tr>
</tbody>
</table>

* A1C goal needs to be individualized by the provider:
  - A reasonable A1C goal for many adults is <7%.
  - Consider a less stringent A1C goal (<8%) in patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions or long-standing diabetes.
  - Consider a more stringent A1C goal in patients with a short duration of diabetes mellitus, long life expectancy or no significant cardiovascular disease.

TYPE 2 DIABETES MELLITUS

Pre-diabetes if one of the following:
1. FPG 100 to 125mg/dl.
2. A1c 5.7 to 6.4%.
3. 2-h Postprandial glucose (PGT) 140 to 189mg/dl.

• Count on exercise, diet and weight loss.
• Provide diabetes education.
• Treat HTN and hyperlipidemia
• Rescreen FPG annually.

Random plasma glucose ≥200mg/dl plus classic symptoms of hyperglycemia OR fasting plasma glucose (FPG) ≥126mg/dl OR 2-hour plasma glucose (2hPG) ≥200mg/dl during an oral glucose tolerance test (OGTT) OR A1c ≥6.5%.

1. Initiate metformin at 500mg during an oral challenge.

2. Follow up in 2 weeks.

Order
Go to box 27 on next page.

A1c <5%?

5. What is A1c?

A1c >5% without symptoms of hyperglycemia?

12. Initiates Monotherapy with metformin: Initiates metformin at 500mg qd bid over 2-4 weeks.

A1c <5% and FPG <130mg/dl?

9. If FPG is <140mg/dl, consider starting ACE-Inhibitor (lisinopril 1.25mg up to 40mg QD) (see HTN DMG).

A1c <9%?

4. Is A1c <9% (Table A.)?

A1c >9% without symptoms of hyperglycemia?

13. Initiates Dual Therapy with metformin and glipizide: Initiates metformin at 500mg qd bid. Titrate up to 1000mg bid over 2-4 weeks.

A1c ≥6.5%?

10. Go to box 13.

No

Start metformin at 500mg bid.

4 weeks to assess FS.

At goal for 6 months (two consecutive lab draws) and FS are stable, check A1C every 6 months. Follow up in DC every 6 months. Obtain CMP and lipid panel annually. Order microalbumin annually if patient is not on an ACE or ARB. Conduct foot & eye exam annually.

Follow up in 2-4 weeks to assess FS.

Go to box 27 on next page.

Evening Basal Insulin

5. Check A1c in 3 months. Is A1c at goal of <7% (Table A.2)?

No

Review compliance with medications, diet and exercise plan.

Visit, Dual Therapy
Go to box 11.

Yes

Review compliance with medications, diet and exercise plan.

Visit, Dual Therapy
Go to box 11.

11. Continue current therapy.

• Review A1c every 3 months. Once A1c is at goal for 6 months (two consecutive lab draws) and FS is stable, check A1C every 6 months. Follow up in DC every 6 months. Obtain CMP and lipid panel annually. Order microalbumin annually if patient is not on an ACE or ARB. Conduct foot & eye exam annually.

Follow up in 2-4 weeks to assess FS.

15. Recheck A1c in 3 months. Is A1c at goal of <7% (Table A.2)?

No

14. Go to box 11.

Yes

16. Initiates Dual Therapy with metformin and intensified insulin regimen:

• Initiates metformin at 500mg qd bid. Titrate up to 1000mg bid over 2-4 weeks.

• Initiates insulin based on 0.5u/kg/day for Total Daily Dose (TDD). Use NPH for basal insulin requirement, which is 60% TDD. Administer 2/3 of NPH dose in AM and 1/3 in PM.

• Remaining 30% of TDD is administered as Regular insulin divided equally before breakfast and supper.

• Adjust NPH or Regular insulin by 10% if AM and PM FS are at goal.

• Monitor for signs and symptoms of hypoglycemia – patient should not be on glipizide and Regular insulin concomitantly. Glipizide and NPH may be used in combination.

• Follow up in 2-4 weeks to assess FS.

• Go to box 27 on next page.

Reevaluate compliance with medications, diet, and exercise plan.

- Initiate Multi-dose Insulin Regimen. Divide current basal NPH insulin into 2/3 AM dose and 1/3 PM dose.

- Adjust dose by 10% until AM and PM FS are at goal.

- Monitor for signs and symptoms of hypoglycemia – if symptomatic, decrease the morning dose of glipizide.

- Follow up in 2-4 weeks to assess FS.

Recheck A1c in 3 months. Is A1c at goal of <7%* (Table A.7)?

- Yes
- Go to box 11

Table A.

<table>
<thead>
<tr>
<th>Glycemic Control Index</th>
<th>Ideal</th>
<th>Goal</th>
<th>Consider action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Blood Glucose (AM FS)</td>
<td>80-120mg/dL</td>
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<td>&lt;180mg/dL</td>
<td>&lt;100mg/dL or &gt;180mg/dL</td>
</tr>
<tr>
<td>A1C*</td>
<td>&lt;7%</td>
<td>&lt;7%</td>
<td>&gt;7%</td>
</tr>
</tbody>
</table>

*A1c goal needs to be individualized by the provider:
- A reasonable A1c goal for many adults is <7%.
- Consider a less stringent A1c goal (HbA1c) in patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions or long-standing diabetes.
- Consider a more stringent A1c goal in patients with a short duration of diabetes mellitus, long life expectancy, or no significant cardiovascular disease.

Endogenous insulin secretion and insulin sensitivity may improve with the Intensive Insulin regimen. It may be possible to reduce and discontinue insulin and manage patient on oral therapy alone in the following order:
1. Decrease and discontinue AM and PM regular insulin.
2. Increase glipizide 5mg qd to bid. Titrate slowly up to 20mg bid over 2-4 weeks as tolerated.
3. Decrease and discontinue AM NPH insulin dose.
4. Decrease and discontinue PM NPH insulin dose.
5. Monitor for hypoglycemia and ensure they are at goal.
6. Follow up every 2-4 weeks during this transition.

Recheck A1c in 3 months. Is A1c at goal of <7%* (Table A.7)?

- Yes
- Go to box 11

- No
- Go to box 16
CONVERTING TYPE 2 DIABETICS FROM ORAL THERAPY TO INSULIN

**Oral agent failure**

- Patient is on maximum dose of metformin and glipizide and A1c is not at goal.
  - A1c ≥ 9%

**Start Evening Basal Insulin**

- Start NPH at 0.2u/kg or 10-15u qPM.
- Check AM and PM finger stick (FS).
- Titrate by 10% of Total Daily Dose (TDD) until fasting plasma glucose (FPG) is at goal.
- Monitor for signs and symptoms of hypoglycemia – if symptomatic, decrease evening dose of glipizide.
- Do not discontinue metformin.
- Follow up every 2-4 weeks to assess FS.

**Start Multi-Dose Insulin Regimen**

- Start NPH at 0.3-0.5u/kg for TDD. Administer 2/3 of dose in the AM and 1/3 of dose in the PM. Titrate by 20% of TDD until AM and PM finger sticks (FS) are at goal.
- Monitor for signs and symptoms of hypoglycemia – if symptomatic, decrease glipizide to 10mg BID. Do not discontinue metformin.
- Check AM and PM FS.
- Follow up every 2-4 weeks to assess FS.

**Start Intensive Insulin Regimen**

- Discontinue glipizide. Do not discontinue metformin.
- Initiate insulin based on 0.5u/kg/day for Total Daily Dose (TDD).
- Use NPH for basal insulin requirement, which is 66% TDD. Administer 2/3 of NPH dose in AM and 1/3 in PM.
- Remaining 33% of TDD is administered as Regular insulin divided equally before breakfast and supper.
- Adjust NPH or Regular insulin by 10% until AM and PM finger stick (FS) are at goal.
- Monitor for signs and symptoms of hypoglycemia – patient should not be on glipizide and Regular insulin concurrently. Glipizide and NPH may be used in combination.
- Follow up every 2-4 weeks to assess FS.

**Are PM FS at goal?**

- Yes
  - Check A1c q 3 months. Is A1c at goal <7%?*?
  - A1c goal needs to be individualized by the provider:
  - A reasonable A1c goal for many adults is <7%.
  - Consider a less stringent A1c goal (<7%) in patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions or long-standing diabetes.
  - Consider a more stringent A1c goal in patients with a short duration of diabetes mellitus, long life expectancy or no significant cardiovascular disease.
  - Continue current insulin therapy.
  - Review A1c every 3 months. Once A1c is at goal for 6 months (two consecutive lab draws) and FS are stable, check A1c every 6 months. Follow up in CCC every 6 months.
  - Obtain DNP and lipid panel annually.
  - Order microalbumin annually if patient is not on an ACEI or ARB (angiotensin receptor blocker).
  - Conduct foot & eye exam annually.
  - Reinforce diet and exercise at each clinic visit.
  - Continue current therapy.

- No
  - Adjust insulin and/or metformin. Review A1c every 3 months.
  - A reasonable A1c goal for many adults is <7%.
  - Consider a less stringent A1c goal (<7%) in patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions or long-standing diabetes.
  - Consider a more stringent A1c goal in patients with a short duration of diabetes mellitus, long life expectancy or no significant cardiovascular disease.

DIABETES DISEASE MANAGEMENT GUIDELINES

I. Assessment
A. Screening
1. T2DM
   a) Asymptomatic patients who are overweight or obese (BMI ≥ 25 kg/m² or BMI ≥ 23 kg/m² in Asian Americans) and who have one or more additional risk factors:
      i. Physical inactivity
      ii. First-degree relative with diabetes
      iii. Member of high-risk ethnic population (e.g., African American, Latino Native American, Asian American, Pacific Islander)
      iv. Women who delivered a baby weighing > 9 lb or have been diagnosed with gestational diabetes mellitus
      v. Hypertension (≥ 140/90) or on therapy for hypertension
      vi. HDL Cholesterol level ≤ 35 mg/dl and/or a triglyceride level > 250 mg/dl
      vii. A1c ≥ 5.7%, impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) on previous testing
      viii. History of cardiovascular disease
      ix. Other clinical conditions associated with insulin resistance (e.g., PCOS or acanthosis nigricans)
      x. Medications to consider: glucocorticosteroids, thiazide diuretics, and atypical antipsychotics are known to increase the risk of diabetes
   b) For all patients, testing should begin at age 45.
   c) If tests are normal, repeat every 3 years. If results are pre-diabetic, repeat annually.
2. T1DM should be considered in individuals that present with acute symptoms of diabetes and markedly elevated blood glucose levels.
B. Diagnostic tests – in the absence of unequivocal hyperglycemia, a second confirmatory test is required. It is recommended the same test be used without delay but using a new blood sample. If two different tests (A1C and FPG) are both above the diagnostic threshold, this also confirms the diagnosis.
   1. Fasting Plasma Glucose (FPG). Fasting is defined as no caloric intake for at least 8 hours.
   2. 2-hour Plasma Glucose (2-h PG) during an Oral Glucose Tolerance Test (OGTT). Preferred test in pregnancy.
   3. HbA1c (A1C) – test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.
   4. Random Plasma Glucose (PG) plus classic symptoms of hyperglycemia or hyperglycemic crisis.
      a) Symptoms of hyperglycemia
         i. Polyuria
         ii. Weight loss with polyphagia
         iii. Polydipsia
         iv. Fatigue
         v. Blurred vision
         vi. Vaginitis or balanitis
         vii. Extremity numbness/paresthesia
         viii. Acanthosis nigricans
C. Diagnosis

<table>
<thead>
<tr>
<th>CRITERIA FOR DIABETES MELLITUS DIAGNOSIS</th>
<th>Fasting Plasma Glucose (FPG)</th>
<th>2hPG following OGTT</th>
<th>HbA1c (A1C)</th>
<th>Random Plasma Glucose (PG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 100 mg/dL</td>
<td>&lt; 140 mg/dL</td>
<td>&lt; 5.7%</td>
<td>&lt; 180 mg/dL + classic symptoms of hyperglycemia</td>
</tr>
<tr>
<td>Pre-diabetes</td>
<td>100 to 125 mg/dL</td>
<td>140 to 199 mg/dL</td>
<td>5.7 to 6.4%</td>
<td>n/a</td>
</tr>
<tr>
<td>Diabetes</td>
<td>≥ 126 mg/dL</td>
<td>≥ 200 mg/dL</td>
<td>≥ 6.5%</td>
<td>≥ 200 mg/dL + classic symptoms of hyperglycemia</td>
</tr>
</tbody>
</table>

D. Medical history
1. Age and characteristics of onset of diabetes (e.g., diabetic ketoacidosis, asymptomatic laboratory finding)
2. Physical activity habits and eating patterns (frequency of going to chow and/or eating out of commissary)
3. Presence of common comorbidities, psychosocial problems, and periodontal disease
4. History of smoking, alcohol consumption and substance abuse
5. Diabetes education, self-management and support history and needs
6. Review of previous treatment regimens and response to therapy (A1C records)
7. Review of AM and PM fingersticks
8. Diabetic ketonuria at frequency, severity and cause
9. Hypoglycemia episodes, awareness and frequency and causes
10. History of blood pressure and lipids
11. Microvascular complications: retinopathy, nephropathy, neuropathy (sensory and autonomic e.g., sexual dysfunction and gastroparesis)
12. Macrovascular complications: coronary heart disease, cerebrovascular disease and peripheral arterial disease
E. Physical Examination: Initial visit and CCC
   1. Vitals: blood pressure, height and weight
   2. Thyroid palpitation
   3. Skin examination (e.g., acanthosis nigricans, insulin injection site reactions, fungal infections)
   4. Comprehensive foot examination, including monofilament exam on feet
   5. Cardiac exam, peripheral vascular exam to include pedal pulses

F. Lab Evaluation (see pathways for frequency)
   1. Complete Metabolic Panel (CMP)
   2. Fasting lipid panel
   3. Microalbumin, urine
   4. A1c
   5. Thyroid-stimulating hormone (TSH)

G. Verify annual dilated eye exam was conducted.

H. Referrals
   1. Dental for comprehensive dental and periodontal examination
   2. Mental health, if indicated

II. Plan/Treatment
A. Diet
   Diet For Health is recommended. Patient should be counseled to increase carbohydrate intake from whole grains, vegetables, legumes and dairy products with an emphasis on foods higher in fiber and lower in glycemic load. Refined carbohydrates should be limited, and sugar sweetened beverages and sucrose-containing foods should be avoided.

B. Exercise
   If there are no medical contraindications, at least 150 min/week of moderate-intensity aerobic physical activity (50-70% of maximum heart rate), spread over at least 5 days/week with no more than 2 consecutive days without exercise if not contraindicated, type 2 DM patients should be encouraged to perform resistance training at least twice per week.

C. Weight loss: In overweight and obese patient, encourage moderate weight loss (5% of initial body weight)

D. Pharmacologic Therapy
   2. Glycemic Goals include A1c <7%, AM fingersticks 90-130mg/dL and PM fingersticks <180mg/dL.

E. Control of Co-morbid disease states such as
   1. HTN – BP goal < 140/90; BP goal of <130/80 in patients with albuminuria. See Hypertension DMG.
   2. Lipid management – Initiate statin therapy based on ASCVD risk. See Hyperlipidemia DMG

F. Vaccinations
   1. Pneumococcal vaccine
   2. Annual influenza

III. Classification
A. HSM -18 Restrictions: Should be an individualized assessment commensurate with the patient’s severity of disease.
   1. Unit of Assignment: If a patient is a brittle Type 1 Diabetic, for example, the patient should be assigned to a unit with 24 hour nursing coverage. Patients with severe diabetes and multi-system end-organ disease would be more appropriately monitored at a 24 hour nursing unit or RMF. Diabetes that require BID insulin dosing should be housed in units with at least 12 hour nursing service.
   2. Housing Assignment: For most diabetics, who are stable, no restrictions. However, severe diabetic should not be assigned to a single cell. Those diabetics who are prone to hypoglycemia or ketoacidosis should also be restricted to a lower bunk, ground floor and restricted from climbing.
   3. Work Assignment: For those prone to hypoglycemia or severe hyperglycemia, consideration should be given to restriction from temperature and humidity extremes. Patients with documented peripheral vascular disease and/or neuropathy should not wear steel toed boots and should limit squatting.
   4. ITP: No restrictions unless severe diabetic, then as needed.
   5. Transportation: No restriction unless severe brittle diabetic that would necessitate nursing/EMS care/monitoring during transport.
### Table 1. Precautions/Contraindications to medications commonly used in Diabetes Management

<table>
<thead>
<tr>
<th>Medication</th>
<th>Precautions/Contraindications</th>
</tr>
</thead>
</table>
| **Metformin** | - Before starting metformin, obtain patient’s eGFR.  
  - eGFR < 30 mL/min/1.73 m² – metformin is contraindicated. If it falls below this level after initiation, discontinue treatment.  
  - eGFR 30 to 60 mL/min/1.73 m² – initiation of metformin is not recommended. If patient is already on it, it is okay to continue.  
  - eGFR falls below 45 mL/min/1.73 m² after initiation – assess the benefits and risks of continuing treatment. Continue if patient is deriving benefit from treatment.  
  - Discontinue metformin at the time of or before an iodinated contrast imaging procedure in the following patients. Re-evaluate eGFR 48 hours after the imaging procedure. Restart metformin if renal function is stable.  
  - In patients with eGFR 30 to 60 mL/min/1.73 m²  
  - In patients with a history of liver disease, alcoholism, or heart failure  
  - In patients who will be administered intra-arterial iodinated contrast  
  - Should be avoided in patients with hepatic insufficiency  
  - Conservative doses should be used in patients aged 80 years or older due to decreased renal function  
  - Contraindicated in metabolic acidosis, acute or chronic, including ketoacidosis  
  - Contraindicated in hypersensitivity to metformin |
| **Glipizide** | - Contraindicated in  
  - Diabetic ketoacidosis  
  - Hypersensitivity to glipizide  
  - Type 1 DM |
| **Insulin** | - Reduced symptomatic awareness of hypoglycemia may occur in those with long-standing diabetes, recurrent hypoglycemia, or beta blocker use; increased monitoring is recommended.  
  - Infection, fever, dehydration, trauma, surgery or stress can increase the risk of hyperglycemia; monitoring and dose adjustment may be necessary.  
  - Contraindicated in hypersensitivity to any component of the formulation |
| **Lisinopril** | - Avoid concomitant use of ACE inhibitors with angiotensin receptor blockers: dual renin-angiotensin system blockers do not provide additional benefit in comparison to monotherapy.  
  - Hyperkalemia; increased risk in patients with renal impairment, diabetes mellitus, or with concomitant use of potassium-sparing diuretics or potassium supplement. Monitoring is recommended.  
  - Contraindicated in  
  - ACE inhibitor-induced angioedema  
  - Hereditary or idiopathic angioedema  
  - Pregnancy  
  - Hypersensitivity to lisinopril or other ACE inhibitors |
| **Aspirin** | - Contraindications  
  - Syndrome of asthma, nasal polyps, and rhinitis  
  - Inherited or acquired bleeding disorders (including factor VII and factor IX deficiency)  
  - Children (<16 years of age) for use in viral infections  
  - Pregnancy (3rd trimester)  
  - Hypersensitivity to aspirin or other NSAIDs, or any component of the formulation |
| **Statins (e.g., Pravastatin and Atorvastatin)** | - Myopathy and rhabdomyolysis is a risk; monitoring is recommended and discontinue statin if myopathy is suspected or diagnosed.  
  - Contraindications  
  - Active liver disease  
  - Unexplained persistent elevations of serum transaminases  
  - Pregnancy and in breastfeeding  
  - Hypersensitivity to statins or any component of the formulation |
Table 2. Comparison of Agents

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Decrease in A1c (%)*</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle monotherapy</td>
<td>1.0-2.0</td>
<td>Low cost, many benefits</td>
<td>Fails in 1 year</td>
</tr>
<tr>
<td>Metformin</td>
<td>1.5</td>
<td>Weight neutral, inexpensive</td>
<td>GI side effects, rare lactic acidosis</td>
</tr>
<tr>
<td>Insulin</td>
<td>1.5</td>
<td>No dose limit, improved lipid profile, hypoglycemia, weight gain</td>
<td></td>
</tr>
</tbody>
</table>

*UKPDS showed that a 1 percent fall in A1c was associated with a 35 percent reduction in microvascular endpoints, an 18 percent reduction in myocardial infarction, and a 17 percent reduction in all-cause mortality.

Table 3. Pharmacokinetics of Insulin*

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Onset of Action</th>
<th>Peak Action</th>
<th>Effective Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular</td>
<td>30 to 60 min</td>
<td>2 to 3 hours</td>
<td>8-10 hours</td>
</tr>
<tr>
<td>NPH</td>
<td>2 to 4 hours</td>
<td>4 to 10 hours</td>
<td>12 to 18 hours</td>
</tr>
</tbody>
</table>

*The pharmacokinetics of insulin preparations may be used to determine which insulin to adjust when a patient is experiencing symptoms of low or high blood glucose.

Examples:
1. If patient is symptomatic of hypoglycemia around 9am and he or she injected NPH and Regular insulin at 4am, most likely it is the NPH that needs to be adjusted as it is peaking 5 hours after injection.
2. If patient is symptomatic of hypoglycemia or hyperglycemia roughly an hour after a meal, the Regular insulin will need to be adjusted as its onset of action is faster than the NPH.

Table 4. Insulin Dosing and Conversion

<table>
<thead>
<tr>
<th>NPH/Regular Insulin</th>
<th>Detemir (Levemir®)/ Regular Insulin</th>
<th>Glargin (Lantus®)/ Regular Insulin</th>
</tr>
</thead>
</table>
| Total Daily Dose (TDD) = 0.5units/kg/day  
Administer 60% of the TDD to NPH insulin  
Administer 50% of the TDD to detemir insulin  
Administer 50% of the TDD to glargin insulin  
Remaining 10% of the TDD is allocated to Regular insulin. | Total Daily Dose (TDD) = 0.5units/kg/day  
Administer 60% of the TDD to NPH insulin  
Administer 50% of the TDD to detemir insulin  
Administer 50% of the TDD to glargin insulin  
Remaining 10% of the TDD is allocated to Regular insulin. | Total Daily Dose (TDD) = 0.5units/kg/day  
Administer 60% of the TDD to NPH insulin  
Administer 50% of the TDD to detemir insulin  
Administer 50% of the TDD to glargin insulin  
Remaining 10% of the TDD is allocated to Regular insulin. |

Example:
40kg patient
40kg x 0.5 units/kg/day = 20u TDD
NPH insulin: 10u  
Detemir insulin 10u  
Reg insulin 10u  

Notes: Refer to Table 3 for the pharmacokinetics of NPH and Regular insulin.

Example:
40kg patient
40kg x 0.5 units/kg/day = 20u TDD
Detemir insulin 10u  
Reg insulin 10u  

Notes: Do not mix detemir with other insulins.

Example:
40kg patient
40kg x 0.5 units/kg/day = 20u TDD
Glarigin insulin 10u  
Reg insulin 10u  

Notes: Do not mix glargin with other insulins.

NPH to glargin conversion: reduce TDD by 20%.

Notes:
Do not mix detemir with other insulins.
NPH to detemir conversion: reduce TDD by 20%.
# Table 6. Indications for Daily Aspirin Therapy in Type 1 and Type 2 Diabetes

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Prevention</td>
<td></td>
</tr>
<tr>
<td>ASCVD risk &gt;10%</td>
<td>Consider aspirin therapy (aspirin 81mg)</td>
</tr>
<tr>
<td>ASCVD risk 5-10%</td>
<td>Use clinical judgement</td>
</tr>
<tr>
<td>ASCVD risk &lt;5%</td>
<td>Aspirin therapy is not recommended</td>
</tr>
<tr>
<td>Secondary Prevention</td>
<td></td>
</tr>
<tr>
<td>Patients with diabetes and a history of ASCVD</td>
<td>Use aspirin therapy</td>
</tr>
<tr>
<td>Patients with diabetes, ASCVD and documented aspirin allergy</td>
<td>Use clopidogrel (75mg/day)</td>
</tr>
<tr>
<td>Patient with diabetes, ASCVD and acute coronary syndrome</td>
<td>Dual antiplatelet therapy (aspirin and clopidogrel) for up to a year after the event.</td>
</tr>
</tbody>
</table>

# Table 7. Indications for Daily Statin Therapy—refer to Hyperlipidemia DMG

<table>
<thead>
<tr>
<th>LDL 70-189 mg/dl, and age 40 – 75 years</th>
<th>Estimated 10 year ASCVD risk ≤ 7.5%</th>
<th>Estimated 10 year ASCVD risk ≥ 7.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate-intensity statin</td>
<td>Atorvastatin 10-20mg, Pravastatin 40-80mg</td>
<td></td>
</tr>
<tr>
<td>High-intensity statin</td>
<td>Atorvastatin 40-80mg</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical ASCVD</th>
<th>Age ≤ 75 years</th>
<th>Age &gt;75 years is not a candidate for high-intensity statin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate-intensity statin</td>
<td>Atorvastatin 10-20mg, Pravastatin 40-80mg</td>
<td></td>
</tr>
</tbody>
</table>

| Age <60 and/or Type 1 Diabetes | Data is not definitive, however similar statin treatment approaches should be considered for patients with type 1 DM as with type 2 DM, particularly in the presence of other cardiovascular risk factors. |
| Age >75 years or LDL < 70 mg/dl | Data is not definitive. Refer to Box 11 in Hyperlipidemia DMG. |
EDUCATION FOR PATIENTS AND PRACTITIONERS

I. Who is educated?
A. Unit Practitioners – updated on diabetes so accurate and easy to understand information is provided to patients.
B. All diabetic patients
   1. Type 1 diabetes – absolute deficiency in insulin secretion.
   2. Type 2 diabetes – a combination of resistance to insulin action and inadequate compensatory insulin secretory response.

II. Who educates?
A. The unit team will delegate educational responsibility
   1. Educator must document date and time of education in patient’s chart.
   2. Physician, Mid-level Provider, and Clinical Pharmacist have final responsibility to ensure education occurs (if not documented on chart as completed by some other designated education provider, must provide diabetes education at clinic visit).

III. The unit medical staff will provide counseling on diet and how to choose the correct foods from the meal line.

IV. When does education take place?
   1. At every clinic visit.

V. What is included in diabetes education (to include health services personnel and diabetic patients)
A. Pathophysiology of Type 1 versus Type 2 diabetes
B. Non-pharmacological treatment plan & importance of lifestyle modifications
C. Signs, symptoms, and treatment for acute complications of diabetes mellitus
   1. Hypoglycemia
      a. Signs and symptoms – dizziness, light-headedness, shakiness, blurry vision
      b. Treatment – Counsel patient to ingest 15 grams of carbohydrates (i.e., 1 slice of bread, 4-5 small pieces of candy, 1/2 cup of soda, 4 oz of orange juice). Have the patient wait 5-10 minutes for blood glucose to rise. If patient continues to be symptomatic, counsel patient to have another 15 grams of carbohydrates or to seek medical attention.
   2. Hyperglycemia
      a. Signs and symptoms – polyuria, polyphagia, polydipsia, blurry vision
      b. Treatment – exercise, hydration, diet counseling
   3. Diabetic ketoacidosis
      a. Signs and symptoms – polyuria, polyphagia, polydipsia, acute abdominal pain, nausea, shortness of breath, altered mental status, tachycardia, ketotic breath
      b. Labs – serum ketones, anion gap/metabolic acidosis
      c. Treatment – manage as infantile or an emergent issue
   D. Monitoring parameters – frequency and importance
      1. A1c – Done every 3 months (if not at goal) or every 6 months (if goal achieved). A1c signifies overall control of patient’s diabetes.
      2. Fingersticks – Ordered at the provider’s discretion. This depicts a snapshot of patient’s blood glucose at the current time. The patient should be counseled to take the finger stick before the meal (i.e., breakfast or supper). They should know what his or her goals are and should be encouraged to self record his or her fingersticks and bring the log to his or her clinic appointments.
      E. The importance of insulin – Patients should be counseled that diabetes is a progressive disease and that eventually he or she may be administrated insulin. Thoroughly counsel patient on potential side effects (i.e., hypoglycemia and possible weight gain), and how to manage them. Counsel patient to administer insulin before meals and that it is important not to skip meals when on insulin.
   F. Proper techniques of administering insulin for all patients on insulin (i.e., proper self-administration, insulin preparation, mixing, and administration sites)
   G. Chronic complications of diabetes (i.e., retinopathy, neuropathy, nephropathy, cardiovascular, cerebrovascular, and peripheral vascular disease) and means for prevention
   H. Patient self-monitoring to include foot, skin, and wound care
      Food/water care tips:
      1. Watch for pain, numbness, and/or wounds that will not heal.
      2. Keep skin supple by drinking plenty of water. Never put lotion or moisturizers between the toes.
      3. Wash feet daily with lukewarm water and soap
      4. Dry feet well, especially between the toes.
      5. Check feet daily (including bottoms and between toes) for sores, redness, and swelling.
      6. Change into clean socks daily.
      7. Keep feet warm and dry.
      8. Never walk barefoot.
      10. Examine shoes daily for things that could hurt your feet such as rocks or debris.
   I. Dental hygiene to include daily brushing in the morning and evening and flossing once daily.
Initial Assessment of Suspected Overdose
Management of TCA, Diphenhydramine, Benztropine, and Anticonvulsants

1. Obtain print pass
2. Document: WHAT, HOW MANY, TIME THEY TOOK IF AVAILABLE (Patient may have taken another patient’s medication).
3. Initiate patient evaluation and assess level of consciousness. Monitor vital signs, oxygen saturation, & EKG. Initiate basic life support as indicated.
4. Monitor for side effects:
   a. Common (mild-moderate poisoning): Somnolence, anticholinergic effects (mydriasis, blurred vision, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, nausea, and vomiting are common after overdose.
   b. Moderate poisoning: Agitation, confusion, and hallucinations.
   c. Severe poisoning: Delirium, psychosis, seizures, coma, respiratory depression, and ventricular dysrhythmias including torsades de pointes.
5. Contact provider at the unit level or by telephone to obtain further orders.
6. Call Poison Center 1-800-222-1222 to report incident.

NURSING ASSESSMENT FOR SUSPECTED OVERDOSE

Patient presents stating he/she has taken an overdose of pills:
1. Obtain print pass
2. Document: WHAT, HOW MANY, TIME THEY TOOK IF AVAILABLE (Patient may have taken another patient’s medication).
3. Initiate patient evaluation and assess level of consciousness. Monitor vital signs, oxygen saturation, & EKG. Initiate basic life support as indicated.
4. Monitor for side effects:
   a. Common (mild-moderate poisoning): Somnolence, anticholinergic effects (mydriasis, blurred vision, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, nausea, and vomiting are common after overdose.
   b. Moderate poisoning: Agitation, confusion, and hallucinations.
   c. Severe poisoning: Delirium, psychosis, seizures, coma, respiratory depression, and ventricular dysrhythmias including torsades de pointes.
5. Contact provider at the unit level or by telephone to obtain further orders.
6. Call Poison Center 1-800-222-1222 to report incident.

Suspected overdose of Diphenhydramine, Benztropine, Anticonvulsants, or Tricyclic Antidepressants (TCA)?
Yes
- OBTAIN APPROPRIATE LAB STUDIES
- Patient presents early and
  • is fully conscious,
  • has protected airway,
  • is not at risk for GI perforation
  or hemorrhage and
  • has not also ingested
  corrosives?
- Stabilize patient and provide
general and supportive care,
provide airway management if
indicated. Transfer to ER.
No
- Does the suspected
overdose exceed the
maximum daily dose?
(See Dosing Table page 2)
- Consider patient medical history
and exposure to other poisons. If
patient is symptomatic transfer to
ER.

Consider patient medical history
and exposure to other poisons. If
patient is symptomatic transfer to
ER.

Administer 8 ounces
of Activated Charcoal slurry
(Actidosell)

Observe 4-6 hours in the medical department.
• Consider additional courses of charcoal as clinically indicated.
• Consider repeat EKG to monitor for QT prolongation, ventricular arrhythmia, or heart block as clinically indicated.
• Obtain report and if asymptomatic release patient.
• Schedule follow up appointment next day and consider Mental Health referral.

The pathways do not replace sound clinical judgment nor are they intended to apply to all patients.
### Diphenhydramine, Benztropine & TCA Therapeutic and Toxic Doses

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual Therapeutic Dosing</th>
<th>Maximum Daily Dose</th>
<th>Common Dose of Severe Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benztropine</td>
<td>1-4 mg/day</td>
<td>8 mg/day</td>
<td></td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>25-50 mg q 4-8h</td>
<td>400 mg divided</td>
<td>&gt; 1 g</td>
</tr>
<tr>
<td>Desipramine</td>
<td>100-200 mg/day</td>
<td>300 mg/day</td>
<td>10-20 mg/kg</td>
</tr>
<tr>
<td>Doxepin</td>
<td>75-150 mg/day</td>
<td>300 mg/day</td>
<td>10-20 mg/kg</td>
</tr>
<tr>
<td>Imipramine</td>
<td>75-150 mg/day</td>
<td>200-300 mg/day</td>
<td>10-20 mg/kg</td>
</tr>
<tr>
<td>Nortriptyline</td>
<td>75-150 mg/day</td>
<td>150 mg/day</td>
<td>10-20 mg/kg</td>
</tr>
</tbody>
</table>

### Phenytoin Therapeutic and Toxic Doses

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual Therapeutic Dosing</th>
<th>Maximum Daily Dose</th>
<th>Common Dose of Severe Toxicity</th>
<th>Usual Toxic Serum Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenytoin</td>
<td>300-400 mg/day divided</td>
<td>1,000 mg divided</td>
<td>&gt;20 mg/kg</td>
<td>&gt;20 mcg/mL</td>
</tr>
</tbody>
</table>

### Valproic Acid Therapeutic and Toxic Doses

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual Therapeutic Dosing</th>
<th>Maximum Daily Dose</th>
<th>Common Dose of Severe Toxicity</th>
<th>Usual Toxic Serum Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valproic Acid</td>
<td>15-60 mg/kg/day</td>
<td>60 mg/kg</td>
<td>&gt;28 g</td>
<td>&gt;450 mcg/mL</td>
</tr>
</tbody>
</table>

### Carbamazepine Therapeutic and Toxic Doses

<table>
<thead>
<tr>
<th>Drug</th>
<th>Usual Therapeutic Dosing</th>
<th>Maximum Daily Dose</th>
<th>Common Dose of Severe Toxicity</th>
<th>Usual Toxic Serum Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Up to 1200 mg/day divided</td>
<td>1600 mg divided</td>
<td>&gt;1600 mg</td>
<td>&gt;12 mcg/mL</td>
</tr>
</tbody>
</table>
END STAGE LIVER DISEASE

Alert Symptoms
- Abdominal Pain
- Mental Status Change
- Fever
- Oliguria/Anuria
- Rapid weight gain or loss
- Hematochezia
- Hematemesis/Melena

Initial Management of Cirrhosis
- Complete baseline evaluation and offer preventive measures (box A)
- Enroll in ESLD CCC and follow up every 3-6 months
- Refer to ESLD clinic or UTMB for TTE if appropriate

The pathway does not replace sound clinical judgment and is intended to help with clinical decision-making for all patients.

Compensated
Lab abnormalities suggestive of cirrhosis:
- Low platelets (platelet count < 70,000)
- Elevated bilirubin (bilirubin < 2.0)
- PT prolongation (< 2 sec.)
- Low albumin (albumin > 3.0)

Varices: Surveillance
- Ultrasound Q 6 months

Primary prophylaxis - see Variceal Surveillance (box 5)
- First line: Propranolol
- Second line: TIPS or shunt

Secondary prophylaxis
- Bactrim DS 1 tab daily
- Alternates: Ciprofloxacin 500mg daily

Esophageal Varices and Portal HTN (see table 3)

Asciates / Edema (see table 4)
- Sodium restriction
- Diuretics
- TIPS or shunt for refractory cases

SBP (see table 5)
- Secondary prophylaxis
- Bactrim DS 1 tab daily
- Alternates: Ciprofloxacin 500mg daily

Hepatorenal Syndrome (see table 6)
- Treatment per specialty clinic

Hepatic Encephalopathy (see table 7)
- Identify and treat precipitating factors
- First line: lactulose
- Second line: lactulose plus neomycin
- Third line: lactulose plus rifaximin

Hepatic Carcinoma
- Ultrasound Q 6 months
- Referral per specialty clinic for surgical resection, TACE, chemotherapy, symptomatic treatment

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 7/2013.
Box A. Initial Management

Baseline Evaluation
- Complete H&P
- Vitals including weight
- Labs: CBC with diff and plts, PT/INR, CMP, alphafetoprotein, A1c if diabetic
- Screening: HIV, anti-HBsAb, anti-HBc, HBsAg, anti-HAV
- Calculate MELD Score (CMC homepage - Tools - Calculators)

Preventive Health Measures
- Vaccinations: HBV, HAV, pneumococcal, annual influenza
- Patient education on disease state, avoidance of hepatotoxic and nephrotoxic medications, treatment, and compliance

Box B. Referral Criteria for UTMB ESLD Telehealth

Routine
- New cirrhosis diagnosis without complications
- History of variceal bleed
- Difficult to control ascites
- Resistant encephalopathy
- Diuretic resistance or refractory ascites (see table 4) and/or increasing Scr (> 1.3 mg/dL)
- An INR increase of > 0.5 within 1-3 months
- MELD score ≥ 12

Expedited
- MELD score ≥ 20
- Melena
- Urgent 911
- Hematochezia/Hematemesis

TABLE 1: Child-Turcotte-Pugh (CTP) Calculator

<table>
<thead>
<tr>
<th>POINTS*</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encephalopathy</td>
<td>None</td>
<td>Grade 1-2 (or precipitant-induced)</td>
<td>Grade 3-4 (or chronic)</td>
</tr>
<tr>
<td>Ascites</td>
<td>None</td>
<td>Mild - Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>&lt; 2</td>
<td>2 - 3</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>Albumin (g/dL)</td>
<td>&gt; 3.5</td>
<td>2.6 - 3.5</td>
<td>&lt; 2.8</td>
</tr>
<tr>
<td>PT (sec prolonged) or INR</td>
<td>&lt; 4</td>
<td>4 - 6</td>
<td>&gt; 6</td>
</tr>
</tbody>
</table>

*CTP score is obtained by adding the score for each parameter
CTP class: A = 5 - 6 points, B = 7 - 9 points, C = 10 - 15 points

TABLE 2: West Haven Criteria for Semi-quantitative Grading of Mental Status (Hepatic Encephalopathy [HE])

Grade 0
- No detectable symptoms

Minimal (or covert) Encephalopathy (MHE)
- Mildest form of the HE continuum. Suble neurocognitive abnormalities primarily affect attention, vigilance, response inhibition, and executive function which are not recognizable on standard neurological or mental status examination, but are evident on psychometric testing. MHE may predict the development of overt HE and is associated with poor survival.

Grade 1
- Focal lack of awareness
- Euphoria or anxiety
- Shortened attention span
- Impaired performance of addition

Grade 2
- Lethargy or apathy
- Impaired performance of time or place
- Subtle personality change
- Inappropriate behavior
- Impaired performance of subtraction

Grade 3
- Somnolence to semi-stupor, but responsive to verbal stimuli
- Confusion
- Gross disorientation

Grade 4
- Coma (unresponsive to verbal or noxious stimuli)

* Not an official stage on the West Haven Scale.
Nonselective beta-blockers (propranolol) are the preferred pharmacologic agent for prevention of bleeding and should be continued indefinitely.
  - Initial Dose: propranolol 200mg po twice daily
  - Titrate to a maximally tolerated dosage (heart rate 55-60 beats/minute and systolic BP not below 90 mmHg).

Primary Prophylaxis
  - Small varice - propranolol
  - Medium/large varices - propranolol. Endoscopic variceal ligation (EVL) may be preferred in patients at high risk of hemorrhage or those who have contraindications or intolerance to beta-blockers. (Decision to perform EVL would be made by ESLD specialty clinic).

Secondary Prophylaxis
  - Combination of EVL and propranolol
  - TIPS may be considered in certain patients with recurrent hemorrhage despite EVL plus maximal doses of propranolol. (Decision to perform EVL or TIPS would be made by ESLD specialty clinic.)
  - Role of proton pump inhibitors (PPI): PPIs are not used to treat varices, but may be considered if acid reflux symptoms are present.
  - Varices bleed by rupturing from within the vessel through thinning of the wall rather than from erosion from acid in the lumen.

TIPS may be considered in certain patients with recurrent hemorrhage despite EVL plus maximal doses of propranolol. (Decision to perform EVL or TIPS would be made by ESLD specialty clinic.)

ROLE

Swelling starts first in the feet/ankles then progresses to the thighs, scrotum, and even penis. In some patients, edema presents with abdominal swelling, after swelling is present to the knees. Edema above the rib cage is not due to cirrhosis.

Consider paracentesis for new onset ascites with fluid analysis (cell count and differential, albumin, total protein concentration, and culture if infection is suspected). A Serum to Ascites Albumin Gradient (SAAG) of > 1.1 gm/L indicates portal hypertension with 97% accuracy.

- Paracentesis may be performed at Estelle-EZ, Young-GC, Hospital Galveston-HG, and Monford-HF. For patients requiring frequent or routine paracentesis, consider requesting a housing change to an appropriate TDU facility.

Salt restriction (< 2 gm/day) should not be used.

- For moderate edema or greater:
  - Furosemide 40mg daily or
  - Spironolactone 100mg daily. Daily doses less that 50mg are insufficient for controlling edema and should not be used.

- For moderate edema or greater:
  - Furosemide 40mg with Spironolactone 100mg. Also useful in patients who do not respond to or have hyperkalemia with spironolactone monotherapy.
  - Furosemide therapy every 5-7 days. This 40:100 ratio of furosemide:spironolactone can be increased to 80mg furosemide plus 100mg spironolactone, and further increased to 80mg BID furosemide plus 100mg BID spironolactone.

- Amiloride 10-40mg daily may be substituted for spironolactone if tender gynecomastia is present, but may be less effective. Nonformulary approval is required.

- If the above program does not work, metolazone 5 mg may be added once per week, increasing to 5mg M-F, then 5mg M-F, and 5mg daily. Renal function and electrolytes must be monitored closely when using > 2 diuretics. Consider BMP every 1-2 weeks until stable, then monthly.

- Monitor for diuretic complications (BMP every 1-2 weeks during titration) which include uncontrolled or recurrent encephalopathy, serum sodium < 120 mmol/L despite fluid restriction, Scr > 2.0 mg/dL, K > 6.0.

- TED hose (knee-high) may be considered for lower leg edema. Patients with thigh swelling or who demonstrate pitting over the thighs need thigh-high TED hose. If the hose will not stay up or if there is abdominal wall swelling, consider referral to Brace & Limb for fitted compression garments (hose up to the waist). Compression hose and garments may help prevent hospitalization for chronic edema and cellulitis.

Tense ascites (massive and/or painful) - consider large volume paracentesis (LVP) followed by sodium restriction and diuretic therapy. Caution as LVP and aggressive diuresis can precipitate HRS.

Continued on page 4
**TABLE 4: ASCITES / EDEMA CONTINUED**

**EVALUATION**
- Refractory Edema or Ascites
  - Fluid overload unresponsive to sodium restriction and high-dose diuretics or recurs rapidly after therapeutic paracentesis.
  - Often due to inadequately titrated diuretics or diuretic complications.
  - Refer to ESLD clinic and consider serial paracentesis. TIPS or peritoneovenous shunt may be necessary.

**MONITORING**
- Weight and 
  CMP every 90 days or sooner during diuretic titration or with paracentesis.

**TABLE 5: SPONTANEOUS BACTERIAL PERITONITIS (SBP)**

**EVALUATION & TREATMENT**
- May be asymptomatic; however, most common symptoms include fever, abdominal pain, abdominal tenderness and altered mental status. Laboratory abnormalities suggestive of infection include worsening Sco, elevated WBC, and acidosis.
- Diagnosis is confirmed by paracentesis with < 250 PMNs/mm³ and/or positive ascitic bacterial culture.
- Acute treatment requires hospitalization and IV antibiotic (ceftriaxone or cefoxitin).
- Outpatient prophylaxis of SBP: All patients with a history of prior SBP should receive indefinite prophylaxis with one of the following:
  - First line - sulfamethoxazole/trimethoprim DS one tab daily
  - Second line - ciprofloxacin 500 mg po once daily. (Reserved for sulfa allergy or renal insufficiency.)

**MONITORING**
- Signs/symptoms and vitals (temperature) at each encounter.
- CMP and CBC every 90 days or more frequently if clinically indicated.

**TABLE 6: HEPATIC ENCEPHALOPATHY (HE)**

**MONITORING**
- Mental status screening at each encounter.
- Signs/symptoms and vitals (temperature) at each encounter.
- CMP and CBC every 90 days or more frequently if clinically indicated.

**TABLE 7: HEPATORENAL SYNDROME (HRS)**

**TREATMENT**
- HRS should be considered in patients with cirrhosis and ascites with a creatinine level above 1.5 mg/dL or GFR = 40 mL/min. It is a diagnosis of exclusion. The following should be ruled out and treated:
  - Sepsis
  - Volume depletion
  - Vasodilators
  - Organic renal failure
- There are two types of HRS:
  - HRS-1: rapidly progressive acute renal failure usually occurring in hospitalized patients. Typically characterized by onset < 2 weeks, two fold increase in creatinine, and clearance < 20 mL/min. Poor prognosis (median survival 2 weeks).
  - HRS-2: slower onset typically seen in outpatients with refractory ascites. Often precipitated by over-diuresis, GI bleed, or infection. Median survival 6 months.
- Hospitalization and specialty care required. Precipitating factors should be treated. Diuretics should be discontinued and intravascular volume expanded with albumin. The only definitive therapy for HRS is transplant.

**MONITORING**
- CMP every 90 days or more frequently if clinically indicated.
### Table 8. Common Medications used in ESLD

<table>
<thead>
<tr>
<th>Medication</th>
<th>Formulary Status</th>
<th>Indication</th>
<th>Dosing</th>
<th>Side Effects / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiloride 5mg tab</td>
<td>NF</td>
<td>Edema / ascites</td>
<td>5mg to 10mg once daily</td>
<td>Hyperkalemia, hyponatremia, acidosis, GI upset</td>
</tr>
<tr>
<td>Ciprofloxacin 500mg tab</td>
<td>NF</td>
<td>SBP prophylaxis</td>
<td>500mg once daily</td>
<td>Nausea, vomiting, diarrhea</td>
</tr>
<tr>
<td>Furosemide 20mg, 40mg tab</td>
<td>F</td>
<td>Edema / ascites</td>
<td>40mg to 160mg daily</td>
<td>Electrolyte disturbances including hyperkalemia and hyponatremia, increased serum creatinine, photosensitivity, rash, dizziness, hypotension, hyperuricemia</td>
</tr>
<tr>
<td>Lactulose 10gm/15ml syr</td>
<td>F</td>
<td>Hepatic encephalopathy</td>
<td>Start at 30 mL BID - TID</td>
<td>Can cause electrolyte imbalance, abdominal discomfort, cramping, nausea, flatulence.</td>
</tr>
<tr>
<td>Metolazone 5mg tab</td>
<td>F</td>
<td>Edema / ascites</td>
<td>Titrate slowly up to 5mg daily</td>
<td>Electrolyte disturbances including hyperkalemia and hyponatremia, increased serum creatinine, photosensitivity, rash, dizziness, hypotension, hyperuricemia</td>
</tr>
<tr>
<td>Neomycin 500mg tab</td>
<td>NF</td>
<td>Hepatic encephalopathy</td>
<td>500mg to 1000mg BID</td>
<td>Nausea, nephrotoxicity, ototoxicity. Avoid in AKI or CKD.</td>
</tr>
<tr>
<td>Propranolol 10mg, 20mg, 40mg tab</td>
<td>F</td>
<td>Esophageal varices</td>
<td>Initial dose 20mg BID</td>
<td>Hypotension, bradycardia, fatigue. Caution in decompensated CHF, sinus bradycardia, heart block, severe asthma or COPD.</td>
</tr>
<tr>
<td>Spironolactone 25mg tab</td>
<td>F</td>
<td>Edema / ascites</td>
<td>100mg to 400mg daily</td>
<td>Gynecomastia, hyperkalemia, rash, renal dysfunction</td>
</tr>
<tr>
<td>Sulfamethoxazole / trimethoprim 800mg/160mg tab</td>
<td>F</td>
<td>SBP prophylaxis</td>
<td>1 double strength tablet once daily</td>
<td>Or oral, rash, urticaria, blood dyscrasia, hyperkalemia, crystalluria</td>
</tr>
</tbody>
</table>

### Table 9. Medications which should be used with caution or contraindicated in ESLD

<table>
<thead>
<tr>
<th>Medication</th>
<th>Formulary Status</th>
<th>Dosing / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>F</td>
<td>May be used up to a maximum daily dose of 2,600mg.</td>
</tr>
<tr>
<td>Acetaminophen / codeine</td>
<td>F*</td>
<td>Up to 2,600mg acetaminophen / codeine. Impaired hepatic conversion of codeine (prodrug) to its active form may result in decreased analgesic effect.</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>F*</td>
<td>Initiate at low doses and titrate slowly. Morphine is extensively metabolized by the liver and accumulation occurs in cirrhosis. Renal insufficiency may result in accumulation of toxic metabolites.</td>
</tr>
<tr>
<td>NSAIDS</td>
<td>F</td>
<td>NSAIDS should generally be avoided in patients with cirrhosis due to increased risk of variceal hemorrhage, impaired renal function, risk of hepato-renal syndrome, and serotonin resistance. Low to moderate doses may be used cautiously, but must be administered with a proton pump inhibitor (omeprazole 20-40mg daily) and monitored closely for adverse effects.</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>F*</td>
<td>Should generally be avoided in cirrhosis as benzodiazepines may trigger or aggravate hepatic encephalopathy.</td>
</tr>
<tr>
<td>Anticonvulsants / Divalproex / Phenytoin / Primidone</td>
<td>F</td>
<td>Phenytoin, carbamazepine, and divalproex are all extensively metabolized by the liver, highly protein bound, and potentially hepatotoxic. They should generally be avoided in cirrhosis due to increased risk of toxicities, including thrombocytopenia. Divalproex is contraindicated with severe hepatic impairment. Primidone is also heavily metabolized by the liver and can accumulate in cirrhosis precipitating hepatic encephalopathy. If anticonvulsant therapy is indicated, levetiracetam may be considered. Levetiracetam requires dose adjustment in renal impairment.</td>
</tr>
</tbody>
</table>

*Formulary restrictions apply
Information for the Provider

I. Screening for Cirrhosis

A. Key History Questions
1. Have you ever been diagnosed with HCV, HAV, HCV, or other liver disorder?
2. Have you ever been jaundiced?
3. Have you used drugs intravenously?
4. Have you shared instruments for body piercing or tattooing?
5. Have you ever had a blood transfusion? If so what year? How many bags?
6. Any liver disease in your family?
7. Before TDCJ, how much alcohol did you drink?
8. Do you bleed excessively or bruise easily?
9. Have you ever had an imaging study (ultrasound, MRI or CT) of the liver? Why?
10. Have you had a liver biopsy, EGD, or colonoscopy? When? Where? Why?
11. Have you ever had your legs or stomach swell with fluid? When?
12. Have you ever had anemia, bloody stools, or black tarry stools? When?
13. Have you ever had periods of confusion or fuzzy thinking? When?

B. Key Physical Findings
1. Always list age, height, weight, and BMI at each visit. Check last visit and note change.
2. Skin/Hands/Nails: jaundice, thin skin, bruises, petechiae, palmar and peri-nail bed erythema, curved nails, Dupuytren's contractures, spider angomas, varicose pattern over abdomen (caput medusa), especially upper abdomen. Varicose veins may account for edema. Acanthosis nigricans in collar area, axilla, groin, under breasts, or belt area is a sign of insulin resistance, pre-diabetes (consider non-alcoholic fatty liver disease, NAFLD).
3. Check for neck vein distention and hepato-jugular reflux. Liver edge and tenderness.
4. Loss of shoulder and pelvic muscle strength.
5. Gynecomastia: off or on spironolactone.
6. Liver enlargement by percussion: 2 cm or less below the xiphoid, 7-11 cm in a line. 2-10 cm to the right of the xiphoid. May be below the ribcage if patient has a low diaphragm due to pulmonary disease.
7. Peripheral edema: pitting over the tibia from ankle to knee. May have enlargement by history of upper leg or pitting. May have penile or scrotal edema. May have pitting over abdomen.
8. Acanthosis: best test is shifting dullness.

C. Key Laboratory Findings
1. CBC with differential: WBC and Platelets decline as the spleen enlarges from congestion in portal hypertension. Anemia may be present due to bleeding.
2. PT/INR elevation.
3. Metabolic panel for low albumin, elevated BUN and serum creatinine, electrolyte imbalance.
4. Liver panels so that you can see if bilirubin is elevated in unconjugated, conjugated, or protein bound (delta) fractions. Elevation in AST, ALT, and/or alkaline phosphatase.
5. HAV antibody, HBV surface antigen and antibody, HBV core antibody, HCV antibody.
6. Order a panel to look for congenital liver disease or other causes of liver disease: ceruloplasmin, iron, iron binding capacity, ferritin, alpha-1 antitrypsin, ANA, SMA, AMA.
7. MELD score
# Gastrointestinal Pathways

The protocol does not replace sound clinical judgment nor is it intended to strictly apply to all patients.

<table>
<thead>
<tr>
<th>Present?</th>
<th>Symptom / Disease</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Acute GI Bleed</td>
<td>Refer to Acute GI Bleed algorithm</td>
</tr>
<tr>
<td>Yes</td>
<td>Heartburn</td>
<td>Refer to Dyspepsia algorithm</td>
</tr>
<tr>
<td>Yes</td>
<td>Reflux</td>
<td>Refer to GERD algorithm</td>
</tr>
<tr>
<td>Yes</td>
<td>H. Pylori Positive</td>
<td>Refer to H. Pylori algorithm</td>
</tr>
<tr>
<td>Yes</td>
<td>Ulcer</td>
<td>Refer to Peptic Ulcer Disease algorithm</td>
</tr>
</tbody>
</table>

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Obtain patient history
- Medical history – prior GI bleed, hepatic disease, peptic ulcer disease, malignancy, comorbidities (esp. heart, respiratory, or renal disease)?
- Medication history – NSAID, steroid, ASA, anticoagulant or antiplatelet agents?
- Associated symptoms – dizziness, confusion, angina, palpitations, cold/clammy extremities, weakness, epigastric pain, dysphagia, GERD, anorexia, abdominal pain, bleeding?

Complete physical exam
- Signs of hypovolemia – resting tachycardia (HR > 100 bpm), tachypnea (RR > 20/min), orthostatic hypotension (SBP decrease > 20 mmHg, DBP decrease > 10 mmHg, or HR increase > 20 bpm), supine hypotension (SBP < 80 mmHg), cold extremities, poor mentation.
  (Note: hematocrit is a poor early indicator of blood loss)
- Perform rectal exam
- Assess for physical signs of liver disease
- Assess for active bleeding – hematemesis, hematochezia, melena

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, 
Approved May 2012; Reviewed 11/2015.
Dyspepsia symptoms defined as chronic or recurrent pain or discomfort centered in the upper abdomen. Discomfort is defined as a subjective negative feeling that is non-painful, and can include early satiety or upper abdominal fullness.

Heartburn and/or regurgitation as presenting complaint, predominant or frequent (more than once a week)?

Yes

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients

No

Manage as GERD

NSAID/Cox-2 inhibitor use?

Yes

Discontinue NSAID if possible. If not, consider lower dose and/or change to PRN.

No

Age > 55 or alarm features present?

Yes

Consider specialty referral

No

See H. Pylori Algorithm

Continued on Page 2

Dyspeptic symptoms defined as chronic or recurrent pain or discomfort centered in the upper abdomen. Discomfort is defined as a subjective negative feeling that is non-painful, and can include early satiety or upper abdominal fullness.

Progressive dysphagia

Odynophagia

Persistent vomitting

Family history of gastrointestinal cancer

Previous esophagogastric malignancy

Previous documented peptic ulcer

Lymphadenopathy

Abdominal mass

Unexplained weight loss (> 10% body weight)

Early satiety

Bleeding

Anemia

See H. Pylori Algorithm

Continued on Page 2

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.

11. H. Pylori Treated?

12. Yes

13. No

14. Symptom resolution

15. Discontinue therapy x 4 weeks and then consider discontinuation of therapy and follow PRN.

16. Symptoms resolved?

17. Yes

18. No


20. Ranitidine 150mg BID

21. No

22. Yes

23. Continued from box 9, page 1.

H. Pylori Treated?

24. No

25. Discontinue therapy.

26. Follow PRN.

27. No


29. If symptoms recur, repeat course.

30. If patient relapses again after medication discontinuation, consider specialty referral.

31. Yes

32. Begin PPI therapy.

33. Omeprazole 20mg QD x 60 days.

34. Consider compliance assessment prior to proceeding.

35. Symptom resolved?

36. Yes

37. Discontinue therapy.

38. Follow PRN.

39. No

40. Discontinue therapy.

41. If symptoms recur, repeat course.

42. If patient relapses again after medication discontinuation, consider specialty referral.

43. Yes

44. Increase PPI therapy to Omeprazole 40mg QD x 60 days.

45. Consider compliance assessment prior to proceeding.

46. Symptom resolved?

47. Yes

48. Discontinue therapy.

49. Follow PRN.

50. No

51. Discontinue therapy.

52. If symptoms recur, repeat course.

53. If patient relapses again after medication discontinuation, consider specialty referral.

54. Yes

55. Reason for diagnosis.

56. Consider specialty referral.

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.
GASTROESOPHAGEAL REFLUX DISEASE

1. Alarm symptoms present (i.e., dysphagia, odynophagia, bleeding, unexplained weight loss, or anemia)?
   - Yes
     - Consider specialty referral.
   - No

2. The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.

IMPLEMENT LIFESTYLE MODIFICATIONS AND ELIMINATE MODIFIABLE RISK FACTORS WHEN POSSIBLE

1. Weight loss.
2. No eating prior to bed.
3. No reclining after eating.
4. Avoid known irritants.
5. Rule out drug induced problems, such as agents that reduce LES tone (e.g., theophylline, estrogens, opiates, calcium channel antagonists).
6. Discontinue NSAID usage when possible. If not, consider lower dose and/or change to PPI.
7. Smaller meal size especially the last meal of the day.

OTHER FACTORS NOT APPLICABLE OR FEASIBLE AT TDCJ

1. Avoid alcohol.
2. Smoking cessation.
3. Elevation of the head of the bed (do not approve extra mattress).
4. Small frequent meals (do not approve AM & HS snacks).
5. Avoid late meals.

3. Symptoms resolved with lifestyle modifications?
   - Yes
     - Go to Box #7, Page 2
   - No

Prepared By: The Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved: August 1995; Revised: 8/98, 6/99, 11/01, 4/03, 9/06, 9/10; Reviewed: 3/12, 11/2015.
Ranitidine 300 mg BID X 60 days. Consider compliance assessment prior to proceeding.

Symptoms resolved?
Yes
No

Discontinue ranitidine and start omeprazole 20mg QD x 30 days. Most patients on QD dosing should take PPI before breakfast but nighttime acid may be better controlled if taken with evening meal. Consider compliance assessment prior to proceeding.

Symptoms resolved?
Yes
No

Continue with lowest effective dose of H2 antagonist that controls symptoms.

Metoclopramide

• Cautions/contraindications: Patients with increased risk for extrapyramidal symptoms, GI obstruction, perforation or hemorrhage, pheochromocytoma, depression or epilepsy.
• Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. The elderly, especially elderly women, are most likely to develop this condition.

Consider specialty referral.
H. Pylori Treatment

Consider Helicobacter pylori infection treatment with combination therapy for 15 days:

**First Choice:**
A. Minocycline 100mg BID  
B. Amoxicillin 1000mg BID  
C. Omeprazole 20mg BID  
D. Bismuth Subsalicylate 2 tabs BID

**Alternative in penicillin allergic patients only:**
A. Minocycline 100mg BID  
B. Metronidazole 1000mg BID  
C. Omeprazole 20mg BID  
D. Bismuth Subsalicylate 2 tabs BID

**Second Alternative Choice:**
A. Amoxicillin 1500mg BID  
B. Rifabutin 150mg QD  
C. Omeprazole 40mg BID

**Third Alternative Choice:**
A. Tetracycline 500mg QID  
B. Metronidazole 500mg QID  
C. Omeprazole 20mg BID  
D. Bismuth Subsalicylate 2 tabs QID

Consider a GI consult or Pharmacotherapy consult for other alternative suggestions.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee,  
Approved September 2010; Revised 3/12, 3/14; Reviewed 11/2015.
Peptic Ulcer Disease (PUD)
1
Known or suspected PUD,
Begin PPI therapy with
Omeprazole 20 mg QD.

2
Age > 55 or alarm features present?
(bleeding, anemia, early satiety, unexplained
weight loss [> 10 % body weight], progressive
dysphagia, odynophagia, persistent vomiting,
a family history of gastrointestinal cancer,
previous esophagogastric malignancy,
previous documented peptic ulcer,
lymphadenopathy,or an abdominal mass)
4
Discontinue NSAID if possible.
If not, consider lower dose
and/or change to PRN.

3

Yes

No
NSAID use?
No

6

5

8
Resolution?
9

7

Yes

Previous H.pylori
treatment?

No
Go to box #8

Yes

No

Yes
See H.Pylori Algorithm

No further treatment
Yes
11

Yes
End therapy. Consider maintenance
therapy with omeprazole 20 mg QD
particularly for patients that remain
on chronic NSAIDs. Reevaluate
periodically for continued need.

10
Resolution?

12

No
Increase PPI therapy to
Omeprazole 40mg QD
x 60 days.

The pathways do
not replace sound
clinical judgement
nor are they
intended to strictly
apply to all patients

14
13
No

Resolution?

Consider specialty
referral.

Yes

15

End therapy. Consider maintenance
therapy with omeprazole 20 mg QD
particularly for patients that remain
on chronic NSAIDs. Reevaluate
periodically for continued need.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee,
Approved August 1995; Revised 8/98, 6/99, 4/03, 3/07, 7/08, 9/10; Reviewed 1/06, 3/12, 11/2015.

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Gender Dysphoria Hormone Monitoring Guideline

The guidelines do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Initial Assessment:
1. Observe Past Medical History: prior history of GD treatment or work-up and assess for possible contraindications to therapy (refer to page 5, section IV.B)
2. Prior GD medical and mental health records from the free world providers who diagnosed and/or treated the offender should be requested
3. Complete physical exam
4. Obtain Baseline Labs: CBC, lipid profile, CMP, prolactin, testosterone, estradiol, A1C, LHV, FSH
5. Documentation of offender education and written consent only if continuing hormone at intake
6. The patient should be continued on the same documented hormone regimen, if any, upon arrival into the TDCJ, unless medically contraindicated. Inform patient that evaluation is required by GDC prior to starting treatment in patients not currently receiving GD treatment or to continue hormone treatment (refer to page 4, section II.A)

Was a GD diagnosis confirmed by GDC?

Medical Treatment Plan:
Evaluate the patient at least every 3 months in the first year and then 1-2 times per year to monitor for development of adverse reactions, corrected thyroid states, drug drug interactions, and risks associated with hormone therapy.
Refer to Table 1 & 2 for evaluation of labs and management of laboratory abnormalities
Refer to Table 3 for risks associated with hormone therapy

Terms:
GD: Gender Dysphoria
GDC: Gender Dysphoria Clinic

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved November 2016.

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Table 1: Laboratory Monitoring Frequencies for Hormonal Therapy in Patients with Gender Dysphoria

<table>
<thead>
<tr>
<th>Vitals</th>
<th>Baseline</th>
<th>Every 3 Months for First Year of Treatment</th>
<th>Every 6-12 months after First Year of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMP*</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>BG/A1c</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Liver functions</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Estradiol</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Testosterone</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Vitals and electrolytes should be monitored at baseline to determine the need for thiazide diuretics and spironolactone. Baseline electrolytes are repeated 1 week after initiation of spironolactone, then every 3 months for the first year of therapy, and then every 3 months thereafter for the first year of treatment. Baseline and follow-up electrolytes are repeated at least monthly for the first 3 months of treatment. Levels should be obtained at baseline and then again as recommended in the UTMB CMC Diabetes DMG if the patient is diabetic.

Liver function tests should also be obtained at baseline.

Prolactin levels should be obtained at baseline and annually. Levels are also warranted when patients exhibit signs or symptoms of a prolactinoma (see Table 2).

Table 2: Monitoring of Hormonal Therapy in Patients with Gender Dysphoria

<table>
<thead>
<tr>
<th>Action</th>
<th>CR</th>
<th>K+</th>
<th>Hematocrit</th>
<th>Lipid panel</th>
<th>ALT, AST</th>
<th>BG</th>
<th>A1c</th>
<th>Prolactin</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCr</td>
<td>If there is a change in SCr by 30% from baseline or if GFR is &lt; 15, stop spironolactone pending reassessment at next scheduled GDC.</td>
<td>Stop spironolactone if K+ rises above 5.5 mmol/L pending reassessment at next scheduled GDC.</td>
<td>Stop testosterone therapy if Hct reaches ≥ 55% pending reassessment at next scheduled GDC.</td>
<td>Stop spironolactone if K+ rises above 5.5 mmol/L pending reassessment at next scheduled GDC.</td>
<td>If LFTs are 3x the upper limit of normal stop hormone therapy pending reassessment at next scheduled GDC.</td>
<td>For elevated fasting or random BG, refer to Diabetes DMG for management of patients with a diagnosis of diabetes.</td>
<td>For elevated A1c, refer to Diabetes DMG for management of patients with a diagnosis of diabetes.</td>
<td>Prolactin levels greater than 100 ng/mL may be suggestive of prolactinoma. Stop hormone therapy and expedite referral to endocrinology.</td>
</tr>
</tbody>
</table>

*For critical levels or symptomatic patients, treat as clinically indicated. If lab abnormalities persist, consider other causes. Monitor for labs to return to baseline.
<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Feminizing hormones</th>
<th>Masculinizing hormones</th>
</tr>
</thead>
<tbody>
<tr>
<td>Likely increased risk</td>
<td>Venous thromboembolic disease</td>
<td>Polycythemia</td>
</tr>
<tr>
<td></td>
<td>Gallstones</td>
<td>Weight gain</td>
</tr>
<tr>
<td></td>
<td>Elevated liver enzymes</td>
<td>Acne</td>
</tr>
<tr>
<td></td>
<td>Weight gain</td>
<td>Androgenic alopecia</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
<td>Sleep apnea</td>
</tr>
<tr>
<td>Likely increased risk with increased age</td>
<td>Cardiovascular disease</td>
<td></td>
</tr>
<tr>
<td>Possible increased risk</td>
<td>Hypertension</td>
<td>Elevated liver enzymes</td>
</tr>
<tr>
<td></td>
<td>Hyperprolactinemia or prolactinoma</td>
<td>Hyperlipidemia</td>
</tr>
<tr>
<td></td>
<td>Emotional instability and depression</td>
<td></td>
</tr>
<tr>
<td>Possible increased risk with increased age</td>
<td>Type 2 diabetes</td>
<td>Hyperprolactinemia or prolactinoma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Emotional instability and depression</td>
</tr>
<tr>
<td>Possible increased risk with increased age</td>
<td>Destabilization of certain psychiatric disorders*</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td></td>
<td>Type 2 diabetes</td>
<td>Hypertension</td>
</tr>
<tr>
<td>No increased risk or inconclusive</td>
<td>Breast cancer</td>
<td>Loss of bone density</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Breast cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cervical cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ovarian cancer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uterine cancer</td>
</tr>
</tbody>
</table>

*Includes bipolar, schizoaffective, and other disorders that may include manic or psychotic symptoms. This adverse event appears to be associated with higher doses or supraphysiologic blood levels of testosterone.

Table adapted from Coleman et al. (2012). Copyright 2012, The World Professional Association for Transgender Health.
I. Terms
A. Gender Dysphoria (GD) – is defined as the clinically significant distress or impairment that is associated with the marked incongruence between one’s experienced or expressed gender and one’s assigned gender for a specific time (e.g., of at least 6 months duration). The diagnosis can be made with a concurrent disorder of sex development.
B. Intersex – a person whose sexual or reproductive anatomy or chromosomal pattern does not seem to fit typical definitions of male or female. Intersex medical conditions are sometimes referred to as sex development disorders.
C. Transgender – a person whose gender identity (i.e., internal sense of feeling male or female) is different from the person’s assigned sex at birth.
D. Male-to-female (MtF) – transgender person who is born as a male (male sex by birth) but whose gender identity is a woman (or in-between man and woman). Also known as transgender woman or trans woman.
E. Female-to-male (FtM) – transgender person who is born as a female (female sex by birth) but whose gender identity is a man (or in-between woman and man). Also known as transgender man or trans man.

II. Initial Assessment
A. Screening
1. At intake, a patient with a reported history of GD prior to incarceration will receive thorough medical and mental health evaluations.
2. The patient will be continued on the same documented hormone regimen, if any, upon arrival into the TDCJ, unless medically contraindicated. Hormone therapy will be requested with indefinite refills through the non-formulary process to ensure that continuity of care is maintained during the initial evaluation process.
3. If continuing hormones at intake, obtain documentation of patient education and written consent which are required prior to submission of the non-formulary request. For this documentation, refer to the Treatment of Offenders with Intersex Conditions, or Gender Dysphoria, Formerly Known as Gender Identity Disorder Policy (Number: G-51.11) located in the Correctional Managed Health Care Policy Manual.
B. Past Medical History
1. Prior history of GD treatment or work-up
2. Assess for possible contraindications to therapy
3. Prior medical and mental health records from the free world providers who diagnosed and/or treated the offender should be requested.
C. Physical Exam
1. Perform complete physical exam
D. Baseline Labs
1. CBC
2. Lipid profile
3. CMP
4. Procalcitonin
5. Testosterone
6. Estradiol
7. A1c
8. LH
9. FSH
E. Complete referral to GDC for GD evaluation and documentation of offender education and written consent.

III. Treatment Options
A. Pharmacologic therapy
1. A treatment plan MtF or FtM will be selected and managed by GDC. Unit providers should not initiate hormone treatment regimens, except for continuation at intake (pending GDC evaluation). Refer to Table 4 for hormone treatment options.
B. Physical changes anticipated during treatment
1. FtM: Refer to table 5 for masculinizing effects in FtM transgender persons.
   a. Potentially irreversible changes include, but are not limited to: deepening of voice, development of
      facial and body hair, fat redistribution, genital changes, infertility, male pattern baldness.
2. MtF: Refer to table 6 for feminizing effects in MtF transgender persons.
   a. Potentially irreversible changes include, but are not limited to: breast growth, fat redistribution,
      genital changes, infertility.

IV. Monitoring of treatment regimens
A. Control of comorbid disease states
1. History of or active venous thromboembolism: stop estrogen hormone therapy pending reassessment
   during next GDC.
2. Cardiovascular disease (CVD) risk is increased in MtF due to higher rates of tobacco use, obesity,
   diabetes, lipid disorders and reduced physical activity. Cardiovascular disease risk is unclear in FtM.
   a. Refer to the Hyperlipidemia Disease Management Guideline (DMG) for management of
      hyperlipidemia.
   b. Currently there is no guidance on whether to use risk calculators based on natal sex or
      affirmed gender. It may be reasonable to use natal sex-based calculators in transgender
      people who have transitioned later in life.
3. Diabetes: The effect of gender-affirming hormone therapy on diabetes risk or disease course is unclear.
   Management of diabetes in transgender patients has not been specifically studied.
   a. Refer to the Diabetes DMG for management.
   b. Generally, diabetes should be reasonably well controlled prior to initiating hormone therapy;
      however, no absolute criteria on hormone initiation is recommended.
4. Bone health and osteoporosis: MtF and FtM patients receiving hormone therapy may be at an increased
   risk of osteoporosis. Osteoporosis should be considered in acute bone fractures.
5. General approach to cancer screening in transgender people: Follow current policy regarding routine
   cancer screening with the addition of an annual mammogram screening for patients >40 years of age on
   estrogen therapy.

B. Assess for contraindications: hormonal therapy, antiandrogen, or medroxyprogesterone therapy should not be
   initiated or continued in the presence of absolute contraindications
1. Absolute contraindications to estrogen therapy include:
   a. Active or history of breast or estrogen-sensitive cancer
   b. End-stage chronic liver disease (refer to CMC Disease Management Guideline)
   c. Current or history of venous thrombotic event
   d. Protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders
   e. Cerebrovascular disease
   f. Active psychosis, suicidality, homicidality
   g. Ischemic cardiovascular disease
   h. Hyperprolactinemia (prolactin level >100 ng/mL)
   i. Inability to provide informed consent
2. Absolute contraindications to testosterone therapy include:
   a. Active or history of breast, prostate, or sex-hormone sensitive cancer
   b. End-stage chronic liver disease (refer to CMC Disease Management Guideline)
   c. Pregnancy
   d. Unstable coronary artery disease
   e. Unreiated polycythemia (hematocrit ≥ 55%)
   f. Active psychosis, suicidality, homicidality
   g. Inability to provide informed consent
3. Absolute contraindications to spironolactone therapy
   a. Renal insufficiency (refer to Table 2)
   b. Hyperkalemia (refer to Table 2)
4. Absolute contraindications to finasteride therapy
   a. Pregnancy, known or suspected
5. Absolute contraindications to medroxyprogesterone therapy
   a. Current or history of venous thrombotic event
   b. Current or history of arterial thromboembolic disease
   c. End-stage chronic liver disease (refer to CMC Disease Management Guideline)
   d. Active estrogen or progesterone dependent tumor
   e. Known, suspected, or history of breast malignancy
   f. Pregnancy

C. Monitoring
1. Evaluate the patient every 3 months in the first year and then 1-2 times per year to monitor for development of adverse reactions, comorbid disease states, drug-drug interactions, and risks associated with hormone therapy. Also obtain potassium level at 1 week after initiation of spironolactone, at least monthly for the first 3 months of therapy and every 3 months thereafter for the first year of treatment.
2. Monitoring for specific drug treatment regimens:
   a. Estrogen
      • Monitoring: For injection therapy, when possible, test hormone level midway between injections. GDC to titrate estrogen dose to result in a physiologic range for young healthy females, not to exceed 200 pg/ml. Monitor for signs and symptoms of thrombotic disorders.
      • Adverse effects include, but are not limited to: increased risk of emotional lability/depression, thrombembolic disease, pituitary prolactinoma, hypertension, diabetes mellitus, liver disease, cholelithiasis, breast cancer, and cardiovascular disease
      • Estrogen therapy may exacerbate pre-existing thromboembolic diseases, macroprolactinoma, liver dysfunction, breast cancer, coronary artery disease, cerebrovascular disease, and migraine headaches
      • Drug Interactions include, but are not limited to:
         • Estrogen levels or effects may be increased by: erythromycin, clarithromycin, azole antifungals, vorapam, diltiazem, isoniazid, fluoxetine, paroxetine, sertraline, ibuprofen, nefazodone, citalopram, saquinavir, atazanavir, etravirine
         • Estrogen levels or effects may be decreased by: carbamazepine, omeprazole, phenytoin, rifampin, ranitidine, cimetidine, dexamethasone, levothyroxine
      • Estrogen therapy may reduce levels or effects of: warfarin, fosamprenavir, levothyroxine
   b. Spironolactone
      • Monitoring: Blood pressure, serum electrolytes (potassium, sodium), renal function
      • Adverse effects include, but are not limited to: hyperkalemia, dehydration, hypomagnesemia
      • Drug Interactions include, but are not limited to: use cautiously with digoxin, ACE inhibitors, and potassium-sparing diuretics (avoid combination)
   c. Finasteride
      • Adverse effects include, but are not limited to: orthostatic hypotension, dizziness, decreased libido, impotence, weakness
      • Drug Interactions: There are no known significant interactions
d. Testosterone:
   - Monitoring: For injection therapy, when possible, test hormone level midway between injections. GDC to titrate the testosterone dose to result in a serum testosterone level within normal physiologic range. The upper limit of normal for the normal physiologic range is 1,000 ng/dl.
   - Adverse effects include, but are not limited to: increased risk of cardiovascular or cerebrovascular disease, hypertension, liver disease and increased LFTs, diabetes mellitus, thrombembolic disease, increased aggression or depression, and adverse changes in lipid profile.
   - Testosterone therapy may exacerbate pre-existing breast or uterine cancer, erythrocytosis, and liver dysfunction
   - Drug interactions include, but are not limited to:
     • Testosterone increases levels or effects of warfarin, cyclosporine

e. Medroxyprogesterone:
   - Monitoring: signs and symptoms of thrombotic disorders
   - Adverse effects include, but are not limited to: weight gain, abdominal pain, amenorrhea, deep vein thrombosis
   - Drug interactions include, but are not limited to:
     • Avoid use with griseofulvin
     • Levels increased with use with mifepristone, voriconazole
### Table 4: Hormonal Therapy in Patients with Gender Dysphoria

<table>
<thead>
<tr>
<th></th>
<th>MtF Transgender Persons</th>
<th>Formulary Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estrogen</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Estradiol</td>
<td>2-8 mg PO per day</td>
<td>Non-formulary</td>
<td></td>
</tr>
<tr>
<td>Parenteral Estradiol</td>
<td>5-20 mg BI every 2 weeks</td>
<td>Non-formulary</td>
<td>When possible, test hormone level midway between injections.</td>
</tr>
<tr>
<td>Parenteral Estradiol</td>
<td>2-10 mg BI every week</td>
<td>Non-formulary</td>
<td></td>
</tr>
<tr>
<td><strong>Antiangenons</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spironolactone</td>
<td>50 mg PO BID – 200 mg PO BID</td>
<td>Formulary</td>
<td>Contraindicated to remain on therapy with renal insufficiency and/or potassium &gt; 5.5 mmol/L. Use cautiously in patients who are receiving digoxin, ACE inhibitors and potassium sparing diuretics.</td>
</tr>
<tr>
<td>Finasteride</td>
<td>5 mg PO daily</td>
<td>Non-formulary</td>
<td>May be an option for those unable to tolerate, or with contraindications to the use of spironolactone.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>FfM Transgender Persons</th>
<th>Formulary Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testosterone</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parenteral Testosterone</td>
<td>100-200 mg BI every 2 weeks or 50% weekly</td>
<td>Non-Formulary</td>
<td>When possible, test hormone level midway between injections. Approximately 15% of patients will experience elevations in liver enzymes.</td>
</tr>
<tr>
<td>Progesterone</td>
<td>5-10 mg PO once daily</td>
<td>Formulary; restricted to female patients</td>
<td>Progestosterone considered if menses persist. Weight gain and depression are side effects.</td>
</tr>
<tr>
<td>Medroxyprogesterone</td>
<td>150 mg IM once every 3 months</td>
<td>Formulary; restricted to female patients</td>
<td>Medroxyprogesterone considered if menses persist. Weight gain and depression are side effects.</td>
</tr>
</tbody>
</table>

*Maximum dosing does not mean maximal effect. Furthermore, these dosage ranges do not necessarily represent a target or ideal dose. Dose increases should be based on patient response and/or monitored hormone levels. Some patients may require less than this amount, and some may require more.*
Table 6: Feminizing effects in MtF transgender persons

<table>
<thead>
<tr>
<th>Effect</th>
<th>Onset (months)</th>
<th>Maximum (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redistribution of body fat</td>
<td>3-6 months</td>
<td>2-5 years</td>
</tr>
<tr>
<td>Decrease in muscle mass and strength</td>
<td>3-6 months</td>
<td>1-2 years</td>
</tr>
<tr>
<td>Softening of skin and decreased oiliness</td>
<td>3-6 months</td>
<td>Unknown</td>
</tr>
<tr>
<td>Decreased libido</td>
<td>1-3 months</td>
<td>1-6 months</td>
</tr>
<tr>
<td>Male sexual dysfunction</td>
<td>Variable</td>
<td>Variable</td>
</tr>
<tr>
<td>Breast growth</td>
<td>3-6 months</td>
<td>2-5 years</td>
</tr>
<tr>
<td>Decreased testicular volume</td>
<td>3-6 months</td>
<td>2-5 years</td>
</tr>
<tr>
<td>Decreased sperm production</td>
<td>Unknown</td>
<td>&gt;3 years</td>
</tr>
<tr>
<td>Scale hair</td>
<td>No regrowth</td>
<td></td>
</tr>
<tr>
<td>Voice changes</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Table adapted from Hembree et al. (2009). Copyright 2009, The Endocrine Society.

Table 5: Masculinizing effects in FtM transgender persons

<table>
<thead>
<tr>
<th>Effect</th>
<th>Onset (months)</th>
<th>Maximum (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin oiliness/ acne</td>
<td>1-6</td>
<td>1-2</td>
</tr>
<tr>
<td>Facial/ body hair growth</td>
<td>6-12</td>
<td>4-5</td>
</tr>
<tr>
<td>Scalp hair loss</td>
<td>6-12</td>
<td></td>
</tr>
<tr>
<td>Increased muscle mass/ strength</td>
<td>6-12</td>
<td>2-5</td>
</tr>
<tr>
<td>Fat redistribution</td>
<td>1-6</td>
<td>2-5</td>
</tr>
<tr>
<td>Cessation of menses</td>
<td>2-6</td>
<td></td>
</tr>
<tr>
<td>Clitoral enlargement</td>
<td>3-6</td>
<td>1-2</td>
</tr>
<tr>
<td>Vaginal atrophy</td>
<td>3-6</td>
<td>1-2</td>
</tr>
<tr>
<td>Deepening of voice</td>
<td>6-12</td>
<td>1-2</td>
</tr>
</tbody>
</table>

Table adapted from Hembree et al. (2009). Copyright 2009, The Endocrine Society.
Establish Diagnosis of Gout

Criteria for definitive diagnosis of gout:
Presence of monosodium urate crystals in the synovial fluid (examined using polarized light microscopy)

Criteria for clinical diagnosis of gout:
In the absence of the means to identify urate crystals or in the presence of a negative polarized light microscopy, a provisional diagnosis of gout is made by a combination of clinical and historical criteria. There are no validated clinical diagnostic criteria. Criteria that may be useful include:
1. Serum uric acid level >7.0 mg/dL
2. Maximum inflammation with symptoms of pain, swelling, redness, and warmth within 24 hours
3. History of one or more episodes of monoarticular arthritis followed by periods of completely free symptoms
4. Unilateral first metatarsophalangeal joint attack
5. Presence of a visible or palpable lesion, which by location or appearance is likely to be a tophus
6. Consider risk factors: family history, age, weight, male gender (See Table 1)

Baseline Recommendations
• Patient education, with initiation of diet and lifestyle recommendations. See Section IV
• Consider secondary causes of hyperuricemia ("Co-morbidity checklist"). See Table 1
• Consider elimination of non-essential prescription medications that induce hyperuricemia. See Table 1
• Clinically evaluate gout disease burden (palpable tophi, frequency and severity of acute and chronic symptoms and signs)

Clinical Features

Asymptomatic

Sudden onset of pain
Erythema
Swelling involving joints

Established diagnosis of gouty arthritis and one or more of the following:
• Tophus or tophi by clinical exam or imaging study
• Frequent attacks of acute gouty arthritis (>2 attacks/year)
• CKD Stage 2 (GFR between 60 to 89) or worse (GFR < 60)
• Recurrent urolithiasis

Therapy not warranted in asymptomatic patients

See Acute Gout (Page 2)

Meets indication for Chronic Gout Prophylaxis (Page 3)

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.
To provide optimal care, pharmacologic treatment should be initiated within 24 hours of acute gout attack onset, therefore treatment should preferably be prescribed as needed KOP in case of an acute gout attack.

Ongoing pharmacologic prophylaxis treatment with urate lowering therapy agents (i.e., allopurinol) should not be interrupted during an acute gout attack.

Initiate monotherapy

NSAIDs (First line):
Naproxen 750 mg x 1 day, then reduce to 250 mg Q12H until attack resolved or Ibuprofen 800 mg three to four times daily until symptoms resolve

Avoid NSAIDs in patients with Chronic Kidney Disease (CKD) whenever possible

Systemic Corticosteroids (Second line):
Prednisone 40-60 mg/day x 3 days, then decrease by 10-15 mg/day every 3 days until discontinued

Colchicine (Third line):
For patients who are intolerant or have an absolute contraindication to NSAIDs and systemic corticosteroids. Must have non-formulary approval. See Table 6 for complete dosing.

Monitoring Recommendations: Patients should be assessed for improvement of pain symptoms after 24 hours of treatment with the selected agent. Typically the total duration for treatment of an acute attack is 5-7 days.

Successful outcomes defined as > 50% improvement in pain score at > 24 hours

Patient Education: Including diet and lifestyle changes and prompt self-treatment of subsequent acute gout attacks. Consider indications for chronic therapy. (Box 6)

Severe Pain, particularly for a polynuicular attack or an attack affecting multiple large joints. See Tables 2-4 and Figure 1

Option: Initial combination therapy. Acceptable combination therapy approaches include the initial simultaneous use of full doses (or, where appropriate, prophylaxis doses) of either: (1) Colchicine and Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), (2) Oral Corticosteroids and Colchicine, or (3) Intra-Articular Steroids with any of the above agents. Refer to Box 6

Inadequate response defined as ≤ 50% improvement in pain score at ≤ 24 hours

Switch to alternate monotherapy

Option: Add-on combination therapy in individuals who have failed monotherapy with all options. Refer to Box 6

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.
Initiate urate-lowering therapy (ULT) and acute gout prophylaxis.

1. ULT – Allopurinol.
   • First Line: Allopurinol
     - Initial Dose: 100 mg/day*  
     - Maintenance Dose: Titrate dose upward by 100 mg every 2-5 weeks to appropriate dose in order to treat to chosen serum uric acid target or max tolerated dose; Max dose: 800 mg daily, even with renal impairment. Monitor for drug toxicity (See Table 7).
     - Monitoring:  
       - Monitor serum urate concentration within 2 to 4 weeks of dose adjustments. Confirm serum urate level 3 months later.  
       - Once serum urate target is achieved, monitor levels every 6 months.
     - Alternatives: (See Table 7 for Dosing)
       - Second Line: Febuxostat - Consider in patients who have an a contraindication or intolerant to allopurinol (Non-formulary)
       - Third Line: Probenecid - Consider in patients who have a contraindication or are intolerant to both allopurinol and febuxostat

2. Acute gout prophylaxis
   • Initiate acute prophylaxis with or just prior to initiating ULT (See Table 6)
   • Duration:
     - At least 6 months OR
     - 3 months after achieving target serum urate if no tophi detected on physical exam
     - 6 months after achieving target serum urate appropriate for the patient if one or more tophi detected on physical exam
   • First line: Low dose NSAIDs (e.g., Naproxen 250 mg twice daily)
     - Avoid NSAIDs in patients with Chronic Kidney Disease (CKD) whenever possible
   • Second line: Low dose Prednisone (≤10mg/day)
   • Third line: Low dose Colchicine: 0.6 mg once or twice daily (non-formulary)

TREAT TO SERUM URATE TARGET
• The minimum serum urate target is <6 mg/dL
• Serum urate lowering below 5 mg/dL may be needed to improve gout signs and symptoms

TREAT TO TARGET
Serum urate target achieved?
• Increase intensity of ULT and re-evaluate serum urate levels every 2-4 weeks during titration of dose until serum urate target achieved
• Consider specialty referral if:
  • Unclear etiology of hyperuricemia;
  • Refractory signs or symptoms of gout;
  • Difficulty in reaching target serum urate, particularly with renal impairment; or
  • Multiple and/or serious adverse events from pharmacologic ULT
• Go to Box 25

Long-term management of gout
• Continue with ULT treatment indefinitely
• Regularly monitor serum urate every 6 months and monitor for ULT side effects
• After palpable tophi and all acute and chronic gout symptoms have resolved, continue with pharmacologic treatment and lifestyle/diet recommendations needed to maintain serum urate <6 mg/dL indefinitely

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.
I. Risk Factors that promote hyperuricemia

Table 1

<table>
<thead>
<tr>
<th>Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidities</td>
</tr>
<tr>
<td>• Hypertension</td>
</tr>
<tr>
<td>• Obesity</td>
</tr>
<tr>
<td>• Metabolic syndrome</td>
</tr>
<tr>
<td>• Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>• Hyperlipidemia</td>
</tr>
<tr>
<td>• Chronic Kidney Disease</td>
</tr>
<tr>
<td>Medications</td>
</tr>
<tr>
<td>• Diuretics (Loop and Thiazides)</td>
</tr>
<tr>
<td>• Niacin</td>
</tr>
<tr>
<td>• Aspirin (75 to 325 mg/day)</td>
</tr>
<tr>
<td>• Pyrazinamide</td>
</tr>
<tr>
<td>Diet</td>
</tr>
<tr>
<td>• Excessive alcohol intake (particularly beer) (&gt;2 servings/day for a male and &gt;1 serving/day for a female)</td>
</tr>
<tr>
<td>• Organ meats high in purine content (e.g., sweetbreads, liver, kidney)</td>
</tr>
<tr>
<td>• Beverages containing high fructose corn syrup</td>
</tr>
<tr>
<td>• Overeating</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>• Adult males (often between the ages of 30-45)</td>
</tr>
<tr>
<td>• &gt;65 years of age (regardless of gender)</td>
</tr>
</tbody>
</table>

II. Acute Gout
A. Define acute gouty arthritis attack features by classifying intensity of attack, duration of attack, and extent (Tables 2–5).

Table 2: Severity of Acute Gouty Arthritis Attack

<table>
<thead>
<tr>
<th>Intensity of attack based on self-reported pain (0-10 visual analog scale)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Severe</td>
</tr>
</tbody>
</table>

Figure 1: Visual Analog Scale (VAS)
Table 4

<table>
<thead>
<tr>
<th>Extent of acute gouty arthritis attack</th>
<th>Based on number of active joints</th>
</tr>
</thead>
<tbody>
<tr>
<td>One or a few small joints</td>
<td></td>
</tr>
<tr>
<td>1 or 2 large* joints</td>
<td>*defined as: ankle, knee, wrist, elbow, hip, shoulder</td>
</tr>
<tr>
<td>Polyarticular</td>
<td></td>
</tr>
<tr>
<td>• 4 or more joints, with arthritis involving more than 1 region†</td>
<td></td>
</tr>
<tr>
<td>†Regions defined as: forefoot (metatarsophalangeal joints, toes), midfoot (tarsal joints), ankle/hindfoot, knee, hip, fingers, wrist, elbow, shoulder, other</td>
<td></td>
</tr>
<tr>
<td>• Acute gout attack involving 3 separate large joints is considered as a form of polyarticular gout</td>
<td></td>
</tr>
</tbody>
</table>

Table 3

<table>
<thead>
<tr>
<th>Duration of the gouty arthritis attack since onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early</td>
</tr>
<tr>
<td>Well-Established</td>
</tr>
<tr>
<td>Late</td>
</tr>
<tr>
<td>&lt;12 hours after attack onset</td>
</tr>
<tr>
<td>12 to 36 hours after attack onset</td>
</tr>
<tr>
<td>&gt;36 hours after attack onset</td>
</tr>
</tbody>
</table>

Table 5

B. Recommendations for combination therapy for acute gout treatment

- Initial combination therapy is an appropriate option for an acute, severe gout attack, particularly with involvement of multiple large organs or polyarticular arthritis.
- Acceptable combination therapy approaches include the initial simultaneous use of full doses (or, where appropriate, prophylaxis doses) of either:
  - (1) Colchicine and Nonsteroidal Anti-Inflammatory Drugs (NSAIDs);
  - (2) Oral Corticosteroids and Colchicine; or
  - (3) Intra-Articular Steroids with any of the above agents;
- For some patients not responding adequately to initial pharmacologic monotherapy, adding a second appropriate agent is an acceptable option.
<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage Forms</th>
<th>Dosing</th>
<th>Side Effects/Contraindications/Monitoring</th>
</tr>
</thead>
</table>
| Colchicine  
(Colcrys®, Probenecid)  
(Status: Non-Formulary) | 0.6 mg tablet | • Initial: 1.2 mg orally (two 0.6 mg tablets) followed by 0.6 mg in 1 hour (Max 1.8 mg over 1 hour)  
• Prophylaxis: 0.6 mg orally once or twice daily beginning 12 hours after initial dose; Max 1.2 mg/day  
• If CrCl below 30 ml/min: 0.3 mg/day (half-tablet) orally initially, may increase dose to a max of 1.2 mg/day with close monitoring for toxicity | • Common Side Effects: Nausea, vomiting, abdominal pain, diarrhea (Approximately 80% of patients at high doses > 1.8 mg)  
• Colchicine toxicity: Myelosuppression, rhabdomyolysis or myopathy, reversible peripheral neuropathy, liver failure, and death possible if overdosed  
• Contraindications: Do not repeat course more than once every 2 weeks in individuals with severe hepatic or renal impairment (CrCl below 30 mL/min)  
• Concomitant use of p-glycoprotein or strong CYP3A4 inhibitors in patients with hepatic or renal impairment (see Table 8) |
| NSAIDs  
(Naproxen (Naprosyn®, others)  
(Status: Formulary) | 250 mg, 500 mg tablet | 750 mg x 1 day, then reduce to 250 mg orally every 8 hours until attack resolved | • Common Side Effects: Nausea, take with food  
• Contraindications: Allergic reaction following NSAIDs or aspirin use  
• Precautions: Avoid NSAIDs in patients with Chronic Kidney Disease (CKD) when possible  
• Consider bleeding risk in patients being treated with anticoagulants or those with active peptic ulcer disease  
• CVD risk (mostly with celecoxib)  
• Indomethacin was 1st NSAID approved and is the traditional drug of choice; however, it is more toxic than ibuprofen (increased risk for GI toxicity) and has risk of psychiatric side effects including confusion, depression, psychosis |
| Ibuprofen (Motrin®, others)  
(Status: Formulary) | 200 mg, 400 mg, 600 mg, 800 mg tablet | 800 mg orally three to four times a day until symptoms resolve |  
| Meloxicam (Mobic®)  
(Status: Formulary) | 7.5 mg, 15 mg tablet | 7.5 mg orally once daily, max 15 mg once daily |  
| Indomethacin (Indocin®, others)  
(Status: Non-Formulary) | 25 mg, 50 mg tablet | 50 mg orally three times a day until pain is tolerable, then taper down to avoid risk of rebound attack |  
| Celecoxib (Celebrex®, others)  
(Status: Non-Formulary) | 50 mg, 100 mg, 200 mg, 400 mg capsule | 800 mg orally immediately, followed by 400 mg 12 hours later, then 400 mg every 12 hours for 7 days |  
| Sulindac (Clinoril®)  
(Status: Non-Formulary) | 150 mg, 200 mg tablet | 300-400 mg orally once daily |
### Table 6

<table>
<thead>
<tr>
<th>Steroids: Can be given PO, IM, IV, intra-articular</th>
<th>Acute Steroid Use Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisone (orally)</td>
<td>Increased blood glucose, elevated blood pressure, nervousness, insomnia, increased appetite, edema.</td>
</tr>
<tr>
<td>Status: Formulary</td>
<td></td>
</tr>
<tr>
<td>Prednisone (orally)</td>
<td></td>
</tr>
<tr>
<td>Status: Formulary</td>
<td></td>
</tr>
<tr>
<td>Methylprednisolone sodium succinate (Solu-Medrol®)</td>
<td>Slight risk of infection, risk of joint damage with repeat injections</td>
</tr>
<tr>
<td>Status: Formulary</td>
<td></td>
</tr>
<tr>
<td>Triamcinolone Acetonide</td>
<td></td>
</tr>
<tr>
<td>Status: Formulary</td>
<td></td>
</tr>
</tbody>
</table>

| 5 mg, 10 mg, 20 mg tablet |  |
| 40-60 mg/day x 3 days, then decrease by 10-15 mg/day every 3 days until discontinued |  |
| Initial 10 to 40 mg IM; may be repeated as clinically indicated (Option in patients with active acute gout affecting 1 or 2 large joints defined as: ankle, knee, wrist, elbow, hip, shoulder) |  |
| 20 mg/mL- 5 mL vial |  |
| 40 mg/mL- 1 mL vial |  |
| 60 mg IM, then oral prednisone as above |  |

Page 7
### III. Chronic Gout

**Table 7**

<table>
<thead>
<tr>
<th>Drug</th>
<th>CMC Formulary</th>
<th>Strengths</th>
<th>Dosing</th>
<th>Side Effects/Contraindications/Monitoring</th>
</tr>
</thead>
</table>
| **Allopurinol (Zyloprim®)** | Formulary     | 100 mg, 300 mg tablet | Mild: 100-300 mg/day orally as a single or divided doses (2-3 times daily) | - **Common Side Effects**: Precipitation of acute gout attacks, Nausea, Skin rash  
  - **Precautions**: Allopurinol hypersensitivity syndrome (AHS) - severe rash, fever, eosinophilia, hepatitis, and renal failure. Starting at lower doses can reduce the risk of AHS. Consider HLA-B*5801 screening in those populations at high risk for developing AHS: Koreans with Stage 3 or worse CKD (GFR < 59), and those of Han Chinese or Thai descent.  
  - **Monitoring**: Check LFTs at 2 and 4 months and periodically thereafter. |
| **Febuxostat (Uloric®)**  | Non-formulary | 40 mg, 80 mg tablet | Initial: 40 mg orally once daily  
  Maintenance: May increase to 80 mg orally once daily in patients who do not achieve a serum uric acid level below 6 mg/dL after 2 weeks. | - **Common Side Effects**: Precipitation of acute gout attacks, Rash, Nausea  
  - **Monitoring**: Liver enzyme elevations (requires LFT monitoring at 2 and 4 months, and then periodically thereafter). |
| **Probenecid**            | Formulary     | 500 mg tablet | Start with 500 mg BID for one week, followed by 500 mg BID thereafter; if symptoms persist, may incrementally increase by 500 mg every 4 weeks as tolerated; MAX 2000 mg/day. | - **Common Side Effects**: Precipitation of acute gout attacks, Rash, GI intolerance, Uric acid stone formation  
  - **Contraindications**: Renal impairment (CrCl < 50 mL/min), Kidney stones |
Table 8
Drug Interactions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interactions</th>
</tr>
</thead>
</table>
| Allopurinol | • Azathioprine, 6-mercaptopurine, cyclophosphamide, cyclosporine - Allopurinol may increase toxicity of these agents  
• Ampicillin and amoxicillin - Allopurinol may result in a higher probability of rash associated with these agents  
• Captopril and enalapril - May result in hypersensitivity reactions including Stevens-Johnson Syndrome in combination  
• Didanosine - contraindicated; allopurinol may increase serum concentrations  
• Pegloticase - May result in an increased risk of anaphylaxis and infusion reactions in combination  
• Warfarin - Increased bleeding risk in combination |
| Colchicine | • Strong CYP3A4 inhibitors (increase colchicine concentrations): atazanavir, clarithromycin, indinavir, lopinavir, ritonavir, saquinavir, telithromycin, and other  
• P-gp inhibitors (increase colchicine concentrations): vinca alkaloids, amiodarone, azole antifungals, clarithromycin, cyclosporine, diltiazem, erythromycin, quinidine, tacrolimus, verapamil, and others.  
• Dose adjustments:  
  • Strong CYP3A4 inhibitors; Gout flare: 1.2 mg oral for 1 dose, do not repeat dose earlier than 3 days.  
  • P-gp inhibitors; Gout flare: 0.6 mg oral for 1 dose, do not repeat dose earlier than 3 days.  
  • CYP3A4 or P-gp inhibitors; Gout Prophylaxis: Avoid use, but if unavoidable, consider reduction of daily dose of 0.3 mg orally every other day to 0.3 mg orally once a day. |
| Febuxostat | • Azathioprine and 6-mercaptopurine - contraindicated; febuxostat may increase plasma concentrations |
IV. Patient Education

A. Causes of Gout

- Gout results from excessive uric acid in the body. Uric acid can build up and form crystals which may lead to kidney stones, joint pain, or deposits under the skin called tophi.

B. Risk Factors

- Certain risk factors increase the risk of developing gout including obesity, using medications that increase uric acid, consuming excessive amounts of alcohol (in particular beer), overeating, and disease states such as high blood pressure and chronic kidney disease (see Table 1).
- Certain characteristics increase the risk of gout flares in patients diagnosed with gout. These include meat, sugary drinks, excessive alcohol intake, and taking medications that increase uric acid.
  - Limit intake of meat, poultry, and fish to 4 to 6 ounces (113 to 170 grams daily).
  - Avoid or limit beverages and food containing high fructose corn syrup (soft drinks, juices, cereals, store-bought goods, ice cream, candy, processed foods at fast food restaurants).
  - For alcohol intake, limit to < 2 servings/day for a male and < 1 serving/day for a female.
  - Some examples of medications that affect blood levels of urate include aspirin (75 to 325 mg/day), diuretics, and niacin.

C. Gout Attacks

- Gout attacks are sudden with severe pain, burning, and swelling. If left untreated, the attacks may continue to develop. Gout attacks usually occur in the big toe but can occur in other joints.

D. Treatment goals

- The goal of treatment is to treat acute attacks, prevent future attacks, and reduce uric acid levels.

E. Acute gout treatment

- Pain and inflammation associated with acute gout attacks are treated using either an NSAID, colchicine, or steroids.
- The pain and inflammation of an acute gout attack usually reaches its peak of intensity within 12 to 24 hours and generally resolves completely within a few days to several weeks, even if untreated.
- Treat acute gout attacks within 24 hours of the onset of symptoms to receive the greatest benefit. Continue with treatment until symptoms resolve (usually within 5-7 days)

- NSAID counseling
  - Take with food to avoid upset stomach.
  - May cause bleeding in the stomach or intestine. Risk is higher in patients older than 60 years of age, history of stomach ulcer, using certain medications (steroids and blood thinners), individuals who smoke or drink regularly, or those with poor health.
  - May increase the risk of heart attack or stroke. Risk higher in patients with heart disease or long-term use of NSAIDs. Seek medical attention immediately if signs of a heart attack or stroke occur.

- Prednisone
  - May cause fluid retention, upset stomach (take with food), mood or behavior changes, increased appetite, weight gain, increase in blood glucose sugars, and high blood pressure.
  - Do not stop taking suddenly if using longer than 2 weeks. Must taper slowly to avoid withdrawal symptoms.

- Colchicine counseling
  - At the first sign of an attack take 2 tablets. Can take an additional tablet in one hour. Do not exceed more than 3 tablets in 24 hours.
  - Do not take 2nd dose if upset stomach, nausea, or diarrhea occurs.
F. Chronic gout

- Long term treatment with medications that lower urate acid levels, such as allopurinol, are used to prevent recurrent gout attacks.
- Therapy for chronic gout is lifelong. Patients should continue taking urate lowering medications even during an acute gout attack.
- Allopurinol counseling
  - Allopurinol decreases uric acid production. This reduces the chances of further gout attacks. It is important to take this medication daily (lifetime treatment).
  - Take once daily with a meal to reduce stomach upset.
  - It may take up to several weeks for this medication to have an effect.
  - Acute gout attacks may occur for several months after starting this medicine while the body removes extra uric acid. If this occurs, treat with NSAIDs or another alternative agent such as colchicine and prednisone.
  - Notify provider if a rash develops. This rash can become serious.

G. Discuss lifestyle and diet recommendations (Tables 9 and 10)

Table 9

<table>
<thead>
<tr>
<th>Lifestyle Recommendations for gout patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise regularly</td>
</tr>
<tr>
<td>Maintain a healthy body weight</td>
</tr>
<tr>
<td>Stay well hydrated</td>
</tr>
</tbody>
</table>

Table 10

<table>
<thead>
<tr>
<th>Diet Recommendations for Gout Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid</td>
</tr>
<tr>
<td>* Organ meats high in purine content (e.g., sweetbreads, liver, kidney)</td>
</tr>
<tr>
<td>* High fructose corn syrup-sweetened sodas, other beverages, or foods</td>
</tr>
<tr>
<td>* Alcohol overuse (Defined as more than 2 servings per day for a male and 1 serving per day for a female) * Any alcohol use in gout during periods of frequent gout attacks, or advanced gout under poor control</td>
</tr>
</tbody>
</table>
Chronic Heart Failure

The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved February 2000.
Revised 2/03, 4/03, 7/04, 9/06, 3/12, 5/17. Reviewed 1/06, 1/09.
The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.

Persisting Fluid Retention Initiate: Panuric acid 25mg once daily. Titrate upward as tolerated. May need to use 2 or more diuretics (thiazide and loop) in combination for enhanced effect. Monitor Na+, BP, electrolytes.

Symptoms persist? Yes

Initiate the combination of hydralazine and *isosorbide dinitrate for patients self-described as African Americans and other patients with unresolved symptoms (See Box #5 for dosing) [Prior Authorization Criteria: HF]

No

Symptoms persist?

Yes Go to Box 12

No

Add Spironolactone 25 mg QAM. If serum K+ levels start to rise, reduce the dose to 25 mg every other day (e.g., MWF). Monitor K+

Yes

Consider Cardiology telephone consult or referral prior to adding any of the following:

Add Digoxin. Initiate and adjust dose based on renal function per recommendations in Table 4 (pg. 6). Measure serum level at 1 week. Target level = 0.5 – 0.8 ng/mL. Monitor K+, Toxicity

Persisting Fluid Retention Initiate: Furosemide 20mg once daily. Titrate upward as tolerated. May need to use 2 or more diuretics (thiazide and loop) in combination for enhanced effect. Monitor Na+, BP, electrolytes.

Symptoms persist? Yes

Yes Go to Box 12

No

Go to Box 12

If patient is chronically symptomatic despite maximally tolerated doses of ACEI or ARB, beta-blockers, spironolactone and digoxin, the following options may be considered via the non-formulary approval process when the request originates from a cardiology specialist:

• ENTRESTO® (sacubitril/valsartan): 49 mg/51 mg PO BID (up to 97 mg/103 mg PO BID) as tolerated

OR

• CORLANOR® (ivabradine): 5 mg PO BID with meals (up to 7.5 mg BID)

SPECIAL NOTES:

• Stop ACEI/ARB if starting ENTRESTO® or other ARNI (Angiotensin II Receptor Blocker Neprilysin Inhibitor)

• DO NOT start ENTRESTO® within 36 hours of stopping an ACEI/ARB

• Patient must have a heart rate of 70bpm or higher at rest before starting CORLANOR®

CLASSIFICATION AND DEFINITION OF MOST COMMONLY USED TERMS IN HEART FAILURE MANAGEMENT

<table>
<thead>
<tr>
<th>ACCF/AHA Stages of HF</th>
<th>NYHA Functional Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>None</td>
</tr>
<tr>
<td>B</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td>C</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td>D</td>
<td>Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.</td>
</tr>
</tbody>
</table>

Table 1: ACCF/AHA Stages of HF and NYHA Functional Classifications

<table>
<thead>
<tr>
<th>Classification</th>
<th>EF (%)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Heart failure with reduced ejection fraction (HFrEF)</td>
<td>≤40</td>
<td>A patient with HFrEF has left ventricular dysfunction and the patient is typically said to have systolic HF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Most of the therapies that have been documented to have morbidity and mortality benefits in HF are mainly efficacious in patients with HFrEF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective therapies include Beta Blockers + ACEI/ARB + aldosterone antagonist if EF is less than 35%.</td>
</tr>
<tr>
<td>II. Heart failure with preserved ejection fraction (HFpEF)</td>
<td>≥50</td>
<td>In patients with HFpEF, the left ventricular systolic is preserved. The problem is a filling one and such patients are said to have diastolic HF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diagnosis is based on excluding other probable causes of symptoms suggestive of CHF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No efficacious therapy has been identified.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Management typically involves controlling blood pressure and heart rate and treatment of symptoms with diuresis.</td>
</tr>
<tr>
<td>a. HFpEF, borderline</td>
<td>41 to 49</td>
<td>These are a subset of the HFpEF group.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The characteristics treatment patterns, and outcomes appear similar to those of patients with HFrEF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Management typically involves controlling blood pressure and heart rate and treatment of symptoms with diuresis.</td>
</tr>
<tr>
<td>B. HFpEF, improved</td>
<td>&gt;40</td>
<td>These are a subset of patients with HFpEF who previously had HFpEF (i.e., those patients previously had EF&lt;50%).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The thought is that patients with improvement or recovery in EF may be clinically distinct from those with persistently preserved or reduced EF.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The patients typically remain on beta-blocker and ACEI/ARB.</td>
</tr>
</tbody>
</table>

Table 2: Definitions of HFrEF and HFpEF
**Preferably, should be started by a cardiologist**

*Carvedilol is the formulary preferred, evidence*

<table>
<thead>
<tr>
<th>Stage</th>
<th>Treatment Recommendations</th>
</tr>
</thead>
</table>
| A     | Initiate ACEI in patients with reduced EF 
Stage includes MI, LVH, Valvular disease, etc. Patients could also be asymptomatic with LV dysfunction or concentric remodeling |

- Initiate ACEI in all patients with reduced EF or ACS who have had a recent or remote history of HF or ACS and reduced EF. Beta-blockers should be initiated in all patients with reduced EF or ACS in the absence of a history of MI or in patients with HFpEF who are either intolerant of ACEI or have severe symptoms (systolic and/or diastolic HF) |

- Initiate beta-blockers in all patients with reduced EF who are either intolerant of ACEI or have severe symptoms |

- Non-dihydropyridine calcium channel blockers (such as diltiazem and verapamil) may be used in asymptomatic patients with low LVEF and no symptoms of HF after MI because of their negative inotropic effects |

- ARBs may be used as an alternative to ACEI |

<table>
<thead>
<tr>
<th>Note</th>
<th>LVEF = Left Ventricular Ejection Fraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MI = Myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>ACS = Acute coronary syndrome</td>
</tr>
<tr>
<td></td>
<td>ARB = Angiotensin Receptor Blockers</td>
</tr>
<tr>
<td></td>
<td>AV = Atrial ventricular false atrial flutter</td>
</tr>
<tr>
<td></td>
<td>EF = Ejection Fraction</td>
</tr>
<tr>
<td></td>
<td>LVEF = Left Ventricular Ejection Fraction</td>
</tr>
</tbody>
</table>

**Table 3: Treatment recommendations based on the various stages of HF**

- **Stage A** 
  - Blockade of neurohumoral activation using angiotensin-converting-enzyme inhibitors (ACEI) and beta blockers. 
  - Avoid or control other factors that may contribute to the development of HF including obesity, diabetes, cigarette smoking, etc. 

- **Stage B** 
  - Initiate therapy for MI with acute coronary syndrome (ACS) or reduced EF. 
  - Initiate therapy for HFpEF in patients with NYHA class II 

- **Stage C** 
  - Initiate therapy for HFpEF in patients with NYHA class III or IV. 
  - Use of diuretics should be guided by symptoms and renal function, considering end-organ damage and the potential for hyperkalemia and renal insufficiency. 

- **Stage D** 
  - Initiate therapy for myocardial infarction (MI) with acute coronary syndrome (ACS) or reduced EF. 
  - Initiate therapy for HFpEF in patients with NYHA class II.
General measures:
- Control hypertension, diabetes, and hyperlipidemia to decrease risk of new cardiac injury
- Monitor weight closely (fast increase is a sign of exacerbation)
- Reduce fluid intake and restrict salt to a moderate degree (< 3 grams)
- Encourage exercise (as tolerated) to prevent or reverse physical deconditioning
- Influenza and pneumococcal vaccines to decrease risk of serious respiratory infections
- Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.
- Medications to be **AVOIDED** include:
  - Non-steroidal anti-inflammatory drugs: can decrease the effectiveness of ACE inhibitors and diuretics and can worsen renal and cardiac function
  - Anti-arrhythmics: heart failure patients can experience cardiodepressant and proarrhythmic effects.
  - Calcium Antagonists: lack of evidence supporting efficacy; safety concerns

Medications (not in any specific order):

**Lisinopril** - ACE Inhibitor
- **Benefit**: All patients should be on ACEI to promote favorable effects on cardiac remodeling and increase survival rate
- **When to use**: In NYHA Class I-IV (at diagnosis or any point thereafter)
- **Dosage titration**: Begin initial dose monitoring potassium, SCr change, and blood pressure. Increase dose to target based on toleration by the patient.
- **Monitoring**: 1) BP for hypotension; 2) K+ for hyperkalemia; 3) SCr for unexpected elevation and renal insufficiency. If these occur, decrease dose and treat appropriately.
- **NOTE**: Class I can remain on an ACEI as sole therapy. If contraindicated due to renal artery stenosis, consider isosorbide dinitrate and hydralazine.

**HCTZ** - thiazide diuretic
- **Benefit**: Will assist in reducing blood pressure if a concomitant problem.
- **When to use**: In NYHA Class III, only use in mild edema (occasional symptoms)
- **Dosage titration**: Start patient at 25 mg. There is no proven benefit to increasing this dose.
- **Monitoring**: 1) BP for symptomatic hypotension; 2) K+ for hypokalemia
- **NOTE**: It does not reduce fluid as efficiently as furosemide. If continuation of symptoms, discontinue and start furosemide.

**Furosemide** - loop diuretic
1. **Benefit**: Manage fluid overload to reduce or minimize symptoms
2. **When to use**: In NYHA Class IV, if HCTZ fails, replace with furosemide. If symptomatic, add to ACE inhibitors to decrease fluid overload
3. **Dosage and titration**: Titrate dose to symptoms – stabilize patient and maintain patient on smallest dose.
4. **Monitoring**: 1) BP for symptomatic hypotension; 2) K+ for hypokalemia
5. **NOTE**: Treat electrolyte imbalances and continue therapy.

**Options**:
1. Small dose of K+ sparing diuretic - spironolactone (assist in reduction of morbidity and mortality)
2. Slow the titration of furosemide and add a K+ supplement
3. Patient may need to tolerate some degree of hypotension and/or renal insufficiency until fluid retention is resolved. Monitor closely.

Options before addition of other pharmacological therapy.
Carvedilol – beta-blocker

- Benefit: Beta-blocker use may prevent disease progression even if symptoms have not responded favorably to treatment
- When to use: Initiate therapy early – should be added to ACE inhibitors, can be used with vasodilators and diuretics
- Dosage and Titration: Delay planned increments until the early side effects produced by the low doses of beta-blockers have disappeared
- Monitoring: 1) BP for hypotension; 2) pulse for symptomatic bradycardia < 60 BPM; 3) fluid retention or worsening heart failure during up-titration
- NOTE: Use in STABLE patients ONLY
- Advise patients
  1) Side effects may occur early in therapy but they do not generally prevent long-term use
  2) Improvements in symptoms may not be seen for 2-3 months
- Contraindications include: Asthma, Type 1 diabetes, bronchospasm, or acutely ill patients

Digoxin

- Benefit: Unknown
- When to use: In NYHA Class II-IV in patients with atrial fibrillation
- Dosage and Titration: Maintain Serum levels between 0.5-1.0 ng/mL (0.5-0.8 ng/mL → 6.3% lower mortality; ≥ 1.2 ng/mL → 11.8% higher mortality)
- Monitoring: 1) K+ for hypokalemia or hyperkalemia (can cause digoxin toxicity); 2) Mg+ for hypomagnesemia (can maintain hypokalemia)
- Side effects: (commonly seen at toxic levels > 2 ng/mL)
  1) cardiac arrhythmias
  2) nausea and vomiting
  3) visual disturbances and confusion
- NOTE:
  - Can initiate in conjunction with ACE inhibitors, diuretics, or beta-blockers if early in therapy and symptoms are still present
  - DO NOT use if acutely decompensating (may need intravenous therapy)
  - Dose adjustment may be necessary if there is any change in clinical status or suspected toxicity

Table 4: Initial digoxin maintenance dose for adults with HF based on renal function

<table>
<thead>
<tr>
<th>Ideal body weight (kg)</th>
<th>Creatinine clearance (mL/minute)</th>
<th>Digoxin oral dose per day (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-50</td>
<td>≤ 60</td>
<td>0.0625*</td>
</tr>
<tr>
<td></td>
<td>&gt; 60</td>
<td>0.125</td>
</tr>
<tr>
<td>51-60</td>
<td>≥ 45</td>
<td>0.0625*</td>
</tr>
<tr>
<td></td>
<td>46-110</td>
<td>0.125</td>
</tr>
<tr>
<td></td>
<td>≥ 110</td>
<td>0.25</td>
</tr>
<tr>
<td>61-70</td>
<td>≤ 35</td>
<td>0.0625*</td>
</tr>
<tr>
<td></td>
<td>36-110</td>
<td>0.125</td>
</tr>
<tr>
<td></td>
<td>≥ 110</td>
<td>0.25</td>
</tr>
<tr>
<td>71-80</td>
<td>≤ 20</td>
<td>0.0625*</td>
</tr>
<tr>
<td></td>
<td>21-90</td>
<td>0.125</td>
</tr>
<tr>
<td></td>
<td>≥ 90</td>
<td>0.25</td>
</tr>
<tr>
<td>81-90</td>
<td>≤ 10</td>
<td>0.0625*</td>
</tr>
<tr>
<td></td>
<td>11-70</td>
<td>0.125</td>
</tr>
<tr>
<td></td>
<td>≥ 70</td>
<td>0.25</td>
</tr>
</tbody>
</table>

* 0.0625 mg daily dose can be given as 0.125 mg every other day (e.g., MWF).

Sources
Ibrutinib

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** in NYHA class III or IV
- **Dosage:** Initiate at 5mg BID with meals
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Indacrinone

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 12.5mg TID
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Vasopressor

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 20mg TID
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Hydralazine

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 5mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Corlanor

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Entresto

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Spironolactone

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Isosorbide Dinitrate

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 20mg TID and up to a maximum of 40mg TID
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Hydralazine

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 5mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Spironolactone

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Isosorbide Dinitrate

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 20mg TID and up to a maximum of 40mg TID
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Spironolactone

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Isosorbide Dinitrate

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 20mg TID and up to a maximum of 40mg TID
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.

Spironolactone

**Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA class III or IV
- **Dosage:** Initiate at 25mg daily
- **Monitor:** 1. Heart rate for bradycardia, 2. Excessive bleeding
- **NOTICE:** In NYHA class III or IV with EF ≤ 35%, stable HF with HFrEF.
HF Patient education

Heart Failure (HF) – Inability of the heart to pump out all the blood that returns to it. Measured by an ejection fraction (EF)

Warning Signals (SEE YOUR DOCTOR IF):
- Difficulty breathing while lying down
- Decreased urination
- Unusual weight gain/weight loss
- Swollen ankles, feet, or hands
- Chest pain
- Irregular heart rate

DO NOT miss your medication (You may be taking one of the following):
- Diuretics – reduce the excess water your body retains (HCTZ, Triamterene/HCTZ, Furosemide)
- ACEI and Vasodilators – relaxes the blood vessels so the heart does not work as hard (Lisinopril, Hydralazine and Isosorbide)
- Beta-blockers – protect the heart by decreasing the heart rate (Metoprolol, Coreg or Carvedilol)
- Digoxin – increase the pumping action of the heart
- Spironolactone – is considered a diuretic that makes the body retain potassium

Diet - Avoid salt to reduce amount of fluid held in the tissues (Peanuts, chips, ramen noodles, pretzels)

Exercise - Consult your doctor. Regular exercise, such as walking, will improve cardiovascular fitness and help strengthen the heart muscle. A strong heart does not have to work as hard to pump blood through the body.

Dental hygiene - Regular dental hygiene is important and should include daily brushing in the morning and evening and flossing once daily.
Obtain baseline tests
- CBC w/platelets
- Bili, Alb, ALT, AST, AFP
- Prothrombin time
- HCV (Hepatitis C)
- HIV, anti-HAV total
- HBV-DNA (Viral Load)
- if potential treatment candidate
- Vaccinate as indicated

Evidence of cirrhosis (compensated, decompensated, or APRI score > 2) and/or co-infected with HIV or HCV?

Age > 30; APRI < 2.0; ALT abnormal; and Viral Load > 20,000?

Prepared By the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved 1/09. Reviewed 01/2012; Revised 11/2015.

CHRONIC HEPATITIS B MONITORING AND REFERRAL GUIDELINE

1. Chronic Hepatitis B (CHB)
2. Obtain baseline tests
- CBC w/platelets
- Bili, Alb, ALT, AST, AFP
- Prothrombin time
- HCV (Hepatitis C)
- HIV, anti-HAV total
- HBV-DNA (Viral Load)
- if potential treatment candidate
- Vaccinate as indicated

3. Evidence of cirrhosis (compensated, decompensated, or APRI score > 2) and/or co-infected with HIV or HCV?

4. Yes
   - Refer for treatment evaluation and perform Level 2 labs.

5. No
   - Age > 30; APRI < 2.0; ALT abnormal; and Viral Load > 20,000?

6. Yes
   - Refer for treatment evaluation and perform Level 2 labs.

7. No
   - Monitor for disease progression & CHB reactivation with ALT, HBV DNA (Viral Load) every 3 months for the first year and then every 6 to 12 months.
   - If parameters change (i.e., age > 30, Abnormal ALT, viral load > 20,000, liver disease progression to cirrhosis) then restart in BOX 3.

8. Do not treat at this time. Follow in CCC and reevaluate for treatment annually.

9. Cirrhosis not present; Viral Load < 2,000; APRI < 2.0; ALT normal?

10. Yes
    - Refer for treatment evaluation and perform Level 2 labs.

HBV-DNA units are in IU/mL. If results are given as log IU/mL, then 2,000 IU/mL = 3.3 log 20,000 IU/mL = 4.3 log

CHRONIC HEPATITIS B MONITORING AND REFERRAL GUIDELINE
Box A - Level 2 Labs for Hepatitis B
- Quantitative HBV-DNA
- Abdominal ultrasound
- Alpha-fetoprotein (AFP)
- CXR and EKG if over 40 or clinically indicated
If not done in the preceding 6 months:
- ALT, AST, bilirubin, albumin, BUN, creatinine
- CBC, platelets, PT
- T4, TSH
- Fe, TIBC

Table 1: Monitoring Schedule on nucleoside analog therapy for hepatitis B

<table>
<thead>
<tr>
<th>Month of Treatment</th>
<th>Continued Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Rx</td>
<td>3</td>
</tr>
<tr>
<td>CBC + diff</td>
<td>X</td>
</tr>
<tr>
<td>LFTs**</td>
<td>X</td>
</tr>
<tr>
<td>Alpha-Fetoprotein (AFP)</td>
<td>X</td>
</tr>
<tr>
<td>Creatinine (if on adefovir, entecavir, or tenofovir)</td>
<td>X</td>
</tr>
<tr>
<td>ALT, AST, bilirubin (conjugated &amp; unconjugated), albumin, Alkaline phosphatase, LDH</td>
<td>X</td>
</tr>
<tr>
<td>HBV-DNA</td>
<td>X</td>
</tr>
<tr>
<td>HBV Ag (if HBeAg positive)</td>
<td>X</td>
</tr>
<tr>
<td>HBsAg (if HBeAg neg and HBV-DNA &lt; 2,000)</td>
<td>X</td>
</tr>
<tr>
<td>Beck Depression Index</td>
<td>X</td>
</tr>
</tbody>
</table>

** Liver tests: ALT, AST, bilirubin (conjugated & unconjugated), albumin, Alkaline phosphatase, LDH

Table 2: Monitoring Schedule on Peg-IFN alpha

<table>
<thead>
<tr>
<th>Week of Treatment</th>
<th>Treatment Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Rx</td>
<td>2</td>
</tr>
<tr>
<td>CBC + diff</td>
<td>X</td>
</tr>
<tr>
<td>PEG-IFN</td>
<td>X</td>
</tr>
<tr>
<td>LFTs**</td>
<td>X</td>
</tr>
<tr>
<td>Alpha-Fetoprotein (AFP)</td>
<td>X</td>
</tr>
<tr>
<td>HBV-DNA</td>
<td>X</td>
</tr>
<tr>
<td>HBsAg (if HBeAg positive)</td>
<td>X</td>
</tr>
<tr>
<td>HBsAg (if HBeAg neg and HBV-DNA &lt; 2,000)</td>
<td>X</td>
</tr>
<tr>
<td>Beck Depression Index</td>
<td>X</td>
</tr>
</tbody>
</table>

** Liver tests: ALT, AST, bilirubin (conjugated & unconjugated), albumin, Alkaline phosphatase, LDH

Note that monitoring schedule is by week for interferon and by month for nucleoside analogs.
Chronic Hepatitis C Evaluation and Treatment Pathway

Initial Management of Chronic Hepatitis C Patients (Page 3)

• Complete baseline evaluation and confirmation of chronic HCV diagnosis
• Offer preventive health measures
• Enroll in chronic care clinic and follow-up at least every 12 months or as clinically indicated (Page 4)
• If patient has cirrhosis, refer to the End Stage Liver Disease guideline for management of ESLD in addition to following this pathway.

Determine if patient should be referred to the designated provider and/or clinic for treatment evaluation. Document in EMR. Refer if all of the following true.

• Willing and interested in undergoing treatment
• Cirrhosis (even if APRI score ≤ 0.5)
• No contraindications to therapy (Page 6)
• Sufficient time left in system to complete work-up, treatment, and follow-up evaluation of SVR
• APRI score > 0.5

Candidate for drug treatment evaluation?

No

Yes

Continue to Monitor:

• Rule out other causes of liver disease (Table 5) & obtain Alpha-1 antitrypsin, ceruloplasmin, ANA, ferritin, serum iron, and TIBC. Consider specialty referral if indicated.
• Screen for Hepatitis B (HBsAg and/or HBsAb) and obtain AFP. If AFP is elevated, consider screening for liver mass (refer to Liver Mass Referral Guideline).
• Follow in chronic care clinic at least every 12 months (Page 4)
• Refer to designated HCV provider and/or clinic for continued treatment evaluation.
• Alpha-fetoprotein (AFP) should be ordered at the time of referral. If AFP is elevated, consider screening for liver mass (refer to Liver Mass Referral Guideline).

Candidate for viral treatment evaluation?

No

Yes

Treatment Evaluation (Completed by Virology HCV Treatment Team in UTMB Sector or per Utilization Management review process for Texas Tech Sector)

• Factors to consider when determining if the patient is an eligible candidate for drug therapy
  • No contraindications to therapies (pages 6)
  • Sufficient time left in the system to complete work-up, treatment, and follow-up evaluation of SVR
  • Life expectancy is not ≤12 months
  • No evidence of ongoing participation in high risk behavior associated with the transmission of hepatitis C
  • Not pregnant
  • Demonstrated willingness to complete therapy, compliant with pretreatment work-up, or has not refused treatment
  • Complete pre-treatment workup (Table 6)

• If the patient is not a candidate or chooses not to receive drug therapy, document the reason(s) in the EMR.

Did patient successfully complete HCV treatment (SVR achieved)?

No

Yes

Patient will continue to follow up by the HCV Provider and/or HCV Clinic

Prepared By: The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved July 2008; Reviewed 5/11; Revised 9/13, 1/15, 11/16, 3/18, 7/18.
Definitions

1. APRI (AST to Platelet Ratio Index) – A non-invasive method for the assessment of fibrosis in chronic liver disease. It is the ratio of the AST level, expressed as a percentage of the upper limit of normal, divided by the platelet count in thousands per cubic millimeter. It is a good predictor of liver fibrosis but cannot replace the liver biopsy in all cases. The APRI may be less predictive when there are co-morbid conditions other than liver disease that may affect the platelet count or AST level.

2. Cirrhosis - Cirrhosis is a chronic disease of the liver in which liver tissue is replaced by connective tissue or scar tissue, resulting in the loss of liver function.
   - Compensated cirrhosis (CTP Class A) is characterized by laboratory evidence of liver dysfunction such as:
     - Low albumin but ≥3.0,
     - Low platelet count but ≥ 70,000,
     - Elevated bilirubin but <2.0, and/or
     - Prolonged prothrombin time but less than 2 seconds greater than control in the absence of clinical complications associated with cirrhosis.
   - Decompensated cirrhosis (CTP Class B or C) is characterized by the presence of one or more of the clinical complications of chronic liver disease including ascites, encephalopathy, spontaneous bacterial peritonitis, variceal bleeding, jaundice, and/or impaired hepatic synthetic function (e.g., hyperbilirubinemia and hypoalbuminemia). Laboratory results consistent with decompensated cirrhosis are:
     - Albumin < 3.0,
     - Platelet count < 70,000,
     - Bilirubin > 2,
     - Prothrombin time > 2 seconds longer than control.

   CTP score is obtained by adding the score for each parameter:
   - CTP class: "A" = 5 – 6 points
     - "B" = 7 – 9 points
     - "C" = 10 - 15 points

3. FRT (Fibrous Routine Test) - A non-invasive method for the assessment of fibrosis in chronic liver disease utilizing routine laboratory markers (age, albumin, APRI and AFP).

<table>
<thead>
<tr>
<th></th>
<th>Encephalopathy</th>
<th>Ascites</th>
<th>Bilirubin (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>None</td>
<td>Mild/Moderate (transient)</td>
<td>&lt; 0.2</td>
</tr>
<tr>
<td>2</td>
<td>Grade 1 (or precipitant-induced)</td>
<td>Moderate (transient)</td>
<td>0.2 – 3.5</td>
</tr>
<tr>
<td>3</td>
<td>Grade 2-4 (or chronic)</td>
<td>Severe (transient)</td>
<td>&gt; 3.5</td>
</tr>
</tbody>
</table>

CTP score is obtained by adding the score for each parameter:
- CTP class: A = 5 – 6 points
  - B = 7 – 9 points
  - C = 10 - 15 points

Table 1: APRI Calculation

\[
\text{APRI} = \left( \frac{\text{AST}}{\text{ULN}} \right) \times \frac{\text{Platelet Count}}{\times 100}
\]

- Use most recent lab results.
- ULN = upper limit of normal for the AST level and platelet count is in 1,000/mm³.
- Available on CMCWEB under Tools and in the EMR under Guidelines.
- APRI ≥ 0.7 associated with significant fibrosis (F2)
- APRI ≥ 1 associated with severe fibrosis (F3)
- APRI ≥ 2 associated with cirrhosis (F4)

Table 2: Child-Turcotte-Pugh (CTP) Calculator

<table>
<thead>
<tr>
<th>Points</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Encephalopathy</td>
<td>None</td>
<td>Grade 1 (or precipitant-induced)</td>
<td>Grade 2-4 (or chronic)</td>
</tr>
<tr>
<td>2. Ascites</td>
<td>None</td>
<td>Mild/Moderate (transient)</td>
<td>Severe (transient)</td>
</tr>
<tr>
<td>3. Bilirubin (mg/dL)</td>
<td>&lt; 0.2</td>
<td>0.2 – 3.5</td>
<td>&gt; 3.5</td>
</tr>
</tbody>
</table>

CTP score is obtained by adding the score for each parameter:
- CTP class: A = 5 – 6 points
  - B = 7 – 9 points
  - C = 10 - 15 points

Table 3: FRT Calculation

\[
\text{FRT} = 3.31 + (\text{age} \times 0.09) + (\text{APRI} \times 1.5) + (\text{AFP} \times 0.4) - (\text{Alb} \times 0.14)
\]

- Use most recent lab results
- Available in the EMR under Guidelines
- FRT > 4 predictive Metavir score F2 – F4 (portal fibrosis with rare bridges – cirrhosis)
4. Liver biopsy scoring schemas

<table>
<thead>
<tr>
<th>Stage</th>
<th>Batts-Ludvig</th>
<th>Metavir</th>
<th>Ishak</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fibrosis</td>
<td>Stage 0</td>
<td>F0</td>
<td>0 = no fibrosis</td>
</tr>
<tr>
<td>Mild portal fibrosis</td>
<td>Stage 1</td>
<td>F1</td>
<td>1 = fibrous expansion some portal areas +/- septa</td>
</tr>
<tr>
<td>Moderate periportal fibrosis or portal septa</td>
<td>Stage 2</td>
<td>F2</td>
<td>3 = fibrous expansion most portal areas with occasional portal-portal bridging</td>
</tr>
<tr>
<td>Severe bridging fibrosis</td>
<td>Stage 3</td>
<td>F3</td>
<td>6 = fibrous expansion portal areas +/- marked bridging</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>Stage 4</td>
<td>F4</td>
<td>6 = cirrhosis, probable or definite</td>
</tr>
</tbody>
</table>

5. Response to therapy

- **End of treatment response (ETR)** - Undetectable HCV RNA level at the conclusion of a course of drug therapy
- **Sustained virologic response (SVR)** - Undetectable HCV RNA level 12 weeks after the conclusion of a course of drug therapy
- **Relapse** - Reappearance of serum HCV RNA after achieving an undetectable level at the conclusion of a course of drug therapy
- **Null response** - Failure to reduce HCV RNA by at least 2 logs after treatment. Considered a non-responder.
- **Partial response** - At least a 2 log drop in HCV RNA, but inability to fully remove the virus from the blood after treatment. Considered a non-responder.

Initial Management

1. **Baseline evaluation**
   - Confirmation of diagnosis - A positive HCV antibody test should be followed by HCV RNA testing.
   - If HCV RNA is detected, the diagnosis of HCV infection is confirmed.
   - If HCV RNA is not detected, this likely represents either past infection that subsequently cleared or a false-positive antibody test.
   - The estimated rate of spontaneous clearance after infection is 20 to 45 percent. These patients do not have chronic HCV and can be diagnosed with HCV Resolved.
   - History including probable date of HCV infection, alcohol use, co-infection with HIV or hepatitis B, drug use, symptoms of liver disease, and previous treatment for HCV.
   - Physical including signs of advanced liver disease, evidence of other causes of liver disease, and extra-hepatic manifestations of HCV (e.g., leukocytoclastic vasculitis, cryoglobulinemia, porphyria cutanea tarda, membranoproliferative glomerulonephritis, and type 2 diabetes).
   - Laboratories
     - CBC with differential & platelets
     - Prothrombin time, INR
     - ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine
   - HIV
   - Anti-HBc, anti-HBs, anti-HBc, anti-HAV

2. **Offer preventive health measures**
   - Vaccinations if indicated
     - Hepatitis B vaccine if hepatitis serum markers are negative
     - Hepatitis A vaccine if the anti-HAV test is negative
   - Patient education
     - Natural history of disease
     - Behaviors to avoid (e.g., alcohol)
     - Avoiding transmission (e.g., sharing needles, tattooing, or grooming items such as razors & toothbrushes; unprotected sex)
     - Potential treatments
   - Additional care if cirrhosis present
   - Annual influenza vaccination
   - Refer to the End Stage Liver Disease (ESLD) guideline for complete recommendations on management

3. **Enroll in chronic care clinic and follow up at least every 12 months or as clinically indicated**

4. **Job assignments**
   - Patients with chronic HCV should be restricted from plumber’s helper or bar trap cleaner job assignments unless they have been vaccinated against hepatitis A or have been documented as positive anti-HAV antibody.
   - Other restrictions should be made on a case-by-case basis if clinically indicated.
Chronic Care Clinic Follow Up

1. Unit provider needs to continue to follow the patient in CCC even after referral has been made to HCV Provider and/or Clinic.

2. Evaluate for clinical signs and symptoms of liver disease.

3. Laboratories
   - ALT, AST, bilirubin, albumin, OSC with differential & platelets, PT, INR
   - APRI score – if not available in the labs, calculate and record in results entry of EMR
   - Other laboratories as clinically indicated

4. If cirrhotic
   - Calculate the MELD score. Available on CMCWEB under Tools and in the EMR under Guidelines
   - Refer to the ESLD guideline for recommendations on management and consider referral to ESLD clinic
   - Patients with decompensated cirrhosis and MELD score ≥ 22 or recurrent ascites, bleed or encephalopathy requires MHS referral
   - Patients with MELD ≥ 30 should be referred to hospice
   - Patients unable to care for themselves in general population should be considered for sheltered housing or assisted living

5. Evaluate patient to determine if he/she is a candidate for drug treatment and document in the medical record.
   - If not a candidate initially
     - Re-evaluate the patient at least annually and refer the patient for evaluation of drug treatment if clinically indicated.
     - Rule out other causes of liver disease & obtain Alpha-1 antitrypsin, ceruloplasmin, ANA, ferritin, serum iron, and TIBC (See Table 5). Consider specialty referral if indicated.

6. If there has been a change in the patient’s health status and referral to HCV Provider and/or clinic has been made, contact the HCV team to notify them of the change.

<table>
<thead>
<tr>
<th>Table 5: Causes of Liver Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signs &amp; Symptoms</td>
</tr>
<tr>
<td>Shortness of breath, cough, wheezing, early COPD ≥ 65, frequent lung infections, necrotizing panniculitis (looks like raised red spots on the skin)</td>
</tr>
<tr>
<td>Swelling of legs, puffy hands, ankle pain, pitting edema, difficulty speaking, walking, &amp; swallowing; drooling, shaking, rash</td>
</tr>
<tr>
<td>Joint pain, irregular heart rhythm, skin color changes (bronze, ashen green), hair loss, enlarged liver or spleen, fatigue</td>
</tr>
<tr>
<td>Associated with other autoimmune diseases, jaundice, abdominal discomfort, enlarged liver, pruritus, spider angiomas, joint pain</td>
</tr>
</tbody>
</table>
Drug Treatment Evaluation

1. Patients should be evaluated for drug therapy by a provider experienced in the treatment of chronic hepatitis C. This is completed by the Virology HCV Treatment Team in the UTMB Sector or per the Utilization Management review process for the Texas Tech Sector.

2. If the patient is not a candidate for drug therapy, document the reason(s) in the medical record.

3. If the patient chooses to not receive drug therapy, document the reason(s) in the medical record.

4. If no contraindications to drug therapy are present and the patient is a potential candidate for drug therapy, complete pre-treatment evaluation.

Table 6: Pre-treatment Workup

- Physical examination if not done in last 12 months
- If not done in preceding 12 weeks: ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine, CBC with differential, prothrombin time, PT, INR, calculated GFR
- A1C if diabetic and not done in preceding 6 months
- HCV RNA and genotype
- Screen for HCC: Alpha-fetoprotein (AFP) and liver imaging
- Obtain liver ultrasound if FIB-4 ≥ 5, clinical evidence of cirrhosis, or as clinically indicated
- Pregnancy test if female
- Chest x-ray and EKG if clinically indicated
- Review previous HCV treatment history and clinical outcome

Candidate for Drug Therapy

1. There are factors to consider when determining if the patient is an eligible candidate for drug therapy.
   - No contraindications to therapy
   - Sufficient time left in the system to complete work-up, treatment, and follow up evaluation of SVR
   - Life expectancy is not ≤ 12 months
   - No evidence of ongoing participation in high risk behavior associated with the transmission of hepatitis C
   - Pregnancy
   - Demonstrated willingness to complete therapy and compliance with pretreatment work-up or refusal of treatment

2. If the patient is an eligible candidate for drug therapy and meets the criteria, he/she will be prioritized for treatment by the HCV provider and/or clinic.

Initiation of Therapy

1. Distribute patient education materials to patient
2. Obtain informed consent and document in the medical record
3. Patients should be housed at a Center of Excellence while on therapy.
4. Patients must be placed on medical hold while on therapy (refer to Standard Operating Procedure: Placing Patients on Medical Hold During Hepatitis C Treatment)
5. Monitor the patient per monitoring schedule while on drug therapy
Contraindications to Drugs Used for the Treatment of Chronic Hepatitis C

Note: Modifiable or treatable contraindications should be controlled or resolved and the patient reconsidered for treatment whenever possible.

### Table 7: Velpatasvir/Sofosbuvir (Epclusa®)

<table>
<thead>
<tr>
<th>Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previously demonstrated hypersensitivity to the drug</td>
<td>- Anticonvulsant: Carbamazepine, Oxcarbazepine, Phenytoin, Phenobarbital</td>
</tr>
<tr>
<td></td>
<td>- Antimycobacterials: Rifampin, Rifabutin, Rifapentine</td>
</tr>
<tr>
<td></td>
<td>- Opamphepside</td>
</tr>
<tr>
<td></td>
<td>- St. John's wort</td>
</tr>
<tr>
<td></td>
<td>- Antithrombotic: Aspirin, Ticlopidine, Clopidogrel</td>
</tr>
<tr>
<td></td>
<td>- HIV medications: Regimens containing tenofovir, TDF/EFV, FTC/TAF, FTC/TAF/RTV</td>
</tr>
<tr>
<td></td>
<td>- Ethinyl estradiol</td>
</tr>
<tr>
<td></td>
<td>- St. John's wort</td>
</tr>
<tr>
<td></td>
<td>- Amiodarone</td>
</tr>
<tr>
<td></td>
<td>- HIV medications: Regimens containing tenofovir, TDF/EFV, FTC/TAF, FTC/TAF/RTV</td>
</tr>
</tbody>
</table>

Concomitant usage with:
- Acid reducing agents:
  - Antacids (e.g., aluminum and magnesium hydroxide)
  - H2-receptor antagonists (e.g., ranitidine)
- Digoxin
- HIV medications: Regimens containing tenofovir
- Rosuvastatin and atorvastatin

1. Co-administration of omeprazole is not recommended. If it is considered necessary to coadminister, velpatasvir/sofosbuvir should be administered with food and taken 4 hours before omeprazole (20 mg od).
2. Separate administration of omeprazole/sofosbuvir by 4 hours.
3. St. John's wort may significantly decrease plasma concentrations of glecaprevir/pibrentasvir, leading to reduced therapeutic effect.
4. Co-administration with cyclosporine is not recommended in patients receiving cyclosporine > 100 mg per day.
5. Measure serum digoxin concentrations before initiating glecaprevir/pibrentasvir. Digoxin dose reduction of 50% may be required.
6. Follow dabigatran prescribing information for dose modifications in combination with P-gp inhibitors in the setting of renal impairment.
7. Increased statin concentration may increase the risk of myopathy including rhabdomyolysis. Co-administration with these statins is not recommended.

### Table 8: Glecaprevir/Pibrentasvir (Mavyret®)

<table>
<thead>
<tr>
<th>Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previously demonstrated hypersensitivity to the drug</td>
<td>- Anticonvulsant: Carbamazepine</td>
</tr>
<tr>
<td></td>
<td>- Cyclosporine</td>
</tr>
<tr>
<td></td>
<td>- Diltiazem</td>
</tr>
<tr>
<td></td>
<td>- Ethinyl estradiol</td>
</tr>
<tr>
<td></td>
<td>- St. John's wort</td>
</tr>
<tr>
<td></td>
<td>- HIV medications: Regimens containing tenofovir, TDF/EFV, FTC/TAF, FTC/TAF/RTV</td>
</tr>
<tr>
<td></td>
<td>- Ethinol</td>
</tr>
<tr>
<td></td>
<td>- Antihypertensives</td>
</tr>
<tr>
<td></td>
<td>- Atorvastatin, lovastatin, simvastatin</td>
</tr>
<tr>
<td></td>
<td>- Rosuvastatin, pravastatin, fluvastatin, pitavastatin</td>
</tr>
</tbody>
</table>

Concomitant usage with:
- Acid reducing agents:
  - Antacids (e.g., aluminum and magnesium hydroxide)
  - H2-receptor antagonists (e.g., ranitidine)
- Digoxin
- HIV medications: Regimens containing tenofovir
- Rosuvastatin and atorvastatin

1. Co-administration of omeprazole is not recommended. If it is considered necessary to coadminister, velpatasvir/sofosbuvir should be administered with food and taken 4 hours before omeprazole (20 mg od).
2. Separate administration of omeprazole/sofosbuvir by 4 hours.
3. H2-receptor antagonists may be administered simultaneously with or 12 hours apart from velpatasvir/sofosbuvir at a dose that does not exceed 20mg twice daily.
4. Therapeutic monitoring of digoxin is recommended when co-administered with velpatasvir/sofosbuvir.
5. Monitor for transfusion-associated adverse reactions in patients receiving velpatasvir/sofosbuvir concomitantly with a regimen containing telaprevir.
6. Co-administration of HMG-CoA reductase inhibitors with velpatasvir/sofosbuvir will increase the concentration of the HMG-CoA reductase inhibitor. Rosuvastatin should be limited to 10 mg daily when co-administered with velpatasvir/sofosbuvir. Side effects of atorvastatin such as myopathy and rhabdomyolysis should be monitored when co-administered.

1. Carbamazepine, efavirenz, and St. John's wort may significantly decrease plasma concentrations of glecaprevir/pibrentasvir, leading to reduced therapeutic effect.
2. Co-administration with cyclosporine is not recommended in patients receiving cyclosporine > 100 mg per day.
3. Measure serum digoxin concentrations before initiating glecaprevir/pibrentasvir. Digoxin dose reduction of 50% may be required.
4. Follow dabigatran prescribing information for dose modifications in combination with P-gp inhibitors in the setting of renal impairment.
5. Co-administration with etoricoxib may increase the risk of ACP elevations, Co-administration with these statins is not recommended.
6. Increased statin concentration may increase the risk of myopathy including rhabdomyolysis. Co-administration with these statins is not recommended.
7. Rosuvastatin may be co-administered at a dose not to exceed 10 mg. Halve pravastatin dose by 50%, use the lowest approved dose of fluvastatin and pitavastatin.
Table 10: Ribavirin

<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy (during treatment and for 6 months afterward; also applies to partners of males who are treated)</td>
<td>None</td>
</tr>
<tr>
<td>Hemoglobinopathies (e.g., sickle cell, thalassemia major)</td>
<td></td>
</tr>
<tr>
<td>Hemolytic or other severe anemias</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency with serum creatinine &gt; 2.0</td>
<td></td>
</tr>
<tr>
<td>Unstable or significant cardiac disease.</td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency with serum creatinine &gt; 2.0</td>
<td></td>
</tr>
<tr>
<td>Co-administration with didanosine</td>
<td></td>
</tr>
<tr>
<td>Previously demonstrated hypersensitivity to the drug</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Sofosbuvir/Velpatasvir/Voxilaprevir (Vosevi®)

<table>
<thead>
<tr>
<th>Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previously demonstrated hypersensitivity to the drug</td>
<td></td>
</tr>
</tbody>
</table>

Concomitant usage with
- Antihypertensives: Candesartan, losartan, telmisartan, valsartan
- Digoxin
- Digoxin
- St. John’s wort

- Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Cyclosporine
- Dabigatran
- HIV medications: Regimens containing atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, or tenofovir DF

1. Severe bradycardia may occur with co-administration of amiodarone.
2. Drugs that increase gastric pH are expected to decrease concentrations of sofosbuvir/velpatasvir/voxilaprevir. Separate oral administration by 4 hours. Antacids may not be administered concomitantly. Separate antacid administration by 4 hours. Other PPIs have not been studied.
3. Therapeutic monitoring of digoxin is recommended when co-administered.
4. Clinical monitoring of dabigatran is recommended. Follow dabigatran prescribing information for dose modifications in the setting of renal impairment.
5. Increased statin concentration may increase the risk of myopathy including rhabdomyolysis. Co-administration with these statins is not recommended.
6. Increased risk of hypoglycemia including rhabdomyolysis. Use the lowest approved statin dose based on risk/benefit assessment.
Drug Selection

1. Selection of drug regimen is based on patient specific characteristics including genotype, prior HCV treatment history, degree of cirrhosis, and co-morbidities.

2. The treatment regimens listed below are no longer recommended unless completing a course of treatment that has been previously initiated.
   - Monotherapy with peginterferon
   - Dual therapy with peginterferon plus ribavirin
   - Triple therapy with peginterferon, ribavirin, plus boceprevir or telaprevir
   - Triple therapy with peginterferon, ribavirin, plus sofosbuvir

3. Antiretroviral regimen changes may be necessary prior to initiating HCV drug treatment due to drug-drug interactions.
   - Glecaprevir/pibrentasvir co-administration is contraindicated with atazanavir.
   - Glecaprevir/pibrentasvir co-administration is not recommended with darunavir, lopinavir, ritonavir and efavirenz.
   - Sofosbuvir/velpatasvir/voxilaprevir co-administration is not recommended with atazanavir, efavirenz, lopinavir, or tipranavir/ritonavir.
   - Sofosbuvir/velpatasvir/voxilaprevir should be used cautiously with tenofovir DF and patients should be monitored for adverse effects associated with tenofovir DF.
   - Velpatasvir/sofosbuvir should be used cautiously with HIV regimens containing tenofovir.
   - Velpatasvir/sofosbuvir should not be used with combinations containing efavirenz or tipranavir/ritonavir.

4. Discontinuation of therapy
   - If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6, then discontinue treatment.
Table 1: Drug Selection

<table>
<thead>
<tr>
<th>HCV Genotype</th>
<th>Treatment History</th>
<th>Cirrhosis Status</th>
<th>Preferred Regimen</th>
<th>Alternative Options (if RBV ineligible)</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1, G2, G3, G4, G5, G6</td>
<td>Naïve</td>
<td>No cirrhosis</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 12 weeks</td>
<td>n/a</td>
</tr>
<tr>
<td>G1, G2, G3, G4, G5, G6</td>
<td>Naïve</td>
<td>Compensated cirrhosis</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 12 weeks</td>
<td>n/a</td>
</tr>
<tr>
<td>GT1, GT2, GT3, GT4, GT5, GT6</td>
<td>Naïve or PEG/RBV Experienced</td>
<td>Decompensated cirrhosis</td>
<td>Epclusa + Ribavirin (Sofosbuvir/velpatasvir) + RBV x 12 weeks</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 24 weeks</td>
</tr>
<tr>
<td>GT1, GT2, GT3, GT4, GT5, GT6</td>
<td>PEG / RBV Experienced</td>
<td>No cirrhosis</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 12 weeks</td>
<td>n/a</td>
</tr>
<tr>
<td>GT1, GT2, GT3, GT4, GT5, GT6</td>
<td>PEG / RBV Experienced</td>
<td>Compensated cirrhosis</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 12 weeks</td>
<td>n/a</td>
</tr>
<tr>
<td>GT3</td>
<td>PEG / RBV Experienced</td>
<td>Compensated cirrhosis</td>
<td>Epclusa + Ribavirin (Sofosbuvir/velpatasvir) + RBV x 12 weeks</td>
<td>Vosevi (sofosbuvir/velpatasvir/voxilaprevir) x 12 weeks</td>
</tr>
<tr>
<td>GT3</td>
<td>NS3 + PEG/RBV Experienced</td>
<td>No cirrhosis</td>
<td>Epclusa (Sofosbuvir/velpatasvir) for 12 weeks</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Compensated cirrhosis = CTP Class A
Decompensated cirrhosis = CTP Class B or C
RBV = Ribavirin
*Starting dose of RBV 600mg/day is recommended with dose increases to 1000mg/day in patients <75kg and 1200mg/day in patients ≥75kg.
†RBV weight based dosing is recommended: 1000mg/day in patients <75kg and 1200mg/day in patients ≥75kg.
### Table 12: Hematological Dose Modification Guide

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Action</th>
</tr>
</thead>
</table>
| Hemoglobin 8.5 - 10 g/dL patient no cardiac disease | • Dose reduction: Ribavirin 600 mg/day  
• Continue dose direct-acting antiviral |
| Hemoglobin < 8 g/dL patient no cardiac disease | • Discontinue ribavirin until resolved†  
• May need to discontinue direct-acting antiviral |
| Hgb ≥ 2 g/dL reduction in 4 weeks patient with stable cardiac disease | • Dose reduction: Ribavirin 600 mg/day  
• Continue dose direct-acting antiviral |
| Hemoglobin < 12 g/dL after 4 weeks at reduced dosage patient with stable cardiac disease | • Discontinue ribavirin until resolved†  
• May need to discontinue direct-acting antiviral |

1. Once ribavirin is discontinued due to a laboratory abnormality or clinical adverse reaction, an attempt may be made to restart at 600 mg/day and further increase the dose to 800 mg/day. However, it is not recommended that ribavirin be increased to the original dose (1000 mg or 1200 mg).

2. Direct acting antiviral for hepatitis C (e.g., velpatisvir/sofosbuvir) may need to be discontinued. Consult experienced physician.

### Table 13: ALT Dose Modification Guide

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-fold increase in ALT at week 4</td>
<td>Promptly discontinue therapy</td>
</tr>
<tr>
<td>Any increase in ALT of less than 10-fold at week 4 if accompanied by any weakness, nausea, vomiting, or jaundice, or accompanied by increased bilirubin, alkaline phosphatase, or INR</td>
<td>Promptly discontinue therapy</td>
</tr>
<tr>
<td>Asymptomatic increases in ALT of less than 10-fold at week 4</td>
<td>Monitor ALT at week 6 and week 8. If levels remain persistently elevated, consideration should be given to discontinuation of therapy.</td>
</tr>
</tbody>
</table>

### Table 14: Renal Impairment Dose Modification

<table>
<thead>
<tr>
<th>Creatinine clearance</th>
<th>Ribavirin</th>
<th>Velpatisvir/sofosbuvir (Epclusa®)</th>
<th>Sofosbuvir/velpatasvir/ voxilaprevir (Vosevi®)</th>
<th>Glecaprevir/Pibrentasvir (Mavyret®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 to 50 mL/min</td>
<td>Alternating doses, 200 mg and 400 mg every other day</td>
<td>1 tablet once daily</td>
<td>1 tablet once daily</td>
<td>3 tablets once daily</td>
</tr>
<tr>
<td>&lt; 30 mL/min</td>
<td>200 mg once daily</td>
<td>No dosage recommendation*</td>
<td>No dosage recommendation*</td>
<td>No dosage adjustment required?</td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>200 mg once daily</td>
<td>No dosage recommendation*</td>
<td>No dosage recommendation*</td>
<td>No dosage adjustment required?</td>
</tr>
</tbody>
</table>

*Up to 20-fold higher exposures of predominant sofosbuvir metabolite.  
†Preferred agent in CKD 4 and 5.
<table>
<thead>
<tr>
<th>Drug Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Table 15: Velpatasvir/sofosbuvir</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Brand Name</strong></td>
<td>Epclusa®</td>
</tr>
<tr>
<td><strong>Special Notes</strong></td>
<td></td>
</tr>
<tr>
<td>• Store only in original container</td>
<td></td>
</tr>
<tr>
<td>• Treatment is not guided by on treatment HCV RNA response</td>
<td></td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Fixed-dose combination tablet velpatasvir 100mg/sofosbuvir 400mg</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>1 tablet orally once daily with or without food</td>
</tr>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td></td>
</tr>
<tr>
<td>• Direct-acting antiviral</td>
<td></td>
</tr>
<tr>
<td>Velpatasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication</td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of Therapy</strong></td>
<td></td>
</tr>
<tr>
<td>G1, G2, G4, G5, G6: Treatment naïve or treatment experienced with no cirrhosis or compensated cirrhosis</td>
<td></td>
</tr>
<tr>
<td>12 Weeks (GT3, treatment experienced, compensated cirrhosis: add ribavirin)</td>
<td></td>
</tr>
<tr>
<td>G1, G2, G4, G5, G6: Treatment naïve or treatment experienced with decompensated cirrhosis</td>
<td></td>
</tr>
<tr>
<td>12 Weeks with ribavirin</td>
<td></td>
</tr>
<tr>
<td><strong>Adverse effects</strong></td>
<td></td>
</tr>
<tr>
<td>• Fatigue (most common)</td>
<td></td>
</tr>
<tr>
<td>• Headache (most common)</td>
<td></td>
</tr>
<tr>
<td>• Nausea</td>
<td></td>
</tr>
<tr>
<td>• Fatigue</td>
<td></td>
</tr>
<tr>
<td>• Transient, asymptomatic lipase elevations of greater than 3 times upper limit of normal</td>
<td></td>
</tr>
<tr>
<td><strong>Drug Interactions</strong></td>
<td></td>
</tr>
<tr>
<td>• Acid reducing agents:</td>
<td></td>
</tr>
<tr>
<td>• Antacids (e.g., aluminum and magnesium hydroxide)</td>
<td></td>
</tr>
<tr>
<td>• H2 antagonists (e.g., ranitidine)</td>
<td></td>
</tr>
<tr>
<td>• Proton-pump inhibitors (e.g., omeprazole)</td>
<td></td>
</tr>
<tr>
<td>• Antidiabetic:</td>
<td></td>
</tr>
<tr>
<td>• Insulin</td>
<td></td>
</tr>
<tr>
<td>• Orlistat</td>
<td></td>
</tr>
<tr>
<td>• St. John's wort</td>
<td></td>
</tr>
<tr>
<td>• HMG-CoA Reductase Inhibitors:</td>
<td></td>
</tr>
<tr>
<td>• Atorvastatin and Rosuvastatin</td>
<td></td>
</tr>
</tbody>
</table>

1. Separate antacid and velpatasvir/sofosbuvir administration by 4 hours
2. Administer H2-receptor antagonist concomitantly with velpatasvir/sofosbuvir on 1-hour apart to a dose that does not exceed ranitidine 150mg bid
3. Co-administration of any proton pump inhibitor is not recommended. If it is considered medically necessary to co-administer, velpatasvir/sofosbuvir should be administered with food and 4 hours before antacid administration
4. Co-administration of amiodarone with velpatasvir/sofosbuvir may result in serious bradycardia. Co-administration is not recommended
5. Co-administration of atorvastatin and velpatasvir/sofosbuvir may result in serious bradycardia. Co-administration is not recommended
6. Co-administration of velpatasvir/sofosbuvir with efavirenz is not recommended as efavirenz may decrease the concentration of velpatasvir
7. Monitor for hMG-CoA Reductase Inhibitors: Atorvastatin and Rosuvastatin
8. Co-administration is not recommended
9. Co-administration of velpatasvir/sofosbuvir with immunosuppressive or antidiabetic medications increases the concentration of the statins, which is associated with increased risk of myopathy. Monitor closely for statin associated adverse reactions, such as myopathy and rhabdomyolysis.

*Note: refer to the manufacturer's product information for additional information and a complete list.
### Table 16: Glecaprevir/pibrentasvir

**Brand Name**
Mavyret®

**Special Notes**
- Store only in original container. Supplied in a 4-week (monthly) carton.
- Treatment is not guided by on-treatment HCV RNA response.
- Preferred in patients with CKD Stage 4 or 5.
- Contraindicated in patients with decompensated cirrhosis.

**Formulation**
Fixed-dose combination tablet glecaprevir 100mg/pibrentasvir 40mg

**Dose**
3 tablets orally once daily with food

**Mechanism of Action**
- Direct-acting antiviral
  - Glecaprevir is an inhibitor of the HCV NS3/4A protease, which is required for viral replication.
  - Pibrentasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication and viral assembly.

**Duration of Therapy**

| G1, G2, G3, G4, G5, G6: Treatment naïve without cirrhosis (compensated cirrhosis) | 8 weeks (12 weeks) |
| G1, G2, G4, G5, G6: PRS† treatment experienced without cirrhosis (compensated cirrhosis) | 8 weeks (12 weeks) |
| G3: PRS† treatment experienced with or without compensated cirrhosis | 16 weeks |

**Adverse effects**
- Fatigue (most common)
- Headache (most common)
- Nausea (most common)
- Elevated of total bilirubin

**Drug Interactions**
- Anticonvulsant: Carbamazepine
- Antimycobacterials: Rifampin
- HIV medications
  - Atazanavir
  - Darunavir, lopinavir, ritonavir
  - Efavirenz
- Cyclosporine
- Diltiazem
- Dapagliflozin
- Ethinyl estradiol
- St. John’s wort
- Antihyperlipidemics
  - Atorvastatin, lovastatin, simvastatin
  - Rosuvastatin, pravastatin, fluvastatin, pitavastatin

---

†Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

*Note: refer to the manufacturer’s product information for additional information and a complete list.

1. Carbamazepine, efavirenz, and St. John’s wort may significantly decrease plasma concentrations of glecaprevir/pibrentasvir, leading to reduced therapeutic effect.
2. Co-administration with atazanavir or rifampin is contraindicated.
3. Co-administration with cyclosporine is not recommended in patients receiving cyclosporine > 100 mg per day.
4. Measure serum digoxin concentrations before initiating glecaprevir/pibrentasvir. Digoxin dose reduction of 50% may be required.
5. Follow dabigatran prescribing information for dose modifications in combination with P-gp inhibitors in the setting of renal impairment.
6. Co-administration with ethinyl estradiol may increase the risk of ALT elevations.
7. Increased statin concentration may increase the risk of myopathy including rhabdomyolysis. Co-administration with these statins is not recommended.
8. Rosuvastatin may be co-administered at a dose not to exceed 10mg, reduce pravastatin dose by 50%, use the lowest approved dose of fluvastatin and pitavastatin.
**Table 17: Sofosbuvir/velpatasvir/voxilaprevir**

<table>
<thead>
<tr>
<th><strong>Brand Name</strong></th>
<th>Vosevi&lt;sup&gt;®&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Notes</strong></td>
<td></td>
</tr>
<tr>
<td>• Store only in original container</td>
<td></td>
</tr>
<tr>
<td>• Treatment is not guided by on-treatment HCV RNA response</td>
<td></td>
</tr>
<tr>
<td>• Not recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or severe renal disease (eGFR less than 30mL/min/1.73m²)</td>
<td></td>
</tr>
<tr>
<td>• Indicated for patients who are DAA treatment experienced</td>
<td></td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Fixed-dose combination tablet sofosbuvir 400mg/velpatasvir 100mg/voxilaprevir 100mg</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>1 tablet orally once daily with food</td>
</tr>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td></td>
</tr>
<tr>
<td>• Direct acting antiviral</td>
<td></td>
</tr>
<tr>
<td>• Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication</td>
<td></td>
</tr>
<tr>
<td>• Velpatasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication</td>
<td></td>
</tr>
<tr>
<td>• Voxilaprevir is an inhibitor of the HCV NS3/4A protease, which is required for viral replication</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of Therapy</strong></td>
<td></td>
</tr>
<tr>
<td>G1, G2, G3, G4, G6 previously treated with a NS5A inhibitor</td>
<td>12 weeks</td>
</tr>
<tr>
<td>G1a, G3 previously treated with sofosbuvir without an NS5A inhibitor</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>
| **Adverse effects**
| | |
| • Fatigue (most common) |
| • Headache (most common) |
| • Nausea (most common) |
| • Diarrhea (most common) |
| • Elevated total bilirubin, lipase, and creatine kinase |
| **Drug Interactions**
| | |
| • Antimicrobials: Rifampin, rifabutin, rifapentine |
| • Amiodarone<sup>2</sup> |
| • Acid reducing agents<sup>2</sup>
| | |
| • Antacids (e.g., aluminum and magnesium hydroxide)<sup>2</sup> |
| • Anticonvulsant: Carbamazepine, Oxcarbazepine, Phenobarbital, Phenytoin |
| • Cyclosporine |
| • Digoxin<sup>3</sup> |
| • Dabigatran<sup>4</sup> |
| • St. John’s wort |
| • HIV medications:
| | |
| • Regimens containing atazanavir, lopinavir, tipranavir/ritonavir, efavirenz, or tenofovir |
| • Antihyperlipidemics
| | |
| • Pravastatin, rosuvastatin, pitavastatin<sup>5</sup> |
| • Atorvastatin, fluvastatin, lovastatin, simvastatin<sup>6</sup> |

*Note: refer to the manufacturer’s product information for additional information and a complete list.

1. Severe bradycardia may occur with co-administration.
2. Drugs that increase gastric pH are expected to decrease concentrations of sofosbuvir/velpatasvir/voxilaprevir. Separate antacid administration by 4 hours. Acid reducing agents may be administered concomitantly. Omeprazole 20mg can be administered with sofosbuvir/velpatasvir/voxilaprevir. Other PPIs have not been studied.
3. Therapeutic monitoring of digoxin is recommended when co-administered.
4. Clinical monitoring of dabigatran is recommended. Follow dabigatran prescribing information for dose modifications in the setting of renal impairment.
5. Increased statin concentration may increase the risk of myopathy including rhabdomyolysis. Co-administration with these statins is not recommended.
6. Increased risk of myopathy including rhabdomyolysis. Use the lowest approved statin dose based on risk/benefit assessment.
### Table 18: Ribavirin

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Rebetol®, Ribasphere®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Notes</strong></td>
<td></td>
</tr>
<tr>
<td>• Not effective as monotherapy</td>
<td></td>
</tr>
<tr>
<td>• Pregnancy category X</td>
<td></td>
</tr>
<tr>
<td>• Do not use in pregnancy and for 6 months after treatment</td>
<td></td>
</tr>
<tr>
<td>• Must have a negative pregnancy test prior to therapy and monthly pregnancy tests</td>
<td></td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>200 mg capsule</td>
</tr>
<tr>
<td><strong>Weight Based Dose</strong></td>
<td></td>
</tr>
<tr>
<td>Weight &lt; 75 kg</td>
<td>• 400mg orally in the morning</td>
</tr>
<tr>
<td></td>
<td>• 600mg orally in the evening</td>
</tr>
<tr>
<td>Weight ≥ 75 kg</td>
<td>• 600mg orally twice daily</td>
</tr>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Not fully understood. Inhibits autonomous HCV RNA replication</td>
</tr>
<tr>
<td><strong>Adverse effects</strong></td>
<td></td>
</tr>
<tr>
<td>• Serious adverse effects:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Birth defects and fetal death</td>
</tr>
<tr>
<td></td>
<td>• Hemolytic anemia resulting in worsening of cardiac disease and myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>• Severe hyperammonemia reactions including cirrhosis, angioedema, bronchoconstriction, and anaphylaxis, and serious skin reactions such as Stevens-Johnson syndrome</td>
</tr>
<tr>
<td><strong>Drug interactions</strong></td>
<td></td>
</tr>
<tr>
<td>• Azathioprine due to reports of severe pancytopenia and myelotoxicity</td>
<td></td>
</tr>
<tr>
<td>• Didanosine due to reports of fatal hepatic failure, as well as peripheral neuropathy, pancreatitis, and symptomatic hyperlactatemia/lactic acidosis</td>
<td></td>
</tr>
<tr>
<td>• Zidovudine due to reports of severe neutropenia and anemia</td>
<td></td>
</tr>
</tbody>
</table>

*Note: refer to the manufacturer's product information for additional information and a complete list*
<table>
<thead>
<tr>
<th>Week of Treatment</th>
<th>Base-line</th>
<th>2</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>Post Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>12 weeks post treatment</td>
</tr>
<tr>
<td>HCV genotype</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV RNA PCR</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>CBC with diff</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>GFR</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>PT/INR</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Adherence</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBc, anti-Hbe, anti-HBsAg, anti-HAV</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alpha-fetoprotein (AFP)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver imaging studies</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
3. CBC = Complete blood count with differential
4. CMP = Complete metabolic panel includes albumin, alkaline phosphatase, AST, ALT, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
5. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6, then discontinue treatment.
### Monitoring Schedule for Ribavirin plus Velpatasvir/sofosbuvir (Epclusa®) – 12 WEEK SCHEDULE

<table>
<thead>
<tr>
<th>Week of Treatment</th>
<th>Baseline</th>
<th>2</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>Post Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 weeks post treatment</td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>✓</td>
<td>12 weeks post treatment</td>
</tr>
<tr>
<td>HCV genotype</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV RNA PCR</td>
<td>✓</td>
<td>x²</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Monthly x 6 months</td>
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<tr>
<td>Urine Pregnancy Test</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Monthly x 6 months</td>
</tr>
<tr>
<td>CBC with diff³</td>
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<td>✓</td>
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</tr>
<tr>
<td>CMP⁴</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Calculated Glomerular filtration rate (GFR)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>PT/INR</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Medication Adherence</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Anti-HBc, Anti-HBs, Anti-HBv, Anti-HAV</td>
<td>✓</td>
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<td></td>
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</tr>
<tr>
<td>EKG⁵</td>
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</tr>
<tr>
<td>Chest x-ray⁶</td>
<td>✓</td>
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<td></td>
</tr>
<tr>
<td>Alpha-fetoprotein (AFP)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver imaging studies</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitation.
3. Urine pregnancy test – females should be tested monthly during treatment and during the 6 months after treatment is stopped if childbearing potential.
4. CBC = Complete blood count with differential.
5. CMP = complete metabolic panel includes albumin, alkaline phosphatase, AST, ALT, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN.
6. If clinically indicated.
7. If detectable during treatment, report the viral load after 2 additional weeks of treatment (treatment week 4) if it has increased by greater than 10-fold (>1 log10 IU/mL) or repeat testing at week 6, then discontinue treatment.
## Monitoring Schedule for Velpatasvir/sofosbuvir (Epclusa®) – 24 WEEK SCHEDULE

<table>
<thead>
<tr>
<th>Week of Treatment</th>
<th>Baseline</th>
<th>2</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>16</th>
<th>20</th>
<th>24</th>
<th>Post Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>12 weeks post treatment</td>
</tr>
<tr>
<td>HCV genotype</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV RNA PCR</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>12 weeks post treatment</td>
</tr>
<tr>
<td>CBC with diff</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CMP</td>
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<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Calculated Glomerular filtration rate (GFR)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT/INR</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Adherence</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HBc, anti-HBx, HBsAg, anti-HAV</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td></td>
</tr>
<tr>
<td>Antinuclear antibody (ANA)</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alpha-fetoprotein (AFP)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td></td>
</tr>
<tr>
<td>Alpha-1 antitrypsin</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitation
3. CBC = Complete blood count with differential
4. CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
5. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6, then discontinue treatment.
**HIV DISEASE MANAGEMENT**

**Initial evaluation of HIV+ patients to be done at the intake facility by facility provider:**

1. Obtain medical history including sexual history, social history, medication history, & history of opportunistic infections.
2. Complete physical examination: vitals, weight, general exam, neurologic examination, and pelvic exam with PAP and GU/Hysterectomy. Perform pelvic exam every 6 months for HIV+ female patients.
3. Obtain baseline laboratories: CBC with differential, Chemistry profile to include LFTs, serum creatinine, fasting blood sugar and lipid profile, Hepatitis serology (HbsAg, Anti-HBc, anti-HBC total antibody), anti-HCV and anti-HAV viral antibodies. Syphilis screen (RPR). Ultrasound, calculated estimate of glomerular filtration rate (GFR) (available in Tools on the CMC Web), CD4+ lymphocyte analysis, HIV RNA viral load, Varicella-Zoster Immune Status, Chest X-ray, PPD skin test.
4. Screen patients for risk of chronic kidney disease by obtaining urinalysis, calculating GFR, and assessing risk. Risk factors include family history of renal disease, African American, CD4 < 200 cells/mm$^3$, VL > 400 copies/ml, certain diseases (diabetes, HTN, hepatitis C co-infection), & concomitant use of nephrotoxic agents. If 1+ proteinuria or calculated GFR < 60 ml/min/1.73m$^2$, consider further evaluation. If normal & high risk based on risk factors, reassess and recheck annually. If normal & patient does not have risk factors, reassess annually in chronic care clinic (CCC).
5. Update vaccines: influenza vaccine annually; pneumococcal vaccine with single revaccination 5 years after the first dose; hepatitis A & B vaccine if not already immune; varicella vaccine if CD4 > 200 and patient born after 1979 with no history of disease, vaccination, or evidence of immunity.
6. Initiate prophylactic medication(s) for opportunistic infection(s) as indicated in box A page 3 & box B page 4.
7. Refer all HIV+ patients regardless of CD4 count to the CMC Virology Clinic offered via DMS (UTMB sector) or designated physician (Texas Tech sector) for evaluation for antiretroviral treatment (ART). If patient refuses, contact the CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) for drug therapy and ITP recommendations.
   a. Expedited referrals should be obtained for patients that are symptomatic or have a CD4 count < 200 cells/mm$^3$. For patients on Selzentry® or Fuzeon® at intake, expedited referrals should be obtained within 2 weeks.

**Follow-up for HIV+ Patients:**

1. Evaluate in chronic care clinic at least every 6 months.
2. Refer patients with CD4 count > 300 cells/mm$^3$ to Ophthalmology for a retinal examination to rule out HIV retinopathy & CMV retinitis.
3. Laboratories: CD4 count every 3 to 6 months if patient meets the following criteria: not on treatment, during the first two years on ART or if treatment develops while on ART. For patients with CD4 > 300 cells/mm$^3$ and virally suppressed on treatment > 2 years, CD4 count may be measured every 6 to 12 months. HIV viral load is measured every 3 to 6 months unless the patient is stable and virally suppressed on treatment > 2 years, then can be extended to every 6 months. Obtain CBC with differential every 3 to 6 months and Chemistries including LFTs, serum creatinine, blood sugar, lipid profile at least annually.
4. Consider discontinuing prophylactic medication(s) for opportunistic infection(s) as indicated in box A & B, pages 3-4.

The pathways do not replace sound clinical judgment, nor are they intended to strictly apply to all patients.
When possible, it is preferred that all HIV medications and laboratories be ordered by the CMC Virology Clinic (UTMB sector) or designated physician (TT sector).

Is adherence for each drug \( \geq 80\%? \)

When adherence \( < 80\% \) for 2 consecutive months:
1) Provide adherence counseling and education. After 3 consecutive counseling attempts 1 month apart, can consider discontinuation.
2) Obtain expedited referral for evaluation by CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) to determine subsequent management.
3) Consideration may be given to discontinuing therapy in patients that do not want to continue therapy, or are non-adherent to medications and clinic appointments, due to the possibility of developing resistance and to pause therapy to reflect on treatment options.
4) Follow up in CCC at least every 3-6 months.

Obtain viral load.

Verify administration is correctly documented on the computer:
1) Counsel patient regarding the importance of adherence and warn patient noncompliance may lead to medication discontinuation.
2) Identify & treat adverse effects.
3) Return to clinic in 1 month.

Is adherence for each drug \( \geq 80\%? \)

Yes

Reinforce education

Return to clinic 1 month

No

Go To Box #5

When adherence \( < 80\% \) for 2 consecutive months:
1) Provide adherence counseling and education. After 3 consecutive counseling attempts 1 month apart, can consider discontinuation.
2) Obtain expedited referral for evaluation by CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) to determine subsequent management.
3) Consideration may be given to discontinuing therapy in patients that do not want to continue therapy, or are non-adherent to medications and clinic appointments, due to the possibility of developing resistance and to pause therapy to reflect on treatment options.
4) Follow up in CCC at least every 3-6 months.

Obtain viral load.

Has viral load decreased \( > 10 \text{ fold} \) (1 log)?

Yes

Continue current drug therapy:
1) Return to CCC at least every 6 months and CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) as indicated.
2) Laboratories: CD4 count every 3 to 6 months if not on treatment, during the first two years on ART; or if viremia develops while on ART. For patients with CD4 > 300 cells/mm\(^3\) and virally suppressed on treatment > 2 years, CD4 count may be measured every 6 to 12 months. HIV viral load is measured every 3 to 4 months unless the patient is stable and virally suppressed on treatment > 2 years, then may be extended to every 6 months.
3) Reinforce education at each visit.
4) Goal of therapy is 10 fold (1 log) decrease in viral load at 8 weeks, non-detectable viral load at 4-6 months after starting drug therapy & increased CD4 count.
5) Obtain expedited referral to CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) to consider change in drug therapy if:
   a. Goal viral load (non-detectable) not achieved within 4-6 months after starting drug therapy.
   b. Re-appearance of viremia after viral load is non-detectable (confirmed by at least 2 tests 4 weeks apart).
   c. Increase in viral load \( \geq 3 \text{ fold} \) from nadir (confirmed by at least 2 tests 4 weeks apart).
   d. Declining CD4 count (at least 2 tests);
   e. Severe, unusual, or life-threatening adverse effect suspected.
   f. Patient wants to discontinue therapy.

No

Go To Box #15

Has viral load decreased \( > 10 \text{ fold} \) (1 log)?

Yes

Repeat viral load in 1 month

No

Yes

Return to clinic in 1 month

Go To Box #15

Repeat viral load in 1 month

No

10

12

13

14

15

16

17

18

19

20

Continue current drug therapy so that reliable resistance testing may be obtained:
1) Refer patient to CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) to evaluate patient for poor adherence, intolerance, versus resistance & to consider changing drug therapy.
2) Reinforce education at each visit.
<table>
<thead>
<tr>
<th>Organism</th>
<th>Recommended Regimen</th>
<th>Alternative Regimen</th>
<th>Discontinuation Criteria****</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. tuberculosis PPD ≥ 5 mm</td>
<td>INH 10mg/kg/day (max 300mg) or 000mg twice a week x 9 months</td>
<td>Rifampin 600mg po qd or Rifabutin 300mg po qd x 4 months</td>
<td></td>
</tr>
<tr>
<td>S. pneumoniae (repeat one time only in 3 years)</td>
<td>Pneumococcal vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza virus</td>
<td>Influenza vaccine (one-dose annual)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A virus****</td>
<td>Hepatitis A vaccine to all susceptible patients (2-dose series)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B virus*</td>
<td>Hepatitis B vaccine (3 dose series)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. pneumoniae</td>
<td>Pneumococcal vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 200**</td>
<td>Dapsone 100mg qd</td>
<td>TMP-SMX DS Once daily or three times weekly</td>
<td>CD4 count &gt; 200 for &gt; 3 months Can consider when CD4 count 100-200 if HIV RNA remains below limit of detection for at least 3-6 months (restart if CD4 count &lt; 100 or 100-200 and HIV RNA above detection limit)</td>
</tr>
<tr>
<td>&gt; 100**</td>
<td>Dapsone 100mg qd + pyrimethamine 25mg q week</td>
<td>TMP-SMX DS Once daily or three times weekly</td>
<td>CD4 count &gt; 200 for &gt; 3 months Can consider when CD4 count 100-200 if HIV RNA remains below limit of detection for at least 3-6 months (restart if CD4 count &lt; 100 or 100-200 and HIV RNA above detection limit)</td>
</tr>
<tr>
<td>&lt; 50</td>
<td>Azithromycin 1200 mg q week</td>
<td>Clarithromycin 500mg bid or clarith 300mg qd</td>
<td>CD4 count &gt; 100 for ≥ 3 months (restart if CD4 count &lt; 50)**</td>
</tr>
</tbody>
</table>

* all susceptible (anti-HBc negative) patients
** start prophylaxis if have oropharyngeal candidiasis regardless of CD4 count
*** also antibody positive
**** primary prophylaxis for CMV and deep fungal infections is generally not recommended
***** in response to ART and virally suppressed

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved 9/96, reviewed 2/03, revised 4/97, 9/97, 9/98, 3/99, 7/02, 4/03, 1/04, 1/05, 5/06, 3/07, 5/07, 9/09, 7/10, 9/14, 5/15, 1/18

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### Box B: Secondary Prophylaxis of Opportunistic Infections

<table>
<thead>
<tr>
<th>Indication</th>
<th>Organism</th>
<th>Recommended Regimen</th>
<th>Alternative Regimen</th>
<th>Discontinuation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior PCP</td>
<td>Pneumocystis jirovecii</td>
<td>TMP-SMX 400 mg qd</td>
<td>TMP-SMX 400 mg qd = 6 hr + Pyrimethamine 25-50 mg po qd = Leucovorin 10-25 mg po qd</td>
<td>CD4 count &gt; 200 for &gt; 3 months (restart if CD4 count &lt; 100 for 100 or 100-200 and HIV RNA above detection limit or PCP recurrence)</td>
</tr>
<tr>
<td>Prior toplasmonic encephalitis</td>
<td>Toxoplasma gondii</td>
<td>Sulfadiazine 1000-2000 mg po bid + Pyrimethamine 15-30 mg po qd + Leucovorin 10-25 mg po qd</td>
<td>Clindamycin 600 mg po q6h + Pyrimethamine 25-50 mg po qd + Leucovorin 10-25 mg po qd</td>
<td>CD4 count &gt; 100 for &gt; 6 months</td>
</tr>
<tr>
<td>Prior disseminated disease</td>
<td>M. avium complex</td>
<td>Clarithromycin 600 mg po bid + Ethambutol 15 mg/kg po qd +/- Rifabutin 300 mg po qd</td>
<td>Azithromycin 500 mg po qd + Ethambutol 15 mg/kg po qd +/- Rifabutin 300 mg po qd</td>
<td>CD4 count &gt; 200 for &gt; 6 months</td>
</tr>
<tr>
<td>Prior genitourinary disease</td>
<td>Cytomegalovirus (CMV)</td>
<td>Ganciclovir 5 mg/kg IV 5-7 days a week or for retinitis ganciclovir 1 gm po TID x 6 weeks</td>
<td>Foscarnet IV 90 mg/kg/day, Cidofovir 5 mg/kg IV q 2 weeks, or Valganciclovir 900 mg po qd</td>
<td>CD4 count &gt; 100 for &gt; 6 months</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Cryptococcus neoformans</td>
<td>Fluconazole 200 mg po qd</td>
<td>Lamivudine 200 mg po qd, or Amphotericin 0.6 mg/kg IV weekly - 3 weeks max</td>
<td>CD4 count &gt; 200 for &gt; 3 months (restart if CD4 count &lt; 100)</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Histoplasma capsulatum</td>
<td>Itraconazole 200 mg po bid</td>
<td>Amphotericin 1 mg/kg IV weekly or Fluconazole 800 mg po qd</td>
<td>Histoplasma antigen &lt; 2 ng/mL, CD4 count &gt; 150 for &gt; 6 months (restart CD4 count &lt; 150)</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Coccidioides immitis</td>
<td>Fluconazole 400-600 mg po qd</td>
<td>Lamivudine 200 mg po bid or Amphotericin 1 mg/kg IV weekly</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Staphylococcal species</td>
<td>Linezolid 600 mg po bid x several months</td>
<td>Lamivudine 200 mg po bid or Amphotericin 1 mg/kg IV weekly</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Herpes simplex virus***</td>
<td>Acyclovir 400 mg po bid</td>
<td>Valacyclovir 500 mg po bid or Famciclovir 250 mg bid</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Candida*** (oropharyngeal, vulvovaginal, esophageal)</td>
<td>Fluconazole 100-200 mg po qd</td>
<td>Fluconazole 200 mg po qd</td>
<td></td>
</tr>
</tbody>
</table>

*if completed ≥ 12 months of treatment and asymptomatic
**if initial treatment completed, asymptomatic, & regular ophthalmology exams
***recommended only if subsequent episodes are frequent or severe
****in response to ART and virally suppressed
## Patient and Provider Education

### I. Who is educated?
- **A. Health Services Personnel** – updated on HIV so accurate and easy to understand information is provided to patients
- **B. All offenders with HIV**

### II. Who educates?
- **A. Unit team will delegate educational responsibility** - physicians and mid-level providers have the final responsibility to ensure education occurs
- **B. Educator must document education in patient’s chart**

### III. When does education take place?
- **A. Upon identification of having HIV**
- **B. Individual education at clinic visit**
- **C. Group education if available**

### IV. What is included in education?
- **A. Health Services Personnel**
  1. Pathophysiology & diagnostic criteria
  2. Monitoring parameters
  3. Pharmacologic treatments
  4. Adverse event monitoring & management
  5. Drug resistance & importance of adherence
  6. Opportunistic infections & prophylactic therapy
  7. Goals of therapy
- **B. Patients**
  1. Pathophysiology
  2. Routes of transmission
  3. Complications/risks of disease
  4. Pharmacologic treatments
  5. Monitoring parameters – frequency & importance
  6. Drug resistance & importance of adherence
  7. Individual treatment plan
  8. Dental hygiene to include daily brushing in the morning and evening and flossing once daily
<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions*</th>
<th>Adverse Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atripla® (emtricitabine 200mg, tenofovir 300mg, &amp; efavirenz 600mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Some as single entity drugs</td>
</tr>
<tr>
<td>Biktarvy® (bictegravir 50mg, emtricitabine 200mg, &amp; tenofovir alafenamide 25mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Headache, diarrhea, dizziness, nausea, increased LDL cholesterol</td>
</tr>
<tr>
<td>Cimduo® (lamivudine 300mg, &amp; tenofovir 300mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Same as single entity drugs</td>
</tr>
<tr>
<td>Combivir® (zidovudine 300 mg &amp; lamivudine 150mg)</td>
<td>1 tablet BID</td>
<td>Some as single entity drugs</td>
<td>Same as single entity drugs</td>
</tr>
<tr>
<td>Complera® (emtricitabine 200mg, tenofovir 300mg, &amp; rilpivirine 25mg)</td>
<td>1 tablet QD with food</td>
<td>Do not use if CrCl &lt; 50</td>
<td>Rifampin, carbamazepine, phenobarbital, phenytoin, H2 antagonists (ranitidine), proton pump inhibitors (omeprazole), dexamethasone</td>
</tr>
<tr>
<td>Delstrigo® (doravirine 100mg, lamivudine 300mg, &amp; tenofovir 300mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Sleep disturbance, dizziness, abnormal dreams, depression, dizziness, nausea, diarrhea, increased serum creatinine</td>
</tr>
<tr>
<td>Epzicom® (lamivudine 300mg &amp; abacavir 600mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Same as single entity drugs</td>
</tr>
<tr>
<td>Genvoya® (emtricitabine 200mg, tenofovir 300mg, elvitegravir 150mg, &amp; cobicistat 150mg)</td>
<td>1 tablet QD with food</td>
<td>Do not use if CrCl &lt; 30</td>
<td>Ergotamine, rifampin, carbamazepine, primidone, midazolam, lovastatin, Maraviroc, triazolam</td>
</tr>
<tr>
<td>Juluca® (dolutegravir 100mg, &amp; rilpivirine 25mg)</td>
<td>1 tablet QD</td>
<td>Some as single entity drugs</td>
<td>Nausea, diarrhea, headache, renal insufficiency, increased LDL cholesterol, decreased bone mineral density, lactic acidosis with hepatic steatosis</td>
</tr>
</tbody>
</table>

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; BID = twice daily; BID = bi-daily; BID = twice daily; cobi = cobicistat; d4T = stavudine; ddI = didanosine; EC = enteric coated; EFV = efavirenz; EVG = elvitegravir; FTC = emtricitabine; HSR = hypersensitivity reaction; MI = myocardial infarction; RPV = rilpivirine; TDF = tenofovir; TID = three times a day; WHO = World Health Organization; ZDV = zidovudine |

*not a complete list of drug interactions or adverse effects
**See “Nonformulary Conversion DMG” for formulary substitutions.
<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions*</th>
<th>Adverse Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stribild®**</td>
<td>1 tablet QD with food</td>
<td>Do not use if CrCl &lt; 70</td>
<td>Nausea, diarrhea, abnormal dreams, headache, insomnia, upper respiratory infection, renal insufficiency.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sym tbl Loct®</td>
<td>1 tablet QD with food</td>
<td>Do not use if CrCl &lt; 70</td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sym tbl Loct®</td>
<td>1 tablet QD with food</td>
<td>Do not use if CrCl &lt; 70</td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virmys®**</td>
<td>1 tablet QD with or without food</td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Virmys®**</td>
<td>1 tablet BID</td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vircordable®**</td>
<td>1 tablet QD</td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as single-entity drugs</td>
</tr>
</tbody>
</table>

**Key to Acronyms:** 3TC = lamivudine; ABC = abacavir; BID = twice daily; cobi = cobicistat; d4T = stavudine; ddI = didanosine; EC = enteric coated; EFV = efavirenz; EVG = elvitegravir; FTC = emtricitabine; FTC = emtricitabine; HSR = hypersensitivity reaction; MI = myocardial infarction; RPV = rilpivirine; TDF = tenofovir; TID = three times a day; WHO = World Health Organization; ZDV = zidovudine

*not a complete list of drug interactions or adverse effects

**See "Nonformulary Conversion DMG" for formulary substitutions.
# Medication Guide

## Table 2: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions*</th>
<th>Adverse Effects*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abacavir (ABC, Ziagen)</td>
<td>300mg BID or 600mg QD</td>
<td>Hypersensitivity reaction characterized by fever, nausea, vomiting, malaise, anorexia, respiratory symptoms, +/− rash Should not be restarted if occurs. Record in medical record as allergy.</td>
<td>Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Didanosine EC (ddI, Videx EC)</td>
<td>&gt; 60kg 400mg QD or &lt; 60kg 250mg QD</td>
<td>Tendinitis, myalgia</td>
<td>Peripheral neuropathy, non pancreatic, nausea, diarrhea Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Emtricitabine (FTC, Emtriva)</td>
<td>Non-formulary 200mg QD</td>
<td></td>
<td>Minimal effects Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Lamivudine (3TC, Epivir)</td>
<td>150mg BID or 300mg QD</td>
<td></td>
<td>Minimal effects Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Stavudine (d4T, Zerit)</td>
<td>Non-formulary &gt; 60kg 40mg BID or &lt; 60kg 30mg BID</td>
<td></td>
<td>Peripheral neuropathy, lipodystrophy, hyperlipidemia, pancreatitis</td>
</tr>
<tr>
<td>Tenofovir (TDF, Viread)</td>
<td>300mg QD best if taken with food</td>
<td></td>
<td>GI upset, flatulence, headache, asthenia, renal insufficiency</td>
</tr>
<tr>
<td>Zidovudine (AZT, ZDV, Retrovir)</td>
<td>300mg BID</td>
<td></td>
<td>Initial GI upset, headache, nail discoloration, fatigue, anemia, neutropenia, myopathy</td>
</tr>
</tbody>
</table>

*Not a complete list of drug interactions or adverse effects.

**Moderate reverse transcriptase inhibitor (MRTIs)**

HIV: Human immunodeficiency virus
### Table 3: Protease Inhibitors (PIs)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage*</th>
<th>Drug Interactions**</th>
<th>Adverse Effects**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atenviroz (ATV, Reyataz)</td>
<td>400mg QD best if taken with food or 600mg BID with food</td>
<td>Clarithromycin, diltiazem, lovastatin, rifabutin, rifapentine, ergotamine, H2 antagonists (contendable), proton pump inhibitors (contendable), rifabutin, amiodarone</td>
<td>Diarrhea, nausea, prolongation of the PR interval, hyperbilirubinemia, pancreatitis, fat redistribution, increase bleeding in hemophilia</td>
</tr>
<tr>
<td>Darunavir (DRV, Prezista)</td>
<td>800mg BID</td>
<td>Levorphanol, thalidomide, pregabalin, quinidine, clozapine, theophylline, cobicistat</td>
<td>Hypersensitivity, fat redistribution, increased bleeding in hemophilia</td>
</tr>
<tr>
<td>Fosamprenavir (FPV, Lexiva)</td>
<td>1400mg BID</td>
<td>Carbamazepine, lovastatin, rifampin, rifabutin, rifapentine, ergotamine</td>
<td>Diarrhea, nausea, vomiting, rash, hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia</td>
</tr>
<tr>
<td>Indinavir (IDV, Crixivan)</td>
<td>800mg q 8 hr drink plenty of fluids, best if taken on empty stomach, best if separate dosing with ddI by 1 hr</td>
<td>Carbamazepine, lovastatin, rifampin, rifabutin, rifapentine, ergotamine</td>
<td>Nephrolithiasis, GI intolerance, nausea, metallic taste, hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia</td>
</tr>
<tr>
<td>Lopinavir 200mg + Ritonavir 50mg (LPV/r, Kaletra)</td>
<td>2 tabs BID or 4 tabs QD</td>
<td>Lovastatin, rifampin, rifabutin, rifapentine, ergotamine</td>
<td>Nausea, vomiting, diarrhea, rash, elevated LFTs</td>
</tr>
<tr>
<td>Nelfinavir (NFV, Viracept)</td>
<td>1250mg BID best if taken with meal or snack</td>
<td>Atorvastatin, lovastatin, rifampin, rifabutin, rifapentine, ergotamine</td>
<td>Diarrhea, hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia</td>
</tr>
<tr>
<td>Ritonavir (RTV, Norvir)</td>
<td>600mg q 12hr food may decrease GI upset</td>
<td>Lovastatin, amiodarone, quinidine, clozapine, theophylline, cobicistat</td>
<td>Nausea, vomiting, diarrhea, pruritus, rash, paresthesias, pancreatitis, elevated LFTs, hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia</td>
</tr>
<tr>
<td>Saquinavir (SQV, Invirase)</td>
<td>SQV 1000 + RTV 100 BID (must be given with RTV) Take with meals or within 2 hours after meal</td>
<td>Lovastatin, rifampin, rifabutin, rifapentine, ergotamine</td>
<td>Nausea, vomiting, diarrhea, rash, elevated LFTs</td>
</tr>
<tr>
<td>Tipranavir (TPV, Aptivus)</td>
<td>500mg + RTV 200mg BID (must be given with RTV) Best taken with food</td>
<td>Lovastatin, amiodarone, quinidine, clozapine, theophylline, cobicistat</td>
<td>Hypersensitivity, rash, hyperlipidemia, hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia</td>
</tr>
</tbody>
</table>

*dosage if used as the only PI in the drug regimen, dosages are often adjusted if used in combination with other agents

**not a complete list of drug interactions or adverse effects
Delavirdine
(DLV, Rescriptor®)
Non-formulary
400mg TID
Lovastatin, rifampin, rifapentine, rifabutin, H2 antagonists (ranitidine), proton pump inhibitors (omeprazole), ergotamine, dapsone, phenytoin, warfarin, carbamazepine, quinidine, clarithromycin
Rash, elevated LFTs, headache

Nevirapine
(NVP, Viramune®)
200mg QD x 14 days then 200mg BID or 400mg QD
Ketoconazole, rifampin, phenytoin, carbamazepine
Rash, elevated LFTs, hepatitis

Elvitegravir
(EVG)
Only as Genvoya® (Prior Authorization) or Stribild® (Non-formulary)
Tablet once daily with food
Ergotamine, rifampin, cisapride, primidone, midazolam, lovastatin, maraviroc, triazolam
Nausea, diarrhea, abnormal dreams, headache, lipoatrophy
Lactic acidosis with hepatic steatosis.

Raltegravir
(RAL, Isentress®)
400mg BID
With rifampin
800mg BID
Nausea, headache, diarrhea, pyrexia, fatigue, elevated CPK
HIV
Page 10
<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions*</th>
<th>Adverse Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CCR5 Antagonist</strong></td>
<td></td>
<td><strong>With Protease Inhibitors except</strong></td>
<td>Abdominal pain, cough, disorientation, musculoskeletal symptoms, pyrexia, rash,</td>
</tr>
<tr>
<td>Maraviroc (MVC, Selzentry®)</td>
<td></td>
<td>- Enfuvirtide, tipranavir, delavirdine, ketoconazole, clarithromycin</td>
<td>upper respiratory tract infections, hepatotoxicity, neutropenia</td>
</tr>
<tr>
<td>Non-formulary</td>
<td></td>
<td>- 150mg BID With all NRTI, Enfuvirtide, TPV, NVP</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 50mg BID With EFV, rifampin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- 600mg BID With EFV, rifampin, carbamazepine, phenytoin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>**Potent CYP3A inhibitors such as protease inhibitors, delavirdine, ketoconazole,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- clarithromycin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>**Potent CYP3A inducers such as efavirenz, rifampin, clarithromycin, phenytoin,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>clarithromycin</td>
<td></td>
</tr>
<tr>
<td><strong>Fusion Inhibitor</strong></td>
<td></td>
<td>90mg SQ BID</td>
<td>Local injection site reaction (e.g., pain, erythema, induration, nodules, cysts),</td>
</tr>
<tr>
<td>Enfuvirtide (T20, Fuzeon®)</td>
<td></td>
<td></td>
<td>increased rate of pneumonia, hypersensitivity reaction (rechallenge is not</td>
</tr>
<tr>
<td>Non-formulary</td>
<td></td>
<td></td>
<td>recommended)</td>
</tr>
<tr>
<td><strong>Anti-CD4 Monoclonal Antibody</strong></td>
<td></td>
<td>2000mg IV loading dose followed by 800mg IV every 2 weeks</td>
<td>Dizziness, skin rash, diarrhea, nausea, decreased neutrophils, leukopenia,</td>
</tr>
<tr>
<td>Ibalizumab (IBA, Trogarzo®)</td>
<td></td>
<td></td>
<td>increased serum creatinine</td>
</tr>
<tr>
<td>Non-Formulary</td>
<td></td>
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</tbody>
</table>

*Key to Acronyms: 3TC = lamivudine; ABC = abacavir; BID = twice daily; cobicistat = cobicistat; ddI = didanosine; d4T = stavudine; HAART = antiretroviral therapy; Efav = efavirenz; EVG = elvitegravir; FTC = emtricitabine; HHS = hypersensitivity reaction; MI = myocardial infarction; RPV = rilpivirine; TDF = tenofovir; TID = three times a day; WHO = World Health Organization; ZDV = zidovudine

*Not a complete list of drug interactions or adverse effects
I. Background
A. More than 50% of people do not know they are HIV-infected until they become symptomatic (an indicator of advanced disease).
B. Since the correctional setting is often an offender’s first interaction with the health care system, a thorough history of risk factors is important and HIV testing should be recommended to all new intakes.

II. Biology
A. HIV (human immunodeficiency virus)
   1. Member of the Lentivirus family of retroviruses.
   2. There are two subtypes: HIV-1 and HIV-2. HIV-1 is the primary subtype in the U.S. HIV-2 is the primary subtype in Africa and is molecularly and serologically distinct. The two subtypes share only about 40% amino acid homology in their env surface glycoproteins.
   3. HIV is characterized by the presence of three main genes. The gag gene encodes for structural proteins of the viral core, the env gene encodes for the surface proteins of the virus, and the pol gene encodes for functional proteins including reverse transcriptase, ribonuclease, integrase, and protease.
B. AIDS (acquired immunodeficiency syndrome)
   1. Clinical syndrome characterized by profound immunologic deficits (CD4 count < 200 cells/mm³), opportunistic infections, and malignant neoplasms seen with prolonged HIV infection.

III. Transmission
A. All routes of transmission involve contact with contaminated blood or bodily fluids
   1. Parenteral
      1. Occupational exposure - needle sticks
      2. Intravenous drug use - sharing contaminated needles
      3. Blood transfusion
      4. Organ transplant
   2. Sexual
      1. Vaginal intercourse
      2. Anal intercourse
      3. Oral intercourse
   3. Perinatal

IV. Presentation
A. Early
   1. Symptoms: fever, lymphadenopathy, pharyngitis, rash, myalgia, arthralgia, diarrhea, headache, nausea, vomiting, hepatitis/nausea, weight loss
   2. Positive HIV antibody usually develops by 4-6 weeks following transmission, but rarely could be up to 12-24 weeks.
   3. Extremely high levels of HIV in the blood during acute infection is a hallmark of this disease stage.
   4. Within days, HIV disseminates into sanctuary sites (lymph nodes, central nervous system) where it “hides out” and remains dormant.
   5. HIV viral levels decrease over the first 4 months post-transmission until plateauing to a set point (varies person to person).
   6. Lower HIV viral set point = longer time it will take for an individual’s disease to progress over time.
B. Intermediate
   1. T cell destruction by HIV begins to weaken the immune system over time (in contrast to the acute stage, where the immune system “keeps pace” by producing an equivalent amount of CD4 cells).
   2. In general, if untreated, there is an 8-10 year period during which an HIV+ individual undergoes a gradual decline in immune function (monitored by laboratory testing of CD4 count) and increase in HIV viral load (monitored by laboratory testing of viral load).
   3. Often no symptoms exhibited during this stage.
   4. Factors which influence how long individuals will remain in this stage before progressing to advanced disease:
      a. How high the viral load is at set point
      b. If and when antiretroviral treatment is initiated
C. Late
   1. Untreated, the rapid replication of HIV will eventually deplete the immune system in most people to such an extent that the patient will lose critical body defenses and can succumb to infections, AIDS, and ultimately death.
   2. Symptoms: opportunistic infections or malignancies, rash, neurosyphilis, diarrhea, recurrent vaginal candidiasis, thrush, herpes zoster, recurrent infections, anemia, weight loss.
   3. Actual diagnosis of AIDS is made when the CD4 count falls below 200 cells/mm³ or when an AIDS-defining condition is diagnosed.
   4. Once a diagnosis of AIDS has been made, it remains with the patient even if his/her CD4 count returns to above 200 with antiretroviral therapy.
V. Diagnosis
A. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection.

No further testing is required for specimens that are nonreactive on the initial immunoassay.

B. Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies.

Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.

C. Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).

VI. Treatment
A. Recommendations for ART therapy

1. ART is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection.

2. ART is also recommended for individuals with HIV to prevent HIV transmission.

3. Primary Care providers should refer patients to CMC Virology Clinic (UTMB Sector) or designated physician (Texas Tech Sector) for recommendations and initiation of therapy.

4. The following ART drugs are no longer recommended for use because of suboptimal antiviral potency, unacceptable toxicities, high pill burden, or pharmacologic concerns: delavirdine (DLV), didanosine (ddI), indinavir (IDV), nelfinavir (NFV), and stavudine (d4T).

B. Table 7: Antiretroviral Regimens or Components That Should Not Be Offered At Any Time*

<table>
<thead>
<tr>
<th>Antiretroviral Regimens Not Recommended</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monotherapy (AI)</td>
<td>NRTI monotherapy is inferior to dual-NRTI therapy</td>
</tr>
<tr>
<td></td>
<td>PI monotherapy is inferior to combination ART</td>
</tr>
<tr>
<td></td>
<td>INSTI monotherapy has resulted in virologic rebound and INSTI resistance</td>
</tr>
<tr>
<td>Dual-NRTI regimens (AI)</td>
<td>Rapid development of resistance</td>
</tr>
<tr>
<td></td>
<td>Inferior ARV activity when compared with combination of three or more ARV agents</td>
</tr>
<tr>
<td>Triple-NRTI regimens (AI)</td>
<td>Triple-NRTI regimens have suboptimal virological activity</td>
</tr>
</tbody>
</table>

*adapted from Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents
Table 7: Antiretroviral Regimens or Components That Should Not Be Offered At Any Time* (continued)

<table>
<thead>
<tr>
<th>Antiretroviral Components Not Recommended as Part of an Antiretroviral Regimen*</th>
<th>Potential adverse drug interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATV + RTV (AIII)</td>
<td>This combination may be prescribed inadvertently, which may result in additive CYP3A4 enzyme inhibition and may further increase the concentrations of ARV drugs or other concomitant medications.</td>
</tr>
</tbody>
</table>
| ddI + d4T (AII) | • High incidence of respiratory, peripheral neuropathy, pancreatitis, and hepatotoxicity.  
• Reports of severe, even fatal, cases of toxic epidermal necrolysis with or without gastrointestinal involvement. |
| ddI + TDF (AII) | • Increased ddI concentrations and serious ddI-associated toxicities.  
• Potential for immunologic cross-reactivity across CD4 cells.  
• Rapid selection of resistance variants at failure. |
| 2-NRTI combination (AII) | • When EFV combined with NVP, higher incidence of clinical adverse events seen when compared with either EFV- or NVP-based regimens.  
• Both EFV and NVP may induce metabolism and may lead to reductions in ETR exposure; thus, they should not be used in combination with ETR. |
| FTC + 3TC (AIII) | • Similar resistance profiles.  
• No potential benefit. |
| ETR + unboosted PI (AII) | • ETR may induce metabolism of these PIs; appropriate doses not yet established. |
| ETR + RTV-boosted PPV (AII) | • ETR may alter the concentrations of these PIs, appropriate doses not yet established. |
| ETR + RTV-boosted TPV (AII) | • ETR concentrations may be significantly reduced by RTV-boosted TPV. |
| NVP in ARV-naive women with CD4 count >250 cells/mm³ or men with CD4 count >400 cells/mm³ (BII) | • High incidence of symptomatic lactoacidosis. |
| d4T + ZDV (AII) | • Antagonistic effect on HIV-1. |
| Unboosted DRV, SQV, or TPV (AII) | • The virologic benefit of these PIs has been demonstrated only when they are used with concomitant RTV, or in the case of DRV, also with Cobicistat. |
| TAF + TDF | • This combination may be prescribed inadvertently, especially during transition from one formulation to another. There is no data supporting any potential additive efficacy or toxicity if TAF and TDF are used in combination. |

*Acronyms: ATV = atazanavir, ABC = abacavir, ATV = atazanavir, COBI = cobicistat, d4T = stavudine, ddI = didanosine, EFV = efavirenz, ETR = etravirine, FPV = fosamprenavir, FTC = emtricitabine, IDV = indinavir, TDF = tenofovir, TAF = tenofovir alafenamide, TPV = tipranavir, ZDV = zidovudine

*adapted from Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.
VII. Monitoring Therapy

A. CD4 Count
1. Indicator of immune system damage and risk for developing opportunistic infection, i.e., measure of immunological response
2. Specifically, it is a measure of the peripheral pool of CD4 cells which only accounts for approximately 2% of total lymphocyte population in the body
3. Together with viral load it is used to predict a patient’s risk for disease progression
4. Used to determine when to start or stop opportunistic infection prophylaxis
5. Measurements can vary due to technical & biological variations and have diurnal variation. As a result, it is important to follow the trend in CD4 count versus single value.
6. CD4 count should be monitored at baseline and every 3 to 12 months based on patient status
7. +/- 30% change is considered a significant change

B. Viral Load
1. Indicator of the magnitude of viral replication & response to drug therapy, i.e., virological response
2. Specifically, it is a measure of viral replication and is reported as number of viral copies/ml of blood
3. Used to monitor a patient’s response to drug therapy
4. Decisions should be based on 2 measurements obtained 1-2 weeks apart due to technical & biological variations
5. Do not obtain within 4 weeks of intercurrent illness or immunization
6. Monitor at baseline, 2-8 weeks after initiating or changing therapy, and every 3 to 6 months thereafter based on status
7. > 0.5 log or 3-fold change in viral load is considered significant
8. Should see 1 log (10-fold) decrease in viral load within 8 weeks (may take as long as 16 weeks if very high) of initiating drug therapy and should be undetectable within 4-6 months

C. Resistance Testing
1. Should be performed by experienced provider (e.g., Infectious Diseases Specialist) since requires expert interpretation
2. Absence of resistance should be interpreted cautiously in conjunction with previous drug use history
3. Should be performed at baseline, while on antiretroviral therapy or immediately (within 4 weeks) after discontinuation of therapy
4. Should not be performed if viral load < 1,000 copies/ml because amplification of virus is unreliable

D. HLA-B*5701 screening
1. Should be considered prior to prescribing abacavir. Abacavir should not be prescribed if positive and an abacavir allergy should be recorded in the patient’s medical record.

E. CCR5 Receptor Tropism Assay
1. Must be obtained prior to prescribing a CCR5 inhibitor.

F. Response to Therapy
1. Generally see virologic, immunologic, and then clinical progression when a patient is failing therapy. These stages may be separated by months to years and discordant responses are possible
2. Virologic Failure
   a. Incomplete virologic response: VL ≥ 200 copies/ml after 24 weeks of therapy
   b. Virologic rebound is the confirmed detectable HIV RNA (to ≥ 200 copies/mL) after virologic suppression.
   c. This excludes isolated episodes of viremia (i.e., single level 50-1000)
3. Immunologic Failure
   a. Failure to increase CD4 count by 25-50 cells/mm³ above baseline over 1 year
   b. CD4 count decreases below baseline
   c. Immunologic failure may not warrant drug therapy change if viral load is undetectable
   d. In the setting of virologic suppression, there is no consensus on how to define or treat immunologic failure.
4. Clinical Progression
   a. Occurrence or recurrence of HIV-related illness after 3 months excluding immune reconstitution which is generally seen within first 3 months of starting therapy
   b. Clinical progression may not warrant drug therapy change if viral load is undetectable
**HYPERLIPIDEMIA**

The pathways do not replace sound clinical judgment; they are intended to strictly apply to all patients based on clinical factors influencing ASCVD risk and potential ASCVD risk reduction benefits, adverse effects, and drug interactions for statin treatment.

1. Does the patient meet criteria for dyslipidemia evaluation? Screen patients:
   - Males > 35 years, females > 40 years, use clinical judgment based on life expectancy when screening patients > 75 years
   - Patients at risk for familial dyslipidemia
   - Patients with diabetes
   - History of clinical atherosclerotic cardiovascular disease (ASCVD)

   **Yes**
   - Go to box 12
   - Recalculate

   **No**
   - Continue as clinically indicated

2. If unclear, consider factors:
   - History of clinical diabetes mellitus, hyperlipidemia, chronic renal disease, obstructive lung disease, drugs eg, progestins, anabolic steroids, corticosteroids, antidepressants
   - Baseline laboratories: urinalysis, thyroid function tests, lipid profile (fasting when possible, comprehensive metabolic panel)

3. Does the patient fall into one of the following groups?
   - Clinical ASCVD
   - Low-density lipoprotein (LDL) ≥ 190 and < 210

   **Yes**
   - Go to box 12
   - Recalculate

   **No**

4. Calculate estimated 10 year ASCVD risk (calculator on CMC webpage and additional information page 6).

5. Does the patient have diabetes, LDL ≥ 160 mg/dL, and age 40 – 75 years?

   **Yes**
   - Go to box 12
   - Recalculate

   **No**

6. In patient age 40 – 75 years, LDL ≥ 190 mg/dL, and estimated 10 year ASCVD risk ≥ 7.5%?

   **Yes**
   - Go to box 12
   - Recalculate

   **No**

7. If the patient has a 10 year ASCVD risk ≥ 7.5%, age > 40 or > 75 years and LDL > 190 mg/dL, or diabetes and age > 40 or > 75 years or LDL > 190 mg/dL:

   - Review additional factors influencing ASCVD risk and potential ASCVD risk reduction benefits, adverse effects, and drug interactions for statin treatment.
   - If unclear, consider factors influencing risk including primary LDL > 160 mg/dL or other evidence of patient hyperlipidemia, family history of premature ASCVD with onset < 55 years in a first degree male relative or < 65 years in a first degree female relative, high sensitivity C reactive protein ≥ 2 mg/L, ankle brachial index < 0.9, or elevated lifetime risk of ASCVD.

   If a statin is not initiated:
   - A fasting lipid profile should be obtained as clinically indicated or every 5 years
   - Baseline estimated 10 yr ASCVD risk every 5 years in individuals aged 40-75 years
   - For isolated hypertriglyceridemia see box 18.

8. Low intensity statin:
   - pravastatin 10-20 mg
   - atorvastatin 10-20 mg

   Moderate-intensity statin:
   - atorvastatin 20-40 mg
   - simvastatin 20-40 mg
   - pravastatin 40 mg

   High-intensity statin:
   - atorvastatin 80 mg
   - simvastatin 80 mg
   - pravastatin 80 mg

   Moderate-intensity therapy should be used instead of high-intensity therapy if any of the following factors are present that are associated with increased risk of statin adverse effects:
   - Multiple or severe comorbidities, including:
     - History of severe or more than moderate chronic kidney disease
     - History of severe or more than moderate chronic heart failure
     - History of severe or more than moderate chronic liver disease
     - History of severe or more than moderate chronic pulmonary disease
   - Patients characteristics or concurrent use of drugs affecting statin metabolism
   - >70 years

9. Does patient have history of ASCVD (eg, ACS, or a history of MI, stroke, or other arterial revascularization, redo, TIA, or PAD preceded by a <1% risk of a cardiovascular event in the next 5 years)?

   **Yes**
   - Go to box 12
   - Recalculate

   **No**

10. Does patient have diabetes, LDL > 189 mg/dL, and age 40 – 75 years?

11. Is patient age 40 – 75 years?

12. Is patient age 40 – 75 years in the following groups?

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114. Is patient age 40 – 75 years?
Goal therapeutic response met?

- Low intensity statin*: LDL lowering of <30%
- Moderate intensity statin ‡: LDL lowering of 30% to 49%
- High intensity statin†: LDL lowering of ≥50%

LDL levels and percent reduction are to be used to assess response to therapy and adherence.

Assess for intolerance to statin therapy.
Reinforce medication adherence.

If LDL levels are <40mg/dL on two consecutive readings, decreasing the statin dose may be considered.

1. Adherence to lifestyle modifications and to statin therapy should be re-emphasized before the addition of a non-statin drug is considered.
2. If clinically indicated, may consider increasing statin dose; however, there is no evidence that titration of statin therapy to achieve specific LDL levels or percent reduction improved ASCVD outcomes.
3. If high risk patients on high intensity statin have inadequate LDL lowering response, may consider addition of non-statin cholesterol lowering drug(s) if the ASCVD risk reduction benefit outweighs potential risk for adverse effects.

High risk groups:
- Individuals with clinical ASCVD who are <75 years
- Individuals with baseline LDL ≥190 mg/dL
- Individuals 40-75 years with diabetes

There is limited data supporting the routine use of non-statin drugs combined with statin therapy to reduce further ASCVD events.

Follow up as clinically indicated or at least annually.

* Low intensity statin: pravastatin 10-20mg
‡ Moderate intensity statin: atorvastatin 10-20mg, pravastatin 40-80mg
† High intensity statin: atorvastatin 40-80mg
Overall, the treatment of elevated triglyceride levels <500 mg/dL focuses on intensive therapeutic lifestyle change as outlined in Table 1.

### Table 1: Effects of Nutrition Practices on Triglyceride Lowering

<table>
<thead>
<tr>
<th>Nutrition Practice</th>
<th>TG-Lowering Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss (5% to 10% of body weight)</td>
<td>20%</td>
</tr>
<tr>
<td>Decrease carbohydrates 1% energy replacement with MUFA/PUFA</td>
<td>1-2%</td>
</tr>
<tr>
<td>Eliminate trans-fat 1% energy replacement with MUFA/PUFA</td>
<td>1%</td>
</tr>
</tbody>
</table>

### Table 2: Causes of Very High Triglycerides that May be Associated with Pancreatitis

- Genetic:
  - Lipoprotein lipase deficiency
  - Apolipoprotein CII or AV deficiency
  - GPIHBP1 deficiency
  - Mariesco-Sjogren syndrome
  - Chylomicron retention disease
- Familial hypertriglyeridemia (in combination with acquired causes)
- Acquired disorders of metabolism:
  - Hypothyroidism
  - Pregnancy
  - Poorly controlled insulinopenic diabetes
- Drugs:
  - Alpha-interferon
  - Atypical antipsychotics
  - Beta-blockers
  - Bile acid resins (cholestyramine)
  - Estrogens, oral
  - Protease inhibitors
  - Raloxifene
  - Sirolimus
  - Steroids
  - Tamoxifen
  - Thiazides
  - Untreated hypercholesterolemia
  - Acetoacetate

### Once therapy is initiated:
1. Enroll in Chronic Care Clinic.
2. Follow up in 12-weeks and repeat lipid profile to assess response and compliance with lifestyle modifications.
3. Monitor LFTs if symptoms suggest hepatotoxicity (e.g., unusual fatigue or weakness, loss of appetite, abdunmenal pain, dark colored urine, or yellowing of skin or sclera).
4. Monitor creatine phosphokinase if patient has symptoms associated with myopathy (e.g., pain, tenderness, stiffness, cramping, weakness, or generalized fatigue).
5. Follow up at least annually or at least annually.

Prepared by: The Correctional Managed Care Pharmacy & Therapeutics Committee.

Table 3: Formulary Statin Therapy as recommended by ACC/AHA

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Starting Dose</th>
<th>Effect on Lipids</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statins</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pravastatin</td>
<td>40-80mg</td>
<td>LDL ↓18-55%</td>
<td>myopathy absolute: liver disease</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>10-20mg</td>
<td>HDL ↑5-15%</td>
<td>LFT relative: certain drugs</td>
</tr>
<tr>
<td>Cholestryramine</td>
<td>4gm QID</td>
<td>LDL ↓15-30%</td>
<td>GI upset relative: dysbetalipoproteinemia</td>
</tr>
<tr>
<td>Gemfibrozil</td>
<td>600mg BID</td>
<td>HDL ↑10-20%</td>
<td>myopathy unexplained non-CHD deaths</td>
</tr>
</tbody>
</table>

Table 4: Lipid-Lowering Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Starting Dose</th>
<th>Effect on Lipids</th>
<th>Contraindications</th>
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<tr>
<td>Statins</td>
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<td>4gm QID</td>
<td>LDL ↓15-30%</td>
<td>GI upset relative: dysbetalipoproteinemia</td>
</tr>
<tr>
<td>Niacin</td>
<td>500mg TED</td>
<td>HDL ↑15-35%</td>
<td>flushing absolute: chronic liver disease, severe gout, relative: PUD, diabetes, hyperuricemia</td>
</tr>
<tr>
<td>Niacin TR</td>
<td>500mg BID</td>
<td>TG ↓20-50%</td>
<td>hyperuricemia</td>
</tr>
<tr>
<td>Gemfibrozil</td>
<td>600mg BID</td>
<td>HDL ↑10-20%</td>
<td>myopathy</td>
</tr>
</tbody>
</table>

Table 5: Key

- TG: Triglycerides
- TC: Total Cholesterol
- HDL: High-density lipoprotein cholesterol
- LDL: Low-density lipoprotein cholesterol
- ASCVD: Atherosclerotic cardiovascular disease
- CHD: Coronary heart disease
- ACS: Acute coronary syndrome
- MI: Myocardial infarction
- TIA: Transient ischemic attack
- PAD: Peripheral artery disease

Atorvastatin is associated with drug interactions due to its effects on the cytochrome P450 enzymatic pathway; however, pravastatin is not metabolized extensively via this pathway and is associated with fewer drug interactions. There is less statin toxicity (CK elevations and rhabdomyolysis) with pravastatin therapy when compared with atorvastatin.

Pravastatin is not metabolized extensively via this pathway and is associated with fewer drug interactions.
Hyperlipidemia Management

EDUCATION FOR PATIENTS AND PRACTITIONERS

I. Who is educated?
   A. Unit Practitioners- updated on hyperlipidemia so accurate and easy to understand information is provided to patients
   B. All patients with hyperlipidemia, including all patients with increased risk of atherosclerotic cardiovascular disease (ASCVD):
      1. Clinical ASCVD: defined as a acute coronary syndrome (ACS), or a history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) presumed to be of atherosclerotic origin
      2. LDL ≥ 190mg/dL and age ≥ 21 years of age
      3. Diabetes 40-75 years of age and LDL 70-189 mg/dL
      4. Age 40-75 years and ≥7.5% or 5 to <7.5% estimated 10 year ASCVD risk

II. Who educates?
   The Unit Team will delegate educational responsibility
   A. The Educator must document date & time of education in patient’s chart
   B. Physicians and midlevel practitioners have final responsibility to ensure education occurs
   C. Units with available dieticians will provide counseling on diet & how to choose the correct foods from the meal line. If dietician is unavailable, the Unit Team designee will complete counseling.

III. When does education take place?
   A. Upon identification as high risk OR for secondary prevention
   B. Group education: provides general information about hyperlipidemia, risk factors, weight, diet and exercise
   C. Individual education: occurs at clinic visit and provides individual risk assessment, goal setting, information about compliance with diet and exercise program and will supplement information provided by group education

IV. What is included in hyperlipidemia education?
   A. Health Services Personnel
      1. Pathophysiology & diagnostic criteria for hyperlipidemia
      2. Identification & management of secondary causes of hyperlipidemia
      3. Non-pharmacologic and pharmacologic treatments
      4. Follow-up evaluations
      5. Adverse event monitoring
   B. Hyperlipidemia patients
      1. Pathophysiology
      2. Individual treatment plan
      3. Lifestyle modifications
      4. Monitoring parameters: frequency and importance
      5. Complications/streets of disease

HEALTH SERVICES PERSONNELS EDUCATION HYPERLIPIDEMIA CLINIC

I. DEFINITION
   Hyperlipidemia is defined as an abnormally high concentration of fats in the blood. The major lipids are cholesterol and triglycerides. Concentrations of total cholesterol and low-density lipoprotein (LDL) cholesterol are highly associated with the development of coronary heart disease (CHD). An elevated, isolated triglyceride level may lead to pancreatitis and meta-analysis of prospective studies indicate that elevated triglycerides are also an independent risk factor for CHD.

II. GENERAL PRINCIPLES
   Studies have shown a direct link between elevated cholesterol and the development of atherosclerosis and coronary heart disease (CHD). Much of the evidence from these studies supports the theory that lowering cholesterol is fundamental in reducing the morbidity and mortality from CHD. More recently, extensive and consistent evidence supports the use of statin therapy in many high-risk individuals for the primary and secondary prevention of ASCVD.
B. Risk Assessment

A. Initial Clinical Evaluation

1. Age
2. Sex
3. Family History of lipid disorders, premature CHD, diabetes mellitus (DM)
4. History of tobacco use
5. Use of cholesterol-lowering medication
6. Current use of antihypertensive medication

Evidence for risk assessment:

- A 2016 ACC/AHA/SCAI guideline states that for individuals aged 18-79 years, the risk assessment is based on the presence and level of cardiovascular disease (CVD) risk factors, including age, sex, race, smoking status, blood pressure, total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), and body mass index (BMI).

- The ASCVD risk equation assumes that all risk factors are present, and it is a tool to estimate the 10-year risk of ASCVD.

- The ASCVD risk assessment tool also assesses for the presence of diabetes, albuminuria, and age-related factors.

- The risk assessment tool is integrated into the ACC/AHA cholesterol guidelines for adults, and it is used to guide the initiation and intensity of lipid-lowering therapy.

- In general, the goal is to reduce the risk of ASCVD by 50% or more when compared to baseline risk.

- The risk assessment tool can be used to make informed decisions about the need for lifestyle changes or medication initiation.

- The risk assessment tool is a useful tool to identify individuals who may benefit from pharmacologic therapy and to guide the selection of the appropriate therapy.
C. Who To Test

1. Primary Prevention

Initial Screening:

<table>
<thead>
<tr>
<th>PATIENTS</th>
<th>INITIAL SCREENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males &gt;35 years &amp; females &gt;40 years</td>
<td>TC, HDL, LDL, TG</td>
</tr>
<tr>
<td>&gt; 75 years</td>
<td>TC, HDL, LDL, TG</td>
</tr>
</tbody>
</table>

Patients at risk for familial dyslipidemia or that have a diagnosis of diabetes should be screened with a fasting lipid profile (TC, HDL, LDL, TG).

2. Secondary Prevention: All patients under 75 years old with known ASCVD should have a fasting lipid profile.

D. Secondary Causes of Lipid Abnormalities

1. Drugs:
   a. Alpha-agonists & antagonists - decrease TC & TG, increase HDL cholesterol
   b. Alpha-interferon - increase TG
   c. Amiodarone - increase LDL cholesterol
   d. Anabolic steroids - increase TG
   e. Atypical antipsychotics - increase TG
   f. Beta-blockers - increase TG, decrease HDL cholesterol
   g. Clofibrate - increase LDL cholesterol
   h. Ethanol - increase TG
   i. Glucocorticoids - increase TC & TG
   j. Isotretinoin - increase TC & TG; decrease HDL cholesterol
   k. Oral contraceptives - increase TC, TG & HDL cholesterol
   l. Raloxifen - increase TG
   m. Sirolimus - increase TG
   n. Tamoxifen - increase TG
   o. Thiazide diuretics - increase TC, TG & HDL cholesterol

2. Effects of Various Conditions

Table adapted from ACC/AHA

<table>
<thead>
<tr>
<th>Secondary Cause</th>
<th>Elevated LDL –C</th>
<th>Elevated Triglycerides</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>Saturated or trans fats, weight gain, anorexia</td>
<td>Weight gain, very low fat diet, high intake of refined carbohydrates, excessive alcohol intake</td>
</tr>
<tr>
<td>Diseases</td>
<td>Biliary obstruction, nephrotic syndrome</td>
<td>Nephrotic syndrome, chronic renal failure, lipodystrophies</td>
</tr>
<tr>
<td>Disorders and altered states of metabolism</td>
<td>Hyperthyroidism, obesity, pregnancy*</td>
<td>Diabetes (poorly controlled), hyperthyroidism, obesity, pregnancy*</td>
</tr>
</tbody>
</table>

*Treatment with statins, niacin, and ezetimibe are contraindicated during pregnancy and lactation.

E. Factors That Alter Lipid Levels

1. Fasting
   TC levels and HDL-cholesterol can be measured in the non-fasting patient. TG concentrations, however, are affected by recent food intake, and will affect the calculation of LDL-cholesterol by the Friedewald equation: LDL = [TC] – [HDL] – [TG/5]. Therefore patients should be fasting for at least 12 hours prior to having blood drawn for lipid profile testing.

2. Elevated TG
   If the TG concentration is > 400 mg/dl, a calculated LDL may be inaccurate. In this instance, a direct LDL measurement may be appropriate.

3. Illness
   Recent myocardial infarction, stroke, surgery, trauma, or infection may transiently lower cholesterol.
MANAGEMENT

A. General Approach: Clinical decisions should be based on 2 lipid profiles, performed 1 to 8 weeks apart.

B. Non-Pharmacologic Therapy
1. Diet
2. Exercise
3. Weight reduction in obese patients
4. Stop smoking
5. Decrease alcohol consumption

C. Pharmacotherapy
1. Dietary changes and exercise should be attempted prior to initiation of drug therapy in select patients where ASCVD prevention benefit of statin therapy may be less clear. In patients who are at particularly high risk, diet therapy and drug therapy may be initiated concurrently.
2. The first-line agents to treat hyperlipidemia are the HMG-CoA Reductase Inhibitors (“Statins”). In the past, niacin and bile acid sequestrants were used, but the shift has been to the statins. This has provided for a more aggressive approach to managing hyperlipidemia. The statins are usually well tolerated and convenient to take.
3. Isolated hypertriglyceridemia may be treated with gemfibrozil or nicotinic acid (see table 4 for a comparison of lipid lowering agents). Triglyceride (TG) levels ≥500 mg/dl have been associated with pancreatitis. Do not routinely offer fibrates in combination with a statin and do not offer nicotinic acid, bile acid sequestrants, or omega 3 fatty acid compounds alone or in combination with a statin. There is limited data supporting the routine use of non-statin drugs combined with statin therapy to reduce further ASCVD events.

D. Follow-up
1. History
   a. Diet Compliance
   b. Compliance with exercise program
   c. Medication compliance and presence of symptoms suggesting adverse drug reactions (if indicated)
   d. Current medications or pertinent changes in other drug therapy
   e. Re-evaluation of the modifiable risk factors
   f. Presence of muscle aches in large muscle groups
2. Physical Examination
   a. Weight
   b. Blood Pressure
3. Laboratory tests
   a. Fasting lipid profile
   b. LFTs as clinically indicated for patients on statins
   c. Creatine kinase (CK) if symptoms of myositis
4. Adverse event monitoring (including but not limited to)
   a. Significant elevations of liver enzymes (>5 times the upper limit of normal) while on statins
   b. Symptoms of myositis while on statin therapy alone or in combination with other drugs

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Hyperlipidemia (hyper = high levels, lipidemia = fats in the blood) may be caused by high levels of cholesterol, high levels of triglycerides, or a combination of the two. In the hyperlipidemia clinic, we will discuss your lipid disorder as well as a plan of treatment for you. The treatment plan will depend on several factors such as your current risk for heart disease, your current disease status, how high your lipids are, what medications you are taking, as well as other factors. You should read the information contained in this handout carefully. If any of the information that you are told is unclear, please do not hesitate to ask for clarification.

HIGH CHOLESTEROL

Many studies have shown that high cholesterol levels in the blood are a major risk factor for developing coronary heart disease (CHD). Some cholesterol in the blood is necessary. However, excess cholesterol in the blood may lead to fatty deposits in the walls of the arteries. These deposits can build up in the blood, making blood flow in the heart more difficult. This process is known as atherosclerosis or "hardening of the arteries." This can lead to a heart attack and/or other heart diseases. If the deposits build up in the carotid arteries in the neck, this could lead to a stroke. Lowering of elevated cholesterol levels has been proven to decrease your risk of death from CHD, decrease the incidence of atherosclerosis and stroke. Cholesterol is a waxy compound that the body needs and uses for many important functions. The liver makes some of the cholesterol from fat in the diet. The fat in the diet comes from meat, eggs and dairy products. There are two types of cholesterol: LDL, cholesterol (which has been called "bad cholesterol") and HDL, cholesterol (which has been called "good cholesterol"). The LDL cholesterol is the type of cholesterol that is associated with atherosclerosis and heart disease. The HDL-cholesterol seems to protect the body from developing heart disease. A simple blood test can determine what a person’s cholesterol level is. Changes in diet are often the most effective way to lower or maintain a healthy cholesterol level. One of the most important changes to make is to lower the amount of fat in the diet.

Food packages, from the commissary, now have the percentage of fat and grams of fat on the label, which makes it easier to keep track of the amount of fat in the diet. Weight loss, even in the slightly overweight patient, can make a big difference in cholesterol level. The Diet for Health, when followed properly, should help with weight loss. A routine exercise program not only helps with weight loss, but also helps to lower overall risk of heart disease. Drug therapy is not a substitute for diet and exercise, but should be considered to be an extension of the therapy. In some patients who are at high risk, diet, exercise and drug therapy may need to be started at the same time.

HIGH TRIGLYCERIDES

Studies have shown that high triglyceride levels are associated with cardiovascular disease. Many, but not all, patients with high triglyceride levels also have high LDL-cholesterol levels and/or low HDL-cholesterol levels. Very high triglyceride levels (greater than 500) have been associated with inflammation of the pancreas (pancreatitis). High levels of triglycerides can sometimes cause the blood to thicken, causing a problem with clotting. High triglyceride levels usually respond well to non-drug therapy, such as changes in diet and increased exercise. Triglyceride is ingested in the diet from fats and sugars, is also made in the body in the liver and is important in the body for energy and fuel storage. High triglyceride levels may be caused by overproduction in the liver or decreased removal by the body. Triglyceride levels have been shown to be increased in certain disease states, in times of extreme stress, and by certain drugs.

Reducing other risks of cardiovascular disease

A healthy diet, regular exercise, and weight loss in overweight people can improve overall health and decrease the risk of heart disease as well as lowering lipid levels. In addition to hyperlipidemia, there are other risk factors for heart disease that should be controlled:

1. Control high blood pressure
2. Control high blood sugar
3. Stop smoking
4. Limit alcohol intake
5. Reduce stress

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Adults ≥18 years of age with HTN

Implement lifestyle interventions.

Initiate blood pressure lowering medication based upon age and comorbidities (e.g., diabetes (DM) and chronic kidney disease (CKD)). The choice of blood pressure medications may also be influenced by other conditions (see table 2).

<table>
<thead>
<tr>
<th>All ages, Diabetes and/or CKD</th>
<th>All ages, Diabetes Only</th>
<th>All ages, Non-DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ages &lt; 60 years</td>
<td>Target BP &lt;140/90</td>
<td>Target BP &lt;140/90</td>
</tr>
<tr>
<td>Ages ≥ 60 years</td>
<td>Target BP &lt;140/90</td>
<td>Target BP &lt;140/90</td>
</tr>
<tr>
<td>No CKD</td>
<td>HCTZ, lisinopril</td>
<td>HCTZ or a CCB</td>
</tr>
<tr>
<td>Black</td>
<td>Labetalol</td>
<td>Labetalol</td>
</tr>
</tbody>
</table>

Target BP <140/90

Some experts recommend <140/80

At follow-up visit, is patient at BP goal?

Yes

- Continue current drug regimen
- Continue to encourage lifestyle modifications
- Follow up in CCC at least annually

No

- Not at BP goal and patient is compliant: If compliant, increase dose, change drug class or add another drug (HCTZ, lisinopril or CCB). Follow-up based on box 15.
- Not at BP goal and patient is non-compliant: Counsel patient regarding IMPORTANCE of compliance, and consider changing status of medications to NONKOP. Follow-up based on box 15.

If adverse effects are present, change drug class or add drug from another class and reduce dose of offending agent.

At follow-up visit, is patient at BP goal?

Yes

- Continue current drug regimen
- Continue to encourage lifestyle modifications
- Follow up in CCC at least annually

No

- Not at BP goal and patient is compliant: If compliant, increase dose, change drug class or add another drug (HCTZ, lisinopril or CCB). Follow-up based on box 15.
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If adverse effects are present, change drug class or add drug from another class and reduce dose of offending agent.
Table 1: CLASSIFICATION OF HYPERTENSION

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>SBP mmHg¹</th>
<th>DBP mmHg²</th>
<th>Lifestyle Modification</th>
<th>Initial Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>&lt;80</td>
<td>Encourage</td>
<td>No antihypertensive indicated</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120-139</td>
<td>80-89</td>
<td>Yes</td>
<td>No antihypertensive indicated</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>140-159</td>
<td>90-99</td>
<td>Yes</td>
<td>See algorithm on page 1</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>≥160</td>
<td>≥100</td>
<td>Yes</td>
<td>See algorithm on page 1</td>
</tr>
</tbody>
</table>

¹ SBP = systolic blood pressure
² DBP = diastolic blood pressure

---

Table 2: Drug Selection in Patients with or without compelling conditions

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Initial Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. When hypertension is the main condition:</td>
<td></td>
</tr>
<tr>
<td>• Black patients</td>
<td>CCB or HCTZ</td>
</tr>
<tr>
<td>• Non-black patients</td>
<td>Lisinopril, CCB or HCTZ</td>
</tr>
<tr>
<td>B. When hypertension is associated with other conditions:</td>
<td></td>
</tr>
<tr>
<td>• Hypertension and diabetes</td>
<td></td>
</tr>
<tr>
<td>• Black patients</td>
<td>CCB or HCTZ</td>
</tr>
<tr>
<td>• Non black patients</td>
<td>Lisinopril, CCB or HCTZ</td>
</tr>
<tr>
<td>• Hypertension and CKD</td>
<td>Lisinopril</td>
</tr>
<tr>
<td>• Hypertension and chronic coronary artery disease</td>
<td>Beta blocker plus lisinopril</td>
</tr>
<tr>
<td>• Hypertension and stroke history</td>
<td>Lisinopril</td>
</tr>
<tr>
<td>• Hypertension and symptomatic heart failure</td>
<td>Lisinopril + carvedilol + diuretic + spironolactone†</td>
</tr>
</tbody>
</table>

Abbreviations:
CCB = calcium channel blocker
CKD = chronic kidney disease
HCTZ = hydrochlorothiazide
NYHA II-IV and who have LVEF of 35% or less provided CrCl >30ml/min and K⁺<5.0 mEq/dL.
## Formulary Antihypertensives

### Diuretics
- Furosemide 20mg, 40mg
- Hydrochlorothiazide 12.5mg, 25mg, 50mg
- Metolazone 5mg
- Triamterene 37.5mg / HCTZ 25mg

### Aldosterone antagonist
- Spironolactone 25mg

### ACE Inhibitor
- Lisinopril 2.5 mg, 5 mg, 10 mg, 20 mg, 40mg

### Calcium Channel Blockers
- Amlodipine 5mg, 10mg
- Diltiazem 90mg XIR, 240mg XIR
- Diltiazem 240mg XIR
- Verapamil 180mg SR
- Verapamil 240mg SR

### Beta Blocker
- Atenolol 25mg, 50mg
- Carvedilol 6.25mg, 12.5mg, 25mg, 50mg
- Metoprolol 25mg, 50mg, 100mg
- Propranolol 10mg, 20mg, 40mg

### Alpha 1 Blocker
- Terazosin 1mg, 2mg, 5mg, 10mg

### Alpha 2 Agonist
- Guanfacine 1mg, 2mg

### Other
- Hydralazine 25mg, 50mg
- Minoxidil 2.5mg, 10mg
Detection and Confirmation

The following procedures are recommended for the detection and confirmation of hypertension:

- Patients should be seated in a chair with their backs supported and their arms bare and supported at heart level. Patients should have refrained from smoking or ingesting caffeine during the 30 minutes prior to the reading.
- BP measurement should begin after the patient has been at rest for at least 5 minutes.
- An appropriate cuff size must be used to ensure accurate readings. The bladder within the cuff should encircle at least 80% of the arm.
- Measurement of BP with a mercury sphygmomanometer is the preferred method. However, a recently calibrated aneroid manometer or a validated electronic device can be used.
- BP and DBP should be recorded.
- Two or more readings separated by 2 minutes should be obtained and averaged for proper confirmation. If these two readings differ by more than 5 mm Hg, additional readings should be obtained two weeks apart.

Recommendation for Follow-up Based on Initial Blood Pressure Readings

<table>
<thead>
<tr>
<th>Initial Blood Pressure (mm Hg)*</th>
<th>Follow-up Recommended**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>Diastolic</td>
</tr>
<tr>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>120-139</td>
<td>80-89</td>
</tr>
<tr>
<td>140-159</td>
<td>90-99</td>
</tr>
<tr>
<td>&gt;160</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>

* If systolic and diastolic categories are different, follow up should be for the shorter time (e.g. 160/86mm Hg should be evaluated or referred within one month).
** Modify the schedule for follow up according to reliable information about past blood pressure measurements, other cardiovascular risk factors, or target organ disease. Provide advice on therapeutic lifestyle modifications.

Medical History

- Known duration and levels of elevated blood pressure.
- Patient history or symptoms of CHD, heart failure, cerebrovascular disease, peripheral vascular disease, retinal disease, diabetes mellitus, dyslipidemia, gout, or renal disease.
- Symptoms suggestive of hypertension (headache, nose bleeds, dizziness, abnormal physical exam).
- History of recent changes in weight, leisure time physical activity, and smoking or tobacco use.
- Dietary assessment including intake of sodium, alcohol, saturated fat, and caffeine.
- History of all prescribed and OTC medication, herbal remedies, and illicit drugs.
- Results and adverse effects of past antihypertensive therapy.
- Psychosocial and environmental factors that may influence hypertensive control.

Cardiovascular Risk Factors

- Hypertension
- Obesity (Body Mass Index ≥ 30kg/m²)
- Physical Inactivity
- Dyslipidemia
- Diabetes Mellitus
- Microalbuminuria or estimated GFR < 60 ml/min
- Age (≥ 55 males, ≥ 65 females)
- Family history of premature cardiovascular disease (male < 55 or females < 65)
Physical Exam
• Two or more blood pressure readings separated by 2 minutes with the patient supine or seated.
• Verification in the contralateral arm (if values are different, the higher value should be used).
• Measurement of weight, height, and waist circumference.
• Fundoscopic examination for hypertensive retinopathy (i.e., arteriolar narrowing, focal arteriolar constrictions, arteriovenous crossing changes, hemorrhages and exudates, disc edema).
• Examination for the neck for carotid bruits, distended veins, or enlarge thyroid gland.
• Examinations of the heart for abnormalities in the rate and rhythm, increase size, precordial heave, clicks, murmurs and third and fourth heart sounds.
• Examination of the lungs for rales and evidence for bronchospasm.
• Examinations of the abdomen for bruits, enlarged kidney, masses and abnormal aortic pulsation.
• Examinations of the extremities for diminished or absent peripheral arterial pulsations, bruits, and edema.
• Neurological assessment.

Routine Laboratory Test
Routine laboratory tests recommended prior to initiating therapy and annually to determine end-organ damage and other risk factors include:
• CBC
• Chemistry profile to include LFTs, serum creatinine, fasting blood sugar and fasting lipid profile
• TSH (baseline)
• Urinalysis
• EKG

Secondary Causes of Hypertension
• Renal disease
• Stenosis of the aorta
• Mineralocorticoid excess states
• Cushing’s syndrome
• Pheochromocytoma
• Pregnancy
• Drug-induced
• Sleep apnea
• Thyroid or parathyroid disease
• Obstructive nephropathy
Appendix C PREHYPERTENSION CLASSIFICATION* Page 6 HTN

Background:
Prehypertension is defined as having a systolic blood pressure within the range of 120-139 mmHg and/or a diastolic blood pressure of 80-89 mmHg.

Several reputable studies support the prehypertension categorization through the following findings:

- Framingham Heart Study found that 55-year-old adults (who were then normotensive in the study) have a 90% probability of developing HTN in their lifetime and a 60% probability of receiving anti-HTN meds.
- Framingham Heart Study found that individuals with blood pressure values in the range of 130-139/85-89 mmHg have a 2-fold increased risk of cardiovascular disease (CVD) versus a person with BP <120/80.
- Meta-analysis of 51 studies indicated that risk of death from CVD and stroke increases linearly with increasing BP beginning as low as 115/75 mmHg and for each increment of 20/10 mmHg the risk of CVD DOUBLES.
- According to Greenlund et al. (2004), persons with prehypertension were found to have a higher prevalence of other risk factors for heart disease and stroke (hyperlipidemia, obesity, diabetes) vs. normotensive persons.

Aggressive Management of the Prehypertensive Patient:
The main purpose of the prehypertension category is to identify persons who are at risk of developing hypertension and hypertension-related long-term complications in the future. It is important that healthcare providers identify prehypertensive patients early and manage their condition aggressively. EDUCATION IS THE KEY HERE! This is the opportunity to counsel patients on the serious complications of HTN and to promote healthy habits and lifestyle changes so that an actual diagnosis of HTN may be avoided.

Therapeutic Lifestyle Modifications**: There is no evidence yet to support the use of medications to treat prehypertension. Lifestyle modifications are currently the gold standard in the management of the condition. Suggested modifications and the extent of systolic blood pressure reduction are as follows:

<table>
<thead>
<tr>
<th>Modification</th>
<th>Recommendation</th>
<th>Approximate SBP Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight reduction</td>
<td>Encourage patients to maintain normal body weight (BMI 18.5-24.9)</td>
<td>0-20 mmHg/10 kg weight loss</td>
</tr>
<tr>
<td>Diet</td>
<td>Consider DFH and encourage adherence: Discourage commissary foods.</td>
<td>8-14 mmHg</td>
</tr>
<tr>
<td>Dietary sodium restriction</td>
<td>Encourage patients to reduce dietary sodium intake to no more than 2.4g sodium or 6g NaCl.</td>
<td>2-8 mmHg</td>
</tr>
<tr>
<td>Physical activity</td>
<td>Encourage patients to engage in aerobic physical activity to lower BP: 3 to 4 sessions a week, lasting on average 40 minutes per session, and involving moderate physical activity.</td>
<td>4-9 mmHg</td>
</tr>
</tbody>
</table>

**Set realistic goals for your patients and discuss the value of self-rewarding and goal setting to their lifestyle, as they are more likely to comply with one change at a time.
HYPERTENSION EMERGENCY

Hypertensive emergencies are characterized by severe elevations in blood pressure (BP) >180/120 mm Hg, complicated by evidence of impending or progressive target organ damage. While hypertensive emergencies occur rapidly, immediate blood pressure reduction is required to limit target organ damage. Target organ damage may be manifested in hypertensive encephalopathy, intracranial hemorrhage, unstable angina pectosa, acute myocardial infarction, acute left ventricular failure with pulmonary edema, dissecting aortic aneurysm, acute renal failure or eclampsia. Most hypertensive emergencies are treated initially with parenteral agents. Blood pressure reduction does not need to reach the normal range immediately. The initial goal of therapy is to reduce the mean arterial blood pressure (MAP) (see box 4) by no more than 25% (within minutes to 1 hour), then, if stable, toward 160/100 mm Hg within 2-6 hours, avoiding excessive falls in pressure that may precipitate renal, cerebral, or coronary ischemia.

HYPERTENSION URGENCY

Hypertensive urgencies are those situations with severe elevations in BP without progressive target organ damage. Examples include stage 3 hypertension associated with severe headache, shortness of breath, opisthotonos, or severe anxiety. Blood pressure may be reduced over a period of hours to days. Elevated blood pressure alone, in absence of symptoms or new or progressive target organ damage, rarely requires emergency therapy. Hypertensive urgencies can be managed with oral doses of drugs which have a relatively fast onset of action.

1. Establish intravenous line
2. Elevate head at 45° angle
3. Obtain history
4. Obtain labs
5. MAP = (1/3) (SBP + DBP + PAP)
6. Normal MAP is: 70 mm Hg

HYPERTENSION EMERGENCY

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Patient presents with signs & symptoms of hypoglycemia (generally BG < 70mg/dL).

1. Patient with known diabetes or insulinoma – go to box #2
2. Patient not known to have diabetes – go to box #2 to treat hypoglycemia and then treat underlying disease such as drugs (e.g., pentamidine, salicylates, ethanol), end stage liver disease, renal disease, endocrine deficiencies, non-beta cell tumors, prior gastric surgery, or inherited metabolic disorders.

Is the patient conscious and cooperative?

Notify unit provider & establish IV access.

Have IV access been established after at least 2 attempts?

If unable to establish IV access, administer Glucagon (1mg/cc) – 1ml. IM or SQ. Dose may be repeated 1 time in 30 minutes.

Administer 50mL of D50 IVP, followed by infusion of 5-10% dextrose. Continue infusion until glucose > 70mg/dL.

Underlying infection should be ruled out as a possible cause of hypoglycemia, especially in recurring hypoglycemia.

Treat orally & notify unit provider.

Administer 1-2 tubes of oral glucose gel (1 tube contains 15 grams of glucose) or glucose-containing fluids, candy, or food. In general, 15-20g oral glucose will be adequate. Recheck blood glucose (BG) in 15 minutes and repeat above until BG > 70mg/dL.

Ingestion of a snack or meal shortly after plasma glucose concentration is raised is advisable if given oral glucose, because response is transient (typically < 2 hours).

Discharge the patient when plasma glucose levels remain > 70mg/dL. Before discharging the patient, it is important to consider medical staff availability, offender housing, and duration of effect of the agent being used for the treatment of hypoglycemia.

Consider scheduling patient who has had recurrent episodes for follow up appointment with unit provider for evaluation and possible medication adjustment.

Ingestion of a snack or meal shortly after glucose levels are raised is advisable. Response to IV dextrose may be transient.

Schedule follow up with unit provider for evaluation and possible medication evaluation.

Have symptoms resolved?

Investigate other etiologies for mental status change and consider transfer to a higher level of care.

Underlying infection should be ruled out as a possible cause of hypoglycemia, especially in recurring hypoglycemia.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, January 2006. Reviewed 5/10, 1/13. Revised 9/16.
**Hypoglycemia**

I. American Diabetes Association has determined that ≤70mg/dL can be used as the cut-off value in the classification of hypoglycemia in diabetes. Hypoglycemia can be further classified as the following:

A. **Severe hypoglycemia** – an event requiring assistance of another person to actively administer carbohydrates, glucagon or take other corrective actions. It is characterized by cognitive impairment that may be recognized or unrecognized and can progress to loss of consciousness, seizure, coma or death.

B. **Documented symptomatic hypoglycemia** – an event during which typical symptoms of hypoglycemia are accompanied by a measured plasma glucose of ≤70mg/dL. This is also called hypoglycemia unawareness (loss of warning symptoms of hypoglycemia). It is often precipitated by recurrent hypoglycemia in type 1 diabetes and advanced type 2 diabetes. Incidence increases with age and duration of diabetes. If the diagnosis of hypoglycemia has been made, consideration of targeting higher glucose levels in the short term should be given. A minimum of a three-week period of avoiding hypoglycemia should be attempted in efforts to return to an awareness of hypoglycemia. An A1 goal of >8% should be considered for the elderly diabetic population.

C. **Asymptomatic hypoglycemia** – an event not accompanied by typical symptoms of hypoglycemia but with a measured plasma glucose of ≤70mg/dL. This is also called hypoglycemia unawareness (loss of warning symptoms of hypoglycemia). It is often precipitated by recurrent hypoglycemia in type 1 diabetes and advanced type 2 diabetes. Incidence increases with age and duration of diabetes. If the diagnosis of hypoglycemia has been made, consideration of targeting higher glucose levels in the short term should be given. A minimum of a three-week period of avoiding hypoglycemia should be attempted in efforts to return to an awareness of hypoglycemia. An A1 goal of >8% should be considered for the elderly diabetic population.

D. **Probable symptomatic hypoglycemia** – an event during which symptoms typical of hypoglycemia are not accompanied by a plasma glucose determination, but presumed to be caused by a plasma glucose of ≤70mg/dL.

E. **Pseudo-hypoglycemia** – an event during which the person with diabetes reports any of the typical symptoms of hypoglycemia, but with a plasma glucose level of >70mg/dL. This phenomenon commonly occurs when patients have been accustomed to hyperglycemia and undergoes intensification of their glucose control. This syndrome is self-limiting and usually takes 2-4 weeks for the brain to readjust to their improved and thus relatively reduced circulating glucose levels.

---

### Table 1. Symptoms of Hypoglycemia

<table>
<thead>
<tr>
<th>Neuronegic Symptoms (caused by falling glucose levels)</th>
<th>Neuroglycemic Symptoms (caused by brain neuronal glucose deprivation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shakiness</td>
<td>Abnormal mentation</td>
</tr>
<tr>
<td>Trembling</td>
<td>Irritability</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Confusion</td>
</tr>
<tr>
<td>Palpitations</td>
<td>Difficulty in thinking</td>
</tr>
<tr>
<td>Clamminess</td>
<td>Difficulty in speaking</td>
</tr>
<tr>
<td>Sweating</td>
<td>Ataxia</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>Paresthesias</td>
</tr>
<tr>
<td>Hunger</td>
<td>Headaches</td>
</tr>
<tr>
<td>Pallor</td>
<td>Stupor</td>
</tr>
<tr>
<td>Pupil dilation</td>
<td>Seizures</td>
</tr>
<tr>
<td></td>
<td>Coma</td>
</tr>
<tr>
<td></td>
<td>Death (if untreated)</td>
</tr>
</tbody>
</table>
II. Risk Factors
A. Type 1 diabetes and advanced type 2 diabetes
B. Medication (insulin or oral agents) excess
C. Decreased influx of exogenous glucose (e.g., skipped or missed meals or snacks)
D. Increased glucose utilization (e.g., increase in exercise)
E. Reduced insulin clearance (e.g., renal failure)
F. Age

III. Prevention
A. Address issue of hypoglycemia at each visit.
   1. Is the patient having episodes of hypoglycemia, how frequently are they occurring, and are they severe?
   2. What is relationship of hypoglycemia to drug administration, meals, and exercise?
B. Educate the patient on symptoms of hypoglycemia and what to do when they occur
C. In patients with recurrent episodes of hypoglycemia or a severe episode of hypoglycemia, consider
   1. Increasing the frequency of glucose monitoring
   2. Adjusting the patient’s medication regimen (see Table 2.)
   3. Ordering HS snacks
   4. Evaluating the patient’s other medications (e.g., non-selective beta blockers) to determine if there is a medication that may be masking the symptoms of hypoglycemia making it difficult for the patient to identify hypoglycemic episodes for early intervention & self-management

### Table 2. Pharmacokinetics of Insulin*

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Onset of Action</th>
<th>Peak Action</th>
<th>Effective Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular</td>
<td>30 to 60 min</td>
<td>2 to 3 hours</td>
<td>8 to 10 hours</td>
</tr>
<tr>
<td>NPH</td>
<td>2 to 4 hours</td>
<td>4 to 10 hours</td>
<td>12 to 18 hours</td>
</tr>
</tbody>
</table>

*The pharmacokinetics of insulin preparations may be used to determine which insulin to adjust when a patient is experiencing symptoms of low or high blood glucose.

Examples:
1. If patient is symptomatic of hypoglycemia around 9am and he or she injected NPH and Regular insulin at 4am, most likely it is the NPH that needs to be adjusted as it is peaking 5 hours after injection.
2. If patient is symptomatic of hypoglycemia or hyperglycemia after dinner, the Regular insulin will need to be adjusted as its onset of action is faster than the NPH.
Ischemic Heart Disease, Stable

- **Angina that is not unstable and that has a new onset of more than two months ago, does not occur at rest, and has not distinctly changed in frequency, duration, or threshold within the last 2 months.**

  **Consider cardiology referral if not previously evaluated by cardiology.**

  - **Sublingual NTG effective?**
    - Yes
      - **History of Vasospastic Angina?**
        - Yes
          - Start Calcium Channel Antagonist (CCA) — preferably the non-dihydropyridine CCA’s (e.g., diltiazem & verapamil) and ASA EC 81-325mg qd. Titrate CCA to maximum tolerated dose. If patient continues to be symptomatic, add Long Acting Nitrate therapy. Go to box 15.
        - No
          - Still experiencing intermittent chest pain relieved with SL NTG?
            - Yes
              - Start or Add Calcium Channel Antagonist (CCA) and ASA 81-325mg qd. Titrate CCA to maximum tolerated dose.
            - No
              - Refer to Checklist for Secondary Prevention of Coronary Artery Disease DMG to ensure risk reduction measures are being followed. Aggressively treat the underlying disease.

  - No
    - **Serious contraindication to Beta-Blocker?**
      - Yes
        - **History of Vasospastic Angina?**
          - Yes
            - Start a cardio-selective Beta-Blocker (BB) (e.g., metoprolol or atenolol) and ASA EC 81-325mg qd. Titrate BB to maximum tolerated dose.
          - No
            - **Serious contraindication to Calcium Channel Antagonist?**
              - Yes
                - **Continue therapy. Initial follow up in 30 days, then 90 days if chest pain is stable. Follow up at least semi-annually thereafter.**
              - No
                - Refer to Checklist for Secondary Prevention of Coronary Artery Disease DMG to ensure risk reduction measures are being followed. Aggressively treat the underlying disease.

  - **Effective?**
    - Yes
      - **Start Isosorbide Mononitrate XR 30-60mg qd and ASA EC 81-325mg qd. Titrate per symptoms up to maximum 240mg/day.**
    - No
      - Refer to Checklist for Secondary Prevention of Coronary Artery Disease DMG to ensure risk reduction measures are being followed. Aggressively treat the underlying disease.

Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. Approved February 2001; Revised 11/02, 1/08, Revised 4/03, 9/09, 7/11, 1/15.
Definition of chronic stable angina
A clinical syndrome characterized by discomfort in the chest, jaw, shoulder, back, or arms, typically elicited by exertion or emotional stress and relieved by rest or nitroglycerin.

Goals of Treatment
- Relief of symptoms
- Prevention or slowing of disease progression
- Prevention of future cardiac events, i.e. myocardial infarction, unstable angina, need for revascularization
- Improvement in survival

Mainstay of therapy in symptomatic treatment
- Short acting nitroglycerin – 1st line therapy
  - Atenolol 50-100mg/day
  - Metoprolol 100-450mg/day in 2-3 divided doses
- Calcium channel antagonists (CCAs) - 2nd line if BB’s are not tolerated, contraindicated, or if symptoms are not alleviated with BB’s alone.
  - Diltiazem XR 180-360mg/day (Non-dihydropyridine CCA)
  - Verapamil 240-480mg/day in 3-4 divided doses (Non-dihydropyridine CCA)
- Long acting nitrates - 3rd line if BB’s and/or CCA’s are not tolerated, contraindicated, or if symptoms are not alleviated with BB’s and/or CCA’s.
  - Isosorbide Mononitrate XR 30-240mg/day
- Ranolazine - 4th line agent for patients with stable ischemic heart disease; should be used in combination with other established antianginal medications such as amiodipine, beta-blockers or nitrates; preferably should only be recommended by a cardiologist. (see other educational information below).

Note: Three anti-anginal drugs (excluding short acting NTG) may actually provide less symptomatic protection than two drugs. Thus, the dose of one drug should be optimized before adding another one, and it is advisable to switch drug combinations before attempting a three drug regimen.

Contraindications
- Beta-blockers
  - Sinus bradycardia (HR <50 bpm)
  - Second or third degree heart block
  - Overt cardiac failure
  - Hypersensitivity to BB’s
- Calcium channel antagonists
  - Sick sinus syndrome
  - Second or third degree heart block
  - Hypotension (systolic <90mmHg)
  - Hypersensitivity to CCA’s
  - Diltiazem: acute MI or pulmonary congestion
  - Verapamil: severe left ventricular dysfunction, cardiogenic shock, atrial flutter or fibrillation
  - Amlodipine: use with caution in patients with heart failure
- Aspirin
  - Hypersensitivity to NSAIDs
  - Syndrome of asthma, rhinitis, and nasal polyps
  - Inherited or acquired bleeding disorders

Counseling on the use of nitrates
- Patients should be counseled to come down to medical if chest pain or discomfort is unimproved or worsening five minutes after one nitroglycerin dose has been taken.
- If the sublingual/nitroglycerin (NTG) is potent, a slight tingling sensation should be felt under the tongue. Tablets that crumble easily should not be used. The sublingual mucosa should be moist for adequate dissolution and absorption of the tablets. A drink of water in patients with dry sublingual mucosa prior to ingestion of the tablet may be necessary.
- NTG tablets are both heat and light sensitive. They should therefore be stored in a tightly capped dark bottle. The prescription should be renewed every three to six months.
- Warn patients about the potential of hypotension when first taking the nitrate and the potential for headaches and flushing.
- NTG can be used for prophylaxis of predictable episodes of angina in response to exertion.

Drug interaction alert: Concomitant use of non-dihydropyridine calcium channel antagonists with beta blockers can possibly potentiate hypotension, bradycardia, heart failure, and conduction abnormalities. These effects are more prevalent in patients with impaired left ventricular function, cardiogenic shock, or acute coronary syndrome.
Mainstay of therapy to improve prognosis in patients with stable angina (please refer to the Checklist for Secondary Prevention of Coronary Artery Disease Disease Management Guidelines):

- Aspirin 81-325mg for all patients
- Beta-blockers for all patients
- Statins for all patients to achieve target LDL <100mg/dl, <70mg/dl for high-risk patients
- Angiotensin Converting Enzyme (ACE) Inhibitor (see below)

Role of ACEI per 2007 Chronic Angina ACC/AHA guidelines:

- ACE inhibitors are recommended for patients with chronic stable angina and a history of myocardial infarction, left ventricular ejection fraction (LVEF) < 40 percent, hypertension, diabetes, or chronic kidney disease
- ACE inhibitors may be considered for lower risk patients with mildly reduced or normal LVEF in whom risk factors are well controlled and revascularization has been performed.

Ranolazine Healthcare Provider Education:

- Ranolazine is an anti-anginal medication that was recently included in the current stable ischemic heart disease guideline.
- The proposed ranolazine mechanism of action is the inhibition of pathologic increases in late Na⁺ current induced during myocardial ischemia. Because of Na⁺/Ca²⁺ coupling, this would be expected to reduce ischemia-induced calcium overload, resulting in more normal diastolic relaxation and decreased wall tension. Improved diastolic function decreases oxygen demand and increases coronary blood supply.
- Ranolazine is approved for treatment of patients with chronic angina who have not achieved an adequate response with other anti-anginal drugs.
- Dosing is 500 mg PO BID initially, may increase to 1,000 mg PO BID, if needed.
- Place in therapy: 4th line agent for patients with stable ischemic heart disease, should be used in combination with other established anti-anginal medications such as amiodipine, beta blockers or nitrates.
- Due to the risk of QTc prolongation, it should not be used with medications that have high QTc prolongation risk. Preferably, ranolazine should only be recommended by a cardiologist.
### Formulary Substitutions for Commonly Prescribed Non-Formulary Medications

Patients should be evaluated for use of formulary agents whenever possible. Clinicians should consider past history of response, contraindications, co-morbidities, medication compliance, and potential for adverse effects and/or drug-drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects. The recommendations listed below are not intended to replace sound clinical judgment.


<table>
<thead>
<tr>
<th>Name of Non-Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency and Dosages Available</th>
<th>Comments/Approximate Equivalent (Non-Formulary to Formulary)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anti-Diabetic Medications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Azathioprine (Imuran®)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfinpyrazone (Anturan®)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sodium Valproate</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regitine (Trasylol®)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metformin (Glumetza®, Glumet®, Amaryll®)</td>
<td></td>
<td>NPH (Novolin®): 100 units/ml vial, 10 ml</td>
<td>Unit-to-unit conversion</td>
<td>Consider 25% dose reduction when switching from Tardus® to NPH. Administer 1/2 of dose in am and 1/2 of daily dose in pm.</td>
</tr>
<tr>
<td>NPH (Humulin®)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assured Protopine 200/Assured 300 NPH, Humalog Mix 70/30®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regitine 72/Assured 30 Humalog Mix 72/28®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glyburide (Diabeta®)</td>
<td>1.25-20 mg q.d.</td>
<td>Glipizide (Glucotrol®)</td>
<td>5-40mg daily in single or divided doses</td>
<td>3 mg qd to 5 mg qd.</td>
</tr>
<tr>
<td>Glyburide micromint (Glimirae Micron®)</td>
<td>1.5 - 12 mg in single or divided doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tolbutamide</td>
<td>100 mg q.d. - 500 mg bid</td>
<td>Tolbutamide</td>
<td>250 mg qd to 5 mg qd</td>
<td></td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>500 - 5000 mg daily in 1-3 divided doses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of Non-Formulary Medication</td>
<td>Dose Range &amp; Frequency</td>
<td>Name of Formulary Medication</td>
<td>Dose Range &amp; Frequency</td>
<td>Comments/Appropriate Equivalent</td>
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<tr>
<td>---------------------------------</td>
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<td>--------------------------------</td>
</tr>
<tr>
<td>Bevacizumab (Linfec daughters)</td>
<td>0.03 mg/kg body weight q 2 weeks</td>
<td>Bevacizumab (Linfec daughters)</td>
<td>0.03 mg/kg body weight q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Trastuzumab (Herceptin)</td>
<td>0.15 mg/kg body weight q 2 weeks</td>
<td>Trastuzumab (Herceptin)</td>
<td>0.15 mg/kg body weight q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Rituximab (Rituxan)</td>
<td>375 mg/m² body surface area q 2 weeks</td>
<td>Rituximab (Rituxan)</td>
<td>375 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Pemetrexed (Alphadex)</td>
<td>250 mg/m² body surface area q 2 weeks</td>
<td>Pemetrexed (Alphadex)</td>
<td>250 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Docetaxel (Taxotere)</td>
<td>75 mg/m² body surface area q 2 weeks</td>
<td>Docetaxel (Taxotere)</td>
<td>75 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Paclitaxel (Taxol)</td>
<td>175 mg/m² body surface area q 2 weeks</td>
<td>Paclitaxel (Taxol)</td>
<td>175 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Gemcitabine (Gemzar)</td>
<td>1000 mg/m² body surface area q 2 weeks</td>
<td>Gemcitabine (Gemzar)</td>
<td>1000 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Cisplatin (Platino)</td>
<td>75 mg/m² body surface area q 2 weeks</td>
<td>Cisplatin (Platino)</td>
<td>75 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Carboplatin (Platino)</td>
<td>50 mg/m² body surface area q 2 weeks</td>
<td>Carboplatin (Platino)</td>
<td>50 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Etoposide (Etoposide)</td>
<td>100 mg/m² body surface area q 2 weeks</td>
<td>Etoposide (Etoposide)</td>
<td>100 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Doxorubicin (Adriamycin)</td>
<td>50 mg/m² body surface area q 2 weeks</td>
<td>Doxorubicin (Adriamycin)</td>
<td>50 mg/m² body surface area q 2 weeks</td>
<td>1 q 2 weeks for injection</td>
</tr>
</tbody>
</table>

**Anti-Hypertensive Medications**

<table>
<thead>
<tr>
<th>Name of Non-Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Comments/Appropriate Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine (Norvasc)</td>
<td>1.25 - 10 mg od</td>
<td>Amlodipine (Norvasc)</td>
<td>1.25 - 10 mg od</td>
<td>1 od for injection</td>
</tr>
<tr>
<td>Tramadol (Tramrac)</td>
<td>5 - 20 mg od</td>
<td>Tramadol (Tramrac)</td>
<td>5 - 20 mg od</td>
<td>1 od for injection</td>
</tr>
<tr>
<td>Acetaminophen (Tylenol)</td>
<td>50 - 80 mg od</td>
<td>Acetaminophen (Tylenol)</td>
<td>50 - 80 mg od</td>
<td>1 od for injection</td>
</tr>
<tr>
<td>Midodrine (Procardia)</td>
<td>30 - 100 mg ad</td>
<td>Midodrine (Procardia)</td>
<td>30 - 100 mg ad</td>
<td>1 ad for injection</td>
</tr>
<tr>
<td>Nifedipine (Procardia)</td>
<td>10 - 40 mg od</td>
<td>Nifedipine (Procardia)</td>
<td>10 - 40 mg od</td>
<td>1 od for injection</td>
</tr>
</tbody>
</table>

**Anti-Hyperlipidemic Medications**

<table>
<thead>
<tr>
<th>Name of Non-Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Comments/Appropriate Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluvastatin (Lescol)</td>
<td>20 - 80 mg od</td>
<td>Fluvastatin (Lescol)</td>
<td>20 - 80 mg od</td>
<td>1 od for injection</td>
</tr>
<tr>
<td>Lovastatin (Mevacor)</td>
<td>10 - 80 mg od</td>
<td>Lovastatin (Mevacor)</td>
<td>10 - 80 mg od</td>
<td>1 od for injection</td>
</tr>
<tr>
<td>Pravastatin (Pravachol)</td>
<td>10 - 80 mg od</td>
<td>Pravastatin (Pravachol)</td>
<td>10 - 80 mg od</td>
<td>1 od for injection</td>
</tr>
</tbody>
</table>

**Anti-Glaucoma Medications**

<table>
<thead>
<tr>
<th>Name of Non-Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Comments/Appropriate Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betaxolol (Betoptic)</td>
<td>0.5% Ophthalmic Solution</td>
<td>Betaxolol (Betoptic)</td>
<td>0.5% Ophthalmic Solution</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Timolol (Timoptic)</td>
<td>0.5% Ophthalmic Solution</td>
<td>Timolol (Timoptic)</td>
<td>0.5% Ophthalmic Solution</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Latanoprost (Xalatan)</td>
<td>0.005% Ophthalmic Solution</td>
<td>Latanoprost (Xalatan)</td>
<td>0.005% Ophthalmic Solution</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Patanol (Patanol)</td>
<td>0.5% Ophthalmic Solution</td>
<td>Patanol (Patanol)</td>
<td>0.5% Ophthalmic Solution</td>
<td>1 q 2 weeks for injection</td>
</tr>
<tr>
<td>Timolol (Timoptic)</td>
<td>2% Ophthalmic Solution</td>
<td>Timolol (Timoptic)</td>
<td>2% Ophthalmic Solution</td>
<td>1 q 2 weeks for injection</td>
</tr>
</tbody>
</table>

213
<table>
<thead>
<tr>
<th>Name of Non-Formulary Medication</th>
<th>Dose Range &amp; Frequency</th>
<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency and Dosages Available</th>
<th>Comments/Approximate Equivalent (Non-Formulary to Formulary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benazepril (Lotensin&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>10 - 40 mg od</td>
<td>Lisinopril (Prinivil&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>10 - 40 mg daily</td>
<td>10 mg od to 10 mg od</td>
</tr>
<tr>
<td>Captopril (Capoten&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>25 - 50 mg bid od</td>
<td>2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg tablets</td>
<td>5 mg od to 10 mg od</td>
<td>25 mg bid to 50 mg od</td>
</tr>
<tr>
<td>Enalapril (Vasotec&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>2.5 - 40 mg od</td>
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<td>5 mg od to 10 mg od</td>
<td>25 mg bid to 40 mg od</td>
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<td>Fosinopril (Monopril&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>Hydrochlorothiazide (Hyzaar&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>10 mg bid to 25 mg od</td>
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<td>Perindopril (Aceon&lt;sup&gt;®&lt;/sup&gt;)</td>
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<tr>
<td>Quinapril (Accupril&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>10 - 40 mg od</td>
<td>2.5 - 10 mg od</td>
<td>7.5 mg od to 25 mg od</td>
<td>7.5 mg bid to 25 mg od</td>
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<tr>
<td>Ramipril (Refax&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>2.5 - 10 mg od</td>
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<td>7 mg od to 10 mg od</td>
<td>7 mg bid to 10 mg od</td>
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<tr>
<td>Telmisartan (Miaza&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>1 - 8 mg od</td>
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<td>2.5 mg od to 10 mg od</td>
<td>2.5 mg bid to 8 mg od</td>
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<td>Atorvastatin (Lipitor&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>10 - 80 mg od</td>
<td>10 - 40 mg daily</td>
<td>10 mg od to 80 mg od</td>
<td>10 mg od to 80 mg od</td>
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<tr>
<td>Ezetimibe (Zetia&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>10 - 40 mg daily</td>
<td>10 mg od to 40 mg od</td>
<td>10 mg od to 40 mg od</td>
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<td>Simvastatin (Zocor&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>5 - 40 mg daily</td>
<td>5 mg od to 40 mg od</td>
<td>5 mg bid to 40 mg od</td>
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<tr>
<td>Rosuvastatin (Crestor&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>20 - 40 mg od</td>
<td>20 - 40 mg daily</td>
<td>20 mg od to 40 mg od</td>
<td>20 mg bid to 40 mg od</td>
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<td>Pravastatin (Pravachol&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>20 - 80 mg daily</td>
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<td>Ezetimibe (Zetia&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>5 - 20 mg daily</td>
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<td>5 mg bid to 20 mg od</td>
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<td>Rosuvastatin (Crestor&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>10 - 40 mg daily</td>
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<td>Pravastatin (Pravachol&lt;sup&gt;®&lt;/sup&gt;)</td>
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<td>5 mg bid to 20 mg bid</td>
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<td>Propranolol long-acting (Inderal&lt;sup&gt;®&lt;/sup&gt;)</td>
<td>60 - 180 mg od</td>
<td>60 - 180 mg daily</td>
<td>60 mg od to 180 mg od</td>
<td>60 mg bid to 180 mg bid</td>
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<td>Dose Range &amp; Frequency</td>
<td>Name of Formulary Medication</td>
<td>Dose Range &amp; Frequency and Dosages Available</td>
<td>Comments/Approximate Equivalent (Non-Formulary to Formulary)</td>
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<td>Timolol (Blockers)</td>
<td>10 - 20 mg divided bid</td>
<td>Telazosin (Hydro™)</td>
<td>1 mg, 3 mg, 5 mg, 10 mg capsules</td>
<td>1 - 20 mg q 8 hs; 1 mg q 12 hs</td>
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<tr>
<td>Captopril (Cardura™)</td>
<td>1 - 16 mg q 8 hs</td>
<td>Guanfacine (Tenex™)</td>
<td>1 mg, 2 mg tablets</td>
<td>1 - 3 mg q 8</td>
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<td>Prazosin (Minipress®)</td>
<td>3 - 20 mg in 2 - 3 doses/day</td>
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<td>0.1 mg tid to 1 mg q 8</td>
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<tr>
<td>Clonidine (Catapres™)</td>
<td>0.1 - 0.8 mg tid</td>
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<td>0.1 mg tid to 1 mg q 8</td>
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**Anti-Retroviral Medications**

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<td>Kaletra (Lopinavir/Ritonavir)</td>
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<td>Darunavir (Crixivan)</td>
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<td>100mg QD</td>
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<tr>
<td>Efavirenz (Sustiva)</td>
<td>600mg TID</td>
<td>150mg, 300mg</td>
<td>150-300mg bid to 210-350mg QD</td>
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<td>Atazanavir (Reyataz™)</td>
<td>300mg QD</td>
<td>300 mg bid to 600 mg bid</td>
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<td>Darunavir (Crixivan)</td>
<td>800 mg TID or 800 mg +</td>
<td>800 mg bid to 200 mg bid</td>
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<tr>
<td>Emtricitabine (Emtriva™)</td>
<td>200mg bid</td>
<td>150mg bid to 300mg bid</td>
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<td>Tenofovir (Viread™)</td>
<td>25mg QD</td>
<td>25mg QD</td>
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<td>Tenofovir (Viread™)</td>
<td>300mg QD</td>
<td>25mg QD to 75mg QD</td>
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<td>Tenofovir (Viread™)</td>
<td>300mg bid</td>
<td>25mg QD to 75mg bid</td>
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<td>Dose Range &amp; Frequency andDosages Available</td>
<td>Comments/Appropriate Equivalent (Non-Formulary to Formulary)</td>
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<tr>
<td>Efavirenz + Etravirine + Tenofovir Disosinate + Fumarate (Atripla®)</td>
<td>600mg + 300mg + 300mg QD</td>
<td>Efavirenz (Sustiva®), Etravirine (Tivicay®), TDF 300mg + Tenofovir (Viread®, TDF) 300mg</td>
<td>600mg + 300mg + 300mg QD, Atripla® to EFV 600mg + TDF 100mg + TDF 300mg QD</td>
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<tr>
<td>Efavirenz + Etravirine + Tenofovir Alafenamide (Bilvy®)</td>
<td>50 mg + 100 mg + 25 mg QD</td>
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<td>Lamivudine + Tenofovir Disosinate Fumarate (Combivir®)</td>
<td>300mg + 300mg QD</td>
<td>Lamivudine (Epivir®), FTC 300mg + Tenofovir (Viread®, TDF) 300mg</td>
<td>300mg + 300mg QD</td>
<td>Combivir® to FTC 300mg + TDF 300mg QD</td>
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<td>Zidovudine + Lamivudine (Combivir®)</td>
<td>300mg BD + 150mg BD</td>
<td>Zidovudine (Hivid®), FTC 300mg + Lamivudine (Epivir®), FTC 300mg</td>
<td>300mg + 150mg BD</td>
<td>Combivir® to FTC 300mg + FTC 150mg BD</td>
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<td>Truvada® (Emtricitabine + Tenofovir (Combivir®))</td>
<td>200 mg + 15 mg + 300 mg QD</td>
<td>Emtricitabine (Emtriva®), FTC 300mg + Tenofovir (Viread®, TDF) 300mg</td>
<td>300mg + 25 mg + 300mg QD</td>
<td>Emtriva® to FTC 300mg + TDF 25mg + TDF 300mg QD</td>
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<td>Truvada® (Emtricitabine + Tenofovir (Combivir®))</td>
<td>200 mg + 15 mg + 300 mg QD</td>
<td>Emtricitabine (Emtriva®), FTC 300mg + Tenofovir (Viread®, TDF) 300mg</td>
<td>300mg + 25 mg + 300mg QD</td>
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<td>Dolutegravir + Lamivudine + Tenofovir Disosinate Fumarate Cipla (®)</td>
<td>100mg + 300mg + 300mg QD</td>
<td>Dolutegravir (Tivicay®), FTC 300mg + Lamivudine (Epivir®), FTC 300mg</td>
<td>100mg + 300mg + 300mg QD</td>
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<td>Abacavir + Lamivudine Gilead (®)</td>
<td>600mg + 300mg QD</td>
<td>Abacavir (Ziagen®), FTC 300mg + Lamivudine (Epivir®), FTC 300mg</td>
<td>600mg + 300mg QD</td>
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<td>Adefovir + Cobicistat (Fortovase®)</td>
<td>300mg + 50 mg QD</td>
<td>Adefovir (Hivid®), FTC 300mg + Cobicistat (Fortovase®), FTC 50mg</td>
<td>500mg + 100mg QD</td>
<td>Fortovase® to ATR 50mg + FTC 100mg</td>
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<tr>
<td>Tenofovir Alafenamide + Bicapivir (Bicapivir®)</td>
<td>10mg + 150mg + 150mg QD</td>
<td>Tenofovir (Viread®, TDF) 300mg + Bicapivir (Bicapivir®), FTC 150mg, FTC 50mg</td>
<td>50 mg + 25 mg QD</td>
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<td>Dolutegravir + Rilpivirine Gilead (®)</td>
<td>50 mg + 25 mg QD</td>
<td>Dolutegravir (Tivicay®), FTC 300mg + Rilpivirine (Eduract®), FTC 25mg</td>
<td>50mg + 25mg QD</td>
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<tr>
<td>Name of Non-Formulary Medication</td>
<td>Dose Range &amp; Frequency</td>
<td>Name of Formulary Medication</td>
<td>Dose Range &amp; Frequency</td>
<td>Comments/Approximate Equivalent (Dose, Equivalent to Formulary)</td>
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<td>------------------------</td>
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<tr>
<td>Darunavir + Cobicistat (Prezista®)</td>
<td>800mg + 150mg OD</td>
<td>Darunavir (Prezista®), DRV</td>
<td>800mg + 100mg OD</td>
<td>800mg + 100mg OD Prezista® to DRV 800mg + RTV 100mg OD</td>
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<td>Telzor + Lõvastatin + Calcium Channel Blocker (Triclabid®)</td>
<td>200mg + 150mg + 150mg + 125mg OD</td>
<td>Telzor (Lõvastatin), CCB</td>
<td>200mg + 150mg + 125mg OD</td>
<td>250mg + 150mg + 125mg OD Telzor to 3TC 300mg + DRV 25mg + TDF 100mg</td>
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<td>600mg + 300mg + 500mg OD Etxoxavir to DRV 800mg + TDF 300mg OD</td>
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<td>Etxoxavir (Lõvastatin), Fumarate</td>
<td>200mg + 300mg OD</td>
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<td>Frequency</td>
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<td>Microsphere</td>
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<td>Neomycin Ointment 0.05%</td>
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<th>Name of Formulary Medication</th>
<th>Dose Range &amp; Frequency and Dosages Available</th>
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<td>Low Potency Topical Steroids</td>
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<td>(Atrolate) 0.05%</td>
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<td>Mometasone (Derm) 0.1% 60 ml solution</td>
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<td>Dexamethasone (Decort) 0.16%</td>
<td></td>
<td></td>
<td>Hydrocortisone (Reposit) 1% 50 gm tube, unit dose packets</td>
<td></td>
</tr>
<tr>
<td>Flucinolone furoate 0.05%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OPIOID DISCONTINUATION

1. Does the patient have any acute psychiatric issues warranting crisis management or psychiatric admission?
   - Yes
     - Transfer patient to a 24 hour medical facility.
     - Order baseline EKG and repeat as clinically indicated.
     - Go to box # 7
   - No
     - Transfer patient to 24 hour medical facility, if patient is not already transferred.
     - Administer clonidine 0.1mg tid up to 0.3mg tid for 7 days; taper over additional 3 days. Maximum total daily dose should not exceed 1mg/day.
     - Monitor vital signs before every administration of clonidine. Clonidine should be held if systolic blood pressure (SBP) <90mmHg, diastolic blood pressure (DBP) <60mmHg, or pulse rate (PR) < 50 bpm.
     - Provide supportive care for pain, nausea, vomiting and diarrhea as clinically indicated.
     - Monitor patient for severe complications, i.e., signs of dehydration and acute mental status changes. If present, transfer to higher level of care.

2. Does the patient have underlying cardiac disease, i.e., CAD, Heart Failure, history of arrhythmias?
   - Yes
     - Transfer patient to an inpatient psychiatric facility.
     - Go to box #7
   - No

3. Is patient having moderately severe withdrawal symptoms (score of >24 on the COWS)?
   - Yes
     - Transfer patient to 24 hour medical facility, if patient is not already transferred.
     - Administer clonidine 0.1mg tid up to 0.3mg tid for 7 days; taper over additional 3 days. Maximum total daily dose should not exceed 1mg/day.
     - Monitor vital signs before every administration of clonidine. Clonidine should be held if systolic blood pressure (SBP) <90mmHg, diastolic blood pressure (DBP) <60mmHg, or pulse rate (PR) < 50 bpm.
     - Provide supportive care for pain, nausea, vomiting and diarrhea as clinically indicated.

4. Does the patient have underlying cardiac disease, i.e., CAD, Heart Failure, history of arrhythmias?
   - Yes
     - Transfer patient to an inpatient psychiatric facility.
     - Go to box #7
   - No

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, October 2008. Revised 01/11. Revised 9/2014
Do not discontinue methadone in a pregnant patient.
- Therapy should be tapered and discontinued postpartum.
- Patient should be transferred to a 24-hour medical facility (Young Unit) for postpartum care.
- Patient should be discharged from the hospital on methadone as part of the postpartum discharge orders.
- Methadone is a non-formulary medication that requires Regional Medical Director approval. Taper should not take longer than 7-10 days. Clinical pharmacists may be consulted for tapering recommendations. See Table 1 for examples.
- Provide supportive care for pain, nausea, vomiting, and diarrhea as clinically indicated.

Table 1. Examples of Methadone Tapering Schedule Postpartum

<table>
<thead>
<tr>
<th>If discharge methadone total daily dose is &gt;40mg:</th>
<th>If discharge methadone total daily dose is ≤40mg:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Decrease dose by 20mg/day until 40mg is reached.</td>
<td>• Decrease dose by 5mg/day until it is discontinued.</td>
</tr>
<tr>
<td>• Then, decrease dose by 5mg/day until it is discontinued.</td>
<td></td>
</tr>
</tbody>
</table>

Example: 100mg/day
- 80mg Day 1
- 60mg Day 2
- 40mg Day 3
- 30mg Day 4
- 20mg Day 5
- 15mg Day 6
- 10mg Day 7
- 5mg Day 8
- Discontinue Day 9

Example: 40mg/day
- 35mg Day 1
- 30mg Day 2
- 25mg Day 3
- 20mg Day 4
- 15mg Day 5
- 10mg Day 6
- 5mg Day 7
- Discontinue Day 8

Monitor patient for severe complications, i.e., signs of dehydration and acute mental status changes. If present, transfer to higher level of care.
Clinical Opiate Withdrawal Scale (COWS)

The Clinical Opiate Withdrawal Scale (COWS) is an 11-item scale. This tool can be used in both inpatient and outpatient settings to rate common signs and symptoms of opiate withdrawal. The summed score for the complete scale can be used to help determine the stage or severity of opiate withdrawal and assess the level of physical dependence on opioids.

For each item, write in the number that best describes the patient’s signs or symptoms.

Score:
- Mild = 5-12
- Moderate = 13-24
- Moderately severe = 25-36
- Severe ≥ 37

<table>
<thead>
<tr>
<th>Signs and Symptoms</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resting Pulse Rate:</strong> (record beats per minute)</td>
<td></td>
</tr>
</tbody>
</table>
  Measured after patient is sitting or lying down for one minute  
  0 = pulse rate 80 or below  
  1 = pulse rate 81–100  
  2 = pulse rate 101–120  
  4 = pulse rate greater than 120 |
| **Sweating:** over past ½ hour not accounted for by room temperature or patient activity |  
  0 = no report of chills or flushing  
  1 = subjective report of chills or flushing  
  2 = flushed or observable moistness on face  
  3 = beads of sweat on brow or face  
  4 = sweat streaming off face |
| **Restlessness:** observation during assessment |  
  0 = able to sit still  
  1 = reports difficulty sitting still, but is able to do so  
  3 = frequent shifting or extraneous movement of legs/arms  
  5 = unable to sit still for more than a few seconds |
| **Pupil size:**  
  0 = pupils pinned or normal size for room light  
  1 = pupils possibly larger than normal for room light  
  2 = pupils moderately dilated  
  5 = pupils so dilated that only the rim of the iris is visible |
| **Bone or joint aches:** if patient was having pain previously, only the additional component attributed to opiate withdrawal is scored |  
  0 not present  
  1 mild/diffuse discomfort  
  2 patient reports severe diffuse aching of joints/muscles  
  4 patient is rubbing joints or muscles and is unable to sit still because of discomfort |

Cont. next page
### Signs and Symptoms

<table>
<thead>
<tr>
<th></th>
<th>Score</th>
</tr>
</thead>
</table>
| Runny nose or tearing| 0 = none present  
|                      | 1 = nasal stuffiness or unusually moist eyes  
|                      | 2 = nose running or tearing  
|                      | 4 = nose constantly running or tears streaming down cheeks  |
| GI upset: over last ½ hour| 0 = no GI symptoms  
|                      | 1 = stomach cramps  
|                      | 2 = nausea or loose stool  
|                      | 3 = vomiting or diarrhea  
|                      | 5 = multiple episodes of diarrhea or vomiting  |
| Tremor: observation of outstretched hands| 0 = no tremor  
|                      | 1 = tremor can be felt, but not observed  
|                      | 2 = slight tremor observable  
|                      | 4 = gross tremor or muscle twitching  |
| Yawning: observation during assessment| 0 = no yawning  
|                      | 1 = yawning once or twice during assessment  
|                      | 2 = yawning three or more times during assessment  
|                      | 4 = yawning several times/minute  |
| Anxiety or irritability| 0 = none  
|                      | 1 = patient reports increasing irritability or anxiousness  
|                      | 2 = patient obviously irritable or anxious  
|                      | 4 = patient so irritable or anxious that participation in the assessment is difficult  |
| Gooseflesh skin| 0 = skin is smooth  
|                      | 3 = piloerrection of skin can be felt or hairs standing up on arms  
|                      | 5 = prominent piloerrection  |
| **Total Score** | |

*COWS adapted from National Institute on Drug Abuse. [http://www.drugabuse.gov/nidamed-medical-health-professionals](http://www.drugabuse.gov/nidamed-medical-health-professionals)
I. Opioid withdrawal
   A. Definition - Clinical syndrome produced by discontinuation of an opioid drug from an opioid-dependent patient
   B. Onset of symptoms - Initial signs and symptoms may occur in a few hours or up to 48 hours after cessation or reduction in dosage of an opioid, depending upon the half-life of the drug concerned. Withdrawal of longer-acting opioids produces a withdrawal syndrome with a more delayed onset, milder severity and prolonged duration. Methadone withdrawal typically begins 36 to 48 hours after the last dose, peaks after about 3 days, and gradually subsides over a period of 3 weeks or longer depending on the dose and duration of use.
   C. Symptoms
      1. Usually are self-limiting and generally non-life threatening, unless there is a concurrent serious medical condition.
      2. Milder symptoms may include restlessness, mydriasis, lacrimation, rhinorrhea, sneezing, piloerection, yawning, perspiration, restless sleep and aggressive behavior.
      3. More severe symptoms may include muscle spasms, back aches, abdominal cramps, hot and cold flashes, insomnia, nausea, vomiting, diarrhea, tachypnea, hypertension, hypotension, tachycardia, bradycardia and cardiac arrhythmias.

II. Management
   A. Educate the patient on signs and symptoms of withdrawal
   B. Monitor the following
      1. Vital signs daily
      2. Signs of dehydration, acute mental changes and aggravation of underlying cardiac disease
   C. Provide supportive care if needed
      1. Pain – ibuprofen, acetaminophen
      2. Nausea & Vomiting – promethazine
      3. Diarrhea – loperamide
   D. Clonidine may be used to alleviate severe symptoms
      1. Usual Dose - 0.1mg po tid up to 0.3mg po tid (0.006mg/kg/day in divided doses, maximum 1mg/day). Severity of withdrawal symptoms and baseline blood pressure should be considered when initiating clonidine.
      2. Continue effective dose for 7 days, then taper and discontinue over the next 3 days.
      3. Monitoring
         a. Vital signs should be checked before every administration of clonidine.
         b. Clonidine should be held if SBP <90mmHg, DBP <60mmHg, or PR< 50 bpm
Nursing Standing Delegation Orders for Administration of Naloxone for Opioid Overdose will be followed. Please refer to UTMB/CMC Nursing Services Policy Manual or Texas Tech Nursing Policy Manual, Suspected Opioid Overdose.

2. If signs of opioid overdose are suspected (Box A, Box B), 911 will be activated and the provider will be notified.

3. Naloxone (Narcan®) nasal spray - one spray (4 mg) in one nostril - will be administered to the patient.

4. If patient has not responded (e.g., presence of respirations, response to external stimuli) in 2 minutes, another dose of naloxone nasal spray will be administered in the alternate nostril. Provider will be notified of the patient’s condition.

5. Naloxone administration may precipitate withdrawal symptoms (Box C). Abrupt withdrawal may result in adverse cardiovascular (CV) effects in patient with pre-existing CV disease. Please refer to Opioid Discontinuation DMG.

6. At any time, the provider will be notified for any changes in the patient’s condition.

**Box A. Overdose Risk Factors**
- High-dose prescription opioids
- Lung, kidney, or liver disease
- Mixing opioids with other drugs
  - Benzodiazepines
  - Gabapentin
  - Promethazine
  - Stimulants

**Box B. Opioid Overdose Signs and Symptoms**
- Unresponsive or less responsive
- Depressed mental status or decreased mentation
- Pinpoint pupils
- Slow/shallow breathing (< 8 breaths per minute)
- Cold skin
- Blue nails or lips
- Choking or gurgling sounds

**Box C. Withdrawal Symptoms**
- Diarrhea
- Fever
- Lacrimation
- Rhinorrhea
- Mydriasis
- Muscle Aches
- Insomnia
- Agitation
- Nausea
- Vomiting

**Box D. Naloxone Nasal Spray 4 mg**
- Opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- It is intended for immediate administration as emergency therapy in settings where opioids may be present.
- It is not a substitute for emergency medical care.
- It will not reverse the effects of synthetic cannabinoids (K-2 or “Spice”).
- Due to the duration of action of naloxone relative to the opioid, repeat doses may be necessary.
- Repeat doses may be necessary if partial agonists or mixed agonists/antagonists such as buprenorphine or pentazocine are present.
- Effectiveness of the nasal spray may be reduced in patients with nasal septal defects, mucosal damage (e.g., cocaine users), obstruction, trauma, epistaxis, or the common cold.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved November 2018.
Chronic Cancer Pain

1. Provider should complete a thorough history and physical including a comprehensive pain assessment (pg 3) to determine location, quality, type and intensity.
2. Provide patient with pain management education (see pg 6).
3. Initiate Step 1 Pharmacological Therapy as outlined and indicated (pg 5).

Mild Pain (Scale:1-3)

**OPIOID NAÏVE:**

- **First line therapy:**
  - Acetaminophen 650mg up to Q 4 hours
  - Naproxen 1500mg

**CURRENTLY PRESCRIBED OPIOID:**

- Failure of first or second line therapy:
  - Consider continuation of current analgesic regimen and increase dose if pain is not controlled
  - Assess pain control & opioid side effects at each visit
  - If pain goals are not met, reassess and consider adjunctive therapy

**SECOND LINE THERAPY**

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

- Naproxen 250mg

**FIRST LINE THERAPY**

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

**SECOND LINE THERAPY**

- Naproxen 250mg

**FIRST LINE THERAPY**

- Naproxen 250mg

**ADJUNCTIVE THERAPY**

- Naproxen 250mg

Moderate Pain (Scale:4-6)

**OPIOID NAÏVE:**

- First line therapy:
  - Acetaminophen 650mg up to Q 4 hours
  - Naproxen 1500mg

- Second line therapy:
  - Naproxen 250mg

**CURRENTLY PRESCRIBED OPIOID:**

- Failure of first or second line therapy:
  - Consider continuation of current analgesic regimen and increase dose if pain is not controlled
  - Assess pain control & opioid side effects at each visit
  - If pain goals are not met, reassess and consider adjunctive therapy

**SECOND LINE THERAPY**

- Naproxen 250mg

**FIRST LINE THERAPY**

- Naproxen 250mg

**SECOND LINE THERAPY**

- Naproxen 250mg

**CURRENTLY PRESCRIBED OPIOID:**

- Failure of first or second line therapy:
  - Consider addition and titration of adjunctive therapy according to pain syndrome (Table 1, pg 3)

Step 1 therapy:

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

Step 2 therapy:

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

Severe Pain (Scale:7-10)

**OPIOID NAÏVE:**

- First line therapy:
  - Acetaminophen 650mg up to Q 4 hours
  - Naproxen 1500mg

- Second line therapy:
  - Naproxen 250mg

**CURRENTLY PRESCRIBED OPIOID:**

- Failure of first or second line therapy:
  - Consider addition and titration of adjunctive therapy according to pain syndrome (Table 1, pg 3)

**SECOND LINE THERAPY**

- Naproxen 250mg

**FIRST LINE THERAPY**

- Naproxen 250mg

**SECOND LINE THERAPY**

- Naproxen 250mg

**CURRENTLY PRESCRIBED OPIOID:**

- Failure of first or second line therapy:
  - Consider addition and titration of adjunctive therapy according to pain syndrome (Table 1, pg 3)

Step 1 therapy:

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

Step 2 therapy:

- Acetaminophen 650mg up to Q 4 hours
- Naproxen 1500mg

**ADJUNCTIVE THERAPY**

- Naproxen 250mg

**ADJUNCTIVE THERAPY**

- Naproxen 250mg

**ADJUNCTIVE THERAPY**

- Naproxen 250mg


227
I. History & Physical – oncologic treatment, radiation, surgery and pre-existing chronic pain

II. Pain Assessment

A. Qualify pain (C.O.L.D.E.R.)
   1. C = character or quality of pain
      a. Somatic pain in skin, muscle, or bone that is well localized and often described as aching, stubbing, throbbing, or pressure
      b. Visceral pain in organs that is poorly localized and is often described as gnawing, cramping, or squeezing
      c. Neuropathic pain that is often described as sharp, tingling, burning, shooting, or stabbing and is associated with numbness
   2. O = onset of pain
   3. L = location of pain including referral pattern and radiation
   4. D = duration of pain
   5. E = exacerbation, what factors aggravate or worsen pain
   6. R = remission, what factors alleviate or improve pain

B. Use pain rating scale to assess intensity of pain
   1. Evaluate pain currently and within last 24 hours
   2. Evaluate pain at rest and with movement

C. Identify associated symptoms such as nausea, vomiting or sleep disturbance

D. Identify potential etiology - cancer, cancer therapy (XRT, chemotherapy, surgery), or not cancer related

E. Determine if pain interferes with activities

F. Observe pain response during physical exam and movement during clinic visit to assess level of pain and interference with daily activities.

G. Current and past pain medication use – reason for use, length of therapy, effectiveness, side effects, and reason for discontinuation

III. Psychosocial Assessment – psychiatric history, risk factors for aberrant use or diversion, risk factors for under-treatment of pain

IV. Management

A. Treat underlying causes
B. Non-Pharmacologic Interventions
   1. Consider assistive devices for bed, bath, and walking if indicated
   2. Consider physical therapy (PT) if indicated. PT techniques may be useful in teaching patients to control pain, by moving in a safe and structured way
   3. Consider thermal therapy with ice or warm compress

C. Pharmacologic Therapy
   1. Stepwise approach including simple analgesics, opioid combinations, and opioid analgesics plus or minus adjunctive therapy.
   2. NSAIDS
      a. If two NSAIDS are tried in succession without efficacy, use another approach to analgesia
      b. If NSAIDS are effective but treatment is limited by toxicities that are not deemed serious, consider trial of another NSAID that is less readily excreted (eg, Meloxicam)
   c. Adverse effects – Toxicity of some anti-cancer treatment may increase the risk profile of NSAIDs
   d. GI - If patient develops gastric upset or nausea, consider discontinuing NSAID, changing agents, or adding protective therapy such as histamine or proton pump inhibitors
   e. Cardiac - Discontinue NSAID if hypertension develops
   f. Renal - Discontinue NSAID if BUN or creatinine doubles or if hypertension develops
   g. Mouth - Discontinue NSAID if oral ulcer or gastrointestinal bleeding develops
   h. Monitoring
      1. Baseline blood pressure, BUN, creatinine, CBC, fecal occult blood
      2. Repeat as clinically indicated every 3 months
   i. Consider – NSAIDS are antiplatelet and may mask fever. Use caution in patients on myelosuppressive chemotherapy.
   j. NSAIDS may have ameliorating effects that can increase the risk of bleeding in patients who are thrombocytopenic or on myelosuppressive chemotherapy and likely to become thrombocytopenic. Consider non-NSAIDS such as acetaminophen.
   k. Adjunctive therapy
      a. Consider addition of adjunctive therapy according to pain syndrome
      b. Titrate dose to adequate response or intolerable side effects.
Cancer Pain Syndrome

**Dosing**

- Medication
- Patient
- Dose
- BID
- Opioid
- 30
- 4
- Exacerbations
- 25
- Upon
- Or
- Additional Information
- Without
- 3
- Or
- Hour
- 24
- Provide
- Without
- 60
- On
- Stable
- If
- 50
- Neuropathic
- More
- Prn
- Opioid
- Of
- Appropriate
- Pain
- 25
- With
- Total
- Dose
- Are
- The
- Schedule
- By
- Increase
- Principles
- Clock
- Converting
- Relieved
- New
- If
- 15
- Sustained
- The
- Dose
- Increase
- Extended
- Analgesics
- Opioid
- Consider
- Total
- –
- The
- Opioids
- Interval
- Rescue
- Dose
- Increase
- Rapidity
- To
- Effects
- To
- Dose-
- Alternative
- To
- –
- Regular
- Is
- Following
- BID
- From
- Or
- (Breakthrough)
- QID
- Dose
- Or
- Downward
- Guide
- Morphine
- Is
- The
- Severity
- Hour
- Symptoms
- Not
- Scheduled
- By
- Of
- An
- 4
- Including
- Related
- Opioids
- Scheduled
- And
- Breakthrough
- Effects
- May
- Be
- Calculated
- In
- A
- Continuous
- Scale
- Experiencing
- (Needed
- Based
- On
- Individual
- Response)
- Max Daily Dose is 60 mg QD
- The
- Opioids
- Require
- Increase
- Requirement,
- Requirement
- Is
- Increased
- Prn
- If
- More
- Than
- Prn
- Increase
- To
- 25
- Or
- More
- Opioids
- May
- Cause
- GI
- Upset
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Increase
- Blood
- Glucose
- May
- Cause
- GI
- Upset
- Increased
- Appetite
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Cause
- GI
- Upset
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Increase
- Blood
- Glucose
- May
- Cause
- GI
- Upset
- Increased
- Appetite
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Increase
- Blood
- Glucose
- May
- Cause
- GI
- Upset
- Increased
- Appetite
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Increase
- Blood
- Glucose
- May
- Cause
- GI
- Upset
- Increased
- Appetite
- May
- Cause
- CNS
- Symptoms
- May
- Cause
- Hepatic
- Dysfunction
- May
- Increase
- Blood
- Glucose
- May
- Cause
- GI
- Upset
- Increased
- Appetite

**Table 1: Adjunctive Therapy**

<table>
<thead>
<tr>
<th>Pain Descriptor</th>
<th>Cancer Pain Syndrome (Drug Class)</th>
<th>Selected Drugs</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aching, dull, localized, tenderness</td>
<td>Neuropathic (Duloxetine or Venlafaxine)</td>
<td>Duloxetine 60 mg QD or Venlafaxine 75 mg QD</td>
<td>Use caution with Mental Health conditions and other Mental Health medications. Potential for causing dose-related increases in blood pressure and heart rate. Duloxetine has been associated with orthostatic hypotension and syncope. Use caution with Mental Health conditions and other Mental Health medications. Potential for abuse. Dosage based on renal and hepatic function.</td>
</tr>
<tr>
<td>Burning, tingling</td>
<td>Neuropathic (Duloxetine or Venlafaxine)</td>
<td>Duloxetine 60 mg QD or Venlafaxine 75 mg QD</td>
<td>Use caution with Mental Health conditions and other Mental Health medications. Potential for causing dose-related increases in blood pressure and heart rate. Duloxetine has been associated with orthostatic hypotension and syncope. Use caution with Mental Health conditions and other Mental Health medications. Potential for abuse. Dosage based on renal and hepatic function.</td>
</tr>
<tr>
<td>Shooting, incising, chronic neuralgias</td>
<td>Neuropathic (Duloxetine or Venlafaxine)</td>
<td>Venlafaxine ER 75 to 300 mg QD</td>
<td>Use caution with Mental Health conditions and other Mental Health medications. Potential for causing dose-related increases in blood pressure and heart rate. Duloxetine has been associated with orthostatic hypotension and syncope. Use caution with Mental Health conditions and other Mental Health medications. Potential for abuse. Dosage based on renal and hepatic function.</td>
</tr>
<tr>
<td>Colic, cramping, abdominal pain, Nausea, vomiting</td>
<td>Smooth muscle spasm (Anticholinergics)</td>
<td>Oxybutynin 5-10 mg TID</td>
<td>Used for bladder spasms and retention. Max daily dose 30 mg</td>
</tr>
</tbody>
</table>

V. Opioid Analgesics

A. General Principles

1. The appropriate dose is the dose that relieves the patient’s pain throughout the dosing interval without causing unmanageable side effects.
2. For continuous pain, provide pain medication on a regular schedule with supplemental doses for breakthrough pain.
3. Consider converting from short-acting opioids to extended-release opioids for control of chronic pain or pain associated with stable disease processes.
4. Provide rescue doses of short-acting opioids for pain not relieved by sustained-release opioids including breakthrough pain or acute exacerbations of pain, activity, or position related pain or pain in the end of dosing interval.
5. Rescue (Breakthrough) Dosing – usually provided at 10-33% of the 24-hour total daily scheduled dose as needed.

B. Dose Titration

1. B.1 For initial doses, dose upward in a 24 hour period, an increase in dose may be necessary.
2. Calculate dose increase based upon total daily opioid dose around the clock including scheduled and prn doses. Example: Total 24 hour opioid requirement, oxycodone 15 mg BID (30 mg) = 3 x 30 mg Breakthrough dose is 90 mg or more opened dose of 30 mg IR BID. As an alternative to calculating the total daily dose needed use the following guide:
   - Pain 4: Increase dose by 25%
   - Pain 5: Increase dose by 50%
   - Pain 6: Increase dose by 100%
3. The rapidity of dose escalation should be related to the severity of the symptoms.
4. If patient is experiencing unmanageable side effects and pain is < 4, consider downward dose titration by approximately 25% and reevaluate. Monitor to ensure pain control without escalation.
C. Switching opioids

1. Switch from fixed combination opioids to single entity opioid when acetaminophen dose > 4000mg/day.

2. Conversion equation:

\[
\text{Equianalgesic dose (route)} \times \text{Current opioid (route)} = \text{Equianalgesic dose (route)} \times \text{New opioid (route)}
\]

3. To convert from one opioid to another:
   a. Total the amount of current opioid (s) taken in a 24 hour period that effectively controls pain.
   b. Calculate the equianalgesic dose of the new opioid (Table 2).
   c. If patient was effectively controlled, reduce the dose by 25-50% to allow for incomplete cross tolerance between different opioids. During the first 24 hours, titrate rapidly to analgesic effect. If previous dose was ineffective, may begin with 100% of equianalgesic dose or increase that by 25%.
   d. Lastly divide the total daily dose of new opioid needed by the number of doses per day to determine the individual dose (e.g., new 24 hour morphine dose of 60mg, may be given as 10mg elixir Q 4 hrs or morphine ER 30mg Q 12 hrs).

<table>
<thead>
<tr>
<th>Opioid</th>
<th>Oral Dose (mg)</th>
<th>Parenteral (IV/SC) Dose</th>
<th>Conversion Factor IV to PO</th>
<th>Duration of Action (hrs)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>15</td>
<td>NA</td>
<td>15</td>
<td>ER: 4 hrs</td>
<td></td>
</tr>
<tr>
<td>Dicyclomine</td>
<td>20</td>
<td>NA</td>
<td>15</td>
<td>ER: 4 hrs</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>100</td>
<td>NA</td>
<td>15</td>
<td>ER: 4 hrs</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>10</td>
<td>5</td>
<td>2</td>
<td>2-3 hrs</td>
<td>• Extremely long half life and should be used with caution to avoid accumulation</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>10</td>
<td>5</td>
<td>2</td>
<td>2-3 hrs</td>
<td>• Extremely long half life and should be used with caution to avoid accumulation</td>
</tr>
<tr>
<td>Morphine</td>
<td>15</td>
<td>NA</td>
<td>15</td>
<td>ER: 4 hrs</td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>50</td>
<td>NA</td>
<td>5</td>
<td>2-3 hrs</td>
<td>• Weak opioid agonist. Recommended max dose is 400mg daily to avoid CNS toxicity.</td>
</tr>
</tbody>
</table>

D. Fentanyl patches

1. Use restricted to hospice patients or inpatients who are NPO without G-tube placement
2. Due to risk of fatal respiratory depression, use of fentanyl is not recommended for opioid-naive patients.
3. Patches should only be used in patients with stable opioid requirements. Due to its long half life, the dose may be difficult to titrate if pain is not well controlled
4. Use cautiously with CYP450 3A4 inhibitors, which can increase fentanyl plasma concentrations
5. For dosages exceeding 100 mcg, multiple patches can be used. Usual duration of action is 72 hours, but may be reduced to 48 hours for some patients.
6. Fever and heat from external sources (lamp, hot compress) accelerates drug release and should be avoided.
7. PRN morphine may be needed particularly during the first 8-24 hours after converting to the patch.
8. Dose adjustments should be based on the average amount of additional (rescue) opioid required over the 72 hour period.

Converting to Fentanyl patch

* Calculate the total 24 hour morphine dose.
* Table 3 displays the range of 24 hour fentanyl doses that are recommended for conversion to each fentanyl dose. Titrate no more frequently than every 3 days after the initial dose and every 6 days thereafter until analgesic efficacy.
* Due to patient variability, the doses suggested in table 3 are a guide. Clinical judgment must be used to titrate to the desired response.
Table 3: Fentanyl Conversion

<table>
<thead>
<tr>
<th>Oral Morphine (mg/24 hours)</th>
<th>Parenteral Morphine (mg/24 hours)</th>
<th>Transdermal Fentanyl Equivalent (mcg/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-65</td>
<td>0-22</td>
<td>25</td>
</tr>
<tr>
<td>65-115</td>
<td>23-57</td>
<td>50</td>
</tr>
<tr>
<td>116-150</td>
<td>58-92</td>
<td>75</td>
</tr>
<tr>
<td>151-190</td>
<td>93-127</td>
<td>100</td>
</tr>
<tr>
<td>201-225</td>
<td>128-162</td>
<td>125</td>
</tr>
<tr>
<td>226-300</td>
<td>163-200</td>
<td>150</td>
</tr>
</tbody>
</table>

Table 4: Management of Opioid Side Effects

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td> Anticipate and treat prophylactically. Goal is 1 BM every 1-2 days.</td>
</tr>
<tr>
<td></td>
<td> Encourage increased fluids, fiber and physical activity. [laxatives polyethylene glycol 3350 tablets (3 to 4 tabs BID)]</td>
</tr>
<tr>
<td></td>
<td> As a proactive measure, a bowel regimen should be prescribed with the initial opioid prescription consisting of at least a stool softener and a lubricant. (discontinue 100mg RBS &amp; bisacodyl (3-10mg HS))</td>
</tr>
<tr>
<td></td>
<td> For acute treatment of constipation, additional agents may be provided as needed.</td>
</tr>
<tr>
<td></td>
<td>- milk of magnesia 15-30 ml daily or</td>
</tr>
<tr>
<td></td>
<td>- lactulose 15-30 ml BID or</td>
</tr>
<tr>
<td></td>
<td>- If no bowel movement in 3 days, consider magnesium citrate or enema</td>
</tr>
<tr>
<td></td>
<td>- Last line – consider use of prokinetic agent (metoclopramide 10-20mg qid)</td>
</tr>
<tr>
<td></td>
<td> For acute treatment of constipation, additional agents may be provided as needed.</td>
</tr>
<tr>
<td></td>
<td> If no bowel movement in 3 days, consider magnesium citrate or enema</td>
</tr>
<tr>
<td></td>
<td>Last line – consider use of prokinetic agent (metoclopramide 10-20mg qid)</td>
</tr>
<tr>
<td>Dizziness</td>
<td> Usually resolves as body adjusts to medication.</td>
</tr>
<tr>
<td></td>
<td> Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.</td>
</tr>
<tr>
<td>Nausea</td>
<td> Take medication with food.</td>
</tr>
<tr>
<td></td>
<td> Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.</td>
</tr>
<tr>
<td>Respiratory Depression</td>
<td> May occur as a result of overaggressive titration, but can occur at any time.</td>
</tr>
<tr>
<td>Sedation</td>
<td> Sedation Scale. (Level 3 or higher – consider intervention)</td>
</tr>
<tr>
<td></td>
<td>4 = Somnolent, minimal or no response to physical stimulation</td>
</tr>
<tr>
<td></td>
<td>3 = Frequently drowsy, easily arousable, drifts off to sleep during conversation</td>
</tr>
<tr>
<td></td>
<td>2 = Slightly drowsy</td>
</tr>
<tr>
<td></td>
<td>1 = Awake and alert</td>
</tr>
<tr>
<td></td>
<td> Sedation can be induced or avoided with slow titration. Consider dose reduction with slow titration.</td>
</tr>
<tr>
<td></td>
<td> Rule out other causes such as concomitant CNS depressants, CNS pathology, hypocalcemia, dehydration, opiates, or infections.</td>
</tr>
<tr>
<td>Sweating</td>
<td> Relatively uncommon. Consider dose reduction as needed.</td>
</tr>
<tr>
<td>Vomiting</td>
<td> May resolve as body adjusts to medication. Hold the next dose. Increase fluids as appropriate. Progressive alimentation.</td>
</tr>
<tr>
<td></td>
<td> Consider short term use of metoclopramide or prochlorperazine.</td>
</tr>
<tr>
<td>Itching</td>
<td> Itching is often self-limiting but may be dose related. Consider antihistamine.</td>
</tr>
<tr>
<td></td>
<td> Pseudoallergies caused by endogenous histamine release from mast cells, include flushing, itching, sneezing, Stevens, reactions, exacerbation of asthma, and low blood pressure.</td>
</tr>
<tr>
<td></td>
<td> A true allergy to opioids is rare and seems to be T-cell mediated. Symptoms of a true opioid allergy include hives, maculopapular rash, erythema multiforme, partial rash, severe hypotension, bronchospasm, and angioedema.</td>
</tr>
<tr>
<td>Urinary Hesitation</td>
<td> May occur as a result of overaggressive titration.</td>
</tr>
<tr>
<td></td>
<td> Consider dose reduction as needed.</td>
</tr>
<tr>
<td></td>
<td> If the patient has the urge to urinate but is unable to void after 6 hours, immediate medical attention is required.</td>
</tr>
</tbody>
</table>

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Table 5: Mosby Pain Rating Scale

<table>
<thead>
<tr>
<th>Verbal/Vocal</th>
<th>Body Movement</th>
<th>Facial</th>
<th>Touching</th>
</tr>
</thead>
</table>
| 0            | Positive      | 0      | Moves easily | 0
| 2-4          | Whimpers/moans| 5      | Neutral, shifting, pacing | 2-4
| 5-7          | Repetitive comment, crying | 10 | Tense, not meeting | 5-7
| 8-10         | Screaming     | 8-10   | Clenched, tight muscles | 8-10

Table 6: Non-Communicative Rating Scale

<table>
<thead>
<tr>
<th>Verbal/Vocal</th>
<th>Body Movement</th>
<th>Facial</th>
<th>Touching</th>
</tr>
</thead>
</table>
| 0            | Positive      | 0      | Moves easily | 0
| 2-4          | Whimpers/moans| 5      | Neutral, shifting, pacing | 2-4
| 5-7          | Repetitive comment, crying | 10 | Tense, not meeting | 5-7
| 8-10         | Screaming     | 8-10   | Clenched, tight muscles | 8-10

E. Patient Education
1. Relaxation and deep breathing techniques – These methods focus the patient’s attention on performing a specific task, instead of concentrating on the pain.
2. Exercise - Helps in the correction of posture and may relieve symptoms in patients with nonspecific neck or lower back pain.
3. Encourage patients to report poor pain control or side effects.
4. Discuss treatment goals and expectations.
5. Discuss treatment options, potential side effects, and management of adverse effects.
6. If prescribed, discuss long-term use of opioid analgesics and concerns of addiction and need to increase dose if tolerance develops.

F. Referrals
1. Consider referral or consultation with pain specialist if pain is not controlled despite adequate dose, titration, and use of adjunctive therapies.
2. Oncologic Emergency – Severe uncontrolled pain is a medical emergency and should be evaluated & treated promptly (e.g., surgery, steroids, radiotherapy, antibiotics). Potential causes are listed below:
   a. Metastases – Brain, epidural, leptomeningeal
   b. Infection
   c. Bone fracture or impending fracture of weight-bearing bone
   d. Obstructed or perforated viscous
3. Consider mental health referral if patient appears to be depressed.

G. Monitoring and Assessment
1. Assess the four A’s at each clinic visit:
   a. Adverse effects
   b. Adherence to treatment & signs of aberrant drug-related behavior
   c. Activity – functional status, both physical and psychosocial
   d. Analgesic efficacy – pain, functioning, effectiveness
2. Use pain rating scales to assess intensity of pain (Table 5 and 6)
3. Prior to changing therapy:
   a. Compare pain assessment scores for changes
   b. Evaluate need for additional medications
   c. Evaluate need for additional medications
   d. Evaluate need for additional medications
   e. Administer the treatment changes in a stepwise manner to minimize daily dose as tolerated before changing drug therapy.
PAIN, BACK

ACUTE

1. Moderate to Severe Pain?

2. Yes

2. No

3. SEVERE PAIN:
(1) Activity Modification as Appropriate
(2) Ibuprofen 400 mg QID PRN X 7 days
(3) Methocarbamol 1500 mg TID X 7 days if Needed

4. Resolved?

5. Yes

5. No

6. Resolved?

7. Yes

7. No

8. Resolved?

9. Yes

9. No

10. Resolved?

11. Yes

11. No

12. Resolved?

13. Yes

13. No

9. Continue NSAID X 30 Days
   - Reevaluate Severity of Injury
   - Provide Self Exercise/Stretch Plan

10. Enter Chronic Back Pain Pathway on page 2 at box # 2

11. End Therapy

12. End Therapy

13. End Therapy

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.  Approved September 1995; Reviewed 3/05, 1/08; Revised 8/98, 4/02, 5/11, 9/17.
1. Consider:
   1) Nonmechanical source of pain;
   2) Imaging studies;
   3) Definitive Procedure.
   Chronic pain persists.

2. Consult Patient Regarding Nature of Disease
   (1) Weight Loss & Exercise
   (2) Coping with Chronic Pain
   (3) Self Exercise/Stretch Plan (Provide Exercise Handout available on CMCWEB DEPD homepage)
   Medication:
   Ibuprofen 600mg TID PRN X 30 days

3. Improved and adequate work up for nonmechanical etiology?
   Yes
   No
   Consider referral to further identify etiology.

4. Continue chronic maintenance at lowest effective dose.
   Utilizing 1 card to last 90 day NSAID orders when appropriate.

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may be increased in patients with cardiovascular disease or risk factors for cardiovascular disease. Ibuprofen is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery. NSAIDs can also cause an increased risk of serious gastrointestinal adverse events especially in the elderly, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved September 1995; Reviewed 3/05, 1/08; Revised 8/98, 4/02, 4/03, 5/11, 11/14, 9/17.
TREATMENT OF MILD TO MODERATE PAIN

Mild pain?

Yes

No

APAP 325 mg – 2 tablets QID prn x 10 days KOP
or
Ibuprofen 200 mg QID prn x 10 days KOP

Resolved?

Yes

No

APAP 325 mg – 2 tablets QID prn x 10 days KOP
or
Ibuprofen 400 mg TID prn x 10 days KOP
or
Naproxen 500 mg BID prn x 10 days KOP

Resolved?

Yes

No

End therapy

Treat another 10 – 20 days. Consider the following:
• Increase dose to maximally tolerated dose.
• Select another agent from a different drug class.
• Re-evaluate etiology of pain.

Resolving?

Yes

No

End therapy

The pathways do not replace usual clinical judgment, nor are they intended to strictly apply to all patients.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996;
Reviewed 3/01, 4/03, 1/07, 9/17; Revised 8/98, 12/98, 9/10, 1/13.
I. History & Physical

- Observe pain response during physical exam and movement during clinic visit to assess level of pain and interference with daily activities.

II. Pain Assessment

A. Qualify pain (C.O.L.D.E.R.)
   1. C = character or quality of pain
      a. Somatic pain in skin, muscle, or bone that is well localized and is often described as aching, stabbing, throbbing, or pressure.
      b. Visceral pain in organs that is poorly localized and is often described as gnawing, cramping, or aching.
      c. Neuropathic pain that is often described as sharp, tingling, burning, shooting, or stabbing and is associated with numbness.
   2. O = onset of pain
   3. L = location of pain including referral pattern and radiation
   4. D = duration of pain
   5. E = exacerbation, what factors aggravate or worsen pain
   6. R = remission, what factors alleviate or improve pain

B. Evaluate pain currently and within last 24 hours and evaluate pain at rest and with movement

C. Identify potential etiology

D. Determine if pain interferes with activities

III. Psychosocial Assessment

- Psychiatric history, risk factors for aberrant use or diversion, risk factors for undertreatment of pain

IV. Pharmacologic Therapy

A. Use simple analgesics
   - If treatment is ineffective:
     1. Increase dose to maximally tolerated dose or
     2. Select another agent from a different drug class

B. Refer to other pain pathways if needed
   1. Low back pain
   2. Neuropathic pain
   3. Chronic cancer pain

Table 1: Formulary Analgesics

<table>
<thead>
<tr>
<th>Formulary Medications</th>
<th>Usual Directions</th>
<th>Max Daily Dose</th>
<th>Drug Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen (APAP) 325mg *</td>
<td>1-2 tablets 2-4 times daily</td>
<td>4,000mg/day</td>
<td>Analgesic</td>
</tr>
<tr>
<td>Ibuprofen 200mg *</td>
<td>1 tablet 2-4 times daily</td>
<td>3,200mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Ibuprofen 400mg</td>
<td>1 tablet 2-4 times daily</td>
<td>3,200mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Ibuprofen 600mg</td>
<td>1 tablet 2-4 times daily</td>
<td>3,200mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Ibuprofen 800mg</td>
<td>1 tablet 2-4 times daily</td>
<td>3,200mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Naproxen 250mg</td>
<td>1 tablet 2-3 times daily</td>
<td>1,500mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Naproxen 500mg</td>
<td>1 tablet 2 times daily</td>
<td>1,500mg/day</td>
<td>NSAID - propionic acid</td>
</tr>
<tr>
<td>Meloxicam 7.5mg</td>
<td>1 tablet once daily</td>
<td>15mg/day</td>
<td>NSAID - oxicam</td>
</tr>
</tbody>
</table>

* Denotes Floor Stock Item
† Ranges should not be used in ordering medications.
NEUROPATHIC PAIN

Pain Assessment:
1. Detailed history
2. Focused physical exam
3. Treat underlying cause(s) appropriately

Initial treatment:
1. Provide patient education
2. Pharmacology Treatment - Monotherapy preferred

<table>
<thead>
<tr>
<th>Drug</th>
<th>Class</th>
<th>Initial Dose</th>
<th>Titration</th>
<th>Target Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Analgesic</td>
<td>325 mg tid pm</td>
<td>325 mg q week</td>
<td>Max dose=4g/day</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Analgesic</td>
<td>200 mg bid tid pm</td>
<td>200 mg q week</td>
<td>Max dose=3-4g/day</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Analgesic</td>
<td>250 mg bid pm</td>
<td>250 mg q week</td>
<td>500mg bid</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>Antidepressant</td>
<td>60 mg qd</td>
<td>-</td>
<td>60 mg qd</td>
</tr>
<tr>
<td>Venlafaxine HCL ER</td>
<td>Antidepressant</td>
<td>75 mg qd</td>
<td>75 mg q month</td>
<td>75 – 225 mg/day</td>
</tr>
<tr>
<td>Duloxetine Sodium</td>
<td>Anticonvulsant</td>
<td>250 mg qd</td>
<td>250 mg q month</td>
<td>500 - 1250 mg/day</td>
</tr>
<tr>
<td>Carbamazepine*</td>
<td>Anticonvulsant</td>
<td>200 mg qd</td>
<td>200 mg q month</td>
<td>1000 - 1600 mg/day</td>
</tr>
<tr>
<td>Pyridoxine**</td>
<td>Other</td>
<td>50 mg qd</td>
<td>-</td>
<td>Max dose = 100 mg/day</td>
</tr>
</tbody>
</table>

*see carbamazepine precaution on page 3
**see drug-induced neuritis (e.g., prescribe pyridoxine prophylactically with isoniazid)

Adequate pain relief?
1. Yes
2. No

Adequate pain relief?
1. Yes
2. Titrate dose as outlined in box 2. Consider switching to a different agent if patient does not respond to adequate trial.
3. No

Adequate pain relief?
1. Yes
2. Titrate dose as outlined in box 2. Consider combination therapy if patient does not respond to adequate trial of monotherapy
3. No

Consider other therapeutic alternatives
1. Yes
2. No

Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. Approved January 2005; Reviewed 11/14; Revised 3/08, 5/11, 01/18, 5/18.
I. Treatment Principles
A. Treat underlying conditions
1. Pain is not a diagnosis, it is a symptom. Patients should be evaluated for underlying medical conditions that might be the cause of pain and those conditions should be managed appropriately.
2. Common causes of neuropathic pain
   a. Disease process (e.g., HIV, diabetes, herpes zoster)
   b. Iatrogenic causes
      i. Antiretrovirals "d" drugs (e.g., zalcitabine = ddC, didenosine = ddI, stavudine = d4T)
      ii. Antibacterials (e.g., dapsone, isoniazid)
      iii. Antineoplastics (e.g., vinblastine, cisplatin)
   c. Nutritional deficiencies (e.g., vitamin B-12 deficiency)
B. Pain relief
1. Important to educate patients and define realistic goals and treatment expectations
2. Complete pain relief is unlikely to be achieved and most therapies only result in 30-50% reduction in pain
3. Generally respond to analgesics, antidepressants, and/or anticonvulsants
4. Combination therapy may be considered for patients that do not respond to monotherapy

II. Patient Evaluation
A. Assessment
1. General history – predisposing factors
   a. Past medical history
   b. Family history
   c. Social history
   a. C=character or quality of pain
   b. O=onset
   c. L=location of pain
   d. D=duration of pain
   e. E=exacerbation, what makes pain worse
   f. R=remission, what makes pain better
   g. Patient pain rating if possible to establish baseline pain severity and assess treatment response
      (See Page 3)
3. Physical exam
   a. Vitals
   b. Functional assessment
   c. Focused physical exam of part of body associated with pain

<table>
<thead>
<tr>
<th>Small Fiber Neuropathy</th>
<th>Large Fiber Neuropathy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal muscle-stretch reflexes</td>
<td>Reduced or absent muscle-stretch reflexes</td>
</tr>
<tr>
<td>Normal proprioception &amp; vibration sensation</td>
<td>Reduced proprioception &amp; vibration sensation</td>
</tr>
<tr>
<td>Reduced distal pinprick sensation</td>
<td>Reduced proprioception &amp; touch sensation</td>
</tr>
</tbody>
</table>


B. Presentation
1. Burning pain
2. Sharp pain described as pins & needles, prickling, or stabbing pain
3. Shooting pain
4. Aching in toes & feet reflects damage to longest axons
5. Tingling
6. Numbness
7. Often exacerbated at night or with standing or walking
III. Management
A. Treat underlying causes such as poor glycemic control in diabetics, correct nutritional deficiencies, and/or discontinue drug therapy if possible that may be causing neuropathic pain

B. Pharmacologic therapy
1. Analgesics, antidepressants, and anticonvulsants are mainstays of therapy
2. Evaluate selection of drugs based on co-morbidities and intensity of pain
3. Allow adequate time between dose adjustments and reassess pain severity prior to dose increases
4. Combination therapy may be considered for patients that do not respond to monotherapy

5. Gabapentin (Neurontin®) - A recent systematic review published by the American Academy of Neurology (http://n.neurology.org/content/neurology/88/20/1958.full.pdf) found gabapentin to be ineffective and reports of gabapentin drug abuse in the literature are increasing. Disadvantages of gabapentin include lack of efficacy, relative cost, multiple daily dosing, and abuse potential. Its use should be avoided.

6. Carbamazepine (Tegretol®) - Genetic Testing Recommended for People with Asian Ancestry
   a. Serious skin reactions (e.g., Stevens Johnson Syndrome) are more common in people with the HLA-B 1502 variant, a mutation found primarily in Asians. Reactions have been fatal.
   b. Carbamazepine should not be prescribed for patients with Asian ancestry unless no other reasonable alternative exists. If so, patients must undergo genetic testing for the mutation before being prescribed carbamazepine. Providers must obtain approval from their Regional or District Medical Director prior to ordering the test.
   c. The risks versus benefits of carbamazepine therapy should be weighed in patients that test positive and discussed with the Regional or District Medical Director prior to initiating therapy.
   d. Carbamazepine therapy may be continued in intake Asian patients or Asian patients already taking the medication for ≥ 3 months if they have not experienced adverse effects.

C. Patient Education
1. Pathophysiology
2. Treatment goals
3. Treatment expectations
4. Treatment plan

D. Consider specialty referral for patients that do not respond to an adequate trial of pharmacologic therapy or that might require additional diagnostic evaluation
POST TRAUMATIC STRESS DISORDER
and ACUTE STRESS DISORDER

1. Rule out medical causes for presentation.
2. Meet DSM-5 criteria for Post-Traumatic Stress Disorder or Acute Stress Disorder?
   Yes → Re-evaluate diagnosis and treat underlying cause.
   No → Move to next question.
3. Does the patient have co-morbid depression, bipolar disorder, or other anxiety disorder?
   Yes → Refer to appropriate co-morbid treatment pathway.
   No → Continue.
4. Obtain baseline BPRS.
   Yes → Psychotherapy should be the initial treatment of choice and should be continued throughout treatment, even if drug therapy is initiated.
   No → Continue.
5. Assess compliance.
   Yes → Continue therapy for 12 months, reassessing as needed by unit mental health provider. After 12 months, consider discontinuing medication.
   No → Refer to appropriate co-morbid treatment pathway.
6. Initiate formulary SSRI antidepressant.
   Yes → Continue therapy for 6-12 weeks at a therapeutic dose (Table 1).
   No → Refer to appropriate co-morbid treatment pathway.
7. Adequate response per BPRS?
   Yes → Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   No → Increase dose of current agent to maximal tolerated dose for 6-12 weeks OR Switch to alternative formulary agent (Table 1).
8. Adequate response per BPRS?
   Yes → Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   No → If compliance < 80%, counsel on medication compliance. Re-evaluate diagnosis and need for medication. Increase dose of current agent to maximal tolerated dose for 6-12 weeks OR Switch to alternative formulary agent (Table 1). OR Consider augmentation with non-formulary prazosin if nightmares are the prevalent symptom (Table 1). OR Consider pharmacotherapy consult.

Refer to appropriate co-morbid treatment pathway.

Proposed By The Correctional Managed Care Pharmacy & Therapeutics Committee.

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Table 1: Formulary Antidepressants

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Dose (Dose Range) mg/day</th>
<th>Therapeutic Range ng/mL</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram</td>
<td>20mg, 40mg tablet</td>
<td>Celexa® (20 – 40)</td>
<td>N/A</td>
<td>- Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Citalopram: EKG at baseline and as clinically indicated if risk factor for QTc prolongation is present</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine</td>
<td>20mg capsule</td>
<td>Prozac® (20 – 60)</td>
<td></td>
<td>- Fluoxetine has also been associated with QTc prolongation. EKG monitoring is encouraged if risk factors for QTc prolongation are present</td>
</tr>
<tr>
<td></td>
<td>Sertraline</td>
<td>50mg, 100mg tablet</td>
<td>Zoloft® (50 – 200)</td>
<td></td>
<td>- Dose-related increases in systolic blood pressure and pulse</td>
</tr>
<tr>
<td>Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)</td>
<td>Venlafaxine XR 75, 150 mg capsule</td>
<td>Effexor XR® (75 – 225 mg)</td>
<td>NA</td>
<td>- Emergence of suicidal ideation or behavior</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duloxetine</td>
<td>30, 60 mg capsules</td>
<td>Cymbalta® (30 – 60) mg</td>
<td></td>
<td>- Muscle rigidity, tremor, and resting tremor (observed with SNRIs)</td>
</tr>
<tr>
<td>Other*</td>
<td>Prazosin</td>
<td>1mg capsule</td>
<td>Minipres®</td>
<td>NA</td>
<td>- When discontinuing, taper over 1 week or more</td>
</tr>
</tbody>
</table>

* Risk factors for QTc prolongation include age > 65 years old, use of other concomitant QTc-prolonging medications, baseline hypokalemia or hypomagnesemia, or pre-existing cardiovascular impairment.  
* venlafaxine functions as an SNRI at doses ≥ 150 mg/day. At lower doses, venlafaxine functions more like an SSRI.  
* Not a formulary agent but may be requested via non-formulary approval process if nightmares are a predominant symptom

BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician

The Brief Psychiatric Rating Scale (BPRS) is a readily used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is initiated. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers.

The BPRS should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The BPRS typically takes 10-20 minutes for the interview and scoring.

Instructons for Use and Scoring:

Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excited, distractibility) can be followed over time.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers.

The BPRS should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The BPRS typically takes 10-20 minutes for the interview and scoring.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>2</td>
<td>ANXIETY - Worry, fear, over-concern for present or future, uneasiness</td>
</tr>
<tr>
<td>3</td>
<td>EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>4</td>
<td>CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>5</td>
<td>IMPULSIVENESS</td>
</tr>
<tr>
<td>6</td>
<td>MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td>7</td>
<td>MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>8</td>
<td>GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td>9</td>
<td>DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.</td>
</tr>
<tr>
<td>10</td>
<td>HOSTILITY - Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td>11</td>
<td>SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td>12</td>
<td>HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>13</td>
<td>MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td>14</td>
<td>UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.</td>
</tr>
<tr>
<td>15</td>
<td>UNUSUAL THOUGHT CONTENT - Unusual, odd, bizarre thought content.</td>
</tr>
<tr>
<td>16</td>
<td>BLURRED AFFECT - Reduced emotional tone, reduction in formal intensity of feelings, flatness.</td>
</tr>
<tr>
<td>17</td>
<td>EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td>18</td>
<td>DISORIENTATION - Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td>19</td>
<td>ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>20</td>
<td>SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td>21</td>
<td>BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>22</td>
<td>SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td>23</td>
<td>DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.</td>
</tr>
</tbody>
</table>
PSYCHOSIS, ACUTE

1. Rule out medical causes for presentation.

2. Meets DSM-IV Criteria for Psychosis? NO

   a. Repeat dose of agent, within limits listed in box #4 OR
   b. Switch to alternative agent listed in box #4 OR
   c. Consider IM lorazepam 0.5-2mg adjunct q 60 minutes as needed for persistent agitation (max 6mg/day)

3. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)? NO

   a. Consider pharmacotherapy consult OR
   b. Consider a second opinion OR
   c. Consider referral to inpatient facility for evaluation

4. EPS present? NO

5. Repeat diphenhydramine dose every 20-30 minutes (max 200mg/day)

6. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)? YES

   a. Schedule follow-up Mental Health Referral as indicated
   b. Patients returning from inpatient psych facilities should be seen by a qualified mental health professional within 48 hours Sunday-Thursday and 72 hours Friday-Saturday
   c. Switch to oral therapy when patient is able
   d. Refer to Chronic Psychosis DMG for continued management

7. WHY? 1. Monitor Parameters: Check patient at least once in first 15 minutes, then every 30 minutes at least twice in the next hour if patient remains on the unit.
   a. Mental Status: Alert and oriented, motor activity, speech, excessive sedation
   b. Extrapyramidal Symptoms (EPS): Dystonia, parkinsonism, akathisia, tremor, dyskinesia
   c. Behavioral: Psychosis (e.g. hallucinations, delusions, disorganized speech/behavior), agitated, agitated
   d. Neuroleptic Malignant Syndrome (NMS): Dehydration, vital signs, muscle rigidity, diaphoresis, alteration in consciousness, autonomic dysfunction (orthostatic hypotension, drooling, urinary incontinence, unusually rapid breathing)
   e. Vital Signs: Blood pressure, pulse, temperature, respiration (as clinically indicated)

8. Management of Adverse Effects
   a. Neuroleptic Malignant Syndrome
      i. Life-threatening emergency; evaluate through medical department for possible referral to hospital ER
      ii. Dantrolene 50mg IM (max 200mg/day)
   b. Acute Dystonic Reaction
   c. Reconsider possible medical etiology for presentation
   d. Reconsider possible medical etiology for presentation

9. Re-evaluate diagnosis and treat underlying causes

10. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?

11. YES


Proposed by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 12/02, reviewed 4/03, 5/03, 5/05, reviewed 11/05, 1/09, 7/10.
Psychosis, chronic

1. Rule out medical causes for presentation.

2. Meet DSM-5 criteria for Psychosis?
   - Yes: Re-evaluate diagnosis and treat underlying causes.
   - No: Obtain baseline information including BPRS, AIMS, and labs as Table 1.

3. Initiate monotherapy with formulary antipsychotic:
   - First Generation Antipsychotic (FGA) – titrate up to a maximum of 1,000mg CPZ equivalents and treat for at least 6 weeks (Table 3).
   - Second Generation Antipsychotic (SGA) – titrate up to a maximum of 6mg/day or ziprasidone up to 160mg/day and treat for at least 6 weeks.
   - Consider formulary SGA if:
     - AIMS positive for tardive dyskinesia
     - First break psychosis
     - History of positive response

4. Adequate response per BPRS?
   - Yes: Continue treatment and taper to lowest effective dose.
   - No: Monitor per recommendations in Tables 1-2.

5. Signs of Adverse Effects?
   - Yes: If at any time adverse effects are noted, go to Adverse Effect Management page 5.
   - No: Adequate response per BPRS?
     - Yes: Continue treatment and taper to lowest effective dose.
     - No: Re-evaluate diagnosis.

6. Assess compliance
   - If patient has received trial of 2 SGAs and has no contraindications, consider trial of a FGA.
   - If patient has not received a trial of an atypical, consider risperidone or ziprasidone.
   - Consider non-formulary SGA.

7. Re-evaluate diagnosis
   - Prefers an antipsychotic trial of adequate dose/duration is 4-6 weeks at FDA approved maximum dosage or maximum tolerated dose with a minimum of 80% adherence.

Note: If at any time compliance is poor, adequate education and prescribed antipsychotic medications are necessary, consider use of long-acting appropriate antipsychotic preparation. These are to be used as a stable dose, switch back to oral therapy. Refer to long acting injectable antipsychotic guidance - page 2.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee; 1/99; revised 4/00, 9/01, 5/02, 7/05, 9/07, 9/10, 5/13, 7/14, 5/16; reviewed 4/03.
Guidelines for Use of Long Acting Injectable Antipsychotic Agents

1. Significant noncompliance or partial compliance leading to decompensation or poor function and/or requirement for compelled medications with oral antipsychotic?

2. First break psychosis or history of tardive dyskinesia per AIMS?

   Yes
   • Consider non-formulary Risperdal Consta injection. Titrate to therapeutic dose (see Page 6).
   • Observe response for 6 months at maximum tolerated dose.

   No
   • Initiate haloperidol or fluphenazine decanoate. Titrate to therapeutic dose (see Page 6).
   • Observe response for 6 months at maximum tolerated dose.

3. Well tolerated and adequate response per BPRS?

   Yes
   • Continue at lowest effective dose.
   • Monitor per recommendations in Table 1 and 2.
   • Attempt switch to oral therapy if compliant and stable.

   No
   • Consider pharmacotherapy consult and/or non-formulary medication.

---

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Table 1: Metabolic and Endocrine Monitoring Guidelines

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Q 6 Months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, Height, BMI</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Complete Metabolic Panel</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td>As clinically indicated</td>
<td>As clinically indicated</td>
<td></td>
</tr>
<tr>
<td>EKG(^2)</td>
<td>As clinically indicated</td>
<td>As clinically indicated</td>
<td></td>
</tr>
</tbody>
</table>

Providers should consider obtaining any of the laboratories listed above more frequently if clinically indicated:

1. Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease or the patient is > 40 years old.
2. Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunction.
   - Routine screening for hyperprolactinemia is not recommended unless symptoms are present
   - The normal range of prolactin is 10-20mcg/L in males and 10-25mcg/L in females
   - Symptoms typically do not appear until levels reach 60-100mcg/L
   - Patients should be referred to medical to rule out other etiologies of hyperprolactinemia

Additional Monitoring Parameters for Specific Agents

- Ziprasidone (Geodon\(^\text{®}\)) - EKG at baseline then annually or as clinically indicated
- Quetiapine (Seroquel\(^\text{®}\)) - Ophthalmic exam checking for cataracts every 6 months
- Clozapine (Clozaril\(^\text{®}\)) - Refer to Pharmacy Policy 55-20 for recommendations

Table 2: Outcome and Adverse Effect Monitoring

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIMS (Abnormal Involuntary Movement Scale)</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td>-Acute EPS - Akathisia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Tardive Dyskinesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental Status Exam</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td>BPRS (Brief Psychiatric Rating Scale)</td>
<td>X</td>
<td>Baseline and at least every 6 months</td>
</tr>
<tr>
<td>-Medication is started, changed, or discontinued</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agent</td>
<td>Formulary Status</td>
<td>Potency</td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Conventional</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>F</td>
<td>Low</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>F</td>
<td>Mid</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Fluphenazine</td>
<td>NF</td>
<td>Low</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Thioridazine</td>
<td>NF</td>
<td>Low</td>
</tr>
<tr>
<td>Thiothixene</td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>F</td>
<td>Mid</td>
</tr>
<tr>
<td>Conventional</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Atypical</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>NF</td>
<td>++/++</td>
</tr>
<tr>
<td>Asenapine</td>
<td>NF</td>
<td>?</td>
</tr>
<tr>
<td>Chlorpromazine</td>
<td>NF</td>
<td>+++/+++</td>
</tr>
<tr>
<td>Risperidone</td>
<td>F</td>
<td>+++/+++</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>NF</td>
<td>+++/+++</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>F</td>
<td>+++/+++</td>
</tr>
</tbody>
</table>

*Should only be used in treatment-resistant illness. Contraindicated for use with agents that are known to prolong QTC, and agents that inhibit metabolites of thioridazine (such as: fluoxetine, paroxetine, fluvoxamine, propranolol)*
§ dose-dependent
# partial D2 agonist

Table 3: Antipsychotic Dosages and Adverse Effects
### Table 4: Adverse Effect Management

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Recommended Management Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EPS</strong></td>
<td>• Lower the dose of the antipsychotic agent to the lowest effective dose or</td>
</tr>
<tr>
<td></td>
<td>• Review table 3 and consider selecting an agent with a lower incidence of EPS or</td>
</tr>
<tr>
<td></td>
<td>• Switch to a SGA or</td>
</tr>
<tr>
<td></td>
<td>• Treat EPS with one of the following agents</td>
</tr>
<tr>
<td></td>
<td>• Benztropine 1 – 6 mg/day</td>
</tr>
<tr>
<td></td>
<td>• Diphenhydramine 25 – 100 mg/day</td>
</tr>
<tr>
<td></td>
<td>• Amantadine 100 – 300 mg/day</td>
</tr>
<tr>
<td></td>
<td>• Propranolol 20 – 120mg/day</td>
</tr>
<tr>
<td></td>
<td>• Short term use of benzodiazepines may be considered in severe cases in an inpatient setting</td>
</tr>
<tr>
<td></td>
<td>• Increase dose of agent or switch to alternate anti-EPS agent if ineffective</td>
</tr>
<tr>
<td>Akathisia</td>
<td>• Lower the dose of the antipsychotic agent to the lowest effective dose or</td>
</tr>
<tr>
<td></td>
<td>• Switch to a SGA or</td>
</tr>
<tr>
<td></td>
<td>• Treat with propranolol 20 – 120mg/day. Titrated dose as tolerated and as needed.</td>
</tr>
<tr>
<td>Tardive Dyskinesia</td>
<td>• Diagnosis supported by AIMS?</td>
</tr>
<tr>
<td></td>
<td>• Treat to a SGA</td>
</tr>
<tr>
<td></td>
<td>• Consider pharmacotherapy consult for treatment options</td>
</tr>
<tr>
<td>Neuroleptic Malignant Syndrome</td>
<td>• Medical emergency</td>
</tr>
<tr>
<td></td>
<td>• Evaluate through medical department for possible referral to emergency room</td>
</tr>
<tr>
<td></td>
<td>• Consider STAT CPK</td>
</tr>
<tr>
<td></td>
<td>• Discontinue antipsychotic</td>
</tr>
</tbody>
</table>

### Appropriate use of Anticholinergic Medications

Benztropine and diphenhydramine are associated with significant side effects and may potentially increase the risk of developing tardive dyskinesia, cognitive impairment, anticholinergic side effects, and delirium. Current treatment guidelines recommend against the use of anticholinergics for prevention of EPS unless the patient has a history of severe EPS.

- Anticholinergic medications use should be limited to the treatment of confirmed EPS and scheduled prophylactic use should be minimized.
- Lower starting doses of typical antipsychotics, with reasonable titration rates could potentially reduce the risk of treatment-emergent EPS.
- When treating EPS, use of anticholinergic medications should be evaluated every 3 months for possible discontinuation, as most cases of EPS are self-limiting and do not require long-term treatment.
Quick Reference Guide for Initiating Long-Acting Injectable Antipsychotics

Haloperidol Decanoate (Haldol-D®)

General information
• Formulary strength available: 100mg/ml solution for injection
• The first dose should be no more than 100mg
  – If > 100mg is needed, administer the remainder 3-7 days later
  – All future injections can be administered in doses up to 300mg at a time
• Inject in the gluteal muscle by z-track administration
• Dosing interval: 4 weeks
• Maximum approved dose = 450mg q4weeks

Loading dose method (preferred)
• Month 1: Initiate haloperidol decanoate at 20 times the oral haloperidol dose
  – Discontinue oral haloperidol at time of first injection
• Month 2: Haloperidol decanoate 15 times the oral haloperidol dose
• Month 3 and thereafter: Haloperidol decanoate 10 times the oral haloperidol dose

Traditional dosing method
• Initiate haloperidol decanoate at 10-15 times the oral haloperidol dose
• Continue oral haloperidol for 1 month, then discontinue

Fluphenazine Decanoate (Prolixin D®)

General information
• Formulary strength available: 25mg/ml solution for injection
• Inject in the gluteal muscle by z-track administration
• Dosing interval: 2-3 weeks
• Maximum approved dose = 100mg q2weeks
• Accumulation may occur over time; consider dose reduction after 6 months of treatment

Dosing method
• Initiate fluphenazine decanoate at 1.2-1.6 times the oral fluphenazine dose
  – Round to the nearest 12.5mg
• Continue oral fluphenazine for 1-4 weeks, then discontinue

Risperdal Consta®

General information
• Requires nonformulary approval
• Oral test dose is required if the patient has no documented history of risperidone use
  – Administer 1-2mg oral risperidone for 2 days prior to injection
• Inject in the deltoid or gluteal muscle
• Dosing interval: 2 weeks
• Maximum approved dose = 50mg q2weeks

Dosing method
• Initiate Risperdal Consta 25mg q2weeks
• Continue oral antipsychotic for 3 weeks, then discontinue
• Adjust dose no sooner than q4weeks, as needed
<table>
<thead>
<tr>
<th></th>
<th>Date of Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Muscles of facial expression</td>
</tr>
<tr>
<td>2</td>
<td>Lips and perioral area</td>
</tr>
<tr>
<td>3</td>
<td>Jaw</td>
</tr>
<tr>
<td>4</td>
<td>Tongue</td>
</tr>
<tr>
<td>5</td>
<td>Upper (arms, wrists, hands, fingers)</td>
</tr>
<tr>
<td>6</td>
<td>Lower (legs, knees, ankles, toes)</td>
</tr>
<tr>
<td>7</td>
<td>Neck, shoulders, hips</td>
</tr>
<tr>
<td>8</td>
<td>Severity of abnormal movements</td>
</tr>
<tr>
<td>9</td>
<td>Incapacitation due to abnormal movements</td>
</tr>
<tr>
<td>10</td>
<td>Patient’s awareness of abnormal movements</td>
</tr>
<tr>
<td>11</td>
<td>Current problems with teeth &amp;/or dentures?</td>
</tr>
<tr>
<td>12</td>
<td>Does patient usually wear dentures?</td>
</tr>
<tr>
<td>13</td>
<td>COMMENTS</td>
</tr>
</tbody>
</table>

- **Muscles of facial expression**: e.g. movements of forehead, eyebrows, preorbital area, cheeks, include frowning, blushing, smiling, grimacing
- **Lips and perioral area**: e.g. puckering, pouting, smacking
- **Jaw**: e.g. biting, clenching, chewing, mouth-opening, lateral movement
- **Tongue**: Rate only increase in movement both in and out of mouth, not inability to sustain movement
- **Upper (arms, wrists, hands, fingers)**: Include chronic movements (i.e. rapid, objectively purposeless, irregular, spontaneous); athetoid movements (i.e. slow, irregular, complex, serpentine). DO NOT include tremor (i.e. repetitive, regular, rhythmic).
- **Lower (legs, knees, ankles, toes)**: e.g. lateral knee movement, foot tapping, heel dropping, foot squirming, inversion, and eversion of foot
- **Neck, shoulders, hips**: e.g. rocking, twisting, squirming, pelvic gyrations

**Severity of Abnormal Movements**

- **Incapacitation due to abnormal movements**
- **Patient’s awareness of abnormal movements**: Rate only patient’s report:
  - No awareness = 0
  - Aware, no distress = 1
  - Aware, mild distress = 2
  - Aware, moderate distress = 3
  - Aware, severe distress = 4

**Current problems with teeth &/or dentures?**
- No = 0
- Yes = 1

**Does patient usually wear dentures?**
- No = 0
- Yes = 1

**COMMENTS**
BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician

Background:
The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measure when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual's behavior over the previous 2-3 days should also be considered and can be reported by the patient's caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed an antipsychotic.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring:
Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
### Brief Psychiatric Rating Scale (BPRS)

<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>SOMATIC CONCERN</strong> - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>2.</td>
<td><strong>ANXIETY</strong> - Worry, fear, over-concern for present or future, uneasiness</td>
</tr>
<tr>
<td>3.</td>
<td><strong>EMOTIONAL WITHDRAWAL</strong> - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>4.</td>
<td><strong>CONCEPTUAL DISORGANIZATION</strong> - Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>5.</td>
<td><strong>IMPULSIVENESS</strong></td>
</tr>
<tr>
<td>6.</td>
<td><strong>MOTOR HYPERACTIVITY</strong> - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td>7.</td>
<td><strong>MANIERSMIS AND POSTURING</strong> - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>8.</td>
<td><strong>GRANDIOSITY</strong> - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td>10.</td>
<td><strong>HOSTILITY</strong> - Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td>11.</td>
<td><strong>SUSPICIOUSNESS</strong> - Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td>12.</td>
<td><strong>HALLUCINATORY BEHAVIOR</strong> - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>13.</td>
<td><strong>MOTOR RETARDATION</strong> - Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td>14.</td>
<td><strong>UNUSUALITY OF THOUGHT CONTENT</strong> - Unusual, odd, strange, bizarre thought content.</td>
</tr>
<tr>
<td>15.</td>
<td><strong>BLUNTED AFFECT</strong> - Reduced emotional tone, reduction in formal intensity of feelings, flatness.</td>
</tr>
<tr>
<td>16.</td>
<td><strong>EXCITEMENT</strong> - Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td>17.</td>
<td><strong>DISORIENTATION</strong> - Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td>18.</td>
<td><strong>ELEVATED MOOD</strong> - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>19.</td>
<td><strong>SUICIDALITY</strong> - Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td>20.</td>
<td><strong>BIZARRE BEHAVIOR</strong> - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>21.</td>
<td>SELF-NEGLECT - Hygiene, appearance, or eating behavior below normal expectations, below socially acceptable standards or life threatening.</td>
</tr>
</tbody>
</table>
| 22. | DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractions are rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noises in an adjoining room, books on a shelf, interviewer’s clothing, etc.
Psychotropic Agents: Dosing, Approximate Equivalent Doses, & Recommendations for Switching Agents

Patients should be evaluated for use of formulary psychotropics when possible. Clinicians should consider history of response, contraindications, comorbidities, compliance, potential adverse effects, and drug interactions when making treatment decisions. When medications are changed, patients should be monitored closely for worsening symptoms and adverse effects. The recommendations listed below are not intended to replace sound clinical judgment. When treating elderly patients with psychotropic agents, lower starting doses and slower titration may be required.

**Note:** UTMB Mental Health Services Policy B-2. Prescribing of Psychoactive Medications. All offenders arriving in TDCJ with a current prescription for psychoactive medications will be continued on such medications (unless clinically contraindicated) until they are assessed by a psychiatrist or psychiatric physician assistant/nurse practitioner. Offenders referred for initial psychiatric assessment must be seen within 30 days of referral.

### ANTIDEPRESSANTS

**Table 1: Antidepressants**

<table>
<thead>
<tr>
<th>Generic Name (Brand Name)</th>
<th>Formulary Agent</th>
<th>Usual Dose (mg/day)</th>
<th>Approximate Equivalent Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline (Elavil®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Amoxapine (Asendin®)</td>
<td>N</td>
<td>100-400</td>
<td>100</td>
</tr>
<tr>
<td>Clomipramine (Anafranil®)</td>
<td>N</td>
<td>100-250</td>
<td>100</td>
</tr>
<tr>
<td>Desipramine (Norpramin®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Doxepin (Sinequan®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Imipramine (Tofranil®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Maprotiline (Ludiomil®)</td>
<td>N</td>
<td>100-225</td>
<td>100</td>
</tr>
<tr>
<td>Nortriptyline (Pamelor®)</td>
<td>N</td>
<td>50-150</td>
<td>50</td>
</tr>
<tr>
<td>Paroxetine (Paxil®)</td>
<td>N</td>
<td>15-60</td>
<td>20</td>
</tr>
<tr>
<td>Trimipramine (Surmontil®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram (Celexa®)</td>
<td>Y</td>
<td>20-40</td>
<td>20</td>
</tr>
<tr>
<td>Escitalopram (Lexapro®)</td>
<td>Y</td>
<td>10-20</td>
<td>10</td>
</tr>
<tr>
<td>Fluoxetine (Prozac®)</td>
<td>Y</td>
<td>20-60</td>
<td>20</td>
</tr>
<tr>
<td>Fluoxetine Delayed Release (Prozac Weekly®)</td>
<td>N Administered weekly (usual dose = 90 mg/week)</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Fluvoxamine (Luvox®)</td>
<td>N</td>
<td>100-300</td>
<td>100</td>
</tr>
<tr>
<td>Paroxetine (Paxil®)</td>
<td>N</td>
<td>IR = 20-30 CR = 25-75</td>
<td>IR = 20 CR = 25</td>
</tr>
<tr>
<td>Sertraline (Zoloft®)</td>
<td>Y</td>
<td>50-200</td>
<td>50</td>
</tr>
<tr>
<td>Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Venlafaxine (Effexor®)</td>
<td>Y (ER only)</td>
<td>IR = 75-375 CR = 75-300</td>
<td>IR = 150 CR = 150</td>
</tr>
<tr>
<td>Duloxetine (Cymbalta®)</td>
<td>Y</td>
<td>40-60</td>
<td>60</td>
</tr>
<tr>
<td>Levomilnacipran (Fetzima®)</td>
<td>N</td>
<td>40-120</td>
<td>N/A</td>
</tr>
<tr>
<td>Desvenlafaxine (Pristiq®, Khedezla®)</td>
<td>N</td>
<td>50</td>
<td>N/A</td>
</tr>
</tbody>
</table>

This dosing tool does not replace sound clinical judgment, nor is it intended to strictly apply to all patients. Caution: Approximate equivalent doses are only applicable within each antidepressant class, not between antidepressant classes.
ANTIDEPRESSANTS

### Norepinephrine Dopamine Reuptake Inhibitors (NDRIs)

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>FORMULARY AGENT</th>
<th>USUAL Dose (MG/DAY)</th>
<th>APPROXIMATE EQUIVALENT DOSE (MG)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bupropion HCl (Wellbutrin®)</td>
<td>N</td>
<td>IR = 300-450</td>
<td>IR = 150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SR = 190-400</td>
<td>SR = 150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>XL = 150-450</td>
<td>XL = 150</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>154</td>
</tr>
</tbody>
</table>

### Monoamine Oxidase Inhibitors (MAOIs)

(For use in inpatients or under the supervision of a qualified professional.)

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>FORMULARY AGENT</th>
<th>USUAL Dose (MG/DAY)</th>
<th>APPROXIMATE EQUIVALENT DOSE (MG)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isocarboxazid (Marplan®)</td>
<td>N</td>
<td>10-30</td>
<td>10</td>
</tr>
<tr>
<td>Phenelzine (Nardil®)</td>
<td>N</td>
<td>15-90</td>
<td>15</td>
</tr>
<tr>
<td>Tranylcypromine (Parnate®)</td>
<td>N</td>
<td>15-90</td>
<td>10</td>
</tr>
<tr>
<td>Selegiline (Eldepryl®)</td>
<td>N</td>
<td>6-12 (transdermal)</td>
<td>6</td>
</tr>
</tbody>
</table>

### Serotonin Receptor Modulators and Tetracyclic Antidepressants

(For use in inpatients or under the supervision of a qualified professional.)

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>FORMULARY AGENT</th>
<th>USUAL Dose (MG/DAY)</th>
<th>APPROXIMATE EQUIVALENT DOSE (MG)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mirtazapine (Remeron®)</td>
<td>N</td>
<td>15-45</td>
<td>15</td>
</tr>
<tr>
<td>Trazodone (Desyrel®)</td>
<td>N</td>
<td>150-600</td>
<td>200</td>
</tr>
<tr>
<td>Vortioxetine (Brintellix®)</td>
<td>N</td>
<td>5-20</td>
<td>N/A</td>
</tr>
</tbody>
</table>

†Doses are approximate equivalencies only within the specified drug class
*No data currently available on equivalent dosing

Switching Antidepressant Agents

**TCA to SSRI/SSRI**
Discontinue the TCA and immediately start SSRI or SNRI. Providers may consider a short, 3-day taper for patients on a high-dose TCA or long-duration of therapy (> 8 weeks).

**SSRI to SSRI or SNRI**
If switching from one SSRI to another, or to an SNRI, a cross-taper is generally not necessary. Fluoxetine in particular may be stopped abruptly due to its long half-life. If switching from fluoxetine, start new SSRI at half normal starting dose 4-7 days later.

**SSRI to non-SSRI/SSRI antidepressant**
Discontinue the SSRI and start Drug #2 the next day. OR discontinue the SSRI by taper and start Drug #2 gradually.

**MAOI to MAOI or other antidepressant**
Discontinue MAOI after a 2-week washout, start MAOI, SSRI, or other antidepressant.

**Other antidepressant to MAOI**
Start MAOI after 5-week washout for fluoxetine or 2-week washout for other antidepressants.
## Table 2: Oral Antipsychotics

<table>
<thead>
<tr>
<th>Generic Name (Brand Name)</th>
<th>Formulary Agent</th>
<th>Usual Dose (mg/day)</th>
<th>Approximate Equivalent Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High-Potency First Generation Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pimozide (Orap)</td>
<td>N</td>
<td>1-10</td>
<td>2</td>
</tr>
<tr>
<td>Fluphenazine (Prolixin)</td>
<td>Y</td>
<td>2.5-20</td>
<td>2</td>
</tr>
<tr>
<td>Haloperidol (Haldol)</td>
<td>Y</td>
<td>1-20</td>
<td>2</td>
</tr>
<tr>
<td><strong>Mid-Potency First Generation Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loxapine (Loxitane)</td>
<td>N</td>
<td>60-100</td>
<td>10</td>
</tr>
<tr>
<td>Perphenazine (Trilafon)</td>
<td>Y</td>
<td>10-64</td>
<td>10</td>
</tr>
<tr>
<td>Thiothixene (Navane)</td>
<td>Y</td>
<td>5-30</td>
<td>4</td>
</tr>
<tr>
<td>Thioridazine (Mellaril)</td>
<td>N</td>
<td>200-800</td>
<td>125**</td>
</tr>
<tr>
<td><strong>Low-Potency First Generation Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine (Thorazine)</td>
<td>N</td>
<td>200-1000</td>
<td>100</td>
</tr>
<tr>
<td>Thioridazine (Mellaril)</td>
<td>N</td>
<td>200-800</td>
<td>100</td>
</tr>
<tr>
<td><strong>Second Generation Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole (Abilify)</td>
<td>Y</td>
<td>10-30</td>
<td>5</td>
</tr>
<tr>
<td>Brexpiprazole (Rexulti®)</td>
<td>N</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Cariprazine (Vraylar®)*</td>
<td>N</td>
<td>1.5-6</td>
<td>N/A</td>
</tr>
<tr>
<td>Clozapine (Clozaril)</td>
<td>N</td>
<td>300-450</td>
<td>125**</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa)</td>
<td>N</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Quetiapine (Seroquel)</td>
<td>N</td>
<td>Regular Release = 400-800</td>
<td>ER = 400-800</td>
</tr>
<tr>
<td>Risperidone (Risperdal)</td>
<td>Y</td>
<td>2-8</td>
<td>1.5</td>
</tr>
<tr>
<td>Ziprasidone (Geodon)</td>
<td>Y</td>
<td>40-160</td>
<td>30</td>
</tr>
<tr>
<td>Paliperidone (Invega)</td>
<td>N</td>
<td>3-12</td>
<td>1</td>
</tr>
<tr>
<td>Iloperidone (Fanapt)</td>
<td>N</td>
<td>15-30</td>
<td>5</td>
</tr>
<tr>
<td>Lurasidone (Latuda)</td>
<td>N</td>
<td>40-80</td>
<td>20</td>
</tr>
</tbody>
</table>

*No data currently available on equivalent dosing

**Caution: clozapine and iloperidone require slow titration at initiation to decrease risk of orthostasis, regardless of approximate equivalent doses calculated.

### Switching Antipsychotic Agents

Studies of abrupt discontinuation versus cross-tapering from other antipsychotics to ziprasidone, olanzapine, aripiprazole, and iloperidone found no difference in outcomes.13,18-22 Methods should be individualized and antipsychotic overlap periods should be minimized if cross-tapering is selected. Cross-tapering may be considered for patients who are clinically unstable or only recently stabilized, are on high doses, have had a recent relapse, are outpatient, or are having a partial response to their current agent and may require slow titration of the new agent to improve tolerability. Cross-tapering may also be preferred when switching to an alternative antipsychotic with a vastly different receptor profile (table 4) to prevent discontinuation reactions and rebound effects (table 5). Unless intolerance is present, switching antipsychotics is not advised until a trial of adequate dose and duration (4-6 weeks) is completed.

### Switching from Clozapine to other Antipsychotics

An cross-taper of at least 4 weeks in duration is preferred when switching from clozapine to other antipsychotics, when possible. This decreases risk of cholinergic rebound and rebound psychosis.
Table 3: Basic Switch Strategies for Antipsychotics

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>DEFINITION</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
<th>RECOMMENDED FOR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrupt Switching</td>
<td>Simultaneous cessation of the prior antipsychotic and initiation of the new antipsychotic.</td>
<td>Low risk of drug interactions</td>
<td>Potential for discontinuation reactions</td>
<td>Patients with serious adverse event(s)</td>
</tr>
<tr>
<td>Gradual Switching</td>
<td>Tapering the current antipsychotic-off, and initiating and titrating the new antipsychotic.</td>
<td>Low risk of discontinuation reactions, low drug interactions</td>
<td>Risk of symptom exacerbation</td>
<td>Patients with low risk of relapse</td>
</tr>
<tr>
<td>Cross-Tapering</td>
<td>Gradually tapering the existing antipsychotic, while at the same time initiating and titrating the new antipsychotic.</td>
<td>Low risk of relapse</td>
<td>Increased risk of drug interactions</td>
<td>Recently stabilized patients</td>
</tr>
<tr>
<td>Plateau Cross-Titration</td>
<td>Gradually titrating the new antipsychotic to a full dose, then tapering and discontinuing the initial antipsychotic.</td>
<td>Low risk of relapse</td>
<td>Increased risk of drug interactions</td>
<td>Initiation of agents with long half-lives that may not build up at speedily (e.g., aripiprazole)</td>
</tr>
</tbody>
</table>

Table 4: Activity of Atypical Antipsychotics at Select Receptors

<table>
<thead>
<tr>
<th>Antipsychotic</th>
<th>5-HT&lt;sub&gt;1A&lt;/sub&gt;</th>
<th>5-HT&lt;sub&gt;2A&lt;/sub&gt;</th>
<th>5-HT&lt;sub&gt;2C&lt;/sub&gt;</th>
<th>D&lt;sub&gt;2&lt;/sub&gt;</th>
<th>n&lt;sub&gt;1&lt;/sub&gt;</th>
<th>n&lt;sub&gt;2&lt;/sub&gt;</th>
<th>H&lt;sub&gt;1&lt;/sub&gt;</th>
<th>M&lt;sub&gt;1&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ziprasidone</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Paliperidone</td>
<td>+</td>
<td>+++</td>
<td>+++</td>
<td>++++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Lurasidone</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Paliperidone</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>+</td>
<td>++</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+/-</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>+++</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
</tr>
<tr>
<td>Brexpiprazole</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

+/- negligible affinity, +/- low affinity, ++ moderate affinity, +++ high affinity, ++++ very high affinity

† Antipsychotic receptor activity may differ slightly by source.
*Activity at individual muscarinic receptors may vary.

First generation antipsychotics (FGAs): High potency FGAs have a high affinity for the D<sub>2</sub> receptor and a low affinity for alpha-adrenergic, histaminergic, and muscarinic receptors vs. low-potency FGAs, which have a low affinity for the D<sub>2</sub> receptor and a high affinity for alpha-adrenergic, histaminergic, and muscarinic receptors.
Table 5: Effects of Receptor Blockade and Associated Discontinuation/Rebound Effects

<table>
<thead>
<tr>
<th>Receptor</th>
<th>Relevant Effects of Receptor Blockade</th>
<th>Expected Rebound/Discontinuation Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>D₂</td>
<td>Antipsychotic, anti-manic, and anti-aggressive effects, extrapyramidal symptoms</td>
<td>Psychosis, mania, agitation/aggression, withdrawal dyskinesias</td>
</tr>
<tr>
<td>M₁</td>
<td>Orthostasis</td>
<td>Tachycardia, hypertension</td>
</tr>
<tr>
<td>H₁</td>
<td>Increased blood pressure</td>
<td>Hypotension</td>
</tr>
<tr>
<td>M₂,₄</td>
<td>Sedation, anxiety, weight gain</td>
<td>Insomnia, restlessness, anxiety, agitation</td>
</tr>
<tr>
<td>5-HT₁A   (partial agonist)</td>
<td>Anxiolysis, antidepressant effects, mitigation of extrapyramidal symptoms</td>
<td>Anxiety, extrapyramidal symptoms</td>
</tr>
<tr>
<td>5-HT₂A</td>
<td>Sedation, mitigation of extrapyramidal symptoms</td>
<td>Insomnia, extrapyramidal symptoms</td>
</tr>
<tr>
<td>5-HT₅₂</td>
<td>Carbohydrate craving, increased appetite, weight gain</td>
<td>Decreased appetite</td>
</tr>
</tbody>
</table>

Long-Acting Injectable (LAI) Antipsychotics

Use of a long-acting injectable antipsychotic should be considered for patients with significant noncompliance or partial compliance leading to decompensation, poor function, and/or requirement for compelled medications. A brief trial of the corresponding oral antipsychotic formulation should be provided when possible to establish tolerability before starting the LAI formulation. A longer (14 day) trial of oral aripiprazole may be necessary due to the long half-life of this medication. After 6 months of LAI treatment, it is recommended that a transition back to oral therapy be considered if the patient’s symptoms have stabilized and compliance with oral medications is >80%.

Table 6: Long-Acting Injectable Antipsychotics

<table>
<thead>
<tr>
<th>Generic Name (Brand Name)</th>
<th>Formulary Agent</th>
<th>Usual Dosage</th>
<th>Maximum Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol decanoate (Haldol® DE)</td>
<td>Y</td>
<td>50-200 mg Q 4 wks</td>
<td>400 mg Q 8 wks</td>
</tr>
<tr>
<td>Fluphenazine decanoate (Prolixin® DE)</td>
<td>Y</td>
<td>25-50 mg Q 2-3 wks</td>
<td>100 mg Q 2 wks</td>
</tr>
<tr>
<td>Risperidone long acting (Risperdal Consta®)</td>
<td>N</td>
<td>25-50 mg Q 2 wks</td>
<td>50 mg Q 2 wks</td>
</tr>
<tr>
<td>Paliperidone palmitate (Invega Spectrum®)</td>
<td>N</td>
<td>39-234 mg Q 4 wks</td>
<td>234 mg Q 4 wks</td>
</tr>
<tr>
<td>Paliperidone-palmitate (Invega Trinza®)</td>
<td>N</td>
<td>273-819 mg Q 3 mos</td>
<td>819 mg Q 3 mos</td>
</tr>
<tr>
<td>Aripiprazole long acting (Abilify Maintena®)</td>
<td>N</td>
<td>400 mg Q 4 wks</td>
<td>400 mg Q 4 wks</td>
</tr>
<tr>
<td>Aripiprazole lauroxil (Aristada)®</td>
<td>N</td>
<td>441-882 mg Q 4 wks</td>
<td>882 mg Q 4 wks</td>
</tr>
</tbody>
</table>
Initiating Long-Acting Injectable Antipsychotics

**Haloperidol Decanoate (Haldol-D®)*

Loading dose method (preferred)
- Month 1: Initiate haloperidol decanoate at 20 times the oral haloperidol dose; discontinue oral haloperidol at time of first injection
- Month 2: Haloperidol decanoate 15 times the oral haloperidol dose
- Month 3 and thereafter: Haloperidol decanoate 10 times the oral haloperidol dose

Traditional dosing method
Initiate haloperidol decanoate at 10-15 times the oral haloperidol dose. Provide oral overlap for 1 month.

*Note: Initial doses > 100 mg should be administered as 2 separate injections spread out by 3-7 days.

**Fluphenazine Decanoate (Prolixin D®)

Initiate fluphenazine decanoate at 1.2-1.6 times the oral fluphenazine dose; continue oral fluphenazine for 1-4 weeks, then discontinue.

**Risperidone Long-Acting Injection (Risperdal Consta®)

Initiate Risperdal Consta at 25mg IM q 2weeks; continue oral risperidone for 3 weeks, then discontinue. A 12.5 mg starting dosage may be considered for patients with poor psychotropic tolerability or those on CYP2D6 inhibitors.

**Paliperidone palmitate (Invega Sustenna®)

Initiate 234 mg IM, then give 156 mg IM in 1 week. A monthly maintenance dose of 117 mg IM may be initiated 4 weeks later and adjusted as necessary thereafter. Oral overlap is not recommended. Dosage adjustment is necessary in renal dysfunction and considered for patients on strong CYP3A4 or P-gp inducers.

**Paliperidone palmitate (Invega Trizna®)

May initiate after 4 monthly injections of Invega Sustenna, as long as the last two doses have been stable. Dosing is determined based on dosage equivalencies in table below.

**Aripiprazole long acting (Abilify Maintena®)

Initiate 400 mg IM once monthly with 14 days of oral overlap. Dosage adjustment is recommended if adverse effects develop, in CYP2D6 poor metabolizers, and in patients prescribed a concomitant CYP2D6 and/or 3A4 inhibitor for >14 days.

**Aripiprazole lauroxil (Aristada®)

Dosing is determined based on previous oral dosage (table 8). Provide oral overlap for 21 days. Dosage adjustment may be required for patients prescribed a CYP2D6 or 3A4 inhibitor for >14 days, or a CYP3A4 inducer.
Converting from one LAI Antipsychotic to an Alternative LAI Antipsychotic*

Table 7. Conversion to and from Risperidone and Paliperidone Long-Acting Injections

<table>
<thead>
<tr>
<th>Risperidone Long-Acting (Risperdal Consta®) Dosage</th>
<th>Approximate Equivalent Paliperidone Palmitate (Invega Sustenna®) Dosage</th>
<th>Approximate Equivalent Paliperidone Palmitate (Invega Trinza®) Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg IM every 2 weeks</td>
<td>78 mg IM every 4 weeks</td>
<td>223 mg IM every 3 months</td>
</tr>
<tr>
<td>37.5 mg IM every 2 weeks</td>
<td>117 mg IM every 4 weeks</td>
<td>410 mg IM every 3 months</td>
</tr>
<tr>
<td>50 mg IM every 2 weeks</td>
<td>156 mg IM every 4 weeks</td>
<td>446 mg IM every 3 months</td>
</tr>
<tr>
<td>75 mg IM every 2 weeks</td>
<td>234 mg IM every 4 weeks</td>
<td>619 mg IM every 3 months</td>
</tr>
</tbody>
</table>

*There is currently insufficient data on dose conversion to and from long-acting injections other than the paliperidone palmitate and risperidone LAIs.

Transitioning from Long-Acting Injectable Antipsychotics back to Oral Therapy

Table 8. Oral Antipsychotic Dosage Equivalents for Long-Acting Injectable Antipsychotics

<table>
<thead>
<tr>
<th>Long-Acting Injection</th>
<th>Dosage (mg)</th>
<th>Approximate Equivalent Oral Dosage (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol decanoate (Haldol®)</td>
<td>10 times the daily oral dose given once monthly</td>
<td>1/10 of the monthly LAI dose given daily</td>
</tr>
<tr>
<td>Fluphenazine decanoate (Prolixin-D®)</td>
<td>12.5 mg IM every 3 weeks</td>
<td>10 mg/day</td>
</tr>
<tr>
<td>Risperidone long acting (Risperdal Consta®)</td>
<td>25 mg IM every 2 weeks</td>
<td>3 mg/day</td>
</tr>
<tr>
<td></td>
<td>37.5 mg IM every 2 weeks</td>
<td>5 mg/day</td>
</tr>
<tr>
<td></td>
<td>50 mg IM every 2 weeks</td>
<td>7.5 mg/day</td>
</tr>
<tr>
<td>Paliperidone palmitate (Invega Sustenna®)</td>
<td>25-75 mg IM every 4 weeks</td>
<td>5 mg/day</td>
</tr>
<tr>
<td></td>
<td>125 mg IM every 4 weeks</td>
<td>10 mg/day</td>
</tr>
<tr>
<td></td>
<td>156 mg IM every 4 weeks</td>
<td>15 mg/day</td>
</tr>
<tr>
<td></td>
<td>225 mg IM every 4 weeks</td>
<td>30 mg/day</td>
</tr>
<tr>
<td>Paliperidone palmitate (Invega Trinza®)</td>
<td>273 mg IM every 3 months</td>
<td>5 mg/day</td>
</tr>
<tr>
<td></td>
<td>410 mg IM every 3 months</td>
<td>10 mg/day</td>
</tr>
<tr>
<td></td>
<td>546 mg IM every 3 months</td>
<td>15 mg/day</td>
</tr>
<tr>
<td></td>
<td>819 mg IM every 3 months</td>
<td>30 mg/day</td>
</tr>
<tr>
<td>Aripiprazole long acting (Abilify Maintena®)*</td>
<td>600 mg IM every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Aripiprazole lauroxil (Aristada®)</td>
<td>441 mg IM every 4 weeks</td>
<td>9 mg/day</td>
</tr>
<tr>
<td></td>
<td>662 mg IM every 4 weeks</td>
<td>15 mg/day</td>
</tr>
<tr>
<td></td>
<td>882 mg IM every 4 weeks</td>
<td>≥ 20 mg/day</td>
</tr>
<tr>
<td></td>
<td>1064 mg IM every 2 months</td>
<td>≥ 40 mg/day</td>
</tr>
</tbody>
</table>

*N/A data available on equivalent dosing

Additional Guidance: Switching from an LAI to an oral antipsychotic may be accomplished by initiating an equivalent oral dosage on the date that the next LAI is due. Alternatively, a 4 week overlap period may be considered to allow for observation of oral adherence prior to discontinuation of the LAI. The LAI may then be abruptly discontinued, as its long half-life should limit the risk of discontinuation reactions. A brief cross-taper is another alternative that may be considered.
Switching Agents for the Treatment of Bipolar Disorder

If intolerance is not present, the new agent should be started and titrated to an effective dose before the current agent is tapered and discontinued. The old agent may then be decreased gradually over the next month. The goal is to avoid abrupt discontinuation of the old medication until the new agent is established.

### Agents Used to Treat Bipolar Disorder

<table>
<thead>
<tr>
<th>Generic Name (Brand Name)</th>
<th>Formulary Agent</th>
<th>Usual Dose (mg/day)</th>
<th>Target Drug Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium</td>
<td>N</td>
<td>N00-2400</td>
<td>0.6 – 1.2 mEq/L</td>
</tr>
<tr>
<td>Olanzapine and Fluoxetine (Symbyax®)</td>
<td>N</td>
<td>6/25-12/50</td>
<td>N/A</td>
</tr>
<tr>
<td>Anticonvulsant Agents</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxcarbazepine (Trileptal®)</td>
<td>N</td>
<td>1200-2400</td>
<td>N/A</td>
</tr>
<tr>
<td>Carbamazepine (Tegretol®)</td>
<td>Y</td>
<td>BO-400-1600</td>
<td>ER=400-1600</td>
</tr>
<tr>
<td>Lamotrigine (Lamictal®)</td>
<td>N</td>
<td>100-400</td>
<td>N/A</td>
</tr>
<tr>
<td>Valproic Acid (Depakene®)</td>
<td>N</td>
<td>1000-2500 (20 mg/kg/d)</td>
<td>50-125 mcg/mL</td>
</tr>
<tr>
<td>Divalproex Sodium (Depakote®)</td>
<td>Y (DR only)</td>
<td>1000-2000 (DR= 20 mg/kg/d)</td>
<td>50-125 mcg/mL</td>
</tr>
<tr>
<td>Second Generation Antipsychotics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olanzapine (Zyprexa®)</td>
<td>N</td>
<td>5-20</td>
<td>N/A</td>
</tr>
<tr>
<td>Quetiapine (Seroquel®)</td>
<td>N</td>
<td>Regular Release = 300-800</td>
<td>ER = 300-800</td>
</tr>
<tr>
<td>Risperidone (Risperdal®)</td>
<td>Y</td>
<td>2-8</td>
<td>N/A</td>
</tr>
<tr>
<td>Ziprasidone (Geodon®)</td>
<td>Y</td>
<td>80-160</td>
<td>N/A</td>
</tr>
<tr>
<td>Asenapine (Saphris®)</td>
<td>N</td>
<td>10-20</td>
<td>N/A</td>
</tr>
<tr>
<td>Lurasidone (Latuda®)</td>
<td>N</td>
<td>20-60</td>
<td>N/A</td>
</tr>
<tr>
<td>Cariprazine (Vraylar®)</td>
<td>N</td>
<td>3-6</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Switching Agents for the Treatment of Bipolar Disorder

If intolerance is not present, the new agent should be started and titrated to an effective dose before the current agent is tapered and discontinued. The old agent may then be decreased gradually over the next month. The goal is to avoid abrupt discontinuation of the old medication until the new agent is established.
Management of Razor Blade Ingestion

1. Patient reports razor blade ingestion

2. Treat bleeding as necessary

3. Symptoms of foreign body lodged in esophagus?
   - Yes
   - No
   - Obtain chest X-ray as soon as available.

4. Obtain chest X-ray as soon as available.
   - Yes
   - No
   - Symptoms of foreign body lodged in esophagus?

5. Obtain STAT chest X-ray (send to ER if not available on the unit).
   - Yes
   - No
   - Mental Health Evaluation (MHE)

6. Mental Health Evaluation (MHE)
   - Yes
   - No
   - Admit to crisis management if indicated by MHE

7. Admit to crisis management if indicated by MHE
   - Yes
   - No
   - Abdominal exam at least daily x 3-4 days.

8. Abdominal exam at least daily x 3-4 days.
   - Yes
   - No
   - Signs of acute abdomen or bleeding?

9. Signs of acute abdomen or bleeding?
   - Yes
   - No
   - Further follow up as needed. Discharge from crisis management when indicated

10. Further follow up as needed. Discharge from crisis management when indicated

11. Further follow up as needed. Discharge from crisis management when indicated

12. Further follow up as needed. Discharge from crisis management when indicated

13. End

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Management of Razor Blade Ingestion

While razor blade ingestion has the potential for severe outcomes, it generally is not as serious as many would think. Once the razor blade reaches the stomach, gastric acid quickly dulls the edge and erodes the body of the razor blade. The most dangerous potential complication of razor blade ingestion is esophageal perforation. Once the blade has passed into the stomach the risk of serious complications is much lower.

When a foreign body is ingested, the most clinically significant locations for it to become lodged are the level of the cricopharyngeus muscle and the ileocecal valve. However, most foreign bodies that have passed through the esophagus will continue to pass through the body uneventfully.

When an offender gives a history of razor blade ingestion, treat clinically significant bleeding if present. A chest x-ray should be obtained and should be adequate to visualize the entire esophagus. This may require 2 films.

If x-ray is not immediately available on the unit, it may be acceptable to observe the patient closely while awaiting the x-ray, if the patient is asymptomatic. Mental health evaluation may be done during this period if indicated. However, if the patient is symptomatic of a foreign body lodged in the esophagus, the CXR should be done as soon as possible and may require transfer to a local medical center.

If the x-ray shows the razor blade above the level of the lower esophageal junction, or if the patient has signs or symptoms of esophageal perforation (swelling, erythema, tenderness or crepitus in the neck region, or fever or chest pain), they should be referred immediately to an appropriate medical center for removal of the foreign body.

If the razor blade has already passed into the stomach, off site referral is rarely needed. Mental health evaluation should be done if indicated. The patient should be examined daily for 3-4 days with particular attention to the RLQ location of the ileocecal valve. The patient should be instructed to return immediately if they experience localized abdominal pain, vomiting, abdominal distension, melena or rectal bleeding, fever or dizziness.
RHINITIS

Consult Patient:
(1) Avoid Precipitating Factors
(2) Increase Fluids

End Intervention

Mild Symptoms?

Contraindications to Decongestants? (e.g. HTN, etc.)

Loratadine 10 mg QD or Chlorpheniramine (CTM) 4 mg QID X 14 days

Resolved?

Infected Present?

Yes

No

Loratadine or CTM plus phenylephrine x 14 days

End Therapy

Consider Alternative Therapy for Chronic Rhinitis

Yes

No

Go To Sinusitis Pathway Box #6

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996; Reviewed 5/11, 11/14, 7/18; Revised 8/98, 12/98, 3/01, 4/03, 3/07, 5/07, 1/10.
Acute Seizures

Seizure Activity for 0-5 Minutes

- Confirm clinical findings by observing continuous seizure activity or one additional seizure.
- Rule out unexpected symptom amplification.
- Rule out underlying medical issue.

New onset seizures: refer to Seizure Disorder DMG for care.

Consider administering extra dose of currently ordered oral AED.

Observe for a minimum of 2 hours and discharge from medical after full recovery.

Follow up next day and obtain AED serum levels.

Follow up in Chronic Care Clinic per ITP.

Confirm medication adherence.

Modify therapy if indicated per Seizure Disorder DMG.

Seizure activity continuing for 5-20 minutes?

Yes

AED (Antiepileptic Drug) therapy should be initiated if seizure lasts 15 minutes.

Administer lorazepam 4 mg or 2 mg/min by slow IV.

May repeat after 10 minutes (usual maximum total dose is 8 mg) if seizures do not stop or another begins.

Monitor BP and watch for signs of respiratory depression.

If IV access is unavailable, transport to a higher level of care.

No

New onset seizures: refer to Seizure Disorder DMG for care.

Consider administering extra dose of currently ordered AED if seizure continues.

Observe for a minimum of 2 hours and discharge from medical after full recovery.

Follow up with medical provider in 48-72 hours.

Follow up in Chronic Care Clinic per ITP.

Confirm medication adherence.

Modify therapy if indicated per Seizure Disorder DMG.

AED (Antiepileptic Drug) therapy should be initiated if seizure lasts 15 minutes.

Administer lorazepam 4 mg or 2 mg/min by slow IV.

May repeat after 10 minutes (usual maximum total dose is 8 mg) if seizures do not stop or another begins.

Monitor BP and watch for signs of respiratory depression.

If IV access is unavailable, transport to a higher level of care.

Seizure activity continuing for 20-40 minutes?

Yes

If the patient does not respond to 2 doses of lorazepam, transport to a higher level of care: transfer to the nearest emergency room.

Follow current unit protocol.

Follow up within 24 hours of patient leaving the emergency room or hospital.

Confirm medication adherence and reinforce education.

Obtain AED serum levels and adjust treatment plan if indicated.

Follow up in chronic care clinic per ITP.

New onset seizures: refer to Seizure Disorder DMG for care.

No

Suspect seizure activity?

Observe x 2 hours; if no activity, discharge from medical department.

New onset seizures: refer to Seizure Disorder DMG for care.

Consider administering extra dose of currently ordered AED if seizure continues.

Observe for a minimum of 2 hours and discharge from medical after full recovery.

Follow up with medical provider in 48-72 hours.

Follow up in Chronic Care Clinic per ITP.

Confirm medication adherence.

Modify therapy if indicated per Seizure Disorder DMG.

If the patient does not respond to 2 doses of lorazepam, transport to a higher level of care: transfer to the nearest emergency room.

Follow current unit protocol.

Follow up within 24 hours of patient leaving the emergency room or hospital.

Confirm medication adherence and reinforce education.

Obtain AED serum levels and adjust treatment plan if indicated.

Follow up in chronic care clinic per ITP.

New onset seizures: refer to Seizure Disorder DMG for care.

Nurses: DMGs are guidelines to assist providers in making treatment decisions and are not to be confused with nursing Standing Delegated Orders (SDOs). As such, treatment recommendations in DMGs cannot be implemented independently by nursing staff without an order from a provider.
Seizure activity and seizure classification documented?*

Attempt accurate diagnosis if new onset. Rule out underlying medical etiology. Consult Neurology if necessary.

Confirm diagnosis of seizure disorder.

Is patient on AED therapy?

Is antiepileptic drug (AED) therapy appropriate for diagnosis?

If seizure disorder is confirmed, initiate AED therapy based on seizure classification (App. A and B). Go to box 7.

OR

If seizure activity is ruled out, discontinue from Chronic Care Clinic.

OR

If no seizure activity for ≥2 years, may consider discontinuing from Chronic Care Clinic and any associated restrictions.

Initiate AED regimen (App. A and B). Once new AED is at therapeutic dose, taper the old agent slowly and discontinue.

Go to box 7.

OR

Discontinue AED if chronic seizure diagnosis is ruled out.

Successful discontinuation of AED may be possible if:
- Seizure free for ≥2 years
- Single type of partial or generalized seizure
- Normal neurological exam
- EEG normalized with AED treatment

Seizure Disorder

Is AED therapy effective and tolerted?

- Monitor & obtain laboratory appropriate for AED utilized (App. C).
- Counsel on importance of compliance.
- Adjust dose.

OR

- Change to alternate AED. Once new AED is at therapeutic dose, taper the old agent slowly and discontinue.

OR

- Add additional AED if patient has failed ≥2 monotherapy regimens.
- Consider referral if patient remains poorly controlled.

Follow up in Chronic Care Clinic as clinically indicated.
- Monitor & obtain laboratory appropriate for AED utilized (App. C).
- Consider discontinuation of AED if patient has a normal EEG and been seizure free for ≥2 years. Slowly taper AED over 3-6 months and then discontinue.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, March 1996, Revised 3/02, 4/03, 11/05, 3/07, 3/08, 10/08, 9/10, 1/13, 11/18.

*One seizure event is not necessarily diagnostic for a seizure disorder and may not require drug from AED therapy.
Definitions:
- Seizure: an isolated clinical event consisting of paroxysmal discharges occurring synchronously in a large population of cortical neurons, characterized on the electroencephalogram (EEG) as a sharp wave or "spike."
- Epilepsy: a chronic disorder of the nervous system characterized by recurrent and unprovoked seizures. Term may be applied after two unprovoked seizures occurring greater than 24 hours apart or one unprovoked seizure with the probability of further seizure events >60% over the next 10 years.
- Status epilepticus: continuous seizure activity or 2 or more seizures without full recovery of consciousness between seizures lasting longer than 30 minutes.

Initial Assessment

A. Medical history:
   1. Verify any existing seizure diagnoses
   2. Identify each seizure type by obtaining a detailed seizure history
      a. Age at onset and frequency of seizure
      b. Symptoms during ictal and post-ictal phase (patient and observer)
      c. Known triggers (e.g., sleep deprivation, alcohol, stress)
      d. Other medical and psychosocial factors
      e. Identify possible causes including family history of epilepsy, history of head trauma, birth complications, tubular correlated, alcohol or drug abuse, cancer, or vascular abnormalities

B. Medication history:
   1. Identify current and prior medications including response and adverse events
   2. Rule out alcohol or other drug withdrawal seizures as these do not generally require AED therapy
   3. Rule out drugs which may cause or exacerbate seizures (e.g., psychotropics, antimicrobials, stimulants, narcotics, lidocaine, meperidine, theophylline, antihypertensives, antiepileptics, barbiturates)

C. Physical examination:
   1. Identify disorders associated with seizures, including head trauma, infections of the ears or sinuses (which may spread to the brain), congenital abnormalities, neurological disorders, alcohol or drug abuse, metabolic disorders, or cancer
   2. A complete neurologic and mental status exam should be performed

D. Electroencephalographic (EEG) studies:
   1. The purpose of the EEG is to confirm the presence of abnormal electrical activity, provide information about the type of seizure disorder, and locate the seizure focus. An EEG should be used to support the diagnosis of epilepsy and cannot rule out a seizure disorder
   2. Approximately 30% of epileptic patients show no abnormality on a single EEG, and 10% of persons with true seizures show no abnormalities on multiple EEG studies

E. Lab tests and neuroimaging:
   The following tests may be useful in determining the underlying cause of seizure activity:
   1. Electrolytes
   2. Blood glucose
   3. Liver and kidney function
   4. Toxins evaluation
   5. MRI (CT if unavailable or contraindicated)
   6. Lumbar puncture if infection suspected

F. Treatment plan:
   1. Treatment with AED therapy is generally recommended after a second epileptic seizure. Selection of an appropriate AED should be based on the following:
      a. Age and child-bearing potential
      b. Seizure type and syndrome
      c. Comedications
      d. Comorbidities
      e. AED adverse effect profile
   2. AED initiation after the first seizure may be warranted in patients with a high risk of recurrence (e.g., unequivocal epileptic activity on EEG, structural abnormality, or family history of seizures)

G. Principles of Treatment
   1. Goals of therapy
      a. Seizure free with minimal adverse effects
      b. Maintain normal lifestyle
      c. Use lowest effective AED dose
   2. Assessment of disease control
      a. Good control – seizure free since last visit or last 6 months
      b. Poor control – > 2 seizures since last visit or in last 6 months
      c. Poor control – 2 seizures since last visit or in last 6 months
   3. Potential reasons for treatment failure
      a. Incorrect diagnosis
      b. Ineffective AED for seizure type/syndrome
      c. Subtherapeutic level (unadequate dosing, drug interactions, poor adherence- most common reason for treatment failure)
      d. Refractory seizures
4. Step therapy
   a. Monotherapy is preferred. Generally consider at least 2 monotherapy trials before using combination therapy. Two-thirds of patients become seizure free with the first or second drug prescribed. When switching agents, the old agent should be continued until a therapeutic level of the new drug is achieved. The old agent is then tapered slowly and discontinued.
   b. Polytherapy with 2 agents – if indicated, add an AED with a different mechanism of action. Start low and titrate slowly. Confirm medication adherence prior to the addition of a second agent.
   c. Polytherapy with 3 agents – rarely needed. Consider only after 2 or more adequate trials of dual AEDs have failed, adherence is confirmed, and a combination of AEDs is tolerated and significantly reduces seizure frequency or severity. Consider referral prior to triple AED therapy.
   d. Consider patient co-morbidities and possible drug interactions upon initiation of therapy, during therapy, and upon drug discontinuation. Many of the AEDs may increase or decrease metabolism of other medications.

5. Use of newer AEDs
   a. Recommended for those who have failed traditional or first generation AEDs or when traditional AEDs are unsuitable (contraindications, drug interactions, intolerance, pregnancy, etc).
   b. Traditional AEDs have the advantage of broad familiarity, lower cost, known efficacy and long term experience.

6. Pregnancy considerations
   a. Benefits versus risks must be weighed during pregnancy. The fewest number of antiepileptic agents (and lowest dose) that control seizures should be used.
   b. Category C - gabapentin, lamotrigine, levetiracetam, oxcarbazepine, tiagabine, vigabatrin. If possible, avoid these agents.
   c. Category D - carbamazepine, phenobarbital, phenytoin, primidone, valproic acid. If possible, avoid these agents.

II. Pseudoseizures
1. Definition—episodes involving affective, autonomic, or sensorimotor manifestations that are precipitated by emotional distress. Also known as non-epileptic seizures, hysterical seizures, pseudoseizures, and nonepileptic attack disorder.
2. Epidemiology—pseudoseizures account for 15-20% of admissions to epilepsy units. Women are affected more frequently than men by a factor of 3.5:1. Peak incidence is in the third to fourth decades.
3. Clinical characteristics of pseudoseizures:
   a. Prolonged duration of event (10-30 minutes)
   b. Preservation of consciousness despite whole body jerking
   c. Bizarre and asynchronous motor movements
   d. pelvic thrusting movements
   e. Not stereotypical
   f. Not unprovoked
   g. Nocturnal generalized tonic clonic or partial seizures (more reliable in tonic clonic seizures)
   h. Blood sample should optimally be drawn within 30 minutes of seizure. A normal prolactin level does not confirm pseudoseizures.

4. Management—Anticonvulsant therapy is not indicated in pseudoseizures; a mental health referral should be considered. Psychotherapy and drug therapy for underlying psychiatric disorder is indicated in most cases. Psychotic seizures occur in patients with conversion disorders, anxiety and panic disorder, depression, post-traumatic stress disorder, schizophrenia, and personality disorders.

Withdrawal of Anticonvulsants
A. Risk of Status Epilepticus
   1. Relapse rates are highest in the first 12 months (especially in the first 6 months) after AED withdrawal.
   2. Risk of relapse continues to decrease with time.

B. Considerations for AED Discontinuation:
   1. Seizure-free for a minimum of two years on AED treatment
   2. Single type of focal seizure or a single type of generalized tonic-clonic seizure
   3. Normal neurological examination and normal intelligence quotient IQ
   4. EEG normalized with treatment
C. Drug Discontinuation:
1. Risks and consequences of seizure recurrence versus continued treatment should be weighed.
2. If discontinuation of AED is warranted, the tapering schedule should be slow (most clinical trials suggest dose should be tapered over 6 months) and tailored to the specific drug, dosage, and serum concentrations for each patient.

D. Phenobarbital Tapering
1. Phenobarbital monotherapy – if AED needs to be continued, the new agent should be started and therapeutic levels achieved prior to initiating phenobarbital taper (Table 1).
2. Phenobarbital polypharmacy – please note that monotherapy is preferred.
   a. If patient is a good candidate for monotherapy (based on type of seizure, history of past treatments, compliance), initiate phenobarbital taper (Table 1) without the addition of another agent.
   b. If patient needs to be continued on polytherapy, a new agent should be started and therapeutic levels achieved prior to initiating the phenobarbital taper (Table 1).

<table>
<thead>
<tr>
<th>Factors Against Drug Withdrawal</th>
<th>Factors in Favor of Drug Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adolescent onset epilepsy</td>
<td>Childhood onset epilepsy</td>
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<tr>
<td>Adult onset epilepsy</td>
<td>Klippel onset epilepsy</td>
</tr>
<tr>
<td>Focal epilepsy</td>
<td>Idiopathic generalized epilepsy</td>
</tr>
<tr>
<td>Lennox-Gastaut syndrome epilepsy</td>
<td>Benign epilepsy with centrotemporal spikes</td>
</tr>
<tr>
<td>Presence of underlying neurological condition</td>
<td>Normal EEG (adults)</td>
</tr>
<tr>
<td>Abnormal EEG (children)</td>
<td>Childhood onset epilepsy</td>
</tr>
<tr>
<td>Abnormal EEG (children)</td>
<td>Co-morbidity with concurrent treatments</td>
</tr>
</tbody>
</table>

Table 1: Phenobarbital taper

| Tapering schedule: Decrease phenobarbital dose by 30mg a month over 1-6 month period. |
|---------------------------------|---------------------------------|
| Example: Patient is receiving | 100mg/day |
| 1st month, patient receives | 70mg/day |
| 2nd month, patient receives | 40mg/day |
| 3rd month, patient receives | 10mg/day |
| 4th month, patient receives | 0mg/day |

Lab: If patient has undetectable phenobarbital levels (< 2mg/L) and a history of noncompliance, a taper may not be necessary.

Monitor: Providers must monitor patient for any new seizure activity. Determine if the underlying disorder has returned or if the seizures were the result of withdrawing the phenobarbital too quickly. Phenobarbital should be tapered more slowly if the latter is true.
The International Classification of Epileptic Seizures

Appendix A

A. Focal seizures - Begin in one hemisphere of the brain and, unless they become focal to bilateral tonic-clonic, result in an asymmetric clinical manifestation. Focal epilepsy may begin in infancy and may be difficult to recognize in the elderly population.

1. Focal aware seizure - no loss of consciousness
   a. Motor function symptoms
   b. Sensory or somatosensory symptoms
   c. Automatisms

2. Focal impaired awareness seizure - alteration/loss of consciousness
   a. Focal aware onset followed by impairment of consciousness, with or without automatisms
   b. Impaired consciousness at onset, with or without automatisms
   c. Other symptoms may include memory loss or alterations of behavior
   d. May be misdiagnosed as psychotic episodes
   e. Generally amnestic to these events

3. Focal to bilateral tonic-clonic - focal onset evolving to generalized tonic-clonic seizures

4. Treatment Options:
   a. Formulary: carbamazepine, divalproex sodium, levetiracetam*, phenytoin, primidone
   b. Nonformulary: eslicarbazepine, gabapentin*, lacosamide, phenobarbital, tiagabine*, vigabatrin, zonisamide*

B. Generalized seizures - Involves both brain hemispheres with bilateral motor manifestations and loss of consciousness

1. Generalized Absence Seizure - Sudden onset, brief (seconds), blank stare, possibly a brief upward rotation of the eyes, and lip-smacking (confused for daydreaming)
   a. Generally occurs in young children through adolescence
   b. Can be precipitated by hyperventilation
   c. EEG during the seizure has a characteristic 2- to 4-cycle/s spike and slow-wave complex
   d. Important to differentiate from focal impaired awareness seizures
   e. Formulary treatment options: divalproex sodium
   f. Nonformulary treatment options: clonazepam, ethosuximide, lamotrigine

2. Generalized Tonic-Clonic Seizure (formerly called grand mal seizure) - includes both a tonic and clonic phase
   a. Tonic phase: rigid, violent, sudden muscular contractions (stiff or rigid), cry or moan, deviation of the eyes and head to one side, rotation of the whole body and distortion of features, suppression of respiration, falls, loss of consciousness; tongue biting; involuntary urination
   b. Clonic phase: repetitive jerks; cyanosis continues; foam at the mouth; small grunting respirations between seizures; deep respirations as all muscles relax at the end of the seizure
   c. Formulary treatment options: carbamazepine, divalproex sodium, levetiracetam*, phenytoin, primidone
   d. Nonformulary treatment options: gabapentin*, lamotrigine, eslicarbazepine, phenobarbital, topiramate

3. Myoclonic Seizure - Brief shock-like muscular contractions of the face, neck, and extremities. May be isolated or rapidly repetitive.

4. Atonic Seizure - sudden loss of muscle tone lasting 1-2 seconds
   a. May be described as a head-drop, the dropping of the limb, or a slamming to the ground
   b. These patients often wear protective head ware to prevent trauma
   c. Formulary treatment options: divalproex sodium, levetiracetam*, primidone
   d. Nonformulary treatment options: phenobarbital, eslicarbazepine, topiramate

5. Juvenile Myoclonic Epilepsy (JME) - Myoclonic seizures precede generalized tonic-clonic seizures
   a. Generally occur upon waking
   b. Sleep deprivation and alcohol commonly precipitate an episode
   c. Formulary treatment options: divalproex sodium
   d. Nonformulary treatment options: lamotrigine

C. Other Seizure Types

1. Catamenial Epilepsy - Associated with hormonal changes during menstruation; may be treated with acetazolamide (Diamox)
2. Post-traumatic Epilepsy - Seizures that occur after head trauma; patients may be started on phenytoin for a period of 7 days; if no seizures occur, it should be discontinued. The utility of this therapy is controversial.

*Adjunctive therapy

Only available through a restricted distribution program called the Vigabatrin REMS Program.
Begin treatment with single AED using recommended initial daily dosing. Up to 80% of patients can be managed with monotherapy.

Ensure proper medication adherence prior to modifying regimen.

### Type of Seizure
- **Focal Aware**
  - Carbamazepine
  - Divalproex
  - Levetiracetam*
  - Phenytoin
  - Primidone
  - Brivaracetam
  - Eslicarbazepine
  - Felbamate
  - Gabapentin*
  - Lacosamide*
  - Lamotrigine
  - Oxcarbazepine
  - Perampanel
  - Phenytoin
  - Pregabalin*
  - Tiagabine*
  - Topiramate
  - Zonisamide*

- **Focal Impaired Awareness**
  - Carbamazepine
  - Divalproex
  - Levetiracetam*
  - Phenytoin
  - Primidone
  - Brivaracetam
  - Eslicarbazepine
  - Felbamate
  - Gabapentin*
  - Lacosamide*
  - Lamotrigine
  - Oxcarbazepine
  - Perampanel
  - Phenytoin
  - Pregabalin*
  - Tiagabine*
  - Topiramate
  - Vigabatrin§
  - Zonisamide*

- **Generalized Tonic-Clonic**
  - Carbamazepine
  - Divalproex
  - Levetiracetam*
  - Phenytoin
  - Primidone
  - Gabapentin*
  - Lamotrigine
  - Oxcarbazepine
  - Phenytoin
  - Topiramate

- **Absence**
  - Divalproex
  - Clonazepam*
  - Ethosuximide
  - Lamotrigine

### Preferred with Clinical Evidence of Cirrhosis
- Carbamazepine
- Divalproex
- Levetiracetam
- Phenytoin
- Primidone
- Gabapentin*
- Lamotrigine

*Adjunctive therapy
- Clonazepam [Schedule III – V controlled substances]
- Ethosuximide
- Lamotrigine

### Appendix C: Monitoring Parameters for Formulary AEDs

<table>
<thead>
<tr>
<th>Medication</th>
<th>Design and Monitoring Parameter &amp; Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>- CBC with platelets (baseline): baseline, twice a month for first 2 months, then annually or when clinically indicated&lt;br&gt;- Chemistry (emphasis hepatic &amp; renal function and electrolytes): baseline, one month, then annually or when clinically indicated&lt;br&gt;- EKG at baseline if &lt;40 years old or as clinically indicated&lt;br&gt;- Levels: monthly for 1 week, then annually or when clinically indicated&lt;br&gt;- Levels: monthly for 1 week, then annually or when clinically indicated&lt;br&gt;- Therapeutic level: 4 to 12 mcg/ml, toxic concentration &gt;15 mcg/ml</td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>- Chemistry: renal function in patients with proteinuria&lt;br&gt;- Therapeutic level: not established</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>- CBC: baseline (emphasis hepatic function): baseline, then annually or when clinically indicated&lt;br&gt;- Levels: one month, one month and then annually or when clinically indicated&lt;br&gt;- EKG: baseline if &lt;60 years old or as clinically indicated&lt;br&gt;- Levels: monthly for 1 week, then annually or when clinically indicated&lt;br&gt;- EKG at baseline if &lt;50 years old or as clinically indicated&lt;br&gt;- Therapeutic level: 10 to 20 mcg/ml, toxic concentration &gt;20 mg/kg</td>
</tr>
<tr>
<td>Primidone</td>
<td>- CBC: baseline (emphasis hepatic function): baseline, then annually or when clinically indicated&lt;br&gt;- Levels: one week, one week and then annually or when clinically indicated&lt;br&gt;- Therapeutic level: 5 to 10 mg/ml, toxic concentration &gt;15 mg/ml</td>
</tr>
</tbody>
</table>
| Valproic Acid | - CBC with platelets: baseline and then clinically indicated<br>- Chemistry (emphasis hepatic function): baseline, then annually or when clinically indicated<br>- Levels: monthly for 1 week, then annually or when clinically indicated<br>- Protime, INR, PPT: baseline at initiation<br>- Levels: monthly for 1 week, then annually or when clinically indicated<br>- Therapeutic level: 50 to 100 mcg/ml, toxic concentration >150 mcg/ml

*Schedule III – V controlled substances
### Generic Name | Usual Dose | Adverse Effects*
---|---|---
**Carbamazepine**
- Tegretol®
  - Initial: 200mg twice daily. Titrate at weekly intervals as indicated.
  - Maintenance: 800-1200mg/day divided in 3 or 4 doses.
- *Examples of enzyme inducers include but are not limited to carbamazepine, lopinavir, phenytoin, and rifampin.*

**Levetiracetam**
- Keppra®
  - Initial: 500mg every 3 days. Titrate every 3-7 days as indicated.
  - Maintenance: 1000-1500mg/day divided in 3 doses (range of 200-2400mg/day).

**Phenytoin**
- Dilantin®
  - Initial: 5-10mg/kg/day as needed.
  - Maintenance: 5-10mg/kg/day divided in 3 doses.

**Primidone**
- Mysoline®
  - Initial: 100mg every 3 days. Increase by 100mg every week.
  - Maintenance: 200-300mg/day divided in 3 or 4 doses.

**Valproic Acid**
- Depakote®
  - Initial: 100mg every 3 days. Increase by 100mg every week.
  - Maintenance: 800-1200mg/day divided in 3 doses (500mg/kg/day).

**Non-Formulary Agents**

**Methotrexate**
- Depo-Medrol®
  - Initial: 7.5mg twice daily.
  - Maintenance: 25-50mg twice daily.

**Erythromycin**
- Erythrocin®
  - Initial: 400mg every 12 hours. Titrate weekly as indicated.
  - Maintenance: 600-800mg/day divided in 2 doses.

**Lamotrigine**
- Lamictal®
  - Initial: 50mg every 3 days. Increase by 50mg every week.
  - Maintenance: 250mg/day divided in 2 doses.

**Gabapentin**
- Neurontin®
  - Initial: 50mg every 3 days. Increase by 50mg every week.
  - Maintenance: 1200mg/day divided in 3 doses.

**Lacosamide**
- Vimpat®
  - Initial: 50mg twice daily. Titrate by 25mg every 2 weeks as indicated.
  - Maintenance: 200mg/day divided in 2 doses.

**Felbamate**
- Fiamcit®
  - Initial: 360mg twice daily divided in 3 doses. Titrate every 2 weeks as indicated.
  - Maintenance: 1200mg/day divided in 3 doses.

**Zonisamide**
- Zonegran®
  - Initial: 400mg twice daily divided in 3 doses.
  - Maintenance: 1200mg/day divided in 3 doses.

**Ethosuximide**
- Zarontin®
  - Initial: 100mg every 3 days. Increase by 100mg every week.
  - Maintenance: 800mg/day divided in 3 doses.

**Aptiom®**
- Briviacl®
  - Initial: 100mg every 3 days. Increase by 100mg every week.
  - Maintenance: 800mg/day divided in 3 doses.

**Ethosuximide**
- Brivaracetam®
  - Initial: 100mg every 3 days. Increase by 100mg every week.
  - Maintenance: 800mg/day divided in 3 doses.
Usual Children, Adolescent and Adult Dose

- Oxcarbazepine
  - Trileptal®
    - Initial: 300mg twice daily. Titrate weekly as indicated.
    - Maintenance: 600mg twice daily.
- Topiramate
  - Topamax®
    - Initial: 25mg/day. Titrate weekly as indicated.
    - Maintenance: up to 200mg/day divided in 2 doses.
- Primidone
  - Phenytoin
    - Initial: 50mg/day divided in 2 to 3 doses. Titrate weekly as indicated.
    - Maintenance: 50-100mg/day divided in 2 doses.
- Sodium Valproate
  - Depakene®
    - Initial: 5mg/m²/day. Titrate weekly as indicated.
    - Maintenance: 5mg/m²/day divided in 2 doses.
- Lamotrigine
  - Lamictal®
    - Initial: 150mg/week divided in 2 doses. Titrate weekly as indicated.
    - Maintenance: 100mg/week divided in 2 doses.
- Levetiracetam
  - Keppra®
    - Initial: 50mg twice daily. Titrate weekly as indicated.
    - Maintenance: 1500mg twice daily.
- Vigabatrin
  - Sabril
    - Initial: 50mg twice daily. Titrate weekly as indicated.
    - Maintenance: 1000mg twice daily.
- Zonisamide
  - Zonegran
    - Initial: 25mg/day. Titrate weekly as indicated.
    - Maintenance: 200-400mg/day divided in 2 doses.
- Sodium Amytal
  - Luminal®
    - Initial: 100mg/day divided in 2 doses. Titrate weekly as indicated.
    - Maintenance: 1500mg/day in 1 divided doses.
- Tiagabine
  - Tegretol
    - Initial: 5mg twice daily. Titrate weekly as indicated.
    - Maintenance: 5-10mg/day divided in 2 doses.
- Carbamazepine
  - Tegretol CR
    - Initial: 200mg twice daily. Titrate weekly as indicated.
    - Maintenance: 800mg twice daily.
SINUSITIS

Consider symptomatic treatment with Loratadine 10 mg 1 QD X 7 Days, or CTM 4 mg 1 QID X 7 Days and/or nasal saline.

Bacterial infection unlikely unless the patient has severe symptoms such as fever, symptoms > 7 days with purulent nasal secretions and maxillary facial or tooth pain or tenderness, then continue on to box #6.

End Therapy

Resolved?

No

Refer to Rhinitis Treatment Pathway.

Yes

Minocycline 100 mg BID X 14 Days KOP

If responding, but not completely resolved, continue current treatment for an additional 4 weeks.

Resolved?

No

End Therapy

Consider Nonformulary Medication for Resistant Organism

Augmentin 575 mg BID X 14 Days

Levofloxacin 500 mg QD X 14 Days

If responding, but not completely resolved, continue current treatment for an additional 4 weeks.

Resolved?

Yes

Evaluate and consider referral to a specialist.

No

End Therapy

Skin & Soft Tissue Infection Treatment

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved 09/2012; Revised 11/2014, 07/2017.

1. Patient presents with symptoms of skin & soft tissue infection.
   (Refer to Correctional Managed Health Care Infection Control Manual Policy B – 14.16 for additional information)

2. Does patient have symptoms of systemic illness such as fever, tachycardia, hypotension?
   Yes: Refer for Acute Care Management
   No: Is cellulitis or impetigo present without abscess or other draining skin lesion?

3. Yes: Treat empirically with combination therapy for both strepococci and staphylococci.
   - Bactrim DS 1 tab BID + Amoxicillin 500 mg TID X ≥7 Days (extend several days beyond resolution)
   - Minocycline 100 mg BID + Amoxicillin 500 mg TID X ≥7 Days (extend several days beyond resolution)
   - Reevaluate if not clinically improving

4. No: Is immunosuppressive condition (Diabetes, Hepatitis B, Hepatitis C, HIV) present or trauma such as bite?
   Yes: Underlying condition should be controlled as well as possible.
   - Obtain culture and sensitivity (C&S) using Levine method*
   - If fluctuant, perform incision and drainage (I&D)
   - If not fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved
   - Start Antibiotics**
   - Go to Page 2, box 15
   - May consider staph decolonization protocol
     - Non-formulary approval: mupirocin 2% ointment apply both nostrils BID for 5 days
     - Refer to protocol in Infection Control Manual Policy B-14.16, Procedure V.D.4
   No: Does the patient have > 3 clinical or culture-proven infections in a six-month period?

5. Yes: Obtain C&S using Levine method*
   - If fluctuant, perform I&D
   - If not fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved
   - Start Antibiotics**
   - Go to Page 2, box 15
   No: Is the lesion fluctuant?

6. Yes: Treat with warm compresses for 20 minutes 2 to 3 times per day until resolved
   Go to Page 2, box 15
   No: Is the lesion fluctuant?

7. Yes: Obtain C&S using Levine method*
   - Treat with I&D
   - Start Antibiotics**
   - Go to Page 2, box 15

8. No: May be treated with I&D alone
   Go to Page 2, box 15

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.
Provide Patient Education
- Bed Patient Education Sheet available on the CED web page under Publications and Offender Education Leaflets
- Return to clinic (RTC) if infection worsens
- RTC if not improving in 3 days
- RTC if not healed in 2 weeks

**Antibiotic Selection**
- If possible, begin after C&S results available. May treat with soaks or dressing changes pending results.
- If empiric therapy must be started, begin empiric therapy with Bactrim.
- If allergic or failure on treatment, consult with Office of Public Health or referral to higher level of care for recommendations.
- Antibiotic therapy should be guided by C&S results once available
- Duration generally at least 7 days & should extend several days past clinical resolution
- Empiric therapy to avoid: rifampin, fluoroquinolone, cephalosporin, clindamycin, or erythromycin.

*A Culture Using the Levine Method*
A. Cleanse the wound with sterile water or normal saline to wash away any slough, necrotic tissue or dried exudate.
B. Moisturize the culture tip. If the wound is moist, a sterile swab can be used straight from the packaging. If the wound is dry, then the swab tip should be moistened with sterile water to increase the chances of recovering organisms from the site.
C. Collect in a zig-zag motion – the swab should be moved across the wound surface in a zig-zag motion, at the same time, being rotated between the fingers.
D. Send to lab – immediately following the collection, the swab should be returned to its container (placed into the transport medium) and accurately labeled.
Screen for thyroid abnormalities upon intake in patients age 50 and older and every 5 years thereafter.

Screen for thyroid abnormalities if patient is enrolled in Hypertension, Diabetes Mellitus, Hyperlipidemia, Depression Chronic Care Clinics or if patient is taking lithium, as part of baseline workup.

Draw Thyroid Stimulating Hormone (TSH).

Is TSH level normal?

(0.45 - 4.7 mIU/L)

Rescreen when clinically indicated

Yes

No

If abnormal, repeat TSH and draw Free T4 within 4-8 weeks.

Low TSH

<0.45 mIU/L

High TSH

>4.7 mIU/L

Is Free T4 normal?

(0.78 - 2.0 ng/dL)

Check Free T3 level.

Is it normal (2.4 - 4.2 pg/dL)?

Primary Hyperthyroidism

(TSH and high Free T3)

Subclinical Hyperthyroidism

(TSH, normal Free T4)

Primary Hypothyroidism

(high TSH and low Free T4)

T3 Toxicosis

T4 >10 and normal Free T4?

T3 <10 and normal Free T4?

Subclinical Hypothyroidism

(high TSH and normal Free T4)

Primary hypothyroidism

(high TSH and low Free T4)

TSH >10 and normal Free T4?

TSH >10 and low Free T4?

TSH 4.8 - 10 and normal Free T4?

TSH >10 and low Free T4?

Levothyroxine Dosing

Initial: 25 - 100 mcg once daily. Consider starting at the lowest dose if pt is >50 yo or has coronary heart disease.

Subclinical Hypothyroidism: 25 - 75 mcg once daily as starting dose

Monitoring Recommendations

After initiation of therapy, free T4 should be monitored every 4-8 weeks. Adjust methimazole dose by 5mg until Free T4 is within normal range.

* Pregnancy - Propylthiouracil is recommended in place of Methimazole
I. Assessment

A. Screening
1. Obtain TSH upon intake in patients age 50 and older and every 5 years thereafter.
2. Consider obtaining TSH in patients enrolled in Chronic Care Clinics for hypertension, hyperlipidemia, diabetes and mental health.

B. Signs and Symptoms:

<table>
<thead>
<tr>
<th>Hypothyroidism</th>
<th>Hyperthyroidism</th>
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<tbody>
<tr>
<td>Constipation</td>
<td>Thyrotoxicosis</td>
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<tr>
<td>Cold sensitivity</td>
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<tr>
<td>Dry skin</td>
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<td>Hair loss or change in texture</td>
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<tr>
<td>Fatigue</td>
<td></td>
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<tr>
<td>Myalgia/arthralgia</td>
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<td>Hoarseness</td>
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<td>Weight gain despite poor appetite</td>
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<td>Bradycardia</td>
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<tr>
<td>Cognitive deficits/depression</td>
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<tr>
<td>Thyroid enlargement/nodules</td>
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<tr>
<td>Carpal tunnel syndrome</td>
<td></td>
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<tr>
<td>Sleep apnea</td>
<td></td>
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<tr>
<td>Females may present with menstrual irregularities and galactorrhea</td>
<td></td>
</tr>
</tbody>
</table>

C. Lab Evaluation – see pathway for frequency
1. TSH
2. Free T3
3. Free T4
D. Physical Exam (Intake and CCC)
1. Vital
2. HEENT (thyroid palpation)
3. Cardiovascular (ECG and auscultation)
4. Skin, nails, hair examination
5. Neurologic (ankle reflex relaxation time)
E. Psychiatric and cognitive evaluation

II. Diagnosis

A. TSH is the primary screening test for thyroid dysfunction. It is recommended to repeat the TSH one to three months later to confirm diagnosis. Note: TSH levels in hospitalized, recently ill, or patients on glucocorticoid therapy may be inaccurate.

B. Free T4 should be drawn along with TSH in order to differentiate subclinical hypothyroidism from primary hypothyroidism and hyperthyroidism.

<table>
<thead>
<tr>
<th>Criteria for Thyroid Disorder Diagnosis</th>
<th>TSH</th>
<th>Free T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal*</td>
<td>0.35 – 5.5 mIU/L</td>
<td>0.78 – 2.2 ng/dL</td>
</tr>
<tr>
<td>Subclinical Hypothyroidism</td>
<td>&gt; 5.6 mIU/L</td>
<td>&gt; 2.2 ng/dL</td>
</tr>
<tr>
<td>Primary Hypothyroidism</td>
<td>&gt;10 mIU/L</td>
<td>&gt;2.2 ng/dL</td>
</tr>
<tr>
<td>Subclinical Hyperthyroidism</td>
<td>&lt;0.35 mIU/L</td>
<td>&lt;0.78 ng/dL</td>
</tr>
<tr>
<td>Primary Hyperthyroidism</td>
<td>&lt;0.35 mIU/L</td>
<td>&lt;0.78 ng/dL</td>
</tr>
</tbody>
</table>

*Values based on UTMB CMC’s normal range of values

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved 3/14.
III. Plan/Treatment

A. Hypothyroidism – Treatment is recommended in those diagnosed with primary hypothyroidism (>10mIU/L TSH). Treatment is considered in patients with subclinical hypothyroidism if the patient is symptomatic of hypothyroidism or has cardiovascular risk factors (e.g. elevated LDL).

1. Pharmacological Therapy: Levothyroxine (Synthroid, Levoxyl) is drug of choice.

### Table 3

<table>
<thead>
<tr>
<th></th>
<th>Primary Hypothyroidism</th>
<th>Patients with Primary Hypothyroidism with CHD</th>
<th>Patients with Primary Hypothyroidism &gt;50 yo</th>
<th>Subclinical Hypothyroidism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting dose</td>
<td>25mg to 100mg once daily</td>
<td>25mg once a day</td>
<td>25mg once a day</td>
<td>25mg to 75mg once a day</td>
</tr>
</tbody>
</table>

CMA Formulary Levothyroxine Strengths: 25mcg, 50mcg, 100mcg, 250mcg

2. Treatment goals include:
   a. Symptom relief
   b. Target TSH within normal value range (0.35 – 5.5 mIU/L)
   c. Free T4 within normal value range (0.78 – 2.2 ng/dL)

3. Monitoring Recommendations:
   a. If TSH is suppressed (<0.35mIU/L) – consider dose reduction by 25 – 50mcg. Excess replacement increases the risk of osteoporosis and arrhythmias, especially in the elderly.
   b. If TSH is wnl – dose has been established. Monitor TSH at 6 months and then every 12 months thereafter.
   c. If TSH is elevated (>5.5mIU/L) – consider dose increase by 25 – 50mcg.

4. Clinical pearls on levothyroxine
   a. Levothyroxine is best absorbed on an empty stomach, at least 30 minutes before breakfast. If taken in the evening, patient should wait at least 4 hours from last meal before taking levothyroxine.
   b. Patients should take levothyroxine 4 hours apart from antacids, iron and calcium supplements.
   c. Patients should taken levothyroxine with a full glass (8oz) of water ONLY.

### Table 4

<table>
<thead>
<tr>
<th>Agents Impacting Levothyroxine Therapy or the Hypothalamic-Pituitary Axis (HPA)</th>
<th>Interferes with absorption of levothyroxine</th>
<th>Increases clearance of levothyroxine</th>
<th>Direct and indirect effects on the HPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Oral biphosphonates</td>
<td>•Phenobarbital</td>
<td>•Decreases TSH secretion</td>
<td></td>
</tr>
<tr>
<td>•Sucralfate</td>
<td>•Fenrootide</td>
<td>•Cephalosporin</td>
<td></td>
</tr>
<tr>
<td>•Esperide</td>
<td>•Phenytoin</td>
<td>•Corticosteroids</td>
<td></td>
</tr>
<tr>
<td>•Calcium salts</td>
<td>•Carbamazepine</td>
<td>•Bromocriptine</td>
<td></td>
</tr>
<tr>
<td>•Calcium acetate</td>
<td>•Valproate</td>
<td>•Dopaminergic agonists</td>
<td></td>
</tr>
<tr>
<td>•Calcium citrate</td>
<td>•Gabapentin</td>
<td>•Dopaminergic agonists</td>
<td></td>
</tr>
<tr>
<td>•Calcium carbonate</td>
<td>•Topiramate</td>
<td>•Glucocorticoids</td>
<td></td>
</tr>
<tr>
<td>•Diet:</td>
<td>•Lamotrigine</td>
<td>•Thyroid hormone analogues</td>
<td></td>
</tr>
<tr>
<td>•Ingestion with a meal</td>
<td>•Valproate</td>
<td>•Metformil</td>
<td></td>
</tr>
<tr>
<td>•Grapefruit juice</td>
<td>•Topiramate</td>
<td>•Opiates</td>
<td></td>
</tr>
<tr>
<td>•Espresso coffee</td>
<td>•Topiramate</td>
<td>•Increased TSH secretion</td>
<td></td>
</tr>
<tr>
<td>•High fiber diet</td>
<td>•Topiramate</td>
<td>•Decreases TSH secretion</td>
<td></td>
</tr>
<tr>
<td>•Any</td>
<td>•Topiramate</td>
<td>•Cephalosporin</td>
<td></td>
</tr>
<tr>
<td>•High fiber diet</td>
<td>•Topiramate</td>
<td>•Corticosteroids</td>
<td></td>
</tr>
<tr>
<td>•any</td>
<td>•Topiramate</td>
<td>•Bromocriptine</td>
<td></td>
</tr>
</tbody>
</table>

Thyroid Disorders page 3
5. Hypothyroidism during pregnancy

a. TSH goals vary depending on the trimester

<table>
<thead>
<tr>
<th>Table 5.</th>
<th>First Trimester</th>
<th>Second Trimester</th>
<th>Third Trimester</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH Goal</td>
<td>0.1-2.5 mIU/L</td>
<td>0.2-3.0 mIU/L</td>
<td>0.3-3.0 mIU/L</td>
</tr>
</tbody>
</table>

b. Treatment for pregnant women with hypothyroidism is oral levothyroxine.

c. At 4-6 weeks pregnant, a dose increase will be needed if the patient is taking levothyroxine, potentially as much as 50%, due to the increase in size of the thyroid gland.

d. Monitor TSH and Free T4 every 4 weeks during the first half of pregnancy and at least once between 26 weeks and 32 weeks.

e. TSH levels decline in the first trimester when HCG levels are high and rise after 10-12 weeks gestation.

f. Please consider consulting with OB/GYN for recommendations on management.

B. Hyperthyroidism – treatment should be managed by the Specialist. While waiting for appointment, the primary care provider may initiate medical management.

1. Pharmacological Therapy:

<table>
<thead>
<tr>
<th>Table 6.</th>
<th>Drug of Choice: Methimazole</th>
<th>Initial/Dose</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulary strength</td>
<td>20-40mg/day for mild hyperthyroidism; 60-80mg/day for moderately severe hyperthyroidism</td>
<td>5-15mg once daily</td>
<td>5-15mg once daily</td>
</tr>
<tr>
<td>In pregnancy</td>
<td>20-40mg/day for mild hyperthyroidism; 60-80mg/day for moderately severe hyperthyroidism</td>
<td>50-150mg (depending on severity) 3 times daily</td>
<td>50mg 2-3 times daily for a total of 12-18 months, then taper or discontinue if TSH is normal at that time.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 7.</th>
<th>Side Effects of Methimazole</th>
<th>Side Effects of Propylthiouracil</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Agranulocytosis</td>
<td>• Agranulocytosis</td>
<td>Bleeding, coagulopathy</td>
</tr>
<tr>
<td>• Thrombocytopenia</td>
<td>• Leukopenia</td>
<td>Hypothyroidism</td>
</tr>
<tr>
<td>• Aplastic Anemia</td>
<td>• Aplastic anemia</td>
<td></td>
</tr>
<tr>
<td>• Hepatitis</td>
<td>• Hepatitis</td>
<td></td>
</tr>
<tr>
<td>BBW</td>
<td>• Agranulocytosis</td>
<td>• Agranulocytosis</td>
</tr>
<tr>
<td></td>
<td>• Leukopenia</td>
<td>• Leukopenia</td>
</tr>
<tr>
<td></td>
<td>• Thrombocytopenia</td>
<td>• Thrombocytopenia</td>
</tr>
<tr>
<td></td>
<td>• Aplastic anemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hepatitis</td>
<td>• Hepatitis</td>
</tr>
<tr>
<td></td>
<td>• Acute renal failure, glomerulonephritis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 8.</th>
<th>Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methimazole may increase the levels of the following agents:</td>
<td>Methimazole may decrease the levels of the following agents:</td>
</tr>
<tr>
<td>Cardioglycosides</td>
<td>Lidocaine</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>Procainamide</td>
</tr>
<tr>
<td>Theophylline derivatives</td>
<td>Oral contraceptives</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Propranolol</td>
<td>Carbohydrate inhibitors</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Propylthiouracil levels may be altered if taken with food. Either always take with food or always take without food.
2. Lithium and Hyperthyroidism
   a. Perform thyroid physical examination upon intake.
   b. Obtain TSH and antithyroid peroxidase antibody titers prior to initiation of lithium treatment.
      i. If thyroid function is abnormal at the initial evaluation, lithium can still be given, but the thyroid dysfunction should be treated. Please refer to Thyroid Disorders pathway.
      ii. If thyroid function is normal at baseline, it should be re-evaluated every 6 to 12 months while on lithium treatment.
   c. Monitor TSH and Free T4 in patients taking lithium as recommended in the Thyroid Disorders pathway.
3. Treatment goals include:
   a. Symptom relief
   b. TSH within normal value range (0.35 – 5.5 mIU/L)
   c. Free T4 within normal value range (0.78 – 2.2ng/dL)
4. Monitoring recommendations
   a. Baseline tests: prothrombin, CBC, and liver function enzymes.
   b. Free T4 level should be drawn 4 weeks after initiating methimazole, and every 3 months thereafter until patient is euthyroidic.
   c. TSH should be monitored at 6 months and then every 6 months until 18 months of therapy are complete. TSH may remain suppressed for several months after starting therapy and is therefore not a good parameter to guide medication adjustment.
   d. Patients should report signs/symptoms of liver injury when using methimazole or propylthiouracil including: anemia, pruritis, right upper quadrant pain.
   e. Liver function tests should be monitored frequently while taking PTU.
   f. Continue to monitor for presence of nodules or goiters in hyperthyroid patients and refer to specialist if needed.
5. Hyperthyroidism during pregnancy
   a. Refer to OB/GYN for management of hyperthyroidism in pregnant patients.
TINEA PEDIS

1. Patient Counseling:
   (1) Wash With Soap & Water
   (2) Dry Feet Well
   (3) Wear Clean Socks

2. Topical Antifungal Cream
   1% Tolnaftate or
   1% Clotrimazole Cream
   BID X 30 days

End Therapy and Reinforce Counseling

3. Resolution?
   Yes

4. Consider other agent not used above
   1% Tolnaftate Cream or
   1% Clotrimazole Cream
   BID X 30 days

   Resolution?
   Yes

   Refer to Box # 4

   No

5. Consider pharmacotherapy consultation

6. Refer to Box # 4

7. Consult Dermatology Consultation

   Resolution?
   Yes

   Refer to Box # 4

   No
Chronic Anticoagulation Using Warfarin

1. Does patient have documented indication for chronic anticoagulation therapy? See Table 5 for indications.

2. Continue to Box #8 on the next page.

3. Warfarin adherence > 75% over last 30 days?

4. Warfarin adherence > 75% over last 30 days?

5. INR value < Goal INR range.

6. INR value < Goal INR range.

7. Warfarin adherence > 75% over last 30 days?

8. INR value < Goal INR range.

9. Warfarin adherence > 75% over last 30 days?

10. Warfarin adherence > 75% over last 30 days?

11. Warfarin adherence > 75% over last 30 days?

12. Warfarin adherence > 75% over last 30 days?

13. Warfarin adherence > 75% over last 30 days?

14. Warfarin adherence > 75% over last 30 days?

15. Warfarin adherence > 75% over last 30 days?

16. Warfarin adherence > 75% over last 30 days?

17. Warfarin adherence > 75% over last 30 days?

18. Warfarin adherence > 75% over last 30 days?

19. Warfarin adherence > 75% over last 30 days?

The pathways do not replace sound clinical judgment, nor are they intended to strictly apply to all patients.

Prepared By: The Correctional Managed Care Pharmacy & Therapeutics Committee
Counsel patient on the effects of medication / food / conditions on INR. Increase total weekly dose of warfarin (Table 6 or 7).

Order INR to be drawn 2 days before next visit. Verify INR will be drawn on a M–F.

Schedule patient for follow-up in 7 to 14 days. Return to Box #8.

The pathways do not replace sound clinical judgment, nor are they intended to strictly apply to all patients.
I. Treatment Principles
   A. Primary vs. Secondary Prevention
      1. Primary prevention: Circumventing a thrombotic event before it happens
      2. Secondary prevention: Avoiding a recurrence of a thrombotic event in a patient who has already experienced one
   B. Negative Consequences of NOT Providing Venous Thromboembolism (VTE) Prophylaxis
      1. Symptomatic deep venous thrombosis (DVT) or pulmonary embolism (PE)
      2. Fatal PE
      3. Costs of tests used to diagnose symptomatic patients
      4. Risks and costs of treating unprevented VTE
      5. Increased risk of recurrence
      6. Development of chronic post-thrombotic syndrome
   C. Risk Factors Associated With Deep Venous Thrombosis (DVT)
      **TABLE 1**
      | Risk Factor                                                                 | Table 1                                                                 |
      |--------------------------------------------------------------------------------|------------------------------------------------------------------------|
      | Cancer: currently on treatment, treatment within past 6 months, or not receiving curative treatment | • History of VTE                                                      |
      | Paralysis, paresis, or any other factor that leads to a severe decrease in ability to move about | • Age > 60 years                                                      |
      | Confined to bed for > 3 days                                                   | • Fracture of hip / pelvis / leg(s)                                    |
      | Major surgery (esp. orthopedic) in the last 12 weeks that required general or regional anesthesia lasting > 30 minutes | • Indwelling central venous catheter                                  |
      | Heparin-Induced Thrombocytopenia (HIT)                                        | • Major medical illness (e.g. HF, MI, TIA, ischemic stroke)            |
      | Pharmacotherapy                                                              | • Hypercoagulable States                                              |
      | o Estrogenic oral contraceptive agents                                        | • Cancer                                                               |
      | o Post-menopausal hormone therapy                                             | o Activated Protein C Resistance Factor / Factor V Leiden mutation    |
      | o Cancer treatments                                                          | o Prothrombin 20210A mutation.                                        |
      | • Hormonal                                                                  | o Protein C or S deficiency                                            |
      | • Radiotherapy                                                              | o Antithrombin deficiency                                             |
      | • Chemotherapy                                                              | o Factor VIII or XI excess (> 90th percentile)                        |
      |                                                                              | o Antiphospholipid Antibody Syndrome                                  |
      |                                                                              | o Dysfibrinogenemia                                                   |
      |                                                                              | o Hyperhomocysteinemia                                                |
      |                                                                              | o Excess of Inhibitor of Plasminogen Activator                    |
      |                                                                              | o Inflammatory Bowel Disease                                          |
      |                                                                              | • Ulcerative Colitis                                                 |
      |                                                                              | • Crohn’s Disease / Crohn’s Colitis                                  |
      |                                                                              | • Neoplastic Syndrome                                                |
      |                                                                              | • Pregnancy and post-partum period                                   |
      | D. Risk Factors Associated With Pulmonary Embolism (PE)                      |                                                                         |
      | 1. History of PE or DVT                                                      |                                                                         |
      | 2. Recent surgery or immobilization (e.g., plaster cast)                     |                                                                         |
      | 3. Resting heart rate consistently > 100 beats per minute                    |                                                                         |
      | 4. Cancer / malignancy                                                       |                                                                         |
      | 5. Age > 60 years                                                           |                                                                         |
E. Risk Factors Associated with Developing A Severe Bleed While On Warfarin Therapy

TABLE 2

<table>
<thead>
<tr>
<th>Factors That Increase Risk of Developing A Severe Bleed During Warfarin Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age &gt; 65 years</td>
</tr>
<tr>
<td>• Diabetes mellitus</td>
</tr>
<tr>
<td>• Cerebrovascular disease</td>
</tr>
<tr>
<td>• Inertia</td>
</tr>
<tr>
<td>• Female gender</td>
</tr>
<tr>
<td>• Alcohol abuse</td>
</tr>
<tr>
<td>• History of GI bleeds, peptic ulcerations, etc.</td>
</tr>
<tr>
<td>• Hypertension</td>
</tr>
<tr>
<td>• Renal insufficiency</td>
</tr>
<tr>
<td>• Antiplatelet therapy</td>
</tr>
<tr>
<td>• History of recent or past bleeding event</td>
</tr>
<tr>
<td>• Drug abuse</td>
</tr>
</tbody>
</table>

F. Determining the target INR (International Normalized Ratio) and INR Range for Warfarin
1. The target, or goal INR represents the intensity of warfarin therapy.
2. For most medical indications, the target INR is 2.5, with a goal range of 2.0 to 3.0.
3. For higher-risk conditions, the target INR is 3.0, with a goal range of 2.5 to 3.5.
4. An INR lower than 2.0 significantly increases the risk of developing a VTE, while an INR > 4.0 significantly increases the risk of developing a bleed.
5. A patient’s INR can be affected by multiple variables such as:
   a. Age
   b. Drug interactions
   c. Food interactions
   d. Medical conditions
   e. Laboratory error
   f. Poor medication adherence
   g. Genetic and environmental factors

G. Determining Treatment Duration
1. Studies have consistently shown that a longer duration of treatment with warfarin is associated with both a decrease in the incidence of VTE and an increase in the risk of experiencing a bleeding event.
2. Duration is determined by indication.

II. Patient Evaluation
A. Physical Exam
1. Assess the patient for signs and symptoms of a possible acute, severe bleed. See Table 3.

TABLE 3

<table>
<thead>
<tr>
<th>Signs &amp; Symptoms Of Possible Acute Severe Bleed</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Severe headache that fails to resolve</td>
</tr>
<tr>
<td>• Decrease ≥ 10 mmHg in systolic BP or an ↑ ≥ 10 beats per minute or more in pulse rate when rising from a lying down position to a standing position</td>
</tr>
<tr>
<td>• Dyspnea</td>
</tr>
<tr>
<td>• Decrease in supine blood pressure</td>
</tr>
<tr>
<td>• Hematuria</td>
</tr>
<tr>
<td>• Hemoptysis</td>
</tr>
<tr>
<td>o Fainting upon rising from a lying position or from a sitting position</td>
</tr>
<tr>
<td>• Hypovolemic shock</td>
</tr>
<tr>
<td>• Tachycardia at rest or with mild exertion (skin may be cool and clammy)</td>
</tr>
<tr>
<td>• Hematemesis</td>
</tr>
<tr>
<td>• Melenas</td>
</tr>
<tr>
<td>• Hypotension as indicated by 1 or more of the following:</td>
</tr>
<tr>
<td>o Bright red colored stool</td>
</tr>
<tr>
<td>o Dark red or maroon stool</td>
</tr>
<tr>
<td>o Pure blood</td>
</tr>
<tr>
<td>o Blood mixed with formed stool</td>
</tr>
<tr>
<td>o Bloody diarrhea</td>
</tr>
</tbody>
</table>
2. Assess the patient for signs and symptoms of venous thromboembolism (VTE) and/or pulmonary embolism (PE). See Table 4.

### TABLE 4

<table>
<thead>
<tr>
<th>Signs &amp; Symptoms Of Venous Thromboembolism (VTE) &amp; Pulmonary Embolism (PE)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Venous Thromboembolism</strong></td>
</tr>
<tr>
<td>• Tenderness localized to deep venous system (e.g. calf)</td>
</tr>
<tr>
<td>• Difference in calf circumference &gt; 3 cm when compared to asymptomatic leg (measure 10 cm (4 in) below the tibial tuberosity)</td>
</tr>
<tr>
<td>• Pitting edema present on symptomatic leg only</td>
</tr>
<tr>
<td>• Collateral superficial veins, non-varicose</td>
</tr>
<tr>
<td>• Elevated D-dimer reading</td>
</tr>
</tbody>
</table>

B. Medical History: Obtain the following information to use with recent INR value to evaluate / develop treatment plan:
1. Indication(s) for treatment
2. Treatment duration
3. Problems
   a. Signs/symptoms of bleeding
   b. Signs/symptoms of VTE / PH
   c. Adherence
   d. Recent illness / hospitalization
4. Review
   a. Most current medication profile
   b. Diet
   c. Commissary
   d. Drug use

III. Management of Chronic Warfarin Anticoagulation Therapy
A. The patient’s indication(s) determine his/her INR goal as well as the duration of treatment. Consult Table 5 below to determine this and to review any special considerations for that particular indication.
B. While the following conditions are often acutely or initially treated with other antithrombotic agents in addition to warfarin therapy, this guideline only addresses the CHRONIC treatment of the conditions with warfarin. AFTER the condition has been acutely treated.
### Table 5: Indications and Target INRs and Acceptable INR Ranges

<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Specific Indication</th>
<th>Target INR</th>
<th>INR Range</th>
<th>Duration of Therapy</th>
<th>Comments/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Fibrillation or Atrial Flutter</td>
<td>Age ≤ 75 years, no risk factors</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81–325 mg daily</td>
</tr>
<tr>
<td></td>
<td>Plus: History of ischemic stroke, history of systemic embolus, history of poor left ventricular systolic function and/or HF, Age &gt; 75 years</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Baseline 7 weeks before elective cardioversion and continue for 3 weeks after successful cardioversion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mitral Valve Stenosis</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>Antiphospholipid Antibody Syndrome or Presence of Lupus Inhibitor</td>
<td>Patients with no additional risk factors</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patients with recurrent thromboembolic events at INR of 2.0 – 3.0 or with additional risk factors</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>Cerebral Venous Sinus Thrombosis</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Up to 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTPH</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1st episode, secondary to reversible risk factor</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1st isolated distal DVT</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recurrent</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cancer</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Until cancer resolution or indefinitely; LMWH recommended for the first 3–6 months.</td>
<td></td>
</tr>
<tr>
<td>Mitral Aneurysm Calcification</td>
<td>Complicated by systemic embolus, ischemic stroke, or TIA under AP</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>Recent episode despite aspirin therapy</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>Mitral Valve Stenosis</td>
<td>New or increasing left atrial thrombus</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Until thrombus resolution is documented by repeat TEE</td>
<td></td>
</tr>
</tbody>
</table>

ACRONYMS: AF = Atrial Fibrillation, CTPH = Chronic Thromboembolic Pulmonary Hypertension, DM = Diabetes Mellitus, DVT = Deep Venous Thrombosis, HF = Heart Failure, HTN = Hypertension, INR = International Normalized Ratio, LMWH = Low Molecular Weight Heparin, PA = Pulmonary Arterial Aortic Fibrillation, PE = Pulmonary Embolism, TEE = Transesophageal Echocardiography, TIA = Transient Ischemic Attack, UFH = Unfractionated Heparin, NSR = Normal Sinus Rhythm, STEMI = ST-segment Elevation Myocardial Infarction, MI = Myocardial Infarction, VKA = Vitamin K Antagonist (ie. warfarin), ASA = Aspirin
<table>
<thead>
<tr>
<th>Medical Condition</th>
<th>Specific Indication</th>
<th>Target INR</th>
<th>INR Range</th>
<th>Duration of Therapy</th>
<th>Comments/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Valve Prolapse</td>
<td>With TIA or ischemic stroke</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>With</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• AF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documented systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Recent TIA with aspirin therapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mitral Valve Prolapse</td>
<td>With</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Left atrial thrombus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NSR with atrial diameter &gt; 55 mm</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• AF with systemic embolism and/or left atrial thrombus while at therapeutic INR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical Mitral Valve Disease</td>
<td>With:</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• AF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Left atrial thrombus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NSR with atrial diameter &gt; 55 mm</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>AORTIC Position in NSR with left atrial enlargement</td>
<td>Bileaflet</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bileaflet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Tilted disk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Anterograde STEMI</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td>Combine with aspirin 81 mg/day in patients with multiple risk factors for thromboembolic and atherosclerotic disease.</td>
</tr>
<tr>
<td></td>
<td>• Left atrial enlargement</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypercoagulable state</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low ejection fraction</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Systemic embolism despite previously therapeutic INR</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td>Combine with aspirin 81 mg/day or upward titrate warfarin dose and INR.</td>
</tr>
<tr>
<td></td>
<td>• Target 2.5 (2.0 – 3.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Target 3.0 (2.5 – 3.5)</td>
<td>3.5</td>
<td>5.0 – 4.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>AORTIC Position in NSR with left atrial enlargement</td>
<td>Bileaflet</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Bileaflet</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Tilted disk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Anterograde STEMI</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Left atrial enlargement</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypercoagulable state</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low ejection fraction</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Systemic embolism despite previously therapeutic INR</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Target 2.5 (2.0 – 3.0)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Target 3.0 (2.5 – 3.5)</td>
<td>3.5</td>
<td>5.0 – 4.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>AORTIC Position with:</td>
<td>• NSR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>• No other VKA indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Anterograde STEMI</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td>AAA 81 mg/day afterwards in patients with NSR and no other indications for warfarin therapy.</td>
</tr>
<tr>
<td></td>
<td>• History of systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AORTIC Position with:</td>
<td>• NSR</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>• No other VKA indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Anterograde STEMI</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td>Combine addition of aspirin 81 mg/day in patients with atherosclerotic disease.</td>
</tr>
<tr>
<td></td>
<td>• History of systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypersensitive state</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Low ejection fraction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Any additional thromboembolic risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
C. Subtherapeutic levels increase the patient’s risk for developing an embolism. Use the following tables to adjust the patient’s dose when his/her INR is more than 0.5 units lower than the lowest INR in the target range.

1. A 10% change in total weekly warfarin dose will result in an approximate INR change of 0.7 to 0.8.
2. A 15% change in total weekly warfarin dose will result in an approximate INR change of 1.

<table>
<thead>
<tr>
<th>INR Range</th>
<th>Warfarin Dose Adjustment</th>
<th>Schedule Next INR To Be Drawn In:</th>
<th>Schedule For Reevaluation In:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 to 1.4</td>
<td>Increase total weekly dose by 10% to 20%</td>
<td>2 days before next visit</td>
<td>7 - 14 days</td>
</tr>
<tr>
<td>1.5 to 1.9</td>
<td>Increase total weekly dose by 5% to 10%</td>
<td>2 days before next visit</td>
<td>7 - 14 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>INR Range</th>
<th>Warfarin Dose Adjustment</th>
<th>Schedule Next INR To Be Drawn In:</th>
<th>Schedule For Reevaluation In:</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 2.0</td>
<td>Increase total weekly dose by 10% to 20%</td>
<td>2 days before next visit</td>
<td>7 - 14 days</td>
</tr>
<tr>
<td>2.0 – 2.4</td>
<td>Increase total weekly dose by 5% to 15%</td>
<td>2 days before next visit</td>
<td>7 - 14 days</td>
</tr>
</tbody>
</table>
D. **Supratherapeutic** levels increase the patient’s risk for developing a severe bleed. Use the following table to adjust the patient’s dose when his/her INR is more than 0.5 units greater than the greatest INR in the target range.

1. A 10% change in total weekly warfarin dose will result in an approximate INR change of 0.7 to 0.8.
2. A 15% change in total weekly warfarin dose will result in an approximate INR change of 1.
3. An oral Vitamin K dose of 1.0 to 2.5 may result in an INR change varying from 2 to 5 INR units. Monitoring essential when using Vitamin K to correct supratherapeutic INR levels.

<table>
<thead>
<tr>
<th>Bleeding Severity</th>
<th>Patient INR</th>
<th>Vitamin K1 (oral dose)</th>
<th>Warfarin Adjustment</th>
<th>Schedule next INR to be drawn in:</th>
<th>Schedule for reevaluation in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without signs &amp; symptoms of serious bleeding, and without urgent or recent surgery</td>
<td>&gt;5 – 8.9</td>
<td>None</td>
<td>Hold 1–2 doses. Decrease total weekly dose by 10% to 20%</td>
<td>Within next 1–2 days.</td>
<td>1 – 2 days. Unit evaluation of signs of excess bleeding should be frequently performed.</td>
</tr>
<tr>
<td>9 – 10</td>
<td>2.5 – 5 mg, based on patient risk for bleeding</td>
<td>Hold warfarin until INR within therapeutic range. Then, resume at a dose that is 20% to 50% less than previous regimen’s total weekly dose.</td>
<td>Within next 1 – 2 days.</td>
<td>As soon as possible. If INR still higher than desirable, may administer another dose of Vitamin K1, 2.5 mg by mouth 24 hours after first dose.</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td></td>
<td></td>
<td></td>
<td>Hold warfarin, give Vitamin K1, and consider transport to higher level of care.</td>
<td></td>
</tr>
<tr>
<td>Serious bleeding</td>
<td>Any INR</td>
<td>Hold warfarin, give Vitamin K1, and consider transport to higher level of care.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Factors That Can Result In A Subtherapeutic or Supratherapeutic Warfarin Level or Alter Warfarin's Effect

<table>
<thead>
<tr>
<th>Table 9: Drugs That Can Change Warfarin's Effects and/or INR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drugs That ↑ Warfarin's Effects and/or INR (SUPRAtherapeutic)</strong></td>
</tr>
<tr>
<td>Aminoglutethimide, Cimetidine, Ciprofloxacin, Levofloxacin, Metronidazole, Fluconazole, Voriconazole, Zafirlukast</td>
</tr>
<tr>
<td>Antiplatelet Agents: aspirin, clopidogrel, ticlopidine, prasugrel</td>
</tr>
<tr>
<td>CYP 2C9 inducing drugs: carbamazepine, phenobarbital, phenytoin, primidone, rifampin, daru, rilpivirine</td>
</tr>
<tr>
<td>Penicillin-based antibiotics: dicloxacillin, nalidixic acid</td>
</tr>
<tr>
<td>Antihyperlipidemic agents: fenofibrate, gemfibrozil, clofibrate, fenofibrate</td>
</tr>
<tr>
<td>NSAID Agents: aspirin, ibuprofen, ibuprofen, Clofibrate</td>
</tr>
<tr>
<td>Macrolide antibiotics: clarithromycin, erythromycin</td>
</tr>
<tr>
<td>Levocarnitine, Cysteine, Carnitine</td>
</tr>
<tr>
<td>Antiarrhythmics: phenylpropanolamine, propafenone</td>
</tr>
<tr>
<td>Antipsychotic Agents: haloperidol, clozapine</td>
</tr>
<tr>
<td>Quinolone Antibiotics: sulfamethoxazole, trimethoprim</td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors: paroxetine, sertraline</td>
</tr>
<tr>
<td>Tricyclic Antidepressants: amitriptyline, doxepine</td>
</tr>
<tr>
<td>Sulfonamide Derivatives: trimethoprim, sulfamethoxazole</td>
</tr>
<tr>
<td><strong>Drugs That ↓ Warfarin Effects and/or INR (SUBtherapeutic)</strong></td>
</tr>
<tr>
<td>Acetaminophen or aspirin &gt; 1.3 g (1300 mg) per day X 7 days or more</td>
</tr>
<tr>
<td>Aminoglutethimide, Carbamazepine, Phenytoin, Primidone, Rifampin, Ritonavir</td>
</tr>
<tr>
<td>CYP 2C9 inhibiting drugs: amiodarone, chloramphenicol, cimetidine, lovastatin, isoniazid, fluoxetine, fluvoxamine, metronidazole, fluconazole, voriconazole, zafirlukast</td>
</tr>
<tr>
<td>Penicillin-based antibiotics: dicloxacillin, nalidixic acid</td>
</tr>
<tr>
<td>Antihyperlipidemic agents: fenofibrate, gemfibrozil, clofibrate, fenofibrate</td>
</tr>
<tr>
<td>NSAID Agents: aspirin, ibuprofen, ibuprofen, Clofibrate</td>
</tr>
<tr>
<td>Macrolide antibiotics: clarithromycin, erythromycin</td>
</tr>
<tr>
<td>Levocarnitine, Cysteine, Carnitine</td>
</tr>
<tr>
<td>Antiarrhythmics: phenylpropanolamine, propafenone</td>
</tr>
<tr>
<td>Antipsychotic Agents: haloperidol, clozapine</td>
</tr>
<tr>
<td>Quinolone Antibiotics: sulfamethoxazole, trimethoprim</td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors: paroxetine, sertraline</td>
</tr>
<tr>
<td>Tricyclic Antidepressants: amitriptyline, doxepine</td>
</tr>
<tr>
<td>Sulfonamide Derivatives: trimethoprim, sulfamethoxazole</td>
</tr>
</tbody>
</table>
### TABLE 10: Foods That Alter the Effects of Warfarin

<table>
<thead>
<tr>
<th>Foods That ↑ Warfarin’s Effects and/or INR</th>
<th>Foods that ↓ Warfarin Effects and/or INR =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages: Juice, cranberry</td>
<td>Beverages: Juice, cranberry</td>
</tr>
<tr>
<td>Foods High in Vitamin K</td>
<td>Foods containing Olestra® synthetic fats</td>
</tr>
<tr>
<td>Fats &amp; Dressings: Margarine</td>
<td></td>
</tr>
<tr>
<td>Oil, canola</td>
<td></td>
</tr>
<tr>
<td>Oil, vegetable</td>
<td></td>
</tr>
<tr>
<td>Oil, soybean</td>
<td></td>
</tr>
<tr>
<td>Oil, olive</td>
<td></td>
</tr>
<tr>
<td>Vegetables: Asparagus</td>
<td></td>
</tr>
<tr>
<td>Avocado</td>
<td></td>
</tr>
<tr>
<td>Broccoli</td>
<td></td>
</tr>
<tr>
<td>Brussels sprouts</td>
<td></td>
</tr>
<tr>
<td>Cabbage</td>
<td></td>
</tr>
<tr>
<td>Cabbage, red</td>
<td></td>
</tr>
<tr>
<td>Collard greens</td>
<td></td>
</tr>
<tr>
<td>Endives, raw</td>
<td></td>
</tr>
<tr>
<td>Green scallions, raw</td>
<td></td>
</tr>
<tr>
<td>Kale, raw leaf</td>
<td></td>
</tr>
<tr>
<td>Lettuce, raw</td>
<td></td>
</tr>
<tr>
<td>Mustard greens</td>
<td></td>
</tr>
<tr>
<td>Parsley</td>
<td></td>
</tr>
<tr>
<td>Peas, green, cooked</td>
<td></td>
</tr>
<tr>
<td>Spinach, raw leaf</td>
<td></td>
</tr>
<tr>
<td>Turnip greens, raw</td>
<td></td>
</tr>
<tr>
<td>Watercress, raw</td>
<td></td>
</tr>
<tr>
<td>Over-the-Counter Supplements: Vitamin E</td>
<td>Over-the-Counter Supplements: Vitamin K</td>
</tr>
<tr>
<td>Vitamin supplements containing Vitamin K</td>
<td>Vitamin C, high-dose</td>
</tr>
<tr>
<td>Nutritional supplement beverages (e.g. Osmolite®)</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 11: Factors That May Change Warfarin’s Effects

<table>
<thead>
<tr>
<th>Factors That Can ↑ Warfarin’s Effects</th>
<th>Factors That Can ↓ Warfarin’s Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Blood dyscrasias</td>
<td>• Diet high in Vitamin K</td>
</tr>
<tr>
<td>• Cancer</td>
<td>• Edema</td>
</tr>
<tr>
<td>• Collagen vascular disease</td>
<td>• Hereditary coumarin resistance</td>
</tr>
<tr>
<td>• Congestive Heart Failure (CHF)</td>
<td>• Hypolipidemia</td>
</tr>
<tr>
<td>• Diarrhea</td>
<td>• Hypothyroidism</td>
</tr>
<tr>
<td>• Dietary deficiencies / poor nutritional state</td>
<td>• Nephrotic syndrome</td>
</tr>
<tr>
<td>• Elevated temperature / fever</td>
<td></td>
</tr>
<tr>
<td>• Hepatic Disorders:</td>
<td></td>
</tr>
<tr>
<td>• Infectious hepatitis</td>
<td></td>
</tr>
<tr>
<td>• Jaundice</td>
<td></td>
</tr>
<tr>
<td>• Hyperthyroidism</td>
<td></td>
</tr>
<tr>
<td>• Prolonged hot weather → dehydration</td>
<td></td>
</tr>
<tr>
<td>• Steatorrhoea</td>
<td></td>
</tr>
<tr>
<td>• Vitamin K deficiency</td>
<td></td>
</tr>
</tbody>
</table>
IV. Patient Education

A. Who educate?
1. Any provider involved in providing clinical warfarin therapy management services
2. Providers caring for a patient on chronic warfarin therapy
3. Specialty clinic providers of care related to the reason for a patient’s chronic warfarin therapy.
   a. For example, cardiology
4. Educator must document in patient’s medical record.

B. When does education occur?
1. Clinical warfarin therapy management sessions
2. When patient is stable, following a thromboembolic event or a hemorrhagic event.
3. Group education if available

C. What topics are covered when educating the patient?
1. Relationship between VTE and the patient’s current medical condition(s)
2. Relationship between INR and:
   a. The patient’s current medical condition(s)
   b. The risk for VTE / bleed
3. Role of adherence in warfarin therapy
4. Role of drug interactions in warfarin therapy
5. Role of changes in diet in warfarin therapy
6. Importance of modifying lifestyle / risk factors in preventing VTE and related conditions, when appropriate
7. Adjusting activities of daily living to minimize the risk of experiencing a bleed while on chronic warfarin therapy
8. Signs and symptoms of VTE and/or bleed, and when to drop a sick call for either of these.
9. Any relevant topic about which the patient requests information
# WOUND CARE PATHWAYS

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

## Wound / Patient Characteristics

<table>
<thead>
<tr>
<th>Present?</th>
<th>If yes,</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No</td>
<td>Refer to Arterial Insufficiency Wound DMG</td>
</tr>
</tbody>
</table>

- Located in lower extremities, below the ankle
- Decreased peripheral pulses
- Smooth/round edges
- Wounds are usually small and deep.
- Wound bed is dry or pale pink.
- "Punched out" lesions
- Poor hair and nail growths
- Distal wounds
- ABI <0.9
- Intermittent clausification

| □ Yes □ No | Refer to Neuropathic Wound DMG |

- Callous formation
- Dry skin
- Decreased sensation
- Located in plantar aspect of foot
- Diabetes

| □ Yes □ No | Refer to Pressure Wound DMG |

- Mobility impaired
- Low Braden Score
- Bony prominence
- Located in areas of pressure
- Malnourished
- Moisture exposure

| □ Yes □ No | Refer to Venous Insufficiency Wound DMG |

- Located in gaited area, mostly in the medial malleolus
- Positive peripheral pulses
- Larger, irregular borders
- Wounds are usually large and superficial
- Wound bed is beefy, red, and moist.
- Painless
- Surrounding skin usually has stasis dermatitis and hemosiderin.
- ABI >0.9
- Presence of scar tissue increases risk of re- ulceration.
- Varicosities

| □ Yes □ No | Refer to Surgical Wound DMG |

- Caused by incisional wound dehiscence or laceration
- Occurred post-op

---

*Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, November 2005. Revised 1/07, 11/07, 5/10, 7/12, 3/14. 5/16 Reviewed 1/08.*
Patient Assessment:
1. Obtain Ankle Brachial Index (ABI). An ABI <0.9 is diagnostic for Arterial Insufficiency.
2. Assess the patient for symptoms of intermittent claudication. Regardless of normal ABI (0.9 to 1.2), patient may still have arterial insufficiency disease if symptoms persist.
3. Counsel patient on smoking cessation, to not cross legs, to avoid constrictive garments and to avoid caffeine.
4. Know that undiagnosed arterial insufficiency wounds can lead to osteomyelitis.
5. Manage underlying diseases that can increase risk of arterial insufficiency disease (e.g., hypertension, hyperlipidemia, cardiovascular disease, and diabetes mellitus).
6. If needed, provide adequate pain control (refer to pain disease management guidelines).
7. Evaluate the patient for any factors that may slow wound healing (e.g., medications and nutritional status).
8. Consider consultation with the Wound Care Specialist.

ARterial INSufficiency Wounds

Does the patient have an arterial insufficiency wound that requires treatment?

Wound Assessment

1. Precautions:
   - Avoid compression therapy
   - Avoid elevation of lower extremities
   - Avoid sharp debridement of chronic, dry, eschar-covered, uninfected ulcers in pts with low ABI's.
2. Treat wound according to wound bed description.
   - Most arterial insufficiency wounds will be dry. Go to "Dry Wound Bed".
   - If wound is stagnant or not improving, consider dressing regimen change or referral to Wound Care Specialist.
   - Continue care and wound is healed and educate on wound care prevention.

Objective

- Protect newly formed tissue
- Support granulation and tissue growth
- Debridement and decrease bacterial burden
- Debridement

OFFLOAD

Use offloading equipment i.e., foot protectors, pressure relieving overlays, crutches and trapezes

CLEANSE

Wash with soap and water or a commercial wound cleanser

Flush with 250cc's of normal saline or sterile water

PROTECT PERIWOUND

Consider using skin prep, hydrocolloid window dressing, or foam with silicone adhesive.

Wet Wound Bed

Primary Dressing
- Hydrocolloid
- Foam
- Cadexomer Iodine
- Silver alginate

Secondary Dressing
- Foam
- Wound cleanser

Dressings to cover WTM dressings
- Collagenase (Santyl®)
- Silver alginate
- Cadexomer Iodine

Dressings to cover WTM dressings

Moist Wound Bed

Primary Dressing
- Hydrocolloid
- Foam
- Cadexomer Iodine
- Silver alginate

Secondary Dressing
- Wound cleanser

Dry Wound Bed

Primary Dressing
- Hydrocolloid
- Cadexomer Iodine
- Hydrogel
- Silver with hydrogel

Secondary Dressing
- Foam
- Hydrocolloid

Wound Care page 2

Yes

No
NEUROPATHIC WOUNDS

Patient Assessment:
1. Check feet for structural changes, bony prominences, or for painless wounds with even margins.
2. Test for sensory function using a 5.07/10gm monofilament.
3. Obtain ABI to rule out arterial insufficiency. Refer to Arterial Insufficiency disease management guidelines.
4. Manage underlying diseases that increase risk of neuropathic wounds (e.g., diabetes mellitus, hypertension, hyperlipidemia).
5. Ensure provide adequate pain control (refer to pain disease management guidelines).
6. Ensure tetanus status is up to date.
7. Evaluate the patient for any factors that may slow wound healing (e.g., medications and nutritional status).
8. Consider consultation with a Wound Care Specialist.

Does the patient have a neuropathic wound that requires treatment?

Wound Bed

<table>
<thead>
<tr>
<th>Objective</th>
<th>Offload</th>
<th>Cleanse</th>
<th>Protect Periwound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epithelialization</td>
<td>Support granulation and tissue growth</td>
<td>Debridement and decrease bacterial burden</td>
<td>Debridement</td>
</tr>
<tr>
<td>Granulation</td>
<td>Use offloading equipment (i.e., foot protectors, pressure-relieving overlays, crutches, and trapezes)</td>
<td>Wash with soap and water or a commercial wound cleanser</td>
<td>Consider using skin prep, hydrocolloid window, padding, or foam with silicone adhesives.</td>
</tr>
<tr>
<td>Local Infection/Colonization</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Calcareous/Neural/Slough</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Wet Wound Bed

Primary Dressing
- Hydrocolloid
- Cadexomer Iodine
- Silver alginate

Secondary Dressing
- Foam
- Hydrocolloid
- Vernanda dressing

Dry Wound Bed

Primary Dressing
- Hydrogel
- Cadexomer Iodine
- Silver alginate

Secondary Dressing
- Foam
- Hydrocolloid

Reassess wound every 4 weeks.

Does wound appear to be healing?

No
- Educate patient on wound prevention and early detection/screening.
- Follow the patient in Chronic Care Clinic.

Yes
- Continue care until wound is healed and educate patient on wound care prevention.

Consider evaluation for osteomyelitis:
- X-ray if indicated
- Bone scan if indicated
- Ortho referral if indicated

Treat wound according to wound bed description. Most neuropathic wounds will be dry.

Debridement is the mainstay of therapy.

To treat wound:
- Use offloading equipment (i.e., foot protectors, pressure-relieving overlays, crutches, and trapezes).
- Wash with soap and water or a commercial wound cleanser.
- Consider using skin prep, hydrocolloid window, padding, or foam with silicone adhesives.
- Use hydrocolloid, foam, or gauze as a secondary dressing.
- Use silver or hydrogel dressings as a primary dressing.

If wound is stagnant or not improving, consider dressing regimen change or referral to Wound Care Specialist.

The pathways do not replace wound clinical judgment, but are intended to modify or update care in all patients.
The pathways do not replace wound clinical judgment nor are they intended to strictly apply to all patients.

**Stage 1** Non-hyperemic erythema of intact skin

- Does the patient have a pressure wound that requires treatment?
  - Yes
    - Perform physical and visually inspect areas prone to wound development at each clinic visit.
    - Ensure tetanus status is up to date.
    - Counsel patient regarding the importance of adequate hydration and nutrition.
    - Evaluate the patient for any factors that may slow wound healing (e.g., medications and nutritional status).
  - No
    - Continue care until wound is healed and educate pt on wound care prevention.

**Stage 2** Partial-thickness skin loss involving damage or increase of subcutaneous tissue/dermis/epidermis extending to underlying tissue

- If wound appears to be worsening, re-assess the patient on the importance of wound care (see box 6).
- Unstageable Full thickness skin loss in which the base of the ulcer is covered by necrotic tissue.

**Stage 3** Full-thickness skin loss involving damage or increase of subcutaneous tissue/dermis/epidermis extending to underlying fascia

- If wound is stagnant or not improving, consider debridement regimen change or refer to Wound Care Specialist.

**Stage 4** Full-thickness loss with destruction, tissue necrosis or damage to muscle, bone, or other structures

- Consider consultation with the Wound Care Specialist.

**Deep tissue injury** Periwound/Extremities

- Does the wound have an area of intact skin?
  - Yes
    - Scalp
    - Apply foam dressing
    - Continue care until wound is healed and educate pt on wound care prevention
  - No
    - Consider debridement regimen change or refer to Wound Care Specialist

**Stage 17** Does the patient have a pressure wound that requires treatment?

- Yes
  - Reassess wound daily and apply offloading equipment i.e., heel protectors, pressure relieving overlay, trapezes, crutches and walker.
  - Local infection/critical illness
    - Do not use silver-containing dressings unless directed by Wound Care Specialist.
    - Do not use steroid-based ointments unless directed by Wound Care Specialist.
  - Granulation tissue
    - Continue care until wound is healed and educate pt on wound care prevention.
  - No
    - Reassess wound every 3 to 5 days for wound healing.

**Stage 12** Does the patient have a pressure wound that requires treatment?

- Yes
  - Reassess wound daily and apply offloading equipment i.e., heel protectors, pressure relieving overlay, trapezes, crutches and walker.
  - Local infection/critical illness
    - Do not use silver-containing dressings unless directed by Wound Care Specialist.
    - Do not use steroid-based ointments unless directed by Wound Care Specialist.
  - Granulation tissue
    - Continue care until wound is healed and educate pt on wound care prevention.
  - No
    - Reassess wound daily and apply offloading equipment i.e., heel protectors, pressure relieving overlay, trapezes, crutches and walker.
    - Local infection/critical illness
      - Do not use silver-containing dressings unless directed by Wound Care Specialist.
      - Do not use steroid-based ointments unless directed by Wound Care Specialist.
    - Granulation tissue
      - Continue care until wound is healed and educate pt on wound care prevention.

**Stage 7** Does the patient have a pressure wound that requires treatment?

- Yes
  - Reassess wound daily and apply offloading equipment i.e., heel protectors, pressure relieving overlay, trapezes, crutches and walker.
  - Local infection/critical illness
    - Do not use silver-containing dressings unless directed by Wound Care Specialist.
    - Do not use steroid-based ointments unless directed by Wound Care Specialist.
  - Granulation tissue
    - Continue care until wound is healed and educate pt on wound care prevention.
  - No
    - Reassess wound daily and apply offloading equipment i.e., heel protectors, pressure relieving overlay, trapezes, crutches and walker.
    - Local infection/critical illness
      - Do not use silver-containing dressings unless directed by Wound Care Specialist.
      - Do not use steroid-based ointments unless directed by Wound Care Specialist.
    - Granulation tissue
      - Continue care until wound is healed and educate pt on wound care prevention.

**Stage 2** Partial-thickness skin loss involving damage or increase of subcutaneous tissue/dermis/epidermis extending to underlying tissue

- If wound is stagnant or not improving, consider dressing regimen change or refer to Wound Care Specialist.

**Stage 3** Full-thickness skin loss involving damage or increase of subcutaneous tissue/dermis/epidermis extending to underlying fascia

- If wound is stagnant or not improving, consider dressing regimen change or refer to Wound Care Specialist.

**Stage 4** Full-thickness loss with destruction, tissue necrosis or damage to muscle, bone, or other structures

- Consider consultation with the Wound Care Specialist.

**Deep tissue injury** Periwound/Extremities

- Does the wound have an area of intact skin?
  - Yes
    - Scalp
    - Apply foam dressing
    - Continue care until wound is healed and educate pt on wound care prevention
  - No
    - Consider debridement regimen change or refer to Wound Care Specialist
**VENOUS INSUFFICIENCY WOUNDS**

### Patient Assessment:
1. Obtain ABI to rule out arterial insufficiency. Refer to Arterial Insufficiency disease management guidelines.
2. May consider monitoring skin cream for stasis dermatitis.
3. Manage underlying diseases that can increase risk of venous insufficiency disease (e.g., hypertension and diabetes mellitus).
4. If needed, provide adequate pain control (refer to pain disease management guidelines).
5. Ensure patient status is up to date.
6. Evaluate the patient for any factors that may slow wound healing (e.g., medications and nutritional status).
7. Consider consultation with the Wound Care Specialist.

**Does the patient have a venous insufficiency wound that requires treatment?**

Yes or No

---

**Does the patient have a venous insufficiency wound that requires treatment?**

Yes or No

---

# Wound Bed

**Epithelialization**
- Protect newly formed tissue
- Support granulation and tissue growth

**Granulation**
- Debridement and decrease bacterial burden

**Local Infection/Critical Colonization**
- Debridement

**Necrotic/Slough**
- Consider consultation with the Wound Care Specialist

## Protect Periwound

- Consider using skin prep, hydrocolloid window dressing, or foam with silicone adhesives

## Offload

- Use offloading equipment, i.e., heel protectors, pressure-relieving overlay, crutches, and trapezes

## Cleanse

- Wash with soap and water or a commercial wound cleanser
- Flush with 250 cc of normal saline or sterile water

## Protect Periwound

- Consider using skin prep, hydrocolloid window dressing, or foam with silicone adhesives

### Wound Bed

#### Wet Wound Bed

- **Primary Dressing:**
  - Hydrocolloid
  - Cadexomer Iodine
  - Silver Alginate
  - Wound to moist (WTM) dressings
- **Secondary Dressing:**
  - Foam
  - Hydrocolloid
  - Permeable dressing

#### Moist Wound Bed

- **Primary Dressing:**
  - Hydrocolloid
  - Silver Dressing
  - Cadexomer Iodine
- **Secondary Dressing:**
  - Foam
  - Gauze

#### Dry Wound Bed

- **Primary Dressing:**
  - Hydrogel
  - Cadexomer Iodine
  - Silver with hydrogel
- **Secondary Dressing:**
  - Foam
  - Hydrocolloid
  - Gauze

**Counsel the patient on:**
- Exercises and mobility training
- Lower extremity elevation

Use compression therapy to manage edema.

**Contraindications:**
- Arterial insufficiency with ABI <0.8
- Acute infection
- Pulmonary edema
- Uncontrolled or severe CHF
- Active deep venous thrombosis

Treat wound according to wound bed description. Most venous insufficiency wounds will be wet or moist. Go to “Wet or Moist Wound Bed”.

### Wound Bed

- **Primary Dressing:**
  - Hydrocolloid
  - Silver Alginate
  - Cadexomer Iodine
  - Silver Alginate
  - Collagenase (Santyl®)
- **Secondary Dressing:**
  - Foam
  - Hydrocolloid
  - Gauze

**Counsel the patient on:**
- Exercises and mobility training
- Lower extremity elevation

- Use compression therapy to manage edema.

**Contraindications:**
- Arterial insufficiency with ABI <0.8
- Acute infection
- Pulmonary edema
- Uncontrolled or severe CHF
- Active deep venous thrombosis

Treat wound according to wound bed description. Most venous insufficiency wounds will be wet or moist. Go to “Wet or Moist Wound Bed”.

**No Continue care until wound is healed and educate pt on wound care prevention.

---

**Reassess wound every 4 weeks.**

**Is the wound healing?**

- **Yes**
  - Educate patient on wound prevention
  - Follow the patient in Chronic Care Clinic
- **No**
  - Continue care until wound is healed and educate pt on wound care prevention.
SURGICAL WOUNDS

Surgical Site Infections
- Delayed Healing
- Bleeding
- Dehiscence
- Evisceration

Primary Intention
- Wounds that are approximated with surgical closure.

Secondary Intention
- Wounds which are left open and filled in with granulation or scar tissue.

Tertiary Intention
- Large or infected wounds which require debridement or drainage prior to closure.

Wound Bed
- Epithelialization
- Granulation
- Local infection/critical colonization
- Necrotic/Slough

Objective
- Protect newly formed tissue
- Support granulation and tissue growth
- Debridement and decrease bacterial burden

Surroundings
- Remove surgical sutures per recommendation
- Keep area dry and clean
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Consider abdominal binders or Montgomery straps
- Use off-loading equipment (e.g., heel protectors, pressure-relieving overlays, crutches, and trapezes)

Cleanse
- Wash with soap and water or a commercial wound cleanser
- Flush with 250 cc of normal saline or sterile water

Protect Periwound
- Consider using skin prep, hydrocolloid window paning dressing, or foam with silicone adhesive.

Moist Wound Bed
- Primary Dressing: Hydrocolloid
- Secondary Dressing: Hydrocolloid

Primary Intention
- Wounds that are approximated with surgical closure.

Secondary Intention
- Wounds which are left open and filled in with granulation or scar tissue.

Tertiary Intention
- Large or infected wounds which require debridement or drainage prior to closure.

Wound Care
- Follow up suture/staple removal
- Educate patient on basic wound care
- Counsel the patient on incision protection and good hygiene
- Educate patient on signs and symptoms of infection and report complications to the medical department
- Refer the patient to a wound care specialist or specialist

Prevent surgical complications
- Debridement
- Avoid mechanical stress on the wound
- Avoid lifting
- This is a surgical emergency.

Reassess wound every 4 weeks.
- Is the wound healing?

Patient Assessment
- Address co-morbidities and optimize treatment e.g., diabetes, insulin, infections (HIV, HCV, skin, bone), circulation/smoking, obesity
- If needed, provide adequate pain control (refer to pain disease management guideline)
- Evaluate the patient for any factors that may delay wound healing (e.g., medications and nutritional status)
- Consider consultation with the Wound Care Specialist

The pathways do not replace sound clinical judgment nor are they intended to apply to all patients.

Dry Wound Bed
- Primary Dressing: Hydrogel
- Secondary Dressing: Hydrogel

Yes
- Educate patient on basic wound care
- Counsel the patient on incision protection and good hygiene
- Educate patient on signs and symptoms of infection and report complications to the medical department
- Refer the patient to a wound care specialist or specialist

No
- Continue care until wound is healed and educate pt on wound care prevention.
To define different kinds of wounds and how to individualize treatment regimens per wound type

Surgical Wounds

Diabetics

Consider moisturizing skin cream for patients with a Braden Scale score of less than 14.

Neuropathic Wounds

Optimize pressure or high

Prevent excessive moisture by changing incontinent patient frequently and using moisture barrier creams.

Patients with peripheral arterial disease

Arterial Insufficiency Wounds:

Geriatric patients

Description of wound: Wound usually located on the plantar aspect of the foot. It will be painful, surrounded by a callus and have even wound margins. Wound bed is usually deep and dry.

Pressure wounds

Counsel patient to prevent excessive moisture by changing incontinent patient frequently and using moisture barrier creams.

Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy.

Manage the risk factors for peripheral arterial disease, e.g. hypertension, hyperlipidemia, smoking.

Counsel patient to offload lower extremities to prevent repetitive pressure and trauma to feet.

Refer for proper fitting footwear.

Venous insufficiency wounds

Pressure wounds

a. Pressure Ulcer
b. Venous Ulcer
c. Diabetic Ulcer
d. Arterial Ulcer

I. Definitions/Description

A. Arterial Insufficiency Wounds:

1. Definition: Wound caused by peripheral neuropathy and constant pressure or repeated trauma to lower extremities, otherwise known as diabetic foot ulcers.

B. Neuropathic Wounds:

1. Description of wound: Wound usually located on the planter aspect of the foot= pressure point. It will be painful, surrounded by a callus and have even wound margins. Wound bed is usually deep and dry.

C. Pressure wounds

1. Description of wound: Wound caused by pressure, applied over a skin integrity or wound ulceration.

II. Prevention of Wounds

A. Management of risk factors

1. Arterial Insufficiency Wounds:

a. Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy.

b. Improve tissue perfusion by avoiding tobacco, caffeine, and wearing constrictive garments, not crossing legs and staying hydrated.

c. Consider amputation medication for peripheral arterial disease.

d. Counsel patient on conducting daily inspection of skin and to notify a health care provider if any lesions start to form.

E. Patient Education

1. Assign patient’s risk for the development of wounds at intake, each clinic visit and Chronic Care Clinic visit to high-risk patients using the Braden Scale (Located in the EMR Note Builder Template as “Wound – Braden Scale”).

2. High risk parameters are:

a. Paraplegic, bowel/bladder, dementia
b. Cytotoxic patient
c. Para/Quadriplegic
d. Diabetic

2. Arterial Insufficiency Wounds

a. Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy.

b. Improve tissue perfusion by avoiding tobacco, caffeine, and wearing constrictive garments, not crossing legs and staying hydrated.

c. Consider amputation medication for peripheral arterial disease.

d. Counsel patient on conducting daily inspection of skin and to notify a health care provider if any lesions start to form.

4. Pressure wounds

a. Prevention: Education on pressure points. Use pressure reducing devices, e.g. high density foam mattress overlay, as available.

b. Use pressure reducing devices, e.g. high density foam mattress overlay, as available.

c. Elevate head of bed 30 degrees.

d. Raise heels off the bed by placing pillows under legs allowing the heels to hang off the edge or use heel protectors.

5. Offload:

a. Reposition at least every 2 hours or as indicated. Use turning sheets, trapeze or lifts to reposition to prevent shear and dr

b. Elevate head of bed to more than 30 degrees.

c. Raise heels off the bed by placing pillows under legs allowing the heels to hang off the edge or use heel protectors.

d. Use pressure reducing devices, e.g. high density foam mattress overlay, as available.
6. Optimize glycemic control in diabetics.
7. Manage the risk factors for peripheral arterial disease, e.g. hypertension, hyperlipidemia, smoking.
8. Treat underlying diseases to improve immune system in immunocompromised patients.
9. Counsel patient on conducting daily inspections of data and to notify a health care provider if any lesions start to form.

D. Ultrasound
1. Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy
2. Counsel patient to implement therapeutic lifestyle changes with diet and exercise to maintain normal body mass index (BMI).
3. Counsel patient to decrease salt consumption.
4. Counsel patient on conducting daily inspections of data and to notify a health care provider if any lesions start to form.
5. Counsel patient that compression therapy is the mainstay of prevention and treatment.

E. Surgical wounds
1. Counsel patient to avoid mechanical stress on the incision.
2. Counsel patient on conducting daily inspections of data and to notify a health care provider if any lesions start to form.

IV. Review vitals, including weight.
A. Anticoagulants
B. Aspirin – suppresses inflammation
C. NSAIDS – suppresses inflammation, prevents synthesis and epidermalization

III. Evaluate nutritional status
A. Counsel patient on conduct important of adequate hydration and nutrition.
B. Assess adequate protein intake.
C. Counsel patient on conducting daily inspections of data and to notify a health care provider if any lesions start to form.

Assessment of Wounds

I. Determine the mechanism of injury. CONSIDER obtaining the appropriate diagnostic work up.

A. Arterial insufficiency wounds
1. Anterior Brachial Index (ABI) Measurement is a non-invasive tool necessary for screening arterial insufficiency. Refer to Vascular Surgery Lab.
   a. ABI is performed:
      i. Equipment: Handheld Doppler device with a vascular probe
      ii. ABD: Ankle Brachial Index
      iii. Using Doppler, measure the systolic BP in the right and left posterior tibial arteries.
      iv. Using Doppler to calculate the ABI for the right leg.
      v. Using Doppler to calculate the ABI for the left leg.
      vi. Using Doppler, measure the systolic BP in the brachial artery in both arms. Use the higher SBP to calculate the ABI for the leg.
   b. ABI Interpretation
      i. ABI < 0.4 is critical ischemia and requires immediate referral to vascular surgery.
      ii. ABI of 0.4 to 0.7 is borderline perfusion. Manage wound according to Arterial Insufficiency DMG.
      iii. ABI of 0.5 to 0.8 is critical ischemia and requires immediate referral to vascular surgery.

B. Neutropenic wounds
1. Check ABI to screen for arterial insufficiency, which may co-exist with peripheral neutropenia.
2. Screen for infections with wound culture, and screen for osteomyelitis with x-ray.
3. Classify the wound according to the Wagner Grading System:
   a. Grade 0 – No open foot lesions.
   b. Grade 1 – Presence of superficial ulcer, partial or full-thickness.
   c. Grade 2 – Ulcer extends to epidermis, tendon, joint capsule or deep fascia without abscess or osteomyelitis.
   d. Grade 3 – Presence of deep abscess with abscess, osteomyelitis or joint space.
   e. Grade 4 – Gangrene localized to the ulcer or joint space.
   f. Grade 5 – Extensive gangrene.

C. Pressure wounds
1. Screen for infections with wound culture, and screen for osteomyelitis with x-ray.
2. Stage the wound based upon the level of tissue involved. Unstage pressure wounds are staged.
   a. Stage 1 – erythema
   b. Stage 2 – partial-thickness skin loss involving the epidermis and part of the dermis.
   c. Stage 3 – full-thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to but not through underlying fascia.
   d. Stage 4 – full-thickness skin loss involving damage to muscles, bones, or supporting structures.
   e. Stage 5 – Ulcerative – Full-thickness skin loss in which the base of the ulcer is covered by necrotic tissue.

D. Vascular insufficiency wounds
1. Screen for arterial insufficiency by checking the ABI. Compression should not be used with ABI <0.8.
2. Screen for DVT (deep vein thrombosis) by checking ultrasonography.

E. Surgical wounds – screen for infections with wound culture, and screen for osteomyelitis with x-ray.

II. Identify any underlying comorbidities – diabetes, hyperlipidemia, hypertensions or chronic infections.

III. Review medication profile
A. Optimize control of underlying comorbidities.
B. Identify medications that may impact wound healing.
IV. Review skin, including weight.
V. Wound documentation (document using the EMR Note Builder Template “Wound – Wound Care Assessment Form”)

A. Type of wound

B. Location of wound

C. Measurement of wound

1. What is the size of the wound (measure in centimeters)?
   a. Measure actual ulcer. Do not include the periwound in the measurement.
   b. Measure the longest length x widest width x deepest depth (cm).

2. Document tunneling (development of sinus tract)

3. Document undermining (when the tissue erodes under the wound edges)

D. Describe the wound bed

1. Red/pink – healthy granulating tissue
2. Yellow/tan – slough
3. Black – eschar
4. Pale – decreased circulation (often seen in arterial insufficiency wounds)

E. Describe the periwound (wound edges)

1. Describe structure and quality: calloused, rolled, healing with epithelization, scarred, or pigmented.
2. Temperature: cool or warm
3. Edematous

F. Describe the wound drainage

1. Amount (mild, moderate, copious) in the wound, NOT on the dressing
2. Color
3. Type
   a. Serous – inflammatory phase of wound healing
   b. Sanguineous – from bleeding
   c. Purulent – from infection
4. Consistency of drainage: thick or thin

G. Note odor

Treatment of Wounds

Step 1: Cleanse the wound, then pat dry.

A. Superficial wounds – cleanse with soap and water or use a commercial cleanser

B. Deeper wounds – flush with 250cc’s of normal saline or sterile water

C. Do not use iodine or betadine as these are cytotoxic to healing skin.

D. Do not soak the wound.

Step 2: Protect the periwound (skin surrounding the edges of the wound). Options include:

A. Copolymer skin prep – do not use with silicone adhesive

B. Hydrocolloid window

C. Silicone adhesive

Step 3: Apply primary dressing directly to the wound bed. Options include:

A. Gauze (wet to moist) dressing (refer to Debridement on page 10, section IV.C.)

B. Alginate – for moderately to highly draining wounds (refer to Debridement on page 10, section IV.A.)

C. Hydrogel – for moist wounds or wounds in moist environment

D. Silver dressing (refer to Management of Infection on page 10, section II.C and D.)

1. Silver infused sheets or gel for dry or moist wounds

2. Silver with alginate for wet wounds

E. Cadexomer iodine dressing (refer to Management of Infection on page 10, section II.C and D.)

F. Chemical debrider – collagenase for debridement of calloused and necrotic wounds (refer to Debridement on page 10, section IV.B.)

Step 4: Apply secondary dressing to wound bed. Options include:

A. Gauze dressing – use with hydrogel, wet to moist dressings or chemical debrider

B. Foam dressing – use with silver dressing or cadexomer iodine

C. Hydrocolloid dressing – use with silver dressing or cadexomer iodine

D. Permeable dressing – use with hydrogel, wet to moist dressing or chemical debrider

Debridement

I. Purpose

A. Decreases bacterial load and reduces risk of infection, as devitalized material is a medium for infection and supports the growth of organisms that cause wound healing

B. Increases effectiveness of topical treatments

C. Decreases wound odor

II. Indication

- For removal of necrotic tissue, debris, calculus, foreign material, eschar and slough

III. Special considerations – referenced in Wound Care Clinic

A. Hypergranulating wounds

B. Hard ulcers with eschar without edema, erythema, fluctuance or drainage

C. Patient factors

1. Comorbidities (e.g. uncontrolled diabetes)
2. Thrombocytopenia
3. Anticoagulation use
4. Patient setting (e.g. hospice)
IV. Different types of debridement

A. Autolytic debridement - uses body’s endogenous enzymes to debride necrotic tissue with moisture-retentive dressing (example: Alginate dressings and hydrogel dressings)

1. Indicated for non-infected wounds with necrotic tissue
2. Advantages
   a. Moist wound healing
   b. Dressing changes can be every 72 to 96 hours
3. Disadvantages - patients often complain of odor.

B. Enzymatic debridement - uses prescribed enzymes to debride necrotic tissue with moisture-retentive dressing (example: collagenase with hydrocolloid dressing; do not use silver or iodine containing dressings as silver and iodine deactivate the collagenase)

1. Indicated for infected and non-infected wounds with necrotic tissue
2. Advantages
   a. Moist wound healing
   b. Dressing changes are fast/easy
3. Disadvantages
   a. Dressing changes are up to BID to TID

C. Mechanical debridement - uses force to remove devitalized tissue (example: gauze (wet to moist) dressings)

1. Advantages
   a. Dressing changes are fast/easy
   b. Decreases odor
   c. Decreases drainage in highly exudative wounds
2. Disadvantages
   a. Nonselective debridement
   b. Painful
   c. Periwound maceration
3. Dressing changes up to BID to TID

D. Sharp debridement

E. Surgical debridement

F. Biological debridement

Management of Infection

I. Prevention of infection

A. Wash hands with soap, water, and friction.
B. Open supplies just prior to use.
C. Keep wound covered at all times except during examination.
D. Treat most infected wound last.
E. Change gloves between dressings.

II. Stages of infection

A. Contamination

1. Description: Existence of non-replicating bacteria within a wound. All chronic wounds are contaminated.
2. Management: irrigate or cleanse with sterile water or normal saline

B. Colonization

1. Description: Presence of replicating bacteria, but does not adversely affect the individual (no odor, no drainage).
2. Management: irrigate or cleanse with sterile water or normal saline

C. Critical colonization

1. Description: Theoretical point when the bacteria becomes a bioburden. Wound may start exuding serous fluid, have an odor and/or have friable or red granulation tissue.
2. Management: Consider a wound culture using the Levine technique, and topical antimicrobial treatment (e.g. antimicrobial dressings such as silver or cadexomer iodine dressings or triple antibiotic cream).

D. Infection

1. Description: When bacteria invade the body tissues of the host. A wound culture will have bacterial levels greater than $10^5$ organisms per gram. Wound healing becomes stalled or reverses. Wound will be warm to touch, edematous and erythematous. Bacteria may gain access to systemic circulation. Patient may start exhibiting systemic symptoms of infection.
2. Management: Consider clinical work-up for infection (monitor vitals, obtain labs such as CBC and cultures via the Levine technique, and order appropriate x-rays if needed). Use appropriate systemic antibiotics plus topical antimicrobial treatment (e.g. antimicrobial dressings such silver or cadexomer iodine dressings or triple antibiotic cream).

E. Culture using the Levine technique

A. Cleanse the wound with sterile water or normal saline to wash away any slough, necrotic tissue or dried exudate.
B. Moisten the culture tip.

1. If the wound is moist, a sterile swab can be used straight from the packaging.
2. If the wound is dry, then the swab tip should be moistened with sterile water to increase the chances of recovering organisms from the wound.
C. Collect in a zig-zag motion - the swab should be moved across the wound surface in a zig-zag motion, at the same time, being rotated between the fingers.
D. Send to lab - immediately following the collection, the swab should be returned to its container (placed into the transport medium) and accurately labeled.
### Braden Scale For Predicting Pressure Sore Risk

Located in the EMR Note Builder template as “Wound-Braden Scale”

**Directions:** Assessment should be done upon intake, every clinic visit, and Chronic Care Clinic visit for high risk patients (defined on page 7). Note: Patients with a total score of 18 or less are considered to be at risk for developing pressure ulcers (15-14 = low risk, 13-14 = moderate risk, 12 or less = high risk).

<table>
<thead>
<tr>
<th>Sensory Perception</th>
<th>Ability to respond to sensory剌</th>
<th>Predicts</th>
<th>Pain</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very Limited</td>
<td>Sensory perception is absent or abnormal</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2. Moderate Limited</td>
<td>Sensory perception is present but not normal</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3. Slight Limited</td>
<td>Sensory perception is present but limited to specific areas</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4. No Impairment</td>
<td>Sensory perception is normal</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mobility</th>
<th>Ability to change body position</th>
<th>Predicts</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very Limited</td>
<td>Cannot change position without assistance</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2. Moderate Limited</td>
<td>Can change position with assistance but with discomfort</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3. Slight Limited</td>
<td>Can change position independently but with discomfort</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4. No Impairment</td>
<td>Can change position independently</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutrition</th>
<th>Usual food intake pattern</th>
<th>Predicts</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very Limited</td>
<td>Cannot receive enough by mouth</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2. Moderate Limited</td>
<td>Cannot receive enough by mouth but can receive supplements</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3. Slight Limited</td>
<td>Can receive enough by mouth with supplements</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>4. No Impairment</td>
<td>Can receive enough by mouth without supplements</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pressure &amp; Shear</th>
<th>Predicts</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Very Limited</td>
<td>Cannot receive enough by mouth</td>
<td>1</td>
</tr>
<tr>
<td>2. Moderate Limited</td>
<td>Can receive enough by mouth but can receive supplements</td>
<td>2</td>
</tr>
<tr>
<td>3. Slight Limited</td>
<td>Can receive enough by mouth with supplements</td>
<td>3</td>
</tr>
<tr>
<td>4. No Impairment</td>
<td>Can receive enough by mouth without supplements</td>
<td>4</td>
</tr>
</tbody>
</table>

**Date of Assessment:**

**Total Score:**

---

<table>
<thead>
<tr>
<th>LOCATION OF WOUND</th>
<th>1. __________________________________________________________</th>
<th>2. __________________________________________________________</th>
<th>3. __________________________________________________________</th>
</tr>
</thead>
<tbody>
<tr>
<td>DESCRIPTION OF WOUND</td>
<td><strong>WOUND 1</strong></td>
<td><strong>WOUND 2</strong></td>
<td><strong>WOUND 3</strong></td>
</tr>
<tr>
<td>SKIN AROUND WOUND</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin color around wound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Normal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Bright red or blanches to touch</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Dark red or purple; non-blanchable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. White or gray pallor, macerated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Irritated, dermatitis or reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral tissue edema (press 5 seconds)</td>
<td><strong>WOUND 1</strong></td>
<td><strong>WOUND 2</strong></td>
<td><strong>WOUND 3</strong></td>
</tr>
<tr>
<td>1. Minimal swelling around wound</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Non-pitting edema, skin shiny and taut</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pitting edema</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral tissue firmness (induration)</td>
<td><strong>WOUND 1</strong></td>
<td><strong>WOUND 2</strong></td>
<td><strong>WOUND 3</strong></td>
</tr>
<tr>
<td>1. Minimal firmness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Cannot gently pinch tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Firmness extends to surrounding tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRAINAGE OF THE WOUND</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exudate type</td>
<td><strong>WOUND 1</strong></td>
<td><strong>WOUND 2</strong></td>
<td><strong>WOUND 3</strong></td>
</tr>
<tr>
<td>1. None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Sanguinous (bloody)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Serous (clear)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Serosanguinous (watery pink)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Purulent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Odor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exudate amount</td>
<td><strong>WOUND 1</strong></td>
<td><strong>WOUND 2</strong></td>
<td><strong>WOUND 3</strong></td>
</tr>
<tr>
<td>1. None or dry wound tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Scant or moist wound tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Small or wet wound tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Moderate or saturated wound tissue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Large or draining obvious</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## DESCRIPTION OF WOUND

### WOUND 1
### WOUND 2
### WOUND 3

### ARCHITECTURE OF UNHEALED WOUND

Measurements in centimeters (cm)

1. Length (vertical dimension) in cm
2. Width (horizontal dimension) in cm
3. Depth (deepest, do not include tunnel) in cm

### WOUND BED CHARACTERISTICS

#### Necrotic type

1. None visible
2. Non-adherent yellow slough
3. Loosely adherent yellow slough
4. Adherent soft, eschar
5. Firmly adherent, hard eschar

#### Granulation tissue type

1. Skin intact
2. Bright, beefy red
3. Pink or dull, dusky red
4. Combination of #2 and #3
5. Obscured

### Undermining/Tunneling Wound

<table>
<thead>
<tr>
<th>Location of undermining/tunneling (use clock as reference)</th>
<th>Depth of tunnel in cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tunnel at 3 o’clock</td>
<td>3 cm</td>
</tr>
</tbody>
</table>

### GOALS

<table>
<thead>
<tr>
<th>GOALS</th>
<th>GOALS MET</th>
<th>NOT MET</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Facilitate granulation and re-epithelialization through use of clean technique during cleansing and dressing change.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Promote granulation/tissue of wound bed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Soften and remove non-viable tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Patient will express understanding and importance of the educational information presented</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PLAN:

- [ ]


---

306
Acne Vulgaris
(Adolescents)

Patient diagnosed with acne vulgaris:
1. Classify severity (table 1, page 3)
2. Begin nonpharmacologic management (page 4)
3. Provide patient education

Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. November 2006. Revised 10/09, 4/12, 1/14.
Assess adherence to treatment plan. Consider referral for patients with any of the following:

1. Hyperandrogenism for possible hormonal therapy
2. Unresponsive scarring acne or acne conglobata for possible isotretinoin therapy
3. Acne fulminans

Is the patient responding to therapy?

- No
  - Continue therapy & follow up as needed. Consider discontinuing oral antibiotic and continuing topical therapy for maintenance.
  
- Yes
  - Continue minocycline.
  
Follow up in 6-8 weeks to assess response.

Assess adherence to treatment plan.

- Benzoyl peroxide 10% applied QD in AM. (Do not apply same time of day as adapalene)
- Differin (adapalene) gel 0.1% applied QD in PM. Non-formulary approval required.
- Continue minocycline.

Follow up in 6-8 weeks to assess response.

Is the patient responding to therapy?

- No
  - Continue therapy & follow up as needed. Consider discontinuing oral antibiotic and continuing topical therapy for maintenance.

- Yes
I. Definitions
A. Acne vulgaris – Disorder of the skin characterized by open or closed comedones. Inflammatory lesions may also be present such as papules, pustules or nodules. It commonly occurs on the face, arms, chest and back.
B. Closed comedones (whiteheads) – Sebaceous follicle plugged with sebum, dead cells and bacteria with a thin overlying epidermal membrane.
C. Open comedones (blackheads) – Sebaceous follicle plugged with sebum, dead cells and bacteria.
D. Acne conglobata – Chronic and severe form of acne vulgaris that is more common in males than females with a usual age of onset between 16 and 30 years. It is characterized by comedones, inflammation, deep abscesses, severe damage to the skin and scarring. It is usually widespread affecting the face, neck, trunk, arms and buttocks.
E. Acne fulminans – Severe form of acne vulgaris that may occur suddenly in a patient with inflammatory acne. It is characterized by ulcerating acne, fever, and inflammation and joint pain especially of the hips and knees.

II. Etiology – Multifactorial disease generally characterized by
A. Abnormal keratinization – Hyperproliferation of keratinocytes and abnormalities in differentiation and desquamation which may prevent normal shedding and obstruct the follicle.
B. Increase in hormones – May lead to enlargement of sebaceous glands and increased production of sebum.
C. Bacterial Growth – Propionibacterium acnes growth in the plugged follicle may contribute to the development of inflammation by activating an immune response.
D. Immune Hypersensitivity – Cells of the immune system accumulate and produce an inflammatory reaction.

III. Diagnosis
A. Lesions are commonly located on the face and upper trunk where sebaceous glands are more concentrated.
   1. Comedones
   2. Pustules
   3. Nodules
   4. Redness & inflammation around skin eruptions
   5. Scarring of skin
B. Evaluate for secondary causes (e.g., Cushing’s, polycystic ovary disease, hyperandrogenism in women)
C. Classification – Correct classification of severity aids in the selection of appropriate treatment. Acne is considered inflammatory if papules, pustules, or nodules are present.

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Comedones present. Small and few (&lt;10) papules and pustules may be present.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderate numbers of comedones (10-40) and papules and pustules (10-40) are present. Mild disease of the trunk may also be present.</td>
</tr>
<tr>
<td>Moderately Severe</td>
<td>Many comedones (40-200) and papules and pustules (40-100), occasional deeper nodular inflamed lesions (&lt;5). Widespread often involving the face and trunk.</td>
</tr>
<tr>
<td>Severe</td>
<td>Many comedones, papules and pustules present. Nodulocystic acne and acne conglobata with many large and painful nodular or pustular lesions.</td>
</tr>
</tbody>
</table>

Mild acne
Moderate
Moderately severe
Severe
IV. Management – Goals of therapy include controlling flares, decreasing lesions, and preventing scar formation. Acne may get worse with treatment before it gets better.

A. Non-pharmacologic Treatment
1. Gently wash skin twice a day with water and mild soap
2. Avoid scrapping hard and abrasive cleaners.
3. Do not squeeze blemishes
4. Avoid factors that may exacerbate acne
   a. Mechanical obstruction (e.g., helmets, shirt collars)
   b. Certain medications (e.g., corticosteroids, isoniazid, lithium, phenytoin)

B. Pharmacologic Treatment
1. Topical Treatment – 6 to 8 weeks generally required to see best results and to determine effectiveness before selecting alternative therapy. Should be used on acne-prone areas not just individual blemishes to prevent formation of new blemishes. Flares may occur when medications are discontinued.

<table>
<thead>
<tr>
<th>Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agent</strong></td>
</tr>
<tr>
<td>Bexarol Perxide 5-10%</td>
</tr>
<tr>
<td>Clindamycin 1% Topical Solution</td>
</tr>
<tr>
<td>Adapalene 0.1% gel (Differin®)</td>
</tr>
</tbody>
</table>

2. Oral Therapy – Generally reserved for moderate to severe inflammatory acne, acne that is extensive and difficult to reach with topical agents, and patients that fail to respond to a combination of topical agents. Oral antibiotic therapy is usually prescribed for 3 to 4 months with the goal to discontinue therapy and to follow up with topical therapy as maintenance if needed. The use of benzoyl peroxide with topical or oral antibiotics decreases the emergence of resistant bacteria. If oral antibiotic therapy is discontinued and restarted, prescribe the same antibiotic the second time as long as it remains effective.

<table>
<thead>
<tr>
<th>Table 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agent</strong></td>
</tr>
<tr>
<td>Erythromycin 250mg - 500mg BID</td>
</tr>
<tr>
<td>Minocycline 100mg QD-BID (recommended maximum 4mg/kg/day)</td>
</tr>
</tbody>
</table>
### Table 4.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Adverse Effects</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Isotretinoin* (Accutane®)          | 0.5 to 1 mg/kg/day in 2 divided doses with food for 15-20 weeks or until total cyst count decreases by 70%, whichever is sooner. If necessary, a second course may be offered after at least 8 weeks of completing first course. | Teratogenic, hypertriglyceridemia, elevated LFTs, dryness of lips, orol, nasal, and oral mucosa and skin, arthralgias, photosensitivity, decreased night vision, case reports of depression, initial flaring at initiation of therapy | • Nonformulary medication.  
• Relapse rates higher for patients < 16 years at initial treatment, for patients with very severe acne that involves the trunk, and for adult women.  
• Reserved for patients with severe acne that does not respond to combination oral and topical therapy.  
• Only treatment that leads to remission that may be permanent  
• Do not use in pregnancy |
| Oral Contraceptives                | 1 tablet QD                                | Nausea, weight gain, thrombosis, edema                                           | • Consider for women with signs of hyperandrogenism, failed conventional therapy, or quickly relapse after isotretinoin.  
• Especially useful in patients that desire contraception or have irregular menstrual cycles or hirsutism.  
• Effects seen within 6 to 9 months  
• Do not use in pregnancy |
| Spironolactone                     | 50 to 100mg QD                             | Teratogenic, drowsiness, GI upset, hyperkalemia                                   | • May be added to oral contraceptive therapy if not effective after several months of therapy  
• Do not use in pregnancy |

*Must meet and follow criteria in iPLEDGE program to prescribe. For more information go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) or call 1-866-495-0654.
Patient Education

1. Cause of acne
2. Goals of Therapy
   a. Decrease and/or resolve lesions
   b. Control and/or prevent flares
   c. Prevent scar formation
3. General Information
   a. Acne is not the result of poor hygiene and excessive skin washing and scrubbing may actually worsen acne.
   b. Face Washing: Gently wash affected areas with warm soapy water; rinse with warm water thoroughly, then use a final rinse with cool water. Do this twice a day in the morning and night as well as after heavy perspiration.
   c. Blemishes and pimples should not be squeezed. This can worsen acne and lead to scarring.
   d. Skin care: Do not pick or squeeze acne lesions. Remember that pimples are temporary, but picking lesions can result in scars and scars are permanent.
4. Treatment Plan
   a. General information
      • Medications used to treat acne do not work immediately. It may take 6-8 weeks to see visible improvements and may take up to 3 months to see maximum effects with some treatments.
      • Acne may get worse with treatment before it gets better.
      • Topical medications should be applied to dry skin, applied sparingly (pea-size amount is usually sufficient to cover the face), and should be applied to all acne prone areas and not just visible blemishes.
      • Certain medications (e.g., adapalene, isotretinoin, certain oral antibiotics) may increase the patient’s risk for sunburns. Avoiding excessive exposure to sunlight is recommended.
      • Shampoo hair regularly. If hair is oily, wash hair daily.
      • Avoid greasy hair-care products. Oily hair-care products such as oil-containing gels and pomades can drip onto skin and clog pores.
      • Water-based lotions and cosmetics are less comedogenic than oil-based products.
      • Wet face prior to shaving and shave lightly.
   b. Information on specific therapy prescribed
5. Importance of Adherence
ANXIETY and PANIC DISORDER
(Adolescents)

1. Rule out medical cause for presentation

2. Presence of panic attacks?
   - Yes
   - No

3. Meets DSM-5 criteria for Anxiety Disorder?
   - Yes
   - No

4. Treat underlying causes?
   - Yes
   - No

5. Meets DSM-5 criteria for Panic Disorder?
   - Yes
   - No

6. Obtained baseline BPRS
   - Yes
   - No

7. Adequate response per BPRS?
   - Yes
   - No

- If compliance < 80%, counsel on medication compliance
- Re-evaluate diagnosis and need for medication
- Increase dose of current agent to maximal tolerated dose for 4-6 weeks
- If trial at max tolerated dose is poorly effective, consider continuing this dose and reassessing response in another 4-6 weeks
- If trial at max tolerated dose is ineffective, switch to another formulary agent (Table 1) or consider pharmacotherapy consult

Prepared By: The Texas Youth Commission and Reviewed By: The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 4/11, Revised 10/11, 5/13, 10/17
### Medication Selection

Patients should be evaluated for use of formulary agents when possible. Practitioners should consider past history of response, contraindications, comorbidities, compliance, and potential for adverse effects and/or drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects.

#### Table 1: Formulary Antidepressants Used to Treat Anxiety or Panic Disorder

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Dose (Dose Range) mg/day</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram</td>
<td>Celexa®</td>
<td>10 (10 – 40)</td>
<td>+ Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Chlorpropamide: EKG at baseline and clinically indicated if risk factors for QTc prolongation are present.</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine</td>
<td>Prozac®</td>
<td>10 (10 – 40)</td>
<td>+ QTc &gt; 450msec for males or &gt; 470msec for females, do not initiate treatment.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Escitalopram: if QTc &gt; 500msec, consider alternative treatment.</td>
</tr>
<tr>
<td></td>
<td>Sertraline</td>
<td>Zoloft®</td>
<td>25 (25 – 200)</td>
<td>• Fluoxetine has also been associated with QTc prolongation. EKG monitoring is encouraged if risk factors for QTc prolongation are present.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+ If QTc is &gt; 470msec, do not initiate citalopram or escitalopram. If pt is on citalopram or escitalopram and QTc is &gt; 500msec, consider alternative treatment.</td>
</tr>
<tr>
<td>Serotonin Norepinephrine Reuptake Inhibitor (SNRI)</td>
<td>Venlafaxine XR</td>
<td>Effexor XR®</td>
<td>75 (75 – 225)</td>
<td>+ Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Dose-related increases in systolic blood pressure and pulse</td>
</tr>
<tr>
<td></td>
<td>Duloxetine</td>
<td>Cymbalta®</td>
<td>30 (30 – 120)</td>
<td>• Dose-related increases in systolic blood pressure and pulse</td>
</tr>
</tbody>
</table>

* Risk factors for QTc prolongation include use of other concomitant QTc prolonging medications, baseline hypokalemia or hypomagnesemia, or pre-existing cardiovascular impairment

|     |     |     |     |                                                                 |

**Suicidality in Children and Adolescents**

Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of any antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.

**BRIEF PSYCHIATRIC RATING SCALE (BPRS)**

**Instructions for the Clinician**

**Background:**

The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measure when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2–3 days should also be considered and can be reported by the patient’s caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10–20 minutes or less for the interview and scoring.

**Instructions for Use and Scoring:**

Each item is rated on a seven-point scale (1 = not present to 7 = extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.</td>
<td>SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td></td>
<td>2.</td>
<td>ANXIETY - Worry, fear, over-concern for present or future, uneasiness</td>
</tr>
<tr>
<td></td>
<td>3.</td>
<td>EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td></td>
<td>4.</td>
<td>CONCEPTUAL DISORGANIZATION - Thought processes confused, disorganized, disrupted.</td>
</tr>
<tr>
<td></td>
<td>5.</td>
<td>IMPULSIVENESS</td>
</tr>
<tr>
<td></td>
<td>6.</td>
<td>MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td></td>
<td>7.</td>
<td>MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td></td>
<td>8.</td>
<td>GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td></td>
<td>9.</td>
<td>DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism</td>
</tr>
<tr>
<td></td>
<td>10.</td>
<td>HOSTILITY - Animosity, contempt, belligerence, disdain for others</td>
</tr>
<tr>
<td></td>
<td>11.</td>
<td>SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td></td>
<td>12.</td>
<td>HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td></td>
<td>13.</td>
<td>MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td></td>
<td>14.</td>
<td>UNCOOPERATIVENESS - Resistance, paralysis, rejection of authority</td>
</tr>
<tr>
<td></td>
<td>15.</td>
<td>UNUSUAL THOUGHT CONTENT - Unreal, odd, strange, bizarre thought content</td>
</tr>
<tr>
<td></td>
<td>16.</td>
<td>BLUNTED AFFECT - Reduced emotional tone, reduction in formal intensity of feelings, flatness.</td>
</tr>
<tr>
<td></td>
<td>17.</td>
<td>EXCITEMENT - Heightened emotional tone, agitation, increased reactivity</td>
</tr>
<tr>
<td></td>
<td>18.</td>
<td>DISORIENTATION - Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td></td>
<td>19.</td>
<td>ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td></td>
<td>20.</td>
<td>SUICIDALITY - Expressions of intent, or actions to harm self or kill self</td>
</tr>
<tr>
<td></td>
<td>21.</td>
<td>BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td></td>
<td>22.</td>
<td>SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td></td>
<td>23.</td>
<td>DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distraction is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual's attention may be drawn to noise in adjoining rooms, books on a shelf, interviewer's clothing, etc.</td>
</tr>
</tbody>
</table>
ATTENTION DEFICIT HYPERACTIVITY DISORDER
(Adolescents)

1. Meets DSM 5 criteria for ADHD

2. Obtain baseline laboratories as indicated in Table 1. Refer to pages 2-3 for medication selection.

3. Contraindication to stimulants, significant history of substance abuse, or comorbid anxiety disorder?
   - Yes
     - Initiate monotherapy with a long acting stimulant (Adderall XR, Ritalin LA, or Concerta). Titrate over 7 days, as appropriate, and observe for immediate effects.
     - Inadequate response per ADHD rating scale
     - Assess compliance
     - Stimulant intolerance
     - Switch to long-acting stimulant from the alternative stimulant class. Titrate over 7 days, as appropriate, and observe for immediate effects.
     - Inadequate response per ADHD rating scale
     - Assess compliance
     - Combination therapy with agents listed above. Continue 4-6 weeks at therapeutic dose.
     - Inadequate response per ADHD rating scale
     - Assess compliance
     - Consider diagnosis and consider psychopharmacology consultation

   - No
     - Continue 4-6 weeks at therapeutic dose.

4. Inadequate response per ADHD rating scale
   - Assess compliance

5. Adequate response per ADHD rating scale
   - Continue treatment and monitor per Table 1.

6. Contraindication to stimulants, significant history of substance abuse, or comorbid anxiety disorder?
   - Yes
     - Switch to Vyvanse* and titrate over 7 days, as appropriate. Observe for immediate effects.
     - Inadequate response per ADHD rating scale
     - Assess compliance
     - *Prior authorization agent (Refer to Page 4, Table 4 for prior authorization criteria)
   - No
     - Continue treatment and monitor per Table 1.

Prepared by The Texas Juvenile Justice Department (formerly the Texas Youth Commission) and Reviewed by The Correctional Managed Care Pharmacy & Therapeutics Committee. Effective 2000; revised 2/25/04, 9/18/04, 4/19/10, 8/15/11, 1/30/12, 2/11/13, 10/22/18.
Table 1: ADHD Monitoring Guidelines*

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Each Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height, weight, BMI</td>
<td>X</td>
</tr>
<tr>
<td>Blood pressure &amp; pulse</td>
<td>X</td>
</tr>
<tr>
<td>EKG</td>
<td>As clinically indicated</td>
</tr>
</tbody>
</table>

*Monitor at increased frequency if clinically indicated.

EKG Monitoring Recommendations: Providers should consider obtaining an EKG at baseline and periodically if there is a personal or family history of cardiovascular disease. This includes a history of severe palpitations, fainting, exercise intolerance not accounted for by obesity, or strong family history of sudden death. Postoperative tetralogy of Fallot, coronary artery abnormalities, and subaortic stenosis are known cardiac problems that require special considerations in using stimulants. Chest pain, arrhythmias, hyperension, or syncope may be signs of hypertrophic cardiomyopathy, which has been associated with sudden, unexpected death in children and adolescents. The risk of sudden, unexplained death was determined by the FDA advisory committee, the American Academy of Pediatrics, and the American Academy of Child and Adolescent Psychiatry to be a very rare event that is not any higher than expected in the general population. The American Heart Association recommends careful assessment through a cardiac history, a physical exam, and evaluation of risk factors in children.

ADHD Rating Scales: Providers should review ADHD rating scale results prior to initiating or changing therapy, and as needed for monitoring progress.

Medication Selection

Newly diagnosed patients should receive a therapeutic trial of formulary stimulants unless clearly not indicated. Select situations in which stimulants may be inappropriate are as follows:

1. Documentation of a significant side effect from stimulant treatment in the past
2. Previous treatment failure after a therapeutic trial of a methylphenidate and amphetamine-based stimulant
3. Presence of a contraindication to stimulant treatment
Formulary Agents – Practitioners may prescribe any agent on the formulary without restrictions based on patient assessment and clinical judgment.

Table 2: Formulary Medications

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Form</th>
<th>Strengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixed amphetamine salts</td>
<td>Adderall®</td>
<td>Tablet</td>
<td>5 mg, 10 mg</td>
</tr>
<tr>
<td></td>
<td>Adderall XR®</td>
<td>Capsule</td>
<td>10 mg, 20 mg, 30 mg</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Ritalin®</td>
<td>Tablet</td>
<td>3 mg, 10 mg</td>
</tr>
<tr>
<td></td>
<td>Ritalin LA®</td>
<td>Capsule</td>
<td>10 mg, 20 mg, 30 mg, 40 mg</td>
</tr>
<tr>
<td></td>
<td>Concerta®</td>
<td>Tablet</td>
<td>18 mg, 27 mg, 36 mg, 54 mg</td>
</tr>
<tr>
<td>Guanfacine</td>
<td>Tenex®</td>
<td>Tablet</td>
<td>1 mg, 2 mg</td>
</tr>
<tr>
<td>Guanfacine ER</td>
<td>Intuniv®</td>
<td>Tablet</td>
<td>1 mg, 2 mg, 3 mg, 4 mg</td>
</tr>
</tbody>
</table>

Psychostimulant General Information

- Common stimulant side effects: loss of appetite, headache, insomnia
- Less common stimulant side effects: tics, agitation, severe rebound
- Growth suppression: up to 3 inch loss of expected growth over 3-8 years. May be dose-related and/or related to length of time on stimulant. Starting stimulants early in life may be a risk factor. Height loss may be permanent in some patients.

ADHD Dose Conversion Recommendations for Psychostimulant Medications

Patients should be evaluated for use of formulary agents when possible. Clinicians should consider history of response, contraindications, comorbidities, medication compliance, and potential adverse effects and drug interactions when making treatment decisions. When medications are changed, patients should be monitored closely for worsening symptoms and adverse effects. If medication adherence is unclear when switching agents, consider re-titrating the new medication from a starting dosage. The recommendations listed below are not intended to replace sound clinical judgment.

Table 3: Dose Equivalencies for Select Psychostimulants

<table>
<thead>
<tr>
<th>Vyvanse</th>
<th>Focalin</th>
<th>Focalin XR</th>
<th>Ritalin LA</th>
<th>Concerta</th>
<th>Adderall IR</th>
<th>Adderall XR</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mg</td>
<td>20 mg</td>
<td>20 mg</td>
<td>30 mg</td>
<td>18 mg</td>
<td>10 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>15 mg</td>
<td>30 mg</td>
<td>30 mg</td>
<td>45 mg</td>
<td>27 mg</td>
<td>15 mg</td>
<td>15 mg</td>
</tr>
<tr>
<td>20 mg</td>
<td>40 mg</td>
<td>40 mg</td>
<td>60 mg</td>
<td>36 mg</td>
<td>20 mg</td>
<td>20 mg</td>
</tr>
<tr>
<td>25 mg</td>
<td>50 mg</td>
<td>50 mg</td>
<td>75 mg</td>
<td>54 mg</td>
<td>30 mg</td>
<td>30 mg</td>
</tr>
<tr>
<td>30 mg</td>
<td>60 mg</td>
<td>60 mg</td>
<td>90 mg</td>
<td>60 mg</td>
<td>40 mg</td>
<td>40 mg</td>
</tr>
<tr>
<td>35 mg</td>
<td>70 mg</td>
<td>70 mg</td>
<td>105 mg</td>
<td>72 mg</td>
<td>50 mg</td>
<td>50 mg</td>
</tr>
<tr>
<td>40 mg</td>
<td>80 mg</td>
<td>80 mg</td>
<td>120 mg</td>
<td>90 mg</td>
<td>60 mg</td>
<td>60 mg</td>
</tr>
</tbody>
</table>


*Package labeling suggests initiation of Daytrana at 10 mg, regardless of previous stimulant treatment; however, some clinicians support starting with higher doses based on proposed equivalences (i.e., a 15 mg patch has been shown to have the same effect as ritalin IR 22.5 mg.)
Prior Authorization Agents – Prior authorization agents may be prescribed if specific clinical criteria are met. The applicable prior authorization criteria must be included in the special instructions field when the medication is ordered in the EHR. All other uses require non-formulary approval.

### Table 4: Prior Authorization Agent for ADHD

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Form</th>
<th>Strengths</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atomoxetine</td>
<td>Strattera®</td>
<td>Capsule</td>
<td>25mg, 40mg, 60mg, 80mg, 100mg</td>
<td>ADHD and failure on adequate dose and trial of both formulary stimulant classes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intolerance to both formulary stimulant classes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contraindication to use of both formulary stimulant classes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Significant history of substance abuse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Comorbid anxiety disorder</td>
</tr>
<tr>
<td>Lisdexamfetamine</td>
<td>Vyvanse®</td>
<td>Capsule</td>
<td>30 mg, 40 mg, 50 mg, 60 mg, 70 mg</td>
<td>Failed treatment with methylphenidate and mixed amphetamine salts</td>
</tr>
</tbody>
</table>

### Atomoxetine General Information

If treatment with amphetamine and methylphenidate-based stimulants is not successful, a trial of atomoxetine may be considered. Atomoxetine may be effective first-line therapy in patients with comorbid anxiety. In children and young adolescents, atomoxetine should be titrated over 1–3 weeks as needed. A therapeutic trial of atomoxetine is six weeks, if titrated to maximum tolerated doses within those weeks.

- **Common side effects:** sedation, mild appetite loss, GI upset
- **Rare side effects:** suicidal ideation (~2%), hepatitis (very rare), urinary retention
- **Elevated blood pressure and heart rate:** ~5-10% of children and adults experience clinically significant changes in heart rate (~20 bpm) or blood pressure (~15-20 mmHg). Caution should be used in patients with a history of or underlying mild to moderate cardiovascular conditions, and atomoxetine should be avoided in patients with severe cardiovascular disorders.

### Table 5: Atomoxetine Dosing

<table>
<thead>
<tr>
<th>Atomoxetine Dosing</th>
<th>Weight ≤ 70kg</th>
<th>Weight &gt; 70kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting dose</td>
<td>0.5mg/kg/day x 3 days</td>
<td>40mg/day x 3 days</td>
</tr>
<tr>
<td>Target dose</td>
<td>1.2mg/kg/day</td>
<td>60mg/day</td>
</tr>
<tr>
<td>Max dose</td>
<td>1.4mg/kg/day or 100mg/day, whichever is less</td>
<td>100mg/day</td>
</tr>
</tbody>
</table>
Alpha Agonist General Information

Treatment with alpha agonists should be initiated as a single bedtime dose and carefully titrated over 2-4 weeks to minimize side effects, particularly sedation. Vital signs should be obtained in lying and standing positions. An adequate trial is 4 weeks at the maximum dose tolerated to evaluate effectiveness. If discontinued due to inefficacy, or for other reasons, alpha agonists should be tapered gradually over approximately 1-2 weeks when possible, to prevent rebound hypertension.

- Common side effects: sedation, dizziness, fainting (sign of low blood pressure).
- Caution is advised when combining alpha agonists and antipsychotics due to combined effects on blood pressure.

Guanfacine ER Dosing: Initiate at 1 mg/day. May increase daily dosage by 1 mg each week, up to a maximum dosage of 4 mg/day, as indicated.

Table 6: Guanfacine IR Dosing*

<table>
<thead>
<tr>
<th>Week</th>
<th>Weight &lt; 45kg</th>
<th>Weight &gt; 45kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>0.5 mg q HS</td>
<td>1 mg q HS</td>
</tr>
<tr>
<td>2-4</td>
<td>0.5 mg BID</td>
<td>1 mg BID</td>
</tr>
<tr>
<td>3-6</td>
<td>0.5 mg TID</td>
<td>1 mg TID</td>
</tr>
<tr>
<td>4-8</td>
<td>0.5 mg QID</td>
<td>1 mg QID</td>
</tr>
</tbody>
</table>

*IR and ER guanfacine formulations are not interchangeable.
### ADHD Rating Scale

- To be completed by Education Department staff (or by Psychology Department staff when initiating a referral to Psychiatry if indicated).
- Complete the ADHD Rating Scale upon request by the Psychiatrist (infirmary staff will contact the Principal with this request).
- Complete the ADHD Rating Scale if you believe a youth needs to be evaluated for suspected symptoms or as requested by the Psychology Department. Provide the completed ADHD Rating Scale with a referral form to the Manager of Institution Clinical Services. The Manager of Institution Clinical Services will include both the referral form and the completed ADHD Rating Scale in the Psychiatric Referral.
- Please check all items that best describe the youth’s symptoms.
- Enter into the comment section any other observation or behavioral concerns regarding the youth and/or clarify the items marked below.

#### Youth Name: ____________________  Review Date: ______________  Youth Stage: ____________

**TJJD Number:** ______________  **Education Staff:** ______________

<table>
<thead>
<tr>
<th>Inattention or Concentration Problems (please check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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<tr>
<td>5.</td>
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<tr>
<td>6.</td>
</tr>
<tr>
<td>7.</td>
</tr>
<tr>
<td>8.</td>
</tr>
<tr>
<td>9.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Impulsivity/Hyperactivity (please check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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<td>5.</td>
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<td>6.</td>
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<tr>
<td>7.</td>
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<tr>
<td>8.</td>
</tr>
<tr>
<td>9.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Oppositional/Aggressive Behavior (please check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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<tr>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
</tr>
<tr>
<td>7.</td>
</tr>
</tbody>
</table>

**Comments:**

---

CCF-114 (1/12)
BIPOLAR DISORDER ADOLESCENTS: MANIA

Rule out other cause for presentation such as medical causes, substance use, or psychosocial stressors.

Meets DSM-5 criteria for manic episode, hypomanic episode, or Bipolar NOS? Yes
No

Re-evaluate diagnosis and treat underlying causes.

6 Is patient currently on an antidepressant? Yes
No

6a Consider discontinuing the antidepressant. Go to box #8.

7 Is patient currently prescribed a mood stabilizer or antipsychotic? Yes
No

7a Obtain baseline BPRS.

7b Maximize dose of mood stabilizer. Adjust dose per serum level. Lithium 0.6–1.2 mEq/L, or divalproex 75–125 mg/mL. Continue for 4-6 weeks at a therapeutic dose.

7c Maximize dose of antipsychotic. Maximum recommended dose of risperidone is 6 mg/day. Maximum recommended dose of ziprasidone is 400 mg/day. Continue for 4-6 weeks at a therapeutic dose.

7d Go to box #11.

8 Is patient currently prescribed a mood stabilizer or antipsychotic? Yes
No

8a Discontinue current therapy and switch to alternative mood stabilizer (lithium or divalproex) or atypical antipsychotic (risperidone or ziprasidone). Continue for 4-6 weeks at a therapeutic dose.

8b Continue treatment & monitor. Follow clinical status and BPRS.

9 Meets DSM-5 criteria for bipolar depression? Yes
No

9a Assess compliance

10 Consider combination therapy:

10a Lithium or divalproex plus risperidone, or

10b Lithium or divalproex plus ziprasidone, or

10c Lithium plus divalproex

11 Continue treatment & monitor. Follow clinical status and BPRS.

12 Adequate response per clinical status and BPRS? Yes
No

13 Discontinue current therapy and switch to alternative mood stabilizer (lithium or divalproex) or atypical antipsychotic (risperidone or ziprasidone). Continue for 4-6 weeks at a therapeutic dose.

14 Continue treatment & monitor. Follow clinical status and BPRS.

15 Adequate response per clinical status and BPRS? Yes
No

16 Consider combination therapy:

16a Lithium or divalproex plus risperidone, or

16b Lithium or divalproex plus ziprasidone, or

16c Lithium plus divalproex

17 Continue treatment & monitor. Follow clinical status and BPRS.

18 Provide medication compliance counseling

19 Re-evaluate diagnosis

*Choice of agent should be based on phase of illness, side effect profile, history of response, and co-morbid presentation. Antipsychotic agents may be preferred in patients with significant psychotic features.
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients. *Choice of agent should be based on phase of illness, side effect profile, history of response, and confounding presentation.*

1. Re-evaluate diagnosis.
2. Counsel regarding medication compliance.
3. Consider pharmacotherapy consultation.
4. Consider alternative formulary SSRI or non-formulary request for lamotrigine.

### BIPOLAR DISORDER ADOLESCENTS: DEPRESSION

1. Rule out medical causes for presentation.

2. Is the patient currently depressed?
   - Yes
   - No

3. Is there a history of at least 1 hypomanic or manic episode?
   - Yes
   - No

4. Follow Depressive Disorder Pathway

5. Is the patient in a manic or hypomanic episode?
   - Yes
   - No

6. Obtain baseline BPRS.
   - Initiate monotherapy with mood stabilizer lithium or divalproex and titrate to therapeutic level. Continue for 4-6 weeks at a therapeutic dose. See box 9.
   - Begin psychotherapy for depression

7. **Adequate response per clinical status and BPRS?**
   - Yes
   - No

8. Discontinue current therapy and switch to alternative mood stabilizer lithium or divalproex. Titrate dose to therapeutic level and continue for 4-6 weeks.
   - *Choice of agent should be based on phase of illness, side effect profile, history of response, and confounding presentation*

9. **Adequate response per clinical status and BPRS?**
   - Yes
   - No

10. Consider combination therapy: Lithium plus divalproex. Titrate to therapeutic level and continue for 4-6 weeks.

11. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

12. Discontinue current therapy and switch to alternative mood stabilizer lithium or divalproex. Titrate dose to therapeutic level and continue for 4-6 weeks.

13. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

14. Consider combination therapy: Lithium plus divalproex. Titrate to therapeutic level and continue for 4-6 weeks.

15. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

16. Consider addition of formulary SSRI.

17. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

18. Consider combination therapy: Lithium plus divalproex. Titrate to therapeutic level and continue for 4-6 weeks.

19. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

20. Consider addition of formulary SSRI.

21. **Adequate response per clinical status and BPRS?**
    - Yes
    - No

22. *Re-evaluate diagnosis.*
Diagnosis

It is important to rule out other causes of behavior changes before diagnosing bipolar disorder.

- Adjustment disorder
- Drug-induced including drug and/or alcohol misuse
- General medical condition (e.g., stroke, hyperthyroidism, hypothyroidism, Cushing’s syndrome)
- Other psychiatric disorder (e.g., depression, ADHD)
- Traumas such as sexual, emotional and physical abuse if the patient exhibits disinhibition, hypervigilance or hypersexuality.

Bipolar disorder should not be diagnosed solely on the basis of a depressive episode in an adolescent with a history of depression or a family history of bipolar disorder.

The DSM-5 criteria used to diagnose adults may be used when diagnosing adolescents:

- A distinct period of abnormally and persistently elevated, expansive, or irritable mood and persistently increased goal-directed activity or energy, lasting at least 1 week and present most of the day, nearly every day
- During the period of mood disturbance and increased energy or activity, 5 or more of the following symptoms are present to a significant degree and represent a noticeable change from usual behavior (if the mood is only irritable):
  1. Inflated self-esteem or grandiosity
  2. Decreased need for sleep
  3. More talkative than usual or pressure to keep talking
  4. Flight of ideas or subjective experience that thoughts are racing
  5. Distractibility
  6. Increase in goal-directed activity or psychomotor agitation
  7. Excessive involvement in pleasurable activities that have a high potential for painful consequences

DSM-5 criteria should be used when making a diagnosis of bipolar in children and adolescents. The diagnosis should be updated as necessary with use of appropriate episode specifier(s) (e.g., most recent episode manic, depressed, mixed, etc.) including severity/psychotic/remission specifier(s) (e.g., mild, moderate, severe, with psychotic features, partial remission, full remission).

Patients should be evaluated for use of formulary agents whenever possible. Practitioners should consider past history of response, contraindications, comorbidities, medication compliance, and potential for adverse effects and/or drug-drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects.

### Table 1: Bipolar Disorder Pharmacotherapy

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Formulary Status</th>
<th>Dosage Form</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antimanic Agent</td>
<td>Lithium carbonate</td>
<td>Eskalith®</td>
<td>Formulary agents</td>
<td>Capsule</td>
<td>300 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cibalith-S®</td>
<td></td>
<td>Syrup</td>
<td>300 mg/5 ml</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>Divalproex sodium</td>
<td>Depakote®</td>
<td>Formulary agent</td>
<td>EC Tablet</td>
<td>250 mg, 500 mg</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>Carbamazepine</td>
<td>Tegretol®</td>
<td>Formulary agent</td>
<td>Tablet</td>
<td>200 mg</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Risperidone</td>
<td>Risperidone</td>
<td>Formulary agent</td>
<td>Tablet</td>
<td>0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Ziprasidone</td>
<td>Geodon®</td>
<td>Formulary agent</td>
<td>Capsule</td>
<td>20 mg, 40 mg, 60 mg, 80 mg</td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Aripiprazole</td>
<td>Abilify</td>
<td>Prior authorization*</td>
<td>Tablet</td>
<td>2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg</td>
</tr>
</tbody>
</table>

*Prior authorization criteria for aripiprazole is as follows: adherence to formulary atypical antipsychotics, treatment failure on formulary antipsychotics after a therapeutic trial of adequate dose and duration, or contraindications to formulary atypical antipsychotics.
**Lithium General Information**

Therapeutic effects of lithium are seen 10-14 days after a therapeutic level has been achieved. It may take up to 6 weeks to see full effects of a given dosage. Laboratory measures and serum lithium levels should be reassessed quarterly during maintenance treatment. Initial levels should be drawn 5-10 days (or more if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase or decrease lithium renal clearance (e.g., ACE inhibitors, calcium channel blockers, diuretics, NSAIDs, SSRIs, theophylline) or if there is a change in renal function. NSAIDs (e.g., ibuprofen) should be not be used in combination with lithium as possible due to a 15-30% increase in serum lithium level. The lithium serum level should be obtained immediately before the next dose and at least 12 hours after the last dose. A therapeutic serum level is 0.6 to 1.2 mEq/L.

**Common side effects**: sedation, thirst, urinary frequency

**Other side effects**: hypothyroid, confusion, toxicity, acne, increased WBC’s

Table 2: Frequency of Lithium Monitoring

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>Every 3 Months</th>
<th>Every 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG*</td>
<td>X</td>
<td>As clinically indicated thereafter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, BUN, creatinine, EMH</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial lithium levels</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance lithium levels</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Providers should consider obtaining an EKG periodically during lithium treatment when there is a personal or family history of cardiovascular disease

**Divalproex General Information**

Divalproex should be started at a dose of 20 mg/kg/day or 1,000 mg/day, whichever is smaller. At baseline, CBC, liver function tests, and platelet counts should be obtained. Dose may be titrated on a weekly basis until 12-hour post-dose serum concentrations reach 75 to 125 mg/L. After therapeutic serum levels have been achieved, it may take as long as 8 weeks for the drug to achieve maximum effectiveness. Obtain levels 1-3 weeks following initiation, change in dose, addition of other CNS agents to the patient's regimen, or observed signs/symptoms of toxicity. Then obtain every 6-12 months thereafter. Warning (1 in 500) for suicidal ideation.

**Common side effects**: sedation, weight gain, hair loss, tremor, bowel changes

**Rare side effects**: liver problems, decreased thyroid function, decreased platelets

Table 3: Frequency of Divalproex Monitoring

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>1 month</th>
<th>2 months</th>
<th>Every 6 Months</th>
<th>Every 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC with differential</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>LFTs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Platelet</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Initial divalproex levels</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance divalproex levels</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Risperidone General Information**

Risperidone may be started at 1 mg daily for most adolescents. The dose may be titrated every two weeks up to a maximum of 6 mg daily. It may take as long as 4-6 weeks for the drug to achieve maximum effectiveness. It is important to monitor for symptoms of EPS, elevated prolactin, and breast discharge. Weight, BMI, glucose, and lipids should also be monitored periodically.

**Titration schedule may vary based on tolerability and response, with some patients stabilizing on lower doses or requiring slower titration.**

**Common side effects**: drowsiness, increased appetite, fatigue, abdominal pain, heartburn, bowel changes, weight gain

**Rare side effects**: abnormal movements, gynecomastia, galactorrhea
Table 4: Risperidone Titration

<table>
<thead>
<tr>
<th>Upward Titration</th>
<th>Receptor</th>
<th>Day 1-4</th>
<th>Day 5-6</th>
<th>Day 9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ziprasidone</td>
<td>0.5-1 mg</td>
<td>1.5-2 mg</td>
<td>3-4 mg</td>
<td></td>
</tr>
<tr>
<td>Divide</td>
<td>Single Dose or 0.5/0.5</td>
<td>Single Dose or 0.5-1</td>
<td>Single Dose or 1-2</td>
<td></td>
</tr>
</tbody>
</table>

Ziprasidone General Information
Ziprasidone may be initiated at 20 mg daily and titrated by 20 mg/day, every 1-2 days, to a target dose. Children ≤ 45 kg should be titrated to a target dose of 60-80 mg/day, whereas children ≥ 45 kg typically require 120-160 mg/day. Daily dosages should be divided and administered once daily, when possible. Each dose should be administered with ≥ 500 calories. Titration schedules may vary based on tolerability and response, with some patients stabilizing on lower doses or requiring slower titration. It may take up to 6 weeks to see maximum effectiveness.

Common side effects: constipation, nausea, drowsiness

Rare side effects: QTc prolongation, severe rash (Stevens-Johnson’s syndrome, DRESS), abnormal movements

Table 5: Antipsychotic Monitoring Parameters
Providers should consider obtaining any of the laboratories listed above more frequently if clinically indicated.

1. Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease. Given ziprasidone’s increased risk for QTc prolongation, an alternative antipsychotic should be considered if the baseline QTc is ≥ 450 msec in males and ≥ 470 msec in females. Ziprasidone discontinuation is advised if the QTc rises above 500 msec, or increases by > 30-60 msec during treatment.

2. Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunction.
• Routine screening for hyperprolactinemia is not recommended unless symptoms are present
• The normal range of prolactin is 10-20mcg/L in males and 10-25mcg/L in females
• Symptoms typically do not appear until levels reach 60-100mcg/L
• Patients should be referred to medical to rule out other etiologies of hyperprolactinemia

Lamotrigine General Information
The lamotrigine dose must be titrated to minimize the risk of severe rash. Serious skin reactions are more likely when starting therapy or after an interruption in therapy within the first 2 to 8 weeks of therapy. Children between the ages of 2 to 16 have a higher risk of serious skin reactions. If therapy is interrupted for ≥ 5 days (5 half-lives), it is recommended that the dose be reinitiated again. Therapy should be discontinued at the first sign of rash unless the rash is clearly identified as not drug-related.
Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses. Target level: 0.6 – 1.2 mEq/L. Doses should not generally exceed 1200mg/day.

- Lithium hypersensitivity
- Severe renal or cardiovascular disease
- Severe debilitation
- Dehydration
- Sodium depletion
- Pregnancy Category D

Lithium toxicity can be FATAL

Acute:
- Apathy
- Coarse hand tremor (spreads to other body parts while patient sitting still)
- Confusion
- Drowsiness
- Dysarthria
- GI symptoms (diarrhea, N/V, etc.)
- Giddiness

Acute To Severe:
- Blurred vision
- Deep tendon reflexes increased
- Muscle rigidity / fasciculations
- Mild ataxia
- Profound lethargy
- Tinnitus
- Vertical nystagmus
- Vomiting

Severe Intoxication:
- Arrhythmias
- Impaired consciousness
- Increase in fasciculations and ataxia
- CV collapse with oliguria and anuria
- Coarse / irregular limb tremors
- Coarse muscle contractions
- Choreoathetoid movements
- Cogwheel rigidity
- Coma
- Generalized tonic-clonic seizures

Divalproex Sodium: 20mg/kg/day or 1,000mg/day, in divided doses up to 60mg/kg/day. Target level: 75 – 125mg/mL.

- Valproate hypersensitivity
- Hepatic dysfunction
- Urea cycle disorder
- Pregnancy Category D

- Somnolence
- Lethargy
- Mental status change
- Coma
- Hyperammonemia
- Hepatomegaly
- Headache
- Vomiting
- Seizures
- Prolongation of bleeding time
- Alopecia
- Pancreatitis
- Fever
- Lymphadenopathy
- Multi-organ dysfunction
- Stevens-Johnson Syndrome
- Toxic epidermal necrolysis
- Polycystic ovarian syndrome

Lamotrigine: Starting Dose:
- 25mg daily for 2 weeks, then 50mg daily for 2 weeks, then 100mg daily for 1 week, then up to 200mg daily.
- Co-administration with enzyme-inducing medications (e.g., carbamazepine, phenytoin, primidone) – 50mg once daily for 2 weeks, then 100mg once daily for 2 weeks, then up to 100mg twice daily. Higher doses may be used to achieve levels of 4 – 10 mcg/mL.
- Co-administration with enzyme-inhibiting medications (e.g., divalproex) – 25mg every other day for 2 weeks, then 50mg once daily for 1 week, then up to 100mg daily.

Serious side effects of lamotrigine: Rash and Stevens-Johnson Syndrome

Extreme caution should be taken in combination with divalproex by using one half the starting dose and monitoring levels.

Table 6: Mood Stabilizers

<table>
<thead>
<tr>
<th>Drug Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Starts at Serum Trough Levels of</th>
<th>Signs &amp; Symptoms of Toxicity (dose-related)</th>
<th>Signs &amp; Symptoms of Toxicity (NOT dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium</td>
<td>Initially 900 – 1200 mg daily in 1 to 3 divided doses.</td>
<td>1 – 1.2 mmol/L. Patients who are sensitive to lithium may manifest toxicity at serum levels of 1 mmol/L. Note: A rise in white blood cell count is to be expected.</td>
<td>Lithium toxicity can be FATAL.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>20mg/kg/day or 1,000mg/day, in divided doses up to 60mg/kg/day.</td>
<td>&gt; 100 – 125 mcg/mL.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Dosing depends on concomitant drug therapy due to drug interactions.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Background:

The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual's behavior over the previous 2-3 days should also be considered and can be reported by the patient's caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring:

Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
<table>
<thead>
<tr>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness</td>
</tr>
<tr>
<td>3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>4. CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>5. IMPULSIVENESS</td>
</tr>
<tr>
<td>6. MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td>7. MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>8. GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td>9. DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.</td>
</tr>
<tr>
<td>10. HOSTILITY - Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td>11. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td>12. HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>13. MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td>14. UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.</td>
</tr>
<tr>
<td>15. UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.</td>
</tr>
<tr>
<td>16. BLUNTED AFFECT - Reduced emotional tone, reduction in normal intensity of feelings, flatness.</td>
</tr>
<tr>
<td>17. EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td>18. DISORIENTATION - Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td>19. ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>20. SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td>21. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>22. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td>23. DISTRACTER - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.</td>
</tr>
</tbody>
</table>
DEPRESSIVE DISORDERS
(Adolescents)

1. Meets DSM-5 criteria for Major Depressive Disorder or severe Dysthymia

2. Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

3. Initiate fluoxetine 10–20 mg/day. Titrate to usual dosage range of 10-40 mg/day, as appropriate, and continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

4. Switch to alternative formulary SSRI citalopram (usual dosage range of 10–40 mg/day), sertraline (usual dosage range of 25–200 mg/day), or escitalopram (usual dose range of 10-20 mg/day). Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

5. Switch to alternative formulary antidepressant with different mechanism of action, venlafaxine XR (usual dosage range of 75–300 mg/day) Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

6. Switch to alternative non-formulary antidepressant and continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

7. Consider combination therapy: SSRI or venlafaxine plus lithium or lamotrigine. Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

8. Consider therapy with antidepressant with best response plus formulary atypical antipsychotic. Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

9. Reconsider diagnosis and consider psychopharmacology consultation.

10. Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

11. Initiate fluoxetine 10–20 mg/day. Titrate to usual dosage range of 10-40 mg/day, as appropriate, and continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
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12. Switch to alternative formulary SSRI citalopram (usual dosage range of 10–40 mg/day), sertraline (usual dosage range of 25–200 mg/day), or escitalopram (usual dose range of 10-20 mg/day). Continue for 4-6 weeks at a therapeutic dose.*

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   - Assess compliance
   - Inadequate response per BPRS

13. Switch to alternative formulary antidepressant with different mechanism of action, venlafaxine XR (usual dosage range of 75–300 mg/day) Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

14. Switch to alternative non-formulary antidepressant and continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

15. Consider combination therapy: SSRI or venlafaxine plus lithium or lamotrigine. Continue for 4-6 weeks at a therapeutic dose.*

   - Adequate response per BPRS
   - Continue treatment
   - Assess compliance
   - Inadequate response per BPRS

16. Reconsider diagnosis and consider psychopharmacology consultation.

*Antidepressant trial of adequate dose/duration is 4-6 weeks at FDA approved maximum dosage or maximum tolerated dose with a minimum of 80% adherence.

Prepared By The Texas Youth Commission and Reviewed By The Correctional Managed Care Pharmacy & Therapeutics Committee: October 2001, revised 5/2002, 2/2004, 8/2006. Revised by Youth Services Pharmacy & Therapeutics Committee 7/10, 8/15/11, 4/16/12, 10/23/17. (Note: original pathway developed by TDCJ Pharmacy & Therapeutics Committee 4/98, revised 7/98 then as above by TYC)
Medication Selection

Patients should be evaluated for use of formulary agents when possible. Practitioners should consider past history of response, contraindications, co-morbidities, compliance, and potential for adverse effects and/or drug interactions when making treatment decisions. When medications are changed, patients should be monitored closely for worsening symptoms and adverse effects.

Suicidality in Children and Adolescents

Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of any antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on antidepressant treatment should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.

Lithium General Information

Therapeutic effects of lithium are seen 10-14 days after a therapeutic level has been achieved. It may take up to 6 weeks to see full effects of a given dosage. Laboratory measures and serum lithium levels should be reassessed every six months during maintenance treatment. Levels should be drawn 5-10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase or decrease lithium renal clearance (e.g., ACE inhibitors, calcium channel blockers, diuretics, NSAIDs, SSRIs, theophylline) or if there is a change in renal function. The lithium serum level should be obtained immediately before the next dose and at least 12 hours after the last dose. A lithium serum level of 0.6-0.8 mmol/L may be sufficient for treatment of MDD.

Common side effects: sedation, thirst, urinary frequency, nausea, fine tremor, weight gain
Other side effects: hypothyroidism, acne, increased WBC’s, confusion, toxicity

Table 1: Frequency of Lithium Monitoring

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>Every 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG*</td>
<td>X</td>
<td></td>
<td>As clinically indicated thereafter</td>
</tr>
<tr>
<td>CBC, Scr, BUN, Electrolytes, TSH</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Lithium levels</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease.
Lamotrigine is reserved for treatment resistant depression and requires non-formulary approval. The dose of lamotrigine must be titrated to minimize the risk of severe rash. Serious skin reactions are more likely to occur when starting therapy or following an interruption in therapy within the first 2 to 8 weeks of treatment. Children between the ages of 2 to 16 have a higher risk of experiencing serious skin reactions. If an interruption in therapy for a period of ≥ 5 days (5 half-lives) occurs, it is recommended that the dose be re-titrated. Therapy should be discontinued at the first sign of rash, unless the rash has been clearly identified as not drug-related.

Starting Dose:
- Usual dosing without concomitant administration of enzyme-inducing or inhibiting medications: 25mg daily for 2 weeks, then 50mg daily for 2 weeks, then 100mg daily for 1 week, then up to 200mg daily.
- Co-administration with enzyme-inducing medications (e.g., carbamazepine, phenytoin, primidone): 50mg once daily for 2 weeks, then 100mg once daily for 2 weeks, then up to 100mg twice daily. Higher doses may be used to achieve levels of 4-18 mcg/mL.
- Co-administration with enzyme-inhibiting medications (e.g., divalproex): 25mg every other day for 2 weeks, then 25mg once daily for 2 weeks, then 50mg once daily for 1 week, then up to 100mg daily. Consider use of lamotrigine levels to guide dosing.

Serious side effects: Rash and Stevens Johnson Syndrome

Table 2: Formulary Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitor (SSRI)</td>
<td>Citalopram 10 mg, 20 mg, 40 mg tablets</td>
<td>Celexa®</td>
<td>• Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine 10 mg, 20 mg capsules</td>
<td>Prozac®</td>
<td>• Citalopram and escitalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present.</td>
</tr>
<tr>
<td></td>
<td>Sertraline 25 mg, 50 mg, 100 mg tablets</td>
<td>Zoloft®</td>
<td>• If QTc ≥ 450msec for males or ≥ 470msec for females, do not initiate citalopram or escitalopram. If pt is on citalopram or escitalopram and QTc ≥ 500msec, consider alternative treatment.</td>
</tr>
<tr>
<td></td>
<td>Escitalopram 5 mg, 10 mg, 20 mg</td>
<td>Lexapro®</td>
<td>• Fluoxetine has also been associated with QTc prolongation. EKG monitoring is encouraged if risk factors for QTc prolongation are present.</td>
</tr>
<tr>
<td>Serotonin/Norepinephrine Reuptake Inhibitor (SNRI)</td>
<td>Venlafaxine XR 75 mg, 150 mg tablets</td>
<td>Effexor XR®</td>
<td>• Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Trazodone 50 mg, 100 mg tablets</td>
<td>Desyrel®</td>
<td>• Priapism</td>
</tr>
<tr>
<td>Other*</td>
<td></td>
<td></td>
<td>• Emergence of suicidal ideation or behavior</td>
</tr>
</tbody>
</table>

* Risk factors for QTc prolongation include use of other concomitant QTc prolonging medications, baseline hypokalemia or hypomagnesemia, or pre-existing cardiovascular impairment.
* Venlafaxine functions as an SSRI at doses ≤ 150 mg/day. Titration to such doses may offer enhanced efficacy vs. lower venlafaxine doses, at which this agent functions as an SNRI.
* Not recommended as first line or second line therapy for treatment of depression in children or adolescents.
## Monitoring Parameters for Antipsychotics

### Table 3: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents in Children and Adolescents

<table>
<thead>
<tr>
<th>Parameter &amp; Frequency</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>8 weeks</th>
<th>12 weeks</th>
<th>6 Months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal Family History</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight-Height-BMI (overweight 25.0-29.9; obese &gt;= 30.0)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC, LFT, BUN, Electrolytes</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EKG*</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Ziprasidone: at baseline, once a stable dose is reached, and as clinically indicated thereafter

* Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease. Given ziprasidone’s increased risk for QTc prolongation, an alternative antipsychotic should be considered if the baseline QTc is > 450 msec in males and 470 msec in females. Ziprasidone discontinuation is advised if the QTc rises above 500 msec, or increases by > 30-60 msec during treatment.

### Table 4: Adverse Effect Monitoring

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIMS (Abnormal Involuntary Movement Scale)</td>
<td>X</td>
<td>Baseline, at 3 months, then annually</td>
</tr>
<tr>
<td><em>Acute EPS - Akathisia</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Tardive Dyskinesia</em></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Background:
The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual's behavior over the previous 2-3 days should also be considered and can be reported by the patient's caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring:
Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SOMATIC CONCERN</td>
<td>Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>2</td>
<td>ANXIETY</td>
<td>Worry, fear, over-concern for present or future, uneasiness.</td>
</tr>
<tr>
<td>3</td>
<td>EMOTIONAL WITHDRAWAL</td>
<td>Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>4</td>
<td>CONCEPTUAL DISORGANIZATION</td>
<td>Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>5</td>
<td>IMPULSIVENESS</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>MOTOR HYPERACTIVITY</td>
<td>Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.</td>
</tr>
<tr>
<td>7</td>
<td>MANNERISMS AND POSTURING</td>
<td>Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>8</td>
<td>GRANDIOSITY</td>
<td>Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
</tr>
<tr>
<td>9</td>
<td>DEPRESSIVE MOOD</td>
<td>Sorrow, sadness, despondency, pessimism.</td>
</tr>
<tr>
<td>10</td>
<td>HOSTILITY</td>
<td>Animosity, contempt, belligerence, disdain for others.</td>
</tr>
<tr>
<td>11</td>
<td>SUSPICIOUSNESS</td>
<td>Mistrust, belief others harbor malicious or discriminatory intent.</td>
</tr>
<tr>
<td>12</td>
<td>HALLUCINATORY BEHAVIOR</td>
<td>Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>13</td>
<td>MOTOR RETARDATION</td>
<td>Slowed, weakened movements or speech, reduced body tone.</td>
</tr>
<tr>
<td>14</td>
<td>UNCOOPERATIVENESS</td>
<td>Resistance, guardedness, rejection of authority.</td>
</tr>
<tr>
<td>15</td>
<td>UNUSUAL THOUGHT CONTENT</td>
<td>Unusual, odd, strange, bizarre thought content.</td>
</tr>
<tr>
<td>16</td>
<td>BLUNTED AFFECT</td>
<td>Reduced emotional tone, reduction in normal intensity of feelings, flatness.</td>
</tr>
<tr>
<td>17</td>
<td>EXCITEMENT</td>
<td>Heightened emotional tone, agitation, increased reactivity.</td>
</tr>
<tr>
<td>18</td>
<td>DISORIENTATION</td>
<td>Confusion or lack of proper association for person, place or time.</td>
</tr>
<tr>
<td>19</td>
<td>ELEVATED MOOD</td>
<td>A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.</td>
</tr>
<tr>
<td>20</td>
<td>SUICIDALITY</td>
<td>Expressed desire, intent, or actions to harm or kill self.</td>
</tr>
<tr>
<td>21</td>
<td>BIZARRE BEHAVIOR</td>
<td>Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.</td>
</tr>
<tr>
<td>22</td>
<td>SELF-NEGLECT</td>
<td>Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
</tr>
<tr>
<td>23</td>
<td>DISTRACTIBILITY</td>
<td>Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.</td>
</tr>
</tbody>
</table>
1. Obtain fasting finger sticks daily and return to clinic every month until euglycemic. Once euglycemic, obtain fasting finger sticks weekly, A1C every 3 months and return to clinic every 6 months. Obtain Chem 10, LK, eye and foot exam annually and TSH every 2 years. Check for microalbuminuria annually. IF A1C not at goal, go to box #4.

2. Patient experiencing hypoglycemia twice a week (≥ 5% of time) (See Table 10).

3. Check A1C every 3 months, is A1C at goal?

   Yes

   No

   4. Patient experiencing hypoglycemia ≥ twice a month (≥ 15% of time) (See Table 10).

   Yes

   No

   5. Reevaluate compliance with medications, exercise and diet.

   Yes

   No

   6. If intolerant to ACE inhibitor, obtain microalbuminuria annually. If microalbuminuria is ≥ 100/mg/dl, consider switching to a diuretic (metoprolol or atenolol).

   Yes

   No

   7. Reevaluate NPH and regular insulin doses

   Yes

   No

   8. Consider referral to specialist

<table>
<thead>
<tr>
<th>Year</th>
<th>Age Range</th>
<th>Goal</th>
<th>Consider Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/07</td>
<td>0-90%</td>
<td>&lt; 2.5</td>
<td>Regular insulin dose, microalbuminuria annually</td>
</tr>
<tr>
<td>4/11</td>
<td>90-180%</td>
<td>&lt; 7.5</td>
<td>Regular insulin dose, microalbuminuria annually</td>
</tr>
<tr>
<td>5/13</td>
<td>180-336%</td>
<td>&lt; 10.0</td>
<td>Regular insulin dose, microalbuminuria annually</td>
</tr>
<tr>
<td>2/16</td>
<td>≥ 336%</td>
<td>&lt; 12.0</td>
<td>Regular insulin dose, microalbuminuria annually</td>
</tr>
</tbody>
</table>

The pathways do not replace sound clinical judgment and are intended to provide a guide to optimal care for all patients.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, November 2006, Revised 11/17, 4/11, 7/12, 2/16
Institute Lifestyle Modifications & Group/Individual Education with Specific Patient Goals
1. H&P and obtain baseline labs: Chem 10, fasting plasma glucose, A1C, UA, and TSH.
2. Obtain fasting lipid profile at baseline after glycemic control is achieved.
   - If normal (LDL <100mg/dl), repeat every 5 years.
   - If abnormal, recheck annually. Institute lifestyle modifications for 6 months. If the child is over the age of two and goal LDL <100mg/dl is not met after 6 months, start statin therapy (pravastatin 10 to 40mg if no contraindications — Table 8) for the following conditions:
     - LDL ≥160mg/dl and patient has at least 2 cardiovascular risk factors.
     - LDL ≥130mg/dl and patient has 2 cardiovascular risk factors.
     - Random lipid panel every 3 months until patient reaches goal (LDL <100mg/dl)
3. Determine if blood pressure at goal of <90th percentile for age, sex, and height. ACE inhibitor (lisinopril 2.5 mg QD) preferred for initial treatment of hypertension if no contraindications (see Table 8). Refer to Hypertension disease management guidelines for children & adolescents.
4. Screen for microalbuminuria with random spot urine sample for all patients-to-creation. Start low dose ACE inhibitor* if microalbuminuria is present (lisinopril 2.5 mg QD) and if no contraindications (see Table 8).
5. Execute exercise plan, diet plan, smoking cessation and weight loss plan if BMI >80
6. Administer annual influenza vaccine. If pneumococcal vaccine not previously given in lifetime, obtain one time.
7. Refer to Dental for oral/periodontal disease evaluation if not completed at intake.
8. Refer to Ophthalmologist for dilated eye exam.
9. Recheck A1C in 3 months. Is A1C at goal?
   - No
   - Yes
     - Start metformin 500mg daily if no contraindication (Table 8). Titrate up to 1500mg/day in 500mg increments over 2 weeks. Maximum dose is 2500mg/day.
     - Monitor fasting finger sticks (FS) for 2 weeks and follow up in clinic in 2 weeks.
     - Recheck A1c in 3 months. Is A1c at goal?
   - Yes
     - Go to box #9
   - No
     - Controlled?
     - No
     - Yes
     - Go to box #7
10. Reevaluate compliance to medications, diet and exercise plan.
    - Continue metformin.
    - Start evening dose of insulin NPH (0.2u/kg or 10u) and if Glucose <90 or >150 and/or A1c >8%
    - Continue current therapy. Follow up in clinic in 2 weeks.
    - Recheck A1c every 6 months.
    - Check for microalbuminuria annually.
11. Recheck A1c in 3 months. Is A1c at goal?
    - Yes
      - Go to box #13
    - No
      - Go to box #14

Table 1: Glycemic Control Goals for All Pediatric Age Groups

<table>
<thead>
<tr>
<th>Fasting</th>
<th>Post-prandial</th>
<th>A1C</th>
<th>Consider Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>90-130mg/dl</td>
<td>100-180mg/dl</td>
<td>&lt; 7.5%</td>
<td>Glucose &lt; 90 or &gt; 150 and/or A1C &gt;8%</td>
</tr>
</tbody>
</table>

*If intolerant to ACE-inhibitor, obtain microalbuminuria annually. If microalbuminuria >30, consider non-dihydropyridine CCB (verapamil or diltiazem).
Are PM FS at goal?

Yes

Recheck A1C in 3 months. Is A1C at goal?

Yes

Go to box #7

No

No

Are AM and PM FS at goal?

Yes

Recheck A1C in 3 months. Is A1C at goal?

Yes

Go to box #7

No

No

Are AM and PM FS at goal?

Yes

Recheck A1C in 3 months. Is A1C at goal?

Yes

Go to box #7

No

No

Are AM and PM FS at goal?

Yes

Recheck A1C in 3 months. Is A1C at goal?

Yes

Go to box #7

No

No

No

Are AM and PM FS at goal?

Yes

Recheck A1C in 3 months. Is A1C at goal?

Yes

Go to box #7

No

No

No

No

Titrate NPH and/or Regular Insulin AM or PM by 10% of TDD. If TDD is >200u/day, consider referral to specialist.

- Continue metformin.
- Start Multi-dose insulin Therapy by increasing NPH to twice daily dosing. Add NPH at 0.3u/kg in the AM to the PM regimen started above in box #11. Titrate AM or PM dose of NPH by 10% of the total daily dose (TDD) until AM and PM finger sticks are at goal.
- Obtain AM and PM FS.
- Monitor for hypoglycemia (Table 10).
- Follow up at least monthly.

Prepared by The Correctional Managed Care Pharmacy and Therapeutics Committee, November 2006. Revised 11/07, 4/11, and 5/13, 2/16.
I. Classification
A. Type 1 diabetes: Diabetes that results in β-cell destruction that usually leads to an absolute deficiency in insulin.
B. Type 2 diabetes: Diabetes that results in a progressive insulin secretory defect with the background of insulin resistance.

II. Screening for type 1 diabetes
A. Type 1 diabetes presents with acute symptoms and markedly elevated blood sugar levels. Most cases identified after the onset of hyperglycemia.
B. Screening is recommended for children and adolescents who are at increased risk for developing type 1 diabetes. Measurement of islet autoantibodies is suggested in individuals with:
   1. Prior transient hyperglycemia
   2. Patient has a relative with type 1 diabetes

III. Screening for type 2 diabetes
A. Screening is only recommended for children and adolescents that are at increased risk for type 2 diabetes – refer to Table 2.
B. Screening should begin at age 10 or at onset of puberty if puberty occurs at a younger age
C. Screen for diabetes every 2 years

IV. Categories of Increased Risk for Diabetes (Pre-diabetes)
A. Some individuals may not meet the criteria for diabetes, but have values that are too high to be considered normal. These individuals have a relatively high risk for the future development of diabetes.
B. This group is defined as having impaired fasting glucose (IFG) levels of 100mg/dl or impaired glucose tolerance (IGT/ 2-h OGTT) values of 140–199 mg/dl (see Table 3). IFG and IGT are risk factors for diabetes and for cardiovascular disease (CVD).
C. Individuals with a hemoglobin A1c of 5.7–6.4% are considered to be at an increased risk for diabetes and CVD.
   1. Counsel patients about strategies to lower their risk such as weight loss of 5–10% of body weight and an increase in physical activity of at least 150 min/week of moderate activity such as walking.
   2. Interventions and follow-up should be the most intensive for very high risk individuals with an ASC > 6.0%.
      a) In addition to lifestyle counseling, metformin may be considered for very high risk individuals that have a combined IFG and IGT plus other risk factors.
      b) Additional risk factors: hypertension, low HDL <35mg/dl, elevated triglycerides, family history in first degree relative, obesity, and under 60 years of age
   3. Monitoring of pre-diabetes patients should be performed every year.
   4. Like glucose measurements, the continuum of risk is curvilinear, so that as ASC rises, the risk of diabetes rises disproportionately. See Table 11 for association of ASC and average glucose.

Table 2: Screening Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overweight</td>
<td>BMI &gt; 85th percentile for age and sex, &gt;85th percentile weight for height, or weight &gt; 120% of ideal for height</td>
</tr>
<tr>
<td>Plus any two of the following factors</td>
<td></td>
</tr>
<tr>
<td>Family history of type 2 diabetes in first or second degree relative</td>
<td></td>
</tr>
<tr>
<td>Racial/ethnicity – Native American, African American, Latino, Asian American, Pacific Islander</td>
<td></td>
</tr>
<tr>
<td>Signs of insulin resistance or conditions associated with insulin resistance (e.g., acanthosis nigricans, hypertension, dyslipidemia, polycystic ovarian syndrome, or small for gestational age birth weight)</td>
<td></td>
</tr>
<tr>
<td>Maternal history of diabetes or gestational diabetes</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Criteria Findings

| Overweight | BMI > 85th percentile for age and sex, >85th percentile weight for height, or weight > 120% of ideal for height |
| Plus any two of the following factors | |
| Family history of type 2 diabetes in first or second degree relative |
| Racial/ethnicity – Native American, African American, Latino, Asian American, Pacific Islander |
| Signs of insulin resistance or conditions associated with insulin resistance (e.g., acanthosis nigricans, hypertension, dyslipidemia, polycystic ovarian syndrome, or small for gestational age birth weight) |
| Maternal history of diabetes or gestational diabetes |
V. Diagnosis
A. Most children with type 1 diabetes present with a short duration of symptoms (several weeks’ history) such as polyuria, polydipsia, polyphagia, weight loss, hyperglycemia, glycosuria, ketonemia, and/or ketonuria.
B. Most children with type 2 diabetes are overweight or obese and present with glycosuria without ketonuria, absent or mild polyuria and polydipsia, and little or no weight loss. They are usually diagnosed after the age of 10 and in middle to late puberty with a family history of diabetes. Acanthosis nigricans and polycystic ovarian syndrome are common.
C. Diagnostic criteria (Table 4)
1. If the patient is asymptomatic and if random plasma glucose is $\geq 200 \text{mg/dl}$, FPG is $\geq 126 \text{mg/dl}$, or 2-hr plasma glucose $\geq 200 \text{mg/dl}$, results should be confirmed with a second test on a different day for confirmation.
2. If the patient is symptomatic and random plasma glucose is $\geq 200 \text{mg/dl}$, diagnosis does not require a repeat value on another day.
3. A1C $\geq 6.5\%$. Confirmation by repeat testing preferred. A1C may not be an effective test in special patient populations with affected hemoglobin disorders.

Table 3: Categories of Increased Risk for Diabetes

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose (FPG)</td>
<td>FPG $\geq 126 \text{mg/dl}$ with no caloric intake within last 8 hours</td>
</tr>
<tr>
<td>Oral glucose tolerance test (OGTT) 2-hr plasma glucose</td>
<td>2-hr plasma glucose $\geq 200 \text{mg/dl}$ during OGTT.</td>
</tr>
<tr>
<td>Hemoglobin A1C</td>
<td>A1C $\geq 6.5%$</td>
</tr>
</tbody>
</table>

VI. Evaluation
A. Medical history
1. Age and characteristics of diabetes onset (e.g. DKA, asymptomatic lab findings)
2. Symptoms of diabetes
3. Recent or current infection or illnesses
4. Growth records & weight history
5. Eating, diet, and exercise patterns
6. Family history of diabetes
7. Risk factors for atherosclerosis such as smoking, hypertension, obesity, dyslipidemia, and family history
8. Previous management of diabetes
9. Previous episodes of ketoacidosis and hypoglycemia
10. Previous testing or treatment of chronic diabetes complications
11. Medications that may affect glucose levels (e.g., atypical antipsychotics, steroids)
12. Social history – alcohol, tobacco, and recreational drug use
13. Review of systems should include gastrointestinal function (including symptoms of celiac disease) and symptoms of other endocrine disorders such as hypothyroidism and Addison’s disease

---

Table 4: Diagnostic Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms of diabetes</td>
<td>Symptoms of diabetes and plasma glucose $\geq 200 \text{mg/dl}$</td>
</tr>
<tr>
<td>Fasting plasma glucose (FPG)</td>
<td>FPG $\geq 126 \text{mg/dl}$ with no caloric intake within last 8 hours</td>
</tr>
<tr>
<td>Oral glucose tolerance test (OGTT) 2-hr plasma glucose</td>
<td>2-hr plasma glucose $\geq 200 \text{mg/dl}$ during OGTT.</td>
</tr>
<tr>
<td>Hemoglobin A1C</td>
<td>A1C $\geq 6.5%$</td>
</tr>
</tbody>
</table>
B. Physical examination
1. Height, weight, and BMI calculations in comparison to age and sex-specific norms
2. Sexual maturation staging during prepubertal period
3. Blood pressure in comparison to age and sex-specific norms
4. Dilated fundoscopic and comprehensive eye examination
5. Oral examination
6. Thyroid palpation
7. Cardiac examination
8. Abdominal examination
9. Evaluation of pulses
10. Hand examination & foot examination - educational opportunity on basic foot care
11. Skin examination for acanthosis nigricans and insulin injection sites
12. Neurological examination.

C. Laboratory tests – refer to Table 5 for frequency of monitoring.

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency of Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose</td>
<td>Baseline, as clinically indicated to monitor/adjust medications</td>
</tr>
<tr>
<td>A1C*</td>
<td>Baseline, every 6 months if stable and meeting treatment goals, every 3 months if not meeting treatment goals</td>
</tr>
<tr>
<td>Fasting lipid profile</td>
<td>At baseline, after glycemic control is achieved, type 1 diabetes: repeat every 5 years if initial screen is normal (LDL &lt; 100mg/dl), if abnormal, institute lifestyle modifications for 6 months. If goal LDL of &lt;100mg/dl is not met after 6 months, start statin therapy (pravastatin 10 to 40mg). If no contraindications, consider another statin. If goal LDL is &gt;100mg/dl or patient has 1 cardiovascular risk factor, recheck lipid panel every 3 months until patient reaches goal LDL of &lt;100mg/dl. If goal LDL is &gt;130mg/dl and patient has at least 1 cardiovascular risk factor, start statin therapy (pravastatin 10 to 80mg). If goal LDL is &gt;160mg/dl and patient has no cardiovascular risk factors, start statin therapy (pravastatin 10 to 80mg). Once goal LDL is met, recheck lipid panel annually. Type 2 diabetes: screen all children at baseline regardless of age, repeat every 5 years if initial screen is normal.</td>
</tr>
<tr>
<td>TSH</td>
<td>Baseline (every 2 years in type 1 diabetics). Measure Free T4 if TSH abnormal.</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>Baseline &amp; annual to screen or as clinically indicated.</td>
</tr>
<tr>
<td>Random spot urine sample</td>
<td>Baseline &amp; annual to screen for microalbuminuria. Screening should be initiated once the child is 10 years of age and has had diabetes for 5 years.</td>
</tr>
<tr>
<td>CHEM 10 (i.e., creatinine)</td>
<td>Baseline &amp; annual or as clinically indicated.</td>
</tr>
</tbody>
</table>

*Specific A1c tests may not be recommended in special populations such as patients with hemoglobinopathy, abnormal red cell turnover including pregnancy, anemia, hemolysis and/or iron deficiency.
VII. Management

A. Goals of therapy
1. Normalization of blood glucose values and A1C (see Table 1 for goals).
2. Decrease risk for acute and chronic complications of diabetes
3. Maintain normal growth and weight
4. Control of co-morbidities such as hypertension and hyperlipidemia

B. Annual influenza vaccination. If pneumococcal vaccine not previously given in their lifetime, administer one time only.

C. Microalbuminuria - ACE inhibitor preferred for patients with persistently elevated microalbuminuria (refer to Table 6).

Table 6: Definition of abnormalities in albumin excretion

<table>
<thead>
<tr>
<th>Category</th>
<th>Spot collection (μg /mg of creatinine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt; 30</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>30-299</td>
</tr>
<tr>
<td>Macroalbuminuria (clinical)</td>
<td>≥ 300</td>
</tr>
</tbody>
</table>

D. Hypertension
1. High-normal blood pressure defined as systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height. Use lifestyle modifications including dietary intervention, increased physical activity, and exercise aimed at weight control if appropriate.
2. If target blood pressure not reached within 3-6 months, initiate pharmacologic treatment.
3. Hypertension defined as an average systolic or diastolic blood pressure above the 95th percentile for age, sex, and height measured on at least three separate days.
4. ACE inhibitor preferred for initial treatment of hypertension if not contraindicated. See Children & Adolescent Hypertension disease management guideline for complete details.

E. Hyperlipidemia
1. Initial therapy consists of optimizing glucose control and instituting lifestyle changes. Recommended to restrict saturated fats to 7% of total calories and restrict dietary cholesterol to 200mg/day.
2. Statin therapy is recommended in children over the age of 10* if LDL is persistently elevated despite lifestyle modifications (refer to Table 7).

Table 7: Treatment of Hyperlipidemia

<table>
<thead>
<tr>
<th>Value</th>
<th>Management*</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL 100-129mg/dl</td>
<td>• Optimize glycemic control and initiate lifestyle changes including diet,</td>
<td>LDL &lt; 100mg/dl</td>
</tr>
<tr>
<td></td>
<td>weight loss if overweight and exercise</td>
<td></td>
</tr>
<tr>
<td>LDL 130-150mg/dl</td>
<td>• Optimize glycemic control and initiate lifestyle changes including diet,</td>
<td>LDL &lt; 150mg/dl</td>
</tr>
<tr>
<td>plus 1 cardiovascular risk factor</td>
<td>weight loss if overweight and exercise</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Consider drug therapy based on patient’s risk factors for CVD if goal LDL not met after 6 months of lifestyle changes.</td>
<td></td>
</tr>
<tr>
<td>LDL &gt; 160mg/dl</td>
<td>• Optimize glycemic control and initiate lifestyle changes including diet,</td>
<td>LDL &lt; 100mg/dl</td>
</tr>
<tr>
<td></td>
<td>weight loss if overweight and exercise</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Initiate drug therapy with statin agent if not contraindicated</td>
<td></td>
</tr>
</tbody>
</table>

*No statin is approved for use under the age of 10 years.
F. Type 1 diabetes

1. All patients should be encouraged to begin lifestyle modifications.
   a) Diet including the reinforcement of consistent food intake based upon individual dietary needs and comorbidities
   b) Exercise
   c) Decreasing time spent in sedentary activities (e.g., watching television)
   d) Weight loss if overweight
   e) Smoking cessation counseling

2. Celiac disease screening
   a) Recommended soon after diagnosis of diabetes if clinically indicated by measuring tissue transglutaminase or antiendomysial antibodies, with documentation of normal serum IgA levels.
   b) Repeat testing if growth failure occurs, failure to gain weight, weight loss, or gastroenterologic symptoms occur.
   c) Gastroenterologist consultation should be considered in children with positive antibodies.
   d) Patients with confirmed celiac disease should be placed on a gluten-free diet.

3. Insulin
   a) Dosing

<table>
<thead>
<tr>
<th>NPH/Regular</th>
<th>Detemir (Levemir®) / Regular Insulin</th>
<th>Glargine (Lantus®) / Regular Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDD = 0.5 units/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Designate 66% of the TDD to NPH insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Administer 1/3 of NPH dose in the am before breakfast, and 1/3 of NPH dose in the pm before dinner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Remaining 33% of the TDD is allocated to Regular insulin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Divide Regular insulin before breakfast and before dinner as required by patient.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example: 40kg patient
40kg x 0.5 units/kg/day = 20u TDD
NPH insulin: 12u → 10u TDD
9u qam and 2u qpm
Reg insulin: 7u → 4u before breakfast and 3u before dinner.

Notes: Refer to Table 9 for the pharmacokinetics of NPH and Regular insulin

<table>
<thead>
<tr>
<th>NPH/Regular</th>
<th>Detemir (Levemir®) / Regular Insulin</th>
<th>Glargine (Lantus®) / Regular Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDD = 0.5 units/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Designate 50% of the TDD to detemir insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Administer 1/2 of the detemir insulin in the am before breakfast and 1/2 of detemir insulin before dinner.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Remaining 50% of the TDD is allocated to Regular insulin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Divide Regular insulin before breakfast, lunch and dinner as required by patient.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example: 40kg patient
40kg x 0.5 units/kg/day = 20u TDD
Detemir insulin: 10u → 5u qam and 5u qpm
Reg insulin: 10u → 4u before breakfast, lunch and dinner.

Notes:
• Do not mix detemir with other insulins.
• NPH to detemir conversion: reduce TDD by 20%

<table>
<thead>
<tr>
<th>NPH/Regular</th>
<th>Detemir (Levemir®) / Regular Insulin</th>
<th>Glargine (Lantus®) / Regular Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDD = 0.5 units/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Designate 50% of the TDD to glargine insulin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Administer 100% of glargine in the am or pm.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• May also be dosed twice daily if necessary for control.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Remaining 50% of the TDD is allocated to Regular insulin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Divide Regular insulin before breakfast, lunch and dinner as required by patient.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example: 40kg patient
40kg x 0.5 units/kg/day = 20u TDD
Glargine insulin: 10u → 10u once a day or 5u qam and 5u qpm
Reg insulin: 10u → 4u before breakfast, lunch and dinner.

Notes:
• Do not mix glargine with other insulins.
• NPH to glargine conversion: reduce TDD by 20%.
b) May need to initiate regular sliding scale as a temporary measure to stabilize blood glucose and to establish dose of regular insulin (refer to Table 12).

c) Honeymoon phase – May occur within weeks of diagnosis and lasting up to several months. It is a period when insulin requirements may fall to 0.1-0.3 units/kg/day and the patient is at increased risk for hypoglycemic episodes. As the honeymoon phase ends, insulin requirements gradually increase over several months.

d) Prepubertal children generally require between 0.5 to 0.9 units/kg/day.

e) During puberty, insulin requirements generally increase due to increased caloric intake, growth spurts, and hormone changes. Insulin requirements may be as high as 1.5 units/kg/day.

f) After puberty, insulin requirements generally decrease to less than 1 unit/kg/day.

G. Type 2 diabetes

1. All patients should be encouraged to begin lifestyle modifications.
   a) Diet including the importance of consistent food intake
   b) Exercise
   c) Decreasing time spent in sedentary activities (e.g., watching television)
   d) Weight loss if overweight
   e) Smoking cessation counseling

2. Symptomatic patients:
   a) Patients with more serious symptoms such as dehydration, ketosis, and acidosis may require insulin for initial treatment. Tapering of insulin and introduction of oral agents can be attempted once symptoms resolve and glycemic control improves.
   b) Patients with less severe symptoms may be treated with oral therapy.

3. Asymptomatic patients: Patients can be given an initial trial of lifestyle modifications. If glycemic control is not achieved, therapy with oral agents should be started.
   a) Metformin - Recommended first line therapy since it does not generally cause hypoglycemia and weight gain.
   b) Patients who present initially with poor glycemic control (BG > 200mg/dl or A1c >9%), but lack evidence of ketosis or ketoacidosis may benefit from initial treatment with insulin. Tapering of insulin and introduction of oral agents can be attempted once glycemic control improves.
   c) Routine use of thiazolidinediones (e.g., rosiglitazone, pioglitazone) is not recommended in children.
   d) Insulin preferred during pregnancy
<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>500mg qd.bid Max 2500mg/day</td>
<td>• Contraindications: Impaired renal function, radiocontrast media, hypoxemic conditions, hepatic disease, metabolic acidosis, hypersensitivity to metformin • Pregnancy category B</td>
</tr>
<tr>
<td>Insulin</td>
<td>0.5 to 1 units/kg/day</td>
<td>• Contraindications: Hypersensitivity to insulin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insulin requirements may decrease in newly diagnosed patients during the honeymoon phase</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Insulin requirements may increase during puberty to as much as 1.5 units/kg/day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pregnancy category B</td>
</tr>
<tr>
<td>Lisinopril</td>
<td>3.5mg qd Max 40mg/day</td>
<td>• Contraindications: ACE-inhibitor induced angioedema, hereditary or idiopathic angioedema, pregnancy, hypersensitivity to lisinopril or other ACE inhibitors • Pregnancy category D</td>
</tr>
<tr>
<td>Pravastatin</td>
<td>Max 80mg/day</td>
<td>• Contraindications: Active liver disease, unexplained persistent elevations of serum transaminases, pregnancy, hypersensitivity to statins or any component of the formulation • Pregnancy category X</td>
</tr>
</tbody>
</table>

**Table 9: Antidiabetic Agents**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Onset of Action</th>
<th>Peak Action</th>
<th>Effective Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular Insulin</td>
<td>30 to 60 min</td>
<td>2 to 3 hours</td>
<td>8 to 10 hours</td>
</tr>
<tr>
<td>NPH Insulin</td>
<td>2 to 4 hours</td>
<td>4 to 10 hours</td>
<td>12 to 18 hours</td>
</tr>
</tbody>
</table>

**Table 10: Pharmacokinetics of Insulin**

*The pharmacokinetics of insulin preparations may be used to determine which insulin to adjust when a patient is experiencing symptoms of low or high blood glucose.

Examples:
1. If patient is symptomatic of hypoglycemia around 9am and he or she injected NPH and Regular insulin at 4am, most likely it is the NPH that needs to be adjusted as it is peaking 5 hours after injection.
2. If patient is symptomatic of hyperglycemia after dinner, the Regular insulin will need to be adjusted as its onset of action is faster than the NPH.

**Table 11: Hypoglycemia Management**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose 15-20g</td>
<td>Preferred treatment for conscious individual with hypoglycemia, but any form of carbohydrate may be used. If blood sugar 15 mins after treatment shows continued hypoglycemia, repeat treatment. Once blood sugar normal, have the individual consume a meal or snack to prevent recurrence.</td>
</tr>
<tr>
<td>Glucagon</td>
<td>Treat individuals at significant risk of severe hypoglycemia</td>
</tr>
<tr>
<td>Hypoglycemia Unawareness</td>
<td>Individuals who are unaware of hypoglycemia and suffer from one or more episodes of severe hypoglycemia should have their glycemic targets raised for at least several weeks.</td>
</tr>
</tbody>
</table>

---

345
### Table 12: Correlation of A1C with average glucose

<table>
<thead>
<tr>
<th>A1C (%)</th>
<th>Mean plasma glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mg/dl</td>
</tr>
<tr>
<td>6</td>
<td>126</td>
</tr>
<tr>
<td>7</td>
<td>154</td>
</tr>
<tr>
<td>8</td>
<td>183</td>
</tr>
<tr>
<td>9</td>
<td>212</td>
</tr>
<tr>
<td>10</td>
<td>240</td>
</tr>
<tr>
<td>11</td>
<td>269</td>
</tr>
<tr>
<td>12</td>
<td>298</td>
</tr>
</tbody>
</table>

### Table 13: Sample Regular Insulin Sliding Scale

<table>
<thead>
<tr>
<th>Blood glucose range (mg/dl)</th>
<th>Units of regular insulin to be administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>150-200</td>
<td>2</td>
</tr>
<tr>
<td>201-250</td>
<td>4</td>
</tr>
<tr>
<td>251-300</td>
<td>6</td>
</tr>
<tr>
<td>301-350</td>
<td>8</td>
</tr>
<tr>
<td>351-400</td>
<td>10</td>
</tr>
<tr>
<td>401-451</td>
<td>12</td>
</tr>
<tr>
<td>&gt;500</td>
<td>Check for ketones. Contact unit provider.</td>
</tr>
</tbody>
</table>
EDUCATION FOR PATIENTS AND PRACTITIONERS

I. Who is educated?
   A. The Unit Team – updated on diabetes so accurate and easy to understand information is provided to patients.
   B. All diabetic patients

II. Who educates?
   A. The Unit Team will delegate educational responsibility
      1. Educator must document date and time of education in the patient’s medical record.
      2. Physician and mid-level providers have final responsibility to ensure education occurs (if not documented on chart as completed by some other designated education provider, must provide diabetes education at clinic visit).
      3. Units with available dieticians will provide counseling on diet and how to choose the correct foods from the meal line; otherwise, diet counseling will be completed by the diabetes educator.

III. When does education take place?
   A. Within the patient’s first week of stay on unit assignment OR at the initial visit to clinic, whichever is sooner.
   B. Education will be reinforced at each clinic visit.

IV. What is included in diabetes education? (to include health services personnel and diabetic patients)
   A. Pathophysiology of Type 1 versus Type 2 diabetes
   B. Non-pharmacologic treatment plan & importance of lifestyle modifications
      Physical activity:
      1. Recommend at least 150 min/week of moderate-intensity aerobic physical activity (50-70% of maximum heart rate).
      2. In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week.
   C. Signs, symptoms, and treatment for acute and chronic complications (i.e., hypoglycemia, hyperglycemia, and DKA if Type 1)
   D. Monitoring parameters – frequency and importance
   E. Complications of diabetes (i.e. retinopathy, neuropathy, nephropathy, cardiovascular, cerebrovascular, and peripheral vascular disease)
   F. Proper techniques of administering insulin for all patients on insulin (i.e. proper self-administration, insulin preparation, mixing, and administration sites)
   G. Patient self-monitoring to include foot, skin, and wound care
      Foot/skin care tips:
      1. Watch for pain, numbness, and/or wounds that will not heal.
      2. Keep skin supple by drinking plenty of water. Never put lotion or moisturizers between the toes.
      3. Wash feet daily with lukewarm water and soap.
      4. Dry feet well, especially between the toes.
      5. Check feet daily (including bottoms and between toes) for sores, redness, and swelling.
      6. Change into clean socks daily.
      7. Keep feet warm and dry.
      8. Never walk barefoot.
      10. Examine shoes daily for things that could hurt your feet such as rocks or debris.
   H. Dental hygiene to include daily brushing in the morning and evening and flossing once daily.
   I. Dietary Modifications (e.g. control of carbohydrate intake)
Prominent reactive, impulsive aggression during explosive outbursts not better accounted for by Bipolar Disorder, depression, psychosis, ADHD, or ODD. May meet DSM-5 criteria for disruptive, impulse-control, and conduct disorders. This DMG may be particularly useful in treating disruptive mood dysregulation disorders (DMDD), as temper outbursts and aggression are cardinal symptoms of DMDD. Individuals with explosive/reactive aggression often display low frustration tolerance, < 3 second impulse control, poor coping skills, lack of regard for consequences, and little awareness of behavior until arousal abates. May have history of developmental disorders, low cognitive functioning, exposure to neurotoxic substances (or other CNS insults) or display subtle congenital anomalies.

1. Treat co-morbid ADHD, affective disorders or psychosis if present.

2. Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

3. Initiate monotherapy with formulary atypical antipsychotic risperidone, and continue for 4-6 weeks at a therapeutic dose.

4. Inadequate response per BPRS: Continue monotherapy with alternative formulary antipsychotic (ziprasidone) after obtaining a pre-treatment EKG. Continue ziprasidone for 4-6 weeks at a therapeutic dose.

5. Inadequate response per BPRS: Assess compliance.

6. Partial response per BPRS: Initiate monotherapy with formulary atypical antipsychotic (ziprasidone) after obtaining a pre-treatment EKG. Continue ziprasidone for 4-6 weeks at a therapeutic dose.


8. Partial response per BPRS: Initiate monotherapy with alternative formulary prior authorization atypical antipsychotic not tried above (aripiprazole), and continue for 4-6 weeks at a therapeutic dose.


10. Partial response per BPRS: Initiate monotherapy with alternative formulary antipsychotic (aripiprazole), and continue for 4-6 weeks at a therapeutic dose.


12. Partial response per BPRS: Consider alternative agents (e.g., propranolol, SSRI) and/or psychopharmacology consultation.

Adequate response per BPRS

The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Prepared by the Texas Juvenile Justice Department (formerly known as the Texas Youth Commission) and Reviewed by the Correctional Managed Care Pharmacy & Therapeutics Committee: October 2001, revised 5/02, 10/02, 10/04, 01/05, 03/06, 09/06, 04/07, 02/10, 06/11, 04/12, 02/14, 05/17.
Formulary agents may be prescribed without restrictions based on patient assessment and clinical judgment. Newly diagnosed patients should receive a therapeutic trial of risperidone and ziprasidone, unless clearly not indicated. Recommended dosing for initiation of risperidone (Table 1) and ziprasidone is provided below.

### Table 1: Risperidone Dosing

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risperidone</td>
<td>0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg tablet</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2: Formulary Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Generation Antipsychotics</td>
<td>Chlorpromazine</td>
<td>50 mg, 100 mg, 200 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Haloperidol</td>
<td>2.5 mg, 5 mg, 10 mg tablet; 2.5 mg/ml inj; 25 mg/ml decanoate inj</td>
</tr>
<tr>
<td></td>
<td>Thiothixene</td>
<td>2.5 mg, 5 mg, 10 mg tablet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Generation Antipsychotics</td>
<td>Risperidone</td>
<td>0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Ziprasidone</td>
<td>20 mg, 40 mg, 60 mg, 80 mg capsule; 20 mg/ml injection</td>
</tr>
</tbody>
</table>

### Notes:

- Titration may vary by tolerability and response. Some may stabilize on lower doses or require slower titration.
- Lower doses of antipsychotic medications are generally adequate in controlling aggressive symptoms compared to doses used to treat psychotic disorders.
- Patients diagnosed with intellectual disabilities tend to have a higher frequency of side effects and may require greater monitoring, lower dosages of medications, and slower dosage titration and tapering.

### Table 3: Prior Authorization Agents*

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication &amp; Strength</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Generation Antipsychotic</td>
<td>Aripiprazole (Abilify®) 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg tablet</td>
<td>Intolerant to formulary 2nd generation antipsychotics</td>
</tr>
<tr>
<td></td>
<td>Met criteria must be listed in the special instructions field of the medication order in the EMR. Other uses require non-formulary approval.</td>
<td></td>
</tr>
</tbody>
</table>

### Switching Medications

Switching stable patients to another antipsychotic is best done by cross-titration. The patient should be titrated to a comparable therapeutic dose of the new antipsychotic and then tapered off the initial antipsychotic by one-third to one-fourth of the initial daily dosage at weekly intervals (beginning one week after the goal dose of the new antipsychotic is achieved) until discontinued. Table 4 outlines alternative strategies for switching patients via agent-specific cross-titration schedules.

### Notes:

- If patient is on more than the maximum dose, taper down to that dose before beginning the cross titration.
- Providers should be sure to complete cross-titration so that patients are not left on two antipsychotics indefinitely.
### Tapering and discontinuing medications

It is recommended that providers consider tapering medications in patients who have experienced remission in aggressive symptoms for 6 months or longer.

- Consider reducing dose by 25% every 2–4 weeks
- If patient tolerates the tapering of dose, the medication should be discontinued

### Antipsychotic Monitoring Parameters in Children and Adolescents Receiving Antipsychotic Pharmacotherapy

#### Table 5: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents in Children and Adolescents

Providers should consider obtaining any of the laboratories listed above more frequently if clinically indicated.

1. Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease. Given ziprasidone’s increased risk for QTc prolongation, an alternative antipsychotic should be considered if the baseline QTc is > 450 msec in males and >470 msec in females.

   Ziprasidone discontinuation is advised if the QTc rises above 500 msec, or increases by > 30-60 msec during treatment.

2. Providers should consider obtaining prolactin at baseline and periodically when there is a history of galactorrhea, amenorrhea, or gynecomastia.

#### Table 6: Outcomes and Adverse Effect Monitoring

Assessment | Baseline | Follow-up
---|---|---
AIMS (Abnormal Involuntary Movement Scale) | X | Baseline, at 3 months, then annually
Acute EPS - Akathisia | | 
Tardive Dyskinesia | | 
BPRS (Brief Psychiatric Rating Scale) | X | Baseline and at each visit to assess response to treatment when a medication is started, changed or discontinued

---

### Medication Tapering

<table>
<thead>
<tr>
<th>Medication Tapering</th>
<th>Max Daily Dose</th>
<th>Day 1-4</th>
<th>Day 5-8</th>
<th>Day 9-12</th>
<th>Day 13-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quetiapine</td>
<td>200 mg TID</td>
<td>100 mg 100 mg 200 mg</td>
<td>100 mg TID</td>
<td>100 mg BID</td>
<td>50 mg BID</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>10 mg daily</td>
<td>10 mg daily</td>
<td>7 mg daily</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7: Occurrence of Adverse Effects of Antipsychotic Agents in Children and Adolescents

<table>
<thead>
<tr>
<th>Drug</th>
<th>EPS</th>
<th>Hyperprolactinemia</th>
<th>Weight Gain</th>
<th>Sedation</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol</td>
<td>+++</td>
<td>++</td>
<td></td>
<td>++</td>
<td>TD, NMS</td>
</tr>
<tr>
<td>Risperidone</td>
<td>+</td>
<td>+++</td>
<td></td>
<td>++</td>
<td>Depression</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>++/-</td>
<td>+++</td>
<td>++; ++</td>
<td>++</td>
<td>Lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Clozapine</td>
<td>-</td>
<td>-</td>
<td>; +++</td>
<td>+++</td>
<td>Agranulocytosis, Seizures, lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>++/-</td>
<td>+/-</td>
<td></td>
<td>+</td>
<td>QTc prolongation</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>++/-</td>
<td>+/-</td>
<td></td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>++/-</td>
<td>+/-</td>
<td></td>
<td>-</td>
<td>EPS is typically akathisia</td>
</tr>
</tbody>
</table>

EPS = extrapyramidal symptoms  - = absent  +++ = most probably rare  ++ = rare  + = low frequency  +++ = high frequency
NMS = neuroleptic malignant syndrome  eps = most probably rare
TD = tardive dyskinesia  ++ = low frequency  +++ = high frequency

Table 8: Adverse Effect Management

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Recommended Management Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPS</td>
<td>• Lower the dose of the antipsychotic agent to the lowest effective dose or&lt;br&gt;• Review table 8 and consider selecting an agent with a lower incidence of EPS or&lt;br&gt;• Treat EPS with one of the following agents:&lt;br&gt;  • Benztropine 1 – 6 mg/day&lt;br&gt;  • Diphenhydramine 25 – 100 mg/day&lt;br&gt;  • Propranolol may be considered for akathisia. Extreme caution should be exercised with dose monitoring for bradycardia and hypotension. Propranolol should be avoided in patients with a diagnosis of asthma.</td>
</tr>
<tr>
<td>Tardive dyskinesia</td>
<td>• Diagnosis supported by AIMS?&lt;br&gt;• Switch to a second generation antipsychotic if currently receiving a first generation antipsychotic&lt;br&gt;• Discontinue anticholinergic medication&lt;br&gt;• Consider pharmacotherapy consult for treatment options</td>
</tr>
<tr>
<td>Neuroleptic Malignant Syndrome</td>
<td>• Medical emergency&lt;br&gt;• Evaluate through medical department for possible referral to emergency room&lt;br&gt;• Discontinue antipsychotic</td>
</tr>
</tbody>
</table>

Table 9: Formulary Mood Stabilizers

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Form</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsant</td>
<td>Carbamazepine</td>
<td>Tegretol®</td>
<td>Tablet</td>
<td>200 mg</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>Divalproex Sodium</td>
<td>Depakote®</td>
<td>EC Tablet</td>
<td>250 mg, 500 mg</td>
</tr>
<tr>
<td>Antimanic Agent</td>
<td>Lithium carbonate</td>
<td>Eskalith®</td>
<td>Capsule</td>
<td>300 mg</td>
</tr>
</tbody>
</table>
Lithium General Information

Therapeutic effects of lithium are seen 10–14 days after a therapeutic level has been achieved. It may take up to 6 weeks to see full effects of a given dosage. Levels should be drawn 5–10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase or decrease lithium renal clearance (e.g., ACE inhibitors, calcium channel blockers, diuretics, NSAIDs, SSRIs, theophylline) or if there is a change in renal function. The lithium serum level should be obtained immediately before the next dose and at least 12 hours after the last dose.

Common side effects: sedation, thirst, urinary frequency. Other side effects: hypothyroid, confusion, toxicity, acne, increased WBCs

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>Every 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG*</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, SCr, Electrolytes, TSH</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Lithium levels</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

*Providers should consider obtaining an EKG periodically during lithium treatment when there is a personal or family history of cardiovascular disease.

Table 10: Frequency of Lithium Monitoring

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>4 weeks</th>
<th>Every 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG*</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, SCr, Electrolytes, TSH</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Lithium levels</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Table 11: Toxicity Information

<table>
<thead>
<tr>
<th>Drug, Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Seen Starting At Trough Serum Level of</th>
<th>Signs &amp; Symptoms of Toxicity (dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium: Initially 900–1200 mg daily in 1 to 3 divided doses. Target level 0.5–1.2 mEq/L</td>
<td>- Hypersensitivity to lithium</td>
<td>- Serum potassium &gt; 5.5 mEq/L</td>
<td>- Dose-related toxicity</td>
</tr>
</tbody>
</table>
Divalproex General Information

At baseline, CBC, liver function tests, and platelet counts should be obtained. Dose may be titrated on a weekly basis until 12-hour post-dose serum concentrations reach 75-115 mg/mL. After therapeutic serum levels have been achieved, it may take up to 4 weeks for the drug to achieve maximum effectiveness. Obtain levels 1-3 weeks following initiation, change in dose, addition of other CNS agents to the patient’s regimen, or observed signs/symptoms of toxicity. Warning (1 in 500) for suicidal ideation.

Common side effects: sedation, weight gain, hair loss, tremor, bowel changes

Rare side effects: liver problems, decreased thyroid function, decreased platelets

Table 12: Frequency of Divalproex Monitoring

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>1 month</th>
<th>2 months</th>
<th>Every 3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC with differential, LFTs</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Platelet</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Divalproex levels</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

Table 13: Toxicity Information

<table>
<thead>
<tr>
<th>Drug/Dose Range</th>
<th>Toxicity Seen Starting At Trough Serum Levels of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divalproex: 15 mg/kg/day or 1,250 mg/day given in divided doses up to 60 mg/kg/day</td>
<td></td>
</tr>
<tr>
<td>Target level: 75-115 mg/mL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptom Cluster</th>
<th>Signs &amp; Symptoms of Toxicity (dose-related)</th>
<th>Signs &amp; Symptoms of Toxicity (NOT dose-related)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity to valproate</td>
<td>Nausea, vomiting</td>
<td>Hypersensitivity, tolerance</td>
</tr>
<tr>
<td>Uremia</td>
<td>Psychosis, confusion</td>
<td>Nausea, vomiting</td>
</tr>
<tr>
<td>Urea cycle disorder</td>
<td>Dysgeusia</td>
<td>Psychosis, confusion</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Hyperammonemia</td>
<td>Dysgeusia</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Hypertrophy</td>
<td>Hyperammonemia</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Hyperactivity</td>
<td>Hypertrophy</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Headache</td>
<td>Hyperactivity</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Vomiting</td>
<td>Headache</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Thrombocytopenia</td>
<td>Vomiting</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Disseminated intravascular coagulation</td>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Alopecia</td>
<td>Disseminated intravascular coagulation</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Pancreatitis</td>
<td>Alopecia</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Do not rechallenge</td>
<td>Pancreatitis</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Hyperammonemic encephalopathy</td>
<td>Do not rechallenge</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Hepatic toxicity, severe or fatal</td>
<td>Hyperammonemic encephalopathy</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Stevens-Johnson Syndrome</td>
<td>Hepatic toxicity, severe or fatal</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Toxic epidermal necrolysis</td>
<td>Stevens-Johnson Syndrome</td>
</tr>
<tr>
<td>Pancytopenia</td>
<td>Polycystic ovarian syndrome</td>
<td>Toxic epidermal necrolysis</td>
</tr>
</tbody>
</table>

**BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician**

**Background:** The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed an antipsychotic.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

**Instructions for Use and Scoring:** Each item is rated on a seven-point scale (1=not present to 7=extremely severe). The assessments may be performed by a clinician or other qualified professional. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe</td>
</tr>
</tbody>
</table>

1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.

2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness.

3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.

4. CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.

5. IMPULSIVENESS - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.

6. MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).

7. GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.

8. DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.

9. HOSTILITY - Animosity, contempt, belligerence, disdain for others.

10. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.

11. HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.

12. MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.

13. UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.

14. DISORIENTATION - Confusion or lack of proper association for person, place or time.

15. ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.

16. SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.

17. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.

18. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.

19. DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual's attention may be drawn to noise in adjoining rooms, books on a shelf, interviewer's clothing, etc.
Hypertension (HTN): (Children & Adolescents)


Blood Pressure Classification

<table>
<thead>
<tr>
<th>Age &lt;13 yrs</th>
<th>Age ≥ 13 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;90&lt;sup&gt;th&lt;/sup&gt; percentile</td>
</tr>
<tr>
<td>Elevated</td>
<td>&gt;90&lt;sup&gt;th&lt;/sup&gt; to &lt;95&lt;sup&gt;th&lt;/sup&gt; percentile OR 120/&lt;80 mmHg to &lt;95&lt;sup&gt;th&lt;/sup&gt; percentile</td>
</tr>
<tr>
<td>Stage 1 HTN</td>
<td>≥ 95&lt;sup&gt;th&lt;/sup&gt; percentile + 12 mmHg OR 130/&lt;89 mmHg (whichever is lower)</td>
</tr>
<tr>
<td>Stage 2 HTN</td>
<td>≥ 95&lt;sup&gt;th&lt;/sup&gt; percentile + 12 mmHg OR 140/&lt;90 mmHg (whichever is lower)</td>
</tr>
</tbody>
</table>

1. Determine blood pressure (BP) classification as normal, elevated, stage 1 HTN, or stage 2 HTN per table 1.

2. Encourage healthy diet, sleep, & exercise.
3. Follow-up as needed and recheck BP at next regularly scheduled visit.

4. Is BP "normal"?
   - Yes
   - No

   Is BP elevated?
   - Yes
   - No

5. Does the patient have compelling indications (diabetes or CKD)?
   - Yes
   - Initiate lisinopril. See table 3 for dosing. Follow up within 4-6 weeks.
   - Yes
   - No

   Proceed to box 3.

6. Encourage healthy diet, sleep, & exercise.
7. Follow-up as needed and recheck BP at next regularly scheduled visit.

8. Is BP still elevated?
   - Yes
   - No

   Check upper and lower extremity BP.
   - Yes
   - No

9. Test results for left arm and right arm:
   - Yes
   - No

   Lifestyle counseling should be repeated and BP should be rechecked in 6 months by auscultation.

10. Is BP still elevated?
    - Yes
    - No

    Lifestyle counseling should be repeated and BP should be rechecked in 3 months by auscultation.

11. Is BP still elevated?
    - Yes
    - No

    Check upper and lower extremity BP.
    - Yes
    - No

    Lifestyle counseling should be repeated and BP should be rechecked in 1 week by auscultation.

12. Is BP still at stage 1?
    - Yes
    - No

    Consider subspecialty referral.

13. Is BP still at stage 2?
    - Yes
    - No

    Initiate lisinopril, hydrochlorothiazide, or amlodipine. See table 3 for dosing. Follow up within 4-6 weeks.

14. Is BP still at stage 2?
    - Yes
    - No

    Lifestyle counseling should be repeated and BP should be rechecked in 1 week by auscultation.

15. Is BP still at stage 2?
    - Yes
    - No

    If symptomatic, proceed to box 25 and initiate treatment.

16. Is BP still at stage 2?
    - Yes
    - No

    Initiate lisinopril, hydrochlorothiazide, or amlodipine. See table 3 for dosing. Follow up within 4-6 weeks.

17. Is BP still at stage 2?
    - Yes
    - No

    Consider subspecialty referral.

18. Proceed to box 26 on page 2.

The pathways do not replace sound clinical judgment as the patient may have other diagnoses.

Elevated BP must be confirmed on repeated visits, using a minimum of 3 readings.

Blood Pressure Classification

<table>
<thead>
<tr>
<th>Age &lt;13 yrs</th>
<th>Age ≥ 13 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;90&lt;sup&gt;th&lt;/sup&gt; percentile</td>
</tr>
<tr>
<td>Elevated</td>
<td>&gt;90&lt;sup&gt;th&lt;/sup&gt; to &lt;95&lt;sup&gt;th&lt;/sup&gt; percentile OR 120/&lt;80 mmHg to &lt;95&lt;sup&gt;th&lt;/sup&gt; percentile (whichever is lower)</td>
</tr>
<tr>
<td>Stage 1 HTN</td>
<td>≥ 95&lt;sup&gt;th&lt;/sup&gt; percentile + 12 mmHg OR 130/&lt;89 mmHg (whichever is lower)</td>
</tr>
<tr>
<td>Stage 2 HTN</td>
<td>≥ 95&lt;sup&gt;th&lt;/sup&gt; percentile + 12 mmHg OR 140/&lt;90 mmHg (whichever is lower)</td>
</tr>
</tbody>
</table>

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
At follow-up visit, is BP at goal? (SBP and DBP < 90th percentile and < 130/80 mmHg in adolescents > 13 years old)

1. Increase dose as tolerated
   - Follow up in 4-8 weeks
   - Continue to increase dose until BP is at goal, the max dose is reached, or adverse effects occur
   - Counsel patient on the importance of medication adherence

2. Is BP at goal on maximized single-agent regimen?
   - Yes
     - 1. Continue current treatment
     - 2. Continue to encourage lifestyle modifications
     - 3. Follow up every 3-4 months
   - No
     - 1. Initiate a second agent
     - Follow up in 4-6 weeks
     - Continue to increase dose until BP is at goal, the max dose is reached, or adverse effects occur
     - Counsel patient on the importance of medication compliance

3. Is BP at goal on maximized dual-agent regimen?
   - Yes
     - 1. Continue current treatment
     - 2. Continue to encourage lifestyle modifications
     - 3. Follow up every 3-4 months
   - No
     - 1. Consider intense individualized counseling
     - 2. Consider DOT for a short time period
     - 3. Consider obtaining a pharmacotherapy consult
I. Detection and Confirmation
   A. Blood pressure (BP) measurement:
      1. Appropriate cuff size must be used to ensure accurate readings. The cuff bladder length should cover
         80-100% of the circumference of the arm and the width at least 40%.
      2. Patients should be seated in a chair with their backs supported, feet on the floor, and their arms
         supported at heart level.
      3. BP measurements should be obtained after the patient has been at rest for at least 3-5 minutes.
   B. Elevated BP must be confirmed on repeated visits (after 3 visits) with an average of at least 3 BP
      measurements.
   C. If the initial BP is elevated, providers should perform 2 additional oscillometric or auscultatory BP
      measurements.
   D. If the averaged reading on an electronic device is >90th percentile, 2 auscultatory measurements should
      be taken and averaged to define the BP category.
   E. BP levels are determined by gender, age, and height in children and adolescents using Appendices A and B.

II. Patient Evaluation
   A. History
      1. Sleep history
      2. Family history
      3. Medication history
      4. Past medical history including known duration and levels of elevated blood pressure
      5. Psychosocial history
      6. Perinatal history including gestational age and birth weight
      7. History of weight and physical activity
      8. Symptoms suggestive of hypertension (headache, nose bleeds, dizziness, abnormal physical exam)
      9. Dietary assessment including intake of sodium, alcohol, saturated fat, total fat, caffeine, and sugary
         beverages. Infrequent consumption of fruits, vegetables, and low-fat dairy should also be identified.
   B. Laboratory/Diagnostic Evaluation – Recommended at baseline and annually.
      1. All patients:
         a) Urinalysis
         b) BUN, creatinine
         c) Electrolytes
         d) Fasting lipid panel
      2. In obese patients (if BMI > 95th percentile), the following additional tests should be obtained:
         a) A1C
         b) AST and ALT
   C. Physical exam
      1. Height and weight - BMI (body mass index)
      2. Blood pressure & other vitals
      3. Fundoscopic examination for retinal changes
      4. Examination of the neck, lungs, abdomen, extremities, and skin for abnormalities
      5. Examination of the heart for abnormalities in rate and rhythm, increased size, precordial heave, clicks, murmurs,
         and third and fourth heart sounds
   D. Evaluate patient for secondary causes – The majority of children with secondary HTN will have renal or
      renovascular causes for blood pressure elevation. Other secondary causes include:
      1. Coarctation of the aorta
      2. Endocrine HTN
      3. Environmental exposures (lead, cadmium, mercury, phthalates)
      4. Neurofibromatosis
      5. Medication-induced (oral contraceptives, CNS stimulants, corticosteroids, OTC decongestants)
III. Treatment
A. Lifestyle and Non-pharmacologic Interventions
1. Dietary modification: the DASH Diet is recommended (high in fruits, vegetables, low-fat milk products, whole grains, fish, poultry, nuts, and lean red meat; limited intake of sugar and sweets along with a low sodium intake)
2. Physical Activity: Recommend moderate to vigorous physical activity at least 3-5 days per week (30-60 minutes per session)
3. Weight reduction for overweight and obese patients
4. Stress reduction techniques
5. Smoking cessation
B. Drug therapy
1. Goal of therapy
   a) Adolescents ≥ 13 years old: SBP and DBP < 90th percentile and <130/80 mmHg
   b) Children under the age of 13: SBP and DBP < 90th percentile
2. Drug selection
   a) May consider ACE inhibitors, long-acting calcium channel blockers (CCB), or a thiazide diuretic as first-line therapy. However, choice should be directed by co-morbidities unless drug selection is contraindicated.
   b) Because African American children may not respond as well to ACE inhibitors, a higher initial ACE inhibitor dose may be considered. Alternatively, a thiazide or long-acting CCB may be preferred as first-line.
   c) May consider step-down therapy in patients that have good blood pressure control with eventual discontinuation. The best candidates are patients that lose weight.

Table 2. Treatment Parameters

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>Lifestyle and Non-pharmacologic Interventions</th>
<th>Follow Up</th>
<th>Drug Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Encourage healthy diet, sleep and exercise</td>
<td>Follow up as needed</td>
<td>No drug therapy indicated</td>
</tr>
<tr>
<td>Elevated BP</td>
<td>• Weight loss if overweight or obese&lt;br&gt;• Exercise program&lt;br&gt;• Diet plan&lt;br&gt;• Stress reduction techniques</td>
<td>Recheck in 6 months. If after 12 months BP is still elevated (i.e., 3 auscultatory readings), consider sub-specialty referral.</td>
<td>No drug therapy indicated</td>
</tr>
<tr>
<td>Stage 1 Hypertension</td>
<td>• Weight loss if overweight or obese&lt;br&gt;• Exercise program&lt;br&gt;• Diet plan&lt;br&gt;• Stress reduction techniques</td>
<td>Recheck in 1-2 weeks. Recheck sooner if the patient is symptomatic. If BP at stage 1 HTN is confirmed on repeated visits (at least 2), begins treatment for stage 1 hypertension.</td>
<td>Initiate treatment with an ACEI, thiazide diuretic, or CCB if: 1. Persistent HTN with lifestyle changes 2. Compelling indication 3. Symptomatic HTN 4. Target organ damage 5. Secondary HTN 6. LV hypertrophy. Follow up should occur within 4-6 weeks</td>
</tr>
<tr>
<td>Stage 2 Hypertension</td>
<td>• Weight loss if overweight or obese&lt;br&gt;• Exercise program&lt;br&gt;• Diet plan&lt;br&gt;• Stress reduction techniques</td>
<td>Recheck within 1 week. If BP at stage 2 HTN is confirmed on repeat visits, treatment should be initiated.</td>
<td>Initiate therapy with ACEI, thiazide diuretic, or CCB. Follow up should occur within 4-6 weeks</td>
</tr>
</tbody>
</table>

358
<table>
<thead>
<tr>
<th>Drug</th>
<th>Place in Therapy</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Lisnopril (Prinivil®)       | First line       | 2.5, 5, 10, 20, and 40 mg     | • Initial: 0.07 mg/kg/day up to 5 mg/day given once daily  
• Max: 0.4 mg/kg/day given once daily  
• ACE inhibitor  
• FDA pediatric labeling for children ≥ 6 and GFR > 30 ml/min/1.73                                                                                     |
| Hydrochlorothiazide, HCTZ   | First line       | 12.5, 25, and 50 mg           | • Initial: 1 mg/kg/day given once daily  
• Max: 2 mg/kg/day up to 37.5 mg/day given once to twice daily  
• Diuretic  
• FDA pediatric labeling for all ages                                                                                                               |
| Amlodipine (Norvasc®)       | First line       | 5 and 10 mg                   | • Initial: ≥ 6 yrs: 2.5 mg/day given once daily  
• Max: 10 mg/day  
• Calcium channel blocker  
• FDA pediatric labeling for children ≥ 6 years old                                                                                                  |
| Atenolol (Tenormin®)        | Second line      | 25 and 50 mg                  | • Initial: 0.5 – 1 mg/kg/day in a single or divided dose  
• Max: 2 mg/kg/day up to 100 mg/day  
• Beta-blocker  
• No FDA pediatric labeling                                                                                                                        |
| Metoprolol (Lopressor®)     | Second line      | 25, 50 and 100 mg             | • No pediatric dosing available for metoprolol tartrate  
• Beta-Blocker                                                                                                                                     |
| Propranolol (Inderal®)      | Second line      | 2.5, 10, and 20 mg            | • Initial: 0.5 – 2 mg/kg/day given daily or bid  
• Max: 6 mg/kg/day  
• Beta-blocker  
• No FDA pediatric labeling                                                                                                                        |
| Furosemide (Lasix®)         | Second line      | 20 and 40 mg                  | • Initial: 0.5-2 mg/kg/day given daily or bid  
• Max: 6 mg/kg/day  
• Diuretic  
• No FDA pediatric labeling                                                                                                                        |
| Spironolactone (Aldactone®)| Second line      | 25 mg                         | • Initial: 1-3 mg/kg/day in single or divided doses  
• Max: 200 mg/24 hours  
• Diuretic  
• Dose should be reduced to 1-2 mg/kg/day for maintenance or when used in combination with other diuretics  
• No FDA pediatric labeling                                                                                                                        |
| Terazosin (Hytrin®)         | Third line       | 1, 2, 5, and 10 mg            | • Initial: 1 mg/kg/day given once daily  
• Max: 20 mg/day  
• Alpha-blocker  
• No FDA pediatric labeling                                                                                                                        |
| Minoxidil (Loniten®)        | Third line       | 2.5 and 10 mg                 | • Initial: 0.2-0.5 mg/kg/day in 4 divided doses  
• Max: 50 mg/day  
• Vasodilator  
• FDA pediatric labeling for refractory HTN  
• Reserved for resistant HTN                                                                                                                        |
| Hydralazine (Apresoline®)   | Third line       | 25 and 50 mg                  | • Initial: 0.25 mg/kg/day in 4 divided doses  
• Max: 75 mg per dose given every 6-8 hours  
• Vasodilator  
• No FDA pediatric labeling                                                                                                                        |
Table 4. Drug therapy for co-morbidities or compelling indications

<table>
<thead>
<tr>
<th>Co-morbidity</th>
<th>Drug Choice</th>
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<tbody>
<tr>
<td>Diabetes</td>
<td>ACE inhibitor</td>
</tr>
<tr>
<td>Heart failure or LVH</td>
<td>ACE inhibitor</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>• Loop diuretic (furosemide) or calcium channel blocker</td>
</tr>
<tr>
<td></td>
<td>• ACE inhibitor use is a relative contraindication in ACE inhibitor naïve patient</td>
</tr>
<tr>
<td>Proteinuria/CKD</td>
<td>ACE inhibitor</td>
</tr>
<tr>
<td>Migraine headache</td>
<td>Beta-blocker or calcium channel blocker</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>• Methyldopa, beta blockers, vasodilators preferred</td>
</tr>
<tr>
<td></td>
<td>• ACE inhibitors and Angiotensin II receptor antagonists are contraindicated</td>
</tr>
</tbody>
</table>

C. Treatment Resistant Hypertension—persistently elevated BP despite treatment with 3 or more antihypertensives of different classes. All of the drugs should be prescribed at maximally effective or tolerated doses and at least 1 of the medications should be a diuretic.

1. Treatment:
   a) Dietary sodium restriction
   b) Elimination of substances known to elevate BP
   c) Ruling out secondary causes
   d) Optimization of current therapy
   e) Addition of additional agents as needed: an aldosterone receptor antagonist (spironolactone) is the optimal additional agent

D. Acute Severe HTN—BP elevation well above the stage 2 HTN threshold, particularly when the BP increases 30 mmHg or more above the 95th percentile.

1. Evaluation for secondary causes should be conducted expeditiously.
2. Assess target organ effects: renal function tests, echocardiography, and CNS imaging.
   a) Patients showing signs of end organ damage should be transferred to the nearest emergency center.
   b) Patients displaying less serious symptoms (severe headache or vomiting) may be treated by either intravenous or oral antihypertensives, depending on the symptomatology. If already prescribed an oral immediate-release antihypertensive, administer an extra dose or consider clonidine, hydralazine, or minoxidil.
   i. Clonidine 2.5–5 mg/kg per dose up to 10 mg/kg per dose given every 6–8 hours orally
   ii. Hydralazine 0.25 mg/kg/dose up to 25mg per dose given every 6–8 hours orally
   iii. Minoxidil 0.1–0.2mg/kg/dose up to 10mg/dose given every 8–12 hours orally
   iv. BP should be reduced by no more than 25% of the planned reduction over the first 8 hours
   v. Multiple doses of medication may be needed over time to adequately reduce blood pressure. Observe for at least 3-6 hours and discharge from medical department when patient is clinically stable. Follow up next day to obtain blood pressure reading. Follow up in Chronic Care Clinic per ITP.
   vi. In select patients, consider investigating for possible illicit drug use as this is a possible cause for hypertensive urgency.
Directions for using Appendices A and B to determine BP percentile:
1. Obtain the patient’s BP and height (inches or centimeters).
2. Use the correct BP table by gender (either appendix A for boys or B for girls) to determine percentile.
3. Find the patient’s age on the left hand side of the table. Identify the height line and follow horizontally to find the correct height of the patient. (The first 7 height values are used to determine SBP percentile; the second set are used to determine DBP percentile).
4. Once you have found the height, move down vertically and find the patient’s SBP to determine percentile.
5. Repeat on the right hand side of the page to find DBP.
6. Once you have found the BP percentile, refer to Table 1 for classification.
## Appendix A

### TABLE 4-BP Levels for Boys by Age and Height Percentile

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>&lt;0.05 Percentile</th>
<th>0.05-99 Percentile</th>
<th>&gt;99 Percentile</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Height (cm)</td>
<td>Height (cm)</td>
<td>Height (cm)</td>
</tr>
<tr>
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<td>30.4</td>
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<tr>
<td>2</td>
<td>35.4</td>
<td>41.8</td>
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<tr>
<td>3</td>
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<td>4</td>
<td>43.6</td>
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<td>69.1</td>
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<td>10</td>
<td>69.9</td>
<td>84.5</td>
<td>107.8</td>
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</table>

### TABLE 4-BP Levels for Girls by Age and Height Percentile

<table>
<thead>
<tr>
<th>Age (yr)</th>
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<th>0.05-99 Percentile</th>
<th>&gt;99 Percentile</th>
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<tbody>
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<td>Age in</td>
<td>BP Percentile</td>
<td>Height Percentile or Measured Height</td>
<td>DHP Percentile</td>
</tr>
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<td>--------------</td>
<td>-------------------------------------</td>
<td>----------------</td>
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<tr>
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<td>% 10% 20% 30% 40% 50% 60% 70% 80% 90%</td>
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</table>

Appendix A continued
**Table 6** Continued

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>BP Percentile</th>
<th>SBP (mmHg)</th>
<th>Height Percentile or Measured Height</th>
<th>DBP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
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*Use percentile to adjust BP readings according to the scheme in Table 1. Calculated BP (95th, 50th, 10th) percentiles, stage 1 (95th, 50th, 10th) percentiles, and stage 2 (95th, 50th, 10th) percentiles are derived by using specific regression on the basis of normal-weight children, 10th and 90th percentiles.*
<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>BMI Percentile</th>
<th>BMI (kg/m²)</th>
<th>BMI Percentile</th>
<th>BMI (kg/m²)</th>
<th>BMI Percentile</th>
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</tr>
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Table 5: Continued
### Appendix B continued

#### Table 6: Continued

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>Height (cm)</th>
<th>Height Percentile or Measured Height</th>
<th>Height Percentile or Measured Height</th>
</tr>
</thead>
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<tr>
<td>99th</td>
<td>211.2</td>
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<td>221.2</td>
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Notes: Percentile values for age (y) and height (cm) are calculated according to the criteria set forth in Table 1. Percentile values for age (y) and height (cm) are calculated according to the criteria set forth in Table 1. Percentile values for age (y) and height (cm) are calculated according to the criteria set forth in Table 1. Percentile values for age (y) and height (cm) are calculated according to the criteria set forth in Table 1.
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

**Prepared by the Youth Services Pharmacy and Therapeutics Committee. Approved 4/2011, revised 4/2014.**
Background
Sleep-related issues in children and adolescents can lead to problems in cognitive functioning. The prevalence of pediatric insomnia that goes beyond bedtime refusal and night wakings ranges from 1% to 6% in the general population; however, in children with neurodevelopmental or psychiatric comorbidities the prevalence is as high as 30% to 75%. Sleep disturbances in the youth population not only have clear associations with neurocognitive and psychosocial impairments but also increase caregiver burden.

Behavioral interventions for pediatric sleep disorders have shown clinical benefit. This is of particular importance given the relative lack of data regarding use of pharmacological interventions in this population. Pharmacologic interventions may be considered for patients with chronic insomnia and generally are not recommended for patients with short-term or intermittent difficulty sleeping.

Evaluation
• Physical Exam including BMI, waist circumference, weight, and evaluation of respiratory, cardiovascular, and neurologic systems.
• Assess for concurrent medical, psychiatric, and developmental disorders.
• Rule out and treat underlying causes
  • Psychiatric disorders such as depression, anxiety, bipolar disorder, or ADHD (if psychiatric disorder is identified, refer to the appropriate DSM-5)
  • Medical conditions such as sleep apnea or restless leg syndrome
  • Medications such as stimulants, SSRIs, bronchodilators, decongestants, and steroids
  • Substance abuse
• Obtain comprehensive sleep history
  • Specific sleep complaints
  • Number of hours of sleep per day
  • Bedtime and awakening time
  • Number and duration of naps
  • Number and duration of awakenings during the night
  • Bedtime routine
  • Daytime routine
  • Daytime fatigue
  • Sleep quality
  • Onset and duration of symptoms
  • Behavior and school problems
  • Consequences of sleep problems
  • Medical history
  • Redcap
  • Psychiatric history
• Request a copy of the Daily Dormitory Shift Log (INS 110) for the 3rd shift for 1-2 weeks to look for evidence of sleep disturbances
• Laboratory sleep studies may be indicated if a physiological sleep disorder, such as sleep apnea or narcolepsy, is suspected.

Diagnosis
Primary Insomnia (DSM-5)
• Predominant complaint is dissatisfaction with sleep quantity or quality, associated with one or more of the following symptoms:
  • Difficulty initiating sleep
  • Difficulty maintaining sleep
  • Early morning awakening with inability to return to sleep
• Sleep disturbance causes significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning.
• The sleep disturbance occurs at least 3 nights per week, is present for at least 3 months, and occurs despite adequate opportunity for sleep.
• Sleep disturbance is not due to drug abuse, medication, coexisting mental disorder or general medical condition.

Circadian Rhythm Sleep Disorder (DSM-5)
• Persistent or recurrent pattern of sleep disruption that is primarily due to an alteration in the circadian system or to a misalignment between the endogenous circadian rhythm and the sleep-wake schedule required by an individual’s physical environment or social or professional schedule.
• Sleep disruption leads to excessive sleepiness or insomnia, or both
• Sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
Parasomnias (DSM-5)

Non-Rapid Eye Movement Sleep Arousal Disorders

- Recurrent episodes of incomplete awakening from sleep, usually occurring during the first third of the major sleep episode, accompanied by one or more of the following:
  - Sleepwalking: Repeated episodes of rising from bed during sleep and walking about. While sleepwalking, the person has a blank, staring face; is relatively unresponsive to the efforts of others to communicate with him or her, and can be awakened only with great difficulty.
  - Sleep terrors: Recurrent episodes of abrupt terror arousals from sleep, usually beginning with a panicky scream. There is intense fear and signs of autonomic arousal, such as mydriasis, tachycardia, rapid breathing, and sweating, during each episode. There is relative unresponsiveness to efforts of others to comfort the individual during the episodes.
  - No or little (e.g., only a single visual scene) dream imagery is recalled.
  - Amnesia for the episodes is present.
  - The episodes cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Nightmare Disorder

- Repeated occurrences of extended and extremely dysphoric, and well-remembered dreams that usually involve efforts to avoid threats to survival, security, or physical integrity and that generally occur during the second half of the sleep episode.
- On awakening from the dysphoric dreams, the individual rapidly becomes oriented and alert.
- The sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The nightmare symptoms are not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication), or a coexisting mental or medical disorder.

Rapid Eye Movement Sleep Behavior Disorder

- Repeated episodes of arousal during sleep associated with vocalization and/or complex motor behaviors.
- These behaviors arise during rapid eye movement (REM) sleep and therefore usually occur more than 90 minutes after sleep onset, are more frequent during the later portions of the sleep period, and uncommonly occur during daytime naps.
- Upon awakening from these episodes, the individual is completely awake, alert, and not confused or disoriented.
  - Either of the following:
    - REM sleep without atonia on polysomnographic recording
    - A history suggestive of REM sleep behavior disorder and an established synucleinopathy diagnosis (e.g., Parkinson’s disease, multiple system atrophy)
- The behaviors cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- The disturbance is not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication), or a coexisting mental or medical disorder.

Sleep Hygiene

- Avoid napping during the day.
- Do not read or study on the bed.
- Establish a regular bedtime routine.
- Get up at the same time every day.
- Avoid heavy, spicy, and sugary meals close to bedtime.
- Exercise regularly. Vigorous exercise should be done in the morning or afternoon.
- Avoid stimulants such as caffeine and certain medications too close to bedtime.

Cognitive Behavioral Therapy (CBT) includes but is not limited to:

- Imagery
- Keeping a worry journal
- Deep-breathing exercises
- Progressive muscle relaxation
- Cognitive techniques to decrease negative thoughts at bedtime

*Non-pharmacological treatments are considered first line therapy*
Pharmacological treatments are not considered first line therapy. In accordance with TJJD general administrative policy and health services policy, psychotropic or other medications may not be prescribed as a sleep aid. They may only be prescribed as second line therapy for a sleep disturbance related to a primary mental health or medical diagnosis and should be used in conjunction with behavioral interventions.

In general medications should only be used short term at the lowest effective dose and tapered whenever possible. When used long-term, use should be re-evaluated at least every 6 months to monitor for efficacy, adverse effects, and problems such as tolerance or abuse. Medication should always be used in combination with non-pharmacologic strategies.

Patients should be evaluated for use of formulary agents whenever possible. Practitioners should consider past history of response, contraindications, co-morbidities, medication compliance, and potential for adverse effects and/or drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects.

Pharmacological agents used in adolescent sleep disorders are listed below:

1. **Melatonin**
   - **Dose**: 5-10 mg/day administered 2-3 hours before sleep onset
   - Useful in circadian rhythm sleep disorders
   - May be used to target sleep-onset delay in children with ADHD and developmental disorders
   - Monitoring: sleep pattern, somnolence, drowsiness, and fatigue

2. **Antihistamines**
   - **Dose**: Diphenhydramine 25-50 mg/day or Hydroxyzine Pamoate 25-100 mg/day
   - Sedative effects are obtained through antihistaminic properties
   - Monitoring: daytime drowsiness, dry mouth, urinary retention, paradoxical hyperactivity, development of tolerance, potentiation of substance abuse due to anxiolytic and anticholinergic properties

3. **Guanfacine**
   - **Dose**: 0.5-4 mg/day
   - Useful in sleep-onset delay in children with ADHD
   - Less sedating and has less anticholinergic and cardiovascular side effects compared to clonidine
   - Monitoring: cardiovascular risk with higher doses, blood pressure, heart rate

4. **Trazodone**
   - **Dose**: 12.5-50 mg/day
   - Use cautiously
   - Should be used at the lowest therapeutic dose
   - Monitoring: priapism, suicidal ideation, dizziness
   - Priapism is rare 1%, but a serious adverse effect and medical emergency. Patients should be counseled and male patients taking trazodone who experience an uncontrolled erection persisting longer than 1 hour should seek immediate medical attention. If not treated promptly, priapism may result in permanent impotence due to damage of vascular structures in the penis.
PSYCHOSIS
(Adolescents)

1. Patient meets DSM-5 criteria for a psychotic diagnosis. Care should be taken to assess cognitive impairment and distress associated with psychosis. The algorithm assumes treatment of co-morbid medical disorders, the appropriate use of non-pharmacologic therapies, and reconsideration of diagnosis with poor response to treatment.

2. Obtain baseline laboratories as indicated in Tables 6-7. Refer to pages 2-3 for medication selection.

3. Initiate monotherapy with formulary atypical antipsychotic risperidone up to 6 mg/day. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

4. Continue treatment and monitor per Tables 6-7.

5. Signs of adverse effects?

6. If at any time adverse effects are noted, go to Adverse Effect Management Table 9.

7. Initiate monotherapy with alternative formulary atypical antipsychotic ziprasidone up to 160 mg/day after obtaining a pre-treatment EKG. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

8. Continue treatment and monitor per Tables 6-7.

9. Consider monotherapy with prior authorization atypical antipsychotic ability up to 30 mg/day. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

10. Continue treatment and monitor per Tables 6-7.

11. Consider monotherapy with nonformulary atypical antipsychotic not tried above or consider a typical antipsychotic. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

12. Continue treatment and monitor per Tables 6-7.

13. Initiate adjunctive therapy with mood stabilized lithium or divalproex and titrate to therapeutic level. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

14. Continue treatment and monitor per Tables 6-7.

15. Initiate adjunctive therapy with alternative mood stabilizer not tried above and titrate to therapeutic level. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

16. Continue treatment and monitor per Tables 6-7.

17. Initiate adjunctive therapy with lithium and divalproex and titrate to therapeutic level. Continue 4-6 weeks at a therapeutic dose. Adequate response per BPRS

18. Continue treatment and monitor per Tables 6-7.

19. Reconsider diagnosis and consider psychopharmacology consultation. Adequate response per BPRS

20. Continue treatment and monitor per Tables 6-7.

Prepared by the Texas Juvenile Justice Department (formerly known as the Texas Youth Commission) and Reviewed by the Correctional Managed Care Pharmacy & Therapeutics Committee. October 2001, revised 5/02, 2/04, 3/06, 4/10, 2/13, 2/16, 2/17.

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### Formulary Agents

**Formulary agents** – Practitioners may prescribe any agent on the formulary without restrictions based on patient assessment and clinical judgment. Newly diagnosed patients should receive a therapeutic trial of formulary agents risperidone and ziprasidone unless it is clearly not indicated. Recommended dosing for initiation of risperidone (Table 1) and ziprasidone is provided below. Titration schedules may vary based on tolerability and response; with some patients stabilizing on lower doses or requiring slower titration.

#### Table 1: Risperidone Dosing

<table>
<thead>
<tr>
<th>Dose</th>
<th>Day 1-4</th>
<th>Day 5-8</th>
<th>Day 9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>0.5-1 mg</td>
<td>1.5-2 mg</td>
<td>3-4 mg</td>
</tr>
<tr>
<td>Divide:</td>
<td>0.5/0.5</td>
<td>0.5/0.5</td>
<td>0.5/1</td>
</tr>
</tbody>
</table>

#### Ziprasidone Dosing

Ziprasidone may be initiated at 20 mg daily and titrated by 20 mg/day, every 1-2 days, to a target dose. Children <45 kg should be titrated to a target dose of 60-80 mg/day, whereas children ≥ 45 kg typically require 120-160 mg/day. Daily dosages should be divided and administered twice daily, when possible. Each dose should be administered with ≥ 500 calories.

#### Table 2: Formulary Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Generation Antipsychotics</td>
<td>Chlorpromazine</td>
<td>50 mg, 100 mg, 200 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Fluphenazine</td>
<td>2.5 mg, 5 mg, 10 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Haloperidol</td>
<td>1 mg, 2 mg/ml oral concentrate</td>
</tr>
<tr>
<td></td>
<td>Perphenazine</td>
<td>4 mg, 8 mg, 16 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Thiothixene</td>
<td>2 mg, 5 mg, 10 mg capsules</td>
</tr>
<tr>
<td></td>
<td>Trifluoperazine</td>
<td>2 mg, 5 mg, 10 mg tablet</td>
</tr>
<tr>
<td>2nd Generation Antipsychotics</td>
<td>Risperidone</td>
<td>0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg tablet</td>
</tr>
<tr>
<td></td>
<td>Ziprasidone</td>
<td>20 mg, 40 mg, 60 mg, 80 mg capsule, 20 mg/ml injection</td>
</tr>
</tbody>
</table>

### Prior Authorization Agents

- **Prior Authorization Agents** – Prior authorization agents are medications that may be prescribed if specific clinical criteria are met. The prior authorization criteria must be met and included in the special instructions field of the order when the medication is ordered in the EHR. All other uses require non-formulary approval.

#### Table 3: Prior Authorization Agent

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication</th>
<th>Strength</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Generation Antipsychotic</td>
<td>Aripiprazole (Abilify®)</td>
<td>2mg, 5mg, 10mg, 15mg, 25mg, 30mg tablet</td>
<td>Intolerant to formulary 2nd generation antipsychotics</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Treatment failure on formulary 2nd generation antipsychotics after a therapeutic trial of adequate dose and duration</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Contraindications to formulary 2nd generation antipsychotics</td>
</tr>
</tbody>
</table>
Switching Medications

Switching stable patients to another antipsychotic agent is best done by cross-titration. The patient should be titrated to a comparable therapeutic dose of the new antipsychotic and then tapered off the initial antipsychotic by one-third to one-fourth of the initial daily dosage at weekly intervals (beginning one week after the goal dose of the new antipsychotic is achieved) until discontinued. Alternately, table 5 below outlines strategies for switching patients by a structured cross-titration schedule that is agent specific.

Notes:
1. If patient is on more than the maximum dose, taper down to that dose before beginning the cross-titration.
2. Practitioners should be sure to complete cross-titration to ensure that the patient is not left on two antipsychotic agents indefinitely.

Table 4: Approximate Chlorpromazine Equivalent Dosage for Antipsychotic Agents

<table>
<thead>
<tr>
<th>Antipsychotic Agent</th>
<th>Dose Equivalent to 100mg of Chlorpromazine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorpromazine</td>
<td>100mg</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>2mg</td>
</tr>
<tr>
<td>Perphenazine</td>
<td>10mg</td>
</tr>
<tr>
<td>Risperidone</td>
<td>2mg</td>
</tr>
<tr>
<td>Clozapine</td>
<td>5mg</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>75mg</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>60mg</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>7.5mg</td>
</tr>
<tr>
<td>Clozapine</td>
<td>50mg</td>
</tr>
</tbody>
</table>

Table 5: Schedule for Tapering Patients off Nonformulary/Prior Authorization Atypical Antipsychotics

<table>
<thead>
<tr>
<th>Medication</th>
<th>Max Daily Dose</th>
<th>Day 1-4</th>
<th>Day 5-8</th>
<th>Day 9-12</th>
<th>Day 13-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quetiapine</td>
<td>200mg TID</td>
<td>100mg/100mg</td>
<td>100mg TID</td>
<td>100mg BID</td>
<td>50mg BID</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>30mg daily</td>
<td>20mg daily</td>
<td>10mg daily</td>
<td>5mg daily</td>
<td></td>
</tr>
</tbody>
</table>

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Providers should consider obtaining any of the laboratories listed above more frequently if clinically indicated.

1. Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease. Given ziprasidone’s increased risk for QTc prolongation, an alternative antipsychotic should be considered if the baseline QTc is > 450 msec in males and 470 msec in females. Ziprasidone discontinuation is advised if the QTc rises above 500 msec, or increases by > 30-60 msec during treatment.

2. Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunction.
   - Routine screening for hyperprolactinemia is not recommended unless symptoms are present
   - The normal range of prolactin is 10-20 mcg/L in males and 10-25 mcg/L in females
   - Symptoms typically do not appear until levels reach 60-100 mcg/L
   - Patients should be referred to medical to rule out other etiologies of hyperprolactinemia

### Table 6: Metabolic and Endocrine Monitoring Guidelines for Antipsychotics in Children and Adolescents

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>4 wks</th>
<th>8 wks</th>
<th>12 wks</th>
<th>6 months</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Height</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (overweight 25.0-29.9, obese &gt;= 30.0)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, LFT, SG, Electrolytes</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EKG1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolactin2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### Table 7: Outcomes and Adverse Effect Monitoring

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIMS (Abnormal Involuntary Movement Scale)</td>
<td>X</td>
<td>Baseline, at 3 months, then annually</td>
</tr>
<tr>
<td>-Acute EPS, Akathisia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-Tardive Dyskinesia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BPRS (Brief Psychiatric Rating Scale)</td>
<td>X</td>
<td>Baseline and at each visit to assess response to treatment when a medication is started, changed or discontinued</td>
</tr>
</tbody>
</table>

---

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### Table 8: Occurrence of Adverse Effects of Antipsychotic Agents in Children and Adolescents

<table>
<thead>
<tr>
<th>Drug</th>
<th>EPS</th>
<th>Hyperprolactinemia</th>
<th>Weight Gain</th>
<th>Sedation</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol</td>
<td>+++</td>
<td>++</td>
<td>+/-</td>
<td>+</td>
<td>TD, NMS</td>
</tr>
<tr>
<td>Risperidone</td>
<td>+</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>Depression</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>+/-</td>
<td>+/–</td>
<td>+++</td>
<td>++</td>
<td>Lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Clozapine</td>
<td>-</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>Agranulocytosis, Seizures, lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>-</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>Lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>+/-</td>
<td>+/–</td>
<td>-</td>
<td>++</td>
<td>QTc prolongation</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>+/-</td>
<td>+/–</td>
<td>-</td>
<td>+/–</td>
<td>EPS is typically akathisia</td>
</tr>
</tbody>
</table>

**EPS** = extrapyramidal symptoms  
**NMS** = neuroleptic malignant syndrome  
**QTc** = corrected QT interval  
**TD** = tardive dyskinesia

---

### Table 9: Adverse Effect Management

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Recommended Management Strategies</th>
</tr>
</thead>
</table>
| EPS                    | • Lower the dose of the antipsychotic agent to the lowest effective dose or  
                          | • Review table 8 and consider selecting an agent with a lower incidence of EPS or  
                          | • Treat EPS with one of the following agents:  
                          | • Benztropine 1 – 6 mg/day  
                          | • Diphenhydramine 25 – 100 mg/day  
                          | • Propranolol may be considered for akathisia. Extreme caution should be exercised with close monitoring for bradycardia and hypotension. Propranolol should be avoided in patients with a diagnosis of asthma. |
| Tardive dyskinesia     | • Diagnosis supported by AIMS?  
                          | • Switch to a second generation antipsychotic if currently receiving a first generation antipsychotic  
                          | • Discontinue anticholinergic medication  
                          | • Consider pharmacotherapy consult for treatment options |
| Neuroleptic Malignant  | • Medical emergency  
                          | • Evaluate through medical department for possible referral to emergency room  
                          | • Discontinue antipsychotic |

**EPS** = extrapyramidal symptoms  
**NMS** = neuroleptic malignant syndrome  
**QTc** = corrected QT interval  
**TD** = tardive dyskinesia
Background:
The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual's behavior over the previous 2-3 days should also be considered and can be reported by the patient's caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed an antipsychotic.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring:
Each item is rated on a seven-point scale (1=not present to 7=extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
**Brief Psychiatric Rating Scale (BPRS)**

<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.</td>
<td>SOMATIC CONCERN</td>
</tr>
<tr>
<td></td>
<td>2.</td>
<td>ANXIETY</td>
</tr>
<tr>
<td></td>
<td>3.</td>
<td>EMOTIONAL WITHDRAWAL</td>
</tr>
<tr>
<td></td>
<td>4.</td>
<td>CONCEPTUAL DISORGANIZATION</td>
</tr>
<tr>
<td></td>
<td>5.</td>
<td>IMPULSIVENESS</td>
</tr>
<tr>
<td></td>
<td>6.</td>
<td>MOTOR HYPERACTIVITY</td>
</tr>
<tr>
<td></td>
<td>7.</td>
<td>MANNERISMS AND POSTURING</td>
</tr>
<tr>
<td></td>
<td>8.</td>
<td>GRANDIOSITY</td>
</tr>
<tr>
<td></td>
<td>9.</td>
<td>DEPRESSIVE MOOD</td>
</tr>
<tr>
<td></td>
<td>10.</td>
<td>HOSTILITY</td>
</tr>
<tr>
<td></td>
<td>11.</td>
<td>SUSPICIOUSNESS</td>
</tr>
<tr>
<td></td>
<td>12.</td>
<td>HALLUCINATORY BEHAVIOR</td>
</tr>
<tr>
<td></td>
<td>13.</td>
<td>MOTOR RETARDATION</td>
</tr>
<tr>
<td></td>
<td>14.</td>
<td>UNCOOPERATIVENESS</td>
</tr>
<tr>
<td></td>
<td>15.</td>
<td>UNUSUAL THOUGHT CONTENT</td>
</tr>
<tr>
<td></td>
<td>16.</td>
<td>BLUNTED AFFECT</td>
</tr>
<tr>
<td></td>
<td>17.</td>
<td>EXCITEMENT</td>
</tr>
<tr>
<td></td>
<td>18.</td>
<td>DISORIENTATION</td>
</tr>
<tr>
<td></td>
<td>19.</td>
<td>ELEVATED MOOD</td>
</tr>
<tr>
<td></td>
<td>20.</td>
<td>SUICIDABILITY</td>
</tr>
<tr>
<td></td>
<td>21.</td>
<td>BIZARRE BEHAVIOR</td>
</tr>
<tr>
<td></td>
<td>22.</td>
<td>SELF-NEGLECT</td>
</tr>
<tr>
<td></td>
<td>23.</td>
<td>DISTRACTIBILITY</td>
</tr>
</tbody>
</table>
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

1. Rule out medical causes for presentation.
2. Meet DSM-5 criteria for Post-Traumatic Stress Disorder?
   - Yes: Re-evaluate diagnosis and treat underlying causes.
   - No: Consider a switch to propranolol 20-160 mg/day (see criteria for use on Page 2) OR
3. Adequate response per BPRS?
   - Yes: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   - No: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
4. Consider pharmacotherapy consult and/or request for nonformulary medication OR
5. Switch to alternative formulary SSRI (Table 1) OR
6. Switch to guanfacine 0.05mg/kg/day up to a maximum of 4mg/day OR
7. Initiate formulary SSRI antidepressant and continue for 6-12 weeks at a therapeutic dose (Table 1) OR
8. Assess compliance?
   - Yes: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   - No: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
9. Does the patient have co-morbid depression, bipolar disorder, or other anxiety disorder?
   - Yes: Refer to appropriate co-morbid treatment pathway.
   - No: Assess compliance.
10. If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication.
11. Increase dose of current agent to maximal tolerated dose for 6-12 weeks OR
12. Switch to propranolol 20-160 mg/day (see criteria for use on Page 2) OR
13. Meet DSM-5 criteria for Post-Traumatic Stress Disorder?
   - Yes: Re-evaluate diagnosis and treat underlying causes.
   - No: Refer to appropriate co-morbid treatment pathway.

Medication Selection

Patients should be evaluated for use of formulary agents whenever possible. Practitioners should consider past history of response, contraindications, co-morbidities, medication compliance, and potential for adverse effects and/or drug-drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects.

Table 1: Treatments for PTSD

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Dose (Dose Range)</th>
<th>Monitoring</th>
</tr>
</thead>
</table>
| Selective Serotonin Reuptake Inhibitor (SSRI) | Citalopram, 10mg, 20mg, 40mg | Celexa® 10mg | 10mg (10 – 40) | • Emergence of suicidal ideation or behavior  
• Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present |
|                     | Fluoxetine, 10mg, 20mg | Prozac® 10mg | 10mg (10 – 40) | | |
|                     | Sertraline, 50mg, 100mg | Zoloft® 50mg | 50mg (50 – 200) | | |
| Alpha antagonist    | Guanfacine, 1mg, 2mg | Tenex® 1mg | 1mg (1 – 6) | • Monitor supine, standing, and sitting BP especially at initiation or change in dose  
• Monitor for orthostatic hypotension  
• Taper over 1 week or more when discontinuing |
| Beta antagonist     | Propranolol, 10mg, 20mg, 40mg | Inderal® 20mg | 20mg (20-160) | • Monitor supine, standing, and sitting BP especially at initiation or change in dose  
• Monitor for orthostatic hypotension  
• Taper over 1 week or more when discontinuing |

Criteria for appropriate use of propranolol: ALL criteria should be met prior to initiating propranolol.
1) Patient has a documented diagnosis of PTSD
2) Patient has failed an adequate trial of SSRI therapy for PTSD
3) Patient is not currently receiving an antipsychotic medication

Note: Once a patient has been started on propranolol, they should be monitored for improvement in PTSD symptoms. If a clear improvement in symptoms is not evident after 4-6 weeks of treatment, propranolol should be tapered and discontinued.

BRIEF PSYCHIATRIC RATING SCALE (BPRS) - Instructions for the Clinician

Background:
The Brief Psychiatric Rating Scale (BPRS) is a widely used instrument for assessing psychopathology at baseline and longitudinally as an outcome measurement when treatment is introduced. The BPRS is a scale measuring positive symptoms, general psychopathology and affective symptoms. It has proven particularly valuable for documenting the efficacy of treatment in patients who have moderate to severe psychopathology. The BPRS has been well validated in the clinical literature and is reportedly the most studied psychometric instrument currently in use.

The BPRS should be administered by a clinician who is knowledgeable concerning psychiatric disorders and is able to interpret the constructs used in the assessment. The individual’s behavior over the previous 2-3 days should also be considered and can be reported by the patient’s caregivers or teachers. It should be utilized at baseline and then at each visit as long as the patient is prescribed a psychotropic medication.

The BPRS utilized in the electronic medical record (EMR) consists of a range of 23 symptom constructs covering a broad array of potential psychopathology. The assessment typically takes 10-20 minutes or less for the interview and scoring.

Instructions for Use and Scoring:
Each item is rated on a seven-point scale (1 = not present to 7 = extremely severe). Zero (0) is entered if the item is not assessed. The scores of the 23 items should be summed and recorded. The total score should be compared to the total score from one evaluation to the next as a measure of response to treatment. In addition, a single subscale (symptom) or cluster of subscales (e.g., grandiosity, elevated mood, excitement, distractibility) can be followed over time.
Brief Psychiatric Rating Scale (BPRS)

Patient Name ______________________  Patient Number __________   Date_______________
Facility ______________  Practitioner _______________

Enter the score for the term that best describes the patient’s condition.
0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score
1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis
2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness
3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.
4. CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.
5. IMPULSIVENESS
6. MOTOR HYPERACTIVITY - Increase in energy level evidenced in more frequent movement and/or rapid speech. Do not rate if restlessness is due to akathisia.
7. MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).
8. GRANDIODITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.
9. DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.
10. HOSTILITY - Animosity, contempt, belligerence, disdain for others.
11. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.
12. HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.
13. MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.
14. UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.
15. UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.
16. BLUNTED AFFECT - Reduced emotional tone, reduction in normal intensity of feelings, flatness.
17. EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.
18. DISORIENTATION - Confusion or lack of proper association for person, place or time.
19. ELEVATED MOOD - A pervasive, sustained and exaggerated feeling of well-being, cheerfulness, or euphoria implying a pathological mood. Optimism that is out of proportion to the circumstances.
20. SUICIDALITY - Expressions of desire, intent, or actions to harm or kill self.
21. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.
22. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.
23. DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual’s attention may be drawn to noise in adjoining room, books on a shelf, interviewer’s clothing, etc.
Acute Seizures (Children & Adolescents)

Seizure Activity for 0-5 Minutes

1. Establish diagnosis by observing continuous seizure activity or one additional seizure.
2. Rule out unconscious symptoms amplification.
3. Treat underlying medical condition as appropriate.

Seizure activity suspected?

Yes

- Administer oxygen by nasal cannula or mask, position head for unobstructed airway, or transfer to higher level of care for advanced respiratory support.
- Obtain and record vital signs.
- Consider establishing an IV (normal saline).
- Obtain glucose finger stick.
- Determine oxygenation with oximetry.

No

- Observe and follow-up as indicated.
- Discharge from medical department.

Seizure activity continuing for >5 minutes?

Yes

- Draw venous samples for glucose, chemistries to include Mg, PO4, and Ca, CBC, toxicology screens, and antiepileptic drug (AED) levels if available.
- Observe for a minimum of two hours and discharge from medical department following full recovery.
- Confirm medication adherence and reinforce education.
- Follow up in chronic care clinic.

No

- Transfer to nearest emergency room.
- If patient is hypoglycemic or blood glucose is not available, inject 2ml/kg dextrose 25% by direct push into the IV (glucagon if IV access cannot be established).
- Obtain ECG.
- Draw venous samples for glucose, chemistries to include Mg, PO4, and Ca, CBC, toxicology screens, and antiepileptic drug (AED) levels if available.
- Observe for a minimum of two hours and discharge from medical department following full recovery.
- Confirm medication adherence and reinforce education.
- Follow up in chronic care clinic.

Follow up with patient within 1 week or next available clinic upon return from emergency room or hospital.

- Confirm medication adherence and reinforce education.
- Obtain AED serum levels and adjust treatment plan if indicated.
- Follow up in chronic care clinic per Individual Treatment Plan (ITP).

Prepared By The Youth Services Pharmacy & Therapeutics Committee. March 2007. Revised 10/11, 10/14, 10/18.
Seizure Disorder (Children & Adolescents)

1. Seizure diagnosis and classification documented?* Seizure type and syndrome (page 5) are important for selecting the appropriate antiepileptic drug (AED).

2. Is seizure disorder confirmed? Is AED therapy appropriate for diagnosis?
   - Yes: Go to box #11.
   - No: Initiate AED therapy based on seizure classification (Appendix A & B).

3. Is patient on AED therapy?
   - Yes: Is AED therapy effective and tolerable?
     - Yes: Follow up in Chronic Care Clinic or as clinically indicated.
     - No: Update Medication Regimen.
   - No: Review seizure history (page 5).

4. Initiate AED regimen (Appendix A & B).
   - If seizure disorder is ruled out, discontinue from Chronic Care Clinic.

5. Is AED therapy effective and tolerable?
   - Yes: Follow up in Chronic Care Clinic or as clinically indicated.
   - No: Update Medication Regimen.

   - Check medication compliance.
   - Obtain AED level if indicated.
   - Obtain baseline labs appropriate for AED (Appendix C).

7. AED therapy effective and tolerable?
   - Yes: Follow up in Chronic Care Clinic or as clinically indicated.
   - No: Update Medication Regimen.

8. If history of seizure disorder but not on therapy and has had no seizure activity for > 2 years, may consider discontinuation from Chronic Care Clinic.

9. Is AED therapy effective and tolerable?
   - Yes: Follow up in Chronic Care Clinic or as clinically indicated.
   - No: Update Medication Regimen.

10. AED therapy effective and tolerable?
    - Yes: Follow up in Chronic Care Clinic or as clinically indicated.
    - No: Update Medication Regimen.

*One seizure event is not necessarily diagnostic for seizure disorder and may not require long-term AED therapy.

1. Initial Assessment
   A. Medical History
      1. Verify any existing seizure diagnoses.
      2. Identify exact seizure type by obtaining a detailed seizure history.
         a. Age at onset and frequency of seizure
         b. Symptoms during ictal and post-ictal phase (patient & observer)
         c. Seizure triggers (e.g. sleep deprivation, alcohol, stress)
      3. Identify all co-morbidities.
      4. Identify possible causes including family history of epilepsy, history of head trauma, birth complications, febrile convulsions, alcohol/drug abuse, cancer, vascular abnormalities.
   B. Medication History
      1. Identify all current and prior medication regimens including response and adverse events.
      2. Rule out alcohol or other drug withdrawal seizures as these do not generally require AED therapy.
      3. Rule out drugs which may cause or exacerbate seizures (e.g. psychotropics, antimicrobials, stimulants, narcotics, lidocaine, metoclopramide, theophylline, antiarrhythmics, antiepileptics, baclofen).
   C. Physical Exam
      1. Identify disorders associated with seizures such as head trauma, infections which could spread to the brain, congenital abnormality, neurological disorder, alcohol or drug abuse, metabolic disorders or cancer.
      2. A complete neurologic and mental status exam should be performed.
   D. Electroencephalographic (EEG) Studies
      - Should be performed on all new onset cases. The purpose of the EEG is to confirm the presence of abnormal electrical activity, provide information about the seizure type and syndrome, and locate the seizure focus. Approximately 50% of patients show no abnormality on a single EEG, and 10% with true seizures show no abnormality on multiple EEG studies. An EEG should be used to support the diagnosis of epilepsy and cannot rule out seizure disorder.
   E. Other Labs & Neuroimaging
      • Electrolytes
      • Blood Glucose
      • Liver & kidney function
      • Toxicology screen
   F. Drug Treatment Plan
      1. Treatment with AED therapy is generally recommended after a second epileptic seizure. Selection of an appropriate AED should be based on the following:
         a. Age & child bearing potential
         b. Seizure type & syndrome
         c. Co-medications
         d. Co-morbidities
         e. AED adverse effect profile
      2. AED initiation after the first seizure may be warranted in patients with a high risk of recurrence (e.g. unequivocal epileptic activity on EEG, neurologic deficit, structural abnormality, family history).
   G. Principles of Treatment
      1. Goals of therapy
         a. Seizure free with minimal adverse effects
         b. Maintains normal lifestyle
         c. Use lowest effective AED dose
      2. Assessment of disease control
         a. Good control – seizure free since last visit or last 6 months
         b. Fair control – 1 seizure since last visit or in last 6 months
         c. Poor control – 2 seizures since last visit or last 6 months
      3. Potential Reasons for Treatment Failure
         a. Incorrect diagnosis
         b. Incorrect AED for seizure type/syndrome
         c. Subtherapeutic level (improper dosing, drug interactions, poor adherence- most common reason for treatment failure)
         d. Refractory seizures
4. Step Therapy
   a. Monotherapy is preferred. Generally consider at least two monotherapy trials before using combination therapy. Two-thirds of patients become seizure-free with the first or second drug prescribed. When switching agents, the old agent should be continued until a therapeutic level of the new drug is achieved. The old agent is then tapered slowly and discontinued.
   b. Polytherapy with 2 agents – if indicated, add an AED with a different mechanism of action. Start low and titrate slowly. Confirm medication adherence prior to the addition of a second agent.
   c. Polytherapy with >3 agents – Rarely needed. Consider only after 2 or more adequate trials of dual AEDs have failed. Adherence is confirmed, and a combination of AEDs is tolerated and significantly reduces seizure frequency or severity. Consider referral prior to triple AED therapy.

5. Use of Newer AEDs
   a. Recommended for those who have failed traditional or first generation AEDs or when traditional AEDs are unsuitable (contraindications, drug interactions, intolerance, pregnancy, etc).
   b. Traditional AEDs have the advantage of broad familiarity, lower cost, known efficacy and long term experience.

6. Pregnancy Considerations
   a. Category C – gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, vigabatrin
   b. Category D – carbamazepine, phenobarbital, phenytoin, primidone, valproic acid
   c. General recommendations – if possible avoid phenobarbital, phenytoin, valproic acid and AED polytherapy. Use the lowest effective dose to control seizures.

7. Indications for Monitoring AED Levels
   a. Detection of non-adherence to prescribed medications
   b. Suspected toxicity
   c. Adjustment of phenytoin dose
   d. Management of pharmacokinetic interactions (e.g., changes in bioavailability, elimination, and drug interactions)
   e. Specific clinical conditions (e.g., status epilepticus, certain situations during pregnancy - such as when seizures increase or are likely to increase, monitoring drug levels may be useful in making dose adjustments)

II. Withdrawal of Anticonvulsants
   A. Risk of Seizure Relapse
      1. Relapse rates are highest in the first 12 months (especially the first 6 months) after AED withdrawal.
      2. Risk of relapse continues to decrease with time.
      3. Approximately 50% of patients with childhood-onset epilepsy have complete remission and no longer require drug therapy.

   B. Considerations for AED Discontinuation
      1. Seizure-free for a minimum of two years on AED treatment
      2. Single type of focal seizure or a single type of generalized tonic-clonic seizure
      3. Normal neurological examination and normal intelligence quotient (IQ)
      4. EEG normalized with treatment

   C. Drug Discontinuation
      1. Risks and consequences of seizure recurrence versus continued treatment should be weighed.
      2. Discontinue by slow taper (over 6 months) and tailor to the specific drug, dosage, and serum concentrations for each patient.

<table>
<thead>
<tr>
<th>Factors Against Drug Withdrawal</th>
<th>Factors in Favor of Drug Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adolescent-onset epilepsy</td>
<td>• Childhood-onset epilepsy</td>
</tr>
<tr>
<td>• Adult-onset epilepsy</td>
<td>• Elderly-onset epilepsy</td>
</tr>
<tr>
<td>• Focal epilepsy</td>
<td>• Idiopathic generalized epilepsy</td>
</tr>
<tr>
<td>• Juvenile myoclonic epilepsy</td>
<td>• Single type of seizure</td>
</tr>
<tr>
<td>• Presence of multiple seizure types</td>
<td>• Benign epilepsy with centrotemporal spikes</td>
</tr>
<tr>
<td>• Presence of underlying neurological condition</td>
<td>• Normal EEG</td>
</tr>
<tr>
<td>• Abnormal EEG</td>
<td>• Childbearing potential and planning pregnancy</td>
</tr>
<tr>
<td></td>
<td>• Co-morbidity with concurrent treatments</td>
</tr>
</tbody>
</table>
### Appendix A: International Classification of Epileptic Seizures

<table>
<thead>
<tr>
<th>Types of Epileptic Seizures</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focal seizures</strong></td>
<td>Beginning in one hemisphere.</td>
</tr>
<tr>
<td>Focal Aware Motor</td>
<td>Motor features, e.g., jerking, rigidity, impaired consciousness</td>
</tr>
<tr>
<td>Focal Impaired Awareness</td>
<td>Focal seizure followed by loss of consciousness or impaired consciousness</td>
</tr>
<tr>
<td>Focal to Bilateral Tonic-Clonic</td>
<td>Focal onset with secondary generalization</td>
</tr>
<tr>
<td><strong>Generalized seizures</strong></td>
<td>Involves both hemispheres with bilateral motor manifestations and loss of consciousness</td>
</tr>
<tr>
<td>Absence (petit mal)</td>
<td>Sudden onset, brief duration. May include blank stare, upward rotation of eyes, lip-smacking. Confined with daydreaming. Generally occurs in young children through adolescence. Important to differentiate from focal impaired awareness</td>
</tr>
<tr>
<td>Myoclonic</td>
<td>Brief muscle contraction of face, trunk, extremities. May be isolated or repetitive</td>
</tr>
<tr>
<td>Clonic</td>
<td>Repetitive jerking, cyanosis on the mouth, small grunting respirations between seizures, deep respirations at the end of seizures</td>
</tr>
<tr>
<td>Tonic</td>
<td>Rigid, contortion, sudden muscular contractions, cyanosis, deviation of eyes and head to one side, rotation of the whole body, and distortion of features, suppression of respiration, falls, tongue biting, involuntary urination</td>
</tr>
<tr>
<td>Tonic-Clonic</td>
<td>Also known as grand mal. Includes both tonic and clonic phase</td>
</tr>
<tr>
<td>Atonic</td>
<td>Sudden loss of postural tone lasting 10-20 seconds. Usually no post-ictal confusion. Violent falls</td>
</tr>
<tr>
<td>Unknown-Non-epileptic</td>
<td>Unclassified due to inadequate information or inability to place in other categories.</td>
</tr>
<tr>
<td>Pseudoseizure (non-epileptic)</td>
<td>Episodes involving affective, autonomic, or somatoform manifestations that are precipitated by stress. Clinical characteristics:</td>
</tr>
<tr>
<td>* Strongly suggestive – prolonged duration (10-30 min), preserved consciousness despite whole body jerking, bizarre and asynchronous motor movements, pupil swelling, not stereotypical</td>
<td></td>
</tr>
<tr>
<td>* Strongly against – injuries during spell, tongue laceration (esp. sides), incontinence</td>
<td></td>
</tr>
</tbody>
</table>

---
Begin treatment with single AED using recommended initial daily dosing. Up to 80% of patients can be managed with monotherapy. Ensure proper medication adherence prior to modifying regimen.

### Type of Seizure

<table>
<thead>
<tr>
<th>Type of Seizure</th>
<th>Formulary Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focal Aware</td>
<td>Carbamazepine, Divalproex Sodium, Levetiracetam, Phenytoin, Primidone, Brivaracetam, Eslicarbazepine, Felbamate, Gabapentin, Lamotrigine, Oxcarbazepine, Perampanel, Tiagabine, Topiramate, Zonisamide</td>
</tr>
<tr>
<td>Focal Impaired Awareness</td>
<td>Carbamazepine, Divalproex Sodium, Levetiracetam, Phenytoin, Primidone, Brivaracetam, Eslicarbazepine, Felbamate, Gabapentin, Lamotrigine, Oxcarbazepine, Perampanel, Tiagabine, Topiramate, Vigabatrin, Zonisamide</td>
</tr>
<tr>
<td>Generalized Tonic-Clonic</td>
<td>Carbamazepine, Divalproex Sodium, Levetiracetam, Phenytoin, Primidone, Gabapentin, Lamotrigine, Oxcarbazepine, Phenobarbital, Topiramate, Vigabatrin, Zonisamide</td>
</tr>
<tr>
<td>Absence</td>
<td>Divalproex Sodium, Clonazepam, Ethosuximide, Lamotrigine, Vigabatrin, Zonisamide</td>
</tr>
</tbody>
</table>

*Adjunctive therapy
+ Schedule III controlled substance
§ Only available through a restricted distribution program called the Vigabatrin REMS Program. Indicated for refractory complex partial seizures in adjunct therapy in patients ≥10 years old that have failed several alternative treatments. Black box warning for possible permanent vision loss.

### Medication Monitoring Parameters for Formulary AEDs

<table>
<thead>
<tr>
<th>Medication</th>
<th>Design and Monitoring Parameter &amp; Frequency</th>
</tr>
</thead>
</table>
| Carbamazepine | • Prior to initiation of therapy, screen patients with ancestry in genetically at-risk populations (i.e., Asians, including South Asian Indians) for the presence of the BRI3063092 allele. The risk of developing Steven-Johnson syndrome and toxic epidermal necrolysis is higher in this patient population.  
• CBC with platelets (emphasis ANC) – baseline, twice a month for first 2 months, then annually or when clinically indicated.  
• Chemistry (emphasis hepatic & renal function and electrolytes) – baseline, one month, then annually or when clinically indicated  
• Physical Findings – perform baseline and periodic eye examinations  
• Levels – weekly for 2 weeks, one month, and then annually or when clinically indicated  
• Therapeutic level – 4 to 12 mcg/ml |
| Levetiracetam | • Chemistry – renal function in patients with preexisting renal impairment  
• Therapeutic level – not established |
| Phenytoin   | • CBC – baseline and annually or when clinically indicated  
• Chemistry (emphasis hepatic & renal function) – baseline, then annually or when clinically indicated  
• Levels – one week, one month, and then annually or when clinically indicated  
• Therapeutic level – 10 to 20 mcg/ml |
| Primidone  | • CBC – baseline and annually or when clinically indicated  
• Therapeutic level – 5 to 12 mcg/ml |
| Valproic Acid | • CBC with platelets – baseline and when clinically indicated  
• Chemistry (emphasis hepatic function) – baseline, one month, then annually or when clinically indicated  
• Protein, IBP, PTT at baseline and annually  
• Levels – weekly for 2 weeks, then annually or when clinically indicated  
• Therapeutic level – 50 to 100 mcg/ml |
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Usual Children, Adolescent and Adult Dose</th>
<th>Adverse Effects*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Tegretol®</td>
<td>• Seizures, disorientation, ataxia, GI upset &lt;br&gt; • Agranulocytosis, hypersensitivity, rash including Stevens Johnson, toxic epidermal necrolysis, hepatic failure, systemic lupus erythematosus, coagulation, arthritis.</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Vimpat®</td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Lacosamide</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity, rash including Stevens Johnson, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Neurontin®</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Gabapentin</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Ethosuximide</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Klonopin</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Clonazepam</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Briviact</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Primidone</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
</tr>
<tr>
<td>Depakote®</td>
<td></td>
<td>• Nausea, vomiting, CV symptoms &lt;br&gt; • Hypersensitivity reactions including risk of Stevens Johnson syndrome, agranulocytosis, hepatitis &amp; hepatic failure, megaloblastic anemia, pancreatitis, thrombocytopenia, hepatotoxicity</td>
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</table>
Appendix D (Continued)

Generic Name | Usual Children, Adolescent and Adult Dose | Adverse Effects*
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**Formulary AED Drug Interactions**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Drug Interactions and Comments</th>
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<tbody>
<tr>
<td>Carbamazepine (CBZ)</td>
<td>*DR - levels increased by VPA, phenytoin, vigabatrin, sulfonamides, trimethoprim, &amp; warfarin; levels decreased by phenytoin &amp; primidone.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>*DR - high-dose clinical significance unknown; not necessarily drug-VPA.</td>
</tr>
<tr>
<td>Botanic</td>
<td>*DR - levels increased by VPA, primidone, ethosuximide, allopurinol, fluconazole, vincristine, trimethoprim, &amp; warfarin; levels decreased by CBZ, vigabatrin, oxcarbazepine, topiramate, &amp; valproic acid (VPA).</td>
</tr>
<tr>
<td>Biodata</td>
<td>*DR - levels increased by oxcarbazepine, phenytoin, &amp; carbamazepine; reduced by phenobarbital &amp; phenytoin.</td>
</tr>
<tr>
<td>Valproic Acid (VPA)</td>
<td>*DR - levels increased by aspirin &amp; nonsteroidal anti-inflammatories; levels decreased by CBZ, phenytoin, &amp; phenobarbital.</td>
</tr>
</tbody>
</table>

*Not a complete list

Note: In 2008, the FDA issued a warning for a possible increased risk of suicidal ideation and behavior associated with antiepileptic drugs. This was based on a FDA review of 199 trials including 11 different antiepileptic drugs. Patients should be monitored for the emergence of suicidal thoughts or changes in behavior. Referral to mental health may be considered if appropriate.
PRODUCT INFORMATION

3TC see LAMIVUDINE

ABACAVIR (Max 11 refills)
   ZIAGEN®
   300 MG TABLET ($0.59)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ABILIFY® see ARIPIPRAZOLE

ABSORBASE
   EUCERIN®
   4 OZ ($2.62), 16 OZ ($3.36) CREAM
   (Note: Restricted to regional medical facilities and dialysis centers. All other uses require non-formulary approval.)

ACETAMINOPHEN
   APAP, TYLENOL®
   325 MG TABLET ($0.01)
   650 MG SUPPOSITORY – 50 SUPP/BOX ($12.94/BOX)
   650 MG/20.3 ML UD SOLUTION ($1.75)
   (Note: Take from stock. No refills allowed.)

ACETAMINOPHEN/CODEINE - CIII, CV
   TYLENOL® #3
   APAP 300 MG/CODEINE 30 MG TABLET – CIII ($0.12)
   APAP 300 MG/CODEINE 30 MG/12.5 ML UD SOLUTION - CV ($1.35)
   (Note: May not be given KOP. Non-formulary approval required for use > 10 days. A minimum 30 day period between orders is required for use beyond 10 days without a non-formulary approval. Take from stock. May only be ordered by a physician or DEA/DPS registered midlevel provider.)

ACETAZOLAMIDE (Max 11 refills)
   DIAMOX®
   250 MG TABLET ($0.93)

ACTIDOSE® see CHARCOAL, ACTIVATED

ACULAR® see KETOROLAC
ACYCLOVIR
  ZOVIRAX®
  400 MG TABLET ($0.07) (Max 11 refills)
  800 MG TABLET ($0.13) (No refills)

ADENOCARD® see ADENOSINE

ADENOSINE
  ADENOCARD®
  6 MG/2ML VIAL ($2.99)
  (Note: Clinic use only. Take from stock. May not be given KOP. Restricted to EMS and RMFs only.)

ADDERALL® see AMPHETAMINE SALTS

ADDERALL XR® see AMPHETAMINE SALTS

ADRENALIN see EPINEPHRINE

ALBUMIN, HUMAN
  PLASBUMIN-25®
  25% INJECTION – 100 ML ($86.50)
  (Note: Restricted to regional medical facilities as floor stock for use in paracentesis. Clinic use only. All other uses require non-formulary approval. May not be given KOP.)

ALBUTEROL
  VENTOLIN® (Clinic use-No refills, KOP use-max 11 refills)
  0.083% NEBULIZER SOLUTION – 3 ML UD 25/BOX ($2.68/BOX)
  (Note: CLINIC USE template-Take from stock. Clinic use only. KOP USE template-Prior Authorization criteria must be met and noted in special instructions field. Criteria is issued nebulizer machine. Must be ordered KOP and orders may not exceed 25 days. Dispensed in increments of 25.)

  PROVENTIL-HFA®, VENTOLIN® (Max 3 refills)
  METERED DOSE INHALER 90MCG/ACTION
  200 ACTUATIONS ($73.98, $49.88)
  (Note: Ventolin (Albuterol HFA) limited to Texas Tech units. Prior authorization criteria must be met and noted in the special instructions field. Criteria include: Texas Tech.)

ALCAINE® OPHTH SOLN see PROPARACAINE OPH SOL

ALDACTONE® see SPIRONOLACTONE
ALDOMET® see METHYLDOPA

ANTACID® see CALCIUM CARBONATE

ALLOPURINOL (Max 11 refills)
   ZYLOPRIM®
   100 MG ($0.06), 300 MG ($0.11) TABLET

ALPHAGAN® see BRIMONIDINE

ALTEPLASE
   (t-PA, CATHFLO ACTIVASE®)
   1 MG/1ML – 2 ML VIAL ($137.66)
   (Note: Clinic use only. Take from stock. May not be given KOP. Use and floor stock restricted to dialysis centers for catheter restoration.)

AMANTADINE HCL (Max 11 refills)
   SYMMETREL®
   100 MG CAPSULE ($0.67)
   (Note: Non-formulary approval required for TJJD facilities.)

AMIODARONE
   CORDARONE®
   200 MG TABLET ($0.21) (Max 11 refills)
   50 MG/ML INJECTION – 3 ML VIAL ($0.80) (No refills)
   (Note: Injection for clinic use only, should be taken from stock, may not be given KOP, and restricted to EMS and regional medical facilities.)

AMIODARONE IN D5W
   NEXTERONE®
   360 MG/200ML INJECTION – 200 ML BAG ($424.89) (No refills)
   (Note: Clinic use only. Take from stock. May not be given KOP. Restricted to regional medical facilities. Infusion rate 1mg/min, over 6 hours with in-line filter.)

AMLODIPINE (Max 11 refills)
   NORVASC®
   5 MG ($0.01), 10 MG ($0.01) TABLET

AMMONIA
   AROMATIC INHALANT - 0.33 ML ($3.71/BOX)
   (35% ALCOHOL, 15% AMMONIA) 12 INHALANTS/BOX
   (Note: Clinic use only. Take from stock. May not be given KOP.)
AMOXICILLIN
AMOXIL®
250 MG ($0.05), 500 MG ($0.05) CAPSULE

AMOXICILLIN/CLAVULANATE
AUGMENTIN®
875-125 MG TABLET ($0.40)
(Note: Allowed KOP at 8-hr units, may not be given KOP at all other units. Allowed as floor stock at E2 and GC only. Non-formulary approval still required for use.)

AMOXIL® see AMOXICILLIN

AMPHETAMINE/DEXTROAMPHETAMINE see AMPHETAMINE SALTS

AMPHETAMINE SALTS - CII
ADDERALL®
5 MG ($0.15), 10 MG ($0.53) TABLET
ADDERALL XR®
10 MG ($6.66), 20 MG ($6.66), 30 MG ($5.26) EXTENDED RELEASE CAPSULE
(Note: May not be given KOP. Restricted to TJJD only. Take from stock TJJD institutions only. May only be ordered by a physician.)

AMPICILLIN
OMNIPEN-N®
500 MG INJECTION, IM OR IV ($1.08)
IV Preparation Standard:
≤ 3 gm in 100 mL NS ONLY over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

ANALGESIC BALM see METHYL SALICYLATE/MENTHOL

ANCEF® see CEFAZOLIN

ANTACID see CALCIUM CARBONATE

ANTILIRIUM® see PHYSOSTIGMINE

ANTIVERT® see MECLIZINE HCL

ANU-MED® SUPPOSITORY see HEMORRHOIDAL SUPPOSITORY

ANUSOL-HC SUPP® see HYDROCORTISONE HEMORRHOIDAL SUPPOSITORY

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APRESOLINE® see HYDRAZINE

ARIPIPRAZOLE (Max 11 refills)
ABILIFY®
5 MG ($0.38), 10 MG ($0.19), 15 MG ($0.45), 20 MG ($0.24), 30 MG ($0.50) TABLET
(Note: May not be given KOP. 5mg restricted to TJJD.)

ARTIFICIAL TEARS SOLUTION see POLYVINYL ALCOHOL

ARZOL® see SILVER NITRATE

ASPIRIN (Max 11 refills)
BAYER® ASPIRIN
325 MG TABLET ($0.01)
ECOTRIN®
81 MG ($0.01), 325 MG ($0.01) ENTERIC-COATED TABLET

ATAZANAVIR (Max 11 refills)
REYATAZ®
200 MG ($4.20), 300 MG ($5.24) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ATENOLOL (Max 11 refills)
TENORMIN®
25 MG ($0.04), 50 MG ($0.03) TABLET

ATIVAN® see LORAZEPAM

ATOMOXETINE (Max 11 refills)
STRATTERA®
25 MG ($2.41), 40 MG ($2.69), 60 MG ($2.69), 80 MG ($2.72), 100 MG ($2.72) CAPSULE
(Note: May not be given KOP. Restricted to TJJD. Prior authorization must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
a. ADHD and failure on adequate dose and trial of both formulary stimulants.
b. ADHD and intolerance to both formulary stimulants.
c. ADHD and contraindication to use of both formulary stimulants.
d. ADHD and significant history of substance abuse.
e. ADHD and co-morbid anxiety disorder.)

ATORVASTATIN (Max 11 refills)
LIPITOR®
10 MG ($0.05), 20 MG ($0.06), 40 MG ($0.12), 80 MG ($0.10) TABLET

394
ATROPINE SULFATE
ATROPINE
0.1 MG/ML INJECTION – 10 ML SYRINGE ($4.54) (No refills)
(Note: Clinic use only. Take from stock. May not be given KOP.)
ISOPTO ATROPINE®
1% OPHTH SOLUTION – 15 ML ($77.70) (Max 11 refills)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ATROVENT HFA® see IPRATROPIUM BROMIDE

AUGMENTIN® see AMOXICILLIN/CLAVULANATE

AVLOSULFON® see DAPSONE

AZATHIOPRINE (Max 11 refills)
IMURAN®
50 MG TABLET ($0.37)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

AZITHROMYCIN (Max 11 refills)
ZITHROMAX®
600 MG TABLET ($2.05)
(Note: There are two ordering templates in the EHR for azithromycin including one for HIV MAC prophylaxis which has 11 allowable refills and one for GC/CT which has no allowable refills. Prior authorization criteria must be met and noted in the special instructions field for use without a non-formulary approval. Criteria include:
   a. HIV patients dosed 1200 milligrams q week for MAC primary prophylaxis when CD4 count < 50. Treatment should be continued for CD4 count of 50 to 100 and discontinued when the CD4 is >100 for ≥ 3 months. [Allowed KOP at 8-hour units, may not be given KOP at all other units.]
   b. Gonorrhea (GC)
      - 1200 milligrams x 1 dose in combination with ceftriaxone 250 mg IM x 1 dose
   c. Pregnancy
      - 1200 milligrams x 1 dose for chlamydia)

AZT see ZIDOVUDINE

AZULFIDINE® see SULFASALAZINE

B-1, VITAMIN see THIAMINE HCL

B-6, VITAMIN see PYRIDOXINE HCL

B-12, VITAMIN see CYANOCOBALAMIN
BACITRACIN/POLYMYXIN
POLYSPORIN®, DOUBLE ANTIBIOTIC OINTMENT
TOPICAL OINTMENT – 15 GM TUBE ($3.73)
POLYSPORIN®
OPHTHALMIC OINTMENT - 3.5 GM TUBE ($21.27)

BACLOFEN (Max 11 refills)
LIORESAL®
- 10 MG ($0.11), 20 MG ($0.38) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior
Authorization criteria must be met and noted in the special instructions field for use
without non-formulary approval. Criteria include:
  a. Spinal cord injury
  b. Multiple sclerosis
  c. Muscular dystrophy
  d. Spastic hemiplegia
  e. Amyotrophic lateral sclerosis
  f. Cerebral palsy)

BACTRIM® see SULFAMETHOXAZOLE/TRIMETHOPRIM
BARAclude® see ENTECAVIR
BAYER® ASPIRIN see ASPIRIN
BENADRYL® see DIPHENHYDRAMINE
BENEMID® see PROBENECID
BENZAC® see BENZOYL PEROXIDE

BENZOCAINE
ORAJEL®
- 10% ORAL GEL – 7 GM ($2.76)

BENZOYL PEROXIDE (Max 3 refills)
BENZAC®
- 10% GEL - 1.5 OZ ($1.95)
(Note: Orders are to be given a 90 day expiration date.)
BENZTROPINE MESYLATE
COGENTIN®
0.5 MG ($0.08), 1 MG ($0.05), 2 MG ($0.06) TABLET (Max 2 refills)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
1 MG/ML, 2 ML SDV ($28.41) (No refills)
(Note: Clinic use only. Take from stock. May not be given KOP. Floor stock and use restricted to psychiatric inpatient facilities (J4, SV, BC, JM). Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: patients with acute dystonia who fail to respond to diphenhydramine injection.

BETAPACE® see SOTALOL

BETANECHEL (Max 11 refills)
URECHOLINE®
25 MG TABLET ($0.45)

BICILLIN-LA® see PENICILLIN G BENZATHINE

BISACODYL
DULCOLAX®
5 MG TABLET ($0.02)
10 MG SUPPOSITORY ($0.08)
(Note: Take from stock.)

BISMUTH SUBSALICYLATE
PEPTO BISMOL®
262 MG CHEWABLE TABLET ($0.06)
(Note: Take from stock.)

BODY LOTION
DERMALUBE, LUBRIDEHM, LUBRISOFT®
LOTION ($1.71)
(Note: May be supplied as a different size depending on product availability. Take from stock.)

BOOSTRIX® see TETANUS/DIPHThERIA/ACELLULAR PERTUSSIS (TDaP)

BRETHINE® see TERBUTALINE SULFATE

BRIMONIDINE (Max 11 refills)
ALPHAGAN®
0.2% OPHTHALMIC SOLUTION -10 ML ($4.44)

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<table>
<thead>
<tr>
<th>Product Name</th>
<th>Formulation</th>
<th>Unit Price</th>
<th>Notes</th>
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</thead>
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<tr>
<td><strong>BROMOCRIPTINE MESYLATE (Max 11 refills)</strong></td>
<td>PARLODEL® 2.5 MG TABLET ($2.00)</td>
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<td>(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. May not be used post-partum to inhibit lactation.)</td>
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<tr>
<td><strong>BUPIVACAINE HCL</strong></td>
<td>MARCAINE® 0.5% INJECTION – 10 ML VIAL ($1.77)</td>
<td></td>
<td>(Note: Clinic use only. Take from stock. May not be given KOP.)</td>
</tr>
<tr>
<td><strong>BUTORPHANOL TARTRATE - CIV</strong></td>
<td>STADOL® 2 MG/ML IM INJECTION – 1 ML VIAL ($4.42)</td>
<td></td>
<td>(Note: Clinic use only. Take from stock. May not be given KOP. May only be ordered by a physician or a DEA/DPS registered midlevel provider.)</td>
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<td><strong>CALAMINE LOTION</strong></td>
<td>LOTION – 6 OZ ($1.28)</td>
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<td>(Note: Take from stock.)</td>
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<tr>
<td><strong>CALAN® SR see VERAPAMIL HCL</strong></td>
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<td><strong>CALAN® see VERAPAMIL HCL</strong></td>
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<tr>
<td><strong>CALCITRIOL (Max 11 refills)</strong></td>
<td>ROCALTROL® 0.25 MCG CAPSULE ($0.18)</td>
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<td>(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)</td>
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<tr>
<td><strong>CALCIUM CARBONATE (Max 11 refills)</strong></td>
<td>OS-CAL® 500 MG ELEMENTAL CALCIUM/1.25 GM CARBONATE SALT TAB ($0.01)</td>
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<td>(Note: For nursing protocol use only. No refills allowed.)</td>
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<tr>
<td><strong>CALCIUM CARBONATE/VITAMIN D (Max 11 refills)</strong></td>
<td>OSCAL 250 + VITAMIN D® 250 MG ELEMENTAL CALCIUM/125 IU VITAMIN D TABLET ($0.01)</td>
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</table>
CALCIUM GLUCONATE
10% INJECTION – 10 ML VIAL ($8.55)
(94 MG CALCIUM GLUCONATE EACH VIAL)
(Note: Clinic use only. Take from stock. May not be given KOP.)

CALCIUM POLYCARBOPHIL (Max 5 refills)
FIBERCON®: FIBER LAXATIVE
625 MG TABLET ($0.06)
(Note: Not allowed as floor stock except cards of 14 for nursing protocol orders only. No refills allowed on nursing protocol orders. Dispensed in increments of 30.)

CARBAMAZEPINE (Max 11 refills)
TEGRETOL®
200 MG TABLET ($0.22)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use cautiously in patients of Asian descent. See seizure pathway for complete details.)
SUSPENSION 100 MG/5 ML – 450 ML ($45.32)
(Note: May not be given KOP. Use cautiously in patients of Asian descent. See seizure pathway for complete details.)

CARBAMIDE Peroxide
DEBROX®
6.5% OTIC SOLUTION – 15 ML ($4.18)
(Note: Clinic use only, should be taken from stock, and may not be given KOP.)

CARBIDOPA/LEVODOPA (Max 11 refills)
SINEMET® 25-250
CARBIDOPA 25 MG/LEVODOPA 250 MG TABLET ($0.16)

CARDIZEM® see DILTIAZEM HCL

CARVEDILOL (Max 11 refills)
COREG®
3.125 MG ($0.04), 6.25 MG ($0.04), 12.5 MG ($0.04), 25 MG ($0.02) TAB

CASTOR OIL
CASTOR OIL – 120 ML ($1.00)
(Note: Take from stock.)

CATAPRES® see CLONIDINE HCL

CATHFLO ACTIVASE® see ALTEPLASE

399
CEFAZOLIN SODIUM
ANCEF®
1 GM INJECTION – 10 ML VIAL ($0.78)
Preparation Standard:
≤ 2 gm in 100mL D5W over 30-60 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

CEFTAZIDIME
FORTAZ®, TAZICEF ®
500 MG INJECTION ($4.98)
1 GM INJECTION ($3.89)
IV Preparation Standard:
100 mL D5W over 30 minutes
(Note: Clinic use only. Take from stock for RMFs and TJJD only. May not be given KOP. Restricted to regional medical facilities (inpatient use only) and TJJD. Should not be used as single injectable dose followed by oral therapy.)

CEFTRIAXONE
ROCEPHIN®
250 MG INJECTION ($0.68)
(Note: Clinic use only. May not be given KOP. Prior authorization criteria must be met and noted in the special instructions field for use. Criteria is: Treatment of GC in combination with azithromycin 1200 milligrams x 1 dose.)
1 GM INJECTION ($1.35)
(Note: Clinic use only. Take from stock for RMFs, infirmaries, and TJJD only. May not be given KOP. Restricted to regional medical facilities (inpatient use only), infirmary units (inpatient use only), and TJJD.)

CELEXA® see CITALOPRAM HBR

CELLCEPT® see MYCOPHENOLATE MOFETIL

CEPHALEXIN
KEFLEX®
500 MG CAPSULE ($0.20)

CHARCOAL
ACTIDOSE® WITH SORBITOL
50 GM ACTIVATED CHARCOAL / 54 GM SORBITOL LIQUID – 8 OZ ($17.56)
(Note: Clinic use only. Take from stock. May not be given KOP.)
CHLORDIAZEPoxide - cIV
LIBRIUM®
10 MG ($0.44), 25 MG ($0.47) CAPSULE
(Note: May not be given KOP. Restricted to benzodiazepine discontinuation. Take from stock. May only be ordered by a physician or a DEA/DPS registered midlevel provider.)

CHLORHEXIDINE GLUCONATE
PERIDEX®
0.12% ORAL RINSE – 16 OZ ($1.86)
(Note: Restricted to floor stock.)

CHLORPHENIRAMINE MALEATE
CTM, CHLOR-TRIMETON®
4 MG TABLET ($0.03)
(Note: Take from stock.)

CHLOR-TRIMETON® see CHLORPHENIRAMINE

CIBALITH-S® see LITHIUM CITRATE

CILoxAN® see CIPROFLOXACIN

CIPRO® see CIPROFLOXACIN

CIPROFLOXACIN
CILOXAN®
0.3% OPHTHALMIC SOLUTION – 5 ML ($4.13)
(Note: Prior authorization criteria must be met and noted in the special instructions field for use without a non-formulary approval. Criteria include: post-cataract surgery or ocular procedures. Floor stock restricted to Montford.)

CIPRO®
500 MG TABLET ($0.15)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use restricted to regional medical facilities (inpatient use only). Available as floor stock to prevent delays in therapy. Not recommended for GC or gram positive infections including S. aureus. Non-formulary approval still required for use at facilities other than RMF's.)

CITALOPRAM HBR (Max 11 refills)
CELEXA®
10 MG ($0.05), 20 MG ($0.02), 40 MG ($0.02) TABLET
(Note: May not be given KOP. 10 mg restricted to TJJD only.)
CLARITIN® see LORATADINE
CLEAR EYES® see NAPHAZOLINE
CLEOCIN®, CLEOCIN-T® see CLINDAMYCIN

CLINDAMYCIN HCL
CLEOCIN®
150 MG CAPSULE ($0.08)

CLINDAMYCIN PHOSPHATE
CLEOCIN®, CLEOCIN-T®
1% TOPICAL SOLUTION – 60 ML ($36.61)
(Nota: Topical solution is restricted to TJJD facilities and may not be given KOP.)
150 MG/ML – 6 ML VIAL ($3.90)
IV Preparation Standard:
> 600 mg in 100mL D5W over 60 minutes. Maximum rate of infusion 30 mg/minute.
900 MG/50 ML D5W PREMIX ($14.50)
(Note: Injection is clinic use only. Take from stock. May not be given KOP.)

CLONIDINE HCL
CATAPRES®
0.1 MG TABLET ($0.05)
(Note: Clinic use only for hypertensive urgency or management of withdrawal symptoms from opioid discontinuation. Take from stock. May not be given KOP. A 30-day supply may be ordered for intake patients without a non-formulary approval to facilitate tapering off the medication and conversion to a formulary agent. Providers must type “intake” in the special instructions field. All other uses require non-formulary approval.)
CLOPIDOGREL (Max 11 refills)

**PLAVIX®**

75 MG TABLET ($0.08)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria includes:

a. Intolerant or allergic to aspirin and needs cardioprotection or prevention

b. Failed aspirin therapy [e.g., event while on aspirin such as MI, stroke, TIA]

c. Acute Coronary Syndrome [e.g., MI, unstable angina, CABG or PCI with or without stent placement] and treatment is in combination with aspirin

d. Brachytherapy

e. Intermittent claudication and failed trial or remained symptomatic while on aspirin plus dipyridamole

f. Dialysis vascular graft.

Available in stock to prevent delays in therapy. Non-formulary approval is still required for all other uses.)

CLOTRIMAZOLE

**LOTRIMIN®**

1% TOPICAL SOLUTION – 10 ML ($33.50)

1% CREAM – 15 GM TUBE ($1.09)

CLOZAPINE (Max 11 refills)

**CLOZARIL®**

25 MG ($0.45), 100 MG ($1.10) TABLET

(Note: May not be given KOP. Non-formulary approval is required for use. Clozapine REMS Program enrollment and monitoring required (Pharmacy Policy 55-20). Floor stock restricted to Skyview.)

CLOZARIL® see CLOZAPINE

COAL TAR

**PC-TAR®**

1% SHAMPOO – 6 OZ ($3.70)

(Note: Should be ordered for 1 bottle to last 90 days.)

COGENTIN® see BENZTROPINE MESYLATED

COLACE ® see DOCUSATE SODIUM
COLLAGENASE
SANTYL®
250 UNITS/GM – 30 GM OINTMENT ($209.47)
(Note: Clinic use only. Take from stock for wound care facilities only. May not be given KOP. Use is restricted to wound care facilities.)

COMPZINE® see PROCHLORPERAZINE

COMPOUND W® see SALICYLIC ACID

CONCERTA® see METHYLPHENIDATE

CONDYLOX® see PODOFILOX

CORDARONE® see AMIODARONE

COREG® see CARVEDILOL

CORTISPORIN® see NEOMYCIN/POLYMYXIN/BACITRAZIN/HYDROCORTISONE

CORTISPORIN® OTIC see NEOMYCIN/POLYMYXIN/HYDROCORTISONE

COUMADIN® see WARFARIN SODIUM

CREON 12® see PANCRELIPASE

CRYSELLE® see NORGESTREL/ETHINYL ESTRADIOL

CTM see CHLORPHENIRAMINE MALEATE

CYANOCOBALAMIN, VITAMIN B-12 (Max 11 refills)
1000 MCG/ML INJECTION – 1 ML VIAL ($2.51)
(Note: Clinic use only. Take from stock. May not be given KOP.)

CYCLOGYL® see CYCLOPENTOLATE HCL

CYCLOPENTOLATE HCL
CYCLOGYL®
1% OPHTHALMIC SOLUTION – 15 ML ($20.61)

CYCLOSPORINE (Max 11 refills)
NEORAL®
25 MG ($0.72), 100 MG ($2.11) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
CYMBALTA® see DULOXETINE
D-T TOXOIDS see TETANUS & DIPHTHERIA TOXOIDS
DACRIOSE® see OPHTHALMIC IRRIGATING SOLUTION
DAPSONE (Max 11 refills)
   AVLOSULFON®
   100 MG TABLET ($1.54)
DARAPRIM® see PYRIMETHAMINE
DARUNAVIR (Max 11 refills)
   PREZISTA®
   600 MG ($24.64), 800 MG ($48.90) TABLET
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. The 600 mg is dosed BID and the 800 mg is dosed QD.)
DDAVP see DESMOPRESSIN
DDI see DIDANOSINE
DEBROX® see CARBAMIDE PEROXIDE
DECADRON® see DEXAMETHASONE
DELTASONE® see PREDNISONE
DEPAKOTE® see DIVALPROEX SODIUM
DEPAKOTE ER® see DIVALPROEX SODIUM ER
DEPO-ESTRADIOL® see ESTRADIOL CYPIONATE
DEPO-PROVERA® see MEDROXYPROGESTERONE
DESMOPRESSIN (Max 5 refills)
   DDAVP®
   0.2 MG TABLET ($0.83)
   (Note: May not be given KOP. Restricted to TJJD use only.)
DESYREL® see TRAZODONE HCL
DEXAMETHASONE
DECADRON®
4 MG/ML – 1 ML VIAL ($0.65) (No refills)
(Note: Clinic use only. Take from stock. May not be given KOP).
4 MG TABLET ($0.92) (Max 11 refills)
(Note: Tablet allowed as floor stock at E2 and GC only. Non-formulary approval still required for use.)

DEXTROAMPHETAMINE/AMPHETAMINE see AMPHETAMINE SALTS

DEXTROSE

DEXTROSE 5% in WATER INJECTION
100 ML ($1.94), 250 ML, ($3.39), 500 ML ($3.52), 1000 ML ($4.20)
DEXTROSE 5% in WATER INJECTION MINI-BAG – 100 ML ($4.97)
DEXTROSE 5% in NS INJECTION – 500 ML ($5.09), 1000 ML ($4.40)
DEXTROSE 5% in 1/4 NS INJECTION – 1000 ML ($5.33)
DEXTROSE 5% in 1/2 NS INJECTION – 1000 ML ($4.63)
DEXTROSE 5% LACTATED RINGERS – 1000 ML ($4.68)
DEXTROSE 10% in WATER INJECTION – 1000 ML ($6.48)
DEXTROSE 50% INJECTION SYRINGE – 50 ML ($7.21)
DEXTROSE 40% GEL 37.5 GM TUBE – 3 TUBES/BOX
GLUTOSE 15® ($2.93/TUBE)
(Note: Clinic use only. Take from stock. May not be given KOP, D10W 1000 mL restricted to Beto, Estelle, Michael, Montford and Young facilities for use until TPN is available.)

DIAMOX® see ACETAZOLAMIDE

DIAZEPAM - CIV (Max 5 refills)
VALIUM®
5 MG TABLET ($0.07)
(Note: May not be given KOP. May only be ordered by a physician or DEA/DPS registered midlevel provider. Prior authorization must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
  a. Spinal cord injury
  b. Multiple sclerosis
  c. Muscular dystrophy
  d. Spastic hemiplegia
  e. Amyotrophic lateral sclerosis
  f. Cerebral palsy)

DICLOxacillin Sodium
DYNAPEN®
250 MG ($0.41), 500 MG ($0.77) CAPSULE

406
DIDANOSINE EC (DDI) (Max 11 refills)
VIDEX-EC®
  250 MG ($4.21), 400 MG ($7.96) ENTERIC COATED CAPSULE
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Best if
taken on an empty stomach in the evening.)

DIFLUCAN® see FLUCONAZOLE

DIGOXIN® see DIGOXIN

DIGOXIN (Max 11 refills)
LANOXIN®, DIGOXIN®
  0.125 MG ($0.79), 0.25 MG ($0.46) TABLET

DILACOR® XR see DILTAZEM HCL

DILANTIN® see PHENYTOIN SODIUM

DILTAZEM (Max 11 refills)
CARDIZEM®
  60 MG ($0.18), 90 MG ($0.28) TABLET
DILACOR® XR (extended release once-daily dosage form)
  180 MG ($0.56), 240 MG ($0.63) CAPSULE

DIPHENHYDRAMINE HCL
BENADRYL®
  25 MG ($0.01), 50 MG CAPSULE ($0.01) (Max 2 refills)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
ELIXIR 12.5 MG/5 ML – 480 ML ($1.87) (No refills)
  (Note: May not be given KOP.)
50 MG/ML INJECTION – 1 ML VIAL ($0.85) (No refills)
  (Note: May not be given KOP. Clinic use only. Take from stock.)

DIPHTHERIA/TETANUS TOXOIDS see TETANUS & DIPHTHERIA TOXOIDS

DIPYRIDAMOLE (Max 11 refills)
PERSANTINE®
  75 MG TABLET ($0.79)
  (Note: Use should be limited to combination therapy with ASA for intermittent
claudication.)

DITROPA® see OXYBUTYNIN

407
Divalproex Sodium EC (Max 11 refills)
  DEPAKOTE EC®
    250 MG ($0.04), 500 MG ($0.07) ENTERIC COATED TABLET
    (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

Divalproex Sodium ER (Max 11 refills)
  DEPAKOTE ER®
    250 MG ($0.40), 500 MG ($0.29) EXTENDED RELEASE TABLET
    (Note: Restricted to TJJD. Allowed KOP at 8-hour units, may not be given KOP at all other units.)

Docusate Sodium (Max 5 refills)
  COLACE®
    100 MG CAPSULE ($0.01)

Dolutegravir (Max 11 refills)
  Tivicay®
    50 MG TABLET ($51.27)
    (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

Dopamine
  DOPAMINE 400 MG IN 5% DEXTROSE 250 ML ($10.97)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

Dorzolamide
  TRUSOPT®
    2% OPHTHALMIC SOLUTION – 10 ML ($11.31)

Double Antibiotic Ointment see Bacitracin/Polymyxin B

D-T Toxoids see see Tetanus & Diphtheria Toxoids

Dulcolax® see Bisacodyl

Duloxetine (Max 11 refills)
  CYMBALTA®
    30 MG ($0.28), 60 MG ($0.10) DELAYED-RELEASE CAPSULE
    (Note: May not be given KOP.)

Duofilm® see Salicylic Acid

Duragesic® see Fentanyl
DYAZIDE® see TRIAMTERENE/HCTZ

DYNAPE® see DICLOXACILLIN SODIUM

ECOTRIN® see ASPIRIN, ENTERIC-COATED

EDURANT® see RILPIVIRINE

EFAVIRENzung (Max 11 refills)
   SUSTIVA®
       600 MG TABLET ($30.33)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

EFFEXOR® XR see VENLAFAXINE HCL

ELECTROLYTE ORAL SOLUTION
   GOLYTELY®
       PEG 3350 & ELECTROLYTE SOLUTION - 4 LITER BOTTLE ($17.93)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

ELIMITE® see PERMETHRIN

ELLA® see ULIPRISTAL

ELOCON® see MOMETASONE FURorate

ELVITEGRAVIR/Cobicistat/Emtricitabine/Tenofovir (Max 11 refills)
   GENVOYA®
       150 MG/150 MG/200 MG/10 MG TABLET ($91.85)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior authorization criteria must be met and noted in the special instructions field for use without a non-formulary approval. Criteria include: Patient on Genvoya or Stribild at intake.)

ENGEX® B see HEPATITIS B VACCINE, RECOMBINANT

ENTECAVIR (Max 11 refills)
   BARACLUDE®
       0.5 MG ($2.00), 1 MG ($2.03) TABLET
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Non-formulary approval required by HCV group from Pharmacy at utmbcme.pharmacyId@utmb.edu for UTMB units and assigned clinical pharmacist for TTUHSC units.)
ENTERAL FEEDING
OSMOLITE® 1.0 CAL
8 OZ ARC ($1.02)
(Note: May not be given KOP. Take from stock. Enteral feeding formulation may be therapeutically interchanged if unavailable. No refills allowed except dialysis may order a maximum of 5 refills.)

ENULOSE® see LACTULOSE

EPCLUSIA® see SOFOSBUVIR/VELPATASVIR

EPINEPHRINE HCL
ADRENALIN®
1:1000 (1 MG) INJECTION – 1 ML VIAL ($13.88)
1:10,000 (0.1 MG) INJECTION – 10 ML SYRINGE ($5.61)
EPIPEN®
1:1000 (0.3 MG/0.3 ML) INJECTION – 2 SYRINGES/PK ($70.16/SYR)
(Note: Clinic use only. Take from stock. May not be given KOP. Epipen restricted to EMS and TJJD institutions for emergency boxes and patients at TJJD halfway houses. Non-formulary approval required for patient orders at TDCJ.)

EPIPEN® see EPINEPHRINE

EPIVIR® see LAMIVUDINE

EPOETIN ALFA (Max 2 refills)
EPOGEN®
10,000 UNIT/ML INJECTION – 2 ML MDV ($307.69)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to dialysis units as floor stock. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: Dialysis.)

EPOGEN see EPOETIN ALFA

ERYTHROMYCIN BASE
ERYTHROMYCIN DR®
250 MG CAPSULE ($4.48)

ERYTHROMYCIN
ILOTYCIN®
0.5% OPHTHALMIC OINTMENT - 3.5 GM ($8.48)

ERYTHROPOIETIN see EPOETIN ALFA
ESCITALOPRAM (Max 11 refills)
LEXAPRO®
5 MG ($0.09), 10 MG ($0.41), 20 MG ($0.18) TABLET
(Note: May not be given KOP. Restricted to TJJD use only.)

ESKALITH® see LITHIUM CARBONATE

ESTRADIOL CYPROLATE (Max 11 refills)
DEPO-ESTRADIOL®
5 MG/ML INJECTION – 5 ML MDV ($97.65)
(Note: May not be given KOP. Injection for clinic use only and should be taken from stock for TDCJ units only. Non-formulary approval still required for use.)

ESTROGENS, BIRTH CONTROL
see ETHYNODIOL DIACETATE / ETHINYL ESTRADIOL (ZOVIA®)
see NORETHINDRONE / ETHINYL ESTRADIOL (ORTHO-NOVUM®, PIRMELLA®)
see NORGESTREL / ETHINYL ESTRADIOL (LOW-OGESTREL®, LO-OVRA®)

ESTROGENS, CONJUGATED
PREMARIN®
0.625 MG ($4.86), 1.25 MG ($4.87) TABLET (Max 11 refills)
(Note: Restricted to use in female patients only.)

ESTROGENS, CONJUGATED, VAGINAL (Max 11 refills)
PREMARIN VAGINAL CREAM®
0.625 MG/GRAM – 30 GRAM TUBE ($330.12)
(Note: Restricted to use in female patients only.)

ETHAMBUTOL HCL (Max 11 refills)
MYAMBUTOL®
400 MG TABLET ($0.80)
(Note: May not be given KOP. Treatment of active TB should be DOT.)

ETHYNOUL DIACETATE/ETHINYL ESTRADIOL (Max 11 refills)
ZOVIA – 1/50®
1/50-28 TABLET ($19.31/pack)
(Note: Restricted to female patients.)

EUCERIN® see ABSORBACE
FENTANYL - CII
DURAGESIC®
25 MCG/HR ($3.27), 100 MCG/HR ($18.00) PATCH
(Note: Floor stock restricted to hospice facilities. May not be given KOP. May only be ordered by a physician. Non-formulary approval is required prior to use.)

FEOSOL® see FERROUS SULFATE

FERROUS SULFATE (Max 11 refills)
FEOSOL®
325 MG TABLET ($0.01)

FIBERCON®, FIBER LAXATIVE see CALCIUM POLYCARBOPHIL

FILGRASTIM (Max 11 refills)
NEUPOGEN®
300 MCG/ML - 1ML SDV ($292.13), 480 MCG/1.6 ML SDV ($465.18)
(Note: Clinic use only. May not be given KOP. Allowed as floor stock at E2 and GC only. Non-formulary approval still required for use.)

FLEETS PHOSPHO SODA® see SODIUM PHOSPHATE ORAL SOLUTION

FLAGYL® see METRONIDAZOLE

FLOVENT® see FLUTICASONE

FLUCONAZOLE (Max 11 refills)
DIFLUCAN®
100 MG ($0.37), 150 MG ($1.91), 200 MG ($1.24) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior authorization must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
   a. 100 mg and 200 mg tablets restricted to treatment of HIV-related opportunistic infections.
   b. 150 mg tablets restricted to single dose therapy for vaginal candidiasis.)

FLULAVAL® see INFLUENZA VIRUS VACCINE

FLUMAZENIL
ROMAZICON®
0.1 MG/ML IV INJECTION – 5 ML VIAL ($2.89)
(Note: Restricted to emergency use only. Clinic use only. Take from stock. May not be given KOP.)
FLUOCINONIDE
LIDEX®
  0.05% OINTMENT – 15 GM ($18.06)
  0.05% CREAM – 15 GM ($15.06)

FLUORET® see FLUORESCIN SODIUM STRIPS

FLUORESCIN SODIUM STRIPS
  FLUORET®, BIO-GLO®, FUL-GLO®
  1 MG OPHTHALMIC STRIPS – 100/BOX ($0.07 each strip)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

FLUOXETINE (Max 11 refills)
  PROZAC®
  10 MG ($0.03), 20 MG ($0.02) CAPSULE
  (Note: May not be given KOP. 10 mg restricted to TJJD only.)

FLUPHENAZINE HCL (Max 11 refills)
  PROLIXIN®
  2.5 MG ($0.51), 5 MG ($0.37), 10 MG ($0.46) TABLET
  2.5 MG/ML INJECTION – 10 ML VIAL ($169.72)
  (Note: May not be given KOP. Injection for clinic use only, should be taken from stock and may not be given KOP.)

FLUPHENAZINE DECANOATE (Max 11 refills)
  PROLIXIN D®
  25 MG/ML INJECTION – 5 ML VIAL ($56.96)
  (Note: Injection for clinic use only, should be taken from stock and may not be given KOP.)

FLUTICASONE HFA (Max 11 refills)
  FLOVENT®
  HFA ORAL INHALER 120 ACTUATIONS/110MCG EACH ($225.75)
  (Note: 1 inhaler will last 60 days at 1 puff BID (maximum 5 refills), 30 days at 2 puffs BID, and 20 days at 3 puffs BID. Inhaler should be ordered accordingly. For doses exceeding 3 puffs BID, seek non-formulary approval for Fluticasone 220 mcg. Drug interaction with protease inhibitors and cobicistat. For these patients seek non-formulary approval for QVAR 80 mcg RediHaler.)

FOLIC ACID (Max 11 refills)
  FOLVITE®
  1 MG TABLET ($0.01)

FOLIC ACID see LEUCOVORIN CALCIUM
FOLVITE® see FOLIC ACID

FORTAZ® see CEFTAZIDIME

FOSAMPRENARVIR (Max 11 refills)
LEXIVA®
700 MG TABLET ($18.06)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

FUROSEMI DE
LASIX®
20 MG ($0.02), 40 MG ($0.03) TABLET (Max 11 refills)
10 MG/ML INJECTION – 4 ML VIAL ($1.16) (No refills)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP.)

GARDASIL 9® see HUMAN PAPILLOMAVIRUS

GEL-KAM® see STANNOUS FLUORIDE

GEMFIBROZIL (Max 11 refills)
LOPID®
600 MG TABLET ($0.05)

GENOPTIC® see GENTAMICIN

GENTAMICIN
GARAMICIN®, GENOPTIC®, GENTAK®
0.3% OPHTHALMIC OINTMENT - 3.5 GM ($13.80)
0.3% OPHTHALMIC SOLUTION – 5 ML ($3.90)

GENTAMICIN
40 MG/ML INJECTION – 2 ML VIAL ($1.01)
IV Preparation Standard:
In 100mL D5W over 60 minutes
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

GENTIAN VIOLET
2% SOLUTION – 60 ML ($11.23)
(Note: Clinic use only. Take from stock. May not be given KOP.)

GENVOYA® see ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR

GEODON® see ZIPRASIDONE
GLIPIZIDE (Max 11 refills)
GLUCOTROL®
  5 MG ($0.02), 10 MG ($0.03) TABLET

GLUCAGON

GLUCAGEN®
  1 MG HYPOKIT ($251.89)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

GLUCOTROL® see GLIPIZIDE

GLUCOLA® see GLUCOSE TOLERANCE TEST

GLUCOPHAGE® see METFORMIN

GLUCOSE TOLERANCE TEST
  GLUCOLA®
  100 GM GLUCOSE - 10 OZ BOTTLE ($5.78)
  (Note: Clinic use only. Take from stock. May not be given KOP. For diagnostic use in
female facilities only.)

GLUTOSE 15® see DEXTROSE 40% GEL

GLYDO® see LIDOCAINE HCL

GOLYTELY® see ELECTROLYTE ORAL SOLUTION

GUANFACINE (Max 11 refills)
  TENEX®
  1 MG ($0.11), 2 MG ($0.15) TABLET
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

GUANFACINE ER (Max 11 refills)
  INTUNIV ER®
  1 MG ($0.41), 2 MG ($0.68), 3 MG ($0.68), 4 MG ($0.68) EXTENDED
  RELEASE TABLET
  (Note: May not be given KOP. Restricted to TJJD use only.)

HALDOL® see HALOPERIDOL, HALOPERIDOL LACTATE

HALDOL D® see HALOPERIDOL DECANOATE
HALOPERIDOL (Max 11 refills)
HALDOL®
1 MG ($0.26), 5 MG ($0.34), 10 MG ($0.51) TABLET
(Note: May not be given KOP.)

HALOPERIDOL LACTATE
HALDOL®
2 MG/ML ORAL CONCENTRATE – 120 ML ($8.08) (Max 11 refills)
5 MG/ML INJECTION – 1 ML VIAL ($0.78) (No refills)
(Note: May not be given KOP. Injection for clinic use only and should be taken from stock.)

HALOPERIDOL DECANOATE (Max 11 refills)
HALDOL D®
100 MG/ML INJECTION – 1 ML SDV ($40.64)
100 MG/ML INJECTION – 5 ML MDV ($176.82)
(Note: May not be given KOP. Injection for clinic use only and should be taken from stock. 5 ML MDV restricted to psychiatric inpatient facilities (J4, SV, BC, JM) and facilities with Therapeutic Diversion Programs (AH, M)).

HAVRIX® see HEPATITIS A VACCINE

HEMORRHOIDAL
PREPARATION H ®
MAXIMUM STRENGTH CREAM 51 GM ($2.27) (Max 11 Refills)
ANU-MED®
SUPPOSITORY - 12/BOX ($0.09/suppos) (No refills)
(Note: Take from stock. Cream contains pramoxine HCL 1% and phenylephrine 0.25%. Suppositories contain phenylephrine HCL 0.25% as active ingredients.)

HEMORRHoidal-HC RECTAL SUPPOSITORY see HYDROCORTISONE

HEP-LOCK® see HEPARIN SODIUM

HEPARIN SODIUM
HEP-LOCK®
100 U/ML – 3 ML SYRINGE ($0.39)
HEPARIN
1,000 U/ML – 30 ML VIAL ($3.21)
5,000 U/ML – 1 ML VIAL ($1.12)
(Note: Clinic use only. Take from stock. May not be given KOP. 1,000 U/ML-30 ML restricted to dialysis centers.)
HEPATITIS A VACCINE, INACTIVATED (Max 1 refill)
HAVRIX®
1440 EL.U/ML – 1 ML SYR ($61.42)
(Note:  May not be given KOP. Restricted from floor stock. Order for 180 days to be given at 0 and 6 months. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: patient is not immune (P&P B-14.07) plus one of the following
a. HIV
b. Chronic hepatitis C
c. Chronic hepatitis B
d. End stage liver disease)

HEPATITIS B VACCINE, RECOMBINANT (Max 2 refills)
ENGERIX B®
20 MCG/ML – 1 ML SDV ($53.14)
(Note: Clinic use only. Restricted from floor stock. May not be given KOP. Order for 60 days with 2 refills to be given at 0, 2, & 4 months. The Pharmacy will send each dose as an individual patient medication order. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: patient is not immune (P&P B-14.07) plus one of the following
a. Chronic hepatitis C
b. HIV
d. Offenders who are subject to a blood borne exposure as outlined in Infection Control Policy B-14.06 (post-exposure prophylaxis)
e. Offender workers in job classifications that have potential for occupational exposure as outlined in Correctional Managed Healthcare Policy B-14.4
f. ≤ 19 year old without documentation of series completion (labwork not required)
g. End stage liver disease)

HEPATITIS B VACCINE, RECOMBINANT, DIALYSIS FORMULATION (Max 2 refills)
RECOMBIVAX HB®
40 MCG/ML – 1 ML SDV ($93.49)
(Note: Clinic use only. Restricted from floor stock. May not be given KOP. Order for 60 days with 2 refills to be given at 0, 2, & 4 months. The Pharmacy will send each dose as an individual patient medication order. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: patient is not immune (P&P B-14.07) plus patient is on dialysis.)
HUMAN PAPILLOMAVIRUS VACCINE (HPV) (Max 2 refills)

GARDASIL®

0.5 ML SINGLE DOSE VIAL ($190.11)
(Note: Clinic use only. Restricted from floor stock. May not be given KOP. Order for 60 days with 2 refills to be given at 0, 2 and 4 months. The Pharmacy will send each dose as an individual patient medication order. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: Female patient age 9 through 26 and has not been previously vaccinated.)

HYDRAZOLE (Max 11 refills)

APRESOLINE®

25 MG ($0.02), 50 MG ($0.03) TABLET

HYDROCHLOROTHIAZIDE (Max 11 refills)

HYDRODIURIL®

12.5 MG CAPSULE ($0.04)
25 MG ($0.01), 50 MG ($0.01) TABLET

HYDROCORTISONE

ANUSOL-HC®

25 MG HEMORRHOIDAL-HC RECTAL SUPPOSITORY–12/BOX ($4.36 EACH)

HYTONE®

1% CREAM – 30 GM ($1.22), U/D PACKET ($0.05)

HYDROCORTISONE SODIUM SUCCINATE

SOLU-CORTEF®

100 MG INJECTION - 2ML VIAL ($9.17)
250 MG INJECTION - 2ML VIAL ($23.19)
IV Preparation Standard:
50-100 mg in 100 mL D5W over 40 minutes
>100 mg in 250 mL D5W over 60 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

HYDRODIURIL® see HYDROCHLOROTHIAZIDE

HYDROXYZINE PAMOATE (Max 2 refills)

VISTARIL®

25 MG ($0.12), 50 MG ($0.015) CAPSULE
(Note: May not be given KOP. Restricted to TJJD only.)

HYTONE® see HYDROCORTISONE CREAM
HYTRIN® see TERAZOSIN

IBUPROFEN (Max 2 refills)
MOTRIN®
  200 MG ($0.02), 400 MG ($0.02), 600 MG ($0.03), 800 MG ($0.06)
  TABLET
  (Note: The 200 mg tablets should be taken from stock, no refills allowed and restricted to Texas Tech TDCJ facilities and TJJD facilities; restricted to dental use only for UTMB TDCJ facilities. 30D and 90D templates for 1 card of 30 to last 30 and 90 days.)

IMDUR® see ISOSORBIDE MONONITRATE

IMIPRAMINE HCL (Max 11 refills)
TOFRANIL®
  25 MG ($0.19), 50 MG ($0.29) TABLET
  (Note: May not be given KOP. Restricted to TJJD for treatment of enuresis.)

IMODIUM® see LOPERAMIDE HCL

IMURAN® see AZATHIOPRINE

INDERAL® see PROPRANOLOL

INFLIXIMAB (Max 5 refills)
REMICADE®
  100 MG IV INJECTION ($1083.62)
  (Note: Floor stock restricted to RMFs. Designated as a Local Control and therefore must be kept and inventoried as a controlled substance (Pharmacy Policies 20-05, 20-10, 20-15). Non-formulary approval is still required prior to use. May not be given KOP.)

INFLUENZA VIRUS VACCINE, WHOLE VIRUS
FLUCELVAX®, FLUVIRIN®
  5 ML MULTI-DOSE VIAL - 10 DOSES/VIAL ($132.50)
  (Note: Clinic use only. Take from stock. May not be given KOP. Seasonally available. Follow Infection Control P&P B-14.51.
  a. ≥ 50 years old
  b. Certain chronic diseases (heart disease, asthma, COPD, diabetes, renal disease, hepatic disease, neurologic disease, asplenic, and hematologic disease)
  c. Immunocompromising diseases (HIV, most cancers, ESRD, sickle cell, medications)
  d. Pregnancy during the influenza season
  e. < 18 years old and on chronic aspirin therapy
  f. Morbidly obese BMI ≥ 40)
INFUVITE® see MULTIVITAMIN

INH see ISONIAZID

INSULIN, HUMAN (Max 11 refills)

NOVOLIN®

- NPH 100 UNITS/ML – 10 ML VIAL ($127.77)
- REGULAR 100 UNITS/ML – 10 ML VIAL ($127.77)

(Note: Clinic use only. Take from stock. May not be given KOP. Once opened, must be discarded after 30 days if stored refrigerated or at room temperature.)

INVTUNIVER® see GUANFACINE ER

INVIRASE® see SAQUINAVIR

IPRATROPium BROMIDE

ATROVENT® (Clinic use - No refills, KOP use - max 11 refills)

- 0.02% NEBULIZER SOLUTION - 2.5 ML UD 25/BOX ($2.78/BOX)

(Note: CLINIC USE template - Take from stock. Clinic use only. KOP USE template - Prior Authorization criteria must be met and noted in special instructions field. Criteria is issued nebulizer machine. Must be ordered KOP and orders may not exceed 25 days. Dispensed in increments of 25.)

ATROVENT HFA® (Max 11 refills)

- HFA ORAL INHALER 200 ACTUATIONS/17 MCG EACH ($333.44)

IRON SUCROSE (Max 11 refills)

VENOFER®

- 20 MG/ML – 5 ML SINGLE DOSE VIAL ($44.54)

(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to dialysis centers.)

ISENTRESS® see RaltegraVIR

ISONIAZID (Max 11 refills)

NYDRAZIDE®, INH

- 300 MG TABLET ($0.17)

(Note: May not be given KOP. Twice weekly dosing for TB should be DOT. Treatment of active TB should be DOT.)

ISOPTO ATROPINE® see ATROPINE SULFATE

ISORDIL® see ISOSORBIDE DINITRATE
ISOSORBIDE DINITRATE (Max 11 refills)
ISORDIL®
10 MG ($0.54), 20 MG ($0.59)
(Note: Prior Authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria is: Heart Failure. Should be used in combination with hydralazine.)

ISOSORBIDE MONONITRATE (Max 11 refills)
ISMN, IMDUR®
30 MG ($0.14), 60 MG ($0.16) EXTENDED RELEASE TABLET

KALETRA® see LOPINAVIR/RITONAVIR

KAYEXALATE® see POLYSTYRENE SODIUM SULFONATE

K-DUR® see POTASSIUM CHLORIDE

KCL see POTASSIUM CHLORIDE

KEFLEX® see CEPHALEXIN

KENALOG® see TRIAMCINOLONE

KENALOG IN ORABASE® see TRIAMCINOLONE DENTAL PASTE

KEPPRA® see LEVETIRACETAM

KETOROLAC
ACULAR®
0.5% OPHTHALMIC SOLUTION – 3 ML ($6.02)

LABETALOL
NORMODYNE®
5 MG/ML – 40 ML MDV ($2.73)
(Note: Restricted to EMS for treatment of HTN emergencies per protocol.)

LACTATED RINGERS
INJECTION 1000 ML ($4.42)
(Note: Clinic use only. Take from stock. May not be given KOP.)

LACTULOSE (Max 11 refills)
ENULOSE®
10 GM/15 ML SYRUP – 473 ML ($6.16)
(Note: Take from stock.)
LAMICTAL® see LAMOTRIGINE

LAMIVUDINE (3TC) (Max 11 refills)
EPIVIR®

- 150 MG ($0.81), 300 MG ($0.78) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use PEP template for post-exposure prophylaxis.)

LAMOTRIGINE (Max 11 refills)
LAMICTAL®

- 25 MG ($0.06), TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. 25 mg allowed as floor stock at TJJD intake facilities only. Non-formulary approval still required for use.)

LANOXIN® see DIGOXIN

LASIX® see FUROSEMIDE

LATANOPROST (Max 11 refills)
XALATAN®

- 0.005% OPHTHALMIC SOLUTION - 2.5 ML ($4.44)
(Note: Requires refrigeration prior to administration. It may be stored outside of the refrigerator for up to 30 days once given to the patient KOP.)

LAVACOL® see ALCOHOL, ETHYL 70%

LEUCOVORIN CALCIUM (Max 11 refills)
WELLCOVORIN®, FOLINIC ACID

- 5 MG TABLET ($0.82)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LEVETIRACETAM (Max 11 refills)
KEPPRA®

- 500 MG ($0.30), 1000 MG ($0.70) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LEVODOPA/CARBIDOPA see CARBIDOPA/LEVODOPA

LEVOTHYROIDINE SODIUM (Max 11 refills)
SYNTHROID®

- 0.025 MG ($0.20), 0.05 MG ($0.38), 0.1 MG ($0.25), 0.15 MG ($0.52)

TABLET
LEXAPRO® see ESCITALOPRAM
LEXIVA® see FOSAMPRENAVIR
LIBRIUM® see CHLORDIAZEPoxide
LIDEX® see FLUOCINONIDE

**LIDOCAINE HCL**
XYLOCAINE®, GLYDO®
2% VISCOS ORAL SOLUTION – 100 ML ($10.21)
2% TOPICAL JELLY PFS - 6 ML ($7.85)
5% OINTMENT – 1.25 OZ ($104.81)
0.4%/D5W IV INJECTION – 500 ML ($2.25)
1% LOCAL INJECTION (10 MG/ML) – 20 ML VIA ($1.31)
2% LOCAL INJECTION (20 MG/ML) – 20 ML VIA ($1.95)
1% WITH EPINEPHRINE 1:100,000 – 20 ML VIA ($1.93)
(Note: Injection and 2% jelly for clinic use only and should be taken from stock. The
2% jelly restricted to emergency use only. Viscous solution may not be given KOP. The
5% ointment is restricted as floor stock to GC and GV for clinic use only by OBGYN
services and may not be given KOP. The 0.4%/D5W 500ml premix bags are restricted
to EMS.)

LIORESAL® see BACLOFEN
LIPITOR® see ATORVASTATIN

**LISDEXAMFETAMINE - CII**
VYVANSE®
30 MG ($9.12), 40 MG ($9.12), 50 MG ($9.12), 60 MG ($9.12), 70 MG
($9.12) CAPSULE
(Note: May not be given KOP. Restricted to TJJD use only. Take from stock TJJD
institutions only. May only be ordered by a physician. Prior authorization criteria must
be met and include: Failed treatment with Methylphenidate and Adderall.)

**LISINOPRIL** (Max 11 refills)
PRINIVIL®, ZESTRIL®
2.5 MG ($0.01), 5 MG ($0.01), 10 MG ($0.01), 20 MG ($0.01), 40 MG
($0.02) TABLET

**LITHIUM CARBONATE** (Max 11 refills)
ESKALITH®
300 MG CAPSULE ($0.03)
(Note: May not be given KOP.)
LITHIUM CITRATE (Max 11 refills)
   CIBALITH-S®
   300 MG/5 ML SYRUP – 500 ML ($139.19)
   (Note: May not be given KOP.)

LO/OVRAL-28® see NORGESTREL/ETHINYL ESTRADIOL

LONITEN® see MINOXIDIL

LOPERAMIDE HCL (Max 2 refills)
   IMODIUM®
   2 MG CAPSULE ($0.25)

LOPID® see GEMFIBrozIL

LOPINAVIR/ RITONAVIR (Max 11 refills)
   KALETRA®
   200 MG/50 MG FILM-COATED TABLET ($7.92)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use PEP template for post-exposure prophylaxis.)

LOPRESSOR® see METOPROLOL TARTRATE

LORATADINE (Max 2 refills)
   CLARITIN®
   10 MG TABLET ($0.03)

LORAZEPAM - CIV
   ATIVAN®
   2 MG/ML INJECTION – 1 ML VIAL ($1.54)
   (Note: Clinic use only. Take from stack. May not be given KOP. May only be ordered by a physician or DEA/DPS registered midlevel provider. Requires refrigeration. Use restricted to: treatment of acute seizures uncontrolled by other measures; short-term treatment of agitation at inpatient psychiatric facilities. All other uses require non-formulary approval.)

LOTRIMIN® see CLOTIRIMAZOLE

LOW-OGESTREL® see NORGESTREL/ETHINYL ESTRADIOL
LUBRICANT, SURGICAL
SURGILUBE®
   4.25 OZ TUBE ($2.41)
   3 GM FOILPACK ($0.09)
(Note: Clinic use only. 4.25 oz is take from stock for RMFs only. May not be given KOP. 4.25 oz tube restricted to regional medical facilities.)

LUBRISOFT® see BODY LOTION

MACRODANTIN® see NITROFURANTOIN

MAGNESIUM CITRATE
   SOLUTION – 300 ML ($1.09)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

MAGNESIUM HYDROXIDE
   MILK OF MAGNESIA®
   2400 MG/30 ML SUSPENSION – 30 ML UNIT DOSE ($1.75)
   (Note: Take from stock.)

MAGNESIUM SULFATE
   50% INJECTION (500 MG/ML) – 2 ML VIAL ($1.46)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

MARCAINE® see BUPIVACAINE

MAXITROL® see NEOMYCIN/POLYMYXIN/DEXAMETHASONE

MEASLES/MUMPS/RUBELLA VACCINE, LIVE
   M-M-R VACCINE
   0.5 ML SC INJECTION ($65.85)
   (Note: Restricted from stock. May not be given KOP. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
   a. ≤ 19 years old without documentation of completion
   b. Immigrants that have not completed the series
   c. Born after 1956 and did not attend public school in Texas.)

MECLIZINE HCL (Max 2 refills)
ANTIVERT®
   25 MG TABLET ($0.13)
MEDROXYPROGESTERONE
DEPO-PROVERA®
  150 MG/ML INJECTION – 1 ML VIAL ($148.99) (Max 3 refills)
PROVERA®
  2.5 MG ($0.11), 10 MG ($0.25) TABLET (Max 11 refills)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP. All dosage forms restricted to use in female patients only.)

MELATONIN (Max 2 refills)
  3 MG TABLET ($0.05)
(Note: May not be given KOP. Restricted to TJJD only.)

MELODICAM (Max 2 refills)
MOBIC®
  7.5 MG ($0.01), 15 MG ($0.01) TABLET
(Note: 30D and 90D templates for 1 card of 30 to last 30 and 90 days.)

MENACTRA® see MENINGOCOCCAL VACCINE

MENINGOCOCCAL VACCINE, POLYSACCHARIDE
MENACTRA®, MENOMUNE®
  50 MCG/0.5 ML SDV ($99.28)
(Note: Restricted from stock. May not be given KOP. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: anatomic or functional asplenic patients who have no history of prior immunization or require a booster. Patients who have no history of prior immunization should receive a 2-dose primary series administered 2 months apart. A single booster dose should be administered every 5 years.)

MENTHOLATUM RUB
VICKS VAPORUB®
  OINTMENT – 50 GM ($3.32)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to TJJD facilities.)

MENOMUNE® see MENINGOCOCCAL VACCINE

METHYTON® see PHYTONADIONE

MERREM® see MEROPENEM
MEROPENEM
MERREM®
1 GM IV INJECTION – 30 ML VIAL ($6.66)
IV Preparation Standard:
1gm in NS or DSW 100 ML over 30 minutes
(Note: Clinic use only. Take from stock for RMFs only. May not be given KOP.
Restricted to regional medical facilities for inpatient use only.)

METFORMIN (Max 11 refills)
GLUCOPHAGE®
500 MG ($0.02), 1000 MG ($0.04) TABLET

METHIMAZOLE (Max 11 refills)
TAPAZOLE®
5 MG TABLET ($0.09)

METHOCARBAMOL
ROBAXIN®
750 MG TABLET ($0.04)
(Note: Tablets restricted to one 7-day supply per injury. A minimum 30 day period
between orders is required. May not be given KOP.)

METHYLDOPA (Max 11 refills)
ALDOMET®
250 MG TABLET ($0.17)
(Note: Floor stock restricted to Carol Young Medical Facility. Non-formulary approval is
still required for use.)

METHYLPHENIDATE- CII
CONCERTA®
18 MG ($10.11), 27 MG ($10.36), 36 MG ($10.69), 54 MG ($11.63)
EXTENDED RELEASE TABLET
RITALIN®
5 MG ($0.63), 10 MG ($0.87) TABLET
RITALIN LA®
10 MG ($2.89), 20 MG ($5.65), 30 MG ($3.36), 40 MG ($2.60) EXTENDED
RELEASE CAPSULE
(Note: May not be given KOP. Restricted to TJJD use only. Take from stock TJJD
institutions only. May only be ordered by a physician.)
METHYLPREDNISOLONE SODIUM SUCCINATE
SOLU-MEDROL®
125 MG INJECTION – 2 ML VIAL ($8.99)
IV Preparation Standard:
3 gm in 100 mL D2W over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

METHYLSALICYLATE/MENTHOL BALM
ANALGESIC BALM
30 GM TUBE ($0.90)
(Note: May not be given KOP. Restricted to TJJD.)

METOCLOPRAMIDE HCL (Max 2 refills)
REGLAN®
10 MG TABLET ($0.04)

METOLAZONE (Max 11 refills)
ZAROXOLYN®
5 MG TABLET ($1.58)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

METOPROLOL TARTRATE (Max 11 refills)
LOPRESSOR®
25 MG ($0.01), 50 MG ($0.01), 100 MG ($0.04) TABLET
5 MG/5 ML INJECTION – 5 ML VIAL ($0.95)
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

METRONIDAZOLE HCL
FLAGYL®
250 MG ($0.28), 500 MG ($0.18) TABLET
500 MG in NS READY-TO-USE 100ML BAG ($2.29)
IV Preparation Standard: over 75 minutes, DO NOT REFRIGERATE, PROTECT FROM LIGHT.
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

MICONAZOLE
MONISTAT-7®
100 MG VAGINAL SUPPOSITORY - 7 SUPP/BOX ($7.00/BOX)
(Note: Restricted to female patients. Generally dosed 1 suppository inserted vaginally q hs x 7 days.)

MILK OF MAGNESIA see MAGNESIUM HYDROXIDE

428
MINOCIN® see MINOCYCLINE

MINOCYCLINE
MINOCIN®
100 MG CAPSULE ($0.35)

Minoxidil (Max 11 refills)
LONITEN®
2.5 MG ($0.13), 10 MG ($0.19) TABLET

M-M-R VACCINE see MEASLES/MUMPS/RUBELLA VACCINE, LIVE

MOBIC® see MELOXICAM

MOMETASONE Furoate
ELOCON®
0.1% TOPICAL SOLUTION – 60 ML ($19.39)

MONISTAT® see MICONAZOLE

MORPHINE SULFATE - CII
4 MG/1 ML INJECTION-1 ML ISECURE PREFILLED SYRINGE ($2.01)
10 MG/5 ML ELIXIR – 5 ML UNIT DOSE ($0.68)
MS CONTIN®
15 MG ($0.59), 30 MG ($1.13) EXTENDED RELEASE TABLET
(Note: Take from stock. May not be given KOP. May only be ordered by a physician. Elixir and extended release tablets restricted to regional medical facilities and hospices for inpatient use only. Non-formulary approval is required for use > 10 days. A minimum 30 day period between orders is required for use beyond 10 days without a non-formulary approval. Non-formulary approval is required for use at all other units. Injection is restricted to one time orders for pain associated with acute trauma or severe medical condition. All other uses require non-formulary approval.)

MOTRIN® see IBUPROFEN

MS-CONTIN® see MORPHINE SULFATE
MULTIVITAMIN (Max 11 refills, tablet)
M.V.I. ADULT™, INFUVITE®
INJECTION – 10 ML VIAL ($3.62)
(Note: Clinic use only. Take from stock. May not be given KOP.)
TABLET ($0.01)
(Note: Prior authorization required for use of tablets. The following prior authorization criteria must be met and noted in the special instructions field of the order: HIV positive, CD4 count < 100 cells/mm³ and not prescribed a nutritional supplement/enteral feeding.)

MURO® 128 see SODIUM CHLORIDE OPTHALMIC OINTMENT
M.V.I. ADULT™ see MULTIVITAMIN
MYAMBUSOTOL® see ETHAMBUTOL HCL
MYCOBUTIN® see RIFABUTIN

MYCOPHENOLATE MOFETIL (Max 11 refills)
CELLCEPT®
250 MG CAPSULE ($0.34)
500 MG TABLET ($0.87)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

MYCOSTATIN® see NYSTATIN
MYLICON® see SIMETHICONE
MYCOSOLINE® see PRIMIDONE
NAFCILL® see NAFCILLIN SODIUM

NAFCILLIN
NAFCILL®
1 GM INJECTION VIAL ($4.86)
IV Preparation Standard:
≤ 1 gm in 100 mL D₂O over 30 minutes
> 1 gm in 100 mL D₂O over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

NALOXONE HCL
NARCAN®
4 MG/0.1 ML SINGLE DOSE NASAL SPRAY 2 PACK - ($115.99)
(Note: Clinic use only. Take from stock. May not be given KOP)
NAPHAZOLINE HCL
CLEAR EYES®, NAPHCONE®
0.012% OPHTHALMIC SOLUTION – 15 ML ($2.68)

NAPHAZOLINE/PHENIRAMINE
OPCON-A®, NAPHCONE-A®
NAPHAZOLINE 0.025%/PHENIRAMINE 0.3%
OPHTHALMIC SOLUTION – 15 ML ($4.59)

NAPHCONE® see NAPHAZOLINE HCL
NAPHCONE-A® see NAPHAZOLINE/PHENIRAMINE

NAPROSYN® see NAPROXEN

NAPROXEN (Max 2 refills)
NAPROSYN®
250 MG ($0.04), 500 MG ($0.06) TABLET
(Note: 30D and 90D templates for 1 card of 30 to last 30 and 90 days.)

NARCAN® see NALOXONE HCL

NATALINS® FA see PRENATAL-FOLIC ACID

NAVANE® see THIOTHIXENE HCL

NELFINAVIR (Max 11 refills)
VIRACEPT®
625 MG TABLET ($9.39)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

NEOMYCIN/BACITRACIN/POLYMYXIN
NEOSPORIN®, TRIPLE ANTIBIOTIC
OPHTHALMIC OINTMENT - 3.5 GM ($21.21)
TOPICAL OINTMENT 1 GM PACKET ($0.13)
(Note: 1 gm packet for clinic use only, should be taken from stock and may not be
given KOP.)

NEOMYCIN/BACITRACIN/POLYMYXIN/HYDROCORTISONE
CORTISPORIN®
OPHTHALMIC OINTMENT - 3.5 GM ($27.47)
NEOMYCIN/POLYMYXIN/DEXAMETHASONE
MAXITROL®
OPHTHALMIC SUSPENSION – 5 ML ($12.87)
OPHTHALMIC OINTMENT - 3.5 GM ($14.24)

NEOMYCIN/POLYMYXIN/HYDROCORTISONE
CORTISPORIN®
OTIC SUSPENSION – 10 ML ($36.93)

NEOMYCIN/GRAMICIDIN/POLYMYXIN
NEOSPORIN®
OPHTHALMIC SOLUTION – 10 ML ($47.37)

NEORAL® see CYCLOSPORINE

NEOSPORIN® see NEOMYCIN/GRAMICIDIN/POLYMYXIN
see also NEOMYCIN/BACITRACIN/POLYMYXIN

NPHRO-VITE® see VITAMIN B COMPLEX & VITAMIN C WITH FOLIC ACID

NEUPOGEN® see FILGRASTIM

NEVIRAPINE (Max 11 refills)
VIRAMUNE®
200 MG TABLET ($0.15)
(Note: Allowed KOP at 8-hr units, may not be given KOP at all other units.)

NEXTERONE® see AMIODARONE IN D5W

NITRO-DUR® see NITROGLYCERIN

NITRO-BID® see NITROGLYCERIN

NITROFURANTOIN
MACRODANTIN®
50 MG CAPSULE ($0.59)
NITROGLYCERIN
NITROSTAT® (Max 1 refill)
0.4 MG SUBLINGUAL TABLET - 25 PER BOTTLE ($10.15/BOTTLE)
(Note: Sublingual tablets should be ordered as 1 bottle to last 6 months.)
NITROBID®
2% TOPICAL OINTMENT – 60 GM ($63.23) (No refills)
(Note: The ointment is restricted to clinic use only for short-term relief of angina, should be taken from stock and may not be given KOP.)
NITRO-DUR® (Max 11 refills)
0.2 MG/HR ($0.38), 0.4 MG/HR ($0.45) PATCH – 30 PATCHES PER BOX
(Note: The Pharmacy will add standardized directions to patches to allow for a nitrate-free interval to minimize tolerance that states “Apply in the morning for 12 hours and then remove in the evening” for 30 days, KOP.)

NITROSTAT® see NITROGLYCERIN

NIX® see PERMETHRIN

NORETHINDRONE/ETHINYL ESTRADIOL (Max 11 refills)
ORTHO NOVUM®, PIRMELLA®
1/35-28 TABLET ($12.30)
(Note: Restricted to female patients)

NORESTREL/ETHINYL ESTRADIOL (Max 11 refills)
LO/OVRAL®, LOW-OGESTREL®, CRYSELLE®
0.3/30-28 TABLET ($14.70)
(Note: Restricted to female patients)

NORMAL SALINE see SODIUM CHLORIDE 0.9%

NORMODYNE® see LABETALOL

NORVASC® see AMLODIPINE

NORVIR® see RITONAVIR

NOVOLIN® see INSULIN, HUMAN

NYDRAZID® see ISONIAZID
NYSTATIN
MYCOSTATIN®
100,000 UNITS/ML ORAL SUSPENSION – 60 ML ($11.19)

OCEAN NASAL MIST® see SODIUM CHLORIDE

OMEPRAZOLE (Max 11 refills)
PRILOSEC®
20 MG CAPSULE ($0.02)

OMNIPEN-N® see AMPICILLIN

ONDANSETRON (Max 2 refills)
ZOFRAN®
4 MG TABLET ($0.15)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Allowed as floor stock at BX, E2-RMF, GC-RMF, HP, J3, ST, and WM. Prior authorization criteria must be met and noted in the special instructions filed. Criteria include: HCV Treatment. All other uses require non-formulary approval.)
2 MG/ML – 2 ML VIAL ($0.40)
(Note: Clinic use only. May not be given KOP. Allowed as floor stock at BX, E2-RMF, GC-RMF, HP, J3, ST, and WM. Prior authorization criteria must be met and noted in the special instructions filed. Criteria include: HCV Treatment. All other uses require non-formulary approval.)

OPCON-A® see NAPHAZOLINE/PHENIRAMINE

OPHTHALMIC IRRIGATING SOLUTION
DACRIOSE®
IRRIGATING EYE WASH – 120 ML ($3.02)

ORAJEL® see BENZOCAINE

ORTHO-NOVUM® see NORETHINDRONE/ETHINYL ESTRADIOL

OS-CAL® see CALCIUM CARBONATE

OS-CAL 250 + VITAMIN D® see CALCIUM CARBONATE/VITAMIN D

OSMOLITE® 1.0 CAL see ENTERAL FEEDING
OXYBUTYNIN  (Max 11 refills)
  DITROPA®
  5 MG TABLET ($0.20)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PANCRELIPASE  (Max 11 refills)
  CREON 12®
  LIPASE 12,000 U/AMYLASE 38,000 U/PROTEASE 60,000 U PER CAPSULE ($271.74/100 count bottle)

PARICALCITOL  (Max 11 refills)
  ZEMPLAR®
  2 MCG CAPSULE ($24.15)
  5 MCG/ML – 1 ML VIAL ($9.28)
  (Capsule Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Restricted to dialysis units. Take from stock for dialysis units. All other uses require non-formulary approval.)
  (Injection Note: Clinic use only. Take from stock. May not be given KOP. Restricted to dialysis centers.)

PARLODEL® see BROMOCRIPTINE MALEATE

PAROXETINE  (Max 11 refills)
  PAXIL®
  10 MG ($0.10) TABLET
  (Note: May not be given KOP. 10 mg allowed as floor stock at TJJD intake facilities only. Non-formulary approval still required for use.)

PAXIL® see PAROXETINE

PC-TAR® see COAL TAR

PEG 3350 see ELECTROLYTE ORAL SOLUTION

PENICILLIN VK
  VEETIDS®
  500 MG TABLET ($0.09)

PENICILLIN G BENZATHINE
  BICILLIN LA®
  1.2 MU/2 ML SYRINGE ($146.01)
  (Note: Clinic use only. Take from stock. May not be given KOP. Prior authorization must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: syphilis.)
**PENICILLIN G POTASSIUM**

PFIZERPEN®

5 MU INJECTION VIAL ($10.19)

IV Preparation Standard:
2 MU in 100 mL D5W over 20 minutes
>2 MU in 100 mL D5W over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

**PEPTO-BISMOL®** see BISMUTH SUBSALICYLATE

**PERIDEX®** see CHLORHEXIDINE GLUCONATE ORAL RINSE

**PERMETHRIN**

NIX®

1% LOTION – 2 OZ ($7.79)

ELIMITE®

5% CREAM – 60 GM ($34.03)

**PERPHENAZINE** (Max 11 refills)

TRILAFON®

4 MG ($0.50), 8 MG ($0.54), 16 MG ($0.84) TABLET
(Note: May not be given KOP.)

**PERSANTINE®** see DIPYRIDAMOLE

**PETROLATUM**

VASELINE®

JELLY – 13 OZ ($1.75)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to use at phototherapy centers [Estelle].)

**PFIZERPEN®** see PENICILLIN G POTASSIUM

**PHENAZOPYRIDINE HCL**

PYRIDIUM®

200 MG TABLET ($0.82)

**PHENERGAN®** see PROMETHAZINE HCL

**PHENYLEPHRINE HCL**

SUDAFED-PE®

10 MG TABLET, 36/box ($0.87/box)
(Note: Limit of 1 box of 36 per order per policy.)
PHENYTOIN (Max 11 refills)
   DILANTIN®
      125 MG/5 ML SUSPENSION - 8 OZ ($16.47)
      (Note: Restricted to regional medical facilities. May not be given KOP.)

PHENYTOIN SODIUM
   DILANTIN®
      100 MG EXTENDED RELEASE CAPSULE ($0.19) (Max 11 refills)
      (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
      50 MG/ML INJECTION – 5 ML VIAL ($1.68) (No refills)
      (Note: May not be given KOP. Restricted to EMS use only. All other uses require non-
           formulary approval.)

PHOSPHATE ENEMA see SODIUM PHOSPHATE/SODIUM SALT

PHYSOSTIGMINE SALICYLATE
   ANTILIRIUM®
      1 MG/ML INJECTION – 2 ML AMPULE ($30.32)
      (Note: Clinic use only. Take from stock. May not be given KOP.)

PHYTONADIONE (VITAMIN K-1)
   MEPHYTON®
      5 MG TABLET ($54.52)

PIRMELLA® see NORETHINDRONE/ETHINYL ESTRADIOL

PLASBUMIN-25® see ALBUMIN, HUMAN

PLAVIX® see CLOPIDOGREL

PNEUMOCOCCAL VACCINE (POLYVALENT)
   PNEUMOVAX-23®
      25 MC3/0.5 ML INJECTION - 0.5 ML SINGLE DOSE VIAL ($85.07)
      (Note: Clinic use only. Take from stock. May not be given KOP. Follow Infection
      Control P&P B-14.07 and standing delegated order when selecting patients.
      a. ≥ 65 years old
      b. Patients with disease associated with increased risk (splenic dysfunction, anatomic
         asplenia, Hodgkin’s disease, multiple myeloma, cirrhosis, alcoholism, renal failure,
         CSF leaks, sickle cell, diabetes mellitus, COPD, emphysema, heart disease)
      c. Immunosuppressed patients (HIV positive, most cancers, sickle cell)

PNEUMOVAX-23® see PNEUMOCOCCAL VACCINE

PODOCON-25® see PODOPHYLLUM RESIN
PODOFLOX
CONDYLOX®
0.5% TOPICAL SOLUTION - 3.5 ML ($44.28)
(Note: Clinic use only. Take from stock. May not be given KOP.)

PODOPHYLLUM RESIN
PODOCON-25®
25% RESIN -15 ML ($91.67)
(Note: Clinic use only. Take from stock. May not be given KOP.)

POLIO VIRUS VACCINE, INACTIVATED
IPOL®
0.5 ML INJECTION – 5 ML MDV – 10 DOES/VIAL ($268.25)
(Note: May not be given KOP. Prior authorization required for use. Criteria: patients < 19 years old. All other uses require non-formulary approval.)

POLYMYXIN B/TRIMETHOPRIM
POLYTRIM®
10,000 U/1 MG OPHTHALMIC SOLUTION – 10 ML ($6.21)

POLYSPORIN® see BACITRACIN/POLYMYXIN B

POLYSTYRENE SODIUM SULFONATE
KAYEXALATE®
SUSPENSION 15 G/60 ML – 16 OZ ($34.61)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Contains 65mEq Na, 15 mEq of potassium exchange capacity per 60 mL.)

POLYTRIM® see POLYMYXIN B/TRIMETHOPRIM

POLYVINYL ALCOHOL
ARTIFICIAL TEARS
1.4% OPHTHALMIC SOLUTION – 15 ML ($1.69)

POTASSIUM CHLORIDE
K-DUR®, KCL
10 MEQ ($0.17), 20MEQ ($0.16) EXTENDED RELEASE TABLET (Max 11 refills)
20 MEQ/1000 ML D5W INJECTION ($7.21) (No refills)
20 MEQ/1000 ML 1/2NS D5W INJECTION ($5.06) (No refills)
(Note: Injection for clinic use only, should be taken from stock, may not be given KOP, and restricted to infirmaries & regional medical facilities.)
PRAVACHOL® see PRAVASTATIN

PRAVASTATIN (Max 11 refills)
PRAVACHOL®
10MG ($0.13), 20MG ($0.03), 40MG ($0.06) TABLET

PRED FORTE® see PREDNISOLONE ACETATE

PREDNISOLONE ACETATE
PRED FORTE®
1% OPTHALMIC SUSPENSION - 5ML ($38.58)
PRED MILD®
0.12% OPTHALMIC SUSPENSION - 5ML ($128.69)

PREDNISONE (Max 11 refills 5mg tablets only)
DELTASONE®
5MG ($0.10), 10MG ($0.16), 20MG ($0.17) TABLET

PREMARIN® see ESTROGENS, CONJUGATED

PREDNISONE (Max 11 refills)
NATALINS FA®
TABLET ($0.04)
(Note: Contains 1mg folic acid. Prior authorization criteria must be met and noted in the special instructions field to use without non-formulary approval. Criteria: pregnancy.)

PREPARATION H® CREAM see HEMORRHOIDAL

PREZISTA® see DARUNAVIR

PRILOSEC® see OMEPRAZOLE

PRIMIDONE (Max 11 refills)
MYSOLINE®
250MG TABLET ($0.14)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PRINIVIL® see LISINOPRIL

PROBENCID (Max 11 refills)
BENEMID®
500MG TABLET ($0.51)

439
PROCHLORPERAZINE
   COMPZINE®
   10MG TABLET ($0.06)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PROGRAF® see TACROLIMUS

PROLIXIN® see FLUPHENAZINE HCL

PROLIXIN D® see FLUPHENAZINE DECANOATE

PROMETHAZINE HCL
   PHENERGAN®
   25MG TABLET ($0.05)
   25MG SUPPOSITORY - 12/BOX ($74.04/BOX)
   25MG/ML INJECTION - 1ML VIAL ($1.01)
   (Note: Tablets allowed KOP at 8-hour units, may not be given KOP at all other units.
    Suppositories may be given KOP. Injection for clinic use only, should be taken from stock, and may not be given KOP.)

PROPARACAINE HCL
   ALCAINE®
   0.5% OPHTHALMIC SOLUTION - 15ML ($24.69)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

PROPRANOLOL HCL (Max 11 refills)
   Inderal®
   10MG ($0.11), 20MG ($0.06), 40MG ($0.20) TABLET

PROTAMINE SULFATE
   50MG INJECTION - 5ML VIAL ($10.92)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

PROVENTIL-HFA® see ALBUTEROL

PROVERA® see MEDROXYPROGESTERONE

PROZAC® see FLUOXETINE

PYRAZINAMIDE (PZA) (Max 11 refills)
   500MG TABLET ($1.36)
   (Note: May not be given KOP. Treatment of active TB should be DOT.)

PYRIDIUM® see PHENAZOPYRIDINE
PYRIDOXINE HCL (VITAMIN B-6) (Max 11 refills)
50MG TABLET ($0.01)

PYRIMETHAMINE (Max 11 refills)
DARAPRIM®
25MG TABLET ($12.68)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PZA see PYRAZINAMIDE

RALTEGRAVIR (Max 11 refills)
ISENTRESS®
400MG TABLET ($23.20)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

RAPAMUNE® see SIROLIMUS

RANITIDINE HCL (Max 11 refills)
ZANTAC®
150MG TABLET ($0.06)

RECOMBIVAX HB® see HEPATITIS B VACCINE RECOMBINANT, DIALYSIS FORMULATION

REGLAN® see METOCLOPRAMIDE HCL

REMICAPE® see INFLIXIMAB

RENVELA® see SEVELAMER

RETROVIR® see ZIDOVUDINE

REYATAZ® see ATAZANAVIR

RHO(D) IMMUNE GLOBULIN
RHOGAM®
300MCG SYRINGE ($118.00)
(Note: Floor stock restricted to Carol Young. Non-formulary approval still required for use.)

RHOGAM® see RHO(D) IMMUNE GLOBULIN

RIBASPHERE® see RIBAVIRIN
RIBAVIRIN (Max 11 refills)
   RIBASPHERE®
   200MG CAPSULE ($0.74)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Allowed as floor stock. Non-formulary approval required by HCV group from pharmacy at utmbmcpharmacyID@utmb.edu for UTMB units and Utilization Management at (806)356-5350 for TTHSC units.)

RIFABUTIN (Max 11 refills)
   MYCOBUTIN®
   150MG CAPSULE ($12.70)
   (Note: May not be given KOP.)

RIFADIN® see Rifampin

RIFAMPIN (Max 11 refills)
   RIFADIN®
   300MG CAPSULE ($0.78)
   (Note: May not be given KOP. Treatment of active TB should be DOT.)

RILPIVIRINE (Max 11 refills)
   EDURANT®
   25MG TABLET ($32.52)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior authorization criteria must be met and noted in the special instructions field for use without a non-formulary approval. Criteria include: Patient on Edurant, Complera, or Odefsey at intake)

RINGERS INJECTION, LACTATED see Lactated Ringers

RISPERDAL® see Risperidone

RISPERIDONE (Max 11 refills)
   RISPERDAL®
   0.5MG TABLET ($0.12)
   (Note: May not be given KOP. Restricted to TJJD.)
   1MG ($0.02), 2MG ($0.03), 3MG ($0.03), 4MG ($0.04) TABLET
   (Note: May not be given KOP.)

RITALIN® see Methylenidate

RITALIN LA® see Methylenidate
RITONAVIR (Max 11 refills)
    NORVIR®
    100MG TABLET ($2.47)
    (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ROBAXIN® see METHOCARBAMOL

ROCALTROL® see CALCITRIOL

ROCEPHIN® see CEFTRIAXONE

ROMAZICON® see FLUMAZENIL

SALICYLIC ACID
    COMPOUND W®, DUOFILM®
    17% TOPICAL SOLUTION - 0.3 OZ ($4.70)
    (Note: Clinic use only. Take from stock. May not be given KOP.)

SALINE see SODIUM CHLORIDE

SALT WATER GARGLE see SODIUM CHLORIDE GARGLE

SANTYL® see COLLAGENASE

SAQUINAVIR (Max 11 refills)
    INVIRASE®
    500MG TABLET ($9.29)
    (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

SELENIUM SULFIDE
    SELSUN®
    2.5% SHAMPOO 4OZ ($6.68)
    (Note: Orders should be written for 1 bottle to last 90 days.)

SELSUN® see SELENIUM SULFIDE

SERTRALINE (Max 11 refills)
    ZOLOFT®
    25mg ($0.06), 50MG ($0.05), 100MG ($0.05) TABLET
    (Note: May not be given KOP. 25mg restricted to TJJD only.)
SEVELAMER CARBONATE (Max 11 refills)
   RENVELA®
   800MG TABLET ($6.60)
   (Note: Prior authorization required and must be noted in the special instructions field for use without non-formulary approval. Criteria include:
   a. chronic kidney disease
   b. dialysis)

SILVADENE® see SILVER SULFADIAZINE

SILVER NITRATE
   ARZOL®
   75% APPLICATOR STICK, 100/BOX ($33.18/BOX)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

SILVER SULFADIAZINE
   SILVADENE®
   1% CREAM - 50GM ($8.45), 400GM ($44.84)
   (Note: 50gm may be given KOP. 400gm for clinic use only, should be taken from stock and may not be given KOP.)

SIMETHICONE (Max 3 refills)
   MYLICON®
   80MG CHEWABLE TABLET, 100/BOTTLE ($1.68/BOTTLE)
   (Note: May be ordered PRN with a limit of one bottle of 100 to be dispensed with a 90-day expiration.)

SINEMET® see CARBIDOPA/LEVODOPA

SIROLIMUS (Max 11 refills)
   RAPAMUNE®
   1MG ($28.78), 2MG ($20.36) TABLET
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

SMZ/TMP see SULFAMETHOXAZOLE/TRIMETHOPRIM

SODIUM BICARBONATE
   SODIUM BICARBONATE
   1mEq/ML INJECTION (8.4%) - 50ML SYRINGE ($9.35)
   (Note: Clinic use only. Take from stock. May not be given KOP.)
SODIUM CHLORIDE
- 0.45% INJECTION - 1000ML ($4.92)
- 0.9% INJECTION - 100ML ($2.05), 250ML ($3.35), 500ML ($3.61), 1000ML ($4.07)
- 0.9% MINI-BAG - 100ML ($4.97)
- 0.9% IRRIGATION SOLUTION - 250ML ($3.31)
- 0.9% BACTERIOSTATIC INJECTION - 30ML VIAL ($0.83)
- 0.9% PRESERVATIVE FREE INJ - 10ML SYR ($0.51)
- 0.9% NEB SOL - 3ML UD 100/BOX ($9.00/BOX)

OCEAN® (Max 2 refills)
- NASAL SPRAY - 45ML ($0.68)

MURO 128® (Max 11 refills)
- 2% OPHTHALMIC SOLUTION - 15ML ($14.09)
- 5% OPHTHALMIC SOLUTION - 15ML ($8.29)
- 5% OPHTHALMIC OINTMENT - 3.5GM ($7.76)

(Note: Injection, irrigating solution, bags, and nebulizer solution are for clinic use only, should be taken from stock, and may not be given KOP.)

SODIUM PHOSPHATE

FLEET’S® ENEMA
- ENEMA - 133ML ($0.73)

(Note: Take from stock.)

SOFSBUVIR/VELPATASVIR (Max 5 refills)

EPCLUSA®
- 400MG-100MG TABLET ($25.83)

(Note: The preferred Hepatitis C therapy. Non-formulary approval required by HCV group from pharmacy at utmbcmc.pharmacyID@utmb.edu Floor stock is allowed at the five designated Centers of Excellence (Dominguez, Jester 3, Stiles, Woodman and Young) and at Mt View and Skyview. Floor stock is designated as a Local Control and therefore must be kept and inventoried as a controlled substance (Pharmacy Policies 20-05, 20-10, 20-15). May not be given KOP.)

SOLU-CORTEF® see HYDROCORTISONE SODIUM SUCCINATE

SOLU-MEDROL® see METHYL PREDNISOLONE SODIUM SUCCINATE

SOTALOL (Max 11 refills)

BETAPACE®
- 80MG ($0.09), 120MG ($0.12), 160MG ($0.16) TABLET

SPRIVA® HANDIHALER see TIOTROPIUM
SPIRONOLACTONE (Max 11 refills)
ALDACTONE®
25MG TABLET ($0.06)

STADOL® see BUTORPHANOL TARTRATE

STANNOUS FLUORIDE
GEL-KAM®
0.4% GEL – 4.3OZ ($12.66)

STELAZINE® see TRIFLUOPERAZINE HCL

STRATTERA see ATOMOXETINE

SUDAFED-PE® see PHENYLEPHRINE

SULAMYD® see SULFACETAMIDE SODIUM

SULFACETAMIDE SODIUM
SULAMYD®
10% OPHTHALMIC SOLUTION - 15ML ($38.45)

SULFAMETHOXAZOLE/TRIMETHOPRIM
BACTRIM® DS
SMZ 800MG/TMP 160MG DOUBLE STRENGTH TABLET ($0.06)
(Max 11 refills)
SMZ 400MG/TMP 80MG per 5ML INJECTION - 10ML VIAL ($11.38)
(No refills)
IV Preparation Standard:
5mL in 250mL D5W ONLY over 60-90 minutes.
(Note: Orders for IV Bactrim should be based on trimethoprim dosage. Injection for
clinic use only, should be taken from stock, and may not be given KOP.)

SULFASALAZINE (Max 11 refills)
AZULFIDINE®
500MG TABLET ($0.17)

SUNSCREEN
SUNSCREEN
SPF 30 LOTION - 240ML ($2.56)
(Note: May be supplied as a different size depending on product availability. Take from
stock.)
SURGILUBE® see LUBRICANT, SURGICAL

SUSTIVA® see EFAVIRENZ

SYMMETREL® see AMANTADINE HCL

SYNTHROID® see LEVOTHYROXINE SODIUM

TACROLIMUS (Max 11 refills)
  PROGRAF®
    0.5 MG ($0.33), 1MG ($0.61), 5MG ($3.15) CAPSULE
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

TAPAZOLE® see METHIMAZOLE

TAZICEF® see CEFTAZIDIME

TDAp see TETANUS/DIPHTHERIA/ACELULAR PERTUSSIS

TDF see TENOFOVIR

TEGRETOL® see CARBAMAZEPINE

TENEX® see GAUNFACINE

TENIVAC™ see TETANUS & DIPHTHERIA TOXOIDS

TENOFOVIR (TDF) (Max 11 Refills)
  VIREAD®
    300MG TABLET ($1.86)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

TENORMIN® see ATENOLOL

TERAZOSIN HCL (Max 11 refills)
  HYTRIN®
    1MG ($0.13), 2MG ($0.14), 5MG ($0.14), 10MG ($0.13) CAPSULE

TERBUTALINE SULFATE
  BRETHINE®
    1MG/ML INJECTION - 1ML VIAL ($1.44)
  (Note: Clinic use only. Take from stock. May not be given KOP. Use restricted to female patients at Carol Young (GC) and Crain (GV) facilities.)
TETANUS/DIPHTHERIA TOXOIDS VACCINE
D-T TOXOIDS, TENIVAC™
0.5ML SINGLE DOSE VIAL ($18.76)
(Note: Clinic use only. Take from stock. May not be given KOP. Follow Infection Control P&P for selecting patients. Criteria include:
  a. < 19 years old without documentation of completion
  b. No history of prior immunization within the last 10 years
  c. Prophylaxis for wound management.)

TETANUS/DIPHTHERIA/ACELLULAR PERTUSSIS (TdaP) VACCINE
BOOSTRIX®
0.5ML SINGLE DOSE VIAL ($37.21)
(Note: May not be given KOP. Clinic use only. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: pregnancy or Td booster indicated and not previously vaccinated with TdaP.)

TETRAHYDROZOLINE HCL
VISINE®
0.05% OPHTHALMIC SOLUTION - 15ML ($0.99)

THIAMINE HCL (VITAMIN B-1)
100MG TABLET ($0.02) (Max 11 refills)
100MG/mL - 2ML VIAL ($7.90) (No refills)
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

THIOTHIXENE (Max 11 refills)
NAVANE®
  2MG ($0.65), 5MG ($1.67), 10MG ($2.49) CAPSULE
(Note: May not be given KOP.)

TIMOLOL MALEATE (Max 11 refills)
TIMOPTIC®
0.5% OPHTHALMIC SOLUTION - 5ML ($4.12)

TINACTIN® see TOLNAFTATE
TIOTROPIUM (Max 11 refills)
SPIRIVA® HANDIHALER
18MCG CAPSULE, 30/BOX ($332.09/BOX)
(Note: May not be given KOP. Prior authorization required. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
   a. Inadequate response to ipratropium HFA 2 puffs QID
   b. Classified as Moderate COPD
   c. Classified as Severe COPD
   c. Classified as Very severe COPD)

TIVICAY® see DOLUTEGRAVIR

TOBRAMYCIN
TOBREX®
0.3% OPHTHALMIC SOLUTION - 5ML ($4.70)
40MG/ML INJECTION – 2ML VIAL ($1.33)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP. The ophthalmic solution may be given KOP.)

TOFRANIL® see IMIPRAMINE HCL

TOLNAFTATE
TINACTIN®
1% CREAM - 15GM ($1.26)

TOPAMAX® see TOPIRAMATE

TOPIRAMATE (Max 11 refills)
TOPAMAX®
25MG ($0.08) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. 25mg allowed as floor stock at TJJD intake facilities only. Non-formulary approval still required for use.)

t-PA (TISSUE-TYPE PLASMINOGEN ACTIVATOR) see ALTEPLASE

TRAZODONE HCL (Max 11 refills)
DESYREL®
50MG ($0.05), 100MG ($0.09) TABLET
(Note: May not be given KOP.)

TRI-CHLOR® see TRICHLOROACETIC ACID
TRIAMCINOLONE
KENALOG®
  0.025% OINTMENT - 15GM ($4.06)
  0.025% CREAM - 15GM ($1.75)
  0.1% CREAM - 15GM ($1.83)
  0.1% CREAM – 80GM ($3.37) (max 5 refills)
  10MG/ML INJECTION - 5ML VIAL ($11.22)
  40MG/ML INJECTION - 1ML VIAL ($7.49)
KENALOG IN ORABASE®
  0.1% DENTAL PASTE – 5GM ($36.12)
(Note: Injection is for clinic use only, should be taken from stock and may not be given KOP.)

TRIAMTERENE/HYDROCHLOROTHIAZIDE (Max 11 refills)
DYAZIDE®
  TRIAMTERENE 37.5MG/HCTZ 25MG CAPSULE ($0.15)

TRICHLOROACETIC ACID
TRI-CHLOR®
  80% SOLUTION – 15ML ($56.90)
(Note: Clinic use only. Take from stock. May not be given KOP.)

TRIFLUOPERAZINE HCL (Max 11 refills)
STELAZINE®
  2MG ($0.85), 5MG ($1.97), 10MG ($1.67) TABLET
(Note: May not be given KOP.)

TRIFLURIDINE
VIROPTIC®
  1% OPHTHALMIC SOLUTION - 7.5ML ($115.41)

TRILAFON® see PERPHENAZINE
TRIMETHOPRIM/POLYMIXIN B see POLYMIXIN B/TRIMETHOPRIM
TRUSOPT® see DORZOLAMIDE

TUBERCULIN INJECTION (PURIFIED PROTEIN DERIVATIVE)
PPD, APLISOL®
  10TESTS/1ML INJECTION - 1ML VIAL ($82.42)
  50TESTS/5ML INJECTION - 5ML VIAL ($310.47)
(Note: Clinic use only. Take from stock. May not be given KOP.)
TYLENOL® see ACETAMINOPHEN
TYLENOL® W/ CODEINE see ACETAMINOPHEN/CODEINE
TYLENOL #3® see ACETAMINOPHEN WITH CODEINE
ULIPRISTAL
ELLA®
30MG TABLET ($33.17)
(Restricted to female units for emergency contraceptive use in sexual assault as defined in Correctional Managed Healthcare Sexual Assault Policy G.57.1. All other uses require non-formulary approval. Take from stock. May not be given KOP. Designated as a Local Control and therefore must be kept and inventoried as a controlled substance (Pharmacy Policies 20-05, 20-10, 20-15).)
URECHOLINE® see BETHANECOL
VALIUM® see DIAZEPAM
VANCOCIN® see VANCOMYCIN HCL
VANCOMYCIN HCL
VANCOCIN®
1G INJECTION VIAL ($3.71)
IV Preparation Standard:
<500mg in 100mL D5W over 60-90 minutes
>500mg in 250mL D5W over 90-120 minutes.
(Note: Dose based on actual body weight. Most patients will need 15mg/kg every 12 hours. Round to the nearest 250 milligrams. Consult pharmacy for obese patients. Medication should be ordered in milligrams. Draw trough 30 minutes before 4th dose. Monitor serum creatinine. Clinic use only. Take from stock. May not be given KOP.)
VARICELLA VACCINE (Max 1 refill)
VARIVAX®
1350 PFU/0.5ML – VIAL ($122.02)
(Note: May not be given KOP. Restricted from floor stock. Order for 30 days with 1 refill to be administered at 0 and 1 month. (For HIV+ patients, order for 90 days with 1 refill to be administered at 0 and 3 months.) Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:
a. Post-exposure prophylaxis with approval from the Office of Public Health
b. ≤ 19 years old without documentation of previous disease or immunization (labwork not required)
c. HIV positive patients without documented immunity and CD4 > 200)
VASELINE® JELLY see PETROLATUM
VEETIDS® see PENICILLIN VK

VENLAFAXINE HCL ER (Max 11 refills)
   EFFEXOR® XR
   75MG ($0.08), 150MG ($0.08) EXTENDED RELEASE CAPSULE
   (Note: Extended release formulation to be dosed once a day. May not be given KOP.
   May not be crushed or chewed.)

VENOFER® see IRON SUCROSE
VENTOLIN® see ALBUTEROL SULFATE

VERAPAMIL HCL
   CALAN®
      80MG ($0.09), 120MG ($0.07) IMMEDIATE RELEASE TABLET (Max 11
      refills)
      2.5MG/ML INJECTION - 2ML VIAL ($26.35) (No refills)
   CALAN SR®
      180MG ($0.13), 240MG ($0.19) SUSTAINED RELEASE CAPLET (Max 11
      refills)
   (Note: Injection for clinic use only, should be taken from stock, may not be given KOP.)

VICKS VAPORUB® see CAMPHOR/EUCALYPTUS/MENTHOL
VIDEX-EC® see DIDANOSINE
VIRACEPT® see NELFINAVIR
VIRAMUNE® see NEVIRAPINE
VIREAD® see TENOFOVIR
VIROPTIC® see TRIFLURIDINE
VISINE® see TETRAHYDROZOLINE HCL
VISTARIL® see HYDROXYZINE PAMOATE
VITAMIN B-1 see THIAMINE HCL
VITAMIN B-6 see PYRIDOXINE HCL
VITAMIN B-12 see CYANOCOBALAMIN

VITAMIN B COMPLEX & VITAMIN C WITH FOLIC ACID (Max 11 refills)
  NEPHRO-VITE® TABLET ($0.10)
  (Note: Prior authorization required. The following prior authorization criteria must be met and noted in the special instructions field on the label: “dialysis.”)

VITAMIN K-1 see PHYTONADIONE

VITAMIN, I.V. INFUSION see MULTIVITAMIN

VYVANSE® see LISDEXAMFETMAINE

WARFARIN SODIUM (Max 11 refills)
  COUMADIN® 2.5MG TABLET ($0.11)
  (Note: May not be given KOP.)

WATER FOR INJECTION
  WATER FOR INJECTION, STERILE - 10ML ($0.79)
  WATER FOR INJECTION, BACTERIOSTATIC - 30ML ($1.11)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

WATER FOR IRRIGATION
  WATER FOR IRRIGATION, STERILE – 250ML ($3.41)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

WELLCOVORIN® see LEUCOVORIN CALCIUM

XALATAN® see LATANOPROST

XYLOCAINE® see LIDOCAINE HCL

ZANTAC® see RANITIDINE

ZAROXOLYN® see METOLAZONE

ZDV see ZIDOVUDINE

ZEMPLAR® see PARICALCITOL

ZESTRIL® see LISINOPRIL

453
ZIAGEN® see ABACAVIR

ZIDOVUDINE (AZT, ZDV) (Max 11 refills)
  RETROVIR®
  300MG TABLET ($0.44)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use PEP template for post-exposure prophylaxis.)

ZIPRASIDONE HCL (Max 11 refills)
  GEODON®
  20MG ($1.25), 40MG ($1.24), 60MG ($0.22), 80MG ($0.27) CAPSULE
  (Note: May not be given KOP. 20mg restricted to TJJD.)

ZIPRASIDONE MESYLATE
  GEODON®
  20MG/ML – 1ML VIAL ($46.47)
  (Note: Clinic use only. Take from stock. May not be given KOP. See the Acute Psychosis pathway for injection dosing recommendations.)

ZITHROMAX® see AZITHROMYCIN

ZOFRAN® see ONDANSETRON

ZOVIA® see ETHYNODIOL DIACETATE/ETHINYL ESTRADIOL

ZOVIRAX® see ACYCLOVIR

ZYLOPRIM® see ALLOPURINOL
# THERAPEUTIC CATEGORY INDEX

The following index provides a list of Formulary items grouped by therapeutic category according to the American Hospital Formulary Service (AHFS) classification system. The major drug classification appears in all capital letters followed by sub-classification when indicated. Major drug classes are listed below with the corresponding page number(s). Drugs may be listed in more than one therapeutic category.

<table>
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<tr>
<th>Category</th>
<th>Page</th>
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<td>Anti-Infective Agents</td>
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<td>Autonomic Drugs</td>
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<td>Blood Derivatives</td>
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<td>Blood Formation and Coagulation</td>
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<td>Cardiovascular Drugs</td>
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<td>Central Nervous System Agents</td>
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<td>Diagnostic Agents</td>
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<td>Electrolyte, Caloric, &amp; Water Balance</td>
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<td>Eye, Ear, Nose, &amp; Throat Preparations</td>
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<td>Gastrointestinal Drugs</td>
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<td>Hormones &amp; Synthetic Substitutes</td>
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<td>Local Anesthetics</td>
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<td>Serums, Toxoids, &amp; Vaccines</td>
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<td>Skin &amp; Mucus Membrane Agents</td>
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<td>Smooth Muscle Relaxants</td>
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<td>Vitamins</td>
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<tr>
<td>Miscellaneous Therapeutic Agents</td>
<td>.</td>
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<tr>
<td>Pharmaceutical Aids</td>
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</tbody>
</table>
04:00 ANTI-HISTAMINES
04:04 First Generation Antihistamines
04:04.04 Ethanolamine Derivatives
diphenhydramine

04:04.12 Phenothiazine Derivatives
promethazine

04:04.20 Propylamine Derivatives
chlorpheniramine

04:08 Second Generation Antihistamines
loratadine

08:00 ANTI-INFECTIVES
08:12 Antibacterials
08:12.02 Aminoglycosides
gentamicin
tobramycin

08:12.06 Cephalosporins
1st Generation
cefazolin
cephalexin

3rd Generation
ceftazidime
ceftriaxone

08:12.07 Miscellaneous β-Lactams
meropenem

08:12.12 Macrolides
azithromycin
erthroycin
<table>
<thead>
<tr>
<th>Time</th>
<th>Category</th>
<th>Examples</th>
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</thead>
<tbody>
<tr>
<td>08:12.16</td>
<td><strong>Penicillins</strong></td>
<td>Natural Penicillins</td>
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<tr>
<td></td>
<td></td>
<td>penicillin G benzathine</td>
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<td></td>
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<td>penicillin G potassium</td>
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<td></td>
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<td>penicillin VK</td>
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<td></td>
<td><strong>Penicillinase-Resistant Penicillins</strong></td>
<td>dicloxacillin</td>
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<td>natcillin</td>
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<td><strong>Aminopenicillins Penicillins</strong></td>
<td>amoxicillin</td>
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<td>ampicillin</td>
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<tr>
<td>08:12.18</td>
<td><strong>Quinolones</strong></td>
<td>ciprofloxacin</td>
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<td>08:12.20</td>
<td><strong>Sulfonamides</strong></td>
<td>sulfamethoxazole/trimethoprim</td>
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<td></td>
<td>sulfasalazine</td>
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<td>08:12.24</td>
<td><strong>Tetracyclines</strong></td>
<td>minocycline</td>
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<td>08:12.28</td>
<td><strong>Miscellaneous Antibacterials</strong></td>
<td>clindamycin</td>
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<td>vancomycin</td>
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<td>08:14</td>
<td><strong>Antifungals</strong></td>
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<td>08:14.08</td>
<td><strong>Azoles</strong></td>
<td>fluconazole</td>
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<td>08:14.28</td>
<td><strong>Polyenes</strong></td>
<td>nystatin</td>
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<td>08:16</td>
<td><strong>Antimycobacterial Agents</strong></td>
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<td>08:16.04</td>
<td><strong>Antituberculosis Agents</strong></td>
<td>ethambutol</td>
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<td>isoniazid</td>
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<td>pyrazinamide</td>
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<td>rifabutin</td>
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<td>rifampin</td>
</tr>
</tbody>
</table>
Miscellaneous Antimycobacterials

dapsone

Antivirals

Adamantanes

amantadine

Antiretroviral Agents

Integrase Inhibitor
raltegravir

Integrase Strand Transfer Inhibitor
dolutegravir
elvitegravir/cobicistat/emtricitabine/tenofovir

Nucleoside reverse transcriptase inhibitors
abacavir
didanosine
lamivudine
zidovudine

Nucleotide reverse transcriptase inhibitors
tenofovir

Non-nucleoside reverse transcriptase inhibitors
efavirenz
nevirapine
rilpivirine

Protease Inhibitors
atazanavir
darunavir
fosamprenavir
lopinavir/ritonavir
nelfinavir
ritonavir
saquinavir

Nucleosides and Nucleotides

acyclovir
entecavir
ribavirin
08:18.40  HCV Antivirals
          sofosbuvir/velpatasvir

08:30  Antiprotozoals
08:30.08  Antimalarials
          pyrimethamine

08:30.92  Miscellaneous
          metronidazole

08:36  Urinary Anti-Infectives
          nitrofurantoin

12:00  AUTONOMIC DRUGS
12:04  Parasympathomimetic Agents
          bethanechol
          physostigmine

12:08  Anticholinergic Agents
12:08.04  Antiparkinson Agents
          benztrapine

12:08.08  Antimuscarinic / Antispasmodics
          atropine
          ipratropium
          tiotropium

12:12  Sympathomimetic Agents
          albuterol
          dopamine
          epinephrine
          phenylephrine
          terbutaline

12:20  Skeletal Muscle Relaxants
          baclofen
          methocarbamol

16:00  BLOOD DERIVATIVES
          albumin, human
20:00 BLOOD FORMATION AND COAGULATION
20:04 Antianemia Drugs
20:04.04 Iron Preparations
ferrous sulfate
iron sucrose

20:12 Antithrombotic Agents
20:12.04 Anticoagulants
heparin
warfarin

20:12.18 Platelet-aggregation Inhibitors
clopidogrel
clopidogrel

20:12.20 Thrombolytic Agents
alteplase
alteplase

20:16 Hematopoietic Agents
epoetin alfa
epoetin alfa

20:28 Antihemorrhagic Agents
20:28.08 Antiheparin Agents
protamine
protamine

24:00 CARDIOVASCULAR DRUGS
24:04 Cardiac Drugs
24:04.04 Antiarrhythmic Agents
adenosine
amiodarone
amiodarone

24:04.08 Cardiotonic Agents
digoxin
digoxin

24:06 Antilipemic Agents
24:06.06 Fibric Acid Derivative
gemfibrozil
gemfibrozil

24:06.08 HMG-CoA Reductase Inhibitor (Statin)
atorvastatin
pravastatin
pravastatin

460
Hypotensive Agents

Central Alpha Agonists
- clonidine
- guanfacine
- methyldopa

Direct Vasodilators
- hydralazine
- minoxidil

Vasodilating Agents

Nitrates and Nitrites
- isosorbide dinitrate
- isosorbide mononitrate
- nitroglycerin

Miscellaneous Vasodilating Agents
- dipyridamole

Alpha-Adrenergic Blocking Agents
- terazosin

Beta-Adrenergic Blocking Agents
- atenolol
- carvedilol
- labetalol
- metoprolol
- propranolol
- sotalol

Calcium-Channel Blocking Agents

Dihydropyridines
- amlodipine

Miscellaneous Calcium-Channel Blocking Agents
- diltiazem
- verapamil

Renin-Angiotensin-Aldosterone System Inhibitors

Angiotensin-Converting Enzyme Inhibitors
- lisinopril

Mineralocorticoid (Aldosterone) Receptor Antagonists
- spironolactone
28:00 CENTRAL NERVOUS SYSTEM AGENTS
28:08 Analgesics and Antipyretics
28:08.04 Nonsteroidal Anti-Inflammatory Agents
   Acetylated salicylates
   aspirin
   Propionic Acids
   ibuprofen
   naproxen
   Oxicams
   meloxicam
28:08.08 Opiate Agonists
   acetaminophen / codeine
   fentanyl
   morphine
28:08.12 Opiate Partial Agonists
   butorphanol
28:08.92 Miscellaneous Analgesics & Antipyretics
   acetaminophen
28:10 Opiate Antagonists
   naloxone
28:12 Anticonvulsants
28:12.04 Barbiturates
   primidone
28:12.12 Hydantoins
   phenytoin
28:12.92 Miscellaneous Anticonvulsants
   carbamazepine
   divalproex sodium, EC and ER
   lamotrigine
   levetiracetam
   magnesium sulfate
Psychotherapeutic Agents

28:16.04 Antidepressants

Selective Serotonin & Norepinephrine Reuptake Inhibitors
- duloxetine
- venlafaxine

Selective Serotonin Reuptake Inhibitors
- citalopram
- escitalopram
- fluoxetine
- sertraline

Serotonin Modulators
- trazodone

Tricyclics and Other Norepinephrine Reuptake Inhibitors
- imipramine

28:16.08 Antipsychotics

Atypical Antipsychotics
- aripiprazole
- clozapine
- risperidone
- ziprasidone

Typical Antipsychotics
- fluphenazine
- haloperidol
- perphenazine
- thiothixene
- trifluoperazine

Anorexigenic Agents and Respiratory & Cerebral Stimulants

28:20.00 Miscellaneous

- ammonia

28:20.04 Amphetamines

- amphetamine salts
- lisdexamfetamine
- methylphenidate

28:20.92 methylphenidate ER
28:24 **Anxiolytics, Sedatives, and Hypnotics**
28:24.08 **Benzodiazepines**
  - chlordiazepoxide
  - diazepam
  - lorazepam

28:24.92 **Misc Anxiolytics, Sedatives, & Hypnotics**
  - hydroxyzine

28:28 **Antimanic Agents**
  - lithium

28:36 **Antiparkinsonian Agents**
28:36.04 **Adamantines**
  - amantadine

28:36.16 **Dopamine Precursors**
  - carbidopa/levodopa

28:36.20 **Dopamine Receptor Agonists**
  - bromocriptine

28:92 **Central Nervous System Agents, Miscellaneous**
  - atomoxetine
  - flumazenil
  - guanfacine ER

36:00 **DIAGNOSTIC AGENTS**
36:58 **Ocular**
  - fluorescein strips

36:84 **Tuberculosis**
  - tuberculin PPD

40:00 **ELECTROLYTIC, CALORIC & WATER BALANCE**
40:08 **Alkalining Agents**
  - sodium bicarbonate

40:10 **Ammonia Detoxicants**
  - lactulose
40:12 Replacement Preparations
- calcium carbonate
- calcium gluconate
- dextrose / lactated ringers
- potassium chloride
- ringers-lactated
- sodium chloride

40:18 Ion-removing Agents
40:18.18 Potassium-Removing Agents
- polystyrene sodium sulfonate

40:18.19 Phosphate-Removing Agents
- sevelamer

40:20 Caloric Agents
- dextrose
- enteral feeding

40:28 Diuretics
Loop Diuretics
- furosemide

Potassium-sparing diuretics
- triamterene / hydrochlorothiazide

Thiazide Diuretics
- hydrochlorothiazide

Thiazide-like Diuretics
- metolazone

40:36 Irrigating Solutions
- sodium chloride
- sterile water

40:40 Uricosuric Agents
- probenecid
52:00 EYE, EAR, NOSE, & THROAT (EENT) PREPARATIONS

52:04 Anti-Infectives
52:04.04 Antibacterials
bacitracin / polymyxin ophth
cefotaxin / polymyxin ophth
eritromycin ophth
gentamicin ophth
neomycin / polymyxin ophth
neomycin / polymyxin / bacitracin ophth
neomycin / polymyxin / hydrocortisone ophth
neomycin / polymyxin / dexamethasone ophth
neomycin / polymyxin / gramicidin ophth
neomycin / polymyxin / hydrocortisone otic
polymyxin B / trimethoprim ophth
sulfacetamide ophth
tobramycin ophth

52:04.20 Antivirals
trifluridine ophth

52:04.92 Miscellaneous Anti-Infectives
carbamide peroxide otic
chlorhexidine

52:08 Anti-Inflammatory Agents
52:08.03 Corticosteroids
prednisolone ophth

52:08.20 Nonsteroidal Anti-Inflammatory Agents
ketorolac ophth

52:16 Local Anesthetics
benzocaine (orajel)
lidocaine viscous
proparacaine ophth

52:24 Mydriatics
atropine ophth
cyclopentolate ophth

52:32 Vasoconstrictors
naphazoline / pheniramine ophth
naphazoline ophth
tetrahydrozoline ophth
52:40  Antiglaucoma agents
   52:40.04  Alpha-Adrenergic Agonists
            brimonidine ophth
   52:40.08  Beta-Adrenergic Agents
            timolol ophth
   52:40.12  Carbonic Anhydrase Inhibitors
            acetazolamide
dorzolamide ophth
   52.40.28  Prostaglandin Analogs
            latanoprost

52:92  Miscellaneous EENT Drugs
       lubricant ophth oint
       ophthalmic irrigating solution
       polyvinyl alcohol ophth (artificial tears)
sodium chloride nasal
       sodium chloride ophth

56:00  GASTROINTESTINAL DRUGS
   56:04  Antacids & Adsorbents
          calcium carbonate
          charcoal, activated
   56:08  Antidiarrheal Agents
          bismuth subsalicylate
          loperamide
   56:10  Antiflatulents
          simethicone
   56:12  Cathartics & Laxatives
          Bowel Evacuants
          PEG-3350 / electrolytes
          Bulk-Forming Laxatives
          calcium polycarbophil
Saline Laxatives
- magnesium citrate
- magnesium hydroxide
- sodium phosphate

Stimulant Laxatives
- bisacodyl
- castor oil

Stool Softeners
- docusate sodium

Digestants
- lipase / protease / amylase (pancrelipase)

Antiemetics
- Antihistamines
  - meclizine
  - prochlorperazine

- 5-HT3 Receptor Antagonists
  - ondansetron

Antacid Agents and Acid Suppressants
- Histamine H2-Antagonists
  - ranitidine

- Proton-pump Inhibitors
  - omeprazole

Prokinetic Agents
- metoclopramide

HORMONES & SYNTHETIC SUBSTITUTES

Adrenals
- dexamethasone
- fluticasone
- hydrocortisone
- methylprednisolone
- prednisone
- triamcinolone
68:12 Contraceptives
ethynodiol diacetate / ethinyl estradiol
norethindrone / ethinyl estradiol
norgestrel / ethinyl estradiol
ulipristal

68:16 Estrogen
68:16.04 Estrogens
conjugged estrogens

68:20 Antidiabetic Agents
68:20.04 Biguanides
metformin

68:20.08 Insulins
insulin, human - NPH
insulin, human – regular

68:20.20 Sulfonylureas
glipizide

68:22 Antihypoglycemic Agents
68:22.12 Glycogenolytic Agents
glucagon

68:28 Pituitary
desmopressin

68:32 Progestins
medroxyprogesterone

68:36 Thyroid & Antithyroid Agents
68:36.04 Thyroid Agents
levothyroxine

68:36.08 Antithyroid Agents
methimazole

72:00 LOCAL ANESTHETICS
bupivacaine
lidocaine
80:00 SERUMS, TOXOIDS, & VACCINES
80:04 Serums
rho(D) immune globulin

80:08 Toxoids
tetanus-diphtheria
tetanus-diphtheria-acellular pertussis

80:12 Vaccines
hepatitis A vaccine
hepatitis B vaccine
human papillomavirus vaccine
influenza virus vaccine
measles-mumps-rubella vaccine
meningococcal polysaccharide vaccine
pneumococcal polyvalent vaccine
poliovirus vaccine, inactivated
varicella vaccine

84:00 SKIN & MUCOUS MEMBRANE AGENTS
84:04 Anti-Infectives
84:04.04 Antibacterials
bacitracin / polymyxin
clindamycin
neomycin / polymyxin / bacitracin

84:04.08 Antifungals
clotrimazole
gentian violet
miconazole
tolnaftate

84:04.12 Scabicides & Pediculicides
permethrin

84:04.92 Miscellaneous Local Anti-Infectives
selenium sulfide
silver sulfadiazine

470
84:06  Anti-Inflammatory Agents
fluocinonide
hydrocortisone
mometasone furoate
triamcinolone
triamcinolone / orabase

84:08  Antipruritics & Local Anesthetics
lidoceaine
phenazopyridine

84:24  Emollients, Demulcents and Protectants
84:24.04  Basic Lotions and Liniments
calamine
body lotion
mentholatum rub

84:24.12  Basic Ointments and Protectants
absorbbase

84:28  Keratolytic Agents
benzoyl peroxide
podophyllum resin
salicylic acid

84:32  Keratoplastic Agents
coil tar

84:80  Sunscreen Agents
sunscreen, SPF 30

84:92  Miscellaneous
collagenase
lubricant, surgical
podofilox
phenylephrine suppositories (hemorrhoidal)
pramoxine/phenylephrine (hemorrhoidal)
trichloroacetic acid

86:00  SMOOTH MUSCLE RELAXANTS
86:12  Genitourinary Smooth Muscle Relaxants
oxybutynin

471
88:00 VITAMINS
88:08 Vitamin B Complex
cyanoocabalamin
topic acid
viroxine
88:16 Vitamin D
calcitriol
paricalcitol
88:24 Vitamin K
phytoadonone
88:28 Multivitamin Preparations
multivitamin, I.V. infusion
multivitamin
prenatal-folic acid

92:00 MISCELLANEOUS THERAPEUTIC AGENTS
92:12 Antidotes
leucovorin
92:16 Antigout Agents
allopurinol
92:28 Cariostatic Agents
stannous fluoride
92:36 Disease-modifying Antirheumatic Drugs
infliximab
92:44 Immunosuppressive Agents
azathioprine
cyclosporine
mycophenolate mofetil
sirolimus
tacrolimus
92:92 Other
melatonin
PHARMACEUTICAL AIDS

- glucose tolerance test
- petrolatum jelly