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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PHARMACY CONTACTS AND PHONE NUMBERS

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McGhee, Trisha 936-437-5306
Patel, Raj 936-437-5488
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Snyder, Jesse 936-437-5490
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Spradling, Linda 936-437-5309
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Texas Tech School of Pharmacy
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EMAIL CT0001
George Jacob, Pharm.D. 806-414-9361
EMAIL JG0021
Livia Macedo, Pharm.D. 325-696-0450
EMAIL ML00100

STATEWIDE POISON CENTER 800-222-1222
UNIT RESTRICTION LIST FOR FLOOR STOCK PURPOSES

Dialysis Units: GC, E2

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

Hospice: JA, MI, GC-RMF

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

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

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

Phototherapy Center: E2-RMF

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

Transient Facilities: 0B, BC, DA, DU, DW, 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, J3, JM, RB

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


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

SAFP = Substance Abuse Felony Punishment
### CONVERSIONS AND CALCULATIONS

<table>
<thead>
<tr>
<th>WEIGHT MEASURE</th>
<th>LIQUID MEASURE</th>
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<tbody>
<tr>
<td><strong>METRIC=APOTHECARY</strong></td>
<td><strong>METRIC=APOTHECARY</strong></td>
</tr>
<tr>
<td>1 kg (kilogram) = 1000 gm (grams)</td>
<td>1 mL (milliliter) = 1 cc</td>
</tr>
<tr>
<td>1 gm = 1000 mg (milligrams)</td>
<td>30 mL = 1 oz</td>
</tr>
<tr>
<td>1 mg = 1000 mcg or μg (micrograms)</td>
<td>15 mL = 1/2 oz</td>
</tr>
<tr>
<td>60 mg or 65 mg = 1 gr (grain)</td>
<td>15 mL = 1 tablespoon (tbsp.)</td>
</tr>
<tr>
<td>125 mg = 2 gr</td>
<td>5 mL = 1 teaspoon (tsp.)</td>
</tr>
<tr>
<td>200 mg = 3 gr</td>
<td>2.5 mL = 1/2 tsp.</td>
</tr>
<tr>
<td>300 mg or 325 mg = 5 gr</td>
<td>960 mL = 1 quart</td>
</tr>
<tr>
<td>600 mg or 650 mg = 10 gr</td>
<td>1 L (liter) = 1000 mL (milliliters)</td>
</tr>
<tr>
<td>0.4 mg or 400 mcg = 1/150 gr</td>
<td></td>
</tr>
<tr>
<td>0.6 mg 600 mcg = 1/100 gr</td>
<td></td>
</tr>
<tr>
<td>15 gm = ½ oz</td>
<td></td>
</tr>
<tr>
<td>30 gm = 1 oz</td>
<td></td>
</tr>
<tr>
<td>60 gm = 2 oz</td>
<td></td>
</tr>
<tr>
<td>240 gm = 8 oz = 1/2 lb</td>
<td></td>
</tr>
<tr>
<td>480 gm = 16 oz = 1 lb</td>
<td></td>
</tr>
<tr>
<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:
\[
\text{total volume} = \frac{\text{mL/hr}}{\text{total hours}} \\
\text{Example:} \quad \frac{1000 \text{ mL}}{8 \text{ hr}} = 125 \text{ mL/hr}
\]

Formula for Calculating Drops (gtts) Per Minute (min):
\[
\frac{\text{mL/hr} \times \text{gtts/mL}}{60 \text{ min}} = \text{gtts/min}
\]

Example: \[
\frac{125 \text{ mL/hr} \times 10 \text{ gtts/mL}}{60 \text{ min}} = \frac{1250}{60} = 20.8 \text{ or } 21 \text{ gtts/min}
\]
ORIENTATION GUIDE FOR HEALTH CARE PROVIDERS
OF THE CORRECTIONAL MANAGED HEALTH CARE PROGRAM

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 the TDCJ Hospital.

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 EMR/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 EMR/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 EMR 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 EMR/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 uthbmcpharmacyHG@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 discharged 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 an on-call 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 Pharmacy Supervisor during business hours or the On-call 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 and ask to speak to a Pharmacy Supervisor during business hours. Normal business hours are 6:00am to 6:00pm 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.
   B. If substitution is not possible, call the nearest unit or facility and borrow the medication.
   C. If steps one and two above fail, contact a Pharmacy representative as outlined above in section I.
      1. Authorization from a Pharmacy Supervisor or the On-call Pharmacist is required to purchase medication from an outside pharmacy.
      2. Unit personnel must provide the Pharmacy Supervisor or On-call Pharmacist with the information listed below:
         a. Facility name
         b. Facility contact person
         c. Patient name and number
         d. Medication requested including strength, dosage form, quantity, and directions for use.
         e. Indication (diagnosis) for medication
         f. Rationale for urgent need
         g. 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.

a. Contract Pharmacy Available - UTMB Sector
   i. On-call Pharmacist
      • The On-call Pharmacist will contact the approved outside pharmacy and verify that the medication is in stock.
      • If the medication is available in stock, the On-call Pharmacist will provide the pharmacy with the billing information.
      • The On-call Pharmacist will notify the unit that the medication is available and the location of the pharmacy.
      • The On-call Pharmacist will approve a 5-day supply or up to a 7-day supply of medication for holiday weekends.
   ii. Unit Personnel
      • Unit personnel will call in or take a written prescription to the pharmacy and pick up the medication.
      • Unit personnel will email a copy of the receipt to the Pharmacy on the next business day. The email should be sent to utmbcmc.pharmacy@utmb.edu.

b. Contract Pharmacy Not Available – UTMB & Texas Tech Sectors
   i. Unit personnel will call in or take a written prescription to the pharmacy and pick up the medication. No more than a 5 day supply or up to a 7 day supply of medication for holiday weekends should be obtained.
   ii. Unit personnel will have to secure payment for the medication(s).
   iii. Unit personnel will email a copy of the receipt to the Pharmacy on the next business day. The email should be sent to utmbcmc.pharmacy@utmb.edu.
   iv. The Pharmacy will submit the receipt and request reimbursement.

D. The Pharmacy Supervisor or On-call Pharmacist authorizing the purchase will provide the UTMB CMC Pharmacy with the purchasing information and reason for approval by completing Attachment A and submitting the form on the next business day. If a Texas Tech Sector facility, the Pharmacy Supervisor or On-Call Pharmacist will also notify the Chief of Managed Health Care Pharmacy Services.

E. 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.
PHARMACY AND THERAPEUTICS COMMITTEE

(Abridged §05.05)

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 Inpatient and Outpatient Senior Medical Directors or designees
   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. Appointments must be reviewed when the current chairperson’s term expires at a minimum.
   L. Committee Officers
      1. Chairperson

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a. The Chair shall be appointed by the TDCJ Director of Health Services 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
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 from a clinical pharmacist 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 at each 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 (Attachment A) will require final approval by the TDCJ Director of Health Services (Attachment B).
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. TDCJ 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 TDCJ or University 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 representative 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 Senior Medical Director (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 Senior Medical Director (UTMB sector) Director of Mental Health Services or Dental Director.
The Regional or Senior Medical Director, 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 Director of Pharmacy 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

(P35.05)

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, nitroglycerin).
      4. Medications that have an unpleasant taste (e.g., ibuprofen).
      5. Medications that may produce mucosal or gastrointestinal tract irritation (e.g., alendronate).
   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.

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>Tablet 2</td>
<td>Extended Release, Enteric Coated</td>
</tr>
<tr>
<td>Bupropion (Wellbutrin® SR &amp; XL, Buproban®, Zyban®)</td>
<td>Tablet</td>
<td>Extended Release, Anesthetizes Mucosa</td>
</tr>
<tr>
<td>Carbamazepine (Tegretol® XR)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Ciprofloxacin (Cipro XR®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Clotrimazole (Mycelex® Troches)</td>
<td>Troches 3</td>
<td>Troche</td>
</tr>
<tr>
<td>Dabigatran (Pradaxa®)</td>
<td>Capsule</td>
<td>75% Increase Bioavailability</td>
</tr>
<tr>
<td>Darifenacin (Enablex®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Didanosine EC (Videx® EC)</td>
<td>Capsule</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Dilazem (Dilacor® 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</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 (Feosol®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Finasteride (Proscar®, Propecia®)</td>
<td>Tablet</td>
<td>Film Coated</td>
</tr>
<tr>
<td>Fluoxetine (Prozac®)</td>
<td>Capsule</td>
<td>Delayed Release</td>
</tr>
<tr>
<td>Glipizide (Glucotrol® XL)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Guaiifenesin (Mucinex®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Hyoscyamine (Symax-SR®, Levbid®)</td>
<td>Capsule, Troche 2</td>
<td>Slow Release</td>
</tr>
<tr>
<td>Lithium Carbonate (Eskalith CR®, 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>Mesalamine (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>Morphin Sulfate (MS Contin®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Mycophenolate (CellCept®, Myfortic®)</td>
<td>Capsule</td>
<td>Mucooe Membrane Irritant, Teratogenic, Enteric Coated Tablet</td>
</tr>
<tr>
<td>Niacin (Niaspan®)</td>
<td>Tablet</td>
<td>Extended Release</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 4</td>
<td>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</td>
</tr>
<tr>
<td>Panoprazole (Protonix®)</td>
<td>Tablet</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>PRODUCT</td>
<td>DOSAGE</td>
<td>COMMENTS/REASON</td>
</tr>
<tr>
<td>---------</td>
<td>--------</td>
<td>----------------</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®, Slow-K®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Propranolol (Inderal® LA, InnoPran® XL)</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 (Renagel®)</td>
<td>Tablet</td>
<td>Tablets expand when exposed to liquid</td>
</tr>
<tr>
<td>Sulfasalazine (Azulfidine® 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 (Uniphyl®, 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</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 tablet (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>
<thead>
<tr>
<th>PRODUCT</th>
<th>DOSAGE</th>
<th>COMMENTS/REASON</th>
</tr>
</thead>
<tbody>
<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>Carbamazepine (Equetrol®, Carbatrol®)</td>
<td>Capsule</td>
<td>Extended Release</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>Duloxetine (Cymbalta®)</td>
<td>Capsule</td>
<td>Enteric-Coated Pellets</td>
</tr>
<tr>
<td>Esomeprazole (Nexum®)</td>
<td>Capsule</td>
<td>Delayed Release</td>
</tr>
<tr>
<td>Etravirine (Intelicence®)</td>
<td>Tablet</td>
<td>Do not crush</td>
</tr>
<tr>
<td>Ibuprofen (various)</td>
<td>Tablet</td>
<td>Bad Taste</td>
</tr>
<tr>
<td>Indinavir (Crixivan®)</td>
<td>Capsule</td>
<td>Bad Taste</td>
</tr>
<tr>
<td>Isosorbide Mononitrate (Imdur®)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Isotretinoin (Amnesteem®, Claravis®)</td>
<td>Capsule</td>
<td>Irritant, Liquid Filled</td>
</tr>
<tr>
<td>Lansoprazole (Prevacid®)</td>
<td>Capsule</td>
<td>Delayed Release</td>
</tr>
<tr>
<td>Leviteracetam (Keppra®)</td>
<td>Tablet</td>
<td>Bitter Taste</td>
</tr>
<tr>
<td>Lisdexamphetamine (Vyvanse®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Methylphenidate (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>Nifedipine (Procardia®)</td>
<td>Capsule</td>
<td>Liquid Filled</td>
</tr>
<tr>
<td>Omeprazole (Prilosec®)</td>
<td>Capsule</td>
<td>Delayed Release</td>
</tr>
<tr>
<td>Pancrelipase (Creon®)</td>
<td>Capsule</td>
<td>Enteric Coated</td>
</tr>
<tr>
<td>Piroxicam (Feldene®)</td>
<td>Capsule</td>
<td>Mucous Membrane</td>
</tr>
<tr>
<td>Theophylline (Theo-24®)</td>
<td>Capsule</td>
<td>Irritant</td>
</tr>
<tr>
<td>Tipranavir (Aptivus®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Topiramate (Topamax®)</td>
<td>Tablet, Capsule</td>
<td>Liquid Filled, Taste</td>
</tr>
<tr>
<td>Venlafaxine (Effexor XR®)</td>
<td>Capsule</td>
<td>Extended Release</td>
</tr>
<tr>
<td>Verapamil (Calan® SR, Isoptin® SR, Verelan® PM, Covera® HS)</td>
<td>Tablet</td>
<td>Extended Release</td>
</tr>
</tbody>
</table>

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. For the UTMB sector, all requests for psychotropic medications should be sent to Dr. Angela Koranek.

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?

Prescribing clinician agrees with pharmacist?
Yes

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

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

No

Approval obtained from Regional Medical Director or Director of Mental Health Services

Forward copy of email referral to Regional Medical Director or Director of Mental Health Services

Yes

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)

No

Retrieve e-mail and retain a copy for your records. Approvals should be scanned into the patient’s medical record.

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 EMR 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 EMR 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 EMR 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., tricyclic 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., alcohol, 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)
12. Medications ordered DOT

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).
<table>
<thead>
<tr>
<th>Prior Authorization Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine (Adenocard®) injection</td>
<td>EMS or RMF</td>
</tr>
<tr>
<td>Absorbase (Eucerin®)</td>
<td>RMF or Dialysis</td>
</tr>
<tr>
<td>Albumin, Human (Plasbumin-25®)</td>
<td>RMF for paracentesis</td>
</tr>
<tr>
<td>Alteplase (Cathflo Activase®)</td>
<td>Dialysis for catheter restoration</td>
</tr>
<tr>
<td>Amiodarone (Cordarone®) injection</td>
<td>RMF</td>
</tr>
</tbody>
</table>
| Aripiprazole (Abilify®)                     | TJJD only. Prior authorization criteria must be met and include:  
|                                            | - Intolerance to risperidone                        |
|                                            | - Treatment failure on risperidone                  |
|                                            | - Contraindication to risperidone                   |
|                                            | - BMI ≥ 90th percentile                              |
| 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  
|                                            | Pregnant patients  
|                                            | - Treatment of GC & chlamydia dosed 2400 milligrams x 1 dose  
|                                            | - 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  
| Birth control (Low-Ogestrel®, Norinyl®, Zovia®) | Females  
| Body Lotion (Lubrisoft®)                    | Eczema  
|                                            | Dermatitis  
|                                            | Psoriasis  
|                                            | Chronic stasis dermatitis  
|                                            | Ichthyosis  
|                                            | Hyperkeratosis  
|                                            | Dialysis  
<p>|                                            | Burn Scars/Skin Grafts                              |</p>
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<tr>
<th>Prior Authorization Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
</tr>
</thead>
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<tr>
<td>Ceftazidime (Fortaz®, Tazicef®)</td>
<td>RMF (inpatient use only) or TJJD patient</td>
</tr>
<tr>
<td>Ceftriaxone (Rochephin®)</td>
<td>RMF (inpatient use only), Infirmary unit (inpatient use only), and TJJD</td>
</tr>
<tr>
<td>Chlordiazepoxide (Librium®)</td>
<td>Restricted to detoxification</td>
</tr>
<tr>
<td>Clonidine (Catapres®)</td>
<td>Hypertensive emergency</td>
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<td></td>
<td>Management of opioid withdrawal</td>
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<td></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>
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<td>Failed aspirin therapy (Event while on aspirin such as MI, stroke, TIA)</td>
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<td></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></td>
<td>Brachytherapy</td>
</tr>
<tr>
<td></td>
<td>Intermittent claudication and failed trial or remained symptomatic while on aspirin plus dipyridamole</td>
</tr>
<tr>
<td></td>
<td>Dialysis vascular graft.</td>
</tr>
<tr>
<td>Ciprofloxacin (Cipro®)</td>
<td>RMF (inpatient use only)</td>
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<tr>
<td>Collagenase (Santyl®)</td>
<td>Wound care facility</td>
</tr>
<tr>
<td>Dextrose 10% Water 1000ml (D10W)</td>
<td>Restricted to Estelle, Michael and Young facilities for use until TPN is available.</td>
</tr>
<tr>
<td>Diazepam (Valium®)</td>
<td>Spinal Cord Injury</td>
</tr>
<tr>
<td></td>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td></td>
<td>Muscular Dystrophy</td>
</tr>
<tr>
<td></td>
<td>Spastic Hemiplegia</td>
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<tr>
<td></td>
<td>Amyotrophic Lateral Sclerosis</td>
</tr>
<tr>
<td></td>
<td>Cerebral Palsy</td>
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<tr>
<td>Doxercalciferol (Hectoral®)</td>
<td>Dialysis</td>
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<tr>
<td>Elvitegravir – Cobicistat – Emtricitabine – Tenofovir (Stribild®)</td>
<td>New intake patient with current therapy</td>
</tr>
<tr>
<td>Enteral feeding (Osmolite®)</td>
<td>RMF and Dialysis</td>
</tr>
<tr>
<td>Epoetin Alfa (Procrit®)</td>
<td>Dialysis</td>
</tr>
<tr>
<td>Estrogens (Premarin®)</td>
<td>Females</td>
</tr>
<tr>
<td>Fluconazole (Diflucan®)</td>
<td>150mg – single dose for vaginal candidiasis</td>
</tr>
<tr>
<td></td>
<td>100mg &amp; 200mg – 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>Substance</td>
<td>Criteria</td>
</tr>
<tr>
<td>-----------</td>
<td>----------</td>
</tr>
<tr>
<td>Heparin</td>
<td>1,000 U/ML – 30ML: Dialysis</td>
</tr>
</tbody>
</table>
| Hepatitis A vaccine (Havrix^®) | - HIV-positive patients who are not immune (B-14.11)  
- Chronic hepatitis C patients who are not immune (B-14.11)  
- Chronic hepatitis B patients who are not immune (B-14.11)  
- ESLD |
| Hepatitis B vaccine (Engerix B^®) | Patient is not immune (P&P B-14.07) plus one of the following  
- Chronic hepatitis C  
- HIV  
- Dialysis (Dialysis patients should be given 2 doses (40mcg) per administration)  
- Post-exposure prophylaxis  
- Job assignment that includes the handling of medical waste  
- ≤ 18 year old without documentation of series completion  
- ESLD |
| Human Papillomavirus – HPV (Gardasil^®) | Females ages 9 through 26 with no previous vaccination. |
| Influenza vaccine (Flulaval^®) | Infection Control P&P B-14.51  
- ≥ 50 years old  
- Certain chronic diseases (heart disease, asthma, COPD, diabetes, renal disease, hepatic disease, neurologic disease, and hematologic disease)  
- Immunocompromising diseases (HIV, most cancers, ESRD, sickle cell, medications)  
- Pregnancy during the influenza season  
- < 18 years old and on chronic aspirin therapy  
- American Indian or Alaska Native  
- Morbidly obese BMI ≥ 40 |
| Iron sucrose (Venofer^®) | Dialysis |
| 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 |
<p>| Lorazepam (Ativan^®) injection | Treatment of acute seizures uncontrolled by |</p>
<table>
<thead>
<tr>
<th>Agent / Restricted Agent</th>
<th>Criteria (Should be typed in Special Instructions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Agent</td>
<td>other measures.</td>
</tr>
<tr>
<td>MMR vaccine (M-M-R®-II)</td>
<td>• ≤18 years old without documentation of series completion</td>
</tr>
<tr>
<td></td>
<td>• Immigrants that have not completed the series</td>
</tr>
<tr>
<td></td>
<td>• Born after 1956 &amp; did not attend public school</td>
</tr>
<tr>
<td>Medroxyprogesterone (Provera®,</td>
<td>Females</td>
</tr>
<tr>
<td>Depo-Provera®)</td>
<td>Anatomic or functional asplenic patients who have no history of prior immunization</td>
</tr>
<tr>
<td>Methocarbamol (Robaxin®)</td>
<td>One 7 day supply per injury</td>
</tr>
<tr>
<td>Miconazole vaginal suppositories</td>
<td>Females</td>
</tr>
<tr>
<td>(Monistat®)</td>
<td>Anatomic or functional asplenic patients who have no history of prior immunization</td>
</tr>
<tr>
<td>Morphine sulfate (MS Contin®)</td>
<td>• Elixir and extended release tablets – RMF inpatient or Hospice (may not exceed 21 day supply)</td>
</tr>
<tr>
<td></td>
<td>• Injection – one time orders for pain associated with acute trauma or severe medical condition</td>
</tr>
<tr>
<td>Multivitamin</td>
<td>HIV-positive + CD4 count &lt; 100 + not on enteral feeding</td>
</tr>
<tr>
<td>Nephro-Vite®</td>
<td>Dialysis</td>
</tr>
<tr>
<td>Paricalcitol (Zemplar®)</td>
<td>Dialysis</td>
</tr>
<tr>
<td>Penicillin G Benzathine (Bicillin LA®)</td>
<td>Syphilis</td>
</tr>
<tr>
<td>Petrolatum (Vaseline®)</td>
<td>Phototherapy at E2</td>
</tr>
<tr>
<td>Phenytoin (Dilantin®)</td>
<td>• Oral suspension restricted to RMFs</td>
</tr>
<tr>
<td></td>
<td>• Injection restricted to Emergency Medical Services (EMS).</td>
</tr>
<tr>
<td>Pneumococcal vaccine (Pneumovax-23®)</td>
<td>• Age ≥ 65 years</td>
</tr>
<tr>
<td></td>
<td>• Certain chronic disease patients (e.g., heart disease, COPD, diabetes)</td>
</tr>
<tr>
<td></td>
<td>• Patients with disease associated with increased risk (splenic dysfunction, anatomic asplenia, Hodgkin’s Disease,</td>
</tr>
<tr>
<td></td>
<td>multiple myeloma, cirrhosis, alcoholism, renal failure, CSF leaks) or immunosuppression (HIV, most cancers, sickle cell disorder)</td>
</tr>
<tr>
<td>Polio vaccine (Ipol®)</td>
<td>Patients under 18 years old</td>
</tr>
<tr>
<td>Potassium Chloride injection</td>
<td>Infirmary or RMF</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>
<tr>
<td>Prenatal vitamins</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Rilpivirine (Edurant®)</td>
<td>New intake patient with current therapy</td>
</tr>
<tr>
<td>Sevelamer (Renagel®)</td>
<td>Chronic kidney disease</td>
</tr>
<tr>
<td></td>
<td>Dialysis</td>
</tr>
<tr>
<td>Stavudine (Zentel®) 20mg</td>
<td>HIV-positive + dialysis patient</td>
</tr>
<tr>
<td>Surgical lubricant (Surgilube®) 4.24 oz tube</td>
<td>RMF</td>
</tr>
<tr>
<td>Terbutaline injections (Brethine®)</td>
<td>Female patients at CYMF and Cram</td>
</tr>
<tr>
<td>Tetanus-Diphtheria (Tenivac®)</td>
<td>≤ 18 years old without documentation of completion</td>
</tr>
<tr>
<td></td>
<td>No history of prior immunization within the last 10 years</td>
</tr>
<tr>
<td></td>
<td>Prophylaxis for wound management</td>
</tr>
<tr>
<td>Tetanus-Diphtheria-Acellular Pertussis Tdap (Boostrix®)</td>
<td>Post-partum and accepted into BAMBI (Baby and Mother Infant Bonding Initiative)</td>
</tr>
<tr>
<td>Tiotropium 18mcg (Spiriva®)</td>
<td>Inadequate response to ipratropium 2 puffs QID</td>
</tr>
<tr>
<td></td>
<td>Severe COPD</td>
</tr>
<tr>
<td></td>
<td>Very severe COPD</td>
</tr>
<tr>
<td>Ulipristal (Ella®)</td>
<td>Female unit/patient for emergency contraception</td>
</tr>
<tr>
<td>Varicella Vaccine (Varivax®)</td>
<td>≤ 18 years old without documentation of previous disease or immunization</td>
</tr>
<tr>
<td></td>
<td>Post-exposure prophylaxis with approval from Office of Public Medicine</td>
</tr>
<tr>
<td>Vasopressin (Pitressin®) injection</td>
<td>RMF</td>
</tr>
<tr>
<td>Ziprasidone (Geodon®)</td>
<td>TJJD only. Prior authorization criteria must be met and include:</td>
</tr>
<tr>
<td></td>
<td>Intolerance to risperidone</td>
</tr>
<tr>
<td></td>
<td>Treatment failure on risperidone</td>
</tr>
<tr>
<td></td>
<td>Contraindication to risperidone</td>
</tr>
<tr>
<td></td>
<td>BMI ≥ 90th percentile</td>
</tr>
</tbody>
</table>
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 powdered medications that are contained in standard 20mm 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 20mm vial to a 250mL 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 250mL bag).

### System Antibiotics That May Be Used With System

<table>
<thead>
<tr>
<th>System</th>
<th>Antibiotics That May Be Used With System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini-Bag Plus Admixture System</td>
<td>Ampicillin (NS only)</td>
</tr>
<tr>
<td></td>
<td>Cefazolin</td>
</tr>
<tr>
<td></td>
<td>Ceftazidime</td>
</tr>
<tr>
<td></td>
<td>Ceftizoxime</td>
</tr>
<tr>
<td></td>
<td>Meropenem</td>
</tr>
<tr>
<td></td>
<td>Nafcillin</td>
</tr>
<tr>
<td></td>
<td>Penicillin G Potassium</td>
</tr>
<tr>
<td>Mini-Bag Vial-Mate Adaptor</td>
<td>Vancomycin</td>
</tr>
</tbody>
</table>

NS=normal saline

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

In addition, clindamycin 900mg in 50 mL D5 and metronidazole 500mg 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 three years or when new national treatment guidelines, landmark clinical studies, and/or new drug entities become available, whichever is sooner.

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<th>Disease Management Guideline</th>
<th>Page</th>
</tr>
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<td>(Tool available on CMCWEB)</td>
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</tr>
</tbody>
</table>

**Disease Management Guidelines for Youth**

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

<table>
<thead>
<tr>
<th>Disease Management Guideline</th>
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<td>Acne</td>
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<td>Diabetes Mellitus</td>
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<td>Explosive/Reactive, Aggression</td>
<td>313-319</td>
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<td>Hypertension</td>
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<td>Insomnia</td>
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<td>Psychosis</td>
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<td>PTSD</td>
<td>341-343</td>
</tr>
<tr>
<td>Seizures, Acute</td>
<td>344</td>
</tr>
<tr>
<td>Seizures, Chronic</td>
<td>345-351</td>
</tr>
</tbody>
</table>

35
Anemia in Pre-Dialysis Chronic Renal Failure
Erythropoietin Dosing and Monitoring

Pretherapy Evaluation

• Anemia with Hgb < 10 g/dL
  Consider initiating erythropoietin stimulating agent (ESA) treatment only when the hemoglobin level is less than 10 g/dL, and the following considerations apply:
  – Reducing the risk of alloimmunization and/or other red blood cell transfusion-related risks is a goal.
  – The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell transfusion.

• 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.

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.

Check Hgb at 2 weeks.

Maintenance Dose

• Titrate dose as needed to maintain Hgb sufficient to:
  – Not exceed 11 g/dL.
  – Not increase Hgb > 2 g/dL during ANY 4 week period.
  – If the hemoglobin level exceeds 10 g/dL, 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 hemoglobin levels at least every two weeks until stable, 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 transfusion.

• Follow monitoring parameters in Table 2 on page 2.
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 (ie thalassemia, refractory anemia or other myelodysplastic disorders)
5. Vitamin deficiencies (folate acid, vitamin B12)
6. Hemolysis
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>
<tbody>
<tr>
<td>Hgb, Hct, and platelets</td>
<td>Hgb every 4 weeks with maintenance therapy</td>
</tr>
<tr>
<td>CMP (including BUN, uric acid, Cr, Phos and K)</td>
<td>Hgb 4 weeks after ANY dose adjustment</td>
</tr>
<tr>
<td>Transferrin saturation and serum ferritin</td>
<td>Hct and platelets regularly</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Transferrin saturation and serum ferritin every 1-3 months. Supplement iron if transferrin saturation &lt; 20% or ferritin &lt;100 ng/mL</td>
</tr>
<tr>
<td>Blood pressure monthly (MUST remain adequately controlled to continue therapy)</td>
<td>CMP regularly (including BUN, uric acid, Cr, Phos, and K)</td>
</tr>
</tbody>
</table>

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.
ANGINA, ACUTE

1. **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, pneumothorax, or pulmonary embolism.

   *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 antihypertensive medication;
     - Smoker within the last 2 years;
     - HDL < 40 mg/dl.
   - **Negative Cardiac Risk Factors:**
     - HDL ≥ 60 mg/dl (subtract 1 risk factor).

   2. **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.

   3. **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

   4. **EKG Q-T Changes?**
      - ST elevation or depression
      - Significant Q-waves
      - Inverted T-wave
      - Changes from previous EKG's
      - NTG SL X 3 ineffective?
      - Positive Troponin Level/ other Cardiac Enzyme Levels?

   5. **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

   6. **Changes in parameters?**
      - **Yes**
      - **No**

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

   *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 2001; Revised 11/02, 11/07, Revised 6/03, 5/08, 3/11, 7/11.
Angina, Chronic Stable

1. **Meets criteria for Chronic Stable Angina?**
   - Yes: See Angina, Acute Pathway
   - No: Consider cardiology referral if not previously evaluated by cardiology

2. **History of Vasospastic Angina?**
   - Yes: Start Calcium Channel Antagonist (CCA) and ASA EC 81-325 mg qd. Titrate CCA to maximum tolerated dose. If patient continues to be symptomatic, add Long Acting Nitrate therapy. Go to Box 15.
   - No: Start Beta-Blocker (BB) and ASA EC 81-325 mg qd. Titrate BB to maximum tolerated dose.

3. **Effective?**
   - Yes: Consider Cardiology Consult
   - No: Refer to Checklist for Secondary Prevention of Coronary Artery Disease (SMG) to ensure risk reduction measures are being followed. Aggressively treat the underlying disease.

4. **Effective?**
   - Yes: Continue therapy. Follow up in 30 days. Restart 90 days if chest pain is stable.
   - No: Refer to Checklist for Secondary Prevention of Coronary Artery Disease (SMG) to ensure risk reduction measures are being followed. Aggressively treat the underlying disease.

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Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. Approved February 2002; Reviewed 11/02, 1/08, Revised 4/03, 9/09, 7/11.
Healthcare Provider Education

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
  - Amdiolin 5-80mg/day
  - Metoprolol 100-480mg/day in 1-2 divided doses
- Calcium channel antagonists (CCA) - 3rd line if BB’s are not tolerated, contraindicated, or if symptoms are not alleviated with BB’s alone.
  - Verapamil 240-480mg/day in 1-2 divided doses
  - Diltiazem XR 360-720mg/day
- Long acting nitroglycerin – 4th line agent 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

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, 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
  - Amdiolin: 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 nitroglycerin

- 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 tablet. 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.
  - Sustained release nitroglycerin SR should be chewed once a day in the morning, which will allow for a nitrate withdrawal period and prevent tolerance from occurring. Extended release tablets should not be crushed or chewed.

Drug interaction alert:

- Concurrent use of non-dihydropyridine calcium channel antagonists with beta blockers can possibly potentiate hypotension, bradycardia, heart failure, and conduction abnormalities. These effects are most prevalent in patients with impaired left ventricular function, cardiac arrhythmias, or aortic stenosis.

Contraindications

- 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
  - Amdiolin: use with caution in patients with heart failure
- Aspirin
  - Hypersensitivity to NSAIDs
  - Syndrome of asthma, rhinitis, and nasal polyps
  - Inherited or acquired bleeding disorders
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 Chonger 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.
ANXIETY and PANIC DISORDER

1. Rule out medical causes for presentation

2. Presence of panic attacks?
   - No
   - Yes

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

4. Treat underlying causes
   - No
   - Yes

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

6. Obtain baseline BPRS
   - Yes
   - No
   - Continue for 6-12 weeks at a therapeutic dose*
   
   • Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started
   
   • Initiate formulary SSRI antidepressant
     - Start at lower end of dosing range and titrate gradually upward to decrease potential for activating side effects
     - Continue for 6-12 weeks at a therapeutic dose*

7. Adequate response per BPRS?
   - No
   - Yes
   - Continue for 6-12 months, reassessing as needed by unit mental health provider
     - After 12-18 months, consider discontinuing pharmacotherapy

8. Assess compliance
   - No
   - Yes
   - 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 weeks or
     - Switch to alternative formulary agent (Table 1) or
     - Consider pharmacotherapy consult

*Continued for 6-12 weeks as a therapeutic dose

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee,
Medication Selection

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: Formulary Antidepressants

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Map Cautions First If</th>
<th>Initial Dose (Dose Range) mg/day</th>
<th>Therapeutic Range mg/d</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram</td>
<td>Celexa®</td>
<td>Atypical</td>
<td>20</td>
<td>N/A</td>
<td>Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine</td>
<td>Paxil®</td>
<td>Atypical</td>
<td>20</td>
<td>20 – 40</td>
<td>EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present</td>
</tr>
<tr>
<td></td>
<td>Sertraline</td>
<td>Zoloft®</td>
<td>Significant anxiety</td>
<td>50</td>
<td>50 – 200</td>
<td>QTc &gt; 450ms for males or &gt; 470ms for females, do not initiate if pt is on citalopram and QTc is &gt; 500ms, consider alternative treatment</td>
</tr>
<tr>
<td>Tricyclic Antidepressants (TCA)</td>
<td>Nortriptyline</td>
<td>Pamelor®</td>
<td>Melancholic features</td>
<td>25 – 50</td>
<td>75 – 150</td>
<td>Liver function test at baseline and as clinically indicated, blood level within 2 weeks, then as clinically indicated</td>
</tr>
<tr>
<td>Other*</td>
<td>Trazodone</td>
<td>Desyrel®</td>
<td>Atypical</td>
<td>100 – 150</td>
<td>N/A</td>
<td>Emergence of suicidal ideation or behavior</td>
</tr>
</tbody>
</table>

*Generally not recommended as first line or second line therapy for treatment of anxiety or panic disorder

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 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.

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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

<table>
<thead>
<tr>
<th>Score</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>____</td>
<td>1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>____</td>
<td>2. ANXIETY - Worry, fear, over-concern for present or future, unassuageable</td>
</tr>
<tr>
<td>____</td>
<td>3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, inability to relate 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, pessimism.</td>
</tr>
<tr>
<td>____</td>
<td>10. HOSTILITY - Animosity, contempt, bitterness, disdain for others.</td>
</tr>
<tr>
<td>____</td>
<td>11. SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory 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 - Disorientation 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 pathological mood. Opinions are out of proportion to the circumstances.</td>
</tr>
<tr>
<td>____</td>
<td>20. SUICIDALITY - Expressions of intent to harm or kill self.</td>
</tr>
<tr>
<td>____</td>
<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>____</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>
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 suggest severe exacerbation.
4) Measure peak respiratory flow (PEF) and compare with personal best.
5) Consider potential triggers for symptoms (e.g. acute viral infection, sinusitis, pneumonia, exposure to toxic environment, heart disease).
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 took oral systemic corticosteroids.

FEV1 or PEF < 50% (Severe)
• Oxygen to achieve SaO2 ≥ 90%
• High-dose inhaled SABA plus ipratropium by nebulizer or MDI plus valved holding chamber, every 20 minutes or continuously for 1 hour.
• Oral systemic corticosteroids.

Impending or Actual Respiratory Arrest
• Transfer to higher level of care.
• Oxygen to achieve SaO2 ≥ 90%
• Nebulized SABA and ipratropium
• Intravenous corticosteroids
• Schedule follow up with unit provider upon return of hospitalization. Refer to Box 11.

Moderate Exacerbation
PEF 50-69% predicted/personal best
Physical exam: moderate symptoms
• Inhaled SABA every 60 minutes
• Oral systemic corticosteroids
• Continue treatment 3-5 hours, provided there is improvement.

Severe Exacerbation
PEF < 50% predicted/personal best
Physical exam: severe symptoms at rest, accessory muscle use, chest retraction
History: high-risk patient
No improvement after initial treatment
• Oxygen
• Nebulized SABA plus ipratropium hourly or continuously
• Oral systemic corticosteroids

Good Response
• PEF ≥ 70%
• No distress
• Physical exam: normal

Incomplete Response
• PEF 50-69%
• Mild-to-moderate symptoms

Poor Response
• PEF <50%
• PCO2 ≥ 42 mm Hg
• Transfer to higher level of care. Contact Utilization Review or follow unit procedures.
• Schedule follow up with unit provider upon return of hospitalization. Refer to Box 11.

Discharge
• Continue treatment with inhaled SABA.
• Consider initiation of an ICS if not currently prescribed.
• Follow up with unit provider within 1 week.
• Review education
• Review/institute action plan
• Review of environmental triggers
• Follow up medical appointment.

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

SABA=Short-acting beta agonist (e.g., albuterol), MDI=Metered Dose Inhaler, ICS=Inhaled Corticosteroid.


Page 45
### 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
- Three or more emergency room visits 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**
- Illicit 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>4-8 puffs every 20 minutes up to 4 hours, then every 1-4 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>8 puffs every 20 minutes as needed up to 3 hours</td>
<td></td>
</tr>
<tr>
<td>Ipratropium with albuterol nebulizer solution (each 3ml 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>40-100mg/day in 1 or 2 divided doses until PEF reaches 70% of predicted or personal best</td>
<td>For outpatient “burst,” use 40-60mg in single or 2 divided doses for total of 5 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.

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*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>
<tr>
<td>Subset: Life threatening</td>
<td>Too dyspneic to speak, perspiring</td>
<td>PEF &lt; 25 percent predicted or personal best</td>
</tr>
</tbody>
</table>

Key: ED, emergency department; FEV1, forced expiratory volume in 1 second; ICU, intensive care unit; PEF, peak expiratory flow; SABA, short-acting beta-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 SaO2 > 90 percent (> 95 percent in pregnant women and in patients with coexistent heart disease). Monitor SaO2 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 hospitalisations. 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.
A thorough screening history by provider is essential to confirm diagnosis during initial visit.

1. Symptoms witnessed/addressed by healthcare giver
2. Complete Peak Flow (suggest spirometry when available)
3. Document peak flow at each asthma related encounter and update personal best as indicated.
4. Classify asthma to determine treatment plan.
5. Provide patient education including proper use of inhaler
6. If patient has a history of intubation, consider transfer to a 24 hour unit

### Classification of Asthma

<table>
<thead>
<tr>
<th>Intermittent</th>
<th>Mild Persistent</th>
<th>Moderate Persistent</th>
<th>Severe Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1 ≥ 80% predicted</td>
<td>FEV1 ≤ 80% &amp; FEV1/FVC normal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms 2-4 days/wk &amp; 1-2 nights/month</td>
<td>Symptoms 2-3 days/wk &amp; 1-2 nights/month</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Treatment Plan

#### Step 1
- **Short-acting β2 Agonist Inhaler**
  - Albuterol HFA 2 puffs tid-qid (1 inhaler should last 60-90 days)
  - Low dose Corticosteroid Inhaler
  - Beclomethasone 1 puff BID (1 inhaler should last 60 days)

#### Step 2

<table>
<thead>
<tr>
<th>Controlled?</th>
<th>Partly Controlled?</th>
<th>Uncontrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Controlled?</td>
</tr>
<tr>
<td>Partial</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Controlled?</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>Controlled?</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Controlled?</td>
</tr>
</tbody>
</table>

#### Step 3
- Continue Regimen.
- Follow up at least every 6 months with peak flow and assess control to determine if step down therapy is appropriate.
- Once stable, follow up at least every 12 months.
- Consider spirometry every 1-2 years.

#### Step 4
- Consider Respiratory Care referral and stepping up therapy to gain control.
- Consider Respiratory Care referral (ACTION: SEE TABLE 1).

#### Step 5
- Consider obtaining nonformulary approval for patient steroid and long-acting beta agent.

### Action Plan
- Once stable, follow up at least every 12 months.
- Consider spirometry every 1-2 years.

The pathways do not replace sound clinical judgment and are not intended to strictly apply to all patients.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. January 1999. Reviewed 4/02, 4/03, 3/05. Revised 10/03, 7/09, 1/10, 1/13. Revised to include children 11/06.
Table 1: Stepwise Approach for Managing Asthma & Recommended Options

Each step:
• Assess control.
• Prescribe short-acting quick relief medication (e.g., short acting beta, against – SABA) for all patients.
• Provide patient education, assess adherence to treatment & environmental control.
• Consider stepping down therapy if asthma is well controlled for at least 3 months.
• Consider stepping up therapy if asthma is not well controlled.

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Treatment</td>
<td>Short acting, 2 agent</td>
<td>Low dose inhaled corticosteroid</td>
<td>Medicated dose inhaled corticosteroid</td>
<td>Medicated or High dose inhaled corticosteroid plus long acting beta 2 agonist</td>
</tr>
<tr>
<td>Formulary Agents</td>
<td>Albuterol HFA</td>
<td>Budesonide medium dose: 2 puffs bid x 30 days</td>
<td>Budesonide medium dose: 2 puffs bid x 30 days</td>
<td>Budesonide: Medium dose x 30 days</td>
</tr>
<tr>
<td>Nonformulary Combination Products</td>
<td>Combination: Dulera®</td>
<td>Combination: Dulera®</td>
<td>Combination: Dulera®</td>
<td>Combination: Dulera®</td>
</tr>
</tbody>
</table>

50
I. Diagnosis is based on the following:

A. History
   1. A thorough history is essential to confirm prior diagnosis
   2. Family history of asthma, allergy, sinusitis, rhinitis, eczema or nasal polyps
   3. Recurrent symptoms such as wheeze, cough, chest tightness, shortness of breath
   4. Pattern of symptoms
      a. Perennial, seasonal or both
      b. Continual, episodic or both
   5. Symptoms occur or worsen in the presence of
      a. Exercise
      b. Allergen (e.g., mold, pollen, dust mites, animal fur)
      c. Influenza (e.g., smoke, chemicals)
      d. Viral infection
      e. Changes in weather
      f. Stress
      g. Menstrual cycles
      h. Strong emotional expression (e.g., laughing or crying hard)
      i. Drugs (e.g., NSAID, aspirin, 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
B. Physical exam
   1. Hyper-expansion of the chest
   2. Wheezing during normal breathing or prolonged forced exhalation. Absence of symptoms during the exam does not exclude the diagnosis.
   3. Signs of allergic skin problems such as atopic dermatitis or eczema
C. Reversible airflow obstruction using spirometry
D. Exclusion of other diagnoses

II. Classification
A. There are 4 asthma classifications. Patients should be classified at the highest level based on the most severe symptoms and/or lung functions. Respiratory Care may be consulted to assist with asthma classification and patient education.
B. Classification is used to determine appropriate initial therapy and the assessment of asthma control is used to adjust therapy as needed.
C. FEV1: % predicted
D. PEF is percent difference between lowest and highest peak flow on same day
III. Treatment Principles

A. Gain control of asthma as soon as possible and step down to the lowest possible dose to maintain control.

B. All patients need to be prescribed a short-acting inhaled beta₂-agonist to use as needed. However, use should be minimized. Asthma is not adequately controlled if the patient is using more than 1 canister a month and therapy with long-term control medications may need to be started or intensified after verifying appropriate inhaler technique.

C. Evaluate causes of poor control before increasing medication doses.
   1. Poor patient inhaler technique
   2. Poor medication compliance
   3. Adverse effects to medications
   4. Exposure to environmental triggers
   5. Other diagnosis such as upper respiratory infection

D. Goals of therapy
   1. Prevent symptoms and exacerbations
   2. Maintain normal activity level
   3. Maintain lung function
   4. Minimize medication adverse effects
   5. Minimize use of short-acting beta₂-agonists

IV. Treatment

A. Non-pharmacologic
   1. Avoid environmental triggers such as allergens or irritants
   2. Patients should be given self-monitoring instructions and given instructions on how to manage worsening symptoms and when to notify the medical department of worsening symptoms.

B. Pharmacologic (Tables 2-4)
   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. Quick relief medications
      a. Used to provide prompt relief of symptoms
      b. Example: short-acting beta₂-agonist such as albuterol
      c. Prescribed as needed
      d. If more than 1 canister used a month by the patient, a long-term control medication may need to be added or intensified after verifying appropriate inhaler techniques.
   3. Long-term control medications
      a. Used to maintain control of symptoms
      b. Examples: inhaled corticosteroids, long-acting inhaled beta₂-agonist, leukotriene modifiers, methylxanthines, and corticosteroids
      c. Inhaled corticosteroids are preferred for adults, adolescents, and children
      d. Prescribed on a scheduled basis and are not effective on “prn” basis
      e. Doses should be reduced after several months of control. The dose of inhaled steroids may be reduced by 25% every 2 to 3 months until the lowest effective dose is reached.
   C. Monitoring
      1. Patients with a diagnosis of asthma should be seen based on acuity and clinical judgment but may not exceed 12 month.
      2. Peak flow reading should be obtained at every chronic care visit.
      3. Classification of asthma severity should be performed at each chronic care visit.
   D. 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 1 canister a month or uses more than 2 days a week for symptom control. Therapy with long-term control medications may need to be started or intensified after verifying appropriate inhaler technique per the stepwise approach to therapy (Table 1).
   E. Assess severity and frequency of symptoms at each chronic care visit.
   F. Patient education and inhaler technique instruction should be provided at each chronic care visit.
   G. Consider spirometry every 1-2 years.
VI. Signs of poorly controlled disease
1. Waking up at night with symptoms > twice a month
2. Increased use of short-acting beta₂-agonists (e.g., > 2 times/week or 1 canister per month)
3. Poor adherence to medication regimen
4. Failure to achieve quick and sustained response (improvement within 10-20 minutes and lasting > 4 hours) to short-acting beta₂-agonist during an acute exacerbation.
5. Poor tolerance to physical activity
6. Unable to perform daily activities (e.g., go to work, school)
7. Hospitalization or emergency treatment of asthma
8. Use of nébulized medications

Table 2: Commonly Prescribed Quick Relief Medications

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type of Medication</th>
<th>Adult Dose</th>
<th>Child ≤ 12 Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol (Proventil HFA®)</td>
<td>Quick relief – short-acting beta₂-agonist</td>
<td>2 puffs tid-qid prn</td>
<td>2 puffs tid-qid prn</td>
</tr>
<tr>
<td>Prednisone (Deltasone®)</td>
<td>Quick relief – used for establishing control when initiating therapy or period of gradual deterioration</td>
<td>40-60mg/day x 3-10 days</td>
<td>1-2mg/kg/day maximum 30mg/day x 3-10 days</td>
</tr>
</tbody>
</table>

Table 3: Commonly Prescribed Long-Term Control

<table>
<thead>
<tr>
<th>Drug</th>
<th>Type of Medication</th>
<th>Adult Dose</th>
<th>Child ≤ 12 Dose</th>
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</thead>
<tbody>
<tr>
<td>Fluticasone HFA (Flovent®)</td>
<td>Long-term control – inhaled corticosteroid</td>
<td>Low dose – 2 puffs (44mcg) bid</td>
<td>Low dose – 2 puffs (44mcg) bid</td>
</tr>
<tr>
<td>Prednisone (Deltasone®)</td>
<td>Long-term control – oral corticosteroid</td>
<td>5-60mg daily or qid</td>
<td>0.25-2mg/kg daily or qid</td>
</tr>
<tr>
<td>Salmeterol (Serevent®)</td>
<td>Long-term control – long-acting beta₂-agonist</td>
<td>1 puff bid</td>
<td>1 puff bid</td>
</tr>
<tr>
<td>Theophylline (Theo-Dur®)</td>
<td>Long-term control – methylxanthine</td>
<td>10mg/kg/day up to 300mg max, usual max 800mg/day</td>
<td>10mg/kg/day; usual max 80mg/kg/day</td>
</tr>
<tr>
<td>Beclomethasone (Qvar®)</td>
<td>Long-term control – inhaled corticosteroid</td>
<td>Low dose – 1 puff bid</td>
<td>Low dose – 1 puff (40mcg or 80mcg) bid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medium dose – 2 puffs bid or 3 puffs bid</td>
<td>Medium dose – 2 puff (40mcg or 80mcg) puffs bid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High dose – 4 puffs bid</td>
<td>High dose – 3 (40mcg) puffs bid</td>
</tr>
</tbody>
</table>

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<tr>
<td></td>
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<td>Medium dose – 2 puffs bid or 3 puffs bid</td>
<td>Medium dose – 2 puff (40mcg or 80mcg) puffs bid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High dose – 4 puffs bid</td>
<td>High dose – 3 (40mcg) puffs bid</td>
</tr>
</tbody>
</table>
Patient Education

I. Avoidance of environmental factors that trigger or worsen asthma such as allergens and irritants.

II. Self-management plan that includes instructions on how to manage worsening symptoms and when to notify the medical department of worsening symptoms.

III. Pathophysiology of disease
   A. What is asthma
   B. Consequence of poor control
   C. What happens during an asthma attack

IV. How to take medications correctly
   A. Role of medications with emphasis on difference between rescue medications (i.e., quick relief medications) and long-term control medications
   B. Instruction on proper inhaler technique (Figure 1)

V. Importance of medication adherence for disease state control
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.
BENZODIAZEPINE DISCONTINUATION

1. Intake screening identifies patient on benzodiazepine

2. Provider assessment of BZD dependence, comorbid conditions, and risk for complicated withdrawal (see Table 1)

3. Risk Factors Present

4. Discontinue benzodiazepine and monitor for signs/symptoms of withdrawal (see Table 2). If signs/symptoms of withdrawal occur, proceed to box #9.

5. One or more risk factors identified from Table 1: benzodiazepine discontinuation to avoid benzodiazepine withdrawal symptoms (see Table 2).

6. Risk Stratification: Assess presence of significant risk factors from Table 1.

7. Less than three risk factors identified

8. Three or more risk factors identified

9. Moderate Supervision/Monitoring Required

   Begin detox program with 24/7 licensed nursing for BZW data collection. Dosing & data collection Q 12 hours.

   • Remain on full equivalent dose for 5 days, then taper dose by 25% every 5 days until discontinued.
   • Monitor via BZW data collection form with frequency based on risk stratification.
   • Consider collaboration with MHS for conversion and taper schedule.

10. Intense Supervision/Monitoring Required

    Begin detox program with 24/7 licensed nursing for BZW data collection. Dosing & data collection 3-4 X daily.

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

11. Signs/symptoms of benzodiazepine withdrawal? (see Table 2)

12. Continue taper

Table 1 – Risk Factors for Complicated Benzodiazepine Withdrawal

- Comorbid medical conditions exacerbated by adrenergic state (i.e. COPD, DM, HTN, CAD, and history of CVA)
- History of seizure disorder
- Comorbid psychiatric illness
- History of complicated benzodiazepine or alcohol withdrawal
- Concurrent dependence to barbiturates, opioids, or alcohol
- Long duration of daily benzodiazepine use (> 3 months)
- Higher dose/frequency (> 1.25x’s FDA approved daily maximum)
- Use of benzodiazepine with short half-life

Table 3 – Benzodiazepine Equivalents (Estimates) & Withdrawal Data

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Mg</th>
<th>FDA Max Daily Dose</th>
<th>Elimination Half Life (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alprazolam*</td>
<td>Xanax</td>
<td>0.5</td>
<td>4mg/day</td>
<td>12-15</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>Librium</td>
<td>10</td>
<td>300mg/day</td>
<td>15-40</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Klonopin</td>
<td>0.25</td>
<td>2mg/day</td>
<td>18-50</td>
</tr>
<tr>
<td>Clorazepate</td>
<td>Tranxene</td>
<td>7.5</td>
<td>60mg/day</td>
<td>50-100</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Valium</td>
<td>5</td>
<td>40mg/day</td>
<td>20-80</td>
</tr>
<tr>
<td>Estazolam*</td>
<td>ProSom</td>
<td>0.3</td>
<td>2mg/day</td>
<td>10-24</td>
</tr>
<tr>
<td>Flurazepam</td>
<td>Dalmane</td>
<td>30</td>
<td>60mg/day</td>
<td>40-100</td>
</tr>
<tr>
<td>Lorazepam*</td>
<td>Ativan</td>
<td>1</td>
<td>1mg/day</td>
<td>10-20</td>
</tr>
<tr>
<td>Oxisepam*</td>
<td>Serax</td>
<td>15</td>
<td>120mg/day</td>
<td>10-20</td>
</tr>
<tr>
<td>Quazepam</td>
<td>Doral</td>
<td>5</td>
<td>15mg/day</td>
<td>30-100</td>
</tr>
<tr>
<td>Temazepam*</td>
<td>Restoril</td>
<td>30</td>
<td>30mg/day</td>
<td>10-40</td>
</tr>
<tr>
<td>Temazepam*</td>
<td>Restoril</td>
<td>15</td>
<td>125mg/day</td>
<td>10-20</td>
</tr>
<tr>
<td>Triazolam</td>
<td>Halcion</td>
<td>0.25</td>
<td>0.25mg/day</td>
<td>2-3</td>
</tr>
</tbody>
</table>

*short acting agent with 24H or less half-life

Table 2 – Signs and Symptoms of Benzodiazepine Withdrawal

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

<table>
<thead>
<tr>
<th>Symptom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Agitation</td>
</tr>
<tr>
<td>Vomiting</td>
</tr>
<tr>
<td>Convulsions</td>
</tr>
<tr>
<td>Blood Pressure Lability</td>
</tr>
<tr>
<td>Tremor</td>
</tr>
<tr>
<td>Delirium</td>
</tr>
<tr>
<td>Tachycardia</td>
</tr>
<tr>
<td>hallucinations</td>
</tr>
<tr>
<td>Perspiration</td>
</tr>
</tbody>
</table>

Table 4. Example Taper Schedule: Patient arrives on alprazolam 4 mg/day and switched to chlordiazepoxide 80 mg/day

<table>
<thead>
<tr>
<th>Approximate Chlordiazepoxide Dose Reductions*</th>
<th>Dose with Formulary Capsules</th>
</tr>
</thead>
<tbody>
<tr>
<td>80 mg/day</td>
<td>Two 25 mg and three 10 mg x 5 days</td>
</tr>
<tr>
<td>60 mg/day</td>
<td>Two 25 mg and one 10 mg x 5 days</td>
</tr>
<tr>
<td>40 mg/day</td>
<td>One 25 mg and two 10 mg x 5 days</td>
</tr>
<tr>
<td>30 mg/day</td>
<td>One 25 mg and one 10 mg x 5 days</td>
</tr>
<tr>
<td>25 mg/day</td>
<td>One 25 mg x 5 days</td>
</tr>
<tr>
<td>20 mg/day</td>
<td>Two 10 mg x 5 days</td>
</tr>
<tr>
<td>10 mg/day</td>
<td>One 10 mg x 5 days</td>
</tr>
<tr>
<td>5 mg/day</td>
<td>One 10 mg every other day for up to 10 days to discontinue</td>
</tr>
</tbody>
</table>

*Dose reductions are approximate to 25%
<table>
<thead>
<tr>
<th>Perspiration (monitor in AC setting)</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>no sweating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>palms moist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>head moist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sweat beads</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>drenching sweats</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tremor</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mild visible tremor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>moderate arms out</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>severe-arms at side</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Restlessness/ agitation</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>uneasy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>restless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>purposeless activity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pacing-unable to sit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of Consciousness</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>unimpaired</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>alert-obey commands</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>confused</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>responds to speech</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stuporous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>responds to pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>comatose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>comatose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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 detox 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 n/v, blood pressure-pulse lability, hyperthermia, restlessness, tremor, perspiration, or agitation will require provider oversight and may indicate need for dose/titration adjustment.
BIPOLAR DISORDER: DEPRESSION

1. Rule out medical causes for presentation.

2. Is patient currently depressed?
   - No: Follow Major Depressive Disorder Pathway
   - Yes: History of at least 1 hypomanic or manic episode?
     - No: History of at least 1 hypomanic or manic episode?
       - No: Re-evaluate diagnosis
       - Yes: Follow Bipolar Mania Pathway
     - Yes: Is patient on Lithium or Divalproex?
       - No: Add Lithium or Divalproex. Titrate to therapeutic level, continue for 4-6 weeks.
       - Yes: Does patient have concurrent psychotic symptoms?
         - No: Monitor medication adherence & evaluate with BPRS.
         - Yes: Initiate antipsychotic per psychosis pathway

3. History of at least 1 hypomanic or manic episode?
   - No: Follow Bipolar Mania Pathway
   - Yes: Is patient on Lithium or Divalproex?
     - No: Yes: Add Lithium or Divalproex. Titrate to therapeutic level, continue for 4-6 weeks.

4. Re-evaluate diagnosis

5. History of at least 1 hypomanic or manic episode?
   - No: Follow Bipolar Mania Pathway
   - Yes: Is patient on Lithium or Divalproex?
     - No: Add Lithium or Divalproex. Titrate to therapeutic level, continue for 4-6 weeks.
     - Yes: Does patient have concurrent psychotic symptoms?
       - No: Dispose response per clinical status and BPRS?
       - Yes: Continue maintenance treatment and reassess as clinically indicated.

6. Follow Major Depressive Disorder Pathway

7. Maximize mood stabilizer. Adjust dose per serum level. Lithium 0.6-1.2 mmol/L, Divalproex 50-125 mg/teaspoon. Continue for 4-6 weeks. Go to Box 11.

8. Is patient currently depressed?
   - No: Follow Major Depressive Disorder Pathway
   - Yes: History of at least 1 hypomanic or manic episode?
     - No: History of at least 1 hypomanic or manic episode?
       - No: Re-evaluate diagnosis
       - Yes: Follow Bipolar Mania Pathway
     - Yes: Is patient on Lithium or Divalproex?
       - No: Add Lithium or Divalproex. Titrate to therapeutic level, continue for 4-6 weeks.
       - Yes: Does patient have concurrent psychotic symptoms?
         - No: Monitor medication adherence & evaluate with BPRS.
         - Yes: Initiate antipsychotic per psychosis pathway

9. Does patient have concurrent psychotic symptoms?
   - No: Dispose response per clinical status and BPRS?
   - Yes: Continue maintenance treatment and reassess as clinically indicated.

10. Monitor medication adherence & evaluate with BPRS.

11. Continue maintenance treatment and reassess as clinically indicated.

12. Initiate antipsychotic per psychosis pathway

13. Taper antipsychotic upon resolution of psychotic symptoms

14. If psychotic symptoms continue, reassess diagnosis of bipolar disorder

15. Symptom-free?
   - No: Assess compliance
   - Yes: Continue maintenance treatment and reassess as clinically indicated.

    Adjust dose per serum level.
    Lithium 0.6-1.2 mmol/L, Divalproex 50-125 mg/teaspoon.
    Continue for 4-6 weeks. Go to Box #11.

17. Does patient have concurrent psychotic symptoms?
    - No: Dispose response per clinical status and BPRS?
    - Yes: Continue maintenance treatment and reassess as clinically indicated.

18. Maximize mood stabilizer.
    Adjust dose per serum level.
    Lithium 0.6-1.2 mmol/L, Divalproex 50-125 mg/teaspoon.
    Continue for 4-6 weeks. Go to Box #11.

19. Is patient on Lithium or Divalproex?
    - No: Is patient currently depressed?
      - No: Follow Major Depressive Disorder Pathway
      - Yes: History of at least 1 hypomanic or manic episode?
        - No: History of at least 1 hypomanic or manic episode?
          - No: Re-evaluate diagnosis
          - Yes: Follow Bipolar Mania Pathway
        - Yes: Is patient on Lithium or Divalproex?
          - No: Add Lithium or Divalproex. Titrate to therapeutic level, continue for 4-6 weeks.
          - Yes: Does patient have concurrent psychotic symptoms?
            - No: Monitor medication adherence & evaluate with BPRS.
            - Yes: Initiate antipsychotic per psychosis pathway

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee: approved 1/99, revised 3/03, 2/05, 4/05, 5/06, 7/08, 5/12.
BIPOLAR DISORDER: DEPRESSION

Monitoring Parameters

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, and TSH at baseline.
2. Repeat every 6 – 12 months.
C. Trough Serum Drug Levels
1. Obtain 2-4 weeks 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. Hepatic – obtain LFTs at baseline, then monthly for first 2 months, then yearly thereafter
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 (eg, carbamazepine, phenytoin, ritonavir,
   lopinavir/ritonavir)
   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 (eg, 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 multiorgan failure/dysfunction.
   b. Lamotrigine should be discontinued if other causes for hypersensitivity are ruled out.
## Table 1: Mood Stabilizers

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose Range</th>
<th>Contraindications</th>
<th>Toxicty Starting At Trough Serum Levels</th>
<th>Signs/symptoms of toxicity (dose-related)</th>
<th>Signs/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. Dose to stay between 0.6 mEq/L and 1.2 mEq/L. It is advised not to order doses &gt; 1200 mg daily</td>
<td></td>
<td></td>
<td>Lithium toxicity can be FATAL</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hypersensitivity to lithium</td>
<td>&gt; 1 – 1.2 mmol/L</td>
<td>Acute:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Severe cardiovascular or renal disease</td>
<td></td>
<td>• Apathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Severe dehydration</td>
<td></td>
<td>• Coarsening hand tremor that spreads to other parts of body</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sodium depletion</td>
<td></td>
<td>• Confusion / Drowsiness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pregnancy</td>
<td></td>
<td>• Dehydration</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Dysarthria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Sodium white blood cell count is to be expected.</td>
<td></td>
</tr>
<tr>
<td>Divalproex</td>
<td>20mg/kg/day, given in divided doses. Dose to stay between 80 mcg/mL and 125 mcg/mL. It is not recommended to exceed 400mg/kg/day</td>
<td></td>
<td></td>
<td>Acute:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hypersensitivity to VPA</td>
<td>&gt; 100-125 mcg/mL</td>
<td>• Arrhythmia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hepatic dysfunction</td>
<td></td>
<td>• Hyperammonemia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Uric acid disorder</td>
<td></td>
<td>• Lethargy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Pregnancy</td>
<td></td>
<td>• Vomiting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Changes in mental status</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Thrombocytopenia</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Prolongation of bleeding time</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Hypotension</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Pancreatitis – DO NOT RECHALLENGE</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Hypoglycemia encephalopathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Hypotension, severe or fatal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Stevens-Johnson Syndrome</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Tonic Epidermal Necrolysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Polycystic ovarian syndrome (PCOS)</td>
<td></td>
</tr>
<tr>
<td>Medication: Daily Dose Range</td>
<td>Contraindications</td>
<td>Toxicity Starting At Trough Serum Levels of</td>
<td>Signs/symptoms of toxicity (dose-related)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------</td>
<td>------------------------------------------</td>
<td>------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lamotrigine: 25 – 400 mg/day</td>
<td>Hypersensitivity to Lamotrigine</td>
<td>Rash (maculopapular and erythematous)</td>
<td>Fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pregnancy Category C</td>
<td>Tourette’s Syndrome</td>
<td>Stevens-Johnson Syndrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Therapeutic plasma concentration has not been established.</td>
<td>Multiorgan dysfunction</td>
<td>Toxic Epidermal Necrolysis</td>
<td></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(Celexa®) 20mg, 40mg tablet</td>
<td>20mg, 40mg tablet (20 – 40)</td>
<td>QTc prolonging agents; Serotoninergic agents; Agents that may increase citalopram levels:azole antianginals, carbamazepine; Antiplatelet/anticoagulant agents</td>
<td>Emergence of suicidal ideation or behavior; EKG for citalopram if risk factors for QTc prolongation are present</td>
</tr>
<tr>
<td>Fluoxetine (Prozac®) 20mg capsule</td>
<td>20mg capsule (20 – 60)</td>
<td>Serotoninergic agents; Agents that may increase fluoxetine levels: carbamazepine, haloperidol, propranolol; Thioridazine- levels increased by fluoxetine; Antiplatelet/anticoagulant agents</td>
<td></td>
</tr>
<tr>
<td>Sertraline(Zoloft®) 50mg, 100mg tablet</td>
<td>50 – 200mg tablet (50 – 200)</td>
<td>Serotoninergic agents; Agents that may increase sertraline levels: haloperidol, propranolol; Antiplatelet/anticoagulant 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=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>Description</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>
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<td>5.</td>
<td>IMPULSIVENESS</td>
</tr>
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<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>
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</tbody>
</table>
I. Lithium
   A. Cardio – 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, SSRI’s, 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. 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. Cardio – 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 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 tapering 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
      1. Serious skin reactions (e.g., Stevens Johnson Syndrome) are more common in people with the HLA-B 5702 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.
### BIPOLAR DISORDER: MANIA

<table>
<thead>
<tr>
<th>Drug</th>
<th>Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Seen 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</td>
<td>Initially 900 – 1200 mg daily as 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.</td>
<td>Lithium toxicity can be FATAL. <strong>Acute:</strong> • Apathy • Coarsening hand tremor that spreads to other parts of body while patient sitting still • Confusion • Drowsiness • Dysarthria • GI symptoms (diarrhea, N &amp; V, etc.) • Giddiness <strong>Acute To Severe:</strong> • Blurred vision • Deep tendon reflexes increased • Muscle rigidity / fasciculations • Mild ataxia • Profound lethargy • Tinnitus • Vertical nystagmus • Vomiting <strong>Severe Intoxication:</strong> • Arrhythmias • Impaired consciousness • Increase in fasciculations and ataxia • CV collapse with oliguria and anuria • Coarse / irregular limb tremors • Coarse muscle contractions • Chorea / athetoid movements • Cogwheel rigidity • Coma • Generalized tonic-clonic seizures</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug: Daily Dose Range</td>
<td>Contraindications</td>
<td>Toxicity Seen</td>
<td>Signs/symptoms of toxicity (dose-related)</td>
<td>Signs/symptoms of toxicity (NOT dose-related)</td>
<td></td>
</tr>
<tr>
<td>------------------------</td>
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<td>---------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Divalproex: 20mg kg/day, given in divided doses</td>
<td>Hypersensitivity to VPA</td>
<td>Daily starting at</td>
<td>Acute:</td>
<td>Pancreatitis - DO NOT RECHALLENGE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hepatic dysfunction</td>
<td>Trough Serum Levels of:</td>
<td></td>
<td>Hyperammonemic encephalopathy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unica-cyclic disorder</td>
<td>≥ 100-125 mcg/mL</td>
<td></td>
<td>Hepatotoxicity, severe or fatal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pregnancy Category D</td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Toxic Epidermal Necrolysis</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Polycystic ovarian syndrome (PCOS)</td>
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</tr>
<tr>
<td>Carbamazepine: 600 – 1600 mg, given in divided doses</td>
<td>Hypersensitivity to carbamazepine or TCAs</td>
<td>≥ 12 mcg/mL</td>
<td>Abnormal reflex response</td>
<td>Atrial arrhythmias</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bone marrow depression</td>
<td></td>
<td></td>
<td>Blood cell dyscrasias</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In combination with or within 14 days of MAOIs</td>
<td></td>
<td></td>
<td>CHF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pregnancy Category D</td>
<td></td>
<td></td>
<td>Nausea / vomiting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Photosensitivity</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SIADH (Syndrome of Inappropriate ADH Secretion)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stevens-Johnson Syndrome</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Toxic epidermal necrolysis</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
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>X</td>
<td></td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>EKG</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolactin1</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 Prolactin at baseline and periodically when there is a history of galactorrhea, amenorrhea, or gynecomastia.

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 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>BPSS (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>
<tr>
<td>Agent (Generic)</td>
<td>Formulary Status</td>
<td>Potency (5HT2/32)</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Atypicals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole (Abilify)</td>
<td>NF</td>
<td>++++/++++</td>
</tr>
<tr>
<td>Olanzapine (Zyprexa)</td>
<td>NF</td>
<td>++++/++</td>
</tr>
<tr>
<td>Quetiapine (Seroquel)</td>
<td>NF</td>
<td>+/+</td>
</tr>
<tr>
<td>Risperidone (Risperdal)</td>
<td>F</td>
<td>+++++/++++</td>
</tr>
<tr>
<td>Ziprasidone (Geodon)</td>
<td>NF</td>
<td>++++++/++++</td>
</tr>
<tr>
<td>Asenapine (Saphris)</td>
<td>NF</td>
<td>?</td>
</tr>
</tbody>
</table>

### Footnotes:
- § dose-dependent
- # partial D2 agonist

---

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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. 

0 = None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

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

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

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2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness
3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.
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CATHETER RESTORATION FOR HEMODIALYSIS PATIENTS

This protocol pertains to registered nurses who have received training and been validated in the procedure.

**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)

If catheter occluded?

- Continue catheter use
- Notify provider and obtain order for Cathflo®

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

**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 healthcare 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. <strong>DO NOT SHAKE.</strong></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. <strong>DO NOT USE.</strong></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>


Go to Page 2
<table>
<thead>
<tr>
<th>ACTION</th>
<th>NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inspect the reconstituted solution prior to administration for foreign matter or discoloration.</td>
<td>If any seen, discard the vial. <strong>DO NOT USE.</strong></td>
</tr>
<tr>
<td>2. Aseptically withdraw the reconstituted solution from the vial. Due to be determined by the provider. The usual dose is 2mg (2mL) for patients ≥ 30 kg.</td>
<td></td>
</tr>
<tr>
<td>3. Wash hands thoroughly. Put on PPE. Hand washing protects the patient and health care staff from cross contamination. PPE is worn for health care staff protection.</td>
<td></td>
</tr>
<tr>
<td>4. Slowly instill the appropriate dose of Cathflo into the occluded catheter. 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.</td>
<td>Vigorous suction should not be applied during attempts to assess catheter function, because of the risk of damage or collapse.</td>
</tr>
</tbody>
</table>
| 5. Assess catheter function by attempting to aspirate blood after 60 minutes of catheter dwell time.  
  *If the catheter is functional, go to step 8  
  *If the catheter is not functional, go to step 6 | |
| 6. Wait an additional 60 minutes for a total of 120 minutes dwell time. Assess catheter function by attempting to aspirate blood.  
  *If the catheter is functional, go to step 8  
  *If the catheter is not functional, go to step 7 | |
| 7. 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. An order must be obtained from the provider to administer a second dose. | |
| 8. 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). | |
| 10. Document administration in the patient medical record. Documentation should include drug, dose, route, time administered, patient response, & signature and title of person administering the drug. | |

---

<table>
<thead>
<tr>
<th>Resume catheter use</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter function restored?</td>
<td></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

1. Patient presents with signs & symptoms of acute COPD exacerbation

2. Assess severity of signs & symptoms
   - Oxygen saturation
   - Administer oxygen therapy

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

4. Are critical symptoms present? (box #4)
   - Yes
   - No

5. Nebulized albuterol with or without ipratropium as needed. May repeat every 20 minutes x 2.
   - Prednisone 30-40mg

6. Critical symptoms present?
   - Yes
   - No
   - Consider transfer off the unit to a higher level of care

7. Patient responding?
   - Yes
   - No
   - Consider obtaining non-formulary approval for antibiotic

8. Stabilize
   - Assess severity of signs & symptoms
   - Oxygen saturation
   - Administer oxygen therapy

9. Patient responding?
   - Yes
   - No

10. Signs of bacterial infection present?
    - Yes
    - No
    - Continue treatment and monitor the patient closely

11. Does the patient have risk factors for more severe infection?
    - Frequent exacerbations 4 in last year, antibiotic use within last 3 months, severe or very severe COPD

12. Consider obtaining non-formulary approval for antibiotic
    - Augmentin 500mg tid x 10 days or
    - Levofloxacin 750mg qd x 10 days

13. Nebulized albuterol with or without ipratropium as needed up to 3 days
    - Prednisone 30-40mg/day for 10-14 days

14. Patient improved after 3 days?
    - Yes
    - No

15. Continue treatment and monitor the patient closely
    - Give pass to return to clinic for evaluation at least twice daily for 3 days then for evaluation as needed for 10 days
    - Nebulized albuterol with or without ipratropium as needed up to 3 days
    - Prednisone 30-40mg/day for 10-14 days

16. Follow up as needed and refer patient to respiratory therapy within 30 days if not already following the patient.

17. Go to page 2 box 9 16
Consider transfer off the unit to a higher level of care.

Follow up as needed and refer patient to respiratory therapy within 30 days if not already following the patient.

The pathways do not replace sound clinical judgment and are intended to apply to all patients.
CHRONIC COPD

1. Spirometry should be obtained to diagnose airflow obstruction with respiratory symptoms.
2. Obtain complete medical history.
3. Classify severity of disease to determine treatment plan.

Mild
- FEV1/FVC <70%
- FEV1<80% of predicted value
- Usually, not a chronic, productive cough

Moderate
- FEV1/FVC <70%
- 50%<FEV1<80% of predicted value
- Chronic, productive cough
- Shortness of breath
- Fatigue and reduced ability to exercise

Severe
- FEV1/FVC <70%
- 30%<FEV1<50% of predicted value
- Chronic, productive cough
- Shortness of breath
- Fatigue and reduced ability to exercise
- Repeated and sometimes severe COPD flare ups

Very Severe
- FEV1/FVC <70%
- FEV1<30% predicted or FEV1<50% predicted plus chronic respiratory failure
- Chronic, productive cough
- Shortness of breath
- Fatigue and reduced ability to exercise
- Repeated and sometimes severe COPD flare ups
- Life-threatening COPD flare ups

Tiotropium is a Prior Authorization Agent. Prior authorization criteria must be met and noted in the Yes peak flow and considered for COPD flare ups.

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- FEV1/FVC <70%
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- Chronic, productive cough
- Shortness of breath
- Fatigue and reduced ability to exercise
- Repeated and sometimes severe COPD flare ups
- Life-threatening COPD flare ups
CHRONIC COPD

Add Inhaled Corticosteroid.
Beclomethasone HFA 1 puff BID
1 inhaler lasts 60 days.
Rerassess if it does not last 50 days.

Continue regimen. Follow up at least every 12 months with peak flow and consider spirometry based on symptoms or every 2 years.

Patient Stable?

Yes

No

Increase dose of inhaled corticosteroid.
Beclomethasone HFA 2 puffs BID (1 inhaler lasts 30 days).
Reinforce Patient Education. Proper use of inhaler, importance of scheduled dosing of anticholinergics and corticosteroid inhalers, and risk factor avoidance.

Patient Stable?

Yes

No

Consider referral to specialist.

Figure 1: Inhaler Technique
Demonstrate proper inhaler technique and verify patient understanding by observing the patient performing the technique:

1. Remove cap and hold upright.
2. Shake inhaler.
3. Tilt head back slightly and breathe out.
4. Position inhaler for open mouth (preferred) or closed mouth technique (see Diagram A&B).
5. Press down on inhaler to release medication as you start to breathe in slowly.
6. Breathe in slowly for 3-5 seconds.
7. Hold breath for 10 seconds to allow drug to reach deeply into lungs.
8. Repeat for next puff waiting 1 minute between puffs to allow second drug to penetrate lungs better.
9. Bronchodilator (B agonist, Albuterol) should be administered before other inhalers to allow best response.
10. Corticosteroid (Triamcinolone) should be taken every dose as prescribed by your doctor even if you are experiencing symptoms to prevent attacks. These drugs do not work well on an as needed basis for acute symptoms.

Note: This technique does not work with dry powder capsule inhalers.
*adapted from NAEP
Figure 2: Inhaler Technique Tiotropium

1. Open the inhaler cap by 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.
6. Raise the inhaler to your mouth and close your lips tightly around the mouthpiece. 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. Open the mouthpiece again and turn the inhaler upside down to discard the capsule.
8. 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

Inhaler parts:
1. Dust cap
2. Mouthpiece
3. Base
4. Piercing Button
5. Center chamber
6. Air intake vents
I. Definition—According to the GOLD guidelines, “COPD is a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases.”

II. Diagnosis

A. Consider diagnosis if patient has symptoms consistent with COPD and/or risk factors associated with the disease:
   1. Cough—present intermittently or every day, often present throughout the day. Seldom only nocturnal
   2. Sputum production
   3. Dyspnea—progressive (worsen over time), persistent (present every day), worse with exercise, worse during respiratory infections.
   4. Acute bronchitis—repeated episodes
   5. Onset in mid-life

B. Diagnosis is confirmed by spirometry:
   1. Post Bronchodilator FEV1 <80% of predicted value
   2. FEV1/FVC < 70%

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>Stage</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>0= At Risk</td>
<td>Normal Spirometry, Chronic Symptoms (e.g., cough, sputum production)</td>
</tr>
<tr>
<td>1-Mild COPD</td>
<td>FEV1/FVC &lt;70%, FEV1 &lt;80% of predicted value, Usually, but not always a chronic productive cough</td>
</tr>
<tr>
<td>2- Moderate COPD</td>
<td>FEV1/FVC &lt;70%, FEV1 &lt;80% of predicted value, Chronic productive cough, Shortness of Breath, especially with exercise, An occasional COPD flare up</td>
</tr>
<tr>
<td>3-Severe COPD</td>
<td>FEV1/FVC &lt;70%, 30%&lt;FEV1&lt;50% of predicted value, Chronic productive cough, Shortness of Breath, Fatigue and reduced ability to exercise, Repetition and sometimes severe COPD flare ups</td>
</tr>
<tr>
<td>4- Very Severe COPD</td>
<td>FEV1/FVC &lt;70%, FEV1 &lt;30% predicted or FEV1 &lt; 50% predicted plus chronic respiratory failure, Chronic productive cough, Shortness of Breath, especially with exercise and dressing and undressing themselves, Weight Loss, Blue skin color, especially in the lips, fingers and toes, Edema lower extremities, Life threatening COPD flare ups</td>
</tr>
</tbody>
</table>
IV. Risk Factors
A. Tobacco Smoke
B. Occupational dust and chemicals
C. Smoke from home cooking and heating fuel

V. Patient Evaluation
A. Obtain thorough medical history
1. Risk factors
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 heart disease and rheumatic disease
7. Past and current treatments
B. Physical Exam- Rarely diagnostic but important

VI. 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

VII. Treatment
A. Nonpharmacologic Treatment
1. Risk factor avoidance (e.g. smoking cessation)
2. Exercise
3. Oxygen- Consider if patient has stage 4 COPD with chronic respiratory failure
4. PaO2 < 7.3 kPa (55mmHg) or SaO2 <88% with or without hypoxemia or PaCO2 between 7.3 kPa-8.8 kPa (55mmHg) or SaO2 <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. Anticholinergics are used daily.
2. Glucocorticosteroids- May be considered in patients with severe COPD with symptomatic improvement with inhaled steroid or repeated exacerbations. Has not been shown to modify decline.
**CHECKLIST FOR SECONDARY PREVENTION OF CORONARY ARTERY DISEASE*  

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

### DISEASE STATE MANAGEMENT

<table>
<thead>
<tr>
<th>ACHIEVED?</th>
<th>GOAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Blood pressure goal achieved?**

- 140/90 mm Hg or less
- 130/80 mm Hg if patient has diabetes or chronic kidney disease

If not, Refer to Hypertension algorithm

**Lipid goal achieved?**

- LDL <100 mg/dL for pre-existing CAD patients
- LDL < 70 mg/dL if patient has pre-existing CAD and diabetes
- If trig > 200 mg/dL, then non-HDL-C* should be at least
  - 130 mg/dL, and be < 100 mg/dL for very high risk patients.

If not, Refer to Hyperlipidemia algorithm

**Diabetes goal achieved?**

- A1C < 7%

If not, Refer to Diabetes algorithm

**Exhibiting heart failure symptoms or is diagnosed with heart failure?**

If so, Refer to Heart Failure algorithm

### LIFESTYLE MODIFICATIONS**

<table>
<thead>
<tr>
<th>ACHIEVED?</th>
<th>GOAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**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

**Physical activity achieved?**

- Minimum of 30 minutes 5 days per week

**Diet for health initiated (or other diet as clinically indicated)?**

- Encourage low salt and low fat

**Dental evaluation annually?**

Yes | No

*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.

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# MEDICATION MANAGEMENT

<table>
<thead>
<tr>
<th>INITIATED?</th>
<th>DRUG THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antiplatelet therapy initiated?&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Yes</td>
<td>• Start aspirin (unless contraindicated).</td>
</tr>
<tr>
<td></td>
<td>• Low dose of 81 mg daily.</td>
</tr>
<tr>
<td>No</td>
<td>• Start clopidogrel 75 mg daily (unless contraindicated)&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• In combination with aspirin for at least 12 months in patients after acute coronary syndrome or percutaneous coronary intervention with stent placement.</td>
</tr>
<tr>
<td></td>
<td>• Start warfarin in atrial fibrillation, prosthetic heart valve, left ventricular thrombus, or concomitant venous thromboembolic disease (unless contraindicated)&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>• INR goal 2-3 or as guidelines or warfarin DMG recommend.</td>
</tr>
<tr>
<td></td>
<td>• Based on appropriate guidelines or if unclear through pharmacotherapy consult.</td>
</tr>
<tr>
<td></td>
<td>ACE inhibitor initiated (unless contraindicated)&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>Yes</td>
<td>• Initiate at least 2.5 mg of enalapril daily</td>
</tr>
<tr>
<td>No</td>
<td>• Titrate to a maximum tolerated dose or to a maximum dose of enalapril 40 mg daily</td>
</tr>
<tr>
<td></td>
<td>• If ACE inhibitor intolerant consider a non-formulary angiotensin receptor blocker (ARB)</td>
</tr>
<tr>
<td></td>
<td>β-blocker initiated (unless contraindicated)&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>Yes</td>
<td>• Titrate to a maximum tolerated dose or to a maximum recommended dose</td>
</tr>
<tr>
<td>No</td>
<td>• Aldosterone blockade initiated (unless contraindicated)&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>Yes</td>
<td>• Initiate spironolactone at 25 mg daily in patients with Ejection Fraction ≤ 40 % and diabetes or heart failure.</td>
</tr>
<tr>
<td>No</td>
<td>• Titrate to a maximum tolerated dose or to a maximum dose of spironolactone 100 mg daily</td>
</tr>
<tr>
<td>No</td>
<td>Influenza vaccine annually (unless contraindicated)&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

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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 >5.0 mEq/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.
MAJOR DEPRESSIVE DISORDER

1. Rule out medical causes for presentation.

2. Does the patient meet DSM-IV criteria for Major Depressive Disorder?
   - Yes → Re-evaluate diagnosis and treat underlying causes.
   - No → Does the patient have concomitant psychotic symptoms?

3. Formulary SSRI antidepressant plus antipsychotic (see Psychosis DMG).
   - Yes → Go to box #8.
   - No → Initiate formulary SSRI antidepressant.

4. Does the patient have concomitant psychotic symptoms?
   - Yes → Formulary SSRI antidepressant plus antipsychotic (see Psychosis DMG).
   - No → Continue for 4-6 weeks at a therapeutic dose* (Table 1).

5. Adequate response per BPRS?
   - Yes → Continue therapy (See Remission box 14).
   - No → Assess compliance:

6. Adequate response per BPRS?
   - Yes → Continue therapy (See Remission box 14) Monitor and follow BPRS.
   - No → Assess compliance:

7. Adequate response per BPRS?
   - Yes → Continue therapy (See Remission box 14).
   - No → Assess compliance:

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

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

10. Assess compliance:
    - Yes → Continue therapy (See Remission box 14) Monitor and follow BPRS.
    - No → Continue therapy (See Remission box 14).

11. Assess compliance:
    - Yes → Consider tapering antidepressant.
    - No → Re-evaluate diagnosis and treat underlying causes.

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

13. Assess compliance:
    - Yes → Consider tapering antidepressant.
    - No → Re-evaluate diagnosis.

14. Remission:
    - Yes → Continue treatment for 6-12 months.
    - No → Consider decreasing frequency of psychotherapy visits.

15. First episode?
    - Yes → Re-evaluate annually for compliance and continued need for medication.
    - No → Consider tapering antidepressant.

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.
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>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>May Consider First If</th>
<th>Initial Dose (Low-Range mg/day)</th>
<th>Therapeutic Range (ng/mL)</th>
<th>Monitoring</th>
</tr>
</thead>
</table>
| Selective Serotonin Reuptake Inhibitors (SSRIs) | Citalopram | Celexa® | Atypical features or dysthymia | 20 (20 – 40) | N/A | - Emergence of suicidal ideation or behavior  
|                    | Fluoxetine   | Prozac®          | Atypical features or dysthymia | 20 (20 – 60) | N/A | - Emergence of suicidal ideation or behavior  
|                    | Sertraline   | Zoloft®          | Significant anxiety     | 50 (50 – 200) | N/A | - Emergence of suicidal ideation or behavior  
| Tricyclic Antidepressants* (TCA) | Nortriptyline | Pamelor® | Melancholic features (75 – 150) | N/A | - Emergence of suicidal ideation or behavior  
| Other*             | Trazodone    | Desyrel®         | Atypical features or dysthymia | 100 – 150 (300 – 600) | N/A | - Emergence of suicidal ideation or behavior  

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

**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.
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>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, unease.</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, passimism.</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, strange, bizarre thought content.</td>
</tr>
<tr>
<td>16</td>
<td>BLUNTED 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>
**TYPE 1 DIABETES MELLITUS**

Institute lifestyle modification & group/individual education with specific patient goals.

- Baseline Labs: Hepatic Function Panel (LFP), UA, Lipid panel, thyroid function, ECG, fasting & 2 hour postprandial serum glucose and A1c.
- Initiate aspirin therapy if indicated (Table 5) and there are no contraindications to therapy (Table 1).
- Start low dose Ac-Diltiazem® (Fastril®12.5 mg QID) if no contraindications (see Table 1).
- Start statin therapy if LDL >100 mg/dl (Pravastatin 10 to 80 mg/day, if no contraindications – see Table 1)
- Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
- Weight loss (10% above IBW), exercise plan, diet plan.
- Refer to Dental for oral periodontal disease evaluation within 30 days from the initial chronic care visit.

**If intolerant to Ac-Diltiazem, microalbumin annually, CCB (verapamil or diltiazem).**

- Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
- Weight loss (10% above IBW), exercise plan, diet plan.
- Refer to Dental for oral periodontal disease evaluation within 30 days from the initial chronic care visit.

**Begin NPH Insulin 0.5-0.6 units/kg/day. Administer 2/3 of dose before breakfast and 1/3 of dose before supper.**

- Begin Regular sliding scale before each meal (AC).
- Order fingersticks (FS) 3 times a day before meals and at bedtime for 2 weeks.
- Follow up in 2 weeks.

**Yes**

- Reevaluate compliance with medications, exercise and diet.
- Adjust am and pm NPH dose by 10% of total daily dose (TDD) until AM and PM FS are at goal, while monitoring for hypoglycemia.
- Follow up every 2 weeks until FS are at goal.

**No**

- Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.

**Yes**

- Reevaluate compliance with medications, exercise and diet.
- Consider referral to specialist.

**No**

- Consider referral to specialist.

---

**GLYCEMIC CONTROL INDEX**

<table>
<thead>
<tr>
<th>Fishing Blood Glucose</th>
<th>Ideal Goal</th>
<th>Consider Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-120</td>
<td>90-130</td>
<td></td>
</tr>
<tr>
<td>100-140</td>
<td>&lt;180</td>
<td></td>
</tr>
</tbody>
</table>

**Glycemic Control Statement:**

Less stringent A1C goals than the general goal of < 7% may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, or extensive comorbid conditions and those with long-standing diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glycemic lowering agents including insulin.
TYPE 2 DIABETES MELLITUS

Categories of increased risk for diabetes:
1. FPG 100 to 125 mg/dl
2. A1C 5.7 to 6.4%
3. 2hPG following OGTT 140 to 199 mg/dL

Random plasma glucose ≥200 mg/dL
Fasting plasma glucose (FPG) ≥126, or A1c ≥6.5% on 2 occasions?

No

1. FPG ≥100 mg/dL
2. A1C ≥5.7%
3. 2hPG after OGTT 140 to 199 mg/dL

Rescreen every 5 years in the near

Yes

1. FPG <100 mg/dL
2. Rescreen every 3 years at the most

Categories of increased risk for diabetes:
1. FPG 100 to 125 mg/dL
2. A1C 5.7 to 6.4%
3. 2hPG following OGTT 140 to 199 mg/dL

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

Institute Lifestyle Modification & Group/Individual Education with Specific Patient Goals

• Start metformin at 500 mg qd if no contraindications (see Table 1).
  Titrate up to ≥1500 mg/day in 500 mg increments every 2 to 4 weeks. Maximum dose 2500 mg/day.
• Order Complete Metabolic Panel (CMP), Hepatic Function Panel (LFP), UA, thyroid function, Lipid Panel and A1C.
• Initiate aspirin therapy if indicated (Table 5) and if there are no contraindications to therapy (Table 1).
• Start low dose Ace-inhibitor (Enalapril 2.5 mg QD) if no contraindications to use (Table 1).
• Start statin therapy if LDL is >100 mg/dL (Pravastatin 10 to 80 mg if no contraindications – see Table 1).
• Weight loss (<10%) above BMI, exercise plan, diet for health (DFH).
• Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
• Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.

Institute Lifestyle Modification & Group/Individual Education with Specific Patient Goals

• Monitor for hypoglycemia.
• Add glipizide if no contraindications (see Table 1).
  Starting dose is 5 mg qd. Titrate up to 40 mg/day in 5 mg increments every 2 to 4 weeks (if dose exceeds 15 mg, divide into at least 2 doses).
• Monitor for hypoglycemia.

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

Institute Lifestyle Modification & Group/Individual Education with Specific Patient Goals

• Order Complete Metabolic Panel (CMP), Hepatic Function Panel (LFP), UA, thyroid function, Lipid Panel and A1C.
• Initiate aspirin therapy if indicated (Table 5) and if there are no contraindications to therapy (Table 1).
• Start low dose Ace-inhibitor (Enalapril 2.5 mg QD) if no contraindications to use (Table 1).
• Start statin therapy if LDL is >100 mg/dL (Pravastatin 10 to 80 mg if no contraindications – see Table 1).
• Weight loss (<10%) above BMI, exercise plan, diet for health (DFH).
• Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
• Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.

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• Weight loss (<10%) above BMI, exercise plan, diet for health (DFH).
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• Start statin therapy if LDL is >100 mg/dL (Pravastatin 10 to 80 mg if no contraindications – see Table 1).
• Weight loss (<10%) above BMI, exercise plan, diet for health (DFH).
• Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
• Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.

Institute Lifestyle Modification & Group/Individual Education with Specific Patient Goals

• Start metformin at 500 mg qd if no contraindications (see Table 1).
  Titrate up to ≥1500 mg/day in 500 mg increments every 2 to 4 weeks. Maximum dose 2500 mg/day.
• Order Complete Metabolic Panel (CMP), Hepatic Function Panel (LFP), UA, thyroid function, Lipid Panel and A1C.
• Initiate aspirin therapy if indicated (Table 5) and if there are no contraindications to therapy (Table 1).
• Start low dose Ace-inhibitor (Enalapril 2.5 mg QD) if no contraindications to use (Table 1).
• Start statin therapy if LDL is >100 mg/dL (Pravastatin 10 to 80 mg if no contraindications – see Table 1).
• Weight loss (<10%) above BMI, exercise plan, diet for health (DFH).
• Evaluate for target organ damage and co-morbidities – do baseline foot and eye exam.
• Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.
Continued from box #11

Recheck A1c at 3 months. Is A1c at goal of <7%?

No

Yes

• Continue metformin and glipizide
• Start Multi-dose Insulin Therapy by increasing NPH to twice daily dosing. Add NPH at 0.5ucg in the AM to the PM regimen started above in box #9. Titrate AM or PM dose of NPH by 10% of total daily dose (TDD) until AM and PM fingersticks are at goal.
• Obtain AM and PM fingersticks (FS)
• Monitor for hypoglycemia
• Follow up at least monthly

Are PM fingersticks at goal?

Yes

No

16

Go to box #7

Recheck A1c at 3 months. Is A1c at goal of <7%?

No

Yes

• Continue metformin
• Intensify insulin regimen by adding Regular Insulin QD or BID if patient is not able to tolerate higher dose of NPH and/or is hyperglycemic after meals.
• Taper and discontinue glipizide
• Obtain AM and PM fingersticks (FS)
• Monitor for hypoglycemia
• Follow up at least monthly

Are AM and PM fingersticks at goal?

Yes

No

18

Go to box #7

Recheck A1c at 3 months. Is A1c at goal of <7%?

No

Yes

• Dispose NPH and/or Regular Insulin QD or BID by TDD at TDD is = 200u/day, consider referral to specialist
• Continue metformin and glipizide
• Start Multi-dose Insulin Therapy by increasing NPH to twice daily dosing. Add NPH at 0.5ucg in the AM to the PM regimen started above in box #9. Titrate AM or PM dose of NPH by 10% of total daily dose (TDD) until AM and PM fingersticks are at goal.
• Obtain AM and PM fingersticks (FS)
• Monitor for hypoglycemia
• Follow up at least monthly

Are AM and PM fingersticks at goal?

Yes

No

22

Go to box #7

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, March 1997, Revised 9/97, 6/01, 4/03, 3/04, 9/06, 9/07, 7/08, 03/10, 3/13, 11/14.
CONVERTING TYPE 2 DIABETICS FROM ORAL THERAPY TO INSULIN

1. Oral agent failure
   - Patient is on maximum dose of glipizide and metformin and A1c is not at goal
   - Do not use fixed dose 70/30 insulin unless A1c ≥ 8.5%
     - Patient is stable and only if doses of NPH and Regular insulin are similar to 70/30 ratio.

Start evening insulin
- Discontinue metformin only if patient has contraindications (see Table 1)
- Start NPH at 0.1 to 0.25u/kg every PM. Titrate by 10% of Total Daily Dose (TDD) until fasting plasma glucose (FPG) is at goal.
- May need to titrate glipizide to prevent hypoglycemia.
- Check AM fingersticks
- Monitor for hypoglycemia

3. A1c > 8.5%

4. Has patient been diabetic ≥10 years?
   - Yes
     - Start Semi-Intensive Insulin Regimen
       - Discontinue metformin only if patient has contraindications (see Table 1)
       - Taper and discontinue glipizide
       - 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 10% of TDD until AM and PM fingersticks are at goal.
       - May need to reduce glipizide 10mg BID to prevent hypoglycemia.
       - Check AM and PM fingersticks
       - Monitor for hypoglycemia.
   - No
     - Check A1c q 3 months. Is A1c at goal <7%?
       - Yes
         - Continue current therapy and follow up in CCC.
         - Obtain A1c every 6 months.
         - Obtain Complete Metabolic Panel (CMP), UA, Hepatic Function Panel (LFP) and Lipid Panel annually.
         - Conduct foot and eye exam annually.
         - Reinforce diet and exercise at each clinic visit.
       - No
         - Check A1c q 3 months. Is A1c at goal <7%?
           - Yes
             - Continue current therapy and follow up in CCC.
             - Obtain A1c every 6 months.
             - Obtain Complete Metabolic Panel (CMP), UA, Hepatic Function Panel (LFP) and Lipid Panel annually.
             - Conduct foot and eye exam annually.
             - Reinforce diet and exercise at each clinic visit.
           - No
             - Check A1c q 3 months. Is A1c at goal <7%?
               - Yes
                 - Refer to specialist.
               - No
                 - Recompute compliance with medications, exercise and diet.
                 - Titrate NPH and/or Regular insulin am or pm by 10% of TDD. If TDD is >200u/day, consider referral to specialist.

I. Assessment

A. Screening: Should be conducted on high risk individuals and those with suggestive symptomatology.

1. Criteria for Testing for Diabetes in Asymptomatic Undiagnosed Individuals
   a. Testing for diabetes should be considered in all individuals at age 45 years and above, if normal, it should be repeated at 3 year intervals.
   b. Testing should be considered at a younger age or be carried out annually in individuals who:
      - are obese (≥ 120% desirable body weight/IBW or BMI ≥ 23 kg/m²)
      - have a first-degree relative with diabetes
      - are members of high-risk ethnic population (e.g., African-American, Latino Native American, Asian American, Pacific Islander)
      - have delivered a baby weighing > 9 lb or have been diagnosed with GDM
      - are hypertensive (≥ 140/90)
      - have an HDL cholesterol level ≤ 35 mg/dl and/or a triglyceride level ≥ 250 mg/dl
      - on previous testing, had IGT or IFG
      - have a history of vascular disease
      - have other clinical conditions associated with insulin resistance (e.g. PCOS or acanthosis nigricans)

B. Symptoms
1. Polyuria
2. Weight loss with polyphagia
3. Polydipsia
4. Blurred vision
5. Vaginitis or balanitis
6. Excretion numbness/paresthesia
7. Fatigue
8. Acanthosis Nigricans

C. Past Medical History: If previously diagnosed with diabetes, relevant history includes:
1. Periodontal disease
2. Exercise pattern
3. Eating patterns (frequency of going to chow and/or eating out of commissary)
4. Prior or current treatment of diabetes and results
5. Prior or current infections, frequency
7. Symptoms and treatment of chronic diabetic complications
   a. Microvascular: eye, kidney, nerve
   b. Macrovascular: cardiac, CVD, PAD
   c. Other: sexual dysfunction, gastroparesis

D. Physical exam: (Initial and CCC) Should include the following:
1. Height & Weight (complete at each visit)
2. Blood pressure (complete at each visit)
3. HEENT: Ophthalmoscopic examination (preferably dilated), oral exam, thyroid palpation
4. CV: cardiac exam, peripheral vascular exam to include pedal pulses
5. Extremists: Especially sensation of hands, fingers and feet
6. Abdominal exam
7. Skin examination
8. Neurological examination (to include monofilament exam on feet)
9. Dental examination

E. Lab Evaluation (See pathways for frequency)
1. Complete Metabolic Panel (CMP)
2. Fasting lipid panel
3. Urinalysis (C & S if U/A abnormal)
4. Calculated GFR
5. Test for microalbuminuria
6. A1c
7. EKG (if age > 35)
8. TSH (baseline)
9. Hepatic Function Panel (LFP)
II. Diagnosis
A. FPG: Ideally after an overnight fast (alternatively, no caloric intake for a minimum of 8 hours)
B. OGTT: Use is reserved for pregnant patients but may be used as an alternative to FPG
C. A1C: The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.

<table>
<thead>
<tr>
<th>CRITERIA FOR DIABETES MELLITUS DIAGNOSIS</th>
<th>Lab:</th>
<th>Categories of increased risk for diabetes</th>
<th>Diabetes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Plasma Glucose (FPG)*</td>
<td>&lt; 100 mg/dL</td>
<td>100 to 125 mg/dL</td>
<td>≥ 126 mg/dL</td>
</tr>
<tr>
<td>2hPG following OGTT**</td>
<td>&lt; 140 mg/dL</td>
<td>140 to 199 mg/dL</td>
<td>≥ 200 mg/dL</td>
</tr>
<tr>
<td>HbA1c (A1C)*</td>
<td>&lt; 5.7 %</td>
<td>5.7 to 6.4 %</td>
<td>≥ 6.5 %</td>
</tr>
</tbody>
</table>

*In the absence of unequivocal hyperglycemia the tests should be confirmed by repeat testing.
**OGTT = Oral glucose tolerance test.

III. Plan/Treatment - Treatment should begin with metformin (see algorithm page 2), weight loss, dietary restrictions (ADA diet) and exercise.
A. Diet: 45-65% total energy from carbohydrates, 20-35% from fat, 10 to 35% from protein and 20-35g of fiber daily.
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) and/or at least 90 min/week of vigorous aerobic exercise (>70% of maximum heart rate) is recommended.
C. Weight loss: Goal to approach ideal body weight
D. Pharmacologic Therapy:
   1. See Treatment Algorithms and tables 1-3.
   2. Glycemic Goals include A1c <7%, AM fingersticks 90-130 mg/dl, and PM fingersticks <180 mg/dl.
E. Control of Co-morbid disease states such as:
   1. HTN – BP goal < 140/80
   2. Lipids – goal TC < 200 mg/dl, LDL < 100 mg/dl, HDL > 40 mg/dl, TG < 150 mg/dl
F. Vaccinations: pneumococcal and annual influenza

IV. 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. Diabetics that require BID insulin dosing should be housed at units with at least 12 hour nursing service.
   2. Housing Assignment: For most diabetics, who are stable, no restrictions. However, a severe diabetic should not be assigned to a single cell. Those diabetics who are prone to hypoglycemia or ketoadicosis should also be restricted to a lower bunk, ground floor and restricted from climbing.
   3. Work Assignment: For patients prone to hypoglycemia or severe hyperglycemic, 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 that would necessitate nursing/EMS care/monitoring during transport.
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, Physician’s Assistant, 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).
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 comes first.
B. Group Education providing individual goals for weight, exercise, glucose levels, diet, etc.
C. Individual Education at clinic visits will supplement information provided by group education.

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
C. Signs, symptoms, and treatment for acute complications of diabetes mellitus
1. Hypoglycemia
   a. Signs and symptoms – dizziness, light-headedness, shakiness, blurred vision
   b. Treatment – Counsel patient to ingest 15 grams of carbohydrates (i.e. 1 slice of bread, 4-5 small pieces of candy, ½ can of soda, 8 oz of orange juice). Have the patient wait 5-10 minutes for blood glucose to rise. If patient is 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. DKA
   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 inpatient or as an emergent issue
D. Monitoring parameters – frequency and importance
1. A1C – Test every 3 months (if not at goal) or every 6 months (if at goal). A1C signifies overall control patient’s diabetes.
2. Finger sticks – Ordained at the provider’s discretion. This depicts a snapshot of patients’ blood glucose at the current time. The patient should be counseled to take the finger stick before the meal (i.e. breakfast and dinner). 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 they may be started on 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
Foot/skin care tips:
1. Watch for pain, numbness, and/or wounds that will not heal.
2. Keep skin supply by drinking plenty of water. Never put lotion or moisturizer between the toes.
3. Wash foot daily with lukewarm water and soap.
4. Dry foot 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.
### Table 1. Contraindications to medications commonly used in Diabetes Management

<table>
<thead>
<tr>
<th>Medication</th>
<th>Absolute Contraindications</th>
</tr>
</thead>
</table>
| **Metformin** | • Renal impairment (i.e. SCr ≥ 1.4mg/dL in females and ≥ 1.5mg/dL in males)  
• Metabolic acidosis, acute or chronic, including lactic acidosis  
• Hemodialysis or continuous ambulatory peritoneal dialysis (CAPD)  
• Hypersensitivity to metformin |
| **Glipizide** | • Diabetic ketoacidosis  
• Hypersensitivity to glipizide |
| **Insulin** | • Hypersensitivity to any component of the formulation |
| **Enalapril** | • ACE-inhibitor induced angioedema  
• Hereditary or idiopathic angioedema  
• Pregnancy  
• Hypersensitivity to enalapril or other ACE inhibitors |
| **Aspirin** | • 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 semester)  
• Hypersensitivity to salicylates, other NSAIDs, 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>1-2</td>
<td>Low cost, many benefits</td>
<td>Falls 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>Glipizide</td>
<td>1.5-2.5</td>
<td>inexpensive</td>
<td>Weight gain, hypoglycemia</td>
</tr>
<tr>
<td>Insulin</td>
<td>1.5</td>
<td>No dose limit, improved lipid profile, inexpensive</td>
<td>Injections, monitoring, hypoglycemia, weight gain</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 insulin</td>
<td>0 to 50 min</td>
<td>2 to 3 hours</td>
<td>8-10 hours</td>
</tr>
<tr>
<td>NPH insulin</td>
<td>0 to 60 min</td>
<td>4 to 10 hours</td>
<td>12 to 18 hours</td>
</tr>
<tr>
<td>70/30 insulin</td>
<td>30 to 60 min</td>
<td>3 to 12 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 hyperglycemia after dinner, the Regular insulin will need to be adjusted as its onset of action is faster than the NPH.

### Table 4. 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>101 to 250</td>
<td>4</td>
</tr>
<tr>
<td>251 to 300</td>
<td>6</td>
</tr>
<tr>
<td>301 to 350</td>
<td>8</td>
</tr>
<tr>
<td>351 to 400</td>
<td>10</td>
</tr>
<tr>
<td>401 to 450</td>
<td>12</td>
</tr>
<tr>
<td>451 to 500</td>
<td>14</td>
</tr>
<tr>
<td>&gt;501</td>
<td>Check for ketones, Contact unit provider</td>
</tr>
</tbody>
</table>

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### Table 5. Indications for Daily Aspirin Therapy*

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Prevention</strong></td>
<td></td>
</tr>
<tr>
<td>Men &gt; 50 years of age with diabetes and at least 1 additional major cardiac risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).</td>
<td>Consider aspirin therapy (75 to 162 mg/day).</td>
</tr>
<tr>
<td>Women &gt; 60 years of age with diabetes and at least 1 additional major cardiac risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria).</td>
<td>Consider aspirin therapy (75 to 162 mg/day).</td>
</tr>
<tr>
<td>Lower risk individuals, such as men &lt; 50 years of age or women &lt; 60 years of age without other major risk factors.</td>
<td>There is not sufficient evidence to recommend aspirin.</td>
</tr>
<tr>
<td>Not recommended for patients &lt; 21 years</td>
<td>Risk of Reye’s syndrome.</td>
</tr>
<tr>
<td><strong>Secondary Prevention</strong></td>
<td></td>
</tr>
<tr>
<td>Patients with diabetes and a history of CVD</td>
<td>Use aspirin therapy (75 to 162 mg/day).</td>
</tr>
<tr>
<td>Patients with diabetes, CVD, and documented aspirin intolerance</td>
<td>Use clopidogrel (75 mg/day).</td>
</tr>
<tr>
<td>Patients with diabetes, CVD, and an Acute Coronary Syndrome.</td>
<td>Combination therapy with aspirin (75 to 162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to 1 year after the event.</td>
</tr>
</tbody>
</table>
NURSING ASSESSMENT FOR SUSPECTED OVERDOSE

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 pointe
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)?

1. Yes
   2. No

Consider patient medical history 3 OBTAIN APPROPRIATE LAB and exposure to other poisons. If STUDIES patient is symptomatic transfer to Patient presents early and ER. • is fully conscious, • has protected airway, • is not at risk for GI perforation or hemorrhage and • has not also ingested corrosives?

4. Yes
   5. No

Does the suspected overdose exceed the maximum daily dose? (See Dosing Table page 2 )

6. Yes
   7. No

Gastric lavage should only be performed within 1 hour of overdose and after an order has been obtained from a provider. Go to box 9 or transfer the patient to the ER if symptomatic.

8. Administer 8 ounces of Activated Charcoal slurry (ActIdose®)

9. Observe 4-6 hours in the medical department.

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

#### 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>≥ 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>

#### 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>80 mg/kg</td>
<td>&gt;28 g</td>
<td>&gt;450 mcg/mL</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>

#### 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>
Alert Symptoms
- Abdominal Pain
- Malnutrition
- Fever
- Oliguria/Anuria
- Rapid weight gain or loss
- Hematomas
- Hematemesis / Melena

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

Initial Management of Cirrhosis
- Complete baseline evaluation and offer preventive measures (box A)
  - Enrol in ESLD CCC and follow up every 3-6 months
  - Refer to ESLD clinic for UTMB (box B), GI director or appropriate specialty clinic for treatment as indicated based on etiology (e.g., UTMB virology - HIV, HCV, HBV).

Compensated
- Lab abnormalities suggestive of cirrhosis:
  - Low platelets but ≥ 70,000, elevated TBil but < 2.0, PTT prolongation > 2 sec. or albumin < 3.0.

HCC Surveillance
- Ultrasound Q6 months

Variceal Surveillance
- Initiate NSBB (preferably) for primary prophylaxis (see table 3).
  - Consider referral for SSG in high risk patients (history of hematemesis, hematemesis, melena, significant anemia or prior bleed).

Laboratory & Clinic Surveillance
- ESLD CCC Q 6 months if compensated or every 3 months if Decompensated.

Decompensated
- Evidenced by
  - Jaundice
  - Encephalopathy
  - HRS or HPS
  - Childs-Pugh > 7

HCC Surveillance
- Ultrasound Q6 months

Variceal Surveillance
- Initiate NSBB (preferably) for primary prophylaxis (see table 3).
  - Consider referral for SSG in high risk patients (history of hematemesis, hematemesis, melena, significant anemia or prior bleed).

Laboratory & Clinic Surveillance
- ESLD CCC Q 6 months if compensated or every 3 months if Decompensated.

Complete physical exam, review for symptoms, medication review, CBC with diff & PL, CMP, PT/INR, blood pressure, pulse, weight, temperature, mental status screening, MELD score.

HCC Surveillance
- Ultrasound Q6 months

Variceal Surveillance
- Initiate NSBB (preferably) for primary prophylaxis (see table 3).
  - Consider referral for SSG in high risk patients (history of hematemesis, hematemesis, melena, significant anemia or prior bleed).

Laboratory & Clinic Surveillance
- ESLD CCC Q 6 months if compensated or every 3 months if Decompensated.

Complete physical exam, review for symptoms, medication review, CBC with diff & PL, CMP, PT/INR, blood pressure, pulse, weight, temperature, mental status screening, MELD score.

Primary prophylaxis - see Variceal Surveillance (box 5)

Secondary prophylaxis
- First Line - Propranolol and EVL
- Second line - TIPS or sham

Identify and treat precipitating factors
- First line - lactulose
- Second line - lactulose plus neomycin
- Third line - lactulose plus rifaximin

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 plt, PT/INR, CMP, alpha-fetoprotein, 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
- Hemotchezias/Hematemesis

<table>
<thead>
<tr>
<th>TABLE 1: Child-Turcotte-Pugh (CTP) Calculator</th>
</tr>
</thead>
<tbody>
<tr>
<td>POINTS*</td>
</tr>
<tr>
<td>Encephalopathy</td>
</tr>
<tr>
<td>Grade 1-2 (or precipitant-induced)</td>
</tr>
<tr>
<td>Grade 3-4 (or chronic)</td>
</tr>
<tr>
<td>Ascites</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Mild / Moderate (diuretic - responsive)</td>
</tr>
<tr>
<td>Severe (diuretic - refractory)</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
</tr>
<tr>
<td>&lt; 2</td>
</tr>
<tr>
<td>2 - 3</td>
</tr>
<tr>
<td>&gt; 3</td>
</tr>
<tr>
<td>Albumin (g/dL)</td>
</tr>
<tr>
<td>&gt; 3.5</td>
</tr>
<tr>
<td>2.8 - 3.5</td>
</tr>
<tr>
<td>&lt; 2.8</td>
</tr>
<tr>
<td>PT (sec prolonged)</td>
</tr>
<tr>
<td>&lt; 4</td>
</tr>
<tr>
<td>4 - 6</td>
</tr>
<tr>
<td>&gt; 6</td>
</tr>
<tr>
<td>INR</td>
</tr>
<tr>
<td>&lt; 1.7</td>
</tr>
<tr>
<td>1.7 - 2.3</td>
</tr>
<tr>
<td>&gt; 2.3</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>
<thead>
<tr>
<th>TABLE 2: West Haven Criteria for Semi-quantitative Grading of Mental Status (Hepatic Encephalopathy [HE])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
</tr>
<tr>
<td>Grade 1</td>
</tr>
<tr>
<td>Grade 2</td>
</tr>
<tr>
<td>Grade 3</td>
</tr>
<tr>
<td>Grade 4</td>
</tr>
</tbody>
</table>

* Not an official stage on the West Haven Scale

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TABLE 3: ESOPHAGEAL VARICES & PORTAL HYPERTENSION

EVALUATION & TREATMENT

- Nonselective beta-blockers (propranolol) are the preferred pharmacologic agent for prevention of bleeding and should be continued indefinitely.
  - Initial Dose: propranolol 20mg 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 varices - propranolol
  - Medium/large varices - propranolol. Endoscopic variceal ligation (EVL) may be preferred in patients of high risk of hemorrhage or those who have contraindications or intolerance to beta-blockers. (Decision to perform EVL or TIPS 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.

MONITORING

- Surveillance
  - Patients on primary prophylaxis with propranolol (no history of hemorrhage) - repeat EGD is not necessary.
  - Patients treated with EVL - surveillance EGD every 6-12 months.

TABLE 4: ASCITES & EDema

EVALUATION & TREATMENT

- 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 Ascitic Albumin Gradient (SAAG) of > 1.1 g/dL, indicates portal hypertension with 97% accuracy.
  - Paracentesis may be performed at Estelle-E2, Young-GC, Hospital Galveston-HG, and Monford-HP. For patients requiring frequent or routine paracentesis, consider requesting a housing change to an appropriate TDCJ facility.
- Salt restriction (< 2 gm/day)
- Diuretic therapy
  - For minimal to mild edema:
    - Furosemide 20mg daily or
    - Spironolactone 100mg daily. Daily doses less than 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.
    - Titrate diuretic therapy every 3-7 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 can be added once per week, increasing to 5mg M-W-F, then 5mg M-F, and 5mg daily. Renal function and electrolytes must be monitored closely when using > 2 diuretics. Consider BNP every 1-2 weeks until stable, then monthly.
  - Monitor for diuretic complications (BNP 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 purulent) - consider large volume paracentesis (LVP) followed by sodium restriction and diuretic therapy. Caution as LVP and aggressive diuresis can precipitate HRS.
TABLE 4: ASCITES / EDEMA CONTINUED

**EVALUATION & TREATMENT**
- 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 Scr, elevated WBC, and ascites.

**Acute treatment** requires hospitalization and IV antibiotic (cefotaxime or ceftriaxone).
- Outpatient prophylaxis of SBP should receive indefinite prophylaxis with one of the following:
  - First line - sulfadiazine/trimethoprim DS one tab daily
  - Second line - ciprofloxacin 500mg po once daily (Reserved for sulfa allergy or renal insufficiency)

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

TABLE 6: HEPATORENAL SYNDROME (HRS)

**TREATMENT**
- Should be considered in patients with cirrhosis and ascites with a creatinine level above 1.5 mg/dL or CrCl < 40mL/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 7: HEPATIC ENCEPHALOPATHY (HE)

**EVALUATION & TREATMENT**
- Varied presentation. May present with sleep disturbances, changes in personality or behavior, sporadic lack of awareness, shortened attention span, slowed mental functioning, asterixis, lethargy, apathy, disorientation, slurred speech, bizarre behavior, stupor, and eventual coma.

Identification and treatment of precipitating factors should be instituted (GI hemorrhage, infection, renal or electrolyte imbalance, dehydtration, psychotropic medications, constipation, poor compliance with medications). HE is a clinical diagnosis and serum ammonia levels are not routinely indicated.

**Pharmacologic/Prophylaxis (indicated)**
- **First line** - lactulose starting at 30 mL BID - TID. Titrate to achieve 3-4 loose stools per day. Consider DOT or pill window dosing for suspected poor compliance.
- Second line - neomycin 500-1000mg po BID plus lactulose.
- Third line - rifaximin 600mg po BID plus lactulose. Reserved for patients who remain symptomatic on optimized lactulose in combination with neomycin who are compliant with their treatment regimen. For patients with a history of renal impairment, rifaximin may be considered prior to a trial of neomycin.

- Patients with acute or significant changes in mental status - consider transport to higher level of care.
  - An additional supplemental dose of po lactulose 15mL given between scheduled TID dosing can maximize the acidifying effect of lactulose without causing a greater number of stools and may be considered.
  - In the infirmary setting, a tap water enema may be considered and is preferred over lactulose enema. Administer 2000 mL and repeat until returns are clear.

**MONITORING**
- Mental status screening at each encounter.
### Table 8. Common Medications used in ESLD

<table>
<thead>
<tr>
<th>Medication</th>
<th>Formulary Status</th>
<th>Indication</th>
<th>Dosing / Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amiloride 5mg tab</td>
<td>NF</td>
<td>Ascites / edema</td>
<td>5mg to 10mg once daily; Doses over 40mg daily should be divided twice daily.</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>NF</td>
<td>SBP Prophylaxis</td>
<td>500mg once daily; Reserved for sulfa allergy or renal insufficiency.</td>
</tr>
<tr>
<td>Furosemide 20mg, 40mg tab</td>
<td>F</td>
<td>Ascites / edema</td>
<td>40mg to 160mg daily; Doses over 80mg daily should be divided twice daily.</td>
</tr>
<tr>
<td>Lactulose 10gm/15ml syr</td>
<td>NF Hepatitis Encephalopathy</td>
<td></td>
<td>Start at 30 ml BID - TID. Titrated to achieve 3-4 loose stools per day.</td>
</tr>
<tr>
<td>Metolazone 5mg tab</td>
<td>F</td>
<td>Hepatitis Encephalopathy</td>
<td>Titrated slowly up to 5mg daily.</td>
</tr>
<tr>
<td>Neomycin 500mg tab</td>
<td>NF Hepatitis Encephalopathy</td>
<td></td>
<td>600mg to 1000mg BID; Avoid in AKI or CKD.</td>
</tr>
<tr>
<td>Propranolol 10mg, 20mg, 40mg tab</td>
<td>F</td>
<td>Hepatitis Encephalopathy</td>
<td>Initial dose 20mg BID; Titrated to a maximally tolerated dosage (heart rate 55-60 beats/minute).</td>
</tr>
<tr>
<td>Rifaximin</td>
<td>NF</td>
<td>Hepatitis Encephalopathy</td>
<td>600mg (3 x 200mg tabs) per BID; Reserved for breakthrough HE despite optimized lactulose and neomycin.</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>F</td>
<td>May be used up to a maximum daily dose of 2,600mg.</td>
<td></td>
</tr>
<tr>
<td>Acetaminophen / codeine</td>
<td>F*</td>
<td>Impaired hepatic conversion of codeine (prodrug) to its active form may result in decreased analgesic effect.</td>
<td></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>
<td></td>
</tr>
<tr>
<td>NSAIDS</td>
<td>F</td>
<td>Should generally be avoided in patients with cirrhosis due to increased risk of serious hemorrhage, impaired renal function, risk of hepatorenal syndrome, and diuretic 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>
<td></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>
<td></td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>F</td>
<td>Phenytoin, carbamazepine, and divalprox 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. Divalprox 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>
<td></td>
</tr>
</tbody>
</table>

*Formulary restrictions apply

---

### 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>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>Should generally be avoided in patients with cirrhosis due to increased risk of serious hemorrhage, impaired renal function, risk of hepatorenal syndrome, and diuretic 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</td>
<td>F</td>
<td>Phenytoin, carbamazepine, and divalprox 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. Divalprox 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>
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? 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 angiomata, venous 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 pitting or scrotal edema. May have pitting over abdomen.
8. Asciites: 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
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>Heartburn</td>
<td>Refer to Dyspepsia algorithm</td>
</tr>
<tr>
<td>Yes</td>
<td>Ulcer</td>
<td>Refer to Peptic Ulcer Disease 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>
</tbody>
</table>
DYSPEPSIA

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 not painful, and can include early satiety or upper abdominal fullness.

1. Heartburn and/or regurgitation are presenting complaints, predominant or frequent (more than once a week)?

2. Yes No

3. Manage as GERD

4. NSAID/Cox-2 inhibitor use?

5. Yes No

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

7. Age > 55 or alarm features present?

8. Yes No

9. Consider specialty referral

10. See H. Pylori Algorithm

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,

109
No Yes 13 12
Yes
15
14
Yes
11
Symptoms resolved?
Discontinue therapy. Follow PRN.
12
Continue therapy x 4 weeks and then consider discontinuation of therapy and follow PRN.
13
14
15
No
Symptoms resolved?
"The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients."
16
17
Yes
Report 8 week course of H2 therapy. Ranitidine 150mg BID. Go to Box #14.
18
19
110
20
21
22
No
Symptoms resolved?
Yes
Discontinue therapy. If symptoms recur, repeat course. If patient refuses repeat after medication discontinuation, consider specialty referral.
23
24
25
26
Yes
Symptoms resolved?
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, dysphagia, parotid swelling, a family history of gastrointestinal cancer, previous neoplastic gastric malignancy, previous documented peptic ulcer, unexplained odynophagia, or an abdominal mass)

3. No

4. Discontinue NSAIDs if possible. If not, consider lower dose and/or change to PEP.

5. No further treatment.

6. Go to box #8

7. Resolution?

8. Yes

9. No

10. Resolution?

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

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

13. Resolution?

14. No

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

GASTROESOPHAGEAL REFLUX DISEASE

1. Alarm symptoms present (i.e., dysphagia, odynophagia, bleeding, unexplained weight loss, or anemia)?
   - Yes
     - The pathways do not replace sound clinical judgement nor are they intended to strictly apply to all patients.
     - Consider specialty referral.
   - No

IMPLEMENT LIFESTYLE MODIFICATIONS AND ELIMINATE MODIFIABLE RISK FACTORS WHEN POSSIBLE

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

OTHER FACTORS NOT APPLICABLE OR FEASIBLE AT TDCJ

3. 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, estrogen, opiates, calcium channel antagonists).
    6. Discontinue NSAID usage when possible. If not, consider lowering dose and/or change to PEN.
    7. Smaller meal size especially the last meal of the day.

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Ranitidine 300 mg BID X 60 days.

Consider compliance assessment prior to proceeding.

Symptoms resolved?

Yes

Consider specialty referral.

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.

No

*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.

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

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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 < 80mmHg), cold extremities, poor mentation. (Note: hematocrit is a poor early indicator of blood loss)
- Assess for acute abdomen (guarding, rebound tenderness, rigidity)
- Perform rectal exam
- Assess for physical signs of liver disease
- Assess for active bleeding – hematemesis, hematochezia, melena

Signs of hypovolemia?
(SBP<100, RR>20/min, HR>100 bpm, orthostatic hypotension)

Evidence of active hemorrhage?
Consider significant history or associated symptoms placing patient at high risk of severe GI bleeding. Note: age > 60, liver disease, and comorbid conditions (heart, respiratory, or renal disease) are associated with higher risk of severe GI bleeding

Unstable patient and/or apparent GI bleed
- Activate EMS/911 system
- Establish IV access and NS infusion
- Administer oxygen by nasal cannula or mask

Stable patient with possible GI bleed
Based on clinical presentation, further evaluation and/or observation may be indicated as follows:
- Consider transfer to nearby 24 hr unit or Emergency Room for evaluation / monitoring
- Consider laboratory studies (CBC, CMP, PT/PTT)
- Consider urgent or expedited referral to GI or tele-consult
- Consider risks associated with continuation versus cessation of antiplatelets and anticoagulants (CV risk vs. bleeding risk)
- Provide clinical education to patient based on presumptive diagnosis

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, May 2012
Chronic Heart Failure

**Left Ventricular Systolic Dysfunction**

1. Control HTN, DM, and hyperlipidemia
2. Weight reduction in obese (educate on exercise)
3. Low sodium diet
4. Pneumococcal and flu vaccination
5. Smoking cessation
6. Discontinuation of alcohol
7. Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.

**NYHA Classification**

- **Class I**
  - No symptoms at rest; ordinary activity does not cause undue fatigue, dyspnea, or palpitation.

- **Class II**
  - Comfortable at rest; ordinary activity causes fatigue, dyspnea, or angina; slight limitation on physical activity.

- **Class III**
  - Comfortable at rest, minimal activity results in symptom occurrence; marked limitations with physical activity.

- **Class IV**
  - Symptoms at rest; inability to carry on ordinary activity without discomfort.

**Criteria:**

- **Simple heart failure**
  - Diagnosis code on problem list
- **Left Ventricular Dysfunction**
  - Ejection fraction < 40% documented

**Symptomatic: (Left Ventricular Systolic Dysfunction)**

**Medication:**

1. **Starvedal HCTZ 25 mg QD**
   - Target Dose = 25 mg QD
   - Monitor BP, K+, SCr

2. **Starvedal Frusemide 20-40 mg QD**
   - Start/instead of HCTZ if previously initiated
   - Titrate to control by 20 mg increments daily (maximum dose = 80 mg BED)
   - Monitor electrolytes, BP, SCr

3. **Start/instead of Enalapril**
   - Initial Dose = 2.5 mg to 10 mg QD
   - Target Dose = 20 mg BID
   - OR
   - Start/instead of ACE inhibitor or ARB
   - Titrate & attempt to increase to target dose for minimum effect.
   - Monitor K+, BP, SCr

4. **Continued Therapy**
   - If patient becomes symptomatic go to Box # 11
   - Monitor Symptoms (weight gain)

5. **Controlled?**
   - No
   - Yes

6. **Mild Edema**
   - **Medicine Edema/Imaging**

7. **Start/instead HCTZ 25 mg QD**
   - Target Dose = 25 mg QD
   - Monitor BP, K+, SCr

8. **Controlled?**
   - No
   - Yes

9. **Moderate Edema/Imaging**
   - **Starvedal HCTZ 25 mg QD**
   - **Monitor BP, K+, SCr**

10. **Start/instead Enalapril**
    - Depending on vials:
    - Initial Dose = 2.5 mg to 10 mg QD
    - Target Dose = 20 mg BID
    - OR
    - Start/instead other ACE Inhibitor or ARB
    - Titrate & attempt to increase to target dose for minimum effect.
    - Monitor K+, BP, SCr

11. **Continue Therapy**
    - If patient becomes symptomatic go to Box # 11
    - Monitor Symptoms (weight gain)

**Asymptomatic:**

- **Starvedal HCTZ 25 mg QD**
  - Monitor BP, K+, SCr

**Criteria:**

- **Simple heart failure**
  - Diagnosis code on problem list
- **Left Ventricular Dysfunction**
  - Ejection fraction < 40% documented

**Substitutions for Contraindications and ADRs with ACE Inhibitor:**

1. Cough - Angiotensin II Blocker (nonformulary)
2. Angioedema or renal stenosis (contraindication)
   - Hydralazine 25 mg TID Target dose = 75 mg TID
   - Isosorbide mononitrate 30 mg QD; Target dose = 60 mg TID

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved February 2000.

Revised 2/03, 4/03, 7/04, 9/06, 3/12. Reviewed 1/06, 1/09.
Consider Internal Medicine/Cardiology telephone consult or referral prior to adding the following:

If patient has been STABLE for at least 1 month and has NO contraindications to Beta-blockers:

Add carvedilol 3.125 mg BID and increase as tolerated.
Target dose = 25 mg BID (Monitor blood pressure and pulse as indicated).

Add Spironolactone 25 mg QD.
If serum K+ levels start to rise reduce to 25 mg QOD.
Monitor K+.

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

Nonstable Patients:
AddDigoxin 0.25 mg QD.
In renal dysfunction decrease dose to 0.125 mg QD.
Measure serum level at 1 week; target level = 0.9 - 1.2 ng/mL.
Monitor K+, Toxicity.
When patient becomes stable, add carvedilol and spironolactone as recommended by consult.
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 unconditioning
- 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 concern

Medications:

Enalapril - 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)
- **Usage instruction:** Begin initial dose monitoring potassium, SCr changes, and blood pressure. Increase dose to target based on tolerance 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 I/II Only use in mild edema (occasional symptoms)
- **Usage instruction:** 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 DC and start furosemide.

Furosemide – loop diuretic
- **Benefit:** Manage fluid overload to reduce or minimize symptoms
- **When to use:** In NYHA Class IV if HCTZ fails, replace with furosemide.
- **Usage instruction:** If symptomatic, add to captopril or other ACE inhibitors to decrease fluid overload.
- **Titration and instruction:** Titrate dose to symptoms – stabilize patient and maintain patient on smallest dose.
- **Monitoring:** 1) BP for symptomatic hypotension; 2) K⁺ for hypokalemia
- **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
- **Stabilize patient before addition of other pharmacological therapy**
Metoprolol – 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 diuretics and ACE inhibitors can be used with vasodilators and digoxin
- **Dosage and titration:** Optimize diuretic therapy before and during initiation of treatment and start low. Delay planned increments until the early side effects produced by the low doses of Beta-blocker have disappeared
- **NOTE:** **Use in STABLE patients ONLY**
  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:** 
  1) 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 0.8ng/ml-2.0ng/ml
- **Monitor:** 1) K+ for hypokalemia or hyperkalemia (can cause digoxin toxicity), 2) Mg+ hypomagnesemia (can maintain hypokalemia)
- **Risk effects:** (commonly seen at toxic levels > 2ng/ml)
  1) cardiac arrhythmias
  2) nausea and vomiting
  3) visual disturbances and confusion
- **NOTE:** **Can initiate in conjunction with ACE inhibitor, diuretics, or Beta-blockers if early in therapy and symptoms are still present**
  **DO NOT use if acutely decompensating (may need intravenous tx)**

Spironolactone

- **Benefit:** Cardioprotective and use can reduce symptoms, and risk of death and hospitalizations
- **When to use:** In NYHA Class III or IV (based on literature)
- **Dosage:** Initiate at 25mg daily.
- **Monitor:** 1) K+ for hypokalemia 2) signs of gynecomastia
- **NOTE:** **Encourage patient developing gynecomastia to continue treatment because benefits of decreased mortality are so great**
Physical exam:
- Daily (or as often as possible) weight measurements – to prevent any unexpected exacerbation
- Measurement of edema
  - Patient’s weight increase over short-term
  - Degree of Jugular Venous Distention (response to abdominal pressure)
  - Presence of organ congestion (lungs, liver)
  - Magnitude of peripheral edema (legs, presacral area, abdomen)

Goals of Therapy:
1. Prolong survival or slow progression of HF
2. Reduce mortality
3. Improve symptoms to increase patient’s QOL
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 (Captopril, Enalapril, 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.
CHRONIC HEPATITIS B MONITORING AND REFERRAL GUIDELINE

The pathway does not replace sound clinical judgement and is not intended to strictly apply to all patients.

1. Chronic Hepatitis B

2. Obtain baseline tests:
   - CBC w/platelets
   - Bili, Alb, ALT, AST, APP
   - Prothrombin time
   - HCV, HIV, anti-HAV total
   - HBeAg, HBV-DNA if potential treatment candidate
   - Vaccinate as indicated

3. Evidence of uncompensated cirrhosis?

4. HBV-DNA detectable?

5. Manage for ESLD

6. Evidence of compensated cirrhosis?

7. HBV-DNA ≥ 2,000?

8. Refer for treatment evaluation

9. Periodic monitoring

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

11. Consider biopsy and treat if disease present

12. Periodic monitoring

13. ALT WNL?

14. HBV-DNA ≥ 2,000?

15. Refer for treatment evaluation

16. HBV-DNA ≥ 20,000?

17. Consider biopsy, especially if over 40, and treat if disease present

18. Periodic monitoring

19. ALT WNL?

20. HBV-DNA ≥ 20,000?

21. Consider biopsy and treat if disease present and treat accordingly (Periodic monitoring if not treated)

22. Refer for treatment evaluation

* Periodic monitoring – HBV-DNA and ALT (HBeAg if previous test positive) q3m for first year, then q6–12m in subsequent years

Prepared By the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 1/09. Reviewed 1/2012.

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Box A – Level 2 Labs for Hepatitis B
- Quantitative HBV-DNA
- Abdominal ultrasound
- alpha-fetoprotein
- Alpha-1 antitrypsin
- Ceruloplasmin
- ANA
- 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 1: Monitoring Schedule on nucleoside analog therapy for hepatitis B |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Month of Treatment** | **Pro Rx** | **1** | **4** | **9** | **12** |
| **Continuous Tx** | **6 mos.** | **Q3 mos.** | **Q6 mos.** | **Q12 mos.** |
| CBC + diff | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| PT/PTT | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Liver tests** | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Free T4, T3, TSH | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| alpha-fetoprotein (AFP) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| T4, TSH, T4, T3, TSH** | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HBV-DNA | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HBeAg/anti-HBe (if initially HBeAg positive) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HBsAg (if HBeAg negative and HBV-DNA < 2,000) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

Table 2: Monitoring Schedule on Peg-IFN alfa

| Table 2: Monitoring Schedule on Peg-IFN alfa |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Week of Treatment** | **Treatment Week** | **Pre Rx** | **2** | **4** | **8** | **12** |
| **Post Rx** | **3 mos.** | **6 mos.** | **9 mos.** | **12 mos.** |
| CBC + diff | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| PT/PTT | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Liver tests** | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Free T4, T3, TSH | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| alpha-fetoprotein (AFP) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HBeAg/anti-HBe (if initially HBeAg positive) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| HBsAg (if HBeAg negative and HBV-DNA < 2,000) | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Beck Depression Index | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

**Liver test: 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

1. Initial Management of Chronic Hepatitis C Patients (Box A)
   - Complete baseline evaluation
   - Offer preventive health measures
   - Enroll in chronic care clinic and follow up at least every 12 months or as clinically indicated (Box B)
   - If patient has cirrhosis, refer to the End Stage Liver Disease guideline for management of ESLD. The pathway does not replace sound clinical judgment nor is it intended to strictly apply to all patients.

2. 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 is true:
   - Willing and interested in undergoing treatment
   - Compensated cirrhosis
   - No contraindications for therapy
   - Sufficient time left in system to complete work-up and treatment
   - APRI score > 0.42

3. Consider specialty referral if indicated.
   - Refer to designated provider and/or clinic for 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). Referral Guideline.
   - Follow in chronic care clinic (Box B).
   - If patient has cirrhosis consider for MRIS, hospice, or transplant submission as indicated.

4. Rule to designated provider and/or clinic for continued treatment evaluation.
   - Refer to designated provider and/or clinic for continued treatment evaluation.

5. Continue to Monitor.
   - Rule out other causes of liver disease (Boxes E & F).
   - Use most recent lab results. ULN = upper limit of normal for the AST level and platelet count is in 1,000/mm3.
   - Physical examination if not done in last 12 months.
   - Obtain liver ultrasound if FRT > 5 or clinical evidence of cirrhosis, or as clinically indicated.
   - Obtain liver biopsy if HIV co-infected, hepatitis B co-infected, four or more detected on imaging, liver abnormalities (>35) or as clinically indicated.
   - Consider treatment if
     - Liver biopsy with evidence of at least moderate fibrosis (Box G)
     - Compensated cirrhosis
     - FRT > 4
     - No contraindications to treatment

6. Treatment Evaluation (Completed by Virology HCV Treatment Team in UTMB Sector or per Utilization Management review process for Texas Tech Sector)
   - Screen for hepatitis C components and rule out other causes of liver disease (Boxes E & F).
   - Evaluate for contraindications for therapy (Box D).
   - Use most recent lab results. ULN = upper limit of normal for the AST level and platelet count is in 1,000/mm3.
   - FRT (Fibrous Routine Test) Calculation
   - FRT > 4 predictive Metavir score F2 – F4 (portal fibrosis with rare bridges – cirrhosis)
   - Liver biopsy with evidence of at least moderate fibrosis (Box G)
   - Compensated cirrhosis
   - No contraindications to treatment

7. Candidate for treatment?
   - Yes
   - No

8. Candidate for treatment?
   - Yes

9. Candidate for treatment?
   - Yes

- Distribute patient education information and obtain informed consent for treatment.
- Follow treatment algorithm and monitoring schedule while on drug therapy.
- Go to dual therapy algorithm on page 3 if
  - Genotypes 2, 3, 4, 5, or 6
  - Genotypes 2 with contraindications to protease inhibitors
- Go to triple therapy algorithm if
gene type 1
- Go to page 4

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved July 2008; Reviewed 5/11; Revised 9/13.
Box A: Initial Management
Baseline Evaluation
- History, physical
- CBC with differential, platelets
- Prothrombin time, INR
- ALT, AST, A/G, albumin
- Renal, endocrine
- Add-HIV, HTLV, HepB, anti-HAV

Preventive Health Measures
- Vaccinations if indicated
  - Hepatitis B
  - Hepatitis A
- Education
  - Natural history of disease
  - Potential treatments
  - Behaviors to avoid (eg, alcohol)
  - Avoiding transmission
- Additional care if cirrhosis present
  - Pneumococcal vaccine
  - Annual influenza vaccination
  - Consider screening for hepatocellular carcinoma and esophageal varices

Box B: Annual Evaluation
- Clinical signs & symptoms of liver disease
- ALT, AST, bilirubin, albumin
- CBC with differential, platelets
- APRI
- Other labs as clinically indicated
- Evaluate periodically for treatment if not initially recommended.

Box C: Evidence of Decompensated Cirrhosis
- Hepatic encephalopathy
- Varices, variceal bleeding
- Ascites
- Jaundice
- Laboratory abnormalities
  - Platelets < 70,000
  - ALT > 3 times normal
  - INR > 2

Box D: Peginterferon Absolute Contraindications
- Decompensated cirrhosis
- Neutropenia or potentially life-threatening non-hepatic disease such as far advanced AIDS, malignancy, severe COPD or severe heart failure
- Uncontrolled autoimmune disorders
- Uncontrolled hyperthyroidism
- Severe alcohol use
- Severe renal impairment
- Severe hepatitis C protease inhibitors

Box E: Pretreatment Workup
- HCV RNA and genotype
- Alpha-1 antitrypsin, ceruloplasmin, ANA, ferritin, serum iron, TIBC
- Pregnancy test if female
- Alpha-fetoprotein (AFP)
- Chest x-ray and EKG if over 40, cardiac disease or clinically indicated

Box F: Causes of Liver Disease
- Alpha-1 antitrypsin deficiency
- Wilson Disease
- Autoimmune hepatitis
- Biliary atresia
- Alcohol

Box G: Comparison of Liver Biopsy Scoring Schemas

<table>
<thead>
<tr>
<th>Stage</th>
<th>Batts-Ludwig</th>
<th>Metavir</th>
<th>Ishak</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>F0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>F1</td>
<td>1</td>
<td>1/2</td>
</tr>
<tr>
<td>2</td>
<td>F2</td>
<td>2-3</td>
<td>2-4</td>
</tr>
<tr>
<td>3</td>
<td>F3</td>
<td>4</td>
<td>5-6</td>
</tr>
<tr>
<td>4</td>
<td>F4</td>
<td>5-6</td>
<td>6</td>
</tr>
</tbody>
</table>
All patients must be monitored while on drug therapy as outlined in the monitoring schedule.

**Candidate for drug therapy**
- Genotype 2, 3, 4, 5, 6 with or without compensated cirrhosis
- Genotype 1 with contraindication to protease inhibitor use
- Co-infection HIV

**Begin Peginterferon (pegIFN) + Ribavirin (RBV).**
- Duration of therapy is dependent on genotype.
- Must be housed at ≥12 hour unit while on therapy.
- Consider addition of Vitamin B12 5,000 mcg IM every 4 weeks.

**Genotype 2 & 3**
- (24 weeks of treatment)
  - HCV RNA at week 4.
  - ≥1 log decrease in HCV RNA.
  - Stop all drugs. Go to Box 15.
  - <2 log decrease in HCV RNA.
  - Go to Box 32.

**Genotype 1, 4, 5 & 6**
- (48 weeks of treatment)
  - HCV RNA at week 4.
  - ≥1 log decrease in HCV RNA.
  - Stop all drugs. Go to Box 15.
  - <2 log decrease in HCV RNA.
  - Go to Box 32.

**HCV RNA at week 12.**
- ≥1 log decrease in HCV RNA.
- ≤2 log decrease in HCV RNA.
- ≥2 log decrease in HCV RNA.
- <2 log decrease in HCV RNA.

**HCV RNA at week 24.**
- ≥2 log decrease in HCV RNA.
- ≤2 log decrease in HCV RNA.
- ≥2 log decrease in HCV RNA.
- <2 log decrease in HCV RNA.

**End of treatment HCV RNA detectable (week 24)?**
- HCV RNA detectable.
- HCV RNA undetectable.
- Continue pegIFN + RBV
- End of treatment HCV RNA detectable (week 48)?
- HCV RNA detectable 6 months post-treatment?
- HCV RNA detectable.
- HCV RNA undetectable.
- Continue pegIFN + RBV
- Stop all drugs. Go to Box 32.

**Discuss treatment results with patient.**
- Document lack of treatment response in EMR.
- Continue to follow in chronic care clinic at least once every 12 months.

**Discuss treatment results with patient.**
- Document treatment success in EMR.
- Continue to follow in chronic care clinic once every 12 months.
All patients must be monitored while on drug therapy as outlined in the monitoring schedule.

- Must be housed at 24 hour unit while prescribed boceprevir.
- Must be placed on medical hold while prescribed boceprevir.

Evaluate for dual therapy with pegIFN + RBV versus deferral of treatment. Document in EMR.

Yes

No

Peginterferon (pegIFN) and Ribavirin (RBV) weeks 1-4

Yes

No

HCV RNA undetectable or < 100?

pegIFN + RBV + BOC weeks 5 – 8.

End of treatment

HCV RNA detectable?

Yes

No

- Discuss treatment results with patient.
- Document lack of treatment response in EMR.
- Continue to follow in chronic care clinic at least once every 12 months.

HCV RNA undetectable or < 100?

Stop all drugs.

Go to Box 46.

HCV RNA detectable?

Continue to follow in chronic care clinic at least once every 12 months.

Discuss treatment results with patient.

Discuss treatment success in EMR.

Compensated cirrhosis

HCV RNA ≥ 100 ≤

pegIFN + RBV + BOC weeks 9 – 12.

Go to Box 27.

Previously Untreated without cirrhosis

Previously Treated without cirrhosis (partial responder or relapser)

Contraindication to boceprevir?

Evaluate for dual therapy with pegIFN + RBV versus deferral of treatment. Document in EMR.

Yes

No

Peginterferon (pegIFN) and Ribavirin (RBV) weeks 1-4

Yes

No

HCV RNA undetectable or < 100?

pegIFN + RBV + BOC weeks 5 – 8.

End of treatment

HCV RNA detectable?

Yes

No

- Discuss treatment results with patient.
- Document treatment success in EMR.
- Continue to follow in chronic care clinic at least once every 12 months.

HCV RNA undetectable or < 100?

Stop all drugs.

Go to Box 46.
Triple Therapy: Telaprevir Treatment Algorithm

1. Generate list candidates for drug therapy:
   - Must be located in 24-hour unit while prescribed telaprevir
   - Must be placed on medical hold while prescribed telaprevir

2. Check for subclinical fibrosis:
   - Yes
   - No

   - Document in EMR

4. Peginterferon (pegIFN) + Ribavirin (RBV) + Telaprevir (TVR) weeks 1-12.

5. Check HCV RNA at week 4 and 12.
   - HCV RNA undetectable weeks 1-12.
     - Continue pegIFN + RBV weeks 13-24.
   - HCV RNA detectable weeks 1-12.
     - Discuss treatment results with patient.

6. Check HCV RNA at week 4.
   - HCV RNA > 1,000
     - Stop all drugs.
     - Go to Box 36.
   - HCV RNA undetectable or ≤ 1,000
     - Continue pegIFN + RBV weeks 13-48.

7. Check HCV RNA at week 12.
   - HCV RNA detectable or > 1,000
     - Stop all drugs.
     - Go to Box 36.
   - HCV RNA undetectable or ≤ 1,000
     - Continue pegIFN + RBV weeks 13-48.

8. Check HCV RNA at week 24.
   - End of treatment HCV RNA detectable?
     - Yes
       - Discuss treatment results with patient.
       - Document treatment success in EMR.
       - Continue to follow in chronic care clinic at least once every 12 months.
     - No
       - Go to Box 36.

9. Discuss treatment results with patient.
   - Document treatment success in EMR.
   - Continue to follow in chronic care clinic at least once every 12 months.

10. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

11. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

12. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

13. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

14. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

15. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

16. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

17. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

18. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

19. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

20. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

21. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

22. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

23. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

24. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

25. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

26. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

27. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

28. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

29. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

30. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

31. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

32. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

33. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

34. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

35. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

36. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

37. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

38. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.

39. Discuss treatment results with patient.
    - Document treatment success in EMR.
    - Continue to follow in chronic care clinic only if clinically indicated.

40. Discuss treatment results with patient.
    - Document lack of treatment response in EMR.
    - Continue to follow in chronic care clinic at least once every 12 months.
### Interferon or Peginterferon

<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Decompensated cirrhosis</td>
<td>- Non-compliance with therapy</td>
</tr>
<tr>
<td>- Neutropenia or thrombocytopenia</td>
<td>- Poorly controlled HIV infection on HAART</td>
</tr>
<tr>
<td>- Potentially life-threatening non-hepatic disease such as far advanced AIDS, malignancy, severe COPD or severe heart failure</td>
<td>- Uncontrolled chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>- Autoimmune hepatitis</td>
<td>- Uncontrolled autoimmune disorders</td>
</tr>
<tr>
<td>- Poorly controlled diabetes</td>
<td>- Uncontrolled hyperthyroidism</td>
</tr>
<tr>
<td>- Solid organ transplant</td>
<td>- Solid organ transplant or other uncontrolled autoimmune disorders</td>
</tr>
<tr>
<td>- Ongoing alcohol or injection drug use</td>
<td>- Poorly controlled seizure disorder</td>
</tr>
<tr>
<td>- Severe heart failure</td>
<td>- Ongoing alcohol or injection drug use</td>
</tr>
</tbody>
</table>

### Ribavirin

<table>
<thead>
<tr>
<th>Absolute Contraindications</th>
<th>Relative Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Previously demonstrated hypersensitivity to the drug</td>
<td>- Pre-existing anemia</td>
</tr>
<tr>
<td>- Pregnancy (during treatment and for 6 months afterward; also applies to partners of males who are treated)</td>
<td>- Pre-existing neutropenia</td>
</tr>
<tr>
<td>- Hemoglobinopathies (e.g., sickle cell, thalassemia major)</td>
<td>- Solid organ transplant</td>
</tr>
<tr>
<td>- Hemolytic or other severe anemias</td>
<td>- Co-administration with medications that are inducers of or metabolized by CYP3A</td>
</tr>
<tr>
<td>- Ischemic cardiovascular or cerebrovascular disease</td>
<td>- Autoimmune hepatitis</td>
</tr>
<tr>
<td>- Renal insufficiency with serum creatinine &gt; 2.0</td>
<td>- History serious skin reactions including drug rash with eosinophilia and systemic symptoms or Stevens-Johnson Syndrome or toxic epidermal necrolysis (e.g., pemphigus, pemphigoid)</td>
</tr>
<tr>
<td>- Co-administration with didanosine</td>
<td>- Dermatologic conditions</td>
</tr>
</tbody>
</table>

### Boceprevir

1. Boceprevir and Telaprevir are only indicated for the treatment of genotype 1 chronic hepatitis C.
2. Boceprevir and Telaprevir must be used in combination with peginterferon and ribavirin. They cannot be used as monotherapy or dual therapy.
3. The manufacturer’s package information should be consulted for a complete list of medications that are contraindicated for use with Boceprevir and Telaprevir.
### Peginterferon Alfa-2a (Pegasys®) and Ribavirin Dose Guide

**Notes:**
- Information is adapted from manufacturer package inserts and is not expected to cover every clinical scenario.
- Information does not preclude the exercise of clinical judgment.

#### Peginterferon Alfa-2a

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Dose</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 or 4</td>
<td>180 mcg</td>
<td>Once weekly</td>
</tr>
</tbody>
</table>

#### Ribavirin

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Dose</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 or 4</td>
<td>If ≤ 75 kg, 400mg orally in the morning; if &gt;75 kg, 600mg orally twice daily</td>
<td></td>
</tr>
<tr>
<td>1 or 4</td>
<td>If ≥ 75 kg, 600mg orally twice daily</td>
<td></td>
</tr>
</tbody>
</table>

#### Hematological Dose Modification Guide

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Dose Reduction</th>
<th>Discontinue When</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC &lt; 750 cells/mm³</td>
<td>Peginterferon 135 micrograms q week</td>
<td>ANC &lt; 500 cells/mm³</td>
</tr>
<tr>
<td>Platelets &lt; 50,000 cells/mm³</td>
<td>Peginterferon 90 micrograms q week</td>
<td>Platelets &lt; 40,000 cells/mm³</td>
</tr>
<tr>
<td>Hemoglobin &lt; 10 g/dL</td>
<td>Ribavirin 600 mg/day</td>
<td>Hemoglobin &lt; 7 g/dL</td>
</tr>
</tbody>
</table>

*Once chemotherapy is discontinued due to a laboratory abnormality or clinical adverse reaction, an attempt may be made to restart at 500mg daily and further increase the dose to 800mg daily. However, it is not recommended that ribavirin be increased to the original dose (1000mg or 1200mg).*

#### Depression Dose Modification Guide

<table>
<thead>
<tr>
<th>Depression Severity</th>
<th>Dose Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>None</td>
</tr>
<tr>
<td>Moderate</td>
<td>Peginterferon 135 micrograms q week. May need to reduce dose to 90 micrograms q week. If symptoms improve and are stable for 4 weeks, may continue reduced dosing or return to normal dose.</td>
</tr>
<tr>
<td>Severe</td>
<td>Discontinue Peginterferon immediately and refer to mental health</td>
</tr>
</tbody>
</table>

*Increase frequency of clinical evaluation if patient develops depression. Evaluate depression weekly.*

#### ALT Dose Modification Guide

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Dose Reduction</th>
<th>Discontinue When</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALT &gt; 2x baseline</td>
<td>Continued ALT increase/deterioration in liver function tests, elevation of bilirubin, or evidence of hepatic decompensation</td>
<td></td>
</tr>
</tbody>
</table>

#### Renal Impairment Dose Modification

<table>
<thead>
<tr>
<th>Creatinine Clearance</th>
<th>Peginterferon</th>
<th>Ribavirin</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 30 mL/min</td>
<td>135 mg once weekly</td>
<td>200 mg once daily</td>
</tr>
<tr>
<td>30-50 mL/min</td>
<td>Alternating dose: 200 mg and 800 mg every other day</td>
<td></td>
</tr>
<tr>
<td>&gt; 50 mL/min</td>
<td>225 mg once weekly</td>
<td>300 mg once daily</td>
</tr>
</tbody>
</table>

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### Peginterferon Alfa-2b (Peg-Intron®) and Ribavirin Dose Guide

**Notes:**
- Information is adapted from manufacturer package inserts and is not expected to cover every clinical scenario.
- Information does not preclude the exercise of clinical judgment

<table>
<thead>
<tr>
<th>Weight kg (lbs)</th>
<th>Peginterferon Alfa-2b Vial Strength to Use</th>
<th>Peginterferon Dose (mcg)</th>
<th>Volume (ml) of Peginterferon to Administer</th>
<th>Ribavirin Daily Dose</th>
<th>Ribavirin Directions (200mg capsule)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 40 (&lt; 88)</td>
<td>50 mcg per 0.5ml</td>
<td>50</td>
<td>0.5</td>
<td>800mg/day</td>
<td>2 capsules BID</td>
</tr>
<tr>
<td>40-50 (88-111)</td>
<td>60 mcg per 0.5ml</td>
<td>60</td>
<td>0.5</td>
<td>800mg/day</td>
<td>2 capsules BID</td>
</tr>
<tr>
<td>51-60 (112-133)</td>
<td>80 mcg per 0.5ml</td>
<td>80</td>
<td>0.5</td>
<td>800mg/day</td>
<td>2 capsules BID</td>
</tr>
<tr>
<td>61-65 (134-146)</td>
<td>96 mcg per 0.5ml</td>
<td>96</td>
<td>0.4</td>
<td>800mg/day</td>
<td>2 capsules BID</td>
</tr>
<tr>
<td>66-75 (145-166)</td>
<td>120 mcg per 0.5ml</td>
<td>120</td>
<td>0.5</td>
<td>1000mg/day</td>
<td>2 capsules AM 3 capsules PM</td>
</tr>
<tr>
<td>76-80 (167-175)</td>
<td>150 mcg per 0.5ml</td>
<td>150</td>
<td>0.5</td>
<td>1200mg/day</td>
<td>3 capsules BID</td>
</tr>
<tr>
<td>81-85 (188-221)</td>
<td>150 mcg per 0.5ml</td>
<td>150</td>
<td>0.5</td>
<td>1200mg/day</td>
<td>3 capsules BID</td>
</tr>
<tr>
<td>86-105 (231-232)</td>
<td>150 mcg per 0.5ml</td>
<td>150</td>
<td>0.5</td>
<td>1200mg/day</td>
<td>3 capsules BID</td>
</tr>
<tr>
<td>≥ 106 (&gt;231)</td>
<td>150 mcg per 0.5ml</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

* The peginterferon dose for patients weighing greater than 105 kg (>231 pounds) should be calculated based on the patient’s weight at 1.5 mcg/kg/week. Two vials of peginterferon may be necessary to provide the dose.

### Depression Dose Modification Guide

<table>
<thead>
<tr>
<th>Depression Severity</th>
<th>Management</th>
</tr>
</thead>
</table>
| Mild                | No dose modification needed.  
  - Depression status:  
    + If depression remains stable, continue weekly evaluations.  
    + If depression improves, resume normal follow up schedule.  
    + If depression worsens, see recommendations for moderate to severe depression. |
| Moderate            | Adjust dose  
  - 1st dose reduction: peginterferon alfa-2b dose reduced to 1 mcg/kg/week  
  - 2nd dose reduction (if needed): peginterferon alfa-2b dose reduced to 0.5 mcg/kg/week  
  - Depression status:  
    + If depression remains stable, continue reduced dosing and consider psychiatric consultation.  
    + If depression improves and are stable for 4 weeks, may continue reduced dosing or return to normal dose.  
    + If depression worsens, see recommendations for severe depression. |
| Severe              | Discontinue Peginterferon immediately and refer to mental health for evaluation.  
  - Increase frequency of clinical evaluations if patient develops depression. Evaluate depression weekly. |

* Increase frequency of clinical evaluations if patient develops depression. Evaluate depression weekly.
# Hematological Dose Modification Guide

## Lab Value

<table>
<thead>
<tr>
<th>Lab Value</th>
<th>Dose Reduction</th>
<th>Hematological Value</th>
<th>Dose Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC 1,000 to 1,500/mm³</td>
<td>1st dose reduction: Peginterferon alfa-2b reduced to 1 mcg/kg/week</td>
<td>&lt; 1,000/mm³</td>
<td>2nd dose reduction if needed: Peginterferon alfa-2b reduced to 0.5 mcg/kg/week</td>
</tr>
<tr>
<td>Neutrophils 500 to &lt; 750/mm³</td>
<td>1st dose reduction: Peginterferon alfa-2b reduced to 1 mcg/kg/week</td>
<td>&lt; 500/mm³</td>
<td>2nd dose reduction if needed: Peginterferon alfa-2b reduced to 0.5 mcg/kg/week</td>
</tr>
<tr>
<td>Platelets 25,000 to &lt; 50,000/mm³</td>
<td>1st dose reduction: Peginterferon alfa-2b reduced to 1 mcg/kg/week</td>
<td>&lt; 25,000/mm³</td>
<td>2nd dose reduction if needed: Peginterferon alfa-2b reduced to 0.5 mcg/kg/week</td>
</tr>
<tr>
<td>Hemoglobin in patients with no history of cardiac disease</td>
<td>Hemoglobin 8.5 to &lt; 10 g/dL</td>
<td>Hemoglobin &lt; 8.5 g/dL</td>
<td>1st dose reduction: Ribavirin dose reduced by 200mg/day; If on ribavirin 1400mg/day, ribavirin dose reduced by 400mg/day</td>
</tr>
<tr>
<td></td>
<td>2nd dose reduction if needed: Ribavirin dose reduced by 200mg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin in patients with history of cardiac disease</td>
<td>Hemoglobin ≥ 2g/dL reduction in 4 weeks</td>
<td>Hemoglobin &lt;8.5g/dL or &lt; 12 g/dL after 4 weeks at reduced dosage</td>
<td>1st dose reduction: Ribavirin dose reduced by 200mg/day; Peginterferon alfa-2b dose reduced by half</td>
</tr>
<tr>
<td></td>
<td>2nd dose reduction if needed: Ribavirin dose reduced by 200mg/day; Peginterferon alfa-2b dose reduced by half</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Peginterferon Alfa-2b (Peg-Intron®) and Ribavirin Dose Guide Cont.

### Weight kg (lbs)

<table>
<thead>
<tr>
<th>Weight kg (lbs)</th>
<th>Peginterferon Alfa-2b Vial Strength to Use</th>
<th>Dose (mcg)</th>
<th>Peginterferon to Administer</th>
<th>Volume (ml) of Peginterferon to Administer</th>
<th>Peginterferon Alfa-2b Vial Strength to Use</th>
<th>Dose (mcg)</th>
<th>Peginterferon to Administer</th>
<th>Volume (ml) of Peginterferon to Administer</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 40 (&lt;88)</td>
<td>50 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>50 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>50 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>40-50 (88-111)</td>
<td>80 mcg per 0.5 ml</td>
<td>45</td>
<td>0.45</td>
<td>80 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>51-60 (112-135)</td>
<td>80 mcg per 0.5 ml</td>
<td>50</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>61-70 (134-166)</td>
<td>80 mcg per 0.5 ml</td>
<td>60</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>71-80 (167-230)</td>
<td>80 mcg per 0.5 ml</td>
<td>64</td>
<td>0.4</td>
<td>80 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>80 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>81-104 (188-230)</td>
<td>120 mcg per 0.5 ml</td>
<td>96</td>
<td>0.4</td>
<td>120 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>120 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>105-125 (231-275)</td>
<td>108 mcg per 0.5 ml</td>
<td>108</td>
<td>0.45</td>
<td>108 mcg per 0.5 ml</td>
<td>25</td>
<td>0.5</td>
<td>108 mcg per 0.5 ml</td>
<td>25 mcg per 0.5 ml</td>
</tr>
<tr>
<td>≥ 126 (276)</td>
<td>150 mcg per 0.5 ml</td>
<td>155</td>
<td>0.45</td>
<td>150 mcg per 0.5 ml</td>
<td>72</td>
<td>0.45</td>
<td>150 mcg per 0.5 ml</td>
<td>72 mcg per 0.5 ml</td>
</tr>
</tbody>
</table>
Boceprevir Dose Guide

Usual Dose
800mg every 8 hours
(Applicable during interval is every 7-9 hours. May not be given TID. Dose must not be reduced or interrupted.)

Food Requirements
Take with light meal or snack

Missed Dose
If within 6 hours of time the dose is usually taken, take the missed dose.

If more than 6 hours has passed since the dose is usually taken, do not take the missed dose and resume usual dosing schedule.

Previously Treated
28 Week Regimen
Week 1 – 4
Peginterferon + Ribavirin
Week 5 – 28
Peginterferon + Ribavirin + Boceprevir

48 Week Regimen
Week 1 – 4
Peginterferon + Ribavirin
Week 5 – 26
Peginterferon + Ribavirin + Boceprevir
Week 27 – 48
Peginterferon + Ribavirin

Previously Treated (partial responders or relapsers)
28 Week Regimen
Week 1 – 4
Peginterferon + Ribavirin
Week 5 – 28
Peginterferon + Ribavirin + Boceprevir

48 Week Regimen
Week 1 – 4
Peginterferon + Ribavirin
Week 5 – 26
Peginterferon + Ribavirin + Boceprevir
Week 27 – 48
Peginterferon + Ribavirin

Compensated Cirrhosis
48 Week Regimen
Week 1 – 4
Peginterferon + Ribavirin
Week 5 – 26
Peginterferon + Ribavirin + Boceprevir
Week 27 – 48
Peginterferon + Ribavirin

1. Boceprevir is only indicated for the treatment of genotype 1 chronic hepatitis C.
2. At week 4 in treatment naïve patients, if viral load has decreased < 1 log, discontinue peginterferon and ribavirin. Virologic response is unlikely in patients that are poorly responsive.
3. At week 8 in patients genotypically resistant, determine treatment duration (i.e., 28 weeks versus 48 weeks). If viral load is undetectable, treat for 28 weeks. If viral load is detectable, treat for 48 weeks.
4. At week 8 in patients previously treated (i.e., 12 weeks versus 24 weeks). If viral load is undetectable, treat for 24 weeks. If viral load is detectable, treat for 48 weeks.
5. Boceprevir has not been studied in null responders.
6. Boceprevir must be used as part of triple therapy (protease inhibitor + peginterferon + ribavirin). It may not be used as monotherapy.
7. Viral load (HCV RNA) should be monitored at weeks 8, 12 and 24 to determine treatment duration.
8. Based on protease inhibitor futility rules, patients with an inadequate viral response at week 8, 12 and 24 are unlikely to achieve a sustained virological response and may develop resistance; therefore, discontinuation of therapy is recommended for all patients (see futility rules below).

Boceprevir Futility Rules for Discontinuing Therapy

Previously Treated
<table>
<thead>
<tr>
<th>HCV RNA Results Week 4</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 8*</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 24**</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 log ↓</td>
<td>Undetectable</td>
<td>Undetectable or Detectable but &lt; 100 IU/mL</td>
<td>Undetectable</td>
<td>28 weeks</td>
<td></td>
</tr>
<tr>
<td>≥ 1 log</td>
<td>Undetectable</td>
<td>Undetectable or Detectable but &lt; 100 IU/mL</td>
<td>Undetectable</td>
<td>28 weeks</td>
<td></td>
</tr>
</tbody>
</table>

Previously Treated (partial responders or relapsers)
<table>
<thead>
<tr>
<th>HCV RNA Results Week 8</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 12</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 24</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 log ↓</td>
<td>Undetectable</td>
<td>Undetectable or Detectable but &lt; 100 IU/mL</td>
<td>Undetectable</td>
<td>28 weeks</td>
<td></td>
</tr>
<tr>
<td>≥ 1 log</td>
<td>Undetectable</td>
<td>Undetectable or Detectable but &lt; 100 IU/mL</td>
<td>Undetectable</td>
<td>28 weeks</td>
<td></td>
</tr>
</tbody>
</table>

*Stop if viral load ≥ 1000
**Stop if viral load detectable
### Boceprevir Drug Interactions

#### Contraindicated for Concomitant Use with Boceprevir

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfuzosin</td>
<td>Potential for increased toxicity of concomitant medication</td>
</tr>
<tr>
<td>Cisapride</td>
<td></td>
</tr>
<tr>
<td>Dihydroergotamine, ergonovine, ergotamine, methylergonovine</td>
<td></td>
</tr>
<tr>
<td>Lovastatin</td>
<td></td>
</tr>
<tr>
<td>Midazolam</td>
<td></td>
</tr>
<tr>
<td>Pimozide</td>
<td></td>
</tr>
<tr>
<td>Sildenafil</td>
<td></td>
</tr>
<tr>
<td>Simvastatin</td>
<td></td>
</tr>
<tr>
<td>Tadalafil</td>
<td></td>
</tr>
<tr>
<td>Triazolam</td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Potential for loss of Boceprevir activity</td>
</tr>
<tr>
<td>Phenytoin</td>
<td></td>
</tr>
<tr>
<td>Phenobarbital</td>
<td></td>
</tr>
<tr>
<td>Rifampin</td>
<td></td>
</tr>
<tr>
<td>St. John's Wort</td>
<td></td>
</tr>
</tbody>
</table>

#### Significant Drug Interactions with Boceprevir

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect on Blood Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budesonide</td>
<td>Increase Substances</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>Decrease Boceprevir</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>Decrease boceprevir</td>
</tr>
<tr>
<td>Fluticasone</td>
<td>Increase fluticasone</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Increase clarithromycin</td>
</tr>
<tr>
<td>Colchicine</td>
<td>Increase colchicine</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Increase digoxin</td>
</tr>
<tr>
<td>Imunosuppressants, cyclosporine, mizoribine, tacrolimus</td>
<td>Increase immunosuppressants</td>
</tr>
<tr>
<td>Narcotic analgesics, methadone, buprenorphine, naltrexone</td>
<td>Increase narcotic analgesics</td>
</tr>
<tr>
<td>Oral contraceptives, diethylstilbestrol, ethinyl estradiol</td>
<td>Decrease contraceptives</td>
</tr>
<tr>
<td>PDE5 inhibitors, sildenafil, tadalafil, vardenafil</td>
<td>Increase PDE5</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>Increase or decrease ranitidine</td>
</tr>
<tr>
<td>Sedatives, alprenolol, haloperidol</td>
<td>Increase sedation</td>
</tr>
<tr>
<td>Naloxone</td>
<td>Increase or decrease naloxone</td>
</tr>
</tbody>
</table>

#### Use with Caution

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect on Blood Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiarrhythmics: amiodarone, bepridil, flecainide, propafenone, quinidine</td>
<td>Increase antiarrhythmic</td>
</tr>
<tr>
<td>Antifungals: ketoconazole, itraconazole, posaconazole, voriconazole</td>
<td>Increase antifungal</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>Increase atorvastatin</td>
</tr>
<tr>
<td>Budesonide</td>
<td>Increase budesonide</td>
</tr>
<tr>
<td>Calcineurin inhibitors, cyclosporine, tacrolimus</td>
<td>Increase calcineurin inhibitors</td>
</tr>
<tr>
<td>Calcium channel blockers, diltiazem, felodipine, nicardipine</td>
<td>Increase calcium channel blocker</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Increase clarithromycin</td>
</tr>
<tr>
<td>Colchicine</td>
<td>Increase colchicine</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Increase digoxin</td>
</tr>
<tr>
<td>Immunosuppressants, cyclosporine, mizoribine, tacrolimus</td>
<td>Increase immunosuppressants</td>
</tr>
<tr>
<td>Narcotic analgesics, methadone, buprenorphine, naltrexone</td>
<td>Increase narcotic analgesics</td>
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<td>PDE5 inhibitors, sildenafil, tadalafil, vardenafil</td>
<td>Increase PDE5</td>
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<tr>
<td>Ranitidine</td>
<td>Increase or decrease ranitidine</td>
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<td>Sedatives, alprenolol, haloperidol</td>
<td>Increase sedation</td>
</tr>
<tr>
<td>Naloxone</td>
<td>Increase or decrease naloxone</td>
</tr>
</tbody>
</table>
Telaprevir Dose Guide

### Usual Dose

- **Usual Dose**: 1250mg every 12 hours (Acceptable dosing interval is every 10-14 hours. May \( \leq \) be given BID. Dose must \( \geq \) be reduced or interrupted.)

### Food Requirements

- **Take with meal**

### Missed Dose

- If within 6 hours of time the dose is usually taken, take the missed dose.
- If more than 6 hours has passed since the dose is usually taken, do not take the missed dose and resume usual dosing schedule.

### Previously Untreated or Prior Relapsers

- **24 Week Regimen**: Week 1 – 12 Peginterferon + Ribavirin + Telaprevir
  - Week 13 – 24 Peginterferon + Ribavirin
- **48 Week Regimen**: Week 1 – 12 Peginterferon + Ribavirin + Telaprevir
  - Week 13 – 48 Peginterferon + Ribavirin

### Prior Partial Responders or Null Responders

- **48 Week Regimen**: Week 1 – 12 Peginterferon + Ribavirin + Telaprevir
  - Week 13 – 48 Peginterferon + Ribavirin

### Telaprevir Futility Rules for Discontinuing Therapy

<table>
<thead>
<tr>
<th>Treatment</th>
<th>HCV RNA Results Week 4*</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 12**</th>
<th>Treatment Duration</th>
<th>HCV RNA Results Week 24***</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable</td>
<td>24 weeks</td>
<td>Undetectable</td>
<td>24 weeks</td>
<td>Undetectable</td>
<td>24 weeks</td>
<td></td>
</tr>
<tr>
<td>Detectable but ( \leq ) 1,000 IU/mL</td>
<td>48 weeks</td>
<td>Detectable but ( \leq ) 1,000 IU/mL</td>
<td>48 weeks</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td></td>
</tr>
</tbody>
</table>

*Stop all treatment if \( > 1,000 \)

**Stop all treatment if \( > 1,000 \)

***Stop all treatment if detectable

### Telaprevir Futility Rules for Discontinuing Therapy

<table>
<thead>
<tr>
<th>Treatment</th>
<th>HCV RNA Results Week 4*</th>
<th>Treatment Duration</th>
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<th>Treatment Duration</th>
<th>HCV RNA Results Week 24***</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable</td>
<td>48 weeks</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td></td>
</tr>
<tr>
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<td>Undetectable</td>
<td>Detectable but ( \leq ) 1,000 IU/mL</td>
<td>Undetectable</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td></td>
</tr>
</tbody>
</table>

*Stop all treatment if \( > 1,000 \)

**Stop all treatment if \( > 1,000 \)

***Stop all treatment if detectable

### Telaprevir Futility Rules for Discontinuing Therapy

<table>
<thead>
<tr>
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<th>Treatment Duration</th>
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<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undetectable</td>
<td>48 weeks</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td></td>
</tr>
<tr>
<td>Detectable but ( \leq ) 1,000 IU/mL</td>
<td>Undetectable</td>
<td>Detectable but ( \leq ) 1,000 IU/mL</td>
<td>Undetectable</td>
<td>Undetectable</td>
<td>48 weeks</td>
<td></td>
</tr>
</tbody>
</table>

*Stop all treatment if \( > 1,000 \)

**Stop all treatment if \( > 1,000 \)

***Stop all treatment if detectable

---

1. Telaprevir is only indicated for the treatment of genotype 1 chronic hepatitis C.
2. At week 4 for patients previously untreated or prior relapsers, determine treatment duration (i.e., 24 weeks versus 48 weeks).
   - If viral load is undetectable, treat for 24 weeks.
   - If viral load is detectable, treat for 48 weeks.
3. Patients that are prior partial responders or null responders should be treated for 48 weeks.
4. Patients with compensated cirrhosis that are treatment naïve and undetectable at week 4 and 12, may benefit from a 48 week regimen.
5. Telaprevir must be used as part of triple therapy (protease inhibitor + peginterferon + ribavirin). It may not be used as monotherapy.
6. Viral load (HCV RNA) should be measured at weeks 4, 12 and 24 to determine treatment duration and to assess response to determine if therapy should be discontinued only based on futility rules.
7. Based on futility rules, patients with an inadequate viral response at weeks 4, 12 and 24 are unlikely to achieve a sustained virological response and may develop resistance. Therefore, discontinuation of therapy is recommended for all patients (see futility rules below).
### Telaprevir Drug Interactions

**Contraindicated for Concomitant Use with Telaprevir**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfuzosin</td>
<td>Potential for increased toxicity of concomitant medication</td>
</tr>
<tr>
<td>Midazolam</td>
<td>Potential for increased toxicity of concomitant medication</td>
</tr>
<tr>
<td>Cisapride</td>
<td>Potential for decreased blood level of concomitant medication</td>
</tr>
<tr>
<td>Pimozide concomitant medication</td>
<td>Potential for decreased blood level of concomitant medication</td>
</tr>
<tr>
<td>Dihydroergotamine</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Sildenafil</td>
<td>Potential for increased blood level of concomitant medication</td>
</tr>
<tr>
<td>Ergonovine</td>
<td>Potential for decreased blood level of concomitant medication</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Methylergonovine</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Rifampin</td>
<td>Potential for loss of Telaprevir activity</td>
</tr>
<tr>
<td>St. John's Wort</td>
<td>Potential for loss of Telaprevir activity</td>
</tr>
</tbody>
</table>

**Significant Drug Interactions with Telaprevir**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voriconazole</td>
<td>Potential for increased blood level of concomitant medication</td>
</tr>
<tr>
<td>Voriconazole</td>
<td>Potential for decreased blood level of concomitant medication</td>
</tr>
<tr>
<td>Rifabutin</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Darunavir/ritonavir</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Fosamprenavir/ritonavir</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Lopinavir/ritonavir</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Budesonide</td>
<td>No expected change in blood level of concomitant medication</td>
</tr>
<tr>
<td>Colchicine</td>
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<tr>
<td>Fluticasone</td>
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<tr>
<td>Methylprednisolone</td>
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<td>Salmeterol</td>
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</tr>
<tr>
<td>Use with Caution</td>
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<tr>
<td>Clarithromycin</td>
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<td>Erythromycin</td>
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<td>Norethindrone</td>
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### Chronic Hepatitis C Treatment Checklist

**Note:** Ensure all information is available and criteria for treatment has been met prior to requesting approval or begin drug therapy.

**Patient Name:** _______________________________
**Unit:** _________________________________
**Patient TDCJ #:**  ___________________________
**Weight:**  _______________________________

#### Indication for Treatment:

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<th>Result</th>
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<tr>
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<tr>
<td>HCV genotype</td>
<td>(Circle one)</td>
<td>1 2 3 4 untypeable</td>
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<tr>
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<td>(if obtained)</td>
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<td>APRI Score</td>
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<td>FIB-4 Score</td>
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</table>

#### Requested Treatment:

- Triple therapy (genotype 1 only): peginterferon + ribavirin + protease inhibitor
- Dual therapy: peginterferon + ribavirin

#### Prior Treatment for HCV:

- No
- Yes If yes, answer the following:

<table>
<thead>
<tr>
<th>Drug Name and Dosages</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Reason Discontinued</th>
</tr>
</thead>
</table>

#### Medical Clearance (check all that apply)

- Informed consent obtained
- Sufficient time left on sentence to complete treatment
- No evidence of ongoing participation in high-risk behavior (e.g., injection drug use, tattooing)
- Compliant with pretreatment workup and pretreatment workup complete
- No evidence of decompensated cirrhosis (ascites, esophageal varices, jaundice, encephalopathy)
- No contraindications to protease inhibitor
- No contraindications to peginterferon
- No contraindications to ribavirin
- No contraindications to other drugs
- HIV viral load undetectable and CD4 ≥ 350
- Physical exam performed in last 12 months
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</table>

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantatite
3. Clinical evaluations should be scheduled monthly during treatment and every 6 weeks after treatment is stopped for childbearing potential.
4. OTC = Over-the-counter
5. CMP = Complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
6. Obtain if diabetes is present, or as clinically indicated.
7. Obtain if over 40, preexisting cardiac disease is present, or as clinically indicated.
8. Obtain for diabetes, patients with a history of ophthalmologic disease, hypertension, dyslipidemia, and older patients (age > 55 years)
## Monitoring Schedule for DUAL THERAPY with Peginterferon and Ribavirin – 24 WEEK SCHEDULE

<table>
<thead>
<tr>
<th>Test</th>
<th>Week</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>Date</td>
<td>Clinical Evaluation</td>
<td>Monthly while on therapy</td>
</tr>
<tr>
<td></td>
<td>HCV genotype</td>
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<tr>
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<td>HCV RNA PCR</td>
<td>12 and 24 weeks post treatment</td>
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<td></td>
<td>Urine Pregnancy Test</td>
<td>Monthly x 6 months after treatment is stopped</td>
</tr>
<tr>
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<td>CBC with diff</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CMP</td>
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<tr>
<td></td>
<td>TSH</td>
<td>Monthly post treatment, as clinically indicated</td>
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<tr>
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<td>PT/INR</td>
<td>Monthly post treatment, as clinically indicated</td>
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<tr>
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<td>Medication Adherence</td>
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<td>Weight</td>
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<tr>
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<td>A1C</td>
<td>Monthly post treatment, as clinically indicated for diabetic patients</td>
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<tr>
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<td>HIV</td>
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<td>Anti-HBs, HBc, HBsAg, anti-HAV</td>
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<td>EKG</td>
<td>Monthly x 6 months after treatment is stopped, if over 40, pre-existing cardiac disease is present, or as clinically indicated</td>
</tr>
<tr>
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<td>Chest x-ray</td>
<td>Monthly x 6 months after treatment is stopped, if over 40, pre-existing cardiac disease is present, or as clinically indicated</td>
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<tr>
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<td>Antinuclear antibody (ANA)</td>
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<td>Ferritin, Serum iron, TIBC</td>
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<td>Alpha-fetoprotein (AFP)</td>
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<td>Visual acuity</td>
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<td>Funduscopic exam</td>
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<td>Liver imaging studies</td>
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</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. Urine pregnancy test = Females should be tested monthly during treatment and during the 6 months after treatment is stopped if of childbearing potential
4. CBC = Complete blood count with differential
5. CMP = Complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
6. Obtain for diabetic patients
7. EKG and Chest x-ray obtained if over 40, pre-existing cardiac disease is present, or as clinically indicated.
8. Perform in patients at higher risk for retinopathy including patients with history of ophthalmological disorders, hypertension, diabetes, and older patients (age > 50 years).
| Week of Treatment | Date | Clinical Evaluation | HCV genotype | HCV RNA PCR | HCV Frequency Test | CBC w/ diff | CMP | TSH | PT/INR | Medication Adherence | Weight | LFT | A1C | HIV | Anti-HBsAb, anti-HBc, anti-HAV | HBsAg | Anti-HAV | EKG | Chest x-ray | Antinuclear antibody (ANA) | Ferritin, Serum iron, TIBC | Alpha-fetoprotein (AFP) | Alpha-1 antitrypsin | Ceruloplasmin | Visual acuity | Funduscopic exam | Liver imaging studies | As clinically indicated |
|-------------------|------|---------------------|--------------|-------------|-------------------|--------------|-----|-----|------|--------|---------------------|-------|-----|-----|-----|--------------------------|--------|----------------|------|-----------|----------------|--------------------------|----------------|------------------------|------------------------|-----------------------|------------------------|-----------------|----------------|-----------------|-------------------|
| Base-line         |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 2                 |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 4                 |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 8                 |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 12                |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 20                |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 32                |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 40                |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| 48                |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |
| Post Treatment    |      | √                   |              |             |                   |              |     |     |      |        |                     |       |     |     |     |                          |        |                |      |           |                |                          |                |                        |                        |                       |                        |                 |               |                 |                   |

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
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, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
6. Obtain for diabetic patients
7. Obtain if over 40, preexisting cardiac disease is present, or as clinically indicated.
8. Perform in patients at higher risk for retinopathy including patients with history of ophthalmologic disorder, hypotension, diabetic retinopathy, or age > 50 years.
<table>
<thead>
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<tbody>
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1. Clinical evaluations should be scheduled a few days after laboratory results can be expected to be available.
2. HCV RNA PCR quantitative.
3. Urine pregnancy test = Females should be tested monthly during treatment and during the 6 months after treatment if childbearing potential.
4. CBC = Complete blood count with differential.
5. CMP = Complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, sodium, potassium, chloride, creatinine, calcium, carbon dioxide, phosphorus, magnesium, protein, BUN.
6. Obtain for diabetic patients.
7. Obtain if over 40, preexisting cardiac disease is present, or as clinically indicated.
8. Obtain if over 40 years and/or normal albumin is present or as clinically indicated.
9. Perform in patients at higher risk for retinopathy including patients with history of ophthalmologic disease, hypertension, diabetes, and older patients (age > 50 years).
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<p>| Week of Treatment | Date | Clinical Evaluation(^1) | telaprevir | HCV RNA PCR | Urine Pregnancy Test(^3) | HCV genotype | HCV RNA PCR quantitative | Monthly while on therapy | Monthly x 6 months | CPT | Monthly x 6 months | Medication Adherence | Weight | A1C(^6) | Lipid Profile | Anti-HBsAB, anti-HBc Ab, HBsAg, anti-HAV | Liver Imaging Studies | as clinically indicated | as clinically indicated | Liver Imaging Studies | as clinically indicated |
|-------------------|------|---------------------------|------------|-------------|--------------------------|--------------|--------------------------|-------------------------|------------------------|-----|---------------------|---------------------|--------|----------|---------------|---------------------|------------------|------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| 1                 |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 2                 |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 3                 |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 4                 |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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| 11                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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| 38                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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| 40                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 41                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 42                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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| 44                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
| 45                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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| 47                |      |                           |            |             |                          |              |                          |                          |                        |     |                     |                     |        |          |               |                     |                  |                        |                        |                        |                        |                        |
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1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
3. Monthly while on therapy
4. Monthly x 6 months
5. Monthly x 6 months
6. Monthly x 6 months
7. Monthly x 6 months
8. As clinically indicated

A1C: Hemoglobin A1C
BGG: Beta globulin
HCV: Hepatitis C virus
INR: International normalized ratio
PT: Prothrombin time
RBV: Ribavirin
Telaprevir
TSH: Thyroid-stimulating hormone
UA: Urine analysis
INR: International normalized ratio
HIV DISEASE MANAGEMENT

Initial evaluation of HIV+ patients:
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 GC/chlamydia tests. Perform pelvic exam every 6 months for HIV+ female patients.
3) Obtain baseline laboratories:
   a. CBC with differential, chemistry, LFTs, lipid profile, chronic hepatitis serology (Hepatitis C-anti-HCV, Hepatitis B – HBsAg, anti-HBc total, anti-HBs and Hepatitis A – anti-HAV total).
   b. CD4 count, HIV RNA viral load, PPD skin test, varicella-zoster titers, fasting blood glucose. Chest x-ray if pulmonary symptoms present or PPD is positive.
4) Obtain resistance testing if HIV RNA > 1,000 copies/mL.
5) 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, VL > 4000, certain diseases (diabetes, HTN, hepatitis C co-infection), & concomitant use of nephrotoxic agents. If i+ proteinuria or calculated GFR < 60, consider further evaluation. If normal & high risk based on risk factors, re-assess and recheck annually.
6) Classify patient according to the 1993 CDC Revised Classification System for HIV Infection & record on the Master Problem List and PULHES periodically thereafter as conditions change. Classification should be based upon the patient’s lowest CD4 count (see box A, page 3).
7) Update vaccines: influenza vaccine annually, pneumococcal vaccine with single revaccination 5 years after the first dose, and hepatitis B & A vaccine if not already immune.
8) Initiate prophylactic medication(s) for opportunistic infection(s) as indicated in box B & C, pages 3 & 4.
9) Refer to dental for oral/periodontal evaluation within 30 days from initial chronic care visit.

Follow-up for HIV+ Patients:
1) Evaluate in chronic care clinic at least every 6 months.
2) Refer patients with CD4 counts < 350 cells/mm3 to Infectious Disease Specialist/Clinic or designated physician (Texas Tech Units) for evaluation (may be done by telemedicine/DMS). Expedited referrals should be obtained for patients that are symptomatic or meet criteria in Box #3. If patient refuses, contact an Infectious Disease Specialist or designated physician (Texas Tech Units) for drug therapy and ITP recommendations.
3) Refer patients CD4 count < 100 cells/mm3 to Infectious Disease Ophthalmologist/Clinic for a retinal examination to rule out HIV retinopathy & CMV retinitis.
4) Laboratories: HIV RNA viral load & CD4 count every 3-6 months. Obtain LFTs, lipid profile, CBC with differential, chemistry, fasting glucose, & urinalysis yearly.
5) Consider discontinuing prophylactic medication(s) for opportunistic infection(s) as indicated in box B&C, pages 3-4.

1. Discuss pros & cons of drug therapy, adherence, resistance, administration, possible adverse effects & management.
2. If patient committed, begin HAART. Consider follow up in 2 weeks to assess medication tolerance. Return to clinic in 1 month.
3. If patient poor candidate for drug therapy and/or does not want to start therapy, return to clinic every 3-4 months for follow-up.
4. Offer drug therapy.
5. Patient CD4 count < 350 cells/mm3, symptomatic, pregnant, HIV-associated nephropathy, or hepatitis B co-infection when HBV treatment is indicated?
   a. Yes
   b. No

5. Yes
   1. Offer drug therapy.
   2. Patient CD4 count < 350 cells/mm3, symptomatic, pregnant, HIV-associated nephropathy, or hepatitis B co-infection when HBV treatment is indicated?
   a. Yes
   b. No
   c. CD4 count 350 to 500 cells/mm3?
   d. Yes
   e. No
   f. CD4 count > 500 cells/mm3?
   g. Yes
   h. No

5. No
   1. Consider drug therapy
   2. CD4 count 350 to 500 cells/mm3?
   a. Yes
   b. No

6. Go to box #10 on page 2

7. CD4 count > 500 cells/mm3?
   a. Yes
   b. No

8. Do not begin therapy.
   a. Monitor patient, return to clinic at least every 6 months.
   b. Obtain CD4 count and viral load every 3-6 months.
   c. Go to box #3 when patient parameters change.
HIV

Page 2

1. Is adherence for each drug ≥ 85%?

2. Obtain viral load.

3. When adherence < 85% for 2 consecutive months:
   1. Whenever possible, refer patient to clinical pharmacist for adherence counseling and education.
   2. Obtain expedited referral for evaluation by Infectious Disease Specialist/Clinic or designated physician (Texas Tech Units) to determine subsequent management.
   3. Consideration may be given to discontinuing therapy, in patients that do not want to continue therapy.
   4. Return to clinic in 1 month.

5. Verify administration is correctly documented on the computer:
   1. Counsel patient regarding importance of adherence.
   2. Identify & treat adverse effects.
   3. Return to clinic in 1 month.
   4. Obtain viral load.

6. Is adherence for each drug ≥ 85%? Reinforce education. Return to clinic 1 month.

7. If adherence < 85% continue drug therapy:
   1. Return to clinic at least q 3-4 months.
   2. Obtain CD4 count q 3-6 months & viral load q 3-6 months.
   3. Reinforce education at each visit.
   4. Goal of therapy is 10 fold (1 log) decrease in viral load at 8 weeks, nondetectable viral load at 4-6 months after starting drug therapy, & increased CD4 count.
   5. Obtain expedited referral to Infectious Disease Specialist/Clinic or designated physician (Texas Tech Units) to consider change in drug therapy if:
      a) Goal viral load (nondetectable) not achieved within 4-6 months after starting drug therapy.
      b) Re-appearance of viremia after viral load is nondetectable (confirmed by at least 2 tests 4 weeks apart).
      c) Increase in viral load ≥ 3 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
   6. UTMB Sector – Obtain resistance test prior to referral to Infectious Disease Specialist if referred for change in therapy.

---

10. Is adherence for each drug ≥ 85%?

12. Verify that administration is correctly documented on the computer:
   1. Counsel patient regarding importance of adherence.
   2. Identify & treat adverse effects.
   3. Return to clinic in 1 month.


16. Is adherence for each drug ≥ 85%?

18. Is adherence for each drug ≥ 85%?

20. Has viral load decreased > 10 fold (1 log)?

22. Repeat viral load in 1 month

24. Has viral load decreased > 10 fold (1 log)?

---

1. Refer patient to Infectious Disease Specialist/Clinic to evaluate patient for poor adherence, intolerance, versus resistance & to consider changing drug therapy.
2. UTMB Sector – Obtain resistance test prior to referral to Infectious Disease Specialist if referred for change in therapy.
3. Return to clinic at least q 3-4 months.
4. Obtain CD4 count and viral load q 3-6 months.
5. Reinforce education at each visit.
**Box A: 1993 CDC Revised Classification System for HIV Infection and Expanded AIDS Surveillance**

**Case Definition for Adolescents and Adults***

<table>
<thead>
<tr>
<th>Clinical Categories</th>
<th>CD4+ T-Cell Categories</th>
<th>(A) Asymptomatic, acute (primary) HIV infection, or persistent generalized lymphadenopathy</th>
<th>(B) Symptomatic, not A or C conditions</th>
<th>(C) AIDS indicator conditions***</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 500 cells/mm³ or ≥ 20%***</td>
<td>A1</td>
<td>B1</td>
<td>C1</td>
<td></td>
</tr>
<tr>
<td>200-499 cells/mm³ or 14-29%***</td>
<td>A2</td>
<td>B2</td>
<td>C2</td>
<td></td>
</tr>
<tr>
<td>&lt; 200 cells/mm³ or 14%***</td>
<td>A3</td>
<td>B3</td>
<td>C3</td>
<td></td>
</tr>
</tbody>
</table>

*patients with AIDS indicator conditions (C1, C2, C3) and CD4 counts < 200 (A3 or B3) are reported as AIDS cases

**CD4% of total lymphocyte count

***candidiasis, coccidioidomycosis, cryptococcosis, cryptosporidiosis, CMV, histoplasmosis, MAC, PCP, toxoplasmosis, wasting due to HIV, HIV encephalopathy, Kaposi’s sarcoma, etc.

---

**Box B: Primary Prophylaxis of Opportunistic Infections**

<table>
<thead>
<tr>
<th>Organism</th>
<th>Initiate based on CD4 count</th>
<th>Recommended Regimen</th>
<th>Alternative Regimen</th>
<th>Discontinuation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. tuberculosis</td>
<td>All (regardless of CD4 count)</td>
<td>INH 5mg/kg/day max 300mg or 300mg 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</td>
<td>All (regardless of CD4 count)</td>
<td>Pneumococcal vaccine (repeat one time only in 5 years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza virus</td>
<td>All (regardless of CD4 count)</td>
<td>Influenza vaccine (one dose annually)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis A virus</td>
<td>All (regardless of CD4 count)</td>
<td>Hepatitis A vaccine (2 dose series)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B virus</td>
<td>All (regardless of CD4 count)</td>
<td>Hepatitis B vaccine (3 dose series)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumocystis jirovecii</td>
<td>&lt; 200***</td>
<td>TMP-SMX DS qd, Men-Fri, or three times a week</td>
<td>Dapsone 100mg qd or Pentamidine aerosolized 300mg q month</td>
<td>1. CD4 count &gt; 200 for &gt; 3 months (restart if CD4 count &lt; 200)</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
<td>&lt; 100***</td>
<td>TMP-SMX DS qd</td>
<td>Dapsone 100mg qd + pyrimethamine 50mg q week + leucovorin 25mg q week</td>
<td>1. CD4 count &gt; 200 for &gt; 3 months (restart if CD4 count &lt; 100-200)</td>
</tr>
<tr>
<td>M. avium complex</td>
<td>&lt; 50</td>
<td>Azithromycin 1200 mg q week</td>
<td>Clarithromycin 500mg bid or rifabutin 300mg qd</td>
<td>1. CD4 count &gt; 100 for &gt; 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

***if also antibody positive

****primary prophylaxis for CMV and deep fungal infections is generally not recommended

*****all susceptible patients

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.

Approved 9/96, revised 2/03, revised 6/97, 6/99, 3/00, 7/02, 2/03, 12/04, 5/06, 3/07, 8/08, 7/10

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### Box C: 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 DS qd</td>
<td>TMP-SMX DS Mon-Fri, Dapsone 100mg qd or Pentamidine aerosolized 100mg q month</td>
<td>CD4 count = 200 for ≥ 3 months (restart if CD4 count &lt; 200 or PCP recurrence)</td>
</tr>
<tr>
<td>Prior toxoplasmic encephalitis</td>
<td>Toxoplasma gondii</td>
<td>SulfaFansine 100-400mg mg po qd + Pyrimethamine 25-50mg po qd + Leucovorin 10-25mg po qd</td>
<td>Trimethoprim 160mg po qd + Fantrike 5mg po qd or Pentamidine aerosolized 100mg q month</td>
<td>CD4 count = 200 &amp; viral load undetectable &gt; 6 months* (restart if CD4 count &lt; 200)</td>
</tr>
<tr>
<td>Prior disseminated disease</td>
<td>Mycobacterium avium complex</td>
<td>Clarithromycin 500mg po bid + Ethambutol 15mg/kg po qd +/- Rifabutin 300mg po qd</td>
<td>Azithromycin 500mg po qd + Ethambutol 15mg/kg po qd +/- Rifabutin 300mg po qd</td>
<td>CD4 count &gt; 100 for ≥ 6 months* (restart if CD4 count &lt; 100)</td>
</tr>
<tr>
<td>Prior end-organ disease</td>
<td>Cytomegalovirus (CMV)</td>
<td>Ganciclovir 5-6 mg/kg/day IV 5-7 days a week or for retinitis ganciclovir 1gm po TID + SR implant q 6-9 months</td>
<td>Foscarnet IV 90mg/kg/day, Ciidofovir 5mg/kg IV q 2 weeks, or Valganciclovir 900mg po qd</td>
<td>CD4 count &gt; 100 for ≥ 6 months** (restart if CD4 count &lt; 100)</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Cryptococcus neoformans</td>
<td>Fluconazole 200mg po qd</td>
<td>Itracazole 200mg po qd, or Amphotericin 0.6-1mg/kg IV weekly + 3 times weekly</td>
<td>CD4 count ≥ 200 for ≥ 6 months* (restart if CD4 count &lt; 200)</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Histoplasma capsulatum</td>
<td>Itraconazole 200mg po bid</td>
<td>Amphotericin 1mg/kg IV weekly or Fluconazole 800mg qd</td>
<td>Negative blood culture, CD4 count &gt; 150 for ≥ 6 months* (restart CD4 count ≥ 150)</td>
</tr>
<tr>
<td>Prior disease</td>
<td>Coccidioides immitis</td>
<td>Fluconazole 400mg po qd</td>
<td>Itracazole 200mg po bid or Amphotericin 1mg/kg IV weekly</td>
<td></td>
</tr>
<tr>
<td>Bacteremia</td>
<td>Salmonella species</td>
<td>Ciprofloxacin 500mg po bid x several months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequent severe recurrences</td>
<td>Herpes simplex virus***</td>
<td>Acyclovir 400mg po bid</td>
<td>Valacyclovir 500mg po bid or Famciclovir 250mg bid</td>
<td></td>
</tr>
<tr>
<td>Frequent severe recurrences</td>
<td>Candida*** (oropharyngeal, vulvovaginal, esophageal)</td>
<td>Fluconazole 100-200mg po qd</td>
<td>Itraconazole 200mg po qd</td>
<td></td>
</tr>
</tbody>
</table>

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* if completed ≥ 12 months of treatment asymptomatic
** if initial treatment completed, asymptomatic, & regular ophthalmology exams
*** recommended only if subsequent episodes are frequent or severe

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.


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**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/risk 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 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. Recorded in medical record as allergy. Lactic acidosis with hepatic steatosis.</td>
<td></td>
</tr>
<tr>
<td>Didanosine EC (ddI, Videx EC®)</td>
<td>80mg 400mg QD or 160mg 230mg QD</td>
<td>Tenovir, methadone</td>
<td>Peripheral neuropathy, pancreatitis, nausea, diarrhea. Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Lamivudine (3TC, Epivir®)</td>
<td>150mg BID or 300mg QD</td>
<td>Didanosine, methadone</td>
<td>Peripheral neuropathy, hyperpigmentation of palms &amp; soles. Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Emtricitabine (FTC, Emtriva®)</td>
<td>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>Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Stavudine (d4T, Zerit®)</td>
<td>&gt; 60kg 40mg BID or 60kg 30mg BID</td>
<td>Nausea, vomiting, diarrhea, headache, hyperpigmentation of palms &amp; soles. Lactic acidosis with hepatic steatosis.</td>
<td></td>
</tr>
<tr>
<td>Zalcitabine (ddC, Hivid®)</td>
<td>0.75mg TID</td>
<td></td>
<td>Peripheral neuropathy, stomatitis. Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Zidovudine (AZT, ZDV, Retrovir®)</td>
<td>500mg BID</td>
<td></td>
<td>Initial GI upset, headache, nae, stomatitis, fatigue, anemia, neutropenia, myopathy. Lactic acidosis with hepatic steatosis.</td>
</tr>
<tr>
<td>Tenofovir** (TDF, Viread®)</td>
<td>300mg QD best if taken with food</td>
<td>Didanosine, emtricitabine</td>
<td>Gl upset, flu-like symptoms, headache, anemia, renal insufficiency. Lactic acidosis with hepatic steatosis.</td>
</tr>
</tbody>
</table>

*Not a complete list of drug interactions or adverse effects
**Nucleotide reverse transcriptase inhibitor (NtRTI)
HD=hemodialysis

**Table 1: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)**
### Table 2: Combination Products

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epzicom®  (lamivudine 300mg &amp; abacavir 600mg)</td>
<td>1 tablet QD</td>
<td>Do not use if CrCl &lt; 50</td>
<td>Same as single entity drugs</td>
</tr>
<tr>
<td>Truvada®  (emtricitabine 200mg &amp; tenofovir 300mg)</td>
<td>1 tablet QD</td>
<td>CrCl &lt; 50: 1 tab q 48hr; &lt; 30: do not use</td>
<td>Same as single entity drugs</td>
</tr>
<tr>
<td>Atripla®  (Emtricitabine 200mg, tenofovir 300mg &amp; efavirenz 600mg)</td>
<td>1 tablet QD</td>
<td>Do not use if CrCl &lt; 50</td>
<td>Same as single entity drugs</td>
</tr>
</tbody>
</table>

### Table 3: Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions</th>
<th>Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delavirdine (DLV, Rescriptor®)</td>
<td>400mg TID</td>
<td>Lovastatin, rifampin, rifapentine, rifabutin, 3-H-2 antagonists (ranitidine), proton pump inhibitors (omeprazole), stomach ulcers, dapsone, phenytoin, warfarin, carbamazepine, quinidine, clarithromycin</td>
<td>Rash, elevated LFTs, headache</td>
</tr>
<tr>
<td>Efavirenz (EFV, Sustiva®)</td>
<td>600mg q HS best if taken on empty stomach</td>
<td>Rifampin, rifabutin, rifapentine, ergotamine, clarithromycin</td>
<td>Rash, CNS symptoms (e.g., dizziness, insomnia, vivid dreams), elevated LFTs, false positive cannabinoid test, avoid in pregnancy</td>
</tr>
<tr>
<td>Etravirine (Intelence®)</td>
<td>200mg BID best if taken with food</td>
<td>Phenytoin, carbamazepine, other NNRTIs, P450 inhibitors (except DRV/RTV, SQV/RTV, and LPV/RTV with caution), clarithromycin, rifampin, warfarin</td>
<td>Rash, nausea</td>
</tr>
<tr>
<td>Nevirapine (NVP, Viramune®)</td>
<td>200mg QD x 14 days then 200mg BID or 400mg QD</td>
<td>Ketoconazole, rifampin, phenytoin, carbamazepine</td>
<td>Rash, elevated LFTs, hepatitis</td>
</tr>
</tbody>
</table>

### Table 4: Fusion Inhibitors

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions</th>
<th>Adverse Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enfuvirtide (Fuzeon®)</td>
<td>90mg SQ BID</td>
<td>Local injection site reaction (e.g., pain, erythema, induration, nodules, cysts), increased rate of pneumonia, hypersensitivity reaction (rechallenge is not recommended)</td>
<td></td>
</tr>
</tbody>
</table>

*not a complete list of drug interactions or adverse effects*
<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage*</th>
<th>Drug Interactions**</th>
<th>Adverse Effects**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atazanavir</td>
<td>400mg QD (boosted with food or Tenofovir or RTV)</td>
<td>Clarithromycin, diltiazem, rifabutin, rifampin, ergotamine, 2D-aryoamine (nonsteroid), potency, pufung inhibition (comparitive), efavirenz, tenofovir</td>
<td>Diarrhea, nausea, prolongation of the QT interval, hypertriglyceridemia, jaundice, hypophosphatemia, severe bleeding in hemophilia</td>
</tr>
<tr>
<td></td>
<td>Boosted or With Tenofovir or RTV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 400 – RTV 100 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Darunavir</td>
<td>Treatment Naive patient</td>
<td>Clarithromycin, rifabutin, rifampin, ergotamine</td>
<td>Diarrhea, nausea, vomiting, rash</td>
</tr>
<tr>
<td></td>
<td>boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DRV 800 – RTV 100 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DRV 300 + RTV 100 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Boosted or With Tenofovir or RTV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 300 – RTV 100 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EFV 800 + RTV 100 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fosamprenavir</td>
<td>1000mg BID</td>
<td>Levcarnitine, rifabutin, rifampin, ergotamine</td>
<td>Diarrhea, nausea, vomiting, rash</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3APV 400 – RTV 100-200 QD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>With EFV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3APV 700 – 100 BID</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3APV 400 – 300 BID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indinavir</td>
<td>800mg q 8 hr drink plenty of fluids, boost if nausea at night, dil the 5 hr</td>
<td>Levcarnitine, rifabutin, rifampin, ergotamine</td>
<td>Diarrhea, nausea, vomiting, rash</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 100-200 q 12 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lopinavir/Ritonavir</td>
<td>1200mg BID (must be taken with meal or snack)</td>
<td>Levcarnitine, rifabutin, rifampin, ergotamine</td>
<td>Diarrhea, nausea, vomiting, rash</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 800 – RTV 100-200 q 12 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>1250mg BID</td>
<td>Levcarnitine, rifabutin, rifampin, ergotamine</td>
<td>Nausea, vomiting, diarrhea, anorexia, elevated LFTs</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 100-200 q 12 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ritonavir</td>
<td>600mg q 12 hr food may decrease GI upset; separate from ddI by at least 2 hrs</td>
<td>Levcarnitine, amiodarone, quinidine, clozapine, rifabutin, rifampin, ergotamine, desipramine, theophylline</td>
<td>Nausea, vomiting, diarrhea, pancreatitis, paronychia, rash or painful erythema, elevated LFTs</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ATV 100-200 q 12 hr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saquinavir</td>
<td>1200mg TID boosted (boosted with a large meal)</td>
<td>Levcarnitine, rifabutin, rifampin, ergotamine</td>
<td>Nausea, vomiting, diarrhea, rash, elevated LFTs</td>
</tr>
<tr>
<td></td>
<td>Boosted</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SQV 1000 – RTV 100 BID</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tipranavir</td>
<td>500mg + RTV 200mg BID</td>
<td>Levcarnitine, amiodarone, quinidine, ergotamine, fluticasone</td>
<td>Hypophosphatemia, rash, hypothyroid anemia</td>
</tr>
<tr>
<td></td>
<td>Boosted or Given with RTV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Best if taken with food; separate from ddI by at least 2 hrs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Dosage if used as the only PI in the drug regimen, dosages are often reduced if used in combination with other agents
**Not a complete list of drug interactions or adverse effects

Table 5: Protease Inhibitors (Pis)
### Table 6: CCR5 Antagonist

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions</th>
<th>Adverse Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maraviroc (Selzentry®)</td>
<td>Tropism testing is required before use</td>
<td>Potent CYP3A inhibitors such as protease inhibitors, delavirdine, iraconazole, ketoconazole, clarithromycin</td>
<td>Abdominal pain, cough, dizziness, musculoskeletal symptoms, pyrexia, rash, upper respiratory track infections, hepatotoxicity, orthostasis</td>
</tr>
<tr>
<td>Nonformulary</td>
<td>150mg BID</td>
<td>With Protease Inhibitors except for tipranavir, delavirdine, indinavir, saquinavir, ritonavir, fosamprenavir, saquinavir-soft</td>
<td>Potent CYP3A inducers such as efavirenz, rifampin, carbamazepine, phenytoin</td>
</tr>
<tr>
<td></td>
<td>300mg BID</td>
<td>NRTI, EFV, TPV, NVP, ALL Included</td>
<td></td>
</tr>
<tr>
<td></td>
<td>600mg BID</td>
<td>With EFV, rifampin</td>
<td></td>
</tr>
</tbody>
</table>

*not a complete list of drug interactions or adverse effects

### Table 7: Integrase Inhibitors

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosage</th>
<th>Drug Interactions</th>
<th>Adverse Effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir (Isentress®)</td>
<td>400mg BID</td>
<td>rifampin</td>
<td>Nausea, headache, diarrhea, pyrexia, fatigue, elevated CPK</td>
</tr>
<tr>
<td></td>
<td>800mg BID</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*not a complete list of drug interactions or adverse effects

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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. Etiology
A. HIV (human immunodeficiency virus)
   1. Member of the Lentinus family of retroviruses.
   2. There are two serotypes: HIV-1 and HIV-2. HIV-1 is the primary serotype in the U.S. HIV-2 is the primary serotype in Africa and is molecularly and serologically distinct. The two serotypes 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
B. Parenteral
   1. Occupational exposure - needle sticks
   2. Intravenous drug user - sharing contaminated needles
   3. Blood transfusion
   4. Organ transplant
C. Sexual
   1. Vaginal intercourse
   2. Anal intercourse
   3. Oral intercourse
D. Perinatal

IV. Presentation
A. Early
   1. Symptoms: fever, lymphadenopathy, pharyngitis, rash, myalgia, arthralgia, diarrhea, headache, nausea, vomiting, hepatosplenomegaly, 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 setpoint = 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 setpoint
      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, rashes, neuropathy, diarreha, 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. HIV antibody testing (if prior documentation unavailable or viral load is undetectable)
   1. Detects antibodies against HIV-1
   2. Median time to develop antibodies is 2 months after initial exposure; > 95% seroconvert within 6 months
   3. False positives: multiparous, recent influenza or hepatitis B vaccine, multiple blood transfusions, hemato logic malignancy, chronic hemodialysis patients, autoimmune disorders such as SLE
   4. False negatives: newly infected & performed prior to antibody production, immunosuppressive therapy, bone marrow transplantation
B. Viral load
   1. Diagnosis of acute HIV can be made by obtaining a quantitative HIV RNA PCR (viral load test)
   2. Infection must ultimately be confirmed with an HIV antibody test
VI. Treatment
A. Table 8: Indication for drug therapy*

<table>
<thead>
<tr>
<th>Clinical Category</th>
<th>CD4 Count</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS-defining illness</td>
<td>Any value</td>
<td>Treat</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Any value</td>
<td>Treat</td>
</tr>
<tr>
<td>HIV nephropathy</td>
<td>Any value</td>
<td>Treat</td>
</tr>
<tr>
<td>Hepatitis B co-infected</td>
<td>Any value</td>
<td>Treat when HBV treatment is indicated</td>
</tr>
<tr>
<td>Asymptomatic &lt; 350 cells/mm³</td>
<td>Treat</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic 350 to 500 cells/mm³</td>
<td>Consider treatment</td>
<td></td>
</tr>
<tr>
<td>Asymptomatic &gt; 500 cells/mm³</td>
<td>Treatment generally deferred but may consider</td>
<td></td>
</tr>
</tbody>
</table>

B. Table 9: Recommended Initial Regimen for Treatment Naïve Patients*

<table>
<thead>
<tr>
<th>Initial Regimen</th>
<th>Option for New Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>NNRTI based</td>
<td>Efavirenz + Tenofovir + Emtricitabine (as triple combination)</td>
</tr>
<tr>
<td>PI based</td>
<td>Atazanavir + Ritonavir QD + (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td></td>
<td>Darunavir + Ritonavir QD + (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td>INSTI based</td>
<td>Raltegravir + (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Lopinavir/ritonavir BID + Zidovudine + Lamivudine</td>
</tr>
</tbody>
</table>

C. Table 10: Alternative Regimens*

<table>
<thead>
<tr>
<th>Initial Regimen</th>
<th>Option for New Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRTI based</td>
<td>Efavirenz + Zidovudine + Emtricitabine</td>
</tr>
<tr>
<td></td>
<td>Efavirenz + Abacavir + Emtricitabine</td>
</tr>
<tr>
<td></td>
<td>Nevirapine + Zidovudine + Emtricitabine</td>
</tr>
<tr>
<td>PI based</td>
<td>Atazanavir + Ritonavir + Zidovudine + Emtricitabine</td>
</tr>
<tr>
<td></td>
<td>Atazanavir + Ritonavir + Abacavir + Emtricitabine</td>
</tr>
<tr>
<td></td>
<td>Fosamprenavir + Ritonavir + (Zidovudine + Emtricitabine) or (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td></td>
<td>Fosamprenavir + Ritonavir + (Abacavir + Emtricitabine) or (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td></td>
<td>Lopinavir/ritonavir + (Zidovudine + Emtricitabine) or (Tenofovir/Emtricitabine)</td>
</tr>
<tr>
<td></td>
<td>Lopinavir/ritonavir + (Abacavir + Emtricitabine) or (Tenofovir/Emtricitabine)</td>
</tr>
</tbody>
</table>

*adapted from Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.
C. Regimens that should not be used

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monotherapy</td>
<td>Lack of potency &amp; sustained efficacy, rapid development of resistance</td>
</tr>
<tr>
<td>Dual nucleosides</td>
<td></td>
</tr>
<tr>
<td>(Abacavir + Tenofovir + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>(Abacavir + Zidovudine + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>(Didanosine + Tenofovir + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>Triple nucleosides</td>
<td>Higher rate of early virologic failure compared to triple drug regimens, resistance</td>
</tr>
<tr>
<td>(Abacavir + Tenofovir + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>(Abacavir + Zidovudine + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>(Didanosine + Tenofovir + Lamivudine)</td>
<td></td>
</tr>
<tr>
<td>Quadruple nucleoside</td>
<td>Inferior virologic efficacy</td>
</tr>
<tr>
<td>(Abacavir + Lamivudine + Zidovudine + Tenofovir)</td>
<td></td>
</tr>
</tbody>
</table>

D. Combinations or Agents that should not be used

<table>
<thead>
<tr>
<th>Combination</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amprenavir + Fosamprenavir</td>
<td>Fosamprenavir is the prodrug of amprenavir. There is a possibility of toxicity without therapeutic benefit.</td>
</tr>
<tr>
<td>Atazanavir + Indinavir</td>
<td>Additive toxicity especially hyperbilirubinemia and jaundice</td>
</tr>
<tr>
<td>Didanosine + Stavudine</td>
<td>Additive toxicity especially neuropathy, pancreatitis, and lactic acidosis.</td>
</tr>
<tr>
<td>Didanosine + tenofovir</td>
<td>High rate of early virologic failure and rapid selection of resistance</td>
</tr>
<tr>
<td>Didanosine + Zalcitabine</td>
<td>Additive toxicity especially neuropathy</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>First trimester of pregnancy, avoid throughout pregnancy</td>
</tr>
<tr>
<td>Stavudine + Zalcitabine</td>
<td>Additive toxicity especially neuropathy</td>
</tr>
<tr>
<td>Stavudine + Zidovudine</td>
<td>Decreased antiviral activity, antagonistic</td>
</tr>
<tr>
<td>Lamivudine + Zalcitabine</td>
<td>Decreased antiviral activity</td>
</tr>
<tr>
<td>Lamivudine + Emtricitabine</td>
<td>Same resistance profile and no benefit</td>
</tr>
<tr>
<td>Unboosted darunavir, saquinavir or tipranavir</td>
<td>Virologic benefit only demonstrated when boosted with ritonavir.</td>
</tr>
<tr>
<td>Nevirapine initiation in females with CD4 &gt; 250 or males with CD4 &gt; 400</td>
<td>Higher incidence of hepatic events, some fatal.</td>
</tr>
</tbody>
</table>
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 antiretroviral therapy and 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 3-6 months.
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 3-6 months thereafter.
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 – 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. Co-receptor tropism assay – 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 (i.e., VL > 400 after 24 weeks of therapy or > 75 after 48 weeks of therapy).
   b. Virologic rebound after suppression. Repeated detectable viral load after prior suppression. 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.

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**

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 secondary causes due to diabetes mellitus, hypothyroidism, chronic kidney disease, or drugs (e.g., progestins, anabolic steroids, corticosteroids, antihypertensives)
   - Baseline laboratory testing: Fasting function tests, lipid profile (testing using triglycerides), comprehensive metabolic panel

2. Does the patient fall into one of the following groups?
   - Clinical ASCVD** or
   - Low-density lipoprotein (LDL) ≥ 190 and ≥ 21yo

3. Calculate estimated 10 year ASCVD risk (calculator on CMC webpage and additional information page 6).

4. Does the patient have diabetes, LDL 70-189 mg/dL, and age 40 – 75 years?

5. If the patient has a 10 yr ASCVD risk < 7.5%; age < 40 or > 75 years and LDL < 190 mg/dL; or diabetes and age < 40 or > 75 years or LDL < 70 mg/dL:
   - ASCVD prevention benefit of statin therapy is less clear. Consider additional factors influencing ASCVD risk and potential ASCVD risk reduction benefits, adverse effects, and drug-drug interactions for statin treatment.
   - If unclear, consider factors influencing risk including primary LDL > 160mg/dL or other evidence of genetic hyperlipidemias, family history of premature ASCVD with onset < 55 years in a first degree relative, high sensitivity C-reactive protein ≥ 2 mg/L, ankle brachial index < 0.9, or elevated lifetime risk of ASCVD.

6. If a statin is not initiated:
   - A fasting lipid profile should be obtained as clinically indicated or every 5 years
   - Recalculate estimated 10 year ASCVD risk every 5 years in individuals aged 60-75 years

---

*Clinical ASCVD defined as: ACS, or a history of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PAD presumed to be of atherosclerotic origin

**10 yr ASCVD defined as: developing 1st ASCVD event, including MI, CAD or stroke

---

*Low intensity statin: pravastatin 10-20mg

*Moderate intensity statin: atorvastatin 10-20mg, pravastatin 40-80mg

*High intensity statin: atorvastatin 40-80mg

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:

1. Multiple or severe co-morbidities, including impaired renal or hepatic function.
2. History of statin intolerance or muscle disorders
3. Unexplained ALT elevations ≥ 3 times the upper limit of normal
4. Patient characteristics or concomitant use of drugs affecting statin metabolism
   - >75 years

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee.
Once statin 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, weakness, loss of appetite, abdominal 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).

Goal therapeutic response may:
- 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.

1. Adherence to lifestyle modifications and 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.

Follow-up in 1 year:
1. Reinforce continued adherence.
2. Monitor lipid profile (TC, LDL, HDL, TG) every 12 months.
3. Monitor LFT and creatine phosphokinase as clinically indicated (see box 11)
4. Continue lifestyle modifications and reinforce at follow-up.

If LDL levels are >160mg/dL, on two consecutive readings, decreasing the statin dose may be considered.

*Low intensity statin: pravastatin 10-20mg
†Moderate intensity statin: atorvastatin 10-20mg, pravastatin 40-80mg
‡High intensity statin: atorvastatin 40-80mg
Does the patient have hypertriglyceridemia?

Yes

No

Consider secondary causes of elevated triglycerides (TG); see Table 2.

Does the patient have elevated TG >500 or history of TG-induced pancreatitis?

Yes

No

Overall, the treatment of elevated triglyceride levels >500 mg/dL focuses on intensive therapeutic lifestyle change as outlined in Table 1.

For patients with elevated TGs, consider gemfibrozil or niacin therapy to a target dose of 1.5-2 gm/day.

TG levels >500 mg/dL have been associated with pancreatitis. In those with a history of triglyceride-induced pancreatitis, it is especially important to keep triglyceride levels well controlled and this will require both lifestyle and pharmacological approaches.

Caution should be used with combination therapy with statins due to an increased risk of rhabdomyolysis, hepatotoxicity and adverse effects.

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, abdominal 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 as clinically indicated or at least annually.

Table 1: Causes of Very High Triglycerides that May be Associated with Pancreatitis

<table>
<thead>
<tr>
<th>Genetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipoprotein lipase deficiency</td>
</tr>
<tr>
<td>Apolipoprotein CII or AV deficiency</td>
</tr>
<tr>
<td>GPIHBP1 deficiency</td>
</tr>
<tr>
<td>Mariesco-Sjogren syndrome</td>
</tr>
<tr>
<td>Chylomicron retention disease</td>
</tr>
<tr>
<td>Familial hypertriglyceridemia (in combination with acquired causes)</td>
</tr>
</tbody>
</table>

| Acquired disorders of metabolism: |
| Hyperthyroidism |
| Pregnancy |
| Poorly controlled insulinopenic diabetes |

| Drugs: |
| Alpha-blockers |
| Antimicrobial agents |
| Beta-blockers |
| Cholesterol-lowering agents |
| Estrogens, oral |
| Proton pump inhibitors |
| Statins |
| Thiazides |
| Tamoxifen |
| Sirolimus |
| Steroids |
| Protease inhibitors |
| Raloxifene |

| Diseases: |
| Renal disease |
| Chronic idiopathic urticaria |

Table 2: Causes of Very High Triglycerides that May be Associated with Pancreatitis

<table>
<thead>
<tr>
<th>Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Obesity</td>
</tr>
<tr>
<td>Chronic alcoholism</td>
</tr>
<tr>
<td>Drugs</td>
</tr>
<tr>
<td>Steroids</td>
</tr>
<tr>
<td>Oral contraceptives</td>
</tr>
<tr>
<td>Oral hypoglycemic agents</td>
</tr>
</tbody>
</table>

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 carbohydrate intake</td>
<td>1% energy replacement with MUFA/PURA 5%</td>
</tr>
<tr>
<td>Eliminate trans fats</td>
<td>1% energy replacement with MUFA/PURA 1%</td>
</tr>
</tbody>
</table>

RUPA, polyunsaturated fatty acids; MFA, monounsaturated fatty acids; Table adapted from the American Heart Association.
<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Starting Dose</th>
<th>Effect on Lipids</th>
<th>ADR</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Statins</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>40-80mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pravastatin</td>
<td>10-20mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. BAS</td>
<td>Cholestyramine 4gm QID</td>
<td>LDL ↓15-50% HDL ↑5-15% cholesterol absorption drugs &amp; TG ↑ or no change</td>
<td>AbsOLUTE: liver disease, relative: renal disease, electrolyte imbalance</td>
<td></td>
</tr>
<tr>
<td>Nicotinic Acid</td>
<td>500mg TED</td>
<td>LDL ↓5-25% HDL ↑5-20%</td>
<td>flushing, hyperglycaemia, hyperuricaemia</td>
<td>absolute: chronic liver disease, relative: PUD, diabetes, hyperuricaemia</td>
</tr>
<tr>
<td>Gemfibrozil</td>
<td>600mg BID</td>
<td>LDL ↓10-20% HDL ↑10-20%</td>
<td>dyspepsia, gallstones, muscle pain, unexplained non-CHD deaths</td>
<td>absolute: severe renal or liver disease</td>
</tr>
</tbody>
</table>

Table 5: Key

- TG: Triglyceride
- 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

1 The starting dose is dependent upon statin indication
2 CYP17 inhibitors, ketoconazole, itraconazole, macrolide antibiotics, azole antifungals, protease inhibitors, cytochrome P450 inhibitors

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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 revascularization (either percutaneous or surgical), stroke, transient ischemic attack (TIA), or peripheral arterial disease (PAD) presumed to be of atherosclerotic origin
   2. LDL ≥190 mg/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 mid-level 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 evaluation
   5. Advance care monitoring
B. Hyperlipidemia patients
   1. Pathophysiology
   2. Individual treatment plan
   3. Lifestyle modifications
   4. Monitoring parameters- frequency and importance
   5. Complications/risk of disease

HEALTH SERVICES PERSONNEL 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-analyses 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.
A. Initial Clinical Evaluation

1. Age
2. Sex
3. Family History of lipid disorders, premature CHD, diabetes mellitus (DM)

5. Diet History

6. Activity Level

7. Medication Profile


B. Risk Assessment:

1. Clinical ASCVD, defined as a ACS, or a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PAD presented to be at risk of cardiovascular death or morbidity.
2. LDL ≥ 190 mg/dL and ≥ 21 years of age
3. Diabetes in individuals ≥ 75 years of age with LDL-C ≥ 100 mg/dL with estimated 10-year ASCVD risk ≥ 7.5% or 5 to <7.5%
4. Additional factors influencing ASCVD risk include primary LDL > 160 mg/dL or other evidence of genetic hyperlipidemia, family history of premature ASCVD with onset <55 years of age in a first degree male relative or <65 years of age 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.

5. ASCVD Risk Calculator (Text adapted from The American Heart Association and the American College of Cardiology)

a. Calculator enables health care providers and patients to estimate 10-year and lifetime risks for ASCVD, defined as coronary death or nonfatal myocardial infarction, or fatal or nonfatal stroke based on the Pooled Cohort Equations and the work of Lolyd-Jones, et al., respectively. The information required to estimate ASCVD risk includes age, sex, race, total cholesterol, HDL cholesterol, systolic blood pressure, blood pressure lowering medication use, diabetes status, and smoking status.

b. Estimates of 10-year risk for ASCVD are based on data from multiple community-based populations and are applicable to African-American and non-Hispanic white men and women 40 through 79 years of age. For other ethnic groups, the American Heart Association recommends use of the equations for non-Hispanic whites, though these estimates may underestimate the risk for persons from some minority groups, especially American Indians, some Asian Americans (e.g., of south Asian ancestry), and some Hispanics (e.g., Puerto Ricans), and may overestimate the risk for others, including some Asian Americans (e.g., of east Asian ancestry) and some Hispanics (e.g., Mexican Americans).

c. Estimates of lifetime risk for ASCVD are provided for adults 20 through 59 years of age and are shown as the lifetime risk for ASCVD for a 50-year-old woman with the risk factor values entered into the spreadsheet. The estimates of lifetime risk are most directly applicable to non-Hispanic whites. We recommend the use of these values for other racial/ethnic groups, though as mentioned above, these estimates may represent under- or overestimations for persons of various ethnic groups. Because the primary use of these lifetime risk estimates is to facilitate the very important discussion regarding risk reduction through lifestyle change, the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results.

d. The ASCVD risk calculator is unable to calculate a risk score if total cholesterol is <130 or >320 mg/dL, HDL <40 or >100 mg/dL, or systolic blood pressure <90 or >200 mmHg.

e. The ASCVD risk calculation evolves existing status prior to estimating risk. This question is a "yes" or "no" answer which should be selected based on current smoking status.

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C. Who To Test
1. Primary Prevention

<table>
<thead>
<tr>
<th>PATIENTS</th>
<th>INITIAL SCREENING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males &gt;35 years</td>
<td>TC, HDL, LDL, TG</td>
</tr>
<tr>
<td>Females &gt;40 years</td>
<td>TC, HDL, LDL, TG</td>
</tr>
<tr>
<td>&gt;75 years</td>
<td>Use clinical judgment based on life expectancy. 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-blockers – increase TG
   c. Amiodarone – increase LDL
   d. Anabolic steroids – increase TG
   e. Atypical antipsychotics – increase TG
   f. Beta-blockers – increase HDL-cholesterol
   g. Bile acid resins – increase LDL-cholesterol
   h. Ethanol – increase TG
   i. Glucocorticoids – increase TC & TG
   j. Oral contraceptives – increase TC, TG & HDL-cholesterol
   k. Protease inhibitors – increase TG
   l. Statins – increase TG
   m. Tamoxifen – increase TG
   n. Thiazide diuretics – increase TC, TG & HDL-cholesterol

2. Effects of Various Conditions

<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, alcohol</td>
<td>Weight gain, very low-fat diets, high intake of refined carbohydrates, excessive alcohol intake</td>
</tr>
<tr>
<td>Nephrotic syndrome</td>
<td>Nephrotic syndrome, chronic renal failure, nephrogenic diabetes insipidus</td>
<td></td>
</tr>
<tr>
<td>Lipid abnormalities</td>
<td>Hyperthyroidism, obesity, pregnancy*</td>
<td></td>
</tr>
<tr>
<td>Disorders and altered states of metabolism</td>
<td>Diabetes poorly controlled, hyperthyroidism, obesity, pregnancy*</td>
<td></td>
</tr>
</tbody>
</table>

*Treatment with statins, niacin, and ezetimibe are contraindicated during pregnancy and lactation.

Table adapted from ACC/AHA

E. Factors That Affect Lipid Levels
1. Fasting
   TC 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.

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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 niacin acid (see table 4 for a comparison of lipid lowering agents). Triglyceride (TG) levels ≥500mg/dl have been associated with pancreatitis. Do not routinely offer fibrates in combination with a statin and do not offer niacin 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. Creatinine kinase (CK) if symptoms of myositis
4. Adverse event monitoring (including but not limited to)
   a. Significant elevations of liver enzymes (>3 times the upper limit of normal) while on statins
   b. Symptoms of myositis while on statin therapy alone or in combination with other drugs
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 states, 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 to 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 deposit build up in the coronary arteries in the heart, 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 elevated levels of triglycerides 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 triglyceride, 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
HYPERTENSION (HTN)

1. Adults ≥ 18 years of age with HTN
2. Implement lifestyle interventions
3. Initiate blood pressure lowering medications 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).

No Diabetes or CKD

Diabetes or CKD present

Ages < 60 years

Ages ≥ 60 years

Target BP <150/90

Target BP <140/90

(If albuminuria is present, <130/80 is recommended)

Nonblack

Black

Target BP <140/90

Target BP <130/80

(If albuminuria is present)

Target BP <140/90

Target BP <150/90

15.

Schedule follow-up to:

Stage I HTN (SBP 140-159, DBP 90-99): follow up 4-8 in weeks, obtain BP readings weekly

Stage II HTN (SBP ≥ 160 or if DBP ≥ 100): follow up in 2-4 weeks, obtain BP readings twice weekly

At follow-up visit, is patient at BP goal?

No

Yes

• Continue current drug regimen

• Continue to encourage lifestyle modifications

• Follow-up in CCC at least annually

If still not at BP goal (noncompliant):

• Intense individualized counseling

• DOT for a short period

• Obtaining a pharmacotherapy consult

• Follow-up based on box 15 or as clinically indicated

If at BP goal:

• Continue current drug regimen

• Continue to encourage lifestyle modifications

• Follow-up in CCC at least annually

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved August 1995; Reviewed 1/08, 5/11; Revised 10/98, 4/02, 4/03, 1/04, 1/06, 5/09, 5/14

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### Table 1: CLASSIFICATION OF HYPERTENSION

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>SBP mmHg(^1)</th>
<th>DBP mmHg(^2)</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>• Nonblack 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 clinical 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 (ACEI)
- Lisinopril 2.5 mg, 5 mg, 10 mg, 20 mg, 40mg

Calcium Channel Blockers (CCB)
- Amlodipine 5mg, 10mg
- Diltiazem 180mg XR, 240mg XR
- Diltiazem 240mg XR
- Verapamil 180mg SR
- Verapamil 240mg SR

Beta Blocker (BB)
- Atenolol 25mg, 50mg
- Carvedilol 3.125mg, 6.25mg, 12.5mg, 25mg
- 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 bared 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.
- 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.
- SBP 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>≥160</td>
<td>≥100</td>
</tr>
</tbody>
</table>

* If systolic and diastolic categories are different, follow up should be for the shorter time (e.g. 160/86 mm 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.
- Family history or symptoms of CHD, heart failure, cerebrovascular disease, peripheral vascular disease, renal disease, diabetes mellitus, dyslipidemia, stroke, or sexual dysfunction.
- Family history of high blood pressure, premature CHD, stroke, diabetes, dislipidemia, or renal disease.
- Symptoms suggestive of hypertension (headache, nosebleeds, dizziness, abnormal physical exam).
- History of recent changes in weight, increase in physical activity, or 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 enlarged thyroid gland.
- Examination 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.
- Examination of the abdomen for bruits, enlarged kidney, masses and abnormal aortic pulsation.
- Examination of the extremities for diminished or absent peripheral arterial pulsations, bruits, and edema.
- Neurological assessment.

Routine Laboratory Test

Routine laboratory test 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
- Coarctation of the aorta
- Mineralocorticoid excess states
- Cushing’s Syndrome
- Pheochromocytoma
- Pregnancy
- Drug-induced
- Sleep apnea
- Thyroid or parathyroid disease
- Obstructive uropathy
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 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 primary 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 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 patient to maintain normal body weight (BMI 18-24.9)</td>
<td>5-20mmHg/10kg weight loss</td>
</tr>
<tr>
<td>Diet</td>
<td>Consider DFH and encourage adherence. Discourage commissary foods.</td>
<td>8-14mmHg</td>
</tr>
<tr>
<td>Dietary sodium restriction</td>
<td>Encourage patient to reduce dietary sodium intake to no more than 2-4g sodium or 6g NaCl.</td>
<td>2-8mmHg</td>
</tr>
<tr>
<td>Physical activity</td>
<td>Encourage patient to engage in aerobic physical activity to lower BP.ze 3-4 sessions a week, lasting on average 40 minutes per session, and involving moderate physical activity.</td>
<td>4-5mmHg</td>
</tr>
</tbody>
</table>

**Set realistic goals for your patients and discuss the value of self-rewarding and goal setting. Encourage patients to make gradual changes to their lifestyle, as they are more likely to comply with one change at a time.
HYPERTENSION EMERGENCY

Hypertensive emergencies are characterized by acute elevations in blood pressure (BP) >180/120 mm Hg, complicated by evidence of impending or progressive target organ damage. While hypertensive emergencies occur rarely, immediate blood pressure reduction is required to limit target organ damage. Target organ damage may be manifested as hypertensive encephalopathy, intracerebral hemorrhage, variable angina pectoris, acute myocardial infarction, acute left ventricular failure with pulmonary edema, dissecting aneurysm, acute renal failure or eclampsia. Most hypertensive emergencies are treated initially with parenteral agents. Blood pressure reductions do 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 to 110 mm Hg within 2-6 hours, avoiding excessive falls in pressure that may precipitate renal, cerebral, or myocardial ischemia.

HYPERTENSION URGENCY

Hypertensive urgencies are those situations with severe elevations in BP without progressive target organ damage. Examples include upper levels of Stage 2 hypertension associated with severe headaches, shortness of breath, spurious, 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 relative fast onset of action.

Clonidine dosing in hypertensive urgency: May consider giving a loading dose of clonidine 0.1mg, followed by 0.1mg hourly until goal is reached up to a total dose of 0.6mg. Clonidine is not recommended for chronic maintenance therapy due to lack of reduction in cardiovascular morbidity and risk of rebound hypertension with discontinuation in nonadherent patients.

Furosemide dosing in hypertensive urgency: May be dosed as 20-40mg every 2-3 hours. Furosemide is useful in patients with volume overload due to hypertension with reduced or normal volume status should be considered.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved August 1995; Revised 10/98, 4/02, 4/03, 3/04, 5/14

Revised 10/98, 4/02, 4/03, 3/04, 5/14

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Patient presents with signs & symptoms of hypoglycemia (generally BG < 70 mg/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.

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

Is the patient conscious and cooperative?

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 > 70 mg/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 > 70 mg/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.

Have symptoms resolved?

Discharge the patient when plasma glucose levels remain > 70 mg/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.

Ingestion of a snack or meal shortly after glucose levels are raised is advisable. Response to IV dextrose may be transient.

Consider scheduling patient who has had recurrent episodes for follow up appointment with unit provider for evaluation and possible medication adjustment.

Has 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 IVF followed by infusion of 5-10% dextrose. Continue infusion until glucose > 70 mg/dL.

Notify unit provider & establish IV access.

Has IV access been established after at least 2 attempts?

No

Yes

Discharge the patient when plasma glucose levels remain > 70 mg/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.

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.

Investigate other etiologies for mental status change and consider transfer to a higher level of care.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, January 2006. Reviewed 5/18, 1/13.
Hypoglycemia

I. Definition – Blood glucose < 70mg/dL. However, glucose thresholds for hypoglycemia-induced symptoms and physiologic responses may vary between patients. Therefore, an important framework for making the diagnosis of hypoglycemia is Whipple’s triad:
(1) symptoms consistent with hypoglycemia,
(2) a low plasma glucose concentration, and
(3) relief of symptoms after the plasma glucose level is raised.
Hypoglycemia can cause significant morbidity and can be lethal, if severe and prolonged; it should be considered in any patient with confusion, altered level of consciousness, or seizures.

II. Signs & Symptoms
A. Behavioral changes
B. Confusion
C. Fatigue
D. Loss of consciousness
E. Seizure
F. Palpitations
G. Tremor
H. Anxiety
I. Sweating
J. Hunger
K. Pallor
L. Increased heart rate & blood pressure
M. Hypothermia
N. Low plasma or blood glucose

III. Risk Factors
A. Medication (insulin or oral agents) excess
B. Decreased influx of exogenous glucose (e.g., skipped or missed meals or snacks)
C. Increased glucose utilization (e.g., increase in exercise)
D. Reduced insulin clearance (e.g., renal failure)

IV. 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
   3. Ordering snacks for ingestion between meals
   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
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, 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>
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<th>Formulary Medication</th>
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<td>Approximate Equivalent Dose (Non-formulary to Formulary)</td>
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<td>Miconazole (Monistat®)</td>
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<td>Mirtazapine (Remeron®)</td>
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<td>Oxytetracycline (Tetracycline®)</td>
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<td>Dose Range and Frequency</td>
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<td>Colesipol (Colestid®)</td>
<td>5-30 g/day given once or in 2-4 doses</td>
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<th>Name of Medication</th>
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<td>Regular (Novolin R®)</td>
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<td>Lispro (Humalog®)</td>
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<td>NPH (Novolin N®)</td>
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<td>Lantus units / 0.8 = NPH units for total daily dose. Administer 2/3 of dose in am and 1/3 of daily dose in pm.</td>
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<td>Lispro Protamine 75/Lispro 25 (Humalog Mix 75/25%)</td>
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*Formulary Substitutions page 3
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<td>Glimepiride (Amaryl®)</td>
<td>1 - 8 mg qd</td>
<td>Glipizide (Glucotrol®) 5mg, 10mg tablets</td>
</tr>
<tr>
<td>Glyburide (Diabeta®)</td>
<td>5 – 20 mg in single or divided doses</td>
<td>Glyburide (Diabeta®) 5mg, 10mg tablets</td>
</tr>
<tr>
<td>Glyburide micronized (Glynase PresTab®)</td>
<td>1.5 - 12 mg in single or divided doses</td>
<td>Glipizide (Glucotrol®) 5mg, 10mg tablets</td>
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<tr>
<td>Tolazamide</td>
<td>100 mg qd = 500 mg bid</td>
<td>Glipizide (Glucotrol®) 5mg, 10mg tablets</td>
</tr>
<tr>
<td>Tolbutamine</td>
<td>500 – 2000 mg daily in 1 - 3 divided doses</td>
<td>Glipizide (Glucotrol®) 5mg, 10mg tablets</td>
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<tr>
<td><strong>Respiratory Medications</strong></td>
<td></td>
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<tr>
<td>Tiotropium (Spiriva®)</td>
<td>1 capsule qd</td>
<td>Ipratropium (Atrovent®) 17 mcg, 200 puffs</td>
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<tr>
<td>Ipratropium (Atrovent®)</td>
<td>2 puffs qid</td>
<td>Ipratropium (Atrovent®) 17 mcg, 200 puffs</td>
</tr>
<tr>
<td>Albuterol (Ventolin®)</td>
<td>2 puffs qid</td>
<td>Ipratropium (Atrovent®) 17 mcg, 200 puffs</td>
</tr>
<tr>
<td>Atrovent / Ipratropium (Combivent®)</td>
<td>2 puffs qid</td>
<td>Ipratropium (Atrovent®) 17 mcg, 200 puffs</td>
</tr>
<tr>
<td>Budesonide (Pulmicort Turbuhaler®)</td>
<td>180 – 1200 mcg/day divided bid</td>
<td>Fluticasone HFA (Flovent MDI®) 80 mcg, 120 puffs</td>
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<tr>
<td>Flunisolide (Aerospan®)</td>
<td>500 – 2000 mcg/day divided bid</td>
<td>Fluticasone HFA (Flovent MDI®) 80 mcg, 120 puffs</td>
</tr>
<tr>
<td>Mometasone (Asmanex Twisthaler®)</td>
<td>200 – 400 mcg/day given once daily or divided bid</td>
<td>Fluticasone HFA (Flovent MDI®) 80 mcg, 120 puffs</td>
</tr>
<tr>
<td>Triamcinolone (Azmacort®)</td>
<td>300 – 1500 mcg/day divided 2 – 4 times/day</td>
<td>Fluticasone HFA (Flovent MDI®) 80 mcg, 120 puffs</td>
</tr>
<tr>
<td>Fluticasone (Flovent MDI®)</td>
<td>88 – 440 mcg/day divided bid</td>
<td>Fluticasone HFA (Flovent MDI®) 80 mcg, 120 puffs</td>
</tr>
</tbody>
</table>

Formulary Substitutions page 5
<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Dose Range and Frequency</th>
<th>Name of Medication and Dosages Available</th>
<th>Dose Range and Frequency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cimetidine (Tagamet®)</td>
<td>100 – 1600 mg/day in single doses or divided bid – qid</td>
<td>Ranitidine (Zantac®) 150mg tablet</td>
<td>150 mg qd – 300 mg bid</td>
<td>400 mg bid to 150 mg bid</td>
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<tr>
<td>Famotidine (Pepcid®)</td>
<td>10 – 80 mg/day in single or divided doses</td>
<td></td>
<td></td>
<td>20 mg bid to 150 mg bid</td>
</tr>
<tr>
<td>Nizatidine (Axid AR®)</td>
<td>150 – 300 mg/day in single or divided doses</td>
<td></td>
<td></td>
<td>150 mg bid to 150 mg bid</td>
</tr>
<tr>
<td>Dexlansoprazole (Dexilant®)</td>
<td>30-60 mg qd</td>
<td>Omeprazole (Prilosec®) 20mg capsule</td>
<td>20-40 mg single or divided doses</td>
<td>60 mg qd to 20 mg qd</td>
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<tr>
<td>Esomeprazole (Nexium®)</td>
<td>20-40 mg qd</td>
<td></td>
<td></td>
<td>20 mg qd to 20 mg qd</td>
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<tr>
<td>Lansoprazole (Prevacid®)</td>
<td>15-30 mg qd</td>
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<td></td>
<td>30 mg qd to 20 mg qd</td>
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<tr>
<td>Pantoprazole (Protonix®)</td>
<td>20-40 mg qd</td>
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<td>40 mg qd to 20 mg qd</td>
</tr>
<tr>
<td>Rabeprazole (Aciphex®)</td>
<td>20-40 mg qd</td>
<td></td>
<td></td>
<td>20 mg qd to 20 mg qd</td>
</tr>
<tr>
<td>Emtricitabine (Emtriva®, FTC)</td>
<td>200 mg qd</td>
<td>Lamivudine (Epivir®, 3TC) 150mg, 300mg tablet</td>
<td>150 mg bid of 300 mg qd</td>
<td>FTC 200 mg qd to 3TC 300 mg qd</td>
</tr>
<tr>
<td>Emtricitabine (Emtriva®, FTC) + Abacavir (Ziagen®, ABC)</td>
<td>200mg qd+600mg qd</td>
<td>Lamivudine (Epivir®, 3TC) 150mg, 300mg tablet + Abacavir (Ziagen®, ABC) 300mg tablet</td>
<td>300 mg qd + 600 mg qd</td>
<td>FTC 200 mg qd to 3TC 300 mg qd; Abacavir available on formulary.</td>
</tr>
<tr>
<td>Emtricitabine (Emtriva®, FTC) + Zidovudine (Retrovir®, AZT)</td>
<td>200mg qd+300mg BID</td>
<td>Lamivudine (Epivir®, 3 TC) 150mg, 300mg tablets + Zidovudine (Retrovir®, AZT) 300 mg tablet</td>
<td>300 mg qd + 300 mg bid</td>
<td>FTC 200 mg qd to 3TC 300 mg qd; Zidovudine available on formulary.</td>
</tr>
</tbody>
</table>

Gastrointestinal Medications

Anti-Retroviral Medications

Formulary Substitutions page 5
<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Dose Range and Frequency</th>
<th>Name of Medication and Dosages Available</th>
<th>Dose Range and Frequency</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Formulary Medication</td>
<td>Formulary Medication</td>
<td>Anti-Retroviral Medications (Continued)</td>
<td>Approximate Equivalent (Non-formulary to Formulary)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine + Lamivudine (Combivir®)</td>
<td>300 mg bid + 150 mg bid</td>
<td>Zidovudine (Retrovir, AZT) 300 mg tablet + Lamivudine (Epivir®, 3TC) 150 mg, 300 mg tablets</td>
<td>300 mg bid + 150 mg bid</td>
<td></td>
</tr>
<tr>
<td>Efavirenz + Emtricitabine + Tenofovir (Atripla®)</td>
<td>600 mg + 300 mg + 300 mg qd</td>
<td>Efavirenz (Sustiva®, 3TC) 200 mg tablet + Lamivudine (Epivir®, 3TC) 100 mg tablet + Tenofovir (Viread®, TDF) 300 mg tablet</td>
<td>600 mg qd + 300 mg qd + 300 mg qd</td>
<td>Atripla® to Efavirenz 600 mg + 3TC 300 mg + TDF 300 mg</td>
</tr>
<tr>
<td>Emtricitabine + Tenofovir (Truvada®)</td>
<td>200 mg + 300 mg qd</td>
<td>Lamivudine (Epivir®, 3TC) 300 mg tablet + Tenofovir (Viread®, TDF) 300 mg tablet</td>
<td>300 mg qd + 300 mg qd</td>
<td>Truvada® to 3TC 300 mg + TDF 300 mg</td>
</tr>
<tr>
<td>Abacavir + Lamivudine (Epzicom®)</td>
<td>600 mg + 300 mg qd</td>
<td>Abacavir (Ziagen®, ABC) 600 mg tablet + Lamivudine (Epivir®, 3TC) 300 mg tablet</td>
<td>600 mg + 300 mg qd</td>
<td>Epzicom to 600 mg abacavir + 300 mg lamivudine</td>
</tr>
<tr>
<td>Abacavir + Lamivudine + Zidovudine (Trizivir®)</td>
<td>300 mg + 150 mg + 300 mg po bid</td>
<td>Abacavir (Ziagen®, ABC) 300 mg tablet + Lamivudine (Epivir®, 3TC) 300 mg tablet + Zidovudine (Retrovir®, AZT) 300 mg tablet</td>
<td>300 mg + 150 mg + 300 mg po bid</td>
<td>Trizivir® to abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg</td>
</tr>
<tr>
<td>Emtricitabine + Rilpivirine + Tenofovir (Complera®)</td>
<td>200 + 25 mg + 300 mg qd</td>
<td>Lamivudine (Epivir®, 3TC) 300 mg tablet + Rilpivirine (Edurant®, RPV) 25 mg tablet + Tenofovir (Viread®, TDF) 300 mg tablet</td>
<td>300 mg + 25 mg + 300 mg po qd</td>
<td>RPV available through prior authorization: Complera to 3TC 300 mg + RPV 25 mg + TDF 300 mg</td>
</tr>
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Formulary Substitutions page 6
<table>
<thead>
<tr>
<th>Non-Formulary Medication</th>
<th>Formulary Medication</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Medication</td>
<td>Dose Range and Frequency</td>
<td>Name of Medication and Dosages Available</td>
</tr>
<tr>
<td>Abacavir+Dolutegravir+Lamivudine (Triumeq®)</td>
<td>600mg+50 mg+300mg qd</td>
<td>Abacavir (Ziagen®, ABC) 600mg tablet+Dolutegravir (Tivicay®, DTG) 50mg tablet+Lamivudine (Epivir®, 3TC) 300mg tablet</td>
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</table>

**Anti-Retroviral Medications (Continued)**

**Very High Potency Topical Steroids**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Formulary</th>
</tr>
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<tbody>
<tr>
<td>Betamethasone dipropionate, augmented (Diprolene®) 0.05%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clobetasol propionate (Temovate®) 0.05% ointment 15 gm tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diflorasone diacetate (ApexCon®) 0.05%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halibetasol propionate 0.05% (Ultravate®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amcinonide (Cyclocort®) 0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone dipropionate (Diprolene®) 0.05%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Betamethasone valerate (Valesone®) 0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diflorasone diacetate (Florone®) 0.05%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halcinonide (Halog®) 0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluocinonide (Lidex®) 0.05% cream 60 gm tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluocinonide (Lidex®) 0.05% ointment 15 gm tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluocinonide (Lidex®) 0.05% cream 15 gm tube</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Formulary Medication</td>
<td>Formulary Medication</td>
<td>Comments</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------</td>
<td>----------</td>
</tr>
<tr>
<td>Name of Medication</td>
<td>Name of Medication and Doses Available</td>
<td>Dose Range and Frequency</td>
</tr>
<tr>
<td>Betamethasone valerate (Psorion Cream®) 0.05%</td>
<td>Triamcinolone acetonide (Kenalog®) 0.025% ointment 15 gm tube 0.025% cream 15 gm tube</td>
<td>Intermediate Potency Topical Steroids</td>
</tr>
<tr>
<td>Clobetasol propionate (Clobex®) 0.05%</td>
<td>Hydrocortisone butyrate (Dermatop®) 0.1%</td>
<td></td>
</tr>
<tr>
<td>Flurandrenolide (Diprolene®) 0.05%</td>
<td>Hydrocortisone valerate (Anusol-HC®) cream—30 gm tube</td>
<td></td>
</tr>
<tr>
<td>Flurandrenolide (Estraderm®) 0.05%</td>
<td>Hydrocortisone valerate (Anusol-HC®) suppository 25 mg</td>
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</tr>
<tr>
<td>Formulary Substitutions page 8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Formulary Medication</td>
<td>Formulary Medication</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------------------</td>
<td>----------------------</td>
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</tr>
<tr>
<td>Name of Medication</td>
<td>Dose Range and Frequency</td>
<td>Name of Medication and Dosages Available</td>
</tr>
<tr>
<td><strong>Anti-Glaucoma Medications</strong></td>
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<tr>
<td>Bimatoprost (Lumigan®) 0.03% Ophthalmic Solution</td>
<td>1 gtt in affected eye q pm</td>
<td>Latanoprost (Kalatan®) 0.005% Ophthalmic solution</td>
</tr>
<tr>
<td>Travoprost (Travatan®) 0.004% Ophthalmic Solution</td>
<td>1 gtt in affected eye q pm</td>
<td>Timolol (Timoptic®) 0.5% Ophthalmic solution</td>
</tr>
<tr>
<td>Betaxolol (Betoptic®) 0.5% Ophthalmic Solution</td>
<td>1-2 gtt in affected eye bid</td>
<td>Timolol (Timoptic®) 0.5% Ophthalmic Solution</td>
</tr>
<tr>
<td>Levobunolol (Betagan®) 0.25% and 0.5% Ophthalmic Solution</td>
<td>0.25% - 1-2 gtt/s in affected eye bid</td>
<td>Timolol (Timoptic®) 0.5% Ophthalmic Solution</td>
</tr>
<tr>
<td>Metipanolol (OptiPranolol®) 0.3% Ophthalmic Solution</td>
<td>1 gtt in affected eye bid</td>
<td>Brimonidine (Alphagan®) 0.2% ophthalmic solution — 10mL</td>
</tr>
<tr>
<td>Timolol (Timoptic-XE®) 0.25% and 0.5% Ophthalmic Gel Forming Solution</td>
<td>1 gtt in affected eye qd</td>
<td>Brimonidine (Alphagan®) 0.2% ophthalmic solution — 10mL</td>
</tr>
<tr>
<td>Apraclonidine (Iopidine®) 1% ophthalmic solution</td>
<td>1 gtt in affected eye tid</td>
<td>Brimonidine (Alphagan®) 0.2% ophthalmic solution — 10mL</td>
</tr>
<tr>
<td>Brinzolamide (Azopt®) 1% Ophthalmic Suspension</td>
<td>1 gtt in affected eye tid</td>
<td>Dorzolamide (Trusopt®) 2% Ophthalmic Solution</td>
</tr>
<tr>
<td>Dorzolamide 2 % Ophthalmic + Timolol 0.5% Ophthalmic Solution (Cosopt®)</td>
<td>1 gtt in affected eye bid</td>
<td>Dorzolamide (Trusopt®) 2% Ophthalmic Solution + Timolol (Timoptic®) 0.5% Ophthalmic Solution</td>
</tr>
<tr>
<td>Name of Medication</td>
<td>Dose and Frequency</td>
<td>Dose Range and Frequency</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Calcium carbonate (Titralac®)</td>
<td>1 tablet qd</td>
<td>1 tablet qd</td>
</tr>
<tr>
<td>Calcium carbonate (Tums®)</td>
<td>1 tablet qd</td>
<td>1 tablet qd</td>
</tr>
<tr>
<td>Ferrous gluconate (Fergon®)</td>
<td>2 tablets bid</td>
<td>1 tablet qd</td>
</tr>
<tr>
<td>Ferrous sulfate (Ferrotablet®)</td>
<td>3 tablets bid</td>
<td>1 tablet qd</td>
</tr>
<tr>
<td>Docusate calcium (Surfak®)</td>
<td>2 tablets bid</td>
<td>1 tablet qd</td>
</tr>
<tr>
<td>Docusate sodium (Colace®)</td>
<td>2 tablets bid</td>
<td>1 tablet qd</td>
</tr>
</tbody>
</table>

Titrallac® contains 168mg elemental calcium
Tums® contains 200mg elemental calcium
Fergon® tablet contains 36mg elemental iron
Feosol® tablet contains 65mg elemental iron

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee July 2008; Revised May 2011, November 2014.
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

OPIOID DISCONTINUATION

1. Counsel the patient on signs and symptoms of opioid withdrawal
   • Evaluate patient's withdrawal symptoms with the Clinical Opiate Withdrawal Scale (COWS); refer to page 3. The COWS can be found in the EMR under Notebuilder Templates.
   • Do not discontinue methadone in a pregnant patient.
   • Therapy should be discontinued postpartum. If patient is postpartum, refer to page 2 box #11 for management.

2. Does the patient have any acute psychiatric issues warranting crisis management or psychiatric admission?
   • Yes
     - Transfer patient to a 24 hour medical facility.
     - Go to box #7
   • No
     - 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
         - Is patient having moderately severe withdrawal symptoms (score of >24 on the COWS)?
           • Yes
             - Transfer patient to a 24 hour medical facility, if patient is not already transferred.
             - Administer clonidine 0.1mg tid up to 0.5mg tid for 7 days; taper over additional 3 days. Maximum total daily dose should not exceed 2mg/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.
           • No
             - Monitor vital signs daily.
             - Provide supportive care for pain, nausea, vomiting and diarrhea as clinically indicated.

3. Does the patient have underlying cardiac disease, i.e., CAD, Heart Failure, history of arrhythmias?
   • Yes
     - Order baseline EKG and repeat as clinically indicated.
     - Go to box #7
   • No
     - Does the patient have any acute psychiatric issues warranting crisis management or psychiatric admission?
       • Yes
         - Transfer patient to a 24 hour medical facility.
         - Go to box #7
       • No
         - 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 0.5mg tid for 7 days; taper over additional 3 days. Maximum total daily dose should not exceed 2mg/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.
           • No
             - Monitor patient for severe complications, i.e., signs of dehydration and acute mental status changes. If present, transfer to higher level of care.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, October 2008. Revised 01/11. Revised ©2014
11. 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.

12. Monitor patient for severe complications, i.e., signs of dehydration and acute mental status changes. If present, transfer to higher level of care.

### 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>• Decrease dose by 5mg/day until it is discontinued.</td>
</tr>
<tr>
<td>Example: 100mg/day</td>
<td>Example: 40mg/day</td>
</tr>
<tr>
<td>80mg</td>
<td>35mg</td>
</tr>
<tr>
<td>40mg</td>
<td>30mg</td>
</tr>
<tr>
<td>40mg</td>
<td>25mg</td>
</tr>
<tr>
<td>35mg</td>
<td>20mg</td>
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<tr>
<td>10mg</td>
<td>15mg</td>
</tr>
<tr>
<td>5mg</td>
<td>10mg</td>
</tr>
<tr>
<td>Discontinue</td>
<td>5mg</td>
</tr>
<tr>
<td>Day 8</td>
<td>Discontinue</td>
</tr>
<tr>
<td>Day 9</td>
<td>Day 10</td>
</tr>
</tbody>
</table>
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>
</table>
| **Resting Pulse Rate:** record beats per 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>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None present</td>
</tr>
<tr>
<td>1</td>
<td>Runny nose or tearing not accounted for by cold symptoms or allergy</td>
</tr>
<tr>
<td>2</td>
<td>Nose running or tearing</td>
</tr>
<tr>
<td>4</td>
<td>Nose constantly running or tears streaming down cheeks</td>
</tr>
</tbody>
</table>

**GI Upset:** over last ½ hour

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No GI symptoms</td>
</tr>
<tr>
<td>1</td>
<td>Stomach cramps</td>
</tr>
<tr>
<td>2</td>
<td>Nausea or loose stool</td>
</tr>
<tr>
<td>3</td>
<td>Vomiting or diarrhea</td>
</tr>
<tr>
<td>5</td>
<td>Multiple episodes of diarrhea or vomiting</td>
</tr>
</tbody>
</table>

**Tremor:** observation of outstretched hands

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No tremor</td>
</tr>
<tr>
<td>1</td>
<td>Tremor can be felt, but not observed</td>
</tr>
<tr>
<td>2</td>
<td>Slight tremor observable</td>
</tr>
<tr>
<td>4</td>
<td>Gross tremor or muscle twitching</td>
</tr>
</tbody>
</table>

**Yawning:** observation during assessment

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No yawning</td>
</tr>
<tr>
<td>1</td>
<td>Yawning once or twice during assessment</td>
</tr>
<tr>
<td>2</td>
<td>Yawning three or more times during assessment</td>
</tr>
<tr>
<td>4</td>
<td>Yawning several times/minute</td>
</tr>
</tbody>
</table>

**Anxiety or Irritability**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>1</td>
<td>Patient reports increasing irritability or anxiosity</td>
</tr>
<tr>
<td>2</td>
<td>Patient obviously irritable or anxious</td>
</tr>
<tr>
<td>4</td>
<td>Patient so irritable or anxious that participation in the assessment is difficult</td>
</tr>
</tbody>
</table>

**Gooseflesh Skin**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Skin is smooth</td>
</tr>
<tr>
<td>3</td>
<td>Piloerection of skin can be felt or hairs standing up on arms</td>
</tr>
<tr>
<td>5</td>
<td>Prominent piloerection</td>
</tr>
</tbody>
</table>

**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
Chronic Cancer Pain

1. Provider should complete a thorough history and physical including a comprehensive pain assessment (pg 2) to determine location, quality, type and intensity.
2. Provide patient with pain management education (see pg 6).
3. Initiate NonPharmacological Therapy as available and indicated (pg 2).

Patient in Cancer Pain Crisis?

Yes

See Oncologic Emergency (pg 6)

No

Mild Pain (Scale: 1-3)

OPIOID NAIVE:
- First line therapy:
  - Acetaminophen 650mg up to Q 4 hours
  - Ibuprofen 400-800mg up to QID
  - Naproxen 250-500mg BID

- Second line therapy:
  - Meloxicam 7.5-15mg once daily

- Failure of first & second line therapy:
  - Consider addition and titration of adjunctive therapy according to pain syndrome (Table 1, pg 3).

OR

CURRENTLY PRESCRIBED OPIOID:
- 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.

Moderate Pain (Scale: 4-6)

OPIOID NAIVE:
- First line therapy:
  - APAP/codeine 300/30mg - 1 or 2 tablets BID to QID.

- Second line therapy:
  - Morphine elixir 10mg or 20mg BID to QID.

- Failure of first or second line therapy:
  - Consider addition and titration of adjunctive therapy according to pain syndrome (Table 1, pg 3).

OR

CURRENTLY PRESCRIBED OPIOID:
- Increase total daily scheduled opioid dose 25-50%. Administer as morphine SR divided doses at 12 hour intervals.
- Provide short acting rescue opioids at 10-15% of total daily scheduled dose. Give in divided doses BID to QID as needed.
- If pain goals are met, reassess and consider adjunctive therapy.

Severe Pain (Scale: 7-10)

OPIOID NAIVE:
- First line therapy:
  - Morphine IR Elixir 10mg/5ml
  - Morphine SR Tabs 15mg, 30mg, 60mg

- Outpatient:
  - For very severe pain, consider inpatient bed placement for initial titration; otherwise, start morphine elixir 10mg BID to QID for the first 24-48 hours to establish pain control.
  - If pain is expected to be continuous, convert to morphine SR 15-30mg every 12 hours. Give morphine elixir 10mg-20mg as needed for breakthrough pain up to QID.

- Inpatient:
  - Start morphine elixir at 10mg every 4 hours. Rescue dose 8-10 tablets per dose every 4 hours. Repeat dose & titrate as needed.
  - Once stable for 24 hours, calculate total daily dosage of morphine and convert to long acting morphine SR. Give in 2 divided doses at 12 hour intervals.
  - Provide short acting rescue opioids at 10-15% of total daily scheduled dose. Give in divided doses as needed.

- OR

  CURRENTLY PRESCRIBED OPIOID:
  - Increase total daily scheduled opioid dose 50-75%. Administer as morphine SR divided (12H)
  - Give morphine elixir 10mg-20mg as needed for breakthrough pain up to QID.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, July 2010. Revised 1/13.
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 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/or 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 undertreatment 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 heat (by hot towels) or ice. Note: Appropriate measures should be used to reduce risk to skin.
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 commonly used (e.g., Meloxicam)
   c. Advise patients to take NSAIDS with food in order to reduce risk of gastrointestinal disturbance
3. Adjunctive therapy
   a. Consider addition of adjunctive therapy according to pain syndrome
   b. Titrate dose to adequate response or intolerable side effects
<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>Bone (NSAIDS)</td>
<td>Ibuprofen 400-800 mg QID</td>
<td>Max daily dose 1200 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Meloxicam 7.5-15 mg QD</td>
<td>Max daily dose 15 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Naproxen 250-500 mg BID</td>
<td>Max daily dose 500 mg, may cause GI upset</td>
</tr>
<tr>
<td>Deep, boring, referred, poorly localized</td>
<td>Visceral (Corticosteroids)</td>
<td>Prednisone 10 – 80 mg daily</td>
<td>May increase blood glucose, may cause GI upset, increased appetite, may cause CNS symptoms, may cause osteopenia</td>
</tr>
<tr>
<td></td>
<td>Neurogenic (Tricyclic Antidepressants)</td>
<td>Nortriptyline 25 – 150 mg divided doses or BID</td>
<td>Less sedating, less anti-cholinergic effects, max daily dose 150 mg</td>
</tr>
<tr>
<td></td>
<td>Neuropathic (Anticonvulsants)</td>
<td>Carbamazepine 200-400 mg BID – QID</td>
<td>Non-formulary medication, sedating, max daily dose 1500 mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gabapentin 100mg TID to 300-900mg TID</td>
<td>Generally requires doses &gt; 1000mg/day, potential for abuse (sedation &amp; dizziness), drug of choice for lancinating pain, non-formulary medication, max daily dose 3600 mg, dosage based on renal function</td>
</tr>
<tr>
<td>Colic-cramping abdominal pain, bladder spasm</td>
<td>Smooth muscle spasm (Anticholinergics)</td>
<td>Oxybutynin 5-10 mg TID</td>
<td>Used for bladder spasm 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 persistent pain when a 24 hour opioid requirement is stable.
4. Provide rescue doses of short-acting opioids for pain not relieved by extended-release opioids including breakthrough pain or acute exacerbations of pain, activity, or position related pain or pain at the end of dosing interval.
5. Rescue breakthrough dosing – usually provided as 10-15% of the 24 hour total daily scheduled dose as needed.
B. Dose Titration
1. If 3 or more rescue doses are needed in a 24 hour period, an increase in dose may be necessary.
2. Calculate dosage increase based upon total daily opioid dose around the clock including scheduled and prn doses. Example, total 24 hour opioid requirement: morphine 15mg BE BID (30mg) + 3 x 10mg breakthrough doses = 60mg or new opioid dose of 30mg BE BID. An alternative to calculating the total daily dose needed is the following guide:
   - Pain < 4: Increase dose by 25%
   - Pain 4-7: Increase dose by 25% to 50%
   - Pain > 7: Increase dose by 50% to 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:

\[
\text{Equianalgesic dose (route) new opioid} = \frac{\text{Equianalgesic dose (route) current opioid}}{\text{Conversion factor (IV to PO)}}
\]

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 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 SR 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>30</td>
<td>10</td>
<td>3</td>
<td>IR: 4hrs, SR: 12hrs</td>
<td></td>
</tr>
<tr>
<td>Oxycodone</td>
<td>20</td>
<td>NA</td>
<td>NA</td>
<td>IR: 4hrs, SR: 12hrs</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>200</td>
<td>NA</td>
<td>1.5</td>
<td>3-4hrs</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>7.5-20</td>
<td>NA</td>
<td>NA</td>
<td>5-7hrs</td>
<td></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-naïve 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 100mcg, 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. Fentanyl should be used 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 patches

* Calculate the total 24 hour morphine dose.

* Table 3 displays the range of 24-hour oral morphine 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.

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### Table 3: Fentanyl Conversion

<table>
<thead>
<tr>
<th>Oral Morphine (mg/24hours)</th>
<th>Parenteral Morphine (mg/24 hours)</th>
<th>Transdermal Fentanyl Equivalent (mcg/hr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-65</td>
<td>8-22</td>
<td>25</td>
</tr>
<tr>
<td>65-115</td>
<td>23-37</td>
<td>50</td>
</tr>
<tr>
<td>116-150</td>
<td>38-52</td>
<td>75</td>
</tr>
<tr>
<td>151-200</td>
<td>53-67</td>
<td>100</td>
</tr>
<tr>
<td>201-225</td>
<td>68-82</td>
<td>125</td>
</tr>
<tr>
<td>226-300</td>
<td>83-100</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></td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
</tr>
<tr>
<td>Sweating</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td></td>
</tr>
<tr>
<td>Itching</td>
<td></td>
</tr>
<tr>
<td>Urinary</td>
<td></td>
</tr>
</tbody>
</table>
| | **Oral Morphine (mg/24hours):** 8-22  
| | **Parenteral Morphine (mg/24 hours):** 23-37  
| | **Transdermal Fentanyl Equivalent (mcg/hr):** 100  
| | **Oral Morphine (mg/24hours):** 116-150  
| | **Parenteral Morphine (mg/24 hours):** 38-52  
| | **Transdermal Fentanyl Equivalent (mcg/hr):** 250  
| | **Oral Morphine (mg/24hours):** 151-200  
| | **Parenteral Morphine (mg/24 hours):** 53-67  
| | **Transdermal Fentanyl Equivalent (mcg/hr):** 200  
| | **Oral Morphine (mg/24hours):** 201-225  
| | **Parenteral Morphine (mg/24 hours):** 68-82  
| | **Transdermal Fentanyl Equivalent (mcg/hr):** 250  
| | **Oral Morphine (mg/24hours):** 226-300  
| | **Parenteral Morphine (mg/24 hours):** 83-100  
| | **Transdermal Fentanyl Equivalent (mcg/hr):** 100  

- **Constipation:**  
  - Antispasmodics prophylactically – lomotil 1 IM every 6-8 hours (may cause additional constipation).  
  - Encourage increased fluids, fiber and physical activity.  
  - If no bowel movement in 3 days, consider magnesium citrate or enema.  
  - Antispasmodics as needed (docusate 100mg BID & bisacodyl 10-15mg BID)  
  - If no bowel movement in 3 days, consider magnesium citrate or enema  
  - Last line – consider use of probiotic agents (metronidazole 10-20mg qd)  

- **Dizziness:**  
  - Usually resolves as body adjusts to medication.  
  - Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.  

- **Nausea:**  
  - Take medication with food.  
  - Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.  

- **Respiratory Depression:**  
  - Infrequent, but requires immediate medical attention.  
  - May occur from drug accumulation as a result of overaggressive titration.  

- **Sweating:**  
  - Relatively uncommon.  
  - Consider dose reduction with slower titration.  

- **Vomiting:**  
  - May resolve as body adjusts to medication.  
  - Hold the next dose – resume fluids as appropriate.  
  - Progressive alimentation  
  - Consider short-term use of metoclopramide or prochlorperazine.  

- **Itching:**  
  - Itching is often self-limiting but may be dose-related.  
  - Consider antihistamine.  
  - Rule out allergies (e.g., developmental reactions: bites)  

- **Urinary Retention:**  
  - Consider fentanyl re-titration as a potential cause for urinary retention.
Table 5: Mosby Pain Rating Scale

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>
<tbody>
<tr>
<td>0</td>
<td>Positive</td>
<td>0</td>
<td>Smiling</td>
</tr>
<tr>
<td>2-4 Whimper/moans</td>
<td>Neutral, shifting, pacing</td>
<td>0</td>
<td>No touching</td>
</tr>
<tr>
<td>5-7 Repetitive comment, crying</td>
<td>Tense, not moving</td>
<td>5-7</td>
<td>Frown, grimace</td>
</tr>
<tr>
<td>8-10 Screaming</td>
<td>8-10</td>
<td>Clenched teeth</td>
<td></td>
</tr>
</tbody>
</table>

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 - Aids 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 adjutantive therapies.
2. Oncologic Emergency - Severe uncontrolled pain is a medical emergency and should be evaluated and treated promptly (e.g., surgery, steroids, radiotherapy, antibiotics). Potential causes are listed below.
   a. Metastases – brain, epidural, leptomeningeval
   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. Ensure analgesics are given as prescribed
   c. Evaluate need for adjutantive medications
   d. Evaluate the appropriateness of dosing intervals
   e. Consider need for dose increase and upward titration to maximum daily dose as tolerated before changing drug therapy.
ACUTE

Mild to Moderate Pain?

- Yes
  - 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. APAP 650 mg TID QID X 7 days or EC ASA 650 mg TID QID X 7 days
    5. Alternatives: Ibuprofen 400 mg QID PRN X 7 days
    6. Other NSAIDs

- No
  - Enter Acute Pathway.

Resolved?

- Yes
  - End Therapy

- No
  - Rescruit severity and etiology of pain. Enter Box #3 of Acute Pathway.

Resolved?

- Yes
  - End Therapy

- No
  - Continue NSAID X 30 Days
  - Rescruit Severity of Injury
  - Provide Self Exercise/Streth Plan

Resolved?

- Yes
  - End Therapy

- No
  - Enter Chronic Back Pain Pathway on page 2 at box #2

CHRONIC

Consider:
1) Nonmechanical source of pain;
2) Imaging studies;
3) Definitive Procedure.

Chronic pain persists.

Counsel Patient Regarding Nature of Disease
(1) Weight Loss & Exercise
(2) Coping with Chronic Pain
(3) Self Exercise/Self Phys Plan (Exercise Handout available on CMCWEB DEPD homepage)

Medication:
Ibuprofen 600 mg TID PRN X 30 days

Improved and adequate work up for nonmechanical etiology?

1 2
3 4

No Yes

Consider referral to further identify etiology.

Continue chronic maintenance at lowest effective dose.

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 peri-operative 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; Revised 1/96, 1/98, 4/02, 4/03, 5/11; 11/14.
TREATMENT OF MILD TO MODERATE PAIN

1. Complete a history and physical including a pain assessment (page 2) to determine location, quality, type and intensity.
   - If applicable, go to other pain pathway:
     • Low back pain
     • Neuropathic pain
     • Chronic cancer pain

2. **Mild pain?**
   - Yes
     - APAP 325 mg – 2 tabs TID prn x 10 days KOP
     - Or
     - Ibuprofen 400 mg TID prn x 10 days KOP
     - Or
     - Naproxen 500mg BID prn x 10 days KOP
   - No
     - End therapy.

3. **Resolved?**
   - Yes
     - End therapy.
   - No
     - Re-evaluate etiology of pain.

4. **Resolved?**
   - Yes
     - End therapy.
   - No
     - Re-evaluate etiology of pain.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996,
Revised 8/98, 12/98, 1/07.

Prepared by The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996,
Revised 8/98, 12/98, 1/07.

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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 referred 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 under-treatment 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></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 2-3 times daily</td>
<td>1,500mg/day</td>
<td>NSAID – propionic acid</td>
</tr>
<tr>
<td>Meloxicam 7.5mg</td>
<td>1-2 tablets 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

1 Pain Assessment:
1. Detailed history
2. Focused physical exam
3. Treat underlying cause(s) appropriately

2 Initial treatment:
1. Provide patient education
2. Pharmacologic 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>325mg tid prn</td>
<td>325mg q week</td>
<td>Max dose=4g/day</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Analgesic</td>
<td>200mg bid-tid prn</td>
<td>200mg q week</td>
<td>Max dose=3.2g/day</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Analgesic</td>
<td>250mg bid prn</td>
<td>250mg q week</td>
<td>500mg bid</td>
</tr>
<tr>
<td>Nortriptyline</td>
<td>Antidepressant</td>
<td>25mg q hs</td>
<td>25mg q month</td>
<td>75-150mg/q day</td>
</tr>
<tr>
<td>Carbamazepine*</td>
<td>Anticonvulsant</td>
<td>200mg qd</td>
<td>200mg q month</td>
<td>1000-1600mg/day</td>
</tr>
<tr>
<td>Divalproex Sodium</td>
<td>Anticonvulsant</td>
<td>250 mg qd</td>
<td>250mg q month</td>
<td>500-1250 mg/day</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Anticonvulsant</td>
<td>100mg qd</td>
<td>100mg q month</td>
<td>300-500mg/day</td>
</tr>
<tr>
<td>Pyridoxine**</td>
<td>Other</td>
<td>50mg qd</td>
<td>-</td>
<td>Max dose=100mg/day</td>
</tr>
</tbody>
</table>

*see carbamazepine precaution on page 3
**for drug-induced neuritis (e.g., prescribe pyridoxine prophylactically with isoniazid)

3 Adequate pain relief?
   Yes
   4 Continue therapy & monitor patient for continued response & adverse effects
   Yes
   5 Titrate dose as outlined in box 2. Consider switching to a different agent if patient does not respond to adequate trial.

4 Yes
   8 Consider other therapeutic alternatives

5 No
   6 Adequate pain relief?
   Yes
   7 Titrate dose as outlined in box 2. Consider combination therapy if patient does not respond to an adequate trial of monotherapy.
   1. Analgesic + antidepressant, or
   2. Analgesic + anticonvulsant, or
   3. Antidepressant + anticonvulsant
   Consider switching to different combination if patient does not respond to first combination.
   No

Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. Approved January 2005; Reviewed 11/14; Revised 3/08, 5/11.
Neuropathic Pain

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, didanosine=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
   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 pinprick &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
   4. Combination therapy may be considered for patients that do not respond to monotherapy
   5. Gabapentin (Neurontin®) – When compared head-to-head with amitriptyline, gabapentin had equal efficacy. Reduction in neuropathic pain required doses higher than 1600mg/day. In some studies, sedation and dizziness were more common with gabapentin compared to amitriptyline. Disadvantages of gabapentin included the relative cost and the divided dosing needed in most patients.
   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. In 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. Does the patient meet DSM-5 criteria for Post-Traumatic Stress Disorder or Acute Stress Disorder?
   - No: Re-evaluate diagnosis and treat underlying causes.
   - Yes: Observe baseline BPRS.

3. Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

4. Does the patient have comorbid depression, bipolar disorder, or other anxiety disorder?
   - No: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   - Yes: Initiate formulary SSRI antidepressant.

5. Continue for 6-12 weeks at a therapeutic dose (Table 1).

6. Adequate response per BPRS?
   - Yes: Continue therapy for 12 months, reassessing as needed by unit mental health provider.
   - No: Assess compliance.

7. 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 nonformulary prazosin if nightmares are the prevalent symptom (Table 1) OR
   - Consider pharmacotherapy consult and/or nonformulary venlafaxine.

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.

9. Re-evaluate diagnosis and need for medication.
   - Switch to another formulary agent from a different class (Table 1) OR
   - Consider augmentation with nonformulary prazosin if nightmares are the prevalent symptom (Table 1) OR

10. Assess compliance.

11. If compliance < 80%, counsel on medication compliance.
   - Re-evaluate diagnosis and need for medication.
   - Switch to another formulary agent from a different class (Table 1) OR
   - Consider pharmacotherapy consult and/or nonformulary venlafaxine.

Prepared By: The Correctional Managed Care Pharmacy & Therapeutics Committee,

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Medication Selection

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: Formulary Antidepressants

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Initial Dose (Dose Range)</th>
<th>Therapeutic Range ng/mL</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td>Citalopram 20mg, 40mg tablet</td>
<td>Celexa®</td>
<td>20 (20 – 40)</td>
<td>N/A</td>
<td>Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine 20mg capsule</td>
<td>Prozac®</td>
<td>20 (20 – 40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sertraline 50mg, 100mg tablet</td>
<td>Zoloft®</td>
<td>50 (50 – 200)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tricyclic Antidepressants* (TCA)</td>
<td>Nortriptyline 25mg, 50mg, 75mg capsule</td>
<td>Pamelor®</td>
<td>25 – 50 (75 – 150)</td>
<td>50 – 110</td>
<td>Emergence of suicidal ideation or behavior</td>
</tr>
<tr>
<td></td>
<td>Prazosin 1mg capsule</td>
<td>Minipres®</td>
<td>Initial dose 1mg, gradually up to 15mg HS based upon response</td>
<td>N/A</td>
<td>Monitor supine, standing, and sitting BP; orthostatic hypotension</td>
</tr>
</tbody>
</table>

*Generally not recommended as first or second line therapy for treatment of PTSD
†Not a formulary agent but may be requested via nonformulary 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 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.

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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

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, retraction 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 - 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.
## ACUTE PSYCHOSIS

1. Rule out medical causes for presentation.
2. Meets DSM-IV Criteria for Psychosis?  
   - Yes: Re-evaluate diagnosis and treat underlying causes.  
   - No: Rule out medical causes for presentation.  

3. EPS present?  
   - Yes: Repeat diphenhydramine dose every 20-30 minutes (max 200mg/day).  
   - No: Administration haloperidol 2-5mg IM. May repeat q 60 minutes as needed (max 20mg/day) along with diphenhydramine 50mg IM, may repeat in 20-30 minutes if necessary (max 200mg/day) OR.  

4. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
   - Yes: Go to box #11.  
   - No: Administer haloperidol 2-5mg IM. May repeat q 60 minutes as needed (max 20mg/day) along with diphenhydramine 50mg IM, may repeat in 20-30 minutes if needed (max 200mg/day) OR.  

5. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol) q 4 hours as needed (max 40mg/day).  

6. Yes: Repeat diphenhydramine dose every 20-30 minutes (max 200mg/day).  
    - No: Consider pharmacotherapy consult OR.  

7. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
   - Yes: Go to box #11.  
   - No: Add diphenhydramine 50mg IM q 4 hours as needed (max 200mg/day) OR.  

8. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
   - Yes: Go to box #11.  
   - No: Add ziprasidone 20mg IM q 4 hours as needed (max 40mg/day).  

9. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
   - Yes: Go to box #11.  
   - No: Consider pharmacotherapy consult OR.  

10. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
    - Yes: Go to box #11.  
    - No: Consider referral to inpatient facility for evaluation.  

11. Effective control of target symptoms (psychosis, agitation, and/or behavioral dyscontrol)?  
    - Yes: Go to box #11.  
    - No: Consider medication change and/or consult.  

Monitoring 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.

- MENTAL STATUS: Alert and oriented, motor activity, speech, excess sedation
- Extrapyramidal Symptoms (EPS): Dystonia, parkinsonism, akathisia, tremor, dyskinesia
- Behavior: Psychosis (ie. hallucinations, delusions, disorganized speech/behavior), assaultive, agitated
- Neuroleptic Malignant Syndrome (NMS): dehydration, vital signs, muscle rigidity, diaphoresis, alteration in consciousness, autonomic dysfunction (orthostatic hypotension, drooling, urinary incontinence, unusually rapid breathing)
- Vital Signs: Blood pressure, pulse, temperature, respiration (as clinically indicated)

Management of Adverse Effects

- Neuroleptic Malignant Syndrome: 
  - Medical emergency, evaluate through medical department for possible referral to hospital ED
  - Acute Dystonic Reaction: 
    - Diphenhydramine 50mg IM (max 200 mg/day)
  - Worsening Mental Status: 
    - Immediately contact psychiatric provider for evaluation
  - Reconsider possible medical etiology for presentation

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 12/02; reviewed 4/03, 3/11; revised 11/05, 1/09, 7/10, 5/13

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Chronic Psychosis

1. Rule out medical causes for presentation.

2. Does the patient meet DSM-5 criteria for Psychosis?
   - Yes: Re-evaluate diagnosis and treat underlying causes.
   - No: Obtain baseline information including BPRS, AIMS, and labs in 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) – respond once up to a maximum of 6mg/day and treat for at least 6 weeks.
   - Consider formulary SGA (risperidone) 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. Assess compliance
   - Yes: The pathways do not replace sound clinical judgment and are not strictly intended to apply to all patients.
   - No: Continue treatment and taper to lowest effective dose.

6. Re-evaluate diagnosis:
   - 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 risperidone, consider trial.
   - Consider non-formulary SGA.

7. Adequate response per BPRS?
   - Yes: Continue treatment and taper to lowest effective dose.
   - No: Monitor per recommendations in Tables 1-2.

8. Assess compliance:
   - Yes: The pathways do not replace sound clinical judgment and are not strictly intended to apply to all patients.
   - No: Continue treatment and taper to lowest effective dose.

9. Re-evaluate diagnosis:
   - If patient has not received trial of 2 SGAs and has no contraindications, consider trial of other FGA.
   - If patient has not received a trial of risperidone, consider trial.
   - Consider augmentation with formulary mood stabilizer lithium or divalproex sodium.

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; 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
   - No

3. Consider non-formulary Risperdal Consta injection. Titrate to therapeutic dose (see Page 6).
   - Observe response for 6 months at maximum tolerated dose.

4. Initiate haloperidol or fluphenazine decanoate. Titrate to therapeutic dose (see Page 6).
   - Observe response for 6 months at maximum tolerated dose.

5. Well tolerated and adequate response per BPRS?
   - Yes
   - No

6. Consider pharmacotherapy consult and/or non-formulary medication.

   - Continue at lowest effective dose.
   - Monitor per recommendations in Table 1 and 2.
   - Attempt switch to oral therapy if compliant and stable.
Antipsychotic Monitoring Parameters

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>X</td>
<td>As clinically indicated</td>
<td></td>
</tr>
<tr>
<td>EKG¹</td>
<td></td>
<td>As clinically indicated</td>
<td></td>
</tr>
<tr>
<td>Prolactin²</td>
<td></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 66-100mcg/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
• Clozapine (Clozaril®) - 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></td>
<td></td>
<td>Medication is started, changed or discontinued</td>
</tr>
<tr>
<td>Agent</td>
<td>Formulary Status</td>
<td>Potency</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Chlorpromazine <em>(Thorazine)</em></td>
<td>F</td>
<td>Low</td>
</tr>
<tr>
<td>Fluphenazine <em>(Prolixin)</em></td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Haloperidol <em>(Haldol)</em></td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Perphenazine <em>(Trilafon)</em></td>
<td>F</td>
<td>Mid</td>
</tr>
<tr>
<td>Thioridazine <em>(Mellaril)</em></td>
<td>NF</td>
<td>Low</td>
</tr>
<tr>
<td>Thiothixene <em>(Navane)</em></td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Trifluoperazine <em>(Stelazine)</em></td>
<td>F</td>
<td>High</td>
</tr>
<tr>
<td>Atypicals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole <em>(Abilify)</em></td>
<td>NF</td>
<td>++++/++++</td>
</tr>
<tr>
<td>Asenapine <em>(Saphris)</em></td>
<td>NF</td>
<td>?</td>
</tr>
<tr>
<td>Clozapine <em>(Tegretol)</em></td>
<td>NF</td>
<td>+++/++</td>
</tr>
<tr>
<td>Diperidone <em>(Faztup)</em></td>
<td>NF</td>
<td>++++/+++</td>
</tr>
<tr>
<td>Lurasidone <em>(Latuda)</em></td>
<td>NF</td>
<td>?</td>
</tr>
<tr>
<td>Olanzapine <em>(Zyprexa)</em></td>
<td>NF</td>
<td>+++/++</td>
</tr>
<tr>
<td>Paliperidone <em>(Invega)</em></td>
<td>NF</td>
<td>+++++/++++</td>
</tr>
<tr>
<td>Quetiapine <em>(Seroquel)</em></td>
<td>NF</td>
<td>++</td>
</tr>
<tr>
<td>Risperidone <em>(Risperdal)</em></td>
<td>F</td>
<td>+++++/++++</td>
</tr>
<tr>
<td>Ziprasidone <em>(Geodon)</em></td>
<td>NF</td>
<td>++++/+++</td>
</tr>
</tbody>
</table>

*Should only be used in treatment refractory illness. Contraindicated for use with agents that are known to prolong QTC, and agents that inhibit metabolism of thioridazine (such as: fluoxetine, paroxetine, fluvoxamine, propranolol)
* dose-dependent
* partial D2 agonist
Table 4: 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 3 and consider selecting an agent with a lower incidence of EPS or  
                      |   • Switch to a SGA or  
                      |   • Treat EPS with one of the following agents  
                      |   • Benztropine 1 – 6 mg/day  
                      |   • Diphenhydramine 25 – 100 mg/day  
                      |   • Amantadine 100 – 300 mg/day  
                      |   • Propranolol 20 – 120mg/day  
                      |   • Short term use of benzodiazepines may be considered in severe cases in an inpatient setting  
                      |   • Increase dose of agent or switch to alternate anti-EPS agent if ineffective |
| Akathisia            | • Lower the dose of the antipsychotic agent to the lowest effective dose or  
                      |   • Switch to a SGA or  
                      |   • Treat with propranolol 20 – 120mg/day. Titrate dose as tolerated and as needed. |
| Tardive dyskinesia   | • Diagnosis supported by AIMS?  
                      |   • Switch to a SGA  
                      |   • Consider pharmacotherapy consult for treatment options |
| Neuroleptic Malignant Syndrome | • Medical emergency  
                      |   • Evaluate through medical department for possible referral to emergency room  
                      |   • Consider STAT CPK  
                      |   • Discontinue antipsychotic |

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.
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 q2 weeks
• 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 q2 weeks
Dosing method
• Initiate Risperdal Consta 25mg q2 weeks
• Continue oral antipsychotic for 3 weeks, then discontinue
• Adjust dose no sooner than q4 weeks, as needed
## 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>0 = None</th>
<th>1 = Minimal</th>
<th>2 = Mild</th>
<th>3 = Moderate</th>
<th>4 = Severe</th>
</tr>
</thead>
</table>

### Date of Evaluation

1. **Muscles of facial expression**
   - e.g. movements of forehead, eyebrows, preorbital area, cheeks, include frowning, blushing, sniffling, grimacing

2. **Lips and perioral area**
   - e.g. puckering, pursing, smacking

3. **Jaw**
   - e.g. biting, clenching, chewing, mouth opening, lateral movement

4. **Tongue**
   - Rate only increase in movement both in and out of mouth, not inability to sustain movement

5. **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).

6. **Lower (legs, knees, ankles, toes)**
   - e.g. lateral knee movement, foot tapping, heel dropping, foot squirming, inversion and eversion of foot

7. **Neck shoulders, hips**
   - e.g., rocking, twisting, squirming, pelvic gyrations

8. **Severity of abnormal movements**

9. **Incapacitation due to abnormal movements**

10. **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

11. **Current problems with teeth &/or dentures?**
    - No = 0
    - Yes = 1

12. **Does patient usually wear dentures?**
    - No = 0
    - Yes = 1

13. **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 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.
<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, depondency, 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, strange, bizarre thought content.</td>
</tr>
<tr>
<td>16.</td>
<td>BLUNTED 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 elation 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. 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 room, books on a shelf, interviewer's clothing, etc.</td>
</tr>
</tbody>
</table>
Psychotropic Agents: Dosing, Approximate Equivalent Doses, & Recommendations for Switching Agents

Patients should be evaluated for use of formulary psychotropic 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.

When treating elderly patients with psychotropic agents, lower starting doses and slower dose titrations 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 the referral.

### ANTIDEPRESSANTS

<table>
<thead>
<tr>
<th>DRUG</th>
<th>FORMULARY AGENT</th>
<th>USUAL DOSE (MG/DBY)</th>
<th>APPROXIMATE EQUIVALENT DOSE (MG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricyclic Antidepressants (TCAs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amitriptyline (Elavil®)</td>
<td>N 100-300</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Amoxapine (Asendin®)</td>
<td>N 100-400</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Clomipramine (Anafranil®)</td>
<td>N 100-250</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Desipramine (Norpramin®)</td>
<td>N 100-300</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Doxepin (Sinequan®)</td>
<td>N 100-300</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Imipramine (Tofranil®)</td>
<td>Y (TJD only)</td>
<td>100-300</td>
<td></td>
</tr>
<tr>
<td>Maprotiline (Ludiomil®)</td>
<td>N 100-225</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Nortriptyline (Pamelor®)</td>
<td>Y 50-150</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Protriptyline (Vivactil®)</td>
<td>N 15-60</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Trimipramine (Surmontil®)</td>
<td>N 100-300</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Selective Serotonin Reuptake Inhibitors (SSRIs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citalopram (Celexa®)</td>
<td>Y 20-40</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Escitalopram (Lexapro®)</td>
<td>N 10-20</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Fluoxetine (Prozac®)</td>
<td>Y 20-80</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Fluvoxamine (Luvox®)</td>
<td>N 100-300</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Paroxetine (Paxil®)</td>
<td>N 20-50</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Sertraline (Zoloft®)</td>
<td>Y 50-200</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Venlafaxine (Effexor®)</td>
<td>N 75-375</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>Duloxetine (Cymbalta®)</td>
<td>N 46-80</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Milnacipran (Savella®)</td>
<td>N 100-200</td>
<td>N.S.</td>
<td></td>
</tr>
<tr>
<td>Monoamine Oxidase Inhibitors (MAOIs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(the following are inexact estimates for approximate equivalent dosing)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isocarboxazid (Marplan®)</td>
<td>N 10-30</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Phenelzine (Nardil®)</td>
<td>N 15-90</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Tranylcypromine (Parnate®)</td>
<td>N 10-60</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Selegiline (Emsam®)</td>
<td>N 6-12 (transdermal)</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

This dosing tool does not replace sound clinical judgment, nor is it intended to strictly apply to all patients.

217
<table>
<thead>
<tr>
<th>DRUG</th>
<th>FORMULARY AGENT</th>
<th>USUAL Dose (MG/day)</th>
<th>APPROXIMATE EQUIVALENT Dose (MG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other (the following are inexact estimates for approximate equivalent dosing)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion (Wellbutrin®)</td>
<td>N</td>
<td>300-450</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>Sr</td>
<td>150-400</td>
<td>Sr = 150</td>
</tr>
<tr>
<td></td>
<td>Xl</td>
<td>150-450</td>
<td>Xl = 150</td>
</tr>
<tr>
<td>Mirtazapine (Remeron®)</td>
<td>N</td>
<td>15-45</td>
<td>15</td>
</tr>
<tr>
<td>Trazodone (Desyrel®)</td>
<td>Y</td>
<td>150-600</td>
<td>50</td>
</tr>
<tr>
<td>Nefazodone (Serzone®)</td>
<td>N</td>
<td>300-600</td>
<td>100</td>
</tr>
<tr>
<td>Vilazodone (Viibryd®)</td>
<td>N</td>
<td>20-40</td>
<td>N/a</td>
</tr>
</tbody>
</table>

†Doses are approximate equivalencies only within the specified drug category.
*No data currently available on equivalent dosing.

Switching Antidepressant Agents

TCA to TCA

If switching from one TCA to another, a cross-taper is generally not necessary. Since the usual dosage range for most TCAs is 100-300mg/day (nortriptyline is 50-150mg/day), it would be acceptable to use the same daily dose when switching between agents except protriptyline and nortriptyline. For example, a patient prescribed 300mg/day of amitriptyline could be switched to 300mg/day of desipramine.

TCA to SSRI

If switching from a TCA to a SSRI, the dose of the TCA may be tapered over 3 days while initiating therapy with the SSRI. A more conservative approach would be to taper the TCA first over 3 days and then begin therapy with the SSRI.

SSRI to SSRI

If switching from one SSRI to another, a cross-taper is generally not necessary. Table 1 should be used when selecting an approximate equivalent dose.

Table 2: Guidelines for Switching Between Antidepressants

<table>
<thead>
<tr>
<th>FROM (Drug #1)</th>
<th>TO (Drug #2)</th>
<th>STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCA or Others</td>
<td>TCA</td>
<td>Discontinue Drug #1 by taper while initiating the new TCA OR Discontinue Drug #1 by taper and then initiate therapy with the new TCA OR Discontinue Drug #1 and start Drug #2 the next day</td>
</tr>
<tr>
<td>TCA or Others</td>
<td>SSRI</td>
<td>Discontinue Drug #1 by taper over 3 days while initiating the SSRI OR Discontinue Drug #1 by taper over 3 days and then initiate therapy with the SSRI</td>
</tr>
<tr>
<td>TCA or Others</td>
<td>Others</td>
<td>Discontinue Drug #1 and start Drug #2 the next day OR Discontinue Drug #1 by taper and start Drug #2 gradually</td>
</tr>
<tr>
<td>TCA</td>
<td>MAOI</td>
<td>Discontinue the TCA by taper (doses &gt;100mg/day). After a 2-week washout, start MAOI</td>
</tr>
</tbody>
</table>

218
FROM (Drug #1) TO (Drug #2) STRATEGY

SSRI (with the exception of Fluoxetine) SSRI Discontinue the SSRI and start the new SSRI the next day
Discontinue the SSRI by taper and start new SSRI gradually

SSRI (with the exception of Fluoxetine) TCA or Others Discontinue the SSRI and start Drug #2 the next day
Discontinue the SSRI by taper and start Drug #2 gradually

Fluoxetine SSRI Stop Drug #1 abruptly and start new SSRI at ½ normal starting dose 4 to 7 days later

Fluoxetine TCA, Others Stop Drug #1 abruptly and start Drug #2 gradually

SSRI MAOI Discontinue SSRI. After a 5-week washout period for Fluoxetine, or 2-week washout period for Sertraline, Paroxetine, or Citalopram, start MAOI

MAOI MAOI, TCA, SSRI, or Others Discontinue MAOI. After a 2-week washout, start MAOI, TCA, SSRI, or other

ANTIPSYCHOTICS

Table 3: Antipsychotics3,4,5,13,15-17

<table>
<thead>
<tr>
<th>DRUG</th>
<th>FORSYLARY AGENT</th>
<th>USUAL DOSE (MG/DAY)</th>
<th>APPROXIMATE EQUIVALENT DOSE (MG)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High-Potency First Generation Agents</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>0.5-20</td>
<td>2</td>
</tr>
<tr>
<td>Haloperidol (Haldol®)</td>
<td>Y</td>
<td>0.5-20</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Mid-Potency First Generation Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loxapine (Loxitane®)</td>
<td>N</td>
<td>25-250</td>
<td>10</td>
</tr>
<tr>
<td>Molindone (Moban®)</td>
<td>N</td>
<td>15-225</td>
<td>10</td>
</tr>
<tr>
<td>Perphenazine (Trilamin®)</td>
<td>Y</td>
<td>16-64</td>
<td>10</td>
</tr>
<tr>
<td>Thiothixene (Navane®)</td>
<td>Y</td>
<td>4-20</td>
<td>5</td>
</tr>
<tr>
<td>Trifluoperazine (Stelazine®)</td>
<td>Y</td>
<td>2-40</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Low-Potency First Generation Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chlorpromazine (Thorazine®)</td>
<td>Y</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></td>
<td>Second Generation Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole (Abilify®)</td>
<td>N</td>
<td>10-30</td>
<td>7.5</td>
</tr>
<tr>
<td>Clozapine (Clozaril®)</td>
<td>N</td>
<td>75-900</td>
<td>50</td>
</tr>
<tr>
<td>Risperidone (Risperid®)</td>
<td>N</td>
<td>0.5-20</td>
<td>5</td>
</tr>
<tr>
<td>Quetiapine (Seroquel®)</td>
<td>N</td>
<td>50-400</td>
<td>75</td>
</tr>
<tr>
<td>ziprasidone (Geodon®)</td>
<td>N</td>
<td>40-150</td>
<td>60</td>
</tr>
<tr>
<td>Paliperidone (Invega®)</td>
<td>N</td>
<td>3-12</td>
<td>8</td>
</tr>
<tr>
<td>Ziprasidone (Geodon®)</td>
<td>N</td>
<td>10-20</td>
<td>N/A</td>
</tr>
<tr>
<td>Ziprasidone (Fujita®)</td>
<td>N</td>
<td>12-24</td>
<td>N/A</td>
</tr>
<tr>
<td>Lurasidone (Latuda®)</td>
<td>N</td>
<td>40-80</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*no data currently available on equivalent dosing
Switching Antipsychotic Agents

Little study data is available, but studies of abrupt discontinuation versus cross-tapering strategies from other antipsychotics to ziprasidone, olanzapine, and aripiprazole found no difference in outcomes. The method used should be individualized based on the patient and the period of overlapping should be minimized if cross-tapering is selected. Cross-tapering may be considered for patients that are clinically unstable or only recently stabilized, are on high doses, have had a recent relapse, are being treated as outpatients, or are having a partial response to their current agent and may require a slower titration rate on the new agent to improve tolerability. Unless there is a medication intolerance, switching of antipsychotic agents is not advised until a trial of adequate dose and duration (4-6 weeks) is completed.

Table 4: Basic Switch Strategies

<table>
<thead>
<tr>
<th>STRATEGY</th>
<th>ADVANTAGE</th>
<th>DISADVANTAGE</th>
<th>RECOMMENDED FOR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrupt Switching</td>
<td>Low risk of drug interactions</td>
<td>Withdrawal reactions</td>
<td>Patients with serious adverse event(s)</td>
</tr>
<tr>
<td>Gradual Switching</td>
<td>Low risk of withdrawal reactions, few drug interactions</td>
<td>Drug interactions complicated</td>
<td>Patients with low risk of relapse</td>
</tr>
<tr>
<td>Cross-tapering</td>
<td>Safest to prevent relapse</td>
<td>Drug interactions complicated</td>
<td>Recently stabilized patients</td>
</tr>
</tbody>
</table>

Abrupt Switching is simultaneous cessation of prior antipsychotic and initiation of new antipsychotic.

Gradual Switching is adding the new antipsychotic at the therapeutic dose, while the previous antipsychotic is slowly tapered off.

Cross-tapering is gradually decreasing and tapering the existing antipsychotic, while at the same time initiating and gradually increasing the new antipsychotic.

Table 5: Study Switch Strategies

<table>
<thead>
<tr>
<th>FROM TYPICAL AGENT TO ZIPRASIDONE STRATEGY</th>
<th>FROM TYPICAL AGENT TO OLANZAPINE STRATEGY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical agent, Risperidone, or Olanzapine</td>
<td>Ziprasidone* 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily</td>
</tr>
<tr>
<td>Abrupt discontinuation: Drug #1 discontinued the day before starting ziprasidone</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Ziprasidone 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily</td>
<td></td>
</tr>
<tr>
<td>Immediate dose reduction with cross-taper: Dose of Drug #1 reduced 30% for first week and then Drug #1 discontinued</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Ziprasidone 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily</td>
<td></td>
</tr>
<tr>
<td>Delayed dose reduction with cross-taper: Dose of Drug #1 continued then reduced 50% on day 4 and then Drug #1 discontinued at the end of 1 week</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Typical agent, Olanzapine</th>
<th>Olanzapine 10mg daily (starting dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrupt discontinuation: Drug #1 discontinued the day before starting olanzapine</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Olanzapine 10mg daily (starting dose)</td>
<td></td>
</tr>
<tr>
<td>Dose reduction with overlap: Dose of Drug #1 given in decreasing doses for 2 weeks then discontinued</td>
<td></td>
</tr>
</tbody>
</table>

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FROM (Drug #1) TO (Drug #2) STRATEGY

Typical or atypical agent

Aripiprazole

- Aripiprazole 15mg daily (starting dose)
- Abrupt discontinuation: Drug #1 discontinued the day before starting aripiprazole or
- Aripiprazole 15mg daily (starting dose)
- Dose reduction with overlap: Dose of Drug #1 reduced by 50% for the first week, reduced another 50% during week 2, and then discontinued or
- Aripiprazole: 10mg/day for 1 week, then 20mg/day for 1 week, then up to 30mg/day thereafter if necessary
- Cross-titration with dose reduction: Dose of Drug #1 reduced by 50% for the first week, reduced another 50% during week 2, and then discontinued

*All patients were on ziprasidone monotherapy by the second week regardless of switching strategy

Long-Acting Injectable Antipsychotics

Use of a long-acting injectable antipsychotic should be considered for patients displaying significant noncompliance or partial compliance leading to decompensation, poor function, and/or requirement for compelled medications. After 6 months of treatment with injections, 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>DRUG</th>
<th>FORMULARY AGENT</th>
<th>USUAL DOSE (MG)</th>
<th>USUAL DOSE INTERVAL</th>
<th>MAXIMUM DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haloperidol decanoate (Haldol-D®)</td>
<td>Y</td>
<td>50-200</td>
<td>Q 4wks</td>
<td>450mg Q 4 wks</td>
</tr>
<tr>
<td>Fluphenazine decanoate (Prolixin-D®)</td>
<td>Y</td>
<td>25-50</td>
<td>Q 2-3wks</td>
<td>100mg Q 2wks</td>
</tr>
<tr>
<td>Risperidone long acting (Risperdal Consta®)</td>
<td>N</td>
<td>25-50</td>
<td>Q 2wks</td>
<td>50mg Q 2wks</td>
</tr>
<tr>
<td>Paliperidone long acting (Invega Sustenna®)</td>
<td>N</td>
<td>78-234</td>
<td>Q 4wks</td>
<td>234mg Q 4wks</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; continue oral haloperidol for 1 month, then discontinue

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.

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### AGENTS USED IN THE TREATMENT OF BIPOLAR DISORDER

#### Table 7: Agents Used to Treat Bipolar Disorder²,⁷

<table>
<thead>
<tr>
<th>DRUG</th>
<th>FORMULARY AGENT</th>
<th>USUAL DOSE (MG/DAY)</th>
<th>TARGET DRUG CONCENTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium and Fluoxetine (Syndrasol™)</td>
<td>N</td>
<td>6-12/18/75</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>800-1600</td>
<td>4-12 mcg/mL</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>1000-2000 (20 mg/kg/d)</td>
<td>50-125 mcg/mL</td>
</tr>
<tr>
<td>Divalproex Sodium (Depakote™)</td>
<td>Y</td>
<td>1000-2800 (20 mg/kg/d) (ER = 25 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>Clozapine (Clozaril®)</td>
<td>N</td>
<td>100-500</td>
<td>350-700 mcg/mL</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>400-800</td>
<td>N/A</td>
</tr>
<tr>
<td>Risperidone (Risperdal®)</td>
<td>Y</td>
<td>1-6</td>
<td>N/A</td>
</tr>
<tr>
<td>Ziprasidone (Geodon®)</td>
<td>N</td>
<td>80-160</td>
<td>N/A</td>
</tr>
<tr>
<td>Aripiprazole (Abilify®)</td>
<td>N</td>
<td>10-30</td>
<td>N/A</td>
</tr>
<tr>
<td>Asenapine (Saphris®)</td>
<td>N</td>
<td>10-20</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Switching Agents for the Treatment of Bipolar Disorder

In general, the new agent should be started and titrated upward to an effective dose if a medication is to be discontinued. The dose of the old agent may then be decreased gradually over the next month. The general goal is to avoid abrupt discontinuation of the old medication until the new agent is established.

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Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved July 2006. Revised 1/10, 9/11, 7/12.
Management of Razor Blade Ingestion

1. Patient reports razor blade ingestion
2. Treat bleeding as necessary
   - Yes
   - No
3. Symptoms of foreign body lodged in esophagus?
   - Yes
   - No
4. Obtain chest X-ray as soon as available.
5. Obtain STAT chest X-ray (send to ER if not available on the unit).
6. Razor blade visualized below the lower esophageal junction?
   - Yes
   - Mental Health Evaluation (MHE)
   - No
7. Admit to crisis management if indicated by MHE
8. Abdominal exam at least daily x 3-4 days.
9. Signs of acute abdomen or bleeding?
   - Yes
   - Further follow up as needed. Discharge from crisis management when indicated
10. Emergent referral to surgeon as indicated.
11. End

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.
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 be come 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

1. Conseil Patient:
   (1) Avoid Precipitating Factors
   (2) Increase Fluids

2. End Intervention
   Yes
   No

3. Mild Symptoms?
   Yes
   No

4. Contraindications to Decongestants?
   (e.g. HTN, etc.)
   Yes
   No

5. Loratadine 10 mg QD or Chlorpheniramine (CTM) 4 mg QID x 14 days
   Yes
   No

6. Loratadine or CTM plus phenylepherine x 14 days
   Yes
   No

7. Resolved?
   Yes
   No

8. End Therapy
   Yes
   No

9. Infection Present?
   Yes
   No

10. Consider Alternative Therapy for Chronic Rhinitis

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, September 1996;

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Acute Seizures

Seizure Activity for 0-5 Minutes
- Confirm clinical findings by observing continuous seizure activity or one additional seizure.
- Rule out suspected symptom amplification.
- Rule out underlying medical issue.

Observe x 2 hours; if no activity, discharge from medical department.

Suspect seizure activity?

Yes

New onset seizures refer to Seizure Disorder (DMG) for care.
- Consider administering extra dose of currently ordered oral antiepileptic drug (AED) if receiving treatment.
- Observe for a minimum of two hours and discharge from medical department following full recovery.
- Follow up with medical provider in 48-72 hours.
- Confirm medication adherence.
- Modify therapy if indicated per Seizure Disorder (DMG).

Seizure Activity continuing for 0-9 minutes?

No

Yes

New onset seizures refer to Seizure Disorder (DMG) for care.
- Consider administering extra dose of currently ordered oral antiepileptic drug (AED).
- Observe for a minimum of two hours and discharge from medical department following full recovery.
- Follow up in Chronic Care Clinic per ITP.
- Confirm medication adherence.
- Modify therapy if indicated per Seizure Disorder (DMG).

Seizure activity continuing for 6-9 minutes?

No

Yes

Observe x 2 hours, if no activity, discharge from medical department.

Suspect seizure activity?

If patient is hypoglycemic or blood glucose is not available, inject 50ml of 50% glucose by direct push into the IV.
- Consider injecting 100mg of thiamine I.V. prior to glucose administration if alcohol abuse is suspected.

Seizure Activity continuing for 6-9 minutes?

No

Yes

Administer oxygen by nasal cannula or mask, position head for unobstructed airway, consider intubation if respiratory assistance is needed.
- Obtain and record vital signs, initiate ECG monitoring.
- Establish an I.V. (normal saline).
- Obtain glucose finger stick.
- Draw venous samples for glucose, chemistries, hematology parameters, toxicology screens, and antiepileptic drug levels (if available).
- Administer oxygenatur with oximetry or arterial blood gases (if available).

Seizure activity continuing for 10-20 minutes?

No

Yes

Go to box #11, page 2.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, March 1998, Reviewed 5/01, 4/03, 1/07, 1/13. Revised 7/07, 10/08, 9/10.
Status epilepticus is defined as continuous seizure activity or two or more seizures without full recovery of consciousness between seizures lasting longer than 30 minutes.

Anticonvulsant drug therapy should be initiated if seizures last 10 minutes.

Administer the following if not already implemented:
- Inject 50ml of 50% glucose by direct push into the I.V.
- Consider injecting 100mg of thiamine I.V. prior to glucose administration if alcohol abuse is suspected.

Administer lorazepam 4 mg at 2 mg/minute by slow IVP.
- May be repeated after 10 minutes (usual maximum total dose 8mg) if seizures do not stop or another begins.
- Monitor blood pressure and watch for signs of respiratory depression.

Seizure activity continuing for 30 minutes?

- Yes
- No

If the patient does not respond to 2 doses of lorazepam, transport the patient to a higher level of care.

New onset seizures—refer to Seizure Disorder DMG for care.

Follow up with the patient within 1 week upon return from the emergency room or hospital.

Transfer to the nearest Emergency room.

Follow current unit protocol.

Follow up with the patient within 1 week upon return from 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.

Follow up next day and obtain AED serum levels.

Follow up in Chronic Care Clinic per ITP.

Modify therapy if indicated per Seizure Disorder DMG.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, March 1998, Revised 3/02, 6/05, 10/05, 7/07, 10/08, 9/08.
Seizure Disorder

Seizure activity and seizure classification documented?

For new onset seizures, attempt accurate diagnosis. Rule out underlying medical etiology. Consult Neurology if necessary.

Is patient on antiepileptic drug (AED) therapy?

If seizure activity is confirmed, initiate AED monotherapy based on seizure classification. (Table 1) Go to box #7. If seizure activity is ruled out, discontinue from Chronic Care Clinic or No seizure activity for ≥2 years, may consider D/C from Chronic Care Clinic.

If AED therapy is appropriate for diagnosis?

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

Is AED therapy effective and tolerated?

Monitor & obtain laboratories appropriate to AED utilized. (Table 2). Consider the following which may apply:
1. Counsel on importance of compliance
2. Adjust dose
3. Change to alternate AED
4. Add additional AED
5. Seek neurology consult.
Go to box #7.

Monitor & obtain laboratories appropriate to AED utilized. (Table 2). Follow up in Chronic Care Clinic. Consider discontinuation of AED when patient with negative EEG has been seizure free for ≥2 years. Taper off AED over 3-6 months.

Begin treatment with single drug using recommended initial daily dosing. Up to 70% of patients can be managed with monotherapy. Ensure proper medication adherence prior to modifying regimen. Medication noncompliance is one of the primary reasons for treatment failure.

### Formulary Medications

<table>
<thead>
<tr>
<th>Seizure Disorder</th>
<th>Simple Partial</th>
<th>Complex Partial</th>
<th>Generalized Tonic-Clonic</th>
<th>Absence</th>
<th>Preferred with Clinical Evidence of Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonic-Clonic</td>
<td>Carbamazepine</td>
<td>Carbamazepine</td>
<td>Carbamazepine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenobarbitol</td>
<td>Carbamazepine</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
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<td></td>
</tr>
<tr>
<td>Levetiracetam</td>
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<td></td>
</tr>
<tr>
<td>Epilepsy</td>
<td>Ethosuximide</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

### Non-Formulary Medications

<table>
<thead>
<tr>
<th>Seizure Disorder</th>
<th>Simple Partial</th>
<th>Complex Partial</th>
<th>Generalized Tonic-Clonic</th>
<th>Absence</th>
<th>Preferred with Clinical Evidence of Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonic-Clonic</td>
<td>Carbamazepine</td>
<td>Carbamazepine</td>
<td>Carbamazepine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
<td></td>
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</tr>
<tr>
<td>Phenobarbitol</td>
<td>Carbamazepine</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
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<tr>
<td>Phenytoin</td>
<td>Divalproex Sodium</td>
<td>Divalproex Sodium</td>
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<tr>
<td>Levetiracetam</td>
<td>Levetiracetam</td>
<td>Levetiracetam</td>
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<tr>
<td>Epilepsy</td>
<td>Ethosuximide</td>
<td>Ethosuximide</td>
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</table>

### Table 1: Monitoring Parameters for Commonly Prescribed Formulary Anticonvulsants

<table>
<thead>
<tr>
<th>Anticonvulsant</th>
<th>Parameter</th>
<th>Baseline</th>
<th>1 week</th>
<th>2 week</th>
<th>3-2 week for 2 months</th>
<th>1 month</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonic</td>
<td>CBC with platelets</td>
<td>X</td>
<td></td>
<td></td>
<td>X or as clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete Metabolic Panel</td>
<td>X</td>
<td></td>
<td>X or as clinically indicated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>BDI</td>
<td>X or &gt;40 years old or as clinically indicated</td>
<td>X or &gt;40 years old or as clinically indicated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood levels</td>
<td>X</td>
<td>X</td>
<td>X or as clinically indicated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table 2: Monitoring Parameters for Commonly Prescribed Formulary Anticonvulsants

<table>
<thead>
<tr>
<th>Anticonvulsant</th>
<th>Parameter</th>
<th>Baseline</th>
<th>1 week</th>
<th>2 week</th>
<th>3-2 week for 2 months</th>
<th>1 month</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenytoin</td>
<td>CBC with platelets</td>
<td>X</td>
<td></td>
<td>X or as clinically indicated</td>
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<tr>
<td></td>
<td>Complete Metabolic Panel</td>
<td>X</td>
<td></td>
<td>X or as clinically indicated</td>
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<td></td>
<td></td>
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<tr>
<td>Phenobarbitol</td>
<td>BDI</td>
<td>X or &gt;40 years old or as clinically indicated</td>
<td>X or &gt;40 years old or as clinically indicated</td>
<td></td>
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<tr>
<td></td>
<td>Blood levels</td>
<td>X</td>
<td>X</td>
<td>X or as clinically indicated</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Anticonvulsant</th>
<th>Parameter</th>
<th>Baseline</th>
<th>1 week</th>
<th>2 week</th>
<th>3-2 week for 2 months</th>
<th>1 month</th>
<th>Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divalproex Sodium</td>
<td>CBC with platelets</td>
<td>X</td>
<td></td>
<td>X or as clinically indicated</td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete Metabolic Panel</td>
<td>X</td>
<td></td>
<td>X or as clinically indicated</td>
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<tr>
<td></td>
<td>BDI</td>
<td>X</td>
<td>X</td>
<td>X or as clinically indicated</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Blood levels</td>
<td>X</td>
<td>X</td>
<td>X or as clinically indicated</td>
<td></td>
<td></td>
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</tbody>
</table>
Practitioner Education

Definitions:
1. **Seizure**—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.”
2. **Epilepsy**—a chronic disorder of the nervous system characterized by recurrent and unprovoked seizures. (Term may be applied after two unprovoked seizures).

Diagnosis:
Seizures are a symptom of an underlying disorder, which may be genetic, traumatic, metabolic, infectious, malignant, or pharmacological (e.g., drug intoxication or withdrawal). Identifying the underlying disorder, accurately classifying the seizure type, and selecting appropriate treatment are imperative for controlling seizures and preventing further brain dysfunction.

Steps for practical clinical evaluation:
1. **Obtain a medical history.** Determine whether there is a family history of epilepsy or personal history of head trauma, birth complications, febrile convulsions, alcohol or drug abuse, cancer, or vascular abnormalities (stroke). Events before, during, and after seizures should be assessed as well as a history of successful and unsuccessful treatments of seizures including medications. Medications that may cause seizures include recreational drugs (e.g., alcohol, cocaine/crack, ephedra), methylphenidate, imipenem, lidocaine, metoclopramide, theophylline, tricyclic antidepressants, meperidine (active metabolite—renal failure), and antiepileptics when used inappropriately for a non-indicated seizure type. It is important to differentiate epilepsy from alcohol or other drug withdrawal seizures because the latter generally do not require antiepileptic drugs.

2. **Physical examination.** Look for disorder associated with epilepsy, including head trauma, infections of the ears or sinuses (which may spread to the brain), congenital abnormalities, neurological disorders, alcohol or drug abuse, and cancer.

3. **Electroencephalographic (EEG) Studies.** Approximately 50% of epileptic patients show no abnormality on a single EEG, and approximately 10% of persons with true seizures, multiple EEG studies show no abnormalities. EEG provides 3 types of information: (1) confirmation of presence of abnormal electrical activity, (2) information about the type of seizure disorder, and (3) location of the seizure focus.

4. **Lab tests and Neuroimaging.** The following tests may be useful in determining the underlying cause of seizure activity:
   - **Electrolytes**
   - **Blood glucose**
   - **Liver function**
   - **Toxic substance screening**
   - **EEG in the waking and sleeping states**
   - **Imaging tests: magnetic resonance imaging (MRI) or computed tomography (CT)**
   - **Prolactin levels may be considered if pseudoseizure is suspected**

5. **Diagnostic Formulation and Treatment Plan.** Once an accurate classification of seizure type has been established, an appropriate antiepileptic drug should be administered for patients who have had two or more seizures. If a patient has only had one seizure, medications are warranted if one or more risk factors for recurrent seizures are present including evidence of a structural lesion, EEG abnormalities, partial type seizures, or a family history of seizures. Otherwise, a patient who has experienced only one seizure is usually monitored but not given medication.

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Seizure Disorder, Page 4

Classification: The International Classification of Epileptic Seizures

There are 2 main types of epilepsy: partial seizures and generalized seizures.

Partial Seizures—Begin in one hemisphere of the brain and, unless they become secondarily generalized, result in an asymmetric clinical manifestation. Partial epilepsy may begin in infancy and may be difficult to recognize in the elderly population.

1. Types of Partial Seizures
   - Simple Partial Seizure — no loss of consciousness
     - Motor function symptoms
     - Sensory or sensory-motor symptoms
     - Automatisms
   - Complex Partial Seizure — alteration/loss of consciousness
     - Simple partial onset followed by impairment of consciousness—with or without automatisms
     - Impaired consciousness at onset—with or without automatisms
     - Other symptoms may include memory loss or aberrations of behavior
     - May be misdiagnosed as psychiatric episodes
     - Patients with complex partial seizures are generally amnestic to these events
   - Secondarily generalized—partial onset evolving to generalized tonic-clonic seizures

2. Treatment Options:
   - Formulary—Carbamazepine, Phenytoin, Divalproex Sodium, Primidone, Levetiracetam,
   - Nonformulary—Gabapentin, Lamotrigine, Oxcarbazepine, Phenytoin, Tiagabine, Topiramate, Zonisamide

Generalized Seizures—Involvement of both brain hemispheres with bilateral motor manifestations and a loss of consciousness

1. Types of Generalized Seizures
   - Generalized Absence Seizure—sudden onset, brief (seconds), blank stare, possibly a brief upward rotation of the eyes, and lip-smacking (confused for daydreaming)
     - Generally occurs in young children through adolescence
     - Can be precipitated by hyperventilation
     - EEG during the seizure has a characteristic 2-to-4 cycle/s spike and slow-wave complex
     - Important to differentiate absence from complex partial seizures
     - Drugs of Choice (formulary)—Ethosuximide or Divalproex Sodium
     - Other options (nonformulary)—Clonazepam, Lamotrigine, Topiramate
   - Generalized Tonic-Clonic Seizure (formerly called grand mal seizure)—there are two phases to this seizure type:
     - 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; fall to the ground; loss of consciousness; tongue biting; involuntary urination
     - Clonic phase: Repetitive jerks; cyanosis continues; foam at the mouth; small grunting respirations between seizures, but deep respirations as all muscles relax at the end of the seizure
     - Drugs of Choice (formulary)—Phenytoin, Carbamazepine, Divalproex Sodium, Primidone, Levetiracetam
   - Other options (nonformulary)—Divalproex Sodium, Levetiracetam, Primidone
   - Myoclonic Seizure—Brief shock-like muscular contractions of the face, trunk, and extremities. May be isolated events or rapidly repetitive
   - Atonic Seizure—a sudden loss of muscle tone
     - May be described as a head-drop, the dropping of the limb, or a clumping to the ground
     - These patients often wear protective head-wear to prevent trauma
     - Drugs of Choice (formulary)—Divalproex Sodium, Levetiracetam, Primidone
   - Other options (nonformulary)—Tiagabine, Phenytoin, Oxcarbazepine
   - Juvenile Myoclonic Epilepsy (JME)—Myoclonic seizures precede generalized tonic-clonic seizures; generally occur upon awakening; severe deprivation and alcohol commonly precipitate; lifelong treatment required. Drug of Choice (formulary)—Divalproex Sodium, Other options (nonformulary)—Lamotrigine
   - Infantile Seizures—Begin in the 1st 6 months of life; occur in clusters, several times a day; parents describe symptoms that sound like clee; high mortality and morbidity; treated with ACTH, oral steroids, or vigabatrin.

2. Other Seizure Types
   - Catamenial Epilepsy— Associated with hormonal changes during menstruation; may be treated with acetazolamide (Diamox®)
   - 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.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Mechanism of Action</th>
<th>Usual Adult Dose</th>
<th>FDA Approved Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Tegretol®</td>
<td>Inhibits voltage-dependent Na channels</td>
<td>800-1200 mg divided bid-qid</td>
<td>Complex partial seizures, generalized tonic-clonic, mixed seizure patterns</td>
</tr>
<tr>
<td>Ethosuximide</td>
<td>Zarontin®</td>
<td>Inhibits NADPH-linked aldehyde reductase</td>
<td>20-40 mg/kg/day divided bid</td>
<td>Absence</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Dilantin®</td>
<td>Inhibits voltage-dependent Na channels</td>
<td>500-600 mg/day at 5-6 mg/kg/day in 3 divided doses (range 200-1200 mg/day)</td>
<td>Generalized tonic-clonic, complex partial seizures; prevention of seizures following head trauma/neurosurgery</td>
</tr>
<tr>
<td>Primidone</td>
<td>Myceral®</td>
<td>Enhances GABA</td>
<td>50-100 mg bid</td>
<td>Monotherapy or adjunctive use for generalized tonic-clonic, psychomotor, and focal seizures</td>
</tr>
<tr>
<td>Depakine</td>
<td>Depakote®</td>
<td>Enhances slow activation of voltage-gated Na+ channels</td>
<td>300 mg/day or 5-6 mg/kg/day in 3 divided doses (range 200-1200 mg/day)</td>
<td>Generalized tonic-clonic, complex partial seizures; prevention of seizures following head trauma/neurosurgery</td>
</tr>
<tr>
<td>Sodium Depakote®</td>
<td>1000-2500 mg/day divided bid-qid (15-60 mg/kg/day)</td>
<td>Monotherapy and adjunctive therapy for complex partial seizures; monoaminoergic effects for absence seizures; adjunctive therapy for mixed seizure types that include absence seizures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>gabapentin</td>
<td>Neurontin®</td>
<td>Unclear, but differs from other available anticonvulsants</td>
<td>900-1800 mg/day divided tid</td>
<td>Adjunctive therapy for partial seizures with and without secondary generalized seizures</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Lamictal®</td>
<td>Inhibits voltage-dependent Na channels and glutamate</td>
<td>100-500 mg/day in 1-2 divided doses</td>
<td>Adjunctive therapy for partial seizures and generalized seizures of Lennox-Gastaut syndrome, generalized tonic-clonic seizures</td>
</tr>
<tr>
<td>Lacosamide</td>
<td>Vimpat®</td>
<td>Enhances slow activation of voltage-gated Na+ channels</td>
<td>200-400 mg/day</td>
<td>Partial seizures</td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>Keppra®</td>
<td>Unknown</td>
<td>1000-3000 mg/day divided bid</td>
<td>Adjunctive therapy for partial and generalized tonic-clonic seizures; adjunctive therapy for juvenile myoclonic epilepsy</td>
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<tr>
<td>Oxcarbazepine</td>
<td>Trileptal®</td>
<td>Inhibits voltage-dependent Na channels</td>
<td>600 mg bid</td>
<td>Monotherapy or adjunctive therapy for partial seizures</td>
</tr>
<tr>
<td>Topiramate</td>
<td>Topamax®</td>
<td>GABA agonist and non-NMDA glutamate receptor antagonist</td>
<td>200-400 mg/day</td>
<td>Adjunctive or monotherapy for partial and generalized tonic-clonic seizures; treatment of seizures associated with Lennox-Gastaut syndrome</td>
</tr>
<tr>
<td>Vigabatrin</td>
<td>Sabril®</td>
<td>Increases the levels of GABA, by inhibiting GABA transaminase</td>
<td>500-1500 mg/day (adult)</td>
<td>Infantile spasms; adult complex partial seizures unresponsive to other alternatives</td>
</tr>
<tr>
<td>Zonisamide</td>
<td>Zonegran®</td>
<td>Inhibits voltage-dependent Na channel &amp; voltage-dependent Ca channels; blockade in GABA receptors and facilitates dopamine and serotonin neurotransmission</td>
<td>100-400 mg/day or divided bid</td>
<td>Adjunctive therapy for partial seizures</td>
</tr>
</tbody>
</table>
Potential Reasons for Treatment Failure

1. Ineffective diagnosis
2. Inappropriate anticonvulsant selected
3. Inappropriate dose
4. Side effects
5. Poor patient adherence

Principles of Treatment with Confirmed Seizure Disorder

1. Therapeutic drug monitoring is essential for verifying compliance and determining cause of toxicity when more than one antiepileptic agent is used.

Potential Benefits of AED Therapy

- May improve quality of life for patients with seizures
- May improve cognitive function
- May reduce the risk of death

Carbamazepine (Tegretol®)

- Genetic Testing Recommended for People with Asian Ancestry
  - The risks versus benefits of carbamazepine therapy should be weighed in patients that test positive and discussed with the patient and family. Patients who test positive should not be prescribed carbamazepine without genetic testing.

Hydantoin FACIES

- Facial swelling
- Acneiform eruptions
- Cutaneous hyperesthesia
- Edema
- Peripheral neuropathy

Phenytoin

- Folate deficiency causing megaloblastic anemia (rare)
- Hyperglycemia due to inhibitory effect on insulin
- Hyponatremia due to inhibition effect on insulin
- Peripheral neuropathy
- Prolonged systolic hypertension

Monitoring of blood levels is useful for verifying compliance and determining cause of toxicity when more than one agent is used. Consider obtaining carbamazepine level weekly for two weeks, then at one month and annually or as clinically indicated. Monitoring of blood levels is useful for verifying compliance and determining cause of toxicity when more than one agent is used. Consider obtaining blood chemistries with emphasis on hepatic and renal function at baseline, then at one month, and annually or as clinically indicated.
3. Divalproex Sodium

- Black box warning—fatal hepatotoxicity
- Black box warning—fatal hemorrhagic pancreatitis
- Black box warning—teratogenic
- C/I—hepatic disease/significant hepatic dysfunction; hypersensitivity to divalproex sodium; known urea cycle disorders; pregnancy
- Increased ammonia levels may occur despite normal liver function. In symptomatic patients, consider measurement of ammonia levels. If ammonia is increased, discontinue valproate and evaluate patient for underlying urea cycle disorder. If ammonia levels are increased and patient is asymptomatic, monitor ammonia levels closely. If elevation persists, consider discontinuation of divalproex.
- Counsel patients to recognize signs and symptoms of pancreatitis and advise patients to seek immediate medical attention if those symptoms occur.
- Thrombocytopenia may occur and appears to be dose-related. Consider obtaining CBC at baseline, then twice monthly for the first two months, and annually or as clinically indicated.
- Patients at higher risk for hepatotoxicity may include the following: patients on multiple anticonvulsants, children, those with congenital metabolic disorders, those with severe seizure disorder accompanied by mental retardation, and those with organic brain disease.
- Discontinue divalproex sodium in the presence of significant hepatic dysfunction, suspected, or apparent (LFTs >3 times normal limit).
- Consider obtaining LFTs at baseline and at frequent intervals thereafter, especially during the first 6 months. Results of careful interim medical history and physical examination should also be considered.
- Consider measurement of divalproex sodium level weekly for two weeks, then annually or as clinically indicated.
- Therapeutic blood level—50-100mcg/ml
- Toxic concentration->150mcg/ml

Table 4

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ADRS</th>
<th>DRUG INTERACTIONS (DI)/COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gabapentin</td>
<td>Weight gain, peripheral edema</td>
<td>D: No known interactions with other AEDs</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Dose-dependent: ataxia, dizziness, GI upset, insomnia.</td>
<td>D: oral contraceptives, enzyme inducing AEDs, rifamycins, VPA levels reduced and VPA may increase lamotrigine levels. Use with caution in renal impairment. Dose adjust—50-75% dose decrease in hepatic impairment. Initiate slowly to reduce the incidence of rash. Pregnancy Category C. Crosses breast milk.</td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>Dose-dependent: dizziness, fatigue, irritability, sedation.</td>
<td>D: probenecid—clinical significance unknown; not metabolized thru CYP450; no known interactions with other AEDs. Renal elimination—dose adjust in renal insufficiency and elderly. No dose adjustment for hepatic impairment. Pregnancy Category C.</td>
</tr>
<tr>
<td>Oxcarbazepine</td>
<td>Dose-dependent: GI (Nausea &amp; vomiting), CNS (dizziness, somnolence), diplopia.</td>
<td>D: oral contraceptives, diuretics, AEDs, dihydropyridine calcium channel blockers. 50% dose reduction recommended in renal insufficiency. Lactic changes not observed in cirrhosis. Does not increase antithrombin. Crosses plasma and breast milk. Pregnancy Category C.</td>
</tr>
</tbody>
</table>
### Pseudoseizures

1. **Definition:** "Psychogenic seizures are episodes involving affective, autonomic, or somatomotor manifestations that are precipitated by emotional distress." Other terms used to refer to these events include nonepileptic seizures, hysterical seizures, pseudoseizure, 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. **Diagnosis:** Epilepsy in patients with psychogenic seizures ranges from 10 to 60 percent. Clinical characteristics of pseudoseizures—Gates et al. successfully identified 96% of pseudoseizures using the following criteria.
   - **Strongly suggestive**
     - Prolonged duration of event (10-30 sec)
     - Preservation of consciousness despite whole body jerking
     - Bizarre and asynchronous motor movements
     - Pelvic thrusting movements
     - Not stereotypical
   - **Strongly against**
     - Injuries sustained during spells
     - Tongue laceration, especially sides of tongue
     - Incontinence
   - Schneker et al. caution that the diagnosis of pseudoseizures should not be solely based on clinical information. Video EEG monitoring is recommended if pseudoseizure is suspected.
   - Elevated prolactin may be predictive of tonic-clonic or partial seizures (more reliable in tonic-clonic seizures). Blood sample should be optimally drawn within 30 minutes of seizure. The reference interval for serum prolactin is in the range of 1 to 25 ng/mL (1 to 25 μg/L) for females and 1 to 20 ng/mL (1 to 20 μg/L) for males. However, 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. Psychogenic seizures occur in patients with conversion disorders, anxiety and panic disorder, depression, post-traumatic stress disorder, schizophrenia, and personality disorders.

### Table 4 continued

<table>
<thead>
<tr>
<th>DRUG</th>
<th>ADRS</th>
<th>DRUG INTERACTIONS &amp; COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tiagabine</td>
<td>Dose-dependent: dizziness, weakness, depression, HA, sedation, difficulty with concentration. Non-dose dependent: exacerbation of generalized seizures.</td>
<td>• DD: AEDs. • Hepatic metabolism impairment may require dosage reduction or longer dosing intervals. • Pregnancy Category C. Excreted in breast milk.</td>
</tr>
</tbody>
</table>

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Withdrawal of Anticonvulsants

1. Risk of Seizure Relapse:
   - Relapse rates are highest among children and adults in the first 12 months (especially in the first 6 months) after antiepileptic drug (AED) withdrawal.
   - The risk of withdrawal continues to decrease with time.

2. Considerations for AED Discontinuation:
   - Patients who have been seizure-free for a minimum of two years on AED treatment
   - Patients who experience only a single type of partial seizure or a single type of generalized tonic-clonic seizure
   - Normal neurological examination and normal intelligence quotient IQ
   - EEG normalized with treatment

3. Drug Discontinuation:
   - Risks and consequences of seizure recurrence versus continued treatment should be weighed.
   - High remission rates 1 and 2 years after AED withdrawal supports discontinuation of treatment when a patient has been seizure-free for 2 years or more.
   - The decision to withdraw AED medications in a seizure-free (>2 years) patient should be based on patient-specific factors.
   - If discontinuation of AED is warranted, the tapering schedule should be slow (most clinical trials suggest done should be tapered over 6 months) and tailored to the specific drug, dosage, and serum concentrations for each patient.

<table>
<thead>
<tr>
<th>Table 5</th>
<th>Factors Against Drug Withdrawal</th>
<th>Factors in Favor of Drug Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factors Against Drug Withdrawal</td>
<td>Factors in Favor of Drug Withdrawal</td>
<td></td>
</tr>
<tr>
<td>Adolescent-onset epilepsy</td>
<td>Childhood-onset epilepsy</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td>Elderly-onset epilepsy</td>
<td></td>
</tr>
<tr>
<td>Partial epilepsy</td>
<td>Idiopathic generalized epilepsy</td>
<td></td>
</tr>
<tr>
<td>Juvenile myoclonic epilepsy</td>
<td>Benign epilepsy with centrotemporal spikes</td>
<td></td>
</tr>
<tr>
<td>Presence of underlying neurological condition</td>
<td>Normal EEG (children)</td>
<td></td>
</tr>
<tr>
<td>Abnormal EEG (childhood)</td>
<td>Childbearing potential and planning pregnancy</td>
<td></td>
</tr>
<tr>
<td>Co-morbidity with concurrent treatments</td>
<td>Comorbidity with concurrent treatments</td>
<td></td>
</tr>
</tbody>
</table>

4. Phenobarbital Tapering

   - Phenobarbital monotherapy – If antiepileptic drug (AED) needs to be continued, the new agent should be started and therapeutic levels achieved prior to initiating phenobarbital taper (see below table).
   - Phenobarbital polypharmacy – please note that monotherapy is preferred
   - If patient is a good candidate for monotherapy (based on type of seizure, history of past treatments, compliance), initiate phenobarbital taper (see below table) without the addition of another agent.
   - If patient needs to be continued on polytherapy, a new agent should be started and therapeutic levels achieved prior to initiating the phenobarbital taper (see below table).

| Table 6 | Tapering schedule: Decrease phenobarbital dose by 30mg a month over 1-6 month period. Example: Patient is receiving 120mg/day |
|---------|---------------------------------|-------------------------------------|
| Tapering schedule: Decrease phenobarbital dose by 30mg a month over 1-6 month period. Example: Patient is receiving 120mg/day |
| 1st month, patient receives 120mg/day | 2nd month, patient receives 90mg/day |
| 3rd month, patient receives 60mg/day | 4th month, patient receives 30mg/day |
| Labs: If patient has undetectable phenobarbital levels (<2mg/L) and a history of noncompliance, a taper may not be necessary | Monitor: Provider must monitor patient for any new seizure activity. If doctor determines 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. |

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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.

1. End Therapy
2. Resolved?
   - Yes
   - No
3. Continue symptomatic treatment as needed.
4. Infection Present?
   - Yes
   - No
5. Refer to Rhinitis Treatment Pathway.
6. Moxycycline 100 mg BID X 14 Days KOP
   - If responding, but not completely resolved, continue current treatment for an additional 4 weeks.
7. Resolved?
   - Yes
   - No
8. End Therapy
9. Consider Nonformulary Medication for Resistant Organism
   - Augmentin 875 mg BID X 14 Days
   - Levofloxacin 500 mg QD X 14 Days
10. If responding, but not completely resolved, continue current treatment for an additional 4 weeks.
11. Resolved?
12. End Therapy
13. Evaluate and consider referral to a specialist

The pathways do not replace sound clinical judgment but are helpful to aid in the management of sinusitis. Refer to Rhinitis Treatment Pathway.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved August 1995; Reviewed 3/05, 5/11; Revised 8/98, 4/02, 4/03, 5/04, 5/08, 11/14
Skin & Soft Tissue Infection Treatment

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
3. Is cellulitis or impetigo present without abscess or other draining skin lesion?
   - Yes: Treat empirically with combination therapy for both strepococci and staphylococci as follows if still clinically improving:
     - 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)
   - No
4. Is immunosuppressive condition (Diabetes, Hepatitis B, Hepatitis C, HIV) present or trauma such as bites?
   - Yes
     a. Underlying condition should be controlled as well as possible.
     b. Obtain culture and sensitivity (C&S) using Levine method
     c. If fluctuant, perform incision and drainage (I&D)
     d. If not fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved.
     e. Start antibiotics
     Go to Page 2, box 15
   - No
5. Assess for recurrence: Has the patient had ≥3 clinical or culture-proven infections in a six-month period?
   - Yes
     a. Obtain C&S using Levine method
     b. If fluctuant, perform I&D
     c. If not fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved.
     d. Start antibiotics
     Go to Page 2, box 15
   - No
6. Is the lesion fluctuant?
   - Yes
     a. Obtain C&S using Levine method
     b. If fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved.
     c. Start antibiotics
     Go to Page 2, box 15
   - No
7. May be treated with I&D alone
   Go to Page 2, box 15
8. Fluctuant and area of redness & swelling < 5cm?
   - Yes
     a. Obtain C&S using Levine method
     b. Treat with I&D
     c. Start antibiotics
     Go to Page 2, box 15
   - No
9. May consider epidermal decolonization protocol:
   a. 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
10. Is the lesion fluctuant?
    - Yes
    a. Obtain C&S using Levine method
    b. If fluctuant, treat with warm compresses for 20 minutes 2 to 3 times per day until resolved.
    c. Start antibiotics
    Go to Page 2, box 15
    - No
11. May be treated with I&D alone
    Go to Page 2, box 15
12. Fluctuant and area of redness & swelling ≥ 5cm?
    - Yes
    a. Obtain C&S using Levine method
    b. Treat with I&D
    c. Start antibiotics
    Go to Page 2, box 15
    - No

The pathways do not replace sound clinical judgment and are not intended to strictly apply to all patients.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved 09/2012; Revised 11/2014.

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**Provide Patient Education**
- Staph Fact Sheet (Infection Control P&P B-14.16, Attachment A)
- 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, consider consult with Office of Public Health 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.
- Consider vancomycin, linezolid, or telithromycin.

**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. Moisten 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 immersed 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, Hypertipedia, Depression Chronic Care Clinics or if patient is taking lithium, as part of baseline workup.

The pathways do not replace usual clinical judgment nor are they intended to drill patients at risk.

If abnormal, repeat TSH and draw Free T4 within 4-8 weeks.

Determine underlying etiology by referring to specialist. Consider ordering thyroid scan while awaiting appointment for specialist. If medical management is warranted pending referral, go to box 20.

Levothyroxine Dosing

Initial: 25 - 50mcg once daily. Consider starting at the lowest dose if pt is <50 yrs or has coronary heart disease.

Subclinical Hyperthyroidism: 25-75mcg once daily as starting dose

Monitoring Recommendations:

Monitor TSH every 3 months. If dose change is needed, titrate by 50mcg.
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>
</tr>
</thead>
<tbody>
<tr>
<td>Constipation</td>
<td>Anorexia</td>
</tr>
<tr>
<td>Cold sensitivity</td>
<td>Weakness</td>
</tr>
<tr>
<td>Dry skin</td>
<td>Tremors</td>
</tr>
<tr>
<td>Hair loss or change in texture</td>
<td>Palpitations</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Heat intolerance</td>
</tr>
<tr>
<td>Myalgia/Arthralgia</td>
<td>Increased perspiration</td>
</tr>
<tr>
<td>Hoarseness</td>
<td></td>
</tr>
<tr>
<td>Weight gain despite poor appetite</td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td></td>
</tr>
<tr>
<td>Cognitive deficits/depression</td>
<td></td>
</tr>
<tr>
<td>Thyroid enlargement/nodules</td>
<td></td>
</tr>
<tr>
<td>Carpal tunnel syndrome</td>
<td></td>
</tr>
<tr>
<td>Sleep apnea</td>
<td></td>
</tr>
<tr>
<td>Females may present with menorrhagia, amenorrhea, and galactorrhea</td>
<td></td>
</tr>
</tbody>
</table>

C. Lab Evaluation – see pathway for frequency
1. TSH
2. Free T4
3. Free T3

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 hypo- and hyperthyroidism from primary hypo- and hyperthyroidism.

Table 1.

<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>5.6-9.9 mIU/L</td>
<td>0.78-2.2 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>0.78-2.2 ng/dL</td>
</tr>
<tr>
<td>Primary Hyperthyroidism</td>
<td>&lt;0.35 mIU/L</td>
<td>&gt;2.2 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).


| CMC Formulary Levothyroxine Strengths: 25mcg, 50mcg, 75mcg, 100mcg |
|-----------------|-----------------|-----------------|-----------------|
| Starting dose   | 25mcg to 100mcg | 25mcg once a day | 25mcg once a day |
| Patients with Primary Hypothyroidism | Patients with Primary Hypothyroidism with CHD | Patients with Primary Hypothyroidism >50 pp | Subclinical Hypothyroidism |

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: TSH should be measured every 3 months post-initiation of levothyroxine or after change in dose. Upon adequate replacement, TSH should be monitored at 6 months and then every 12 months thereafter.
   a. If TSH is suppressed (0.25mIU/L) – consider dose reduction by 25 – 50mcg. Excess replacement increases the risk of osteoporosis and arrhythmias, especially in the elderly.
   b. If TSH is undetectable, TSH should be monitored 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 take levothyroxine with a full glass (8oz) of water ONLY.

<table>
<thead>
<tr>
<th>Interference 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>• Milk and milk products</td>
<td>• Phenobarbital</td>
<td>• Decreases TSH secretion</td>
</tr>
<tr>
<td>• Sucralose</td>
<td>• Phenyletox</td>
<td>• Dopamine analogues</td>
</tr>
<tr>
<td>• Kayeolate</td>
<td>• Carbamazepine</td>
<td>• Bromocriptine</td>
</tr>
<tr>
<td>• Oral bisphosphonates</td>
<td>• Milamap</td>
<td>• Glucocorticoids</td>
</tr>
<tr>
<td>• Proton pump inhibitors</td>
<td>• Gentamycin</td>
<td>• Thyroid hormone analogues</td>
</tr>
<tr>
<td>• Multiemulants (containing ferrous sulfate or calcium carbonate)</td>
<td>• Quinapril</td>
<td>• Methimazole</td>
</tr>
<tr>
<td>• Ferric sulfate</td>
<td>• Levastine</td>
<td>• Spironolactone</td>
</tr>
<tr>
<td>• Phosphate binders</td>
<td>• Laxative</td>
<td>• Opiates</td>
</tr>
<tr>
<td>• Calcium salts</td>
<td></td>
<td>• Increases TSH secretion</td>
</tr>
<tr>
<td>• Alproflaxian</td>
<td></td>
<td>• Dopamine receptor blockers</td>
</tr>
<tr>
<td>• H2 receptor antagonists</td>
<td></td>
<td>• Metoclopramide</td>
</tr>
<tr>
<td>Diet:</td>
<td></td>
<td>• Amphetamines</td>
</tr>
<tr>
<td>• Ingestion with a meal</td>
<td></td>
<td>• St. John’s Wort</td>
</tr>
<tr>
<td>• Grapefruit juice</td>
<td></td>
<td>• Hypothyroidism</td>
</tr>
<tr>
<td>• Espresso coffee</td>
<td></td>
<td>• Hypoglycemia</td>
</tr>
<tr>
<td>• High fiber diet</td>
<td></td>
<td>• Antithyroidal antibodies</td>
</tr>
<tr>
<td>• Soy</td>
<td></td>
<td>• THRs</td>
</tr>
</tbody>
</table>

Table 5.
5. Hypothyroidism during pregnancy
   a. TSH goals vary depending on the trimester

<table>
<thead>
<tr>
<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>
</tr>
<tr>
<td></td>
<td>0.3-3.0 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>Drug of Choice: Methimazole</th>
<th>Formulary strength</th>
<th>Initial Dose</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Dose</td>
<td>Maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3 mg/day for mild hyperthyroidism</td>
<td>3 divided doses daily</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-40 mg/day for moderately severe hyperthyroidism</td>
<td>3 divided doses daily for severe hyperthyroidism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-10 mg/day (depending on severity)</td>
<td>3 times daily</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   - Propylthiouracil
     - Nonformulary
     - 50–150 mg (depending on severity)
     - 3 times daily
     - 50 mg 2–3 times daily for a total of 12–18 months, then taper or discontinue if TSH is normal at that time.

<table>
<thead>
<tr>
<th>Side Effects of Methimazole</th>
<th>Side Effects of Propylthiouracil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agranulocytosis</td>
<td>Agranulocytosis</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>Thrombocytopenia</td>
</tr>
<tr>
<td>Aplastic Anemia</td>
<td>Aplastic anemia</td>
</tr>
<tr>
<td>Hepatitis</td>
<td>Hepatitis</td>
</tr>
<tr>
<td>BBW Severe liver injury and acute liver failure have been reported</td>
<td>Acute renal failure, glomerulonephritis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methimazole may increase the levels of the following agents:</td>
</tr>
<tr>
<td>Methimazole may decrease the levels of the following agents:</td>
</tr>
<tr>
<td>Propranolol* may increase the levels of the following agents:</td>
</tr>
<tr>
<td>Propranolol* may decrease the levels of the following agents:</td>
</tr>
</tbody>
</table>

   - Aripiprazole |
   - Cardiac glycosides |
   - Clozapine |
   - Lomitapide |
   - Pimozide |
   - Theophylline derivatives |
   | Sodium valproate |
   | Thiazide diuretics |
   | Cardiac glycosides |
   | Clozapine |
   | Theophylline derivatives |
   | Sodium valproate |

   *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 – 2.2 ng/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: anorexia, pruritus, 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 OBGYN 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

3. End Therapy and Reinforce Counseling

4. Resolution?
   Yes: End Therapy and Reinforce Counseling
   No: Consider other agent not used above
   1% Tolnaftate Cream
   or
   1% Clotrimazole Cream
   BID X 30 days

5. Resolution?
   Yes: Refer to Box # 4
   No: Consider pharmacotherapy consultation

6. Consider Dermatology Consultation
   Yes: Refer to Box # 4
   No: End Therapy and Reinforce Counseling

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

Chronic Anticoagulation Using Warfarin

1. Does patient have documented indication for chronic anticoagulation therapy? See Table 5 for indications.

2. If yes, order a PT/INR to be drawn in 3 days. Make note of time of draw in M-F. Reassess patient to be seen in 7 days. Continue to Box 5.

3. Was PT/INR value measured ≤ 28 days ago?

4. Yes

5. Does patient have > 1 medical indication for chronic anticoagulation therapy? Refer to Table 5.

6. Does patient have documented indication for chronic anticoagulation therapy? See Table 5 for indications.

7. Compare the goal INR ranges and therapy durations for each indication. If the INRs differ, choose the higher goal. Continue therapy for the longest duration suggested. Document date therapy will be completed if applicable.

8. Has the patient recently experienced signs/symptoms of thromboembolism? See Table 4.

9. Has the patient recently experienced signs/symptoms of moderate to severe bleeding? See Table 3.

10. Does patient have documented indication for chronic anticoagulation therapy? See Table 5 for indications.

11. Determine the goal INR range and therapy duration for the patient’s indication. Document date of therapy completion, if applicable.


13. Duration of therapy completed?

14. In patient’s INR value within the goal range two times in a row?

15. In patient’s INR value above highest value of goal INR range?

16. Warfarin adherence > 75% over last 30 days?

17. INR value ≥ Goal INR range.

18. Counsel patient on importance of warfarin adherence. Order PT/INR to be drawn 2 days before next visit. Verify date of draw is M-F. Schedule patient in 60, 66, or 90 days as clinically indicated. Return to Box 9.

19. INR value < Goal INR range.

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


No

Are any of the following occurring?
1. Taking (failing to take, if ordered) medication or nutritional supplements that can modify warfarin’s effects (Tables 10 & 11)
2. Changes in intake of foods that can modify warfarin’s effects (Table 11)
3. Recent development of a condition that can modify warfarin’s effects (Table 12)

Yes

Is / are the change(s) expected to stay consistent?

Yes No

Counsel patient on the effects of medication / food / conditions on INR. Increase total weekly dose of warfarin (Table 6 or 7). Schedule INR to be drawn 2 days before next visit, verifying the day is M – F. Schedule patient for follow-up in 7 to 14 days. Return to Box #8.

No

Counsel patient on the effects of medication / food / conditions on INR. Adjust the warfarin dose as specified in Table 7 or 8. Schedule INR to be drawn 2 days before next visit, verifying the day is M – F. Schedule patient for follow-up in 7 to 14 days, unless recommended sooner by Table 7 or 9. Return to Box #8.

Yes

Counsel patient on the effects of medication / food / conditions on INR. Adjust the warfarin dose according to the change(s) as specified in Table 7 or 8. Schedule INR to be drawn 2 days before next visit, verifying the day is M – F. Schedule patient for follow-up in 7 to 14 days, unless recommended sooner in Table 7 or 8. 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

<table>
<thead>
<tr>
<th>Risk Factors Associated With Deep Venous Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Cancer: currently on treatment, treatment within past 6 months, or not receiving curative treatment</td>
</tr>
<tr>
<td>- Paralysis, paresis, or any other factor that leads to a severe decrease in ability to move about</td>
</tr>
<tr>
<td>- Confined to bed for &gt; 3 days</td>
</tr>
<tr>
<td>- Major surgery (esp. orthopedic) in the last 12 weeks that required general or regional anesthesia lasting &gt; 30 minutes</td>
</tr>
<tr>
<td>- Heparin-Induced Thrombocytopenia (HIT)</td>
</tr>
<tr>
<td>- Pharmacotherapy o Estrogenic oral contraceptive agents o Post-menopausal hormone therapy o Cancer treatments ▪ Hormonal ▪ Radiotherapy ▪ Chemotherapy</td>
</tr>
<tr>
<td>- History of VTE</td>
</tr>
<tr>
<td>- Age &gt; 60 years</td>
</tr>
<tr>
<td>- Fracture of hip / pelvis / leg(s)</td>
</tr>
<tr>
<td>- Indwelling central venous catheter</td>
</tr>
<tr>
<td>- Major medical illness (e.g. HF, MI, TIA, ischemic stroke)</td>
</tr>
<tr>
<td>- Hypercoagulable States o Cancer</td>
</tr>
<tr>
<td>- Activated Protein C Resistance Factor / Factor V Leiden mutation</td>
</tr>
<tr>
<td>- Prothrombin 20210A mutation, Protein C or S deficiency</td>
</tr>
<tr>
<td>- Factor VIII or XI excess (&gt; 90th percentile)</td>
</tr>
<tr>
<td>- Antithrombin deficiency</td>
</tr>
<tr>
<td>- Antiphospholipid Antibody Syndrome</td>
</tr>
<tr>
<td>- Dysfibrinogenemia</td>
</tr>
<tr>
<td>- Excess of Inhibitor of Plasminogen Activator</td>
</tr>
<tr>
<td>- Inflammatory Bowel Disease ▪ Ulcerative Colitis ▪ Crohn’s Disease / Crohn’s Colitis</td>
</tr>
<tr>
<td>- Antithrombin deficiency</td>
</tr>
<tr>
<td>- Factor VIII or XI excess (&gt; 90th percentile)</td>
</tr>
<tr>
<td>- Antithrombin deficiency</td>
</tr>
<tr>
<td>- Antiphospholipid Antibody Syndrome</td>
</tr>
<tr>
<td>- Inflammatory Bowel Disease ▪ Ulcerative Colitis ▪ Crohn’s Disease / Crohn’s Colitis</td>
</tr>
<tr>
<td>- Antithrombin deficiency</td>
</tr>
<tr>
<td>- Factor VIII or XI excess (&gt; 90th percentile)</td>
</tr>
<tr>
<td>- Antiphospholipid Antibody Syndrome</td>
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<tr>
<td>- Inflammatory Bowel Disease ▪ Ulcerative Colitis ▪ Crohn’s Disease / Crohn’s Colitis</td>
</tr>
<tr>
<td>- Antithrombin deficiency</td>
</tr>
<tr>
<td>- Factor VIII or XI excess (&gt; 90th percentile)</td>
</tr>
<tr>
<td>- Antiphospholipid Antibody Syndrome</td>
</tr>
<tr>
<td>- Inflammatory Bowel Disease ▪ Ulcerative Colitis ▪ Crohn’s Disease / Crohn’s Colitis</td>
</tr>
</tbody>
</table>

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

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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>• Anemia</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>• Hematemesis</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>• Hematuria</td>
</tr>
<tr>
<td>• Melena</td>
</tr>
<tr>
<td>• Meningeal</td>
</tr>
<tr>
<td>• Hematemesis as indicated by 1 or more of the following:</td>
</tr>
<tr>
<td>o Bright red colored stool</td>
</tr>
<tr>
<td>o Mahogany colored 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

| Signs & Symptoms of Venous Thromboembolism (VTE) & Pulmonary Embolism (PE) |
|-----------------------------|-----------------------------|
| **Venous Thromboembolism**  | **Pulmonary Embolism**       |
| • Tenderness localized to deep venous system (e.g. calf) | • Hemoptysis                |
| • Difference in calf circumference > 3 cm when compared to asymptomatic leg (measure 10 cm (4 in) below the tibial tuberosity) | • Chest pain                 |
| • Pitting edema present on symptomatic leg only | • Recent onset and/or worsening dyspnea |
| • Collateral superficial veins, non-varicose | • Any clinical signs or symptoms of VTE |
| • Elevated D-dimer reading | • Elevated D-dimer reading (> 500 micrograms / L) |

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 / PE
   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 condition with warfarin, AFTER the condition has been acutely treated.
## Table 5: Indications and Target INRs and Acceptable INR Ranges

**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, PAF = Paroxysmal (intermittent) Atrial Fibrillation, PE = Pulmonary Embolism, TEE = Transesophageal Echocardiography, TIA = Transient Ischemic Attack, UFH = Unfractionated Heparin, NSR = Normal Sinus Rhythm, STEMII = 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>Atrial Fibrillation or Atrial Flutter</td>
<td>Age &lt; 75 years, no risk factors</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td>Aspirin 81 – 325 mg daily</td>
</tr>
<tr>
<td></td>
<td>Plus:</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>History of ischemic stroke</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>History of systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>History of poor left ventricular ejection fraction and/or HF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age &gt; 75 years</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>DM</td>
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<tr>
<td></td>
<td>HTN</td>
<td></td>
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<tr>
<td></td>
<td>History of ischemic stroke</td>
<td></td>
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<tr>
<td></td>
<td>History of systemic embolism</td>
<td></td>
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<tr>
<td></td>
<td>History of poor left ventricular ejection fraction and/or HF</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Age &gt; 75 years</td>
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<td></td>
<td>DM</td>
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<tr>
<td></td>
<td>HTN</td>
<td></td>
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</tr>
<tr>
<td>Paroxysmal Atrial Flutter</td>
<td>Planned conversion to sinus rhythm</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td>Start 3 weeks before elective cardioversion and continue for 4 weeks after successful cardioversion</td>
</tr>
<tr>
<td>Antiphospholipid Antibody Syndrome or Presence of Lupus Anticoagulant</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 – 3.5 or with additional risk factors</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>Ventricular Septal Defect</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Up to 12 months</td>
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<td></td>
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<tr>
<td>CTPH</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DVT or PE</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Plus:</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>History of systemic embolism, ischemic stroke, or TIA without AF</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preprocedural TEE showing left atrial thrombus</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td>LMWH recommended for the first 3 – 6 months.</td>
</tr>
<tr>
<td>Mitral Valve Stenosis</td>
<td>Non-complexed by calcification</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>Aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>Recurrence despite aspirin therapy</td>
<td>2.5</td>
<td>2.0 – 3.0</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td>Medical Condition</td>
<td>Specific Indication</td>
<td>Target INR</td>
<td>INR Range</td>
<td>Duration of Therapy</td>
<td>Comments/Notes</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td><strong>Mitral Valve Prolapse</strong></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>With:</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Atrial fibrillation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Documented systemic embolism</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>* Recent embolism with atrial fibrillation therapy</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>With:</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>At least 3 months post-MI</td>
<td>Combination with aspirin 81 mg/day</td>
</tr>
<tr>
<td></td>
<td>* Large anterior MI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Significant left atrial thrombus</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>* Atrial fibrillation</td>
<td></td>
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<tr>
<td></td>
<td>* History of thromboembolic event</td>
<td></td>
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<tr>
<td><strong>Rheumatic Mitral Valve Disease</strong></td>
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<tr>
<td></td>
<td>With:</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Atrial fibrillation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Systemic embolism</td>
<td></td>
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<tr>
<td></td>
<td>* Left atrial thrombus</td>
<td></td>
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<tr>
<td></td>
<td>* NSR with atrial diameter &gt; 55 mm</td>
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<td></td>
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</tr>
<tr>
<td><strong>Other Heart, Mechanical</strong></td>
<td></td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>with:</td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Bileaflet</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Tilted disk</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Any position</td>
<td>3.0</td>
<td>2.5 – 3.5</td>
<td>Indefinite</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Aortic position</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* NSR with left atrial enlargement</td>
<td></td>
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<tr>
<td></td>
<td>* Bileaflet</td>
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</tr>
<tr>
<td></td>
<td>* Tilted disk</td>
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</tr>
<tr>
<td></td>
<td>* Mitral position</td>
<td></td>
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<tr>
<td></td>
<td>* Bileaflet</td>
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<tr>
<td></td>
<td>* Tilted disk</td>
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<tr>
<td></td>
<td>* Any position</td>
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<tr>
<td></td>
<td>* Aortic position</td>
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</tr>
<tr>
<td><strong>Valves, Heart, Bioprosthetic</strong></td>
<td></td>
<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
<td></td>
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<td></td>
<td>with:</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>* history of systemic embolism</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>* No other indications</td>
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<tr>
<td><strong>Valves, Heart, Mechanical</strong></td>
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<td>2.5</td>
<td>2.0 – 3.5</td>
<td>Indefinite</td>
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<td>with:</td>
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<tr>
<td></td>
<td>* history of systemic embolism</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* No other indications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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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 6. Unit Management of Subtherapeutic INR, with INR Target 2.5, Goal Range 2.0 – 3.0 |
|---------------------------------|---------------------------------|------------------|------------------|
| Patient INR | Warfarin Dose Adjustment | Schedule Next INR To Be Drawn In: | Schedule For Reevaluation In: |
| 1.1 to 1.4 | Increase total weekly dose by 10% to 20% | 2 days before next visit | 7 – 14 days |
| 1.5 to 1.9 | Increase total weekly dose by 5% to 10% | 2 days before next visit | 7 – 14 days |

| Table 7. Unit Management of Subtherapeutic INR with INR Target 3.0, Goal Range 2.5 – 3.5 |
|---------------------------------|---------------------------------|------------------|------------------|
| Patient INR | Warfarin Dose Adjustment | Schedule Next INR To Be Drawn In: | Schedule For Reevaluation In: |
| < 2.0 | Increase total weekly dose by 10% to 20% | 2 days before next visit | 7 – 14 days |
| 2.0 – 2.4 | Increase total weekly dose by 5% to 10% | 2 days before next visit | 7 – 14 days |

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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 2.5 mg 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 8. Unit Management of Supratherapeutic INR

<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>More than therapeutic up to 5</td>
<td>None</td>
<td>Hold 1 dose or Decrease total weekly dose by 5% - 15%</td>
<td>2 days before next visit</td>
<td>7 – 14 days</td>
</tr>
<tr>
<td>6 – 8</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. Until evaluation of signs of excess bleeding should be frequently performed.</td>
<td></td>
</tr>
<tr>
<td>2.5 mg</td>
<td>Hold 1 dose. Decrease total weekly dose by 10% to 20%</td>
<td>Within next 1 – 2 days.</td>
<td>1 – 2 days. Until evaluation of signs of excess bleeding should be frequently performed.</td>
<td></td>
<td></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 K, 2.5 mg by mouth 24 hours after first dose.</td>
<td></td>
</tr>
<tr>
<td>&gt;10</td>
<td>Hold warfarin, give Vitamin K, and consider transport to higher level of care.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Serious Bleeding

Any INR: Hold warfarin, give Vitamin K, and consider transport to higher level of care.
### TABLE 9

<table>
<thead>
<tr>
<th>Drugs That Can Change Warfarin’s Effects and/or INR</th>
<th>Drugs that ↓ Warfarin Effects and/or INR (SUBtherapeutic)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SUPRATHERAPEUTIC</strong></td>
<td><strong>SUBLTHERAPEUTIC</strong></td>
</tr>
<tr>
<td>Anticoagulants: aspirin &gt; 1.3 g (1300 mg) per day × 7 days or more</td>
<td>Anticoagulants: propylthiouracil</td>
</tr>
<tr>
<td>Acenocoumarol</td>
<td>Aminoglutethimide</td>
</tr>
<tr>
<td>Amedotesone</td>
<td>Acetylsalicylic acid</td>
</tr>
<tr>
<td>Antidepressants: tricyclic antidepressants</td>
<td>Acyclovir</td>
</tr>
<tr>
<td>Cephalosporins: cephalexin, cefazolin, cefadroxil, ceftriaxone</td>
<td>Atenolol</td>
</tr>
<tr>
<td>Antiplatelet agents: aspirin, clopidogrel, ticlopidine, prasugrel</td>
<td>Azithromycin</td>
</tr>
<tr>
<td>CYP2C9 inducing drugs: carbamazepine, phenobarbital, phenytoin, rifampin, rifapentine, ritonavir</td>
<td>Bortezomib</td>
</tr>
<tr>
<td>CYP2C9 inhibiting drugs: amiodarone, chloramphenicol, cimetidine, lovastatin, isoniazid, fluoxetine, fluvoxamine, metronidazole, fluconazole, voriconazole</td>
<td>Buspirone</td>
</tr>
<tr>
<td>Antihyperlipidemic agents: gemfibrozil, clofibrate, fenofibrate</td>
<td>Captopril</td>
</tr>
<tr>
<td>NSAID Agents: aspirin, ibuprofen, indomethacin, naproxen, meloxicam</td>
<td>Clofibrate</td>
</tr>
<tr>
<td>Hormonal Contraceptives: norethindrone / ethinyl estradiol, norgestrel / ethinyl estradiol, ethynodiol diacetate / ethinyl estradiol</td>
<td>Clozaone</td>
</tr>
<tr>
<td>Anticonvulsants: phenytoin, valproic acid</td>
<td>Coenzyme A</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>Conjugated Estrogens</td>
</tr>
<tr>
<td>Quinolone antibiotics: ciprofloxacin, levofloxacin</td>
<td>Colestilamate</td>
</tr>
<tr>
<td>Antacids: antacids, sucralfate</td>
<td>Cimetidine</td>
</tr>
<tr>
<td>Selective serotonin reuptake inhibitors: citalopram, fluoxetine, paroxetine, sertraline</td>
<td>Cimetidine</td>
</tr>
<tr>
<td>Sulfonamide derivatives: trimethoprim / sulfamethoxazole</td>
<td>Citalopram</td>
</tr>
<tr>
<td>Tetracycline derivatives: tetracycline, doxycycline</td>
<td>Captopril</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>
<th>Foods High in Vitamin K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages: Juice, cranberry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fats &amp; Dressings: Margarine, Mayonnaise, Olive, canola Oil, vegetable Oil, soybean Oil, olive Fats containing Olestra® synthetic fats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foods containing Olestra® synthetic fats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetable: Asparagus</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Avocado</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Broccoli</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brussel sprouts</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cabbage</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cabbage, n°</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collard greens</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Endives, raw</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Green scallions, raw</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Kale, raw leaf</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lettuce, raw</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mustard greens</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Parsley</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peas, green, cooked</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spinach, raw leaf</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Turnip greens, raw</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Watercress, raw</td>
<td></td>
</tr>
<tr>
<td>Over-the-Counter Supplements: Vitamin E</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vitamin supplements containing Vitamin K</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vitamin C, high-dose</td>
<td></td>
</tr>
<tr>
<td></td>
<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>
<th>Factors That Can → Warfarin’s Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood dyscrasias</td>
<td></td>
<td>Diet high in Vitamin K</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td>Edema</td>
</tr>
<tr>
<td>Collagen vascular disease</td>
<td></td>
<td>Hereditary coumarin resistance</td>
</tr>
<tr>
<td>Congestive Heart Failure (CHF)</td>
<td></td>
<td>Hyperlipidemia</td>
</tr>
<tr>
<td>Diarrhea</td>
<td></td>
<td>Hypothyroidism</td>
</tr>
<tr>
<td>Dietary deficiencies / poor nutritional state</td>
<td></td>
<td>Nephrotic syndrome</td>
</tr>
<tr>
<td>Elevated temperature / fever</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatic Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Infections hepatitis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Jaundice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolonged hot weather</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dehydration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin K deficiency</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
IV. Patient Education
A. Who educates?
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.

<table>
<thead>
<tr>
<th>Wound / Patient Characteristics</th>
<th>Present?</th>
<th>If yes,</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Mobility impaired</td>
<td>Yes</td>
<td>Refer to Pressure Wound DMG</td>
</tr>
<tr>
<td>* Low Braden Score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Bony prominence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Located in areas of pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Malnourished</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Moisture exposure</td>
<td>Yes</td>
<td>Refer to Pressure Wound DMG</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>* Callus formation</td>
<td>Yes</td>
<td>Refer to Neuropathic Wound DMG</td>
</tr>
<tr>
<td>* Dry skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Tissue necrosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Located in plantar aspect of foot</td>
<td>Yes</td>
<td>Refer to Neuropathic Wound DMG</td>
</tr>
<tr>
<td>* Diabetic</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>* Located in lower extremities, below the ankle</td>
<td>Yes</td>
<td>Refer to Arterial Insufficiency Wound DMG</td>
</tr>
<tr>
<td>* Decreased peripheral pulses</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>* Smooth/wound edges</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Wounds are usually small and deep</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Wound bed is dry or pink</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* &quot;Punched out&quot; lesions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Poor hair and nail growth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Blunt wounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* ABI &lt;0.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Interstument depapsulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Located in gaited area, mostly in the medial radiiases</td>
<td>Yes</td>
<td>Refer to Arterial Insufficiency Wound DMG</td>
</tr>
<tr>
<td>* Positive peripheral pulses</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>* Larger, irregular borders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Wounds are usually large and superficial</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Wound bed is bloody, red and moist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Paedal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Surrounding skin usually has eczema dermatitis and hemosideresis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* ABI &gt;0.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Presence of scar tissue increases risk of re-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Varicosities</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* Caused by incisional wound dehiscence or laceration</td>
<td>Yes</td>
<td>Refer to Surgical Wound DMG</td>
</tr>
<tr>
<td>* Occurred post-op</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, November 2005. Revised 1/07, 11/07, 5/10, 7/12, 3/14

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ARTERIAL INSUFFICIENCY WOUNDS

Wound Care page 2

Patient Assessment:
1. Obtain 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 symptomatic, and further work-up is warranted.
3. Counsel the patient on smoking cessation, to not cross legs, to avoid constrictive garments and to avoid caffeine.
4. Consider AHA 10 to 20 for the maximum of intermittent claudication.
5. Know that undiagnosed arterial insufficiency wounds can lead to osteomyelitis.
6. Manage underlying diseases that can increase risk of arterial insufficiency disease (e.g. hypertension, hyperlipidemia, cardiovascular disease and diabetes mellitus).
7. If needed, provide adequate pain control (refer to pain disease management guidelines).
8. Ensure tetanus status is up to date.
9. Evaluate the patient for any factors that may slow wound healing (e.g. medications and nutritional status).
10. Consider consultation with the Wound Care Specialist.

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

---

Precautions:
1. Avoid compression therapy
2. Avoid elevation of lower extremities
3. Avoid sharp debridement of chronic, dry, eschar-covered, uninfected ulcers in pts with low ABI's.

---

Treat wound according to wound bed description. Most arterial insufficiency wounds will be dry. Go to “Dry Wound Bed”.

---

Wound Bed | Epithelialisation | Granulation | Local infection/colonisation | Necrosis/Shock
---|---|---|---|---
Wet Wound Bed | Hydrocolloid, foam | Silver alginate, hydrocolloid | Debridement, decrease bacterial load | Debridement
Secondary Dressing | Wet to moist (WTM) dressings | Cadexomer Iodine | Foam, Hydrocolloid

Moist Wound Bed | Hydrocolloid, foam | Silver dressing, Cadexomer Iodine | Debridement, decrease bacterial load | Debridement
Secondary Dressing | WTM dressings | Foam, Hydrocolloid

Dry Wound Bed | Hydrogel, Cadexomer Iodine, Silver alginate | Silver alginate | Foam, Hydrocolloid, Gauze
Secondary Dressing | Hydrogel, Cadexomer Iodine, Silver alginate | Foam, Hydrocolloid, Gauze

Precautions:
1. Avoid compression therapy
2. Avoid elevation of lower extremities
3. Avoid sharp debridement of chronic, dry, eschar-covered, uninfected ulcers in pts with low ABI's.

---

If wound is stagnant or not improving, consider dressing regimen change or referral to Wound Care Specialist.

---

Reassess wound every 4 weeks to follow the patient in Ulcer Care Clinic.
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 can increase risk of neuropathic wounds (e.g., diabetes mellitus, hypertension, hyperlipidemia).
5. If needed, 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.

The pathways above replace wound clinical judgment and are intended to strictly apply to all patients.

Does the patient have a neuropathic wound that requires treatment?

• Educate patient on wound prevention and early detection/screening
• Follow the patient in Chronic Care Clinic

Treat wound according to wound bed description. Most neuropathic wounds will be dry. Go to “Dry Wound Bed”. Debridement is the mosting of tissue.

Wound Bed  Epitheliazation Granulation Local infection/critical colonization Callus/Neurotic Ulcer
Primary Dressing

Hydrocolloid

Gauze

Silver alginate

Santyl®

Silver alginate

Cadexomer Iodine

Wound Cleanser

Wound Bed Secondary

Hydrocolloid

Foam

Hydrocolloid

Gauze

Hydrogel

Cadexomer Iodine

Dry Wound Bed

Hydrogel

Cadexomer Iodine

Hydrogel

Cadexomer Iodine

Foam

Hydrocolloid

Gauze

If wound is stagnant or not improving, consider dressing regimen change or refer to Wound Care Specialist.

Continue care until wound is healed and educate on wound care prevention.
Patient Assessment
1. Risk for development of wounds should be determined at intake, each clinic visit and each Chronic Care Clinic visit in high risk patients (e.g., paraplegic, quadriplegic, hemiplegic, geriatric, pt with incontinence, diabetics, immunocompromised patients, patients with peripheral arterial disease, & malnourished patients) using the Braden Scale for Predicting Pressure Sore Risk (Located in the EMR Note Builder Template as “Wound - Braden Scale”).
2. May consider moisturizing skin cream for patients with a Braden Scale score less than 14 to protect skin integrity.
3. Perform physical and visually inspect areas prone to wound development at each clinic visit.
4. Counsel patient regarding the importance of adequate hydration and nutrition.
5. Counsel patient regarding the importance of offloading for wound prevention.
6. If needed, provide adequate pain control (refer to pain disease management guideline).
7. Ensure tetanus status is up to date.
8. Evaluate the patient for any factors that may slow wound healing (e.g. medications and nutritional status).
9. Consider consultation with the Wound Care Specialist.

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

**Patient Assessment:**
1. Obtain ABI to rule out arterial insufficiency. Refer to Arterial Insufficiency disease management guidelines.
2. May consider moisturizing 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 appropriate pain control (refer to pain disease management guidelines).
5. Ensure tetanus 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.

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

**Counsel the patient on:***
- Exercises and mobility training
- Lower extremity elevation

Use compression therapy to manage edema.

**Contraindications:**
- Arterial insufficiency with an ABI <0.8
- Acute infection
- Pulmonary edema
- Uncontrolled or severe CHF
- Active deep vein thrombosis

**Does the patient have a venous insufficiency wound that requires treatment?**
- Yes
- No

**If yes:**
1. Educate patient on wound prevention.
2. Follow the patient in Chronic Care Clinic.

**If no:**
- Continue care until wound is healed and educate on wound care prevention.

---

**Wound Bed** | **Epitheliazation** | **Granulation** | **Local Infection/Infection** | **Necrosis/Slough**
---|---|---|---|---

<table>
<thead>
<tr>
<th>Objective</th>
<th>Preserve newly formed tissue</th>
<th>Support granulation and tissue growth</th>
<th>Debridement and decrease bacterial burden</th>
<th>Debridement</th>
</tr>
</thead>
<tbody>
<tr>
<td>OFFLOAD</td>
<td>Use offloading equipment (e.g., heel protectors, pressure-relieving overlays, crutches and trapezes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLEANSE</td>
<td>Wash with soap and water or a commercial wound cleanser. Flush with 250cc's of normal saline or sterile water</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROTECT</td>
<td>Use compression therapy to manage edema.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Wound Bed Epitheliazation**

<table>
<thead>
<tr>
<th>Wet Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Granulation**

<table>
<thead>
<tr>
<th>Wet Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
<tr>
<td>Foam</td>
<td>Foam</td>
<td></td>
</tr>
</tbody>
</table>

**Wound Bed Local Infection/Infection**

<table>
<thead>
<tr>
<th>Wet Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Necrosis/Slough**

<table>
<thead>
<tr>
<th>Wet Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

---

**Wound Bed Epitheliazation**

<table>
<thead>
<tr>
<th>Moist Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Granulation**

<table>
<thead>
<tr>
<th>Moist Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
<tr>
<td>Foam</td>
<td>Foam</td>
<td></td>
</tr>
</tbody>
</table>

**Wound Bed Local Infection/Infection**

<table>
<thead>
<tr>
<th>Moist Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Necrosis/Slough**

<table>
<thead>
<tr>
<th>Moist Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocolloid</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

---

**Wound Bed Epitheliazation**

<table>
<thead>
<tr>
<th>Dry Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogel</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Granulation**

<table>
<thead>
<tr>
<th>Dry Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogel</td>
<td>Foam</td>
<td>Foam</td>
</tr>
<tr>
<td>Foam</td>
<td>Foam</td>
<td></td>
</tr>
</tbody>
</table>

**Wound Bed Local Infection/Infection**

<table>
<thead>
<tr>
<th>Dry Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogel</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

**Wound Bed Necrosis/Slough**

<table>
<thead>
<tr>
<th>Dry Wound Bed</th>
<th>Primary Dressing</th>
<th>Secondary Dressing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogel</td>
<td>Foam</td>
<td>Foam</td>
</tr>
</tbody>
</table>

---

**Wound Bed Epitheliazation**

| Wound is stagnant or not improving, consider dressing regimen change or referred to Wound Care Specialist |
|---|---|

**Wound Bed Granulation**

| Wound is stagnant or not improving, consider dressing regimen change or referred to Wound Care Specialist |
|---|---|

**Wound Bed Local Infection/Infection**

| Wound is stagnant or not improving, consider dressing regimen change or referred to Wound Care Specialist |
|---|---|

**Wound Bed Necrosis/Slough**

| Wound is stagnant or not improving, consider dressing regimen change or referred to Wound Care Specialist |
|---|---|
**Patient Assessment:**
1. Address co-morbidities and optimize treatment e.g., diabetes, renal disease, infections (HIV, HCV, skin, bone), circulation/smoking, obesity.
2. If needed, provide adequate pain control (refer to pain disease management guideline).
3. Ensure tetanus status is up-to-date.
4. Evaluate the patient for any factors that may slow wound healing (e.g., medications and nutritional status).
5. Consider consultation with the Wound Care Specialist.

**Prevent surgical complications**
- Remove surgical sutures per recommendation
- Keep area dry and clean
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound
- Avoid mechanical stress on the wound

**Surgical Site Infections**
- Delayed Healing
- Bleeding
- Dehiscence
- Evisceration

**Educate patient on:**
- Basic wound care
- Incision protection and good hygiene
- Signs and symptoms of infection and to report complications to the medical department

**Follow the patient for suture/staple removal.**

**Treat wound according to method of closure and wound bed.**

**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.

**Objective**
- Protect newly formed tissue
- Support granulation and tissue growth
- Debridement and decrease bacterial burden

**OFFLOAD**
- Use offloading equipment e.g., heel protectors, pressure relieving overlay, 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 paning dressing, or foam with silicone adhesive

**Wound Bed**
- Epitheliazation
- Granulation
- Necrotic/Slough

**Primary Dressing**
- Hydrocolloid
- Foam
- Cadexomer Iodine
- Silver dressing
- Hydrogel
- Hydrocolloid

**Secondary Dressing**
- Hydrocolloid
- Foam
- Hydrocolloid
- Gauze

**Dry Wound**
- Primary Dressing
- Hydrogel
- Cadexomer Iodine
- Silver with hydrogel
- Collagenase (Santyl®)

**Wet Wound**
- Primary Dressing
- Hydrogel
- Cadexomer Iodine
- Silver alginate
- Wet to moist (WTM) dressings

**Necrosis/Slough**
- Debridement

**Local Infection/wound colonization**
- Debridement

---

The pathways do not replace sound clinical judgment, nor are they intended to strictly apply to all patients. The pathways do not replace sound clinical judgment, nor are they intended to strictly apply to all patients.
IV. Venous insufficiency wounds

III. Pressure wounds

II. Neuropathic Wounds

I. Manage underlying risk factors

Provider Education

webpage...
I. Assessment of Wounds

II. Determine the mechanism of injury. CONSIDER obtaining the appropriate diagnostic work-up.

III. Evaluate nutritional status

A. Anticoagulants – forms hematomas
B. Arterial insufficiency wounds
C. Pressure wounds
D. Venous insufficiency wounds

Screen for medications that may impede wound healing.

A. NSAIDS – suppress inflammation, protein synthesis and epithelization
B. Aspirin – suppresses inflammation
C. Anticoagulants
D. Venous Insufficiency Wounds

Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.

B. Screen for concomitant arterial insufficiency by checking the ABI. Compression should not be used with ABI < 0.8.
C. Stage the wound based upon the level of tissue involved. ONLY pressure wounds are staged.
D. Stage IV – full thickness skin loss involving damage to muscle, bone, or supporting structures
E. Unstageable – full thickness tissue loss in which the base of the ulcer is covered by necrotic tissue

IV. Review risk, including weight

Optimize glycemic control in diabetics.

Optimize management of hypertension, hyperlipidemia and diabetes through Therapeutic lifestyle changes and pharmacotherapy.
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 (cm) x widest width (cm) 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
      a. Serous – inflammatory phase of wound healing
      b. Sanguineous – from bleeding
      c. Purulent – from infection
   3. 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 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 paring
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 moderate to heavily draining wounds (refer Debridement on page 10, section IV. A.)
C. Hydrogel – for minimally or moderately draining wounds (refer to Debridement on page 10, section IV. A.)
D. Silver dressing (refer to Management of Infection on page 9, 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. Removes 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. Reduces wound odor

II. Indication – for removal of necrotic tissue, debris, callus, foreign material, eschar and slough

III. Contraindications
A. Red, granular wounds
B. Hard Ulcers with eschar without edema, erythema, fluctuance or drainage
C. Patient factors
   1. Co-morbidities (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 (example: Alginate dressings and hydrogel dressings)

1. Indicated for non-infected wounds with necrotic tissue
2. Advantages
   a. Moist wound healing
   b. Dressing changes are infrequent and can be every 72 to 96 hours
3. Disadvantages
   a. Can cause pain or discomfort

B. Enzymatic debridement - uses prescribed enzymes to debride necrotic tissue (example: collagenase with hydrocolloid dressings)

1. Indicated for infected and non-infected wounds with necrotic tissue
2. Advantages
   a. Moist wound healing
   b. Dressing changes are up to BID to TID
3. Disadvantages
   a. Nonselective debridement
   b. Painful
   c. Increased drainage
   d. Dressing changes 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
   d. Dressing changes up to BID to TID

D. Sharp debridement - uses forceps, scissors or scalpel to remove devitalized tissue

E. Surgical debridement - debridement in a sterile operating room environment

F. Biological debridement - uses maggot larvae for debridement of necrotic tissue

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: Presence 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 silver or cadexomer iodine dressings or triple antibiotic cream).

D. Infection

1. Description: Bacteria invade the body tissue of the host. A wound culture will have bacterial levels greater than 10^7 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).
3. SYSTEMIC antibiotics are only indicated when the wound is INFECTED.

III. 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 dry wound surface.
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.
<table>
<thead>
<tr>
<th>Sensory Perception</th>
<th>Painful stimuli due to discomfort except by always communicating</th>
<th>1. 14 Very Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>and verbal commands should be used.</td>
<td>2. 13 Very Limited</td>
</tr>
<tr>
<td></td>
<td>Can respond only to painful stimuli.</td>
<td>3. 12 High Limitation</td>
</tr>
<tr>
<td></td>
<td>Can respond to verbal commands but not painful stimuli.</td>
<td>4. 11 Moderate Limitation</td>
</tr>
<tr>
<td></td>
<td>Must be turned in bed some sensory impairment.</td>
<td>5. 10 Low Limitation</td>
</tr>
<tr>
<td></td>
<td>Must be turned in bed several times daily at least once per shift.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mobility</th>
<th>Ability to change body position</th>
<th>1. 10 Completely Limited</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cannot make any change in body position independent.</td>
<td>2. 9 Very Limited</td>
</tr>
<tr>
<td></td>
<td>Must be moved or turned by others.</td>
<td>3. 8 Slightly Limited</td>
</tr>
<tr>
<td></td>
<td>Can move own body but assistance is required.</td>
<td>4. 7 Limited</td>
</tr>
<tr>
<td></td>
<td>Can move own body with assistance.</td>
<td>5. 6 Adequate</td>
</tr>
<tr>
<td></td>
<td>Can move own body without assistance.</td>
<td>6. Excellent</td>
</tr>
</tbody>
</table>

|-----------|--------------------------|-----------------------|-------------------------|------------------------|----------------------------------------|----------------------------------------|-----------------------------|

<table>
<thead>
<tr>
<th>Friction &amp; Shear</th>
<th>1. Problem</th>
<th>Requires assistance to maintain position in bed or chair.</th>
<th>2. Potential Problem</th>
<th>Moves freely, maintains position in bed or chair.</th>
<th>3. No Appropriate Problem</th>
<th>Moves in bed and clear of pressure properly.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4. Adequate</td>
<td>Ara is not on a tube regimen.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Total Score | 268 |

---

**Braden Scale For Predicting Pressure Sore Risk**

Located in the EMR Year 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 3). Patients with a total score of 15 or less are considered to be at risk for developing pressure ulcers (15-16 = low risk, 13-14 = moderate risk, 12 or less = high risk).
# Wound Care Assessment Form

Located in the EHR Note Builder Template as “Wound - Wound Care Assessment Form”

**Patient Name:**

**TDCJ#:**

**Date and time of evaluation:**

**Admit Date:**

**Patient Diagnosis:**

**Braden Score:**

**Location of Wound 1:**

2.

3.

<table>
<thead>
<tr>
<th>DESCRIPTION OF WOUND</th>
<th>WOUND 1</th>
<th>WOUND 2</th>
<th>WOUND 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Skin Around Wound</strong></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>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</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>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</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><strong>Drainage of the Wound</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exudate type</td>
<td>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</td>
</tr>
<tr>
<td>1. None</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Sanguineous (bloody)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Seros (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>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</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>
<tr>
<td>DESCRIPTION OF WOUND</td>
<td>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>ARCHITECTURE OF UNHEALED WOUND</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurements in centimeters (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Length (vertical dimension) in cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Width (horizontal dimension) in cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Depth (deepest, do not include tunnel) in cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WOUND BED CHARACTERISTICS</td>
<td>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</td>
</tr>
<tr>
<td>Necrotic type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. None visible</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Non-adherent yellow slough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Loosely adherent yellow slough</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Adherent soft, eschar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Firmly adherent, hard eschar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granulation tissue type</td>
<td>WOUND 1</td>
<td>WOUND 2</td>
<td>WOUND 3</td>
</tr>
<tr>
<td>1. Skin intact</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Bright, beefy red</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pink or dull, dusky red</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Combination of #2 and #3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Obscured</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undermining/Tunneling Wound</td>
<td>Location of undermining/tunneling (use clock as reference)</td>
<td>Depth of tunnel in cm</td>
<td></td>
</tr>
<tr>
<td>For example, right ischial wound with tunnel</td>
<td>Tunnel at 3 o'clock</td>
<td>3 cm</td>
<td></td>
</tr>
<tr>
<td>GOALS</td>
<td>GOALS MET</td>
<td>NOT MET</td>
<td></td>
</tr>
<tr>
<td>1. Facilitate granulation and re-epithelialization through use of clean technique during cleansing and dressing change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Promote granulation tissue of wound bed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Soften and remove non-viable tissue</td>
<td></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>
<td></td>
</tr>
<tr>
<td>PLAN:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>☐</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

Moderate Acne

Start benzoyl peroxide 5% applied QD - BID to acne prone areas obtained from dorm. Follow up in 6-8 weeks to assess response.

5. Is the patient responding to therapy?
   Yes
   6. Continue therapy & follow up as needed. Consider tapering therapy for maintenance.
   No
   7. Assess adherence to treatment plan.
      • Intensify treatment to BID dosing if began with QD dosing.
      • If began with BID dosing, add clindamycin 1% topical solution applied BID to acne prone areas.
      Follow up in 6-8 weeks to assess response.

4. Moderate Severe Acne

Start combination therapy.
1. Benzoyl peroxide 10% applied BID
2. Clindamycin 1% topical solution applied BID to acne prone areas
Follow up in 6-8 weeks to assess response.

23. Severe Acne

Start combination therapy.
1. Benzoyl peroxide 10% applied BID (Do not apply same time of day as adapalene)
2. Minocycline 100 mg orally QD-BID (recommended maximum 4mg/kg/day)
3. Differin (adapalene) gel 0.1% applied QD in PM. Non-formulary approval required.
   Follow up in 6-8 weeks to assess response.

25. Go to Box # 21 page 2

Assess adherence to treatment plan.
1. Benzoyl peroxide 10% applied BID (Do not apply same time of day as adapalene)
2. Minocycline 100 mg orally QD-BID (recommended maximum 4mg/kg/day)
   (Note: Erythromycin 250-500 mg orally BID may be considered if the patient is intolerant or unable to take minocycline)
   Follow up in 6-8 weeks to assess response.

16. Go to Box # 17 page 2

Assess adherence to treatment plan.
1. Benzoyl peroxide 10% applied BID
2. Minocycline 100 mg orally QD-BID (recommended maximum 4mg/kg/day)
   (Note: Erythromycin 250-500 mg orally BID may be considered if the patient is intolerant or unable to take minocycline)
   Follow up in 6-8 weeks to assess response.

9. No
   Assess adherence to treatment plan.
   • Intensify treatment plan by adding second topical agent if not already on it or
   • Intensify treatment plan by starting oral therapy if already on combination topical therapy (go to box #15).

Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. November 2006. Revised 10/05, 4/12, 1/14.
17 Continued from box 16, page 1

18 Are patient responding to therapy?

Yes

No

Assess adherence to treatment plan:  
- Benzoyl peroxide 10% applied QD to 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.

20

21 Is the patient responding to therapy?

Yes

No

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

19 Continue therapy & follow up as needed. Consider discontinuing oral antibiotic and continuing topical therapy for maintenance.
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 and 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 18 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>
Acne Page 4

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 soaping 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>Agent</th>
<th>Dose</th>
<th>Adverse Effects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoyl Peroxide 5-10%</td>
<td>Apply QD-BID</td>
<td>Skin irritation, erythema, dryness, scaling</td>
<td>Effective for inflammatory lesions. Bactericidal &amp; mild keratolytic. May bleach clothing &amp; bedding.</td>
</tr>
<tr>
<td>Clindamycin 1% Topical Solution</td>
<td>Apply BID</td>
<td>Skin irritation, may stain clothing</td>
<td>Effective for inflammatory lesions. Resistance a problem when used alone. Use in combination with benzoyl peroxide limits resistance. No role in therapy if oral antibiotics are used.</td>
</tr>
<tr>
<td>Adapalene 0.1% gel (Differin®)</td>
<td>Apply q HS. May use every other day to minimize irritation</td>
<td>Skin irritation, erythema, dryness, scaling, photosensitivity</td>
<td>Non-formulary medication. Maximum response usually requires 12 weeks. Not recommended in pregnancy. Apply sparingly.</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>Agent</th>
<th>Dose</th>
<th>Adverse Effects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin</td>
<td>250mg - 500mg BID</td>
<td>GI upset</td>
<td>Resistance more common compared to other agents therefore reserve for patients that are intolerant or unable to take tetracycline or doxycycline. Response may take 6 weeks and full effect may take up to 3 months.</td>
</tr>
<tr>
<td>Minocycline</td>
<td>100mg QD-BID (recommended maximum 4mg/kg/day)</td>
<td>Common: Dizziness, headache, fatigue, photosensitivity Rare: Severe: drug hypersensitivity syndrome, Stevens-Johnson syndrome, lupuslike syndrome, pseudotumor cerebri, cutaneous and/or mucosal hyperpigmentation</td>
<td>Do not use in pregnancy or children &lt;8 years of age. Response may take 6 weeks and full effect may take up to 3 months.</td>
</tr>
</tbody>
</table>
Table 4.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Dose</th>
<th>Adverse Effects</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Isotretinoin</strong></td>
<td>0.5 to 1 mg/kg day in 2 divided doses given 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.</td>
<td>Teratogenic, hypertriglyceridemia, elevated LFTs, dryness of lips, ocular, nasal, and oral mucosa and skin, arthralgias, photosensitivity, decreased night vision, case reports of depression, initial flaring at initiation of therapy</td>
<td>Teratogenic, nonformulary medication. Relapse rates higher for patients &lt; 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. Must enroll in iPLEDGE program to prescribe* Must meet and follow criteria in iPLEDGE program to prescribe. For more information go to <a href="http://www.ipledgeprogram.com">www.ipledgeprogram.com</a> or call 1-866-495-0654.</td>
</tr>
<tr>
<td><strong>Oral Contraceptives</strong></td>
<td>1 tablet QD</td>
<td>Nausea, weight gain, thrombosis, edema</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Spironolactone</strong></td>
<td>50 to 100mg QD</td>
<td>Teratogenic, drowsiness, GI upset, hyperkalemia</td>
<td>May be added to oral contraceptive therapy if not effective after several months of therapy. Do not use in pregnancy.</td>
</tr>
</tbody>
</table>
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 causes for presentation

2. Presence of panic attacks?
   - No
   - Yes

3. Meets DSM-IV criteria for Anxiety Disorder?
   - No
   - Yes

4. Treat underlying causes
   - No
   - Yes

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

6. • Obtain baseline BPRS
   • Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started
   • Initiate formulary SSRI antidepressant
     - Start at lower end of dosing range and titrate gradually upward to decrease potential for activating side effects
     - Continue for 6-12 weeks at a therapeutic dose*

7. • Continue therapy for 6-12 months, reassessing as needed by unit mental health provider
   • After 12-18 months, consider discontinuing pharmacotherapy
   • Adequate response per BPRS?
     - No
     - Yes

8. • If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication
   • Re-evaluate diagnosis
   • Increase dose of current agent to maximal tolerated dose for ≥6 weeks or
   • Switch to alternative formulary agent (Table 1) or
   • Consider pharmacotherapy consult

*Trial of adequate dosing is 6-12 weeks up to maximum dosage or maximum tolerated dose

Prepared By The Texas Youth Commission and Reviewed By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 4/11, Revised 10/11, 5/13.
Medication Selection

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: 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)</th>
<th>Monitoring</th>
</tr>
</thead>
</table>
| Selective Serotonin Reuptake Inhibitors (SSRIs) | Citalopram 20mg, 40mg tablet | Celexa® 20 | (20 – 40) | • Emergence of suicidal ideation or behavior  
  • Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present |
|                                 | Fluoxetine 20mg capsule | Prozac® 20 | (20 – 60) |  |
|                                 | Sertraline 50mg, 100mg tablet | Zoloft® 50 | (50 – 200) |  |
| Serotonin Norepinephrine Reuptake Inhibitor (SNRI) | Venlafaxine 37.5mg, 75mg tablet | Effexor® 37.5 | (37.5 – 375) | • Emergence of suicidal ideation or behavior  
  • Blood pressure and pulse |

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 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, guiltlessness, 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 formal 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>
ATTENTION DEFICIT HYPERACTIVITY DISORDER
(Adolescents)

1. Meets DSM-IV criteria for ADHD

2. Obtain baseline/laboratories as indicated in Table 1. Refer to pages 2-5 for medication selection.

3. Initiate monotherapy with Adderall XR. Titrate to a maximum of 30mg/day. Continue 4-6 weeks at therapeutic dose.

4. Inadequate response per ADHD rating scale: Assess compliance. Continue treatment and monitor per Table 1.

5. Initiate monotherapy with Ritalin LA. Titrate to a maximum of 60mg/day. Continue 4-6 weeks at therapeutic dose.

6. Inadequate response per ADHD rating scale: Assess compliance. Continue treatment and monitor per Table 1.

7. Initiate monotherapy with prior authorization agent atomoxetine. See Table 5 for atomoxetine dosing information. Continue 6 weeks at therapeutic dose.

8. Inadequate response per ADHD rating scale: Assess compliance. Continue treatment and monitor per Table 1.

9. Consider one of the following options:
   1. Guanfacine: see Table 6 for dosing information. Continue 4-6 weeks at therapeutic dose.
   2. Nonformulary bupropion XL: see page 5 for dosing information. Continue 4-6 weeks at therapeutic dose.

10. Inadequate response per ADHD rating scale: Assess compliance. Continue treatment and monitor per Table 1.

11. Combination therapy with agents listed above. Continue 4-6 weeks at therapeutic dose.

12. Inadequate response per ADHD rating scale: Assess compliance. Continue treatment and monitor per Table 1.

13. Reconsider diagnosis and consider psychopharmacology consultation.

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

Prepared by The Texas Youth Commission and Reviewed By The Correctional Managed Care Pharmacy & Therapeutics Committee. October 2001, revised 5/12/02, 2/25/04, 3/1/06, 4/19/10, 8/15/11, 2/11/13.
Table 1: Monitoring Guidelines

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Frequency</th>
<th>Baseline</th>
<th>Each Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD rating scale1</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Height, weight, BMI</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Blood pressure &amp; pulse</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>EKG2</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1Providers should review the results of the ADHD rating scale prior to initiating therapy, changing therapy, and at each visit. The ADHD rating scale should be completed during Multi-Disciplinary Team meetings every 30 days.

2Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease. This would include 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, hypertension, 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 what would be expected in the general population. The American Heart Association does recommend careful assessment through a cardiac history, a physical exam, and evaluation for risk factors in children.

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

Medication Selection

Newly diagnosed patients should receive a therapeutic trial of the formulary stimulants unless it is clearly not indicated.

1. If the patient has had a documented significant side effect to the agents in the past.
2. If the patient has already failed a trial of both agents after a therapeutic trial of adequate dose and duration (4-6 weeks).
3. If the patient has a contraindication to therapy.
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>5mg, 10mg</td>
</tr>
<tr>
<td></td>
<td>Adderall XR</td>
<td>Capsule</td>
<td>10mg, 20mg, 30mg</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Ritalin®</td>
<td>Tablet</td>
<td>5mg, 10mg</td>
</tr>
<tr>
<td></td>
<td>Ritalin LA®</td>
<td>Capsule</td>
<td>10mg, 20mg, 30mg, 40mg</td>
</tr>
<tr>
<td>Guanfacine</td>
<td>Tenex</td>
<td>Tablet</td>
<td>1mg, 2mg</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 1 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 whenever possible. Clinicians 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. If there is a question or concern regarding medication adherence with a given regimen prior to conversion, consider re-titrating from starting dosage with formulary alternative. The recommendations listed below are not intended to replace sound clinical judgment.

Table 3: Psychostimulant Dose Equivalencies

<table>
<thead>
<tr>
<th>Vyvanse</th>
<th>Focalin XR</th>
<th>Ritalin SR</th>
<th>Concerta</th>
<th>Ritalin IR</th>
<th>Adderall IR</th>
<th>Adderall XR</th>
<th>Adderall NF</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mg</td>
<td>5 mg</td>
<td>10 mg</td>
<td>18 mg</td>
<td>10-15 mg</td>
<td>10-15 mg</td>
<td>5-10 mg</td>
<td>5-10 mg</td>
</tr>
<tr>
<td>30 mg</td>
<td>7-10 mg</td>
<td>20 mg</td>
<td>20-30 mg</td>
<td>15-20 mg</td>
<td>15-20 mg</td>
<td>10-15 mg</td>
<td>10-15 mg</td>
</tr>
<tr>
<td>40 mg</td>
<td>10-15 mg</td>
<td>30-40 mg</td>
<td>30 mg</td>
<td>20-30 mg</td>
<td>20-30 mg</td>
<td>15-20 mg</td>
<td>15-20 mg</td>
</tr>
<tr>
<td>50 mg</td>
<td>15-20 mg</td>
<td>40-60 mg</td>
<td>40 mg</td>
<td>25-40 mg</td>
<td>25-40 mg</td>
<td>20-30 mg</td>
<td>20-30 mg</td>
</tr>
</tbody>
</table>
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 entered in the EMR. 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>Strength</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 stimulants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intolerance to both formulary stimulants</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contraindication to use of both formulary stimulants</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>
</tbody>
</table>

Atomoxetine General Information
If treatment with amphetamine or methylphenidate 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 three 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>80mg/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>
Bupropion General Information

The dosing strategy suggested for bupropion is 3mg/kg/day by the end of the first week, titrated to 6mg/kg/day or 300mg/day by week 3, whichever is less. It may take as long as 4 weeks to observe maximum effectiveness with bupropion. Bupropion XL is recommended for convenience of use because it requires less frequent dosing.

Alpha Agonist General Information

The table below indicates the dosages of alpha agonists recommended, utilizing a weight-based approach. Vital signs should be obtained with the patient situated in both lying and standing positions. Treatment with alpha agonists should be initiated as a single bedtime dose and carefully titrated over a period of 2-4 weeks to minimize side effects, particularly sedation. An adequate trial is 2-8 weeks at the maximum dose tolerated to evaluate effectiveness.

- Common side effects: sedation, dizziness, fainting (sign of low blood pressure).
- Avoid large (0.2-0.3 mg) doses of clonidine at bedtime.
- Do not combine alpha agonists and second generation antipsychotics due to combined effect on blood pressure.

Table 6: Alpha Agonist Dosing

<table>
<thead>
<tr>
<th>Week</th>
<th>Weight &lt; 45kg</th>
<th>Weight &gt; 45kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clonidine (Nonformulary)</td>
<td>Guanfacine (Formulary)</td>
</tr>
<tr>
<td>Baseline</td>
<td>0.05mg q HS</td>
<td>0.5mg q HS</td>
</tr>
<tr>
<td>1-2</td>
<td>0.05mg BID</td>
<td>0.5mg BID</td>
</tr>
<tr>
<td>2-4</td>
<td>0.05mg BID</td>
<td>0.5mg BID</td>
</tr>
<tr>
<td>3-6</td>
<td>0.05mg qID</td>
<td>0.5mg qID</td>
</tr>
<tr>
<td>4-8</td>
<td>0.05mg qID</td>
<td>0.5mg qID</td>
</tr>
</tbody>
</table>

Total daily dose ranges:
- Clonidine 0.05-0.4 mg/day
- Guanfacine 0.5-4 mg/day
### INATTENTION

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Just a little</th>
<th>Pretty Much</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Fails to pay attention to details or makes careless errors.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Doesn't stay on task for school work or chores.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Doesn't listen when spoken to directly.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Doesn't finish through an instructions.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Has difficulty completing tasks or activities.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Often avoids or dislikes activities that require sustained mental effort.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Often leaves things necessary for tasks or activities.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Is often easily distracted by things around him/her.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Is often forgetful in daily activities.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

### IMPULSIVITY/HYPERACTIVITY

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Just a little</th>
<th>Pretty Much</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Often fidgets with hands or feet or squirms in seat.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Often leaves seat in classroom or other situation in which it is inappropriate.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Often runs about or climbs excessively in situations in which it is inappropriate.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Has difficulty playing or engaging in leisure activities quietly.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Is often &quot;on the go&quot; or acts as if &quot;driven by a motor&quot;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Often talks excessively.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Often blurts out answers before questions have been completed.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Often has difficulty awaiting turns.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Often intrudes or interrupts others.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

### OPPOSITIONAL BEHAVIOR

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Just a little</th>
<th>Pretty Much</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Often loses temper.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Often argues with adults.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Often actively defies adults' requests or rules.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Often deliberately annoys people, peers refuse to play with because he/she does mean or silly things.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Often blames others for his/her mistakes.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Is often touchy or easily annoyed by others.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Is often angry or resentful for long periods of time.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Often does mean or spiteful things to others.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL**

**COMMENTS:**

____

285
BIPOLAR DISORDER ADOLESCENTS

1. Rule out other cause for presentation such as medical causes, substance use, or psychosocial stressors.

2. Meet DSM-IV criteria for manic episode, hypomanic episode, or Bipolar NOS?
   - Yes
     - Go to page 2, box #20
   - No
     - Re-evaluate diagnosis and treat underlying causes.

3. Does patient currently report on an antidepressant?
   - Yes
     - Consider discontinuing the antidepressant. Go to box #3.
   - No
     - Obtain BPRS
     - Maximize dose of mood stabilizer or antipsychotic. Lithium 0.9 – 1.2 mEq/L or Divalproex 75 – 115 mg/mL. Continue for 4-6 weeks at a therapeutic dose.

4. Is patient currently taking an antidepressant?
   - Yes
     - Consider discontinuing the antidepressant. Go to box #4.
   - No
     - Obtain BPRS
     - Maximize dose of mood stabilizer or antipsychotic. Lithium or Divalproex. Continue for 4-6 weeks at a therapeutic dose.

5. Is patient currently prescribed a mood stabilizer or antipsychotic?
   - Yes
     - Continue treatment and monitor. Follow clinical status and BPRS.
   - No
     - Assess compliance
     - Consider combination therapy:
       - Lithium plus Divalproex
       - Lithium or Divalproex plus Risperidone

6. Adequate response per clinical status and BPRS?
   - Yes
     - Continue treatment and monitor. Follow clinical status and BPRS.
   - No
     - Assess compliance
     - Re-evaluate diagnosis
     - Counsel regarding medication compliance
     - Consider pharmacotherapy consult

Prepared by The Texas Juvenile Justice Department October 2001. Revised 5/12/02, 2/23/04, 5/1/06, Youth Services Pharmacy and Therapeutics Committee. Revised 10/18/10, 4/16/12.
Is the patient currently depressed?  
No  Yes  
Is there a history of at least 1 hypomanic or manic episode?  
No  Yes  
Reevaluate Diagnosis  
Go to page 3, box 35  
Follow Depressive Disorder Pathway  

- Obtain baseline BPRS.  
- Initiate monotherapy with mood stabilizer Lithium or Divalproex and titrate to therapeutic level. Continue for 4-6 weeks at therapeutic dose. See box 9.  
- Begin psychotherapy for depression.  

- Adequate response per clinical status and BPRS?  
  Yes  
  • Continue treatment & monitor.  
  • Follow clinical status and BPRS.  
  
  No  
  Assess compliance  
  Discontinue current therapy and switch to alternative mood stabilizer Lithium or Divalproex. Titrate dose to therapeutic level and continue for 4-6 weeks.  

- Adequate response per clinical status and BPRS?  
  Yes  
  • Continue treatment & monitor.  
  • Follow clinical status and BPRS.  
  
  No  
  Assess compliance  
  Consider combination therapy: Lithium plus Divalproex. Titrate to therapeutic level and continue for 4-6 weeks.  

- Adequate response per clinical status and BPRS?  
  Yes  
  • Continue treatment & monitor.  
  • Follow clinical status and BPRS.  
  
  No  
  Assess compliance  
  Consider addition of formulary SSRI (fluoxetine, citalopram or sertraline)  

- Adequate response per clinical status and BPRS?  
  Yes  
  • Continue treatment & monitor.  
  • Follow clinical status and BPRS.  
  
  No  
  Assess compliance  
  Consider discontinuation of antidepressant after depressive symptoms have been absent for at least 2 months.  

1. Re-evaluate diagnosis.  
2. Counsel regarding medication compliance.  
3. Consider pharmacotherapy consult.  
4. Consider alternative formulary SSRIs or substitute non-formulary request for Lamotrigine.

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

Bipolar disorder should be distinguished from a mood disorder due to a general medical condition, substance-induced mood disorder, major depression, and ADHD.

The DSM-IV criteria used to diagnose adults may be used when diagnosing adolescents.

- A distinct period of abnormally and persistently elevated, expansive, or irritable mood
- During the period of mood disturbance, 3 or more of the following symptoms have persisted and have been present to a significant degree (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
  7. Excessive involvement in pleasurable activities that have a high potential for painful consequence

The DSM-IV 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 specifiers (e.g., most recent episode manic, depressed, mixed, etc.) including severity and psychotic features, partial remission, full remission.

Bipolar I Disorder - Characterized by one or more manic or mixed episodes, usually accompanied by major depressive episodes.

Bipolar II Disorder - Characterized by one or more major depressive episodes accompanied by at least one hypomanic episode.

Bipolar Disorder NOS (not otherwise specified) - Characterized by bipolar features that do not meet criteria for any of the specific bipolar disorders or bipolar symptoms where there is inadequate or contradictory information.

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.

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 dose. Lithium serum levels should be measured every six months during maintenance treatment. Levels should be drawn 5-10 days (or more often if clinically indicated) after 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 therapeutic serum level is 0.9 to 1.2 mEq/L.

Common side effects: sedation, thirst, urinary frequency

Other side effects: hypothyroid, confusion, toxicity, acne, increased WBC’s

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>X</td>
</tr>
<tr>
<td>CBC, GGC, BUN, Electrolytes, TSH</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Initial Lithium levels</td>
<td>5-10 days after each dose change</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Maintenance Lithium levels</td>
<td>X</td>
<td></td>
<td></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.
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 115 mg/mL. After therapeutic serum levels have been achieved, it may take as long as 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. 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 2: 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></td>
<td></td>
</tr>
<tr>
<td>LFTs</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelet count</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial divalproex levels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance divalproex levels</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Risperidone General Information

Risperidone may be started at 1mg daily for most adolescents. The dose may be titrated every two weeks up to a maximum of 6mg daily. It may take as long as 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.

Table 3: Risperidone Titration

<table>
<thead>
<tr>
<th>Upward Titration</th>
<th>Risperidone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1-4</td>
<td>0.5-1 mg</td>
</tr>
<tr>
<td>Day 5-8</td>
<td>1.5-2 mg</td>
</tr>
<tr>
<td>Day 9-12</td>
<td>3-4 mg</td>
</tr>
</tbody>
</table>

Common side effects: drowsiness, increased appetite, fatigue, abdominal pain, heart burn, bowel changes, weight gain

Rare side effects: abnormal movements, gynecomastia, galactorrhea
Table 4: Antipsychotic Monitoring Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>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>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</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>
<td></td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, LFT, SCr, Electrolytes</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AIMS</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSG^1</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolactin^2</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
<td></td>
<td></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.
2. Providers should consider obtaining Prolactin at baseline and periodically when there is a history of galactorrhea, amenorrhea, or gynecomastia.

Lamotrigine General Information

Lamotrigine is a third-line agent that may be used if a patient fails to respond to an adequate trial of formulary agents or combination therapy. Its use is reserved for patients that are treatment-resistant and require non-formulary approval for use.

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 therapy. Children under the age of 2 to 16 have a higher risk of experiencing serious skin reactions. If an interruption in therapy for a period of ≥ 5 days occurs, it is recommended that the dose be titrated again. Therapy should be discontinued at the first sign of rash unless the rash has been clearly identified as not drug-related.

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 200mg 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.

Serious side effects: Rash and Stevens Johnson Syndrome

Extreme caution: Extreme caution should be taken in combination with divalproex by using one half the starting dose and monitoring levels.
Formulary Agents – Practitioners may prescribe any agent on the formulary without restrictions based on patient assessment and clinical judgment.

Table 5: Formulary Agents

<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>Antimanic</td>
<td>Lithium carbonate</td>
<td>Eskalith®</td>
<td>Capsule</td>
<td>300mg</td>
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<tr>
<td></td>
<td></td>
<td>Cibalith-S®</td>
<td>Syrup</td>
<td>300mg/5ml</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>Divalproex Sodium</td>
<td>Depakote® EC Tablet</td>
<td>250mg, 500mg</td>
<td></td>
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<tr>
<td>Anticonvulsant</td>
<td>Carbamazepine</td>
<td>Tegretol® Tablet</td>
<td>200mg</td>
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</tr>
<tr>
<td>Antipsychotic</td>
<td>Risperidone</td>
<td>Risperdal® Tablet</td>
<td>0.5mg, 1mg, 2mg, 3mg, 4mg</td>
<td></td>
</tr>
</tbody>
</table>

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 entered in the EMR. All other uses require non-formulary approval.

Table 6: Prior Authorization Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Form</th>
<th>Strength</th>
<th>Prior Authorization Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic</td>
<td>Aripiprazole</td>
<td>Abilify® Tablet</td>
<td>2mg, 5mg, 10mg, 15mg, 20mg, 30mg</td>
<td>Intolerant to formulary 2nd generation AP</td>
<td></td>
</tr>
<tr>
<td>Antipsychotic</td>
<td>Ziprasidone</td>
<td>Geodon® Capsule</td>
<td>20mg, 40mg, 60mg, 80mg</td>
<td>Treatment failure on formulary 2nd generation AP</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Contraindication to formulary 2nd generation AP BMI &gt;90%</td>
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<tr>
<td>Drug</td>
<td>Daily Dose Range</td>
<td>Contraindications</td>
<td>Toxicity Seen/Starting At trough Serum Levels of:</td>
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<tr>
<td>Lithium</td>
<td>900 – 1,200 mg/day</td>
<td>Hypersensitivity to lithium; Sustained ventricular tachycardia; Seizures; Hypothyroidism; Acute kidney failure; Perforated ulcer; Endocarditis; Alcohol or drug abuse; Renal disease; Severe cardiovascular disease</td>
<td>Signs &amp; Symptoms of Toxicity (dose-related):</td>
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<td>Note: A rise in white blood cell count is to be expected.</td>
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<td>Signs &amp; Symptoms of Toxicity (NOT dose-related):</td>
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<td>At more than 1 mmol/L:</td>
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<td>Acute:</td>
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<td>• Apathy</td>
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<td>• Severe debilitation</td>
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<td>• Dehydration</td>
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<td>• Coarsening hand tremor that spreads to other parts of body</td>
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<td>• Target level:</td>
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<td>• Sodium depletion; Note: A rise in white blood cell count is to be expected.</td>
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<td></td>
<td>• Drowsiness</td>
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<td>• Dysarthria</td>
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<td>• GI symptoms (diarrhea, nausea, vomiting, etc.)</td>
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<td>• Giddiness</td>
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<td>• 0.9 – 1.2 mEq/L</td>
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<td>• blurred vision</td>
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<td>• Deep tendon reflexes increased</td>
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<td>• Muscle rigidity / fasciculations</td>
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<td>• Mild ataxia</td>
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<td>• Profound lethargy</td>
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<td>• Tinnitus</td>
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<td>• Vertical nystagmus</td>
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<td>• Severe intoxication:</td>
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<td>• Arrhythmias</td>
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<td>• Impaired consciousness</td>
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<td>• Increase in fasciculations and ataxia</td>
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<td>• CV collapse with oliguria and anuria</td>
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<td>• Coarse / irregular limb tremors</td>
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<td>• Cogwheel rigidity</td>
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<td>• Heart block</td>
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<td>• Stevens-Johnson Syndrome</td>
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<td>• Vomiting Syndrome</td>
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<td>• Prolongation of bleeding time</td>
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<td>• Thrombocytopenia</td>
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<td>Lamotrigine plasma concentration has not been established.</td>
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<td>• Pancytopenia – Do not rechallenge</td>
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<td>• Overdose</td>
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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.
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>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.</td>
</tr>
<tr>
<td>0</td>
<td>ANXIETY - Worry, fear, over-concern for present or future, uneasiness</td>
</tr>
<tr>
<td>0</td>
<td>EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.</td>
</tr>
<tr>
<td>0</td>
<td>CONCEPTUAL DISORGANIZATION - Thought processes confused, disconnected, disorganized, disrupted.</td>
</tr>
<tr>
<td>0</td>
<td>IMPULSIVENESS</td>
</tr>
<tr>
<td>0</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>0</td>
<td>MANNERISMS AND POSTURING - Peculiar, bizarre, unnatural motor behavior (not including tic).</td>
</tr>
<tr>
<td>0</td>
<td>GRANDIOSITY - Exaggerated self-opinion, arrogance, conviction of unusual power or abilities.</td>
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<tr>
<td>0</td>
<td>DEPRESSIVE MOOD - Sorrow, sadness, despondency, pessimism.</td>
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<tr>
<td>0</td>
<td>HOSTILITY - Animosity, contempt, belligerence, disdain for others.</td>
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<tr>
<td>0</td>
<td>SUSPICIOUSNESS - Mistrust, belief others harbor malicious or discriminatory intent.</td>
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<tr>
<td>0</td>
<td>HALLUCINATORY BEHAVIOR - Perceptions without normal external stimulus correspondence.</td>
</tr>
<tr>
<td>0</td>
<td>MOTOR RETARDATION - Slowed, weakened movements or speech, reduced body tone.</td>
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<tr>
<td>0</td>
<td>UNCOOPERATIVENESS - Resistance, guardedness, rejection of authority.</td>
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<tr>
<td>0</td>
<td>UNUSUAL THOUGHT CONTENT - Unusual, odd, strange, bizarre thought content.</td>
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<tr>
<td>0</td>
<td>BLUNTED AFFECT - Reduced emotional tone, reduction in formal intensity of feelings, flatness.</td>
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<tr>
<td>0</td>
<td>EXCITEMENT - Heightened emotional tone, agitation, increased reactivity.</td>
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<tr>
<td>0</td>
<td>DISORIENTATION - Confusion or lack of proper association for person, place or time.</td>
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<tr>
<td>0</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>
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<tr>
<td>0</td>
<td>SUICIDALITY - Expressed desire, intent, or actions to harm or kill self.</td>
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<tr>
<td>0</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>
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<tr>
<td>0</td>
<td>SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.</td>
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<tr>
<td>0</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>
DEPRESSIVE DISORDERS (Adolescents)

Meets DSM-IV criteria for Major Depressive Disorder or severe Dysthymia

Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

Switch to alternative formulary SSRI citalopram 10 – 40mg/day or sertralin 50 – 200mg/day.

Switch to alternative formulary antidepressant with different mechanism of action, venlafaxine 37.5 – 225mg/day.

Switch to alternative non-formulary antidepressant, bupropion XL.

Consider alternative combination therapy: SSRI or venlafaxine plus formulary atypical antipsychotic.

Consider therapy with antidepressant with best response plus formulary antipsychotic.

Reconsider diagnosis and consider psychopharmacology consultation.

Prepared by The Texas Juvenile Justice Department and Reviewed by the Correctional Managed Care Pharmacy & Therapeutics Committee.

October 2001, revised 5/12/02, 2/25/04, 3/1/06. Revised by Youth Services Pharmacy & Therapeutics Committee 7/10, 8/15/11, 4/16/12.

Notes: original pathway developed by TDCJ Pharmacy & Therapeutics Committee 4/98, revised 7/98 then as above by TJJD.
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.

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.

Bupropion General Information

The dosing strategy suggested for bupropion is 3mg/kg/day by the end of the first week and then titrated to 6mg/kg/day or 300mg/day by week 3, whichever is less. It may take as long as 4 weeks to observe maximum effectiveness with bupropion. Bupropion XL is recommended for convenience of use because it requires less frequent dosing.

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 therapeutic serum level is 0.9 to 1.3 mEq/L.

Common side effects: sedation, thirst, urinary frequency
Other side effects: hypothyroid, confusion, toxicity, acne, increased WBC’s

<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>As clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, Cr, BUN, 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 at baseline and periodically when there is a personal or family history of cardiovascular disease.
Lamotrigine General Information

Lamotrigine is a third line agent that may be used if a patient fails to respond to an adequate trial of two formulary SSRIs, venlafaxine, bupropion XL, and a combination of antidepressants. Its use is reserved for patients with treatment resistant depression and requires non-formulary approval for use.

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 therapy. 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 titrated again. Therapy should be discontinued at the first sign of rash unless the rash has been clearly identified as not drug-related.

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 4-18 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.

Serious side effects: Rash and Stevens Johnson Syndrome

Extreme caution: Extreme caution should be taken in combination with Valproate by using one half the starting dose and monitoring levels.

Formulary agents – Practitioners may prescribe any agent on the formulary without restrictions based on patient assessment and clinical judgment.

Table 2: Formulary Agents

<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>Selective Serotonin Reuptake Inhibitor (SSRI)</td>
<td>Citalopram</td>
<td>Celexa®</td>
<td>Tablet</td>
<td>10mg, 20mg, 40mg</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine</td>
<td>Prozac®</td>
<td>Capsule</td>
<td>10mg, 20mg</td>
</tr>
<tr>
<td></td>
<td>Sertraline</td>
<td>Zoloft®</td>
<td>Tablet</td>
<td>50mg, 100mg</td>
</tr>
<tr>
<td>Serotonin/Norepinephrine Reuptake Inhibitor (SNRI)</td>
<td>Venlafaxine</td>
<td>Effexor®</td>
<td>Tablet</td>
<td>75mg, 150mg</td>
</tr>
<tr>
<td>Other*</td>
<td>Trazodone</td>
<td>Desyrel®</td>
<td>Tablet</td>
<td>50mg, 100mg</td>
</tr>
</tbody>
</table>

*Not recommended as first line or second line therapy for treatment of depression in children or adolescents
### 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></td>
<td></td>
<td>X</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>X</td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>CBC, LFT, SCr, Electrolytes</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>EKG†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>Prolactin**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</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.
2. Providers should consider obtaining Prolactin at baseline and periodically when there is a history of galactorrhea, amenorrhea, or gynecomastia.

### 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.
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. 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.
*TYPE 1 DIABETES MELLITUS*

(Children & Adolescents)

1. Institute Lifestyle Modifications & Group/Individual Education with Specific Patient Goals

1.1. Perform fasting blood glucose profile at baseline after glycemic control achieved if:
   - ≥ 10 years:
     - If normal (LDL <100mg/dl), repeat every 5 years.
     - If abnormal, initiate lifestyle modifications for 6 months. If goal LDL ≤< 100mg/dl is not met after 6 months, start statin therapy (Table 8) if:
       - LDL <100mg/dl and patient has at least 1 cardiovascular risk factor.
       - LDL ≥100mg/dl and patient has 0 cardiovascular risk factors.
     - Recheck lipid panel every 3 months until patient reaches goal (LDL ≤< 100mg/dl). Once at goal, recheck lipid panel annually.
   - ≤ 10 years only if family history is positive for cardiovascular disease. If normal (LDL <100mg/dl), repeat every 5 years.

1.2. Obtain H&P and obtain baseline labs: Chem 10, fasting plasma glucose, A1C, UA, TSH. Consider screening for thyroid disease, vitamin B12 deficiency and celiac disease based on clinical symptoms.

1.3. Obtain fasting lipid profile at baseline after glycemic control achieved if:
   - ≥ 10 years:
     - If normal (LDL ≤≤ 100mg/dl), repeat every 5 years.
     - If abnormal, institute lifestyle modifications for 6 months. If goal LDL ≤≤ 100mg/dl is not met after 6 months, start statin therapy (pravastatin 10 to 80mg if no contraindications – Table 8) if:
       - LDL ≤≤ 100mg/dl and patient has at least 1 cardiovascular risk factor.
       - LDL >100mg/dl and patient has 0 cardiovascular risk factors.
     - Recheck lipid panel every 3 months until patient reaches goal (LDL ≤≤ 100mg/dl). Once at goal, recheck lipid panel annually.
   - ≤ 10 years only if family history is positive for cardiovascular disease. If normal (LDL ≤≤ 100mg/dl), repeat every 5 years.

1.4. Determine if blood pressure at goal < 90th percentile for age, sex, and height. ACE-inhibitor (enalapril 2.5mg QD) preferred for initial treatment of hypertension if no contraindications (Refer to Table 8 for ACEI contraindications). Refer to Hypertension disease management guidelines for children & adolescents.

1.5. Screen for microalbuminuria with random spot urine sample for albumin-to-creatinine ratio once the child is 10 years old and has had diabetes for at least 5 years. Start low dose ACE-inhibitor* (Enalapril 2.5mg QD) and obtain creatinine and estimate GFR annually.

1.6. Institute lifestyle modifications (i.e., exercise, diet, smoking cessation and weight loss) if BMI >80th percentile.

1.7. Administer annual influenza vaccine. If pneumococcal vaccine was not previously given in their lifetime, administer one time only.

1.8. Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit if not completed at intake.

1.9. Refer for dilated eye exam evaluation if patient ≥≥ 10 years of age and has had diabetes for at least 3-5 years.

2. Begin multiple daily insulin injections. Dose insulin 0.5 units/kg/day. Use NPH insulin for basal insulin requirements, which should be 50% of total daily dose (TDD) of insulin. Administer 2/3 of the NPH dose in the morning and 1/3 in the evening. Remaining 50% of TDD is administered as Regular insulin divided before meals (Table 9).

2.1. Obtain fasting finger sticks 3 times a day before meals and at bedtime for 2 weeks.

2.2. Follow up in 2 weeks.

3. Reevaluate compliance with medications, exercise and diet.

3.1. Adjust Regular and NPH doses by 10% of TDD until AM and PM finger sticks (FS) are at goal.

3.2. Monitor for hypoglycemia (Table 10).

3.3. Follow up every 2 weeks until FS at goal. (Table 11).

4. Obtain fasting finger sticks twice a week (FS 70-100mg/dl). See Table 12.

4.1. If patient experiencing hypoglycemia ≥ twice a week (FS ≤70mg/dl) See Table 13.

4.2. Check A1C every 3 months.

4.3. Is A1c at goal?

   - Yes
     - 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 3 months.
     - Patient 13 yrs. UA, eye and foot exam annually and TSH every 2 years.
     - Check for microalbuminuria annually.
     - If A1C not at goal, go to box #4.

   - No
     - Reevaluate compliance with medications, exercise and diet.
     - Reevaluate NPH and regular insulin doses
     - Consider referral to specialist.

5. If A1C is not at goal, go to box #4.

6. Reevaluate compliance with medications, exercise and diet.

6.1. Consider refer to specialist.

Table 1: Glycemic Control Goals

<table>
<thead>
<tr>
<th>Age</th>
<th>Prandial BG</th>
<th>Bedtime/Oversight BG</th>
<th>A1C</th>
<th>Consider Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-12 yrs</td>
<td>90-140</td>
<td>100-150</td>
<td>&lt;7%</td>
<td>glucose &lt;90 or ≤≤ 100 and A1C ≤≤ 9%</td>
</tr>
<tr>
<td>13-19 yrs</td>
<td>90-150</td>
<td>90-150</td>
<td>≤≤ 7%</td>
<td>glucose &lt;90 or ≤≤ 100 and A1C ≤≤ 9%</td>
</tr>
</tbody>
</table>

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, November 2006, Revised 11/07, 4/11, 5/13

The pathways do not replace sound clinical judgment nor are they intended to apply to all patients.
TYPE 2 DIABETES MELLITUS (Children & Adolescents)

Random plasma glucose ≥ 200mg/dL or fasting plasma glucose (FPG) ≥ 126 mg/dL is considered Type 2 diabetes mellitus in children and adolescents.

2. 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.
   - If normal (LDL ≤ 100mg/dL), repeat every 3 years.
   - If abnormal, recheck annually. Institute lifestyle modifications for 6 months. If the child is over the age of ten and LDL > 100mg/dL and patient is at least 1 cardiovascular risk factor, LDL ≥ 130mg/dL and patient has 6 cardiovascular risk factors.
   - Recheck lipids and repeat fasting plasma glucose (FPG) if A1C ≥ 6.5% on 2 occasions.
   - Once at goal, recheck lipids panel annually.

3. Determine if blood pressure is at goal (≤ 90th percentile for age, sex, and height. ACE inhibitor (enalapril 2.5 mg QD) preferred for initial treatment of hypertension if no contraindications (see Table 3). Refer to Hypertension disease management guidelines for children & adolescents. If normal (LDL < 100mg/dL), repeat every 5 years. Increased Risk for child is over the age of ten and goal LDL of < 100mg/dL is not met after 6 months, start statin therapy (pravastatin 10 to 40mg if no contraindications. If abnormal, recheck annually. Institute lifestyle modifications for 6 months. If the child is over the age of ten and LDL > 130mg/dL, and patient has 6 cardiovascular risk factors.
   - Recheck lipids and repeat fasting plasma glucose (FPG) if A1C ≥ 6.5% on 2 occasions.
   - Once at goal, recheck lipids panel annually.

4. Screen for microalbuminuria with random spot urine sample for albumin-to-creatinine. Start low dose ACE inhibitor if microalbuminuria is present (enalapril 2.5 mg QD) and if no contraindications (see Table 8).
   - Examine exercise plan, diet plan, smoking cessation and weight loss if BMI > 80th percentile.
   - Recheck fasting plasma glucose (FPG) 100 to 125mg/dL or A1C 5.7-6.4%
     - If normal (LDL < 100mg/dL), repeat every 5 years. Increased Risk for child is over the age of ten and goal LDL of < 100mg/dL is not met after 6 months, start statin therapy (pravastatin 10 to 40mg if no contraindications. If abnormal, recheck annually. Institute lifestyle modifications for 6 months. If the child is over the age of ten and LDL > 130mg/dL, and patient has 6 cardiovascular risk factors.
   - Recheck lipids and repeat fasting plasma glucose (FPG) if A1C ≥ 6.5% on 2 occasions.
   - Once at goal, recheck lipids panel annually.

5. Determine if blood pressure is at goal (≤ 90th percentile for age, sex, and height. ACE inhibitor (enalapril 2.5 mg QD) preferred for initial treatment of hypertension if no contraindications (see Table 3). Refer to Hypertension disease management guidelines for children & adolescents. If normal (LDL < 100mg/dL), repeat every 5 years. Increased Risk for child is over the age of ten and goal LDL of < 100mg/dL is not met after 6 months, start statin therapy (pravastatin 10 to 40mg if no contraindications. If abnormal, recheck annually. Institute lifestyle modifications for 6 months. If the child is over the age of ten and LDL > 130mg/dL, and patient has 6 cardiovascular risk factors.
   - Recheck lipids and repeat fasting plasma glucose (FPG) if A1C ≥ 6.5% on 2 occasions.
   - Once at goal, recheck lipids panel annually.

6. Administer annual influenza vaccine. If pneumococcal vaccine not previously given in lifetime, administer one time only.
   - Refer to Dental for oral/periodontal disease evaluation if not completed at intake.
   - Refer for dilated eye exam.

7. Refer to Dental for oral/periodontal disease evaluation if not completed at intake.
   - Refer for dilated eye exam.

8. Recheck A1C in 3 months. If A1C at goal?
   - Yes
   - Go to box #7
   - No
   - Recheck A1C in 3 months. Is A1C at goal?
   - Yes
   - How to box #7
   - No

9. Reevaluate compliance to medications, diet and exercise plan.
   - Continue metformin.
   - Start evening dose of insulin NPH (0.2u/kg or 10-15u) and check FS. Titrate evening dose of NPH by 10% of TDD until AM FS are at goal.
   - Monitor for hypoglycemia (Table 10).
   - Follow up at least monthly.

10. Recheck A1C in 3 months. Is A1C at goal?
    - Yes
    - Go to box #7
    - No

11. Recheck A1C in 3 months. Is A1C at goal?
    - Yes
    - Go to box #7
    - No

12. Yes
    - Recheck A1C in 3 months. Is A1C at goal?
    - Yes
    - Go to box #7
    - No

13. Yes
    - Recheck A1C in 3 months. Is A1C at goal?
    - Yes
    - Go to box #7
    - No

Table 1: Glycemic Control Goals

<table>
<thead>
<tr>
<th>Age</th>
<th>Premeal BG</th>
<th>Bedtime/Overnight BG</th>
<th>A1C</th>
<th>Consider Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-12 yrs</td>
<td>90-150</td>
<td>100-180</td>
<td>&lt; 8%</td>
<td>Glucose &lt; 90 or ≥ 150 and/or A1C &lt; 8%</td>
</tr>
<tr>
<td>13-19 yrs</td>
<td>90-150</td>
<td>100-180</td>
<td>&gt; 7.5%</td>
<td>Glucose ≥ 90 or ≥ 150 and/or A1C &lt; 8%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If FPG &lt;100mg/dL or A1C &lt; 5.7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rescreen no later than every 3 years</td>
</tr>
</tbody>
</table>

The pathways do not replace sound clinical judgment and are not intended to strictly apply to all patients.

The pathways do not replace sound clinical judgment and are not intended to strictly apply to all patients.
Continued from box #12

15

Are PM FS at goal? Yes

16

Recheck A1C in 3 months. Is A1C at goal? Yes

17

Go to box #7

No

18

• Continue metformin.
• Start Multi-dose Insulin Therapy by increasing NPH to twice daily dosing. Add NPH at 0.3 u/kg to 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.

19

Are AM and PM FS at goal? Yes

20

Recheck A1C in 3 months. Is A1C at goal? Yes

21

Go to box #7

No

22

• Continue metformin.
• Intensify insulin regimen by adding Regular Insulin QD or BID if patient is not able to tolerate higher dose of NPH and/or is hyperglycemic after meals.
• Obtain AM and PM FS.
• Monitor for hypoglycemia (Table 10).
• Follow up at least monthly.

23

Are AM and PM FS at goal? Yes

24

Recheck A1C in 3 months. Is A1C at goal? Yes

25

Go to box #7

No

26

Titrate NPH and/or Regular Insulin AM or PM by 10% of TDD. If TDD is >200u/day, consider referral to specialist.

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

<table>
<thead>
<tr>
<th>Table 2: Screening Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria</strong></td>
</tr>
<tr>
<td>Overweight</td>
</tr>
<tr>
<td>Plus any two of the following risk factors</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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 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 A1C > 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 A1C rises, the risk of diabetes rises disproportionately. See Table 11 for association of A1C and average glucose.
Table 3: Categories of Increased Risk for Diabetes

<table>
<thead>
<tr>
<th>FPG</th>
<th>100 – 125mg/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-hr plasma glucose on the 75g OGTT</td>
<td>140-199mg/dl</td>
</tr>
<tr>
<td>A1c</td>
<td>5.7-6.4%</td>
</tr>
</tbody>
</table>

V. Diagnosis

A. Most children with type 1 diabetes present with a short duration of symptoms (usually weeks) 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 ≥ 200mg/dl, FPG is ≥ 126 mg/dl, or 2-hr plasma glucose ≥ 200mg/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 ≥ 200 mg/dl, diagnosis does not require a repeat value on another day.
3. A1c ≥ 6.5%. Confirmation by repeat testing preferred. A1C may not be an effective test in special patient populations with affected hemoglobin disorders.

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 ≥ 200mg/dl</td>
</tr>
<tr>
<td>Fasting plasma glucose (FPG)</td>
<td>FPG ≥ 126mg/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 ≥ 200mg/dl during OGTT.</td>
</tr>
<tr>
<td>Hemoglobin A1C</td>
<td>A1C ≥ 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 ketonacidosis 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
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 5: Laboratory Monitoring

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency of Monitoring</th>
</tr>
</thead>
</table>
| Fasting plasma glucose   | ▪ Baseline  
                           ▪ As clinically indicated to monitor/adjust medications                                    |
| A1C*                     | ▪ Baseline  
                           ▪ Every 6 months if stable and meeting treatment goals  
                           ▪ Every 3 months if not meeting treatment goals                                               |
| Fasting lipid profile    | ▪ At baseline, after glycemic control is achieved  
                           ▪ Type 1 diabetes  
                           ▪ ≥ 10 years: repeat every 5 years if initial screen is normal (LDL < 100mg/dl)  
                           ▪ If abnormal, institute lifestyle modifications for 6 months. If goal LDL of ≤100mg/dl is not met after 6 months, start statin therapy (pravastatin 10 to 80mg/dl as clinical indications – Table 8) if:  
                           ▪ LDL ≥130mg/dl and patient has at least 1 cardiovascular risk factor  
                           ▪ LDL ≥160mg/dl and patient has ≥2 cardiovascular risk factors  
                           ▪ Recheck lipid panel every 3 months until patient reaches goal (LDL ≤100mg/dl). Once at goal, recheck lipid panel annually.  
                           ▪ < 10 years: Only begin ≥ 2 yo and has positive family history (FH) of hypercholesterolemia (TC > 240 mg/dl), family CV event before age 55, or if family history unknown. If FH is not a concern, first lipid screening at puberty (≥10 years). Repeat every 5 years if initial screen is normal. If abnormal, annual monitoring. Statins not recommended in children < 10 years of age.  
                           ▪ Type 2 diabetes - screen all children at baseline regardless of age, repeat every 5 years if initial screen is normal |
| TSH                       | Baseline (every 2 years in type 1 diabetes). Measure Free T4 if TSH abnormal.            |
| Urinalysis                | Baseline & annual to screen or as clinically indicated                                   |
| Random spot urine sample  | Baseline & annual to screen for microalbuminuria. Screening should be initiated once the child is 10 years of age and has had diabetes for 5 years. |
| CHEM 10 (i.e. creatinine) | Baseline & annual or as clinically indicated                                           |

*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 HbA1C (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>
<thead>
<tr>
<th>Table 6: Definition of abnormalities in albumin excretion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
</tr>
<tr>
<td>Normal</td>
</tr>
<tr>
<td>Microalbuminuria</td>
</tr>
<tr>
<td>Macroalbuminuria (clinical)</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. Recommend 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>
<thead>
<tr>
<th>Table 7: Treatment of Hyperlipidemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value</td>
</tr>
<tr>
<td>LDL 100-129mg/dl</td>
</tr>
<tr>
<td>LDL 130-190mg/dl plus 1 cardiovascular risk factor</td>
</tr>
<tr>
<td>LDL &gt; 160mg/dl</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 consult 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) Initial dose 0.5 units/kg/day for total daily dose (TDD). Designate 50% of the TDD to NPH insulin. Two thirds of the NPH dose should be administered in the am before breakfast and 1/3 of the NPH dose should be administered in the pm before dinner. The remaining 50% of the TDD is for Regular Insulin. Divide Regular insulin between the three meals as required by the patient.
      Example:
      Patient: 40 kg x 0.5 u/kg/day = 20 total units for TDD
      NPH insulin: 10 units = 7 units QAM, 3 units QPM
      Reg insulin: 10 units → 3 units TID (May adjust depending on specific patient)
   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) Regimen usually consists of a short-acting insulin (Regular) and intermediate-acting insulin (NPH) (refer to Table 9 for pharmacokinetics of insulin).
   d) 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.
   e) Prepubertal children generally require between 0.5 to 0.9 units/kg/day.
   f) 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.
   g) 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 modification. 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 usually preferred during pregnancy
Table 8: Antidiabetic Agents

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>500mg qd-bid</td>
<td>• Contraindications: Impaired renal function, radiocontrast media, hypoxemic conditions, hepatic disease, metabolic acidosis, hypersensitivity to metformin  \n• Pregnancy category B</td>
</tr>
<tr>
<td>Insulin</td>
<td>0.5 to 1 units/kg/day</td>
<td>• Contraindication: Hypersensitivity to insulin  \n• Insulin requirements may decrease in newly diagnosed patients during the honeymoon phase  \n• Insulin requirements may increase during puberty to as much as 1.5 units/kg/day  \n• Pregnancy category B</td>
</tr>
<tr>
<td>Enalapril</td>
<td>2.5mg qd</td>
<td>• Contraindications: ACE-inhibitor induced angioedema, hereditary or idiopathic angioedema, pregnancy, hypersensitivity to enalapril or other ACE inhibitors \n• 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  \n• Pregnancy category X</td>
</tr>
</tbody>
</table>

Table 9: 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 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>
<tr>
<td>70/30 Insulin</td>
<td>30 to 60 min</td>
<td>3 to 12 hours</td>
<td>8 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 hyperglycemia after dinner, the Regular insulin will need to be adjusted as its onset of action is faster than the NPH.

Table 10: 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 individual 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>
Table 11: 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 12: 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. Recommended 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 lotions 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. Individuals 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. Partial response per BPRS
   - Initiate monotherapy with formulary atypical antipsychotic risperidone and continue for 4-6 weeks at a therapeutic dose.
   - Inadequate response per BPRS
     - Assess compliance

4. Partial response per BPRS
   - Continue treatment. Re-evaluate after 6 months of remission for possible taper and discontinuation.

5. Adequate response per BPRS
   - Continue treatment. Re-evaluate after 6 months of remission for possible taper and discontinuation.


7. Inadequate response per BPRS
   - Initiate monotherapy with alternative formulary prior authorization atypical antipsychotic not tried above (aripiprazole or ziprasidone) and continue for 4-6 weeks at a therapeutic dose.
   - Adequate response per BPRS
     - Assess compliance

8. Partial response per BPRS
   - Continue treatment. Re-evaluate after 6 months of remission for possible taper and discontinuation.

9. Partial response per BPRS
   - Initiate adjutantive therapy with mood stabilizer lithium or divalproex and continue for 4-6 weeks at therapeutic doses.
   - Inadequate response per BPRS
     - Consider alternative agents (e.g., propranolol, SSRI) and/or psychopharmacology consultation.

10. Adequate response per BPRS
    - Continue treatment. Re-evaluate after 6 months of remission for possible taper and discontinuation.

Prepared By The Texas Youth Commission and Reviewed By The Correctional Managed Care Pharmacy & Therapeutics Committee. October 2001, revised 5/02, 2/04, 3/06, 1/12, 4/14.
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 risperidone unless it is clearly not indicated. Table 1 details the recommended dosing for initiating risperidone. Titration schedule 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>Risperidone</th>
<th>Day 1-4</th>
<th>Day 5-8</th>
<th>Day 9-12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily Dose</td>
<td>0.5-1mg</td>
<td>1.5-2mg</td>
<td>2-4mg</td>
</tr>
<tr>
<td>Divide</td>
<td>Single Dose or 0.5-1.5</td>
<td>Single Dose or 0.5-2</td>
<td>Single Dose or 1-2</td>
</tr>
</tbody>
</table>

Notes:
- 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 2: Formulary Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication &amp; Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Generation Antipsychotics</td>
<td>Chlorpromazine 20mg, 100mg, 200mg tablet; Fluphenazine 2.5mg, 5mg, 10mg tablet; 2.5mg/ml inj; 25mg/ml decanoate inj; Haloperidol 1mg, 5mg tablet; 2mg/ml oral concentrate; 5mg/ml inj; 100mg/ml decanoate inj; Perphenazine 4mg, 8mg, 16mg tablet; Trifluoperazine 2mg, 5mg, 10mg capsule; 2mg, 5mg, 10mg tablet</td>
</tr>
<tr>
<td>2nd Generation Antipsychotics</td>
<td>Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg tablet; 20mg/ml injection</td>
</tr>
</tbody>
</table>

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 EMR. All other uses require non-formulary approval.

Table 3: Prior Authorization Agents

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Medication &amp; Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Generation Antipsychotic</td>
<td>Aripiprazole (Abilify®) 2mg, 5mg, 10mg, 15mg, 20mg, 30mg tablet; Contramol (formulary 2nd generation antipsychotic) 20mg, 40mg, 60mg, 80mg capsule</td>
</tr>
<tr>
<td></td>
<td>Ziprasidone (Geodon®) 20mg, 40mg, 60mg, 80mg capsule</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 risperidone and then tapered off the initial antipsychotic agent by one-third to one-fourth of the initial daily dosage at weekly intervals (beginning one week after the goal dose of risperidone is achieved) until discontinued. Alternately, table 4 below outlines strategies for switching patients by a structured cross-titration schedule that is agent specific.

Notes:
- If patient is on more than the maximum dose, taper down to that dose before beginning the cross titration.
- Practitioners should be sure to complete cross-titration to ensure that the patient is not left on two antipsychotic agents indefinitely.
Table 4: 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</td>
<td>100mg</td>
<td>50mg</td>
<td>00mg</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>80mg BID</td>
<td>60mg</td>
<td>40mg</td>
<td>20mg</td>
<td>00mg</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>

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

Table 5: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents 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>Personal Family History</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Weight-Height-BMI (overweight 25-29.9; obesity ≥ 30)</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>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC, LFT, SEA, Electrolytes</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td></td>
<td></td>
<td>As clinically indicated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EKG</td>
<td>As clinically indicated</td>
<td></td>
<td></td>
<td></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.
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

<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>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 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>&lt;&lt;/=</td>
<td></td>
<td>TD, NMS</td>
</tr>
<tr>
<td>Risperidone</td>
<td>&lt;</td>
<td>+++</td>
<td>++</td>
<td></td>
<td>Depression</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>+/-</td>
<td>&lt;/=-</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>Lipid and glucose dysregulation, Seizures</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>-</td>
<td></td>
<td>&lt;/=-</td>
<td>++</td>
<td>QTc prolongation</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>+/-</td>
<td>&lt;/=-</td>
<td>-</td>
<td>&lt;/=-</td>
<td>EPS is typically akathisia</td>
</tr>
</tbody>
</table>

EPS = extrapyramidal symptoms  
NMS = neuroleptic malignant syndrome  
+/− = 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>
</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 |  
| Neuroleptic Malignant Syndrome |  
| Drug Class | Generic Name | Brand Name | Form | Strength |
| Anticonvulsant | Carbamazepine | Tegretol® | Tablet | 200mg |
| Anticonvulsant | Divalproex Sodium | Depakote® | EC Tablet | 250mg, 500mg |
| Antimanic | Lithium carbonate | Eskalith® | Capsule | 300mg, 500mg/7ml |
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 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, MCV, Electrolytes, TSH</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Lithium levels</td>
<td></td>
<td></td>
<td>X X</td>
</tr>
</tbody>
</table>

Table 11: Toxicity Information

<table>
<thead>
<tr>
<th>Drug</th>
<th>Daily Dose Range</th>
<th>Contraindications</th>
<th>Toxicity Seen Starting At Trough Serum Level(s)</th>
<th>Signs &amp; Symptoms of Toxicity (dose-related)</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>Serum levels of lithium may manifest toxicity at trough serum levels &lt; 1 mmol/L.</td>
<td>Lithium toxicity can be FATAL</td>
</tr>
<tr>
<td></td>
<td>Target level: 0.5-1.2 mEq/L</td>
<td>Low cardiovascular output disorder</td>
<td>Doses should not generally exceed 1200 mg/day</td>
<td>Note: A rise in white blood cell count is expected</td>
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Lithium toxicity can be FATAL:

**Signs & Symptoms:**
- Apathy
- Coarse hand tremor that spreads to other parts of body
- Confusion
- Dizziness
- GI symptoms (diarrhea, nausea)
- Giddiness

**Contraindications:**
- Hypersensitivity to lithium
- Severe cardiovascular output disorder
- Severe debilitation
- Sodium depletion
- Pregnancy Category D

**Toxicity:**
- Plasma levels of lithium may manifest toxicity at trough serum levels < 1 mmol/L.

**Note:** A rise in white blood cell count is expected.

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<tr>
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<th>Contraindications</th>
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- Apathy
- Coarse hand tremor that spreads to other parts of body
- Confusion
- Dizziness
- GI symptoms (diarrhea, nausea)
- Giddiness

**Contraindications:**
- Hypersensitivity to lithium
- Severe cardiovascular output disorder
- Severe debilitation
- Sodium depletion
- Pregnancy Category D

**Toxicity:**
- Plasma levels of lithium may manifest toxicity at trough serum levels < 1 mmol/L.

**Note:** A rise in white blood cell count is expected.

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<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC, MCV, Electrolytes, TSH</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Lithium levels</td>
<td></td>
<td></td>
<td>X X</td>
</tr>
</tbody>
</table>

**Table 11:** Toxicity Information

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<th>Daily Dose Range</th>
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Lithium toxicity can be FATAL:

**Signs & Symptoms:**
- Apathy
- Coarse hand tremor that spreads to other parts of body
- Confusion
- Dizziness
- GI symptoms (diarrhea, nausea)
- Giddiness

**Contraindications:**
- Hypersensitivity to lithium
- Severe cardiovascular output disorder
- Severe debilitation
- Sodium depletion
- Pregnancy Category D

**Toxicity:**
- Plasma levels of lithium may manifest toxicity at trough serum levels < 1 mmol/L.

**Note:** A rise in white blood cell count is expected.
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 6 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>Platelets</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divalproex levels</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 13: Toxicity Information

<table>
<thead>
<tr>
<th>Drug/Drug Dose Range</th>
<th>Contraindications</th>
<th>Totality/Total Serum Level (mg/mL)</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>Divalproex: 1,500mg/day or 1.25mg/kg/day given as divided doses up to 60mg/kg/day</td>
<td>• Hypersensitivity to sulfonamides • Hepatic dysfunction • Uraemic encephalopathy • Pregnancy, Category D</td>
<td>&gt;100-125</td>
<td>• Somnolence, lethargy • Mental status change • Coma • Hypertension • Hypertoxicity • Heart block • Vomiting • Thrombocytopenia • Prolongation of bleeding time • Alopecia</td>
<td>• Pancreatitis – Do not challenge • Hypersensitivity • Hypothyroidism • Hypocalcemia, severe or fatal • Severe hyperammonemia • Toxic epidermal necrolysis • Polycystic ovarian syndrome</td>
</tr>
<tr>
<td>Target level: 75-115mg/mL</td>
<td></td>
<td></td>
<td></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—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. 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, 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.

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### Hypertension (Children & Adolescents)

#### Table 1: Classification and Management of Hypertension

<table>
<thead>
<tr>
<th>Blood Pressure Classification</th>
<th>SBP or DBP Percentile</th>
<th>Therapeutic Lifestyle Changes</th>
<th>Drug Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;90th percentile</td>
<td>Encourage healthy diet, sleep &amp; exercise</td>
<td>None</td>
</tr>
</tbody>
</table>
| Prehypertension              | 90th to 94th percentile or BP > 120/80mmHg even if <90th percentile up to 94th percentile | • Weight loss if overweight  
• Exercise program  
• Diet plan | None unless compelling indications³ |
| Stage 1 Hypertension         | 95th to 99th percentile plus 5mmHg | • Weight loss if overweight  
• Exercise program  
• Diet plan | Initiate therapy with ACEI, BB, CCB, or diuretic if:  
1. Persistent HTN with lifestyle changes  
2. Compelling indication  
3. Symptomatic HTN  
4. Target organ damage  
5. Secondary HTN |
| Stage 2 Hypertension         | >99th percentile plus 5mmHg | • Weight loss if overweight  
• Exercise program  
• Diet plan | Initiate therapy with ACEI, BB, CCB, or diuretic. More than 1 drug may be required. |

1Adapted from 4th Report on the Diagnosis, Evaluation and Treatment of High Blood Pressure in Children & Adolescents  
2For gender, age, and height (use tables) measured on 3 separate occasions. Categorize based on the highest value if SBP and DBP differ  
3Compelling indications include diabetes, chronic kidney disease, and heart failure  
₄This BP level typically occurs for SBP at 12 years old and for DBP at 16 years old  
5Manage secondary causes as indicated and initiate antihypertensive therapy as indicated (go to box #6 to treat hypertension)  
6Go to box #9, Page 2  
7Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. November 2006. Revised 4/09.
Does the patient have compelling indications (diabetes, kidney disease, heart failure)?

No
Yes

Does the patient have compelling indications (diabetes, kidney disease, heart failure)?

No
Yes

Proceed to the next step.

Treat with lifestyle modifications & start drug therapy for compelling indication (table 8).

Go to box 26.

Determine blood pressure classification.

Stage 2 HTN
- Treat with lifestyle modifications
- Initiate drug therapy ACEI, BB, CCB, or diuretic.

Stage I HTN
- Is the patient symptomatic, have target organ damage or secondary HTN?

No
Yes

Continue with lifestyle modifications.

Obtain BP readings weekly, follow up 1-2 months.

Stage I HTN or compelling indication: Obtain BP readings twice weekly, follow up 2-4 weeks.

Stage II HTN: Obtain BP readings twice weekly, follow up 2-4 weeks.

Goal BP achieved?

Yes
No

Is the patient adherent?

Yes
No

Increase dose as tolerated. Follow up based on box # 26.

Counsel patient regarding importance of compliance.

Continue current treatment. Follow up as needed at least every 12 months.

Consider intensive counseling, DOT, stabilization in infirmary, or consultation.

Change drug class or add drug from another class and reduce dose of offending agent. Follow up based on box # 26.

Goal BP achieved?

Yes
No

Is the patient experiencing adverse effects?

Yes
No

Goal BP achieved?

Yes
No

Continue current treatment. Follow up as needed at least every 12 months.

Obtain BP readings monthly. Follow up in 3 months.

Obtain BP readings weekly, follow up 1-2 months.

Obtain BP readings twice weekly, follow up 2-4 weeks.

Is blood pressure at goal <95th percentile? Proceed to the next step.

Continue lifestyle modifications. Follow up as needed at least every 12 months.

Is the patient symptomatic, have target organ damage or secondary HTN?

Continue lifestyle modifications. Follow up as needed at least every 12 months.

Increase dose as tolerated. Follow up based on box # 26.

Counsel patient regarding importance of compliance.

Continue current treatment. Follow up as needed at least every 12 months.

Consider intensive counseling, DOT, stabilization in infirmary, or consultation.

Change drug class or add drug from another class and reduce dose of offending agent. Follow up based on box # 26.
I. Detection and Confirmation
   A. Appropriate cuff size must be used to ensure accurate readings. The cuff bladder length should cover 80% of the circumference of the arm. BP measurements can be overestimated with a cuff that is too small.
   B. Elevated BP must be confirmed on repeated visits. At least an average of 3 BP measurements.
   C. Preferred method of BP measurement is auscultation. If using an electronic device, all measurements that exceed the 90th percentile should be confirmed by auscultation.
   D. Patients should be seated in a chair with their backs supported, feet on the floor, and their arms supported at heart level.
   E. BP measurements should be obtained after the patient has been at rest for at least 5 minutes.
   F. Blood pressure is determined by gender, age, and height in children and adolescents. Directions are listed below.
      1. Use the standard CDC growth charts (page 6 or 8) to determine height percentile.
      2. Obtain the patient’s blood pressure.
      3. Use the correct gender blood pressure table (page 5 or 7) to determine the blood pressure percentile.
      4. Find the patient’s age on the left hand side of the table and follow the age row horizontally until it intersects the line for the height percentile.
      5. BP < 90th percentile is normal.
      6. BP between 90th and 94th percentile is prehypertension. In adolescents, BP ≥ 120/80 mmHg is prehypertension even if it is less than the 90th percentile.
      7. Any BP > 90th percentile should be repeated twice during the visit and an average SBP and DBP should be used to determine blood pressure.
      8. Any BP > 95th percentile, should be staged to determine treatment.
   G. Follow-up based on initial blood pressure reading

### Table 2

<table>
<thead>
<tr>
<th>Blood Pressure (SBP or DBP)</th>
<th>Frequency of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 90th percentile</td>
<td>Recheck at next regularly scheduled visit.</td>
</tr>
<tr>
<td>90th to 94th percentile or BP &gt; 120/80mmHg even if &lt; 90th percentile up to 94th percentile</td>
<td>Recheck in 6 months</td>
</tr>
<tr>
<td>95th to 99th percentile plus 5mmHg</td>
<td>Recheck in 1-2 weeks. Recheck sooner if the patient is symptomatic. If elevated BP is confirmed on repeated visits (at least 3), begin treatment for stage 1 hypertension.</td>
</tr>
<tr>
<td>&gt; 99th percentile plus 5mmHg</td>
<td>Recheck within 1 week or evaluate immediately if patient is symptomatic. If elevated BP is confirmed on repeated visits (at least 3), begin treatment for stage 2 hypertension.</td>
</tr>
</tbody>
</table>

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II. Patient Evaluation

A. Cardiovascular risk factors
   1. Hypertension
   2. Overweight/obesity
   3. Low HDL cholesterol
   4. Elevated triglycerides
   5. Abnormal glucose tolerance/diabetes
   6. Sleep problem/disorder
   7. Family history of hypertension or cardiovascular disease

B. History
   1. Sleep history
   2. Family history
   3. Medication history
   4. Social history
   5. History of weight and physical activity
   6. Known duration and levels of elevated blood pressure
   7. Symptoms suggestive of hypertension (headache, nose bleeds, dizziness, abnormal physical exam)
   8. Dietary assessment including intake of sodium, alcohol, saturated fat and caffeine

C. Laboratory/Diagnostic Evaluation – Recommended at baseline and annually.
   1. Urinalysis
   2. CBC
   3. BUN, creatinine
   4. Electrolytes
   5. Fasting lipid panel (baseline only)
   6. Fasting glucose (baseline only)
   7. Renal ultrasound (baseline only as clinically indicated)
   8. TSH (baseline only)
   9. Drug screen (baseline only if have suggestive history)

D. Physical exam
   1. Height & weight - BMI (body mass index)
   2. Blood pressure & other vitals
   3. Fundoscopic examination for retinal changes (i.e., arteriolar narrowing, focal arteriolar constrictions, arteriovenous crossing changes, hemorrhages and exudates, disc edema)
   4. Examination for the neck for carotid bruits, distended veins, or enlarge thyroid gland
   5. Examinations of the heart for abnormalities in the rate and rhythm, increase size, precordial heave, clicks, murmurs and third and fourth heart sounds
   6. Examination of the lungs for rales and evidence for bronchospasm
   7. Examination of the abdomen for bruits, enlarged kidney, masses and abnormal aortic pulsation
   8. Examinations of the extremities for diminished or absent peripheral arterial pulsations, bruits, and edema

E. Evaluate patient for secondary causes – Secondary hypertension is more common in children than adults. The majority of children with secondary hypertension will have renal or renovascular causes for blood pressure elevation.
   1. Drug-induced
   2. Mineralocorticoid excess states
   3. Renovascular disease
   4. Cushing syndrome
   5. Pheochromocytoma
   6. Thyroid or parathyroid disease
   7. Coarctation of the aorta
   8. Pregnancy
   9. Sleep disorder
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Table 3: BP Level For Males by Age and Height
Table 5: BP Level For Females by Age and Height

<table>
<thead>
<tr>
<th>Age</th>
<th>SBP (mmHg)</th>
<th>Percentile of Height</th>
<th>DBP (mmHg)</th>
<th>Percentile of Height</th>
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<td>5y</td>
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<td>90th</td>
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</tbody>
</table>

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III. Treatment

A. Therapeutic lifestyle changes
1. Weight reduction for overweight patients
2. Regular physical activity – aerobic activity 30 to 60 minutes per day
3. Dietary modification – increased vegetable and fruit consumption, low-fat dairy products, reduction in dietary sodium, reduction in sugar-containing beverages, portion-size control with regular meals
4. Smoking cessation

B. Drug therapy
1. Goal of therapy
   a. BP < 95th percentile
   b. BP < 90th percentile diabetes, chronic kidney disease, target organ damage
2. Indications for therapy
   a. Secondary hypertension
   b. Persistent hypertension despite lifestyle modifications
   c. Symptomatic hypertension
   d. Presence of target-organ damage
   e. Compelling indication (e.g., diabetes, chronic renal disease)

Table 7: Formulary Antihypertensive Agents For Children and Adolescents*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enalapril (Vasotec®)</td>
<td>2.5, 5, 10, &amp; 20mg</td>
<td>• Initial: 0.08mg/kg/day up to 5mg/day&lt;br&gt;• Max: 0.6mg/kg/day up to 40mg/day&lt;br&gt;• Qd or bid&lt;br&gt;• ACE inhibitor&lt;br&gt;• FDA pediatric labeling for children ≥ 6 and creatinine clearance ≥ 30ml/min&lt;br&gt;• Contraindicated in pregnancy</td>
</tr>
<tr>
<td>Atenolol (Tenormin®)</td>
<td>25, 50mg</td>
<td>• Initial: 0.5-1 mg/kg/day given qd or bid&lt;br&gt;• Max: 2mg/kg/day up to 100mg/day&lt;br&gt;• Beta-blocker&lt;br&gt;• No FDA pediatric labeling</td>
</tr>
<tr>
<td>Metoprolol (Lopressor®)</td>
<td>25, 50, &amp; 100mg</td>
<td>• Initial: 1mg/kg/day given once daily (initial dose should not exceed 50mg/day)&lt;br&gt;• Max: 6mg/kg/day up to 200mg/day&lt;br&gt;• Beta-blocker&lt;br&gt;• FDA pediatric labeling for children ≥ 6 years old</td>
</tr>
<tr>
<td>Propranolol (Inderal®)</td>
<td>10, 20 &amp; 40mg</td>
<td>• Initial: 1-2mg/kg/day given bid or tid&lt;br&gt;• Max: 4mg/kg/day up to 640mg/day&lt;br&gt;• Beta-blocker&lt;br&gt;• FDA pediatric labeling</td>
</tr>
<tr>
<td>Amlodipine (Norvasc®)</td>
<td>1 &amp; 10mg</td>
<td>• Initial: 2.5mg/day given qd&lt;br&gt;• Max: 5mg/day&lt;br&gt;• Calcium channel blocker&lt;br&gt;• FDA pediatric labeling for children ≥ 6 years old</td>
</tr>
<tr>
<td>Hydrochlorothiazide,HCTZ</td>
<td>12.5, 25 &amp; 50mg</td>
<td>• Initial: 1mg/kg/day given qd&lt;br&gt;• Max: 3mg/kg/day up to 50mg/day&lt;br&gt;• Diuretic&lt;br&gt;• FDA pediatric labeling</td>
</tr>
<tr>
<td>Furosamide (Lasix®)</td>
<td>20 &amp; 40mg</td>
<td>• Initial: 0.5-2 mg/kg/dose given qd or bid&lt;br&gt;• Max: 4mg/kg/day&lt;br&gt;• No FDA pediatric labeling</td>
</tr>
<tr>
<td>Spironolactone (Aldactone®)</td>
<td>25mg</td>
<td>• Initial: 1mg/kg/day given qd or bid&lt;br&gt;• Max: 3.3mg/kg/day up to 100mg/day&lt;br&gt;• Diuretic&lt;br&gt;• No FDA pediatric labeling</td>
</tr>
<tr>
<td>Doxazosin (Cardura®)</td>
<td>1, 2, &amp; 4mg</td>
<td>• Initial: 1mg/day given qd&lt;br&gt;• Max: 6mg/day&lt;br&gt;• Alpha-blocker&lt;br&gt;• No FDA pediatric labeling</td>
</tr>
<tr>
<td>Minoxidil (Loniten®)</td>
<td>2.5 &amp; 10mg</td>
<td>• Initial: 5mg/day given qd or tid&lt;br&gt;• Max: 100mg/day&lt;br&gt;• Vasodilator&lt;br&gt;• FDA pediatric labeling&lt;br&gt;• Reserved for resistant HTN</td>
</tr>
</tbody>
</table>

*Drugs with FDA approval or have pediatric data available.
C. Drug selection
1. May consider ACE inhibitors, beta-blockers, calcium channel blockers, or diuretics as first-line therapy. However, choice should be directed by co-morbidities.

<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 beta-blocker or ACE inhibitor if ACE inhibitor naïve patient.</td>
</tr>
<tr>
<td>Microalbuminuria or proteinuria</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. ACE inhibitor and Angiotensin II receptor antagonist (ARB) contraindicated</td>
</tr>
</tbody>
</table>

2. May consider step-down therapy in patients that have good blood pressure control with eventual discontinuation. The best candidates are patients that lose weight.

D. Hypertensive Emergencies and Urgencies- Severe, symptomatic hypertension with blood pressure well above the 99th percentile may occur in some children and requires prompt attention. These children usually have underlying renal disease.
1. Hypertensive Emergencies are usually accompanied by signs of hypertensive encephalopathy, typically causing seizures. These patients should be transferred to the nearest emergency center.
2. Hypertensive Urgencies are accompanied by less serious symptoms, such as severe headache or vomiting. Hypertensive urgencies may be treated by either intravenous or oral antihypertensives, depending on the child’s symptomatology.
   a. Oral Treatment
      i. If prescribed an oral immediate-release antihypertensive agent, administer an extra dose or
      ii. Clonidine 0.05-0.1mg/dose and may be repeated hourly up to 0.6mg total dose or
      iii. Minoxidil 0.1-0.2mg/kg/dose.
   b. 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 obtained blood pressure reading. Follow up in Chronic Care Clinic per ITP. Counsel patients with poor compliance.
Rule out other causes for presentation such as medical or psychiatric disorders, substance use, medications, or psychosocial stressors

Evaluate Patient (see Evaluation page 2)
- Physical exam including BMI, waist circumference, weight, and evaluation of respiratory, cardiovascular, and neurologic systems
- Assess for concurrent medical, psychiatric, and developmental disorders
- Obtain comprehensive sleep history
- If patient has Depression or ADHD refer to the respective pathways

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

Consider melatonin up to Adequate response
- Adequate response
  - Meets DSM-5 criteria for Primary Insomnia?
  - Meets DSM-5 criteria for Circadian Rhythm Disorder?

- Inadequate response
  - Rule-out underlying seizure disorder

- Continue behavioral interventions
  - Reconsider diagnosis and consider psychopharmacology consultation

Sleep-Related Movement Disorder (SRMD) suspected?
- Yes
  - Consider referral to sleep clinic for sleep study

- No
  - Continue behavioral interventions (Table 1)

Sleep-Related Breathing Disorder (SRBD) suspected?
- Yes
  - Consider referral to sleep clinic for sleep study

- No
  - Continue behavioral interventions (Table 1)

Table 1. Behavioral Interventions
- Education regarding adequate sleep hygiene
- Enforcement of strict bedtime and wake-up times 7 days/week
- Decrease environmental stimulation prior and at bedtime
- Relaxation exercises
- Imagery rehearsal
- Scheduled awakenings

**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 50% to 75%. Sleep disorders 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
  - Bedwetting
  - 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 does not occur exclusively during a course of narcolepsy, breathing-related sleep disorder, circadian rhythm sleep disorder, or parasomnia.
- 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 of 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 disturbance 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.

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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 either one 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 episode.
- 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.
- 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.

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 about 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 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.

Pharmacological agents used in adolescent sleep disorders are listed below:

1. Melatonin
   - Dose: 3-10 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, seizures, sedation, 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 counselled and male patients taking trazodone who experience an uncontrollable 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)

Patient meets DSM-IV criteria for 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.

Obtain baseline laboratories as indicated in Tables 6-7. Refer to pages 2-3 for medication selection.

Adequate response

Continue treatment and monitor per Tables 6-7.

Signs of adverse effects? Yes

If at any time adverse effects are noted, go to Adverse Effect Management Table 9

Adequate response

Continue treatment and monitor per Tables 6-7.

Inadequate response per BPRS

Assess compliance

Consider monotherapy with alternative prior authorization atypical antipsychotic not tried above or consider a typical antipsychotic. Continue 4-6 weeks at a therapeutic dose.

Adequate response

Continue treatment and monitor per Tables 6-7.

Inadequate response per BPRS

Assess compliance

Initiate adjunctive therapy with mood stabilizer lithium or divalproex and titrate to therapeutic level. Continue 4-6 weeks at a therapeutic dose.

Adequate response

Continue treatment and monitor per Tables 6-7.

Inadequate response per BPRS

Assess compliance

Initiate monotherapy with formulary atypical antipsychotic risperidone up to 6mg/day. Continue 4-6 weeks at a therapeutic dose.

Adequate response

Continue treatment and monitor per Tables 6-7.

Inadequate response per BPRS

Assess compliance

Reconsider diagnosis and consider psychopharmacology consultation.

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

Prepared By The Texas Youth Commission and Reviewed By The Correctional Managed Care Pharmacy & Therapeutics Committee. October 2001, revised 5/12/02, 2/25/04, 1/18/06, 4/19/10, 2/11/13.
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 risperidone unless it is clearly not indicated. Table 1 details the recommended dosing for initiating risperidone. Titration schedule 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></th>
<th>Day 1-4</th>
<th>Day 5-8</th>
<th>Day 9-12</th>
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</thead>
<tbody>
<tr>
<td>Daily Dose</td>
<td>0.5-1 mg</td>
<td>1.5-2 mg</td>
<td>3-4 mg</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 1-2/2</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 Antipsychotic</td>
<td>Chlorpromazine</td>
<td>50mg, 100mg, 200mg tablet; 25mg/ml inj</td>
</tr>
<tr>
<td></td>
<td>Fluphenazine</td>
<td>2.5mg, 5mg, 10mg tablet; 2.5mg/ml inj; 25mg/ml decanoate inj</td>
</tr>
<tr>
<td></td>
<td>Haloperidol</td>
<td>1mg, 5mg tablet; 2mg/ml oral concentrate; 5mg/ml inj, 100mg/ml decanoate inj</td>
</tr>
<tr>
<td></td>
<td>Perphenazine</td>
<td>4mg, 8mg, 16mg tablet</td>
</tr>
<tr>
<td></td>
<td>Thoridazine</td>
<td>2mg, 5mg, 10mg capsule</td>
</tr>
<tr>
<td></td>
<td>Thiothixene</td>
<td>2mg, 5mg, 10mg tablet</td>
</tr>
<tr>
<td>2nd Generation Antipsychotic</td>
<td>Risperidone</td>
<td>0.5mg, 1mg, 2mg, 3mg, 4mg tablet</td>
</tr>
<tr>
<td></td>
<td>Ziprasidone</td>
<td>20mg/ml injection</td>
</tr>
</tbody>
</table>

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 EMR. All other uses require non-formulary approval.

Prior authorization criteria include:
1. If the patient has had a documented significant side effect to risperidone in the past.
2. If the patient has already failed risperidone after a therapeutic trial of adequate dose and duration (6mg/day for 4-6 weeks).
3. If the patient has a contraindication to risperidone therapy.
4. If the patient’s BMI is greater than or equal to the 90th percentile.

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®) 2mg, 5mg, 10mg, 15mg 20mg, 30mg tablet</td>
<td>Insufficient to formulary 2nd generation antipsychotic</td>
</tr>
<tr>
<td></td>
<td>Ziprasidone (Geodon®) 20mg, 40mg, 60mg, 80mg capsule</td>
<td>BMI ≤ 90th percentile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contraindication to formulary 2nd generation antipsychotic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Treatment failure on formulary 2nd generation antipsychotic</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 risperidone and then tapered off the initial antipsychotic agent by one-third to one-fourth of the initial daily dosage at weekly intervals (beginning one week after the goal dose of risperidone is achieved) until discontinued. Alternatively, 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>
<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>Olanzapine</td>
<td>5mg</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>7.5mg</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>
<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>200mg TID</td>
<td>100mg/100mg/200mg</td>
<td>100mg TID</td>
<td>100mg BID</td>
<td>50mg BID</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>80mg BID</td>
<td>60mg BID</td>
<td>40mg BID</td>
<td>20mg BID</td>
<td></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>
Antipsychotic Monitoring Parameters in Children and Adolescents Receiving Antipsychotic Pharmacotherapy

Table 6: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents 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>Personal Family History</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Weight, Height, BMI (overweight 25.0-29.9, obese &gt;= 30.0)</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Blood Pressure, Pulse</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Plasma Glucose</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Fasting Lipid Profile</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>CBC, LFT, SCr, Electrolytes</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TSH</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>EKG1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>Prolactin2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>As clinically indicated</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.
2. Providers should consider obtaining prolactin at baseline and periodically when there is a history of galactorrhea, amenorrhea, or gynecomastia

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 Dyskinesis</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>
### 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>Depressan</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>+/-</td>
<td>+/-</td>
<td>+++</td>
<td>++</td>
<td>Lipid and glucose dysregulation</td>
</tr>
<tr>
<td>Clorzapine</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>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  
++/− = most probably rare  
TD = tardive dyskinesia  
++ = low frequency  
+++ = high frequency  

### 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 Syndrome | Medical emergency  
Evaluate through medical department for possible referral to emergency room  
Discontinue antipsychotic |
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)

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, disorganized, disoriented, 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, ill-will, 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, unusual 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. Distractions 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.
POST-TRAUMATIC STRESS DISORDER
(Adolescents)

Rule out medical causes for presentation.

Meets DSM-5 criteria for Post-Traumatic Stress Disorder?

Re-evaluate diagnosis and treat underlying causes.

Obtain baseline BPRS.
Psychotherapy should be the initial treatment of choice and should be continued throughout treatment even if drug therapy is started.

Does the patient have comorbid depression, bipolar disorder, or other anxiety disorder?

Refer to appropriate co-morbid treatment pathway.

Initiate formulary SSRI antidepressant and continue for 6-12 weeks at a therapeutic dose (Table 1).

Adequate response per BPRS?

Assess compliance.

If compliance < 80%, counsel on medication compliance and 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 SSRI (Table 1) OR.
Switch to guanfacine 0.05mg/kg/day up to a maximum of 4mg/day.

Adequate response per BPRS?

Assess compliance.

If compliance < 80%, counsel on medication compliance and re-evaluate diagnosis and need for medication.
Consider pharmacotherapy consult and/or request for formulary medication OR.
Consider a switch to propranolol 20-160 mg/day (see criteria for use on Page 2) OR.

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) mg/day</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective Serotonin Reuptake Inhibitor (SSRI)</td>
<td>Citalopram 5mg, 20mg, 40mg</td>
<td>Celexa® 10mg</td>
<td>(10 – 40)</td>
<td>Emergence of suicidal ideation or behavior; Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present</td>
</tr>
<tr>
<td></td>
<td>Fluoxetine 10mg, 20mg</td>
<td>Prozac® 10mg</td>
<td>(10 – 60)</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>Sertraline 50mg, 100mg</td>
<td>Zoloft® 50mg</td>
<td>(50 – 200)</td>
<td></td>
</tr>
<tr>
<td>Alpha antagonist Guanfacine 1mg, 2mg</td>
<td>Tenex® 1mg</td>
<td>(1 – 4)</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Beta antagonist Propranolol 10mg, 20mg, 40mg</td>
<td>Inderal® 20mg</td>
<td>(20-160)</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

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., grossly disorganized, elevated mood, excitement, distractibility) can be followed over time.
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, 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.
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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.
Acute Seizures
(Children & Adolescents)

Seizure Activity for 0-5 Minutes
Establish diagnosis by observing continuous seizure activity or one additional seizure. Rule out suspected symptom amplification. Treat underlying medical condition as appropriate.

1. Seizure activity suspected?
   - Yes: Observe and follow-up as indicated. Discharge from medical department.
   - No: Establish diagnosis by observing continuous seizure activity or one additional seizure.

2. Seizure activity for 0-5 minutes:
   - Establish diagnosis by observing continuous seizure activity or one additional seizure. Rule out suspected symptom amplification.
   - Treat underlying medical condition as appropriate.

3. Seizure activity suspected?
   - Yes: Observe and follow-up as indicated. Discharge from medical department.
   - No: Establish diagnosis by observing continuous seizure activity or one additional seizure.

4. Seizure activity continuing for greater than or equal to 6 minutes?
   - Yes: 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 I.V. (Glucagon if IV access can not be established).
     - Obtain ECG.
     - Draw venous samples for glucose, chemistries to include Mg, PO4 and Ca, CBC, toxicology screens, and antiepileptic drug levels (if available).
     - Consider administering extra dose of currently ordered oral antiepileptic drug (AED).
     - Observe for a minimum of two hours and discharge from medical department following full recovery.
     - Confirm medication adherence and reinforce education.

5. Seizure activity continuing for greater than or equal to 6 minutes?
   - No: Observe and follow-up as indicated. Discharge from medical department.

6. Follow up with patient within 1 week or next available clinic upon return from emergency room/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 (HTP).

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

Seizure Disorder (Children & Adolescents)

**One seizure event is not necessarily diagnostic for seizure disorder and may not require long-term AED therapy.**

---


Seizure diagnosis and classification documented?***

Seizure type & syndrome (see page 5) are important for selecting the appropriate antiepileptic drug therapy (AED).

1. Is patient on AED therapy?
   - Yes
     - 2. Confirm Diagnosis of Seizure Disorder
     - 3. Seizure type & syndrome (see page 5)
   - No
     - 4. If seizure disorder is confirmed, initiate AED therapy based on seizure classification (see Appendix A&B). Go to box #7.
     - or
     - If seizure disorder is ruled out, discontinue from Chronic Care Clinic.

5. Is AED therapy appropriate for diagnosis?
   - Yes
     - 6. Initiate rational AED regimen (see Appendix A).
     - or
     - Once new AED is at therapeutic dose, taper the old agent slowly and discontinue.
     - Go to box #7.
   - No
     - 7. Assess Medication Regimen
       - Check medication compliance.
       - Obtain AED level if indicated.
       - Obtain baseline lab appropriate for AED (see Appendix C).
     - Is AED therapy effective and tolerable?
     - Yes
     - 8. Follow up in Chronic Care Clinic or as clinically indicated.
     - or
     - Add additional AED if patient already failed 2 monotherapy regimens.
     - or
     - Consider referral if patient remains poorly controlled.
     - or
     - Monitor & obtain laboratories appropriate to AED utilized (Appendix C). Consider the following which may apply:
       - Counsel on importance of compliance
       - Adjust dose
       - Change to alternate AED - Once new AED is at therapeutic dose, taper the old agent slowly and discontinue.
       - or
       - Add additional AED if patient already failed 2 monotherapy regimens.
       - Consider referral if patient remains poorly controlled.
     - or
     - Follow up in Chronic Care Clinic or as clinically indicated.
     - or
     - Add additional AED if patient already failed 2 monotherapy regimens.
     - or
     - Consider referral if patient remains poorly controlled.
     - or
     - Monitor & obtain laboratories appropriate to AED utilized (Appendix C).
     - Consider discontinuation of AED if the patient has normal EEG and has been seizure free for > 2 years. AED should be slowly tapered over 3-6 months and then discontinued.

---

I. 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, bclodren).
   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. Approximately 50% of patients show no abnormality on a single EEG. Approximately 10% with true seizure show no abnormality on multiple EEG studies. EEG should be used to support the diagnosis of epilepsy and cannot rule out seizure disorder. There are three important benefits of the EEG, 1) Confirm the presence of abnormal electrical activity, 2) provide information about the seizure type and syndrome, and 3) locate the seizure focus.
   
   E. Other Labs & Neuroimaging
      • Electrolytes
      • Blood Glucose
      • Liver & kidney function
      • Toxicology screen
      • MRI (CT if unavailable or contraindicated)
      • Lumbar puncture if infection suspected
   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. 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. 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 (inadequate 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 ≥ 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, eslicarbazepine, tiagabine, 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 1st 12 months (especially in the 1st 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 partial 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.
Factors Against Drug Withdrawal
- Adolescent-onset epilepsy
- Adult-onset epilepsy
- Partial epilepsy
- Juvenile myoclonic epilepsy
- Presence of multiple seizure types
- Presence of underlying neurological condition
- Absence EEG

Factors in Favor of Drug Withdrawals
- Childhood-onset epilepsy
- Early-onset generalized epilepsy
- Single type of seizure
- Benign epilepsy with centrotemporal spikes
- Normal EEG
- Childbearing potential and planning pregnancy
- Co-morbidity with concurrent treatments

Appendix A: International Classification of Epileptic Seizures

<table>
<thead>
<tr>
<th>Types of Epileptic Seizures</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial (focal) seizures</td>
<td>Begins in one hemisphere. Asymmetric clinical manifestation unless secondarily generalized.</td>
</tr>
<tr>
<td>Simple partial</td>
<td>Motor, sensory, autonomic, or psychic signs; consciousness is not impaired.</td>
</tr>
<tr>
<td>Complex partial</td>
<td>Simple partial followed by loss of consciousness or impaired consciousness at onset. Generally amnestic to events. May be misdiagnosed as psychiatric episode.</td>
</tr>
<tr>
<td>Partial Seizures evolving to secondarily generalized</td>
<td>Partial onset with secondary generalization.</td>
</tr>
<tr>
<td>Primarily generalized seizures</td>
<td>Involves both hemispheres with bilateral motor manifestations and loss of consciousness.</td>
</tr>
<tr>
<td>Myoclonic</td>
<td>Brief muscle contraction of face, trunk, or extremities. May be isolated or repetitive.</td>
</tr>
<tr>
<td>Tonic</td>
<td>Rigid, violent, fixed sustained contractions; rhythmic, deceleration of eye and head to one side; rotation of the whole body and distortion of features; suppression of inspiration; falls; tongue biting; respiratory arrestation.</td>
</tr>
<tr>
<td>Tonic/Clonic</td>
<td>Also known as grand-mal; may appear at time of seizure.</td>
</tr>
<tr>
<td>Atonic</td>
<td>Sudden loss of postural tone lasting 1 to 2 seconds. Usually no postictal confusion. Violent falls.</td>
</tr>
<tr>
<td>Pseudoseizure (non-epileptic)</td>
<td>Episodes involving affective, autonomic, or somatomotor manifestations that are precipitated by stress. Clinical characteristics:</td>
</tr>
<tr>
<td></td>
<td>Strongly suggestive – prolonged duration (10-30 min), preserved consciousness despite whole body jerking, br hive and asynchronous motor movements, pelvic thrusting, not stereotypical</td>
</tr>
<tr>
<td></td>
<td>Strongly against – history during spell, tongue laceration (esp. sides), incontinence</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.

<table>
<thead>
<tr>
<th>Type of Seizure</th>
<th>Formulary Medications</th>
<th>Nonformulary Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple Partial</td>
<td>Carbamazepine</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td></td>
<td>Dividox Sodin</td>
<td>Lamotrigine</td>
</tr>
<tr>
<td></td>
<td>Levetiracetan*</td>
<td>Topiramate</td>
</tr>
<tr>
<td></td>
<td>Gabapentin*</td>
<td>Perampanel*±</td>
</tr>
<tr>
<td></td>
<td>Primidone</td>
<td>Lacosamide*</td>
</tr>
<tr>
<td></td>
<td>Oxcarbazepine</td>
<td>Topiramate</td>
</tr>
<tr>
<td>Complex Partial</td>
<td>Carbamazepine</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td></td>
<td>Dividox Sodin</td>
<td>Lamotrigine</td>
</tr>
<tr>
<td></td>
<td>Levetiracetan*</td>
<td>Topiramate</td>
</tr>
<tr>
<td></td>
<td>Gabapentin*</td>
<td>Perampanel*±</td>
</tr>
<tr>
<td></td>
<td>Primidone</td>
<td>Lacosamide*</td>
</tr>
<tr>
<td></td>
<td>Oxcarbazepine</td>
<td>Topiramate</td>
</tr>
<tr>
<td></td>
<td>Vigabatrin§*</td>
<td></td>
</tr>
<tr>
<td>Generalized Tonic-Clonic</td>
<td>Carbamazepine</td>
<td>Phenobarbital</td>
</tr>
<tr>
<td></td>
<td>Dividox Sodin</td>
<td>Lamotrigine</td>
</tr>
<tr>
<td></td>
<td>Levetiracetan*</td>
<td>Topiramate</td>
</tr>
<tr>
<td></td>
<td>Gabapentin*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Primidone</td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>Ethosuximide</td>
<td>Clonazepam*</td>
</tr>
<tr>
<td></td>
<td>Dividox Sodin</td>
<td>Lamotrigine</td>
</tr>
</tbody>
</table>

*Adjunctive therapy
[§Only available through a special distribution program called SHARE. Indicated for refractory complex partial seizures as adjunct therapy in patients ≥10 years old that have failed several alternate treatments. Black box warning related to possible permanent vision loss.
±Schedule III controlled substance

Appendix C. Monitoring Parameters for Formulary AED

<table>
<thead>
<tr>
<th>Drug</th>
<th>Design and Monitoring Parameters &amp; Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>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 HLA-B*1502 allele. The risk of developing Stevens-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.</td>
</tr>
<tr>
<td>Levetiracetan</td>
<td>Chemistry – renal function in patients with preexisting renal impairment</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>CBC – baseline and when clinically indicated. Chemistry (emphasis hepatic &amp; 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</td>
</tr>
<tr>
<td>Primidone</td>
<td>CBC – baseline and annually or when clinically indicated. Therapeutic level – 5 to 12 mcg/ml</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>CBC with platelets – baseline and when clinically indicated. Chemistry (emphasis hepatic function) – baseline, one month, then annually or when clinically indicated. Protein, INR, PPT at baseline and annually. Levels – weekly for 2 weeks, then annually or when clinically indicated. Therapeutic level – 50 to 100 mcg/ml</td>
</tr>
<tr>
<td>Generic Name</td>
<td>Usual Children, Adolescent and Adult Dose</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td><strong>Formulary Agents</strong></td>
<td></td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>6-12yrs: 10mg/kg/day or 100mg bid up to 1000mg/day 2-4 divided doses</td>
</tr>
<tr>
<td>Tegretol®</td>
<td>6-12yrs: 10mg/kg/day divided 2 doses up to 60mg/kg/day divided 2 doses</td>
</tr>
<tr>
<td>&gt;12yrs: 200mg bid, up to 1000mg/day for 12-15yrs or 1200mg/day &gt;15yrs 2-4 divided doses</td>
<td></td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>4-15yrs: 20mg/kg/day divided 2 doses up to 60mg/kg/day divided 2 doses</td>
</tr>
<tr>
<td>Keppra®</td>
<td></td>
</tr>
<tr>
<td>&gt;16yrs: 500mg bid up to 3000mg/day divided bid</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Loading dose if not already on phenytoin: 15-20mg/kg in 3 divided doses q 2-4 hours apart</td>
</tr>
<tr>
<td>Dilantin®</td>
<td>Maintenance dose: Children: 4-8mg/kg/day 1-3 divided doses up to 300mg/day</td>
</tr>
<tr>
<td>Adult: 300 mg/day in 1-3 divided doses up to 600mg/day</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Primidone</td>
<td>&lt;8years: 50mg/day up to 25mg/kg/day in 3-4 divided doses tid-qid</td>
</tr>
<tr>
<td>Mysoline®</td>
<td></td>
</tr>
<tr>
<td>≥8 years: 250mg/day up to 750-1500 mg/day in divided doses tid-qid</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>Children 10 years and older (in the absence of concomitant enzyme-inducing antiepileptic drugs (AED)), initial, 2 mg (500mg) once daily or bedtime up to 12 mg or bedtime</td>
</tr>
<tr>
<td>Depakote®</td>
<td></td>
</tr>
</tbody>
</table>
Appendix D. (Continued)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Usual Children, Adolescent and Adult Dose</th>
<th>Adverse Effects*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phenobarbital</strong> Luminal®</td>
<td>• 5-12yrs: 4-6mg/kg/day in 1-2 divided doses &lt;3 yr 1-3mg/kg/day in 1-2 divided doses or 50-100mg bid-tid</td>
<td>• Drowsiness, somnolence, headache, dizziness, ataxia, cognitive effects, GI upset &lt;br&gt; • Seizures, rash including: Stevens Johnson, agranulocytosis</td>
</tr>
<tr>
<td><strong>Topiramate</strong> Topamax®</td>
<td>• &lt;12yrs: 0.5-1mg/kg/day up to 1mg/kg/day &lt;br&gt; • 12-18yrs: 4-5mg/kg/day divided bid-qid &lt;br&gt; • &gt;18yrs: 25-30mg/day up to 400-600mg/day</td>
<td>• Somnolence, dizziness, tremor, headache, weakness, difficulty concentrating &lt;br&gt; • Seizures, status epilepticus, ataxia, behavioral disturbances &lt;br&gt; • Serious: Stupor or spike wave status &lt;br&gt; • Nephrolithiasis, renal failure, open angle glaucoma, hypohidrosis especially in children</td>
</tr>
<tr>
<td><strong>Vigabatrin</strong> Sabril®</td>
<td>• 10-16yrs and weight 25-60kg: 250mg bid up to 1000mg bid &lt;br&gt; • 10-16yrs and weight greater than 60kg or older than 16 yrs: 500mg bid up to 1500mg bid</td>
<td>• Drowsiness, fatigue, headache, and dizziness &lt;br&gt; • Serious: Black box warning: possible permanent visual loss, severe hypersensitivity reactions and angioedema have been reported &lt;br&gt; • Reserved for refractory cases that have failed several alternative treatments &lt;br&gt; • Limited number of specialty pharmacies in the US dispense this drug as part of SHARE program &lt;br&gt; • Physicians must be registered to dispense this drug</td>
</tr>
</tbody>
</table>

*Not a complete list

*Appendix E: Formulary AED Drug Interactions

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DRUG INTERACTIONS (DI) &amp; COMMENTS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine (CBZ)</td>
<td>• DI: levels increased by VPA, phenytoin, vigabatrin, ethinyl estradiol, fluoxetine, lamotrigine, propoxyphene, &amp; verapamil &lt;br&gt; • levels decreased by phenobarbital &amp; primidone</td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>• DI: probenecid - clinical significance unknown; not metabolized thru CYP450 &lt;br&gt; • renal elimination - dose adjust in renal insufficiency &lt;br&gt; • no dose adjustment for hepatic impairment</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>• DI: levels increased by VPA, topiramate, eslicarbazepine, zebrafenox, dilantin, fluoxetine, lamotrigine, tiagabine, lamotrigine, sulfa, phenytoin, prednisolone, prednisone, propoxyphene, ritonavir, bactrim; levels decreased by CBZ, vigabatrin, acetazolamide, clonazepam, disulfiram, ibuprofen</td>
</tr>
<tr>
<td>Primidone</td>
<td>• Potent and broad spectrum inducer of CYP &lt;br&gt; • Dose adjustment is needed in renal impairment &lt;br&gt; • Use with caution in patients with hepatic insufficiency</td>
</tr>
<tr>
<td>Valproic Acid (VPA)</td>
<td>• DI: levels increased by aspirin &amp; lamotrigine; levels decreased by CBZ, phenobarbital, &amp; phenytoin &lt;br&gt; • Contraindicated in hepatic disease/significant hepatic dysfunction, known urea cycle disorder</td>
</tr>
</tbody>
</table>

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®
   300MG TABLET ($4.56)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ABILIFY® see ARIPIPRAZOLE

ABSORBASE
   EUCERIN®
   4OZ ($2.34), 16OZ ($3.08) CREAM
   (Note: Restricted to regional medical facilities and dialysis centers.)

ACETAMINOPHEN
   APAP, TYLENOL®
   325MG TABLET ($0.01)
   650MG SUPPOSITORY – 50 SUPP/BOX ($7.90/BOX)
   650MG/20.3ML UD SOLUTION ($0.39)
   (Note: Take from stock. No refills allowed.)

ACETAMINOPHEN/CODEINE - CIII, CV
   TYLENOL® #3
   APAP 300MG/CODEINE 30MG TABLET – CIII ($0.10)
   APAP 300MG/CODEINE 30MG/12.5ML UD SOLUTION - CV ($1.01)
   (Note: May not be given KOP. Non-formulary approval required for use > 21 days. A
    minimum 30 day period between orders is required for use beyond 21 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®
   250MG TABLET ($1.94)

ACETIC ACID/AL ACET OTIC SOLN
   DOMEBORO® OTIC
   2% OTIC SOLUTION - 60ML ($26.19)

ACTIDOSE® see CHARCOAL, ACTIVATED
ACYCLOVIR
ZOVI RAX®
400MG TABLET ($0.04) (Max 11 refills)
800MG TABLET ($0.10) (No refills)

ADENOCARD® see ADENOSINE

ADENOSINE
ADENOCARDS®
6MG/2ML VIAL ($2.25)
(Note: 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 - 100ML ($83.60) (No refills)
(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® (No refills)
0.083% NEBULIZER SOLUTION - 3ML UD 25/BOX ($2.57/BOX)
(Note: Restricted to acute asthma management. Orders should not exceed 72 hours. Clinic use only. Take from stock. May not be given KOP.)
PROVENTIL-HFA® (Max 3 refills)
METERED DOSE INHALER 90MCG/ACTION
200 ACTUATIONS ($32.19)

ALCAINE® OPTH SOLN see PROPARACAINE OPH SOL

ALCOHOL
LAVACOL®
ETHYL 70% - 16OZ ($1.45)
(Note: Clinic use only. Take from stock. May not be given KOP.)

ALDACTONE® see SPIRONOLACTONE

353
ALDOMET® see METHYLDOPA

ALCALAK® see CALCIUM CARBONATE

ALLOPURINOL (Max 11 refills)
ZYLOPRIM®
100MG ($0.03), 300MG ($0.05) TABLET

ALPHAGAN® see BRIMONIDINE

ALTEPLASE
(t-PA, CATHFLO ACTIVASE®)
1MG/1ML - 2ML VIAL ($108.81)
(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®
100MG CAPSULE ($1.27)
(Note: Non-formulary approval required for TJD facilities.)

AMIODARONE (Max 11 refills, tablet only)
CORDARONE®
200MG TABLET ($0.14)
50MG/ML INJECTION – 3ML VIAL ($0.91)
(Note: Injection for clinic use only, should be taken from stock, may not be given KOP, and restricted to EMS and regional medical facilities.)

AMLODIPINE (Max 11 refills)
NORVASC®
5MG ($0.16), 10MG ($0.02) TABLET

AMMONIA
AROMATIC INHALANT - 0.33ML ($1.54/BOX)
(35% ALCOHOL, 15% AMMONIA) 12 INHALANTS/BOX
(Note: Clinic use only. Take from stock. May not be given KOP.)

AMOXICILLIN
AMOXIL®
250MG ($0.06), 500MG ($0.05) CAPSULE
AMOXIL® see AMOXICILLIN

AMPHETAMINE/DEXTROAMPHETAMINE see AMPHETAMINE SALTS
AMPHETAMINE SALTS - CII

ADDERALL®
5MG ($0.89), 10MG ($0.86) TABLET

ADDERALL XR®
10MG ($6.66), 20MG ($6.66), 30MG ($6.66) 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®
500MG INJECTION, IM OR IV ($0.72)
IV Preparation Standard:
< 3gm in 100mL 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

ANTIPYRINE/BENZOCAINE OTIC

AURALGAN®
OTOR DROPS - 15ML ($10.32)

ANTIVERT® see MECLIZINE HCL

ANUSOL® OINTMENT see HEMORRHoidal OINTMENT

ANUSOL® SUPPOSITORY see HEMORRHoidal SUPPOSITORY

ANUSOL-HC® CREAM see HYDROCORTISONE RECTAL CREAM

APRESOLINE® see HYDRALAZINE

ANUSOL-HC SUPP® see HYDROCORTISONE HEMORRHoidal SUPPOSITORY

AQUAMEPHYTON® see PHYTONADIONE
ARIPIPRAZOLE (Max 11 refills)

ABILIFY®

2MG ($24.21), 5MG ($24.21), 10MG ($24.21), 15MG ($24.21), 20MG ($34.23), 30MG ($24.23) TABLET

(Note: May not be given KOP. Restricted to TJJD. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:

a. Intolerance to risperidone.
b. Treatment failure on risperidone.
c. Contraindication to risperidone.
d. BMI ≥ to 90th percentile.)

ARTIFICIAL TEARS SOLUTION see POLYVINYL ALCOHOL

ARZOL® see SILVER NITRATE

ASPIRIN (Max 11 refills)

BAYER® ASPIRIN

325MG TABLET ($0.01)

ECOTRIN®

81MG ($0.01), 325MG ($0.01) ENTERIC-COATED TABLET

ATAZANAVIR (Max 11 refills)

REYATAZ®

200MG ($17.49), 300MG ($18.49) CAPSULE

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ATENOLOL (Max 11 refills)

TENORMIN®

25MG ($0.02), 50MG ($0.02) TABLET

ATIVAN® see LORAZEPAM

ATOMOXETINE (Max 11 refills)

STRATTERA®

25MG ($7.56), 40MG ($8.20), 60MG ($8.20), 80MG ($8.90), 100MG ($8.86) 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®
10MG ($0.07), 20MG ($0.10), 40MG ($0.10) TABLET

ATROPINE SULFATE
ATROPINE
0.1MG/ML INJECTION - 10ML SYRINGE ($3.18) (No refills)
(Note: Clinic use only. Take from stock. May not be given KOP.)
ISOPTO ATROPINE®
1% OPHTH SOLUTION - 15ML ($11.52) (Max 11 refills)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ATROVENT HFA® see IPRATROPIUM BROMIDE

AURALGAN® see ANTIPYRINE/BENZOCAINE OTIC

AVLOSULFON® see DAPSONE

AZATHIOPRINE (Max 11 refills)
IMURAN®
50MG TABLET ($0.45)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

AZITHROMYCIN (Max 11 refills)
ZITHROMAX®
600MG TABLET ($2.66)
(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:
  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.
  b. Pregnancy
     - 2400 milligrams x 1 dose for GC & chlamydia
     - 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

357
B-12, VITAMIN see CYANOCOBALAMIN

BACITRACIN/POLYMYXIN
POLYSPORIN®, DOUBLE ANTIBIOTIC OINTMENT
TOPICAL OINTMENT - 15GM TUBE ($2.86)
POLYSPORIN®
OPHTHALMIC OINTMENT - 3.5GM TUBE ($6.61)

BACLOFEN (Max 11 refills)
LIORESAL®
10MG ($0.19), 20MG ($0.33) 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

BECLOMETHASONE HFA (Max 11 refills)
QVAR®
HFA ORAL INHALER 120 ACTUATIONS/80MCG EACH ($155.13)
(Note: 1 inhaler will last 60 days at 1 puff BID (maximum 5 refills), 30 days at 2 puffs
BID, 20 days at 3 puffs BID, and 15 days at 4 puffs BID. Inhaler should be ordered
accordingly.)

BENADRYL® see DIPHENHYDRAMINE

BENEMID® see PROBENECID

BENZAC® see BENZOYL PEROXIDE

BENZOYL PEROXIDE (Max 3 refills)
BENZAC®
10% GEL - 1.5 OZ ($1.59)
(Note: Orders are to be given a 90 day expiration date.)
**BENZTROPINE MESYLATE** (Max 2 refills)
- COGENTIN®
  - 0.5mg ($0.12), 1MG ($0.13), 2MG ($0.17) TABLET
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

**BETAPACE®** see SOTALOL

**BETHANECHOL** (Max 11 refills)
- URECHOLINE®
  - 25MG TABLET ($0.54)

**BICILLIN-LA®** see PENICILLIN G BENZATHINE

**BISACODYL**
- DULCOLAX®
  - 5MG TABLET ($0.02)
  - 10MG SUPPOSITORY ($0.05)
  (Note: Take from stock.)

**BISMUTH SUBSALICYLATE**
- PEPTO BISMOL®
  - 262MG CHEWABLE TABLET ($0.06)
  (Note: Take from stock.)

**BOCEPRAVIR**
- VICTRELIS®
  - 200MG CAPSULE ($18.61)
  (Note: The preferred Hepatitis C protease inhibitor as part of triple combination therapy including peg-interferon and Ribavirin for Genotype 1 only. Non-formulary approval required by HCV group from pharmacy at utmbcmc.pharmacyID@utmb.edu for UTMB units and Utilization Management at (806)356-5350 for TTUHSC units. Floor stock allowed at the two designated Centers of Excellence including Darrington and Young. 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.)
BODY LOTION

LUBRISOFT® (No refills)
19OZ LOTION - ($1.70)
(Note: Prior Authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. One bottle must last 90 days. Criteria include:
a. Eczema
b. Dermatitis
c. Psoriasis
d. Chronic stasis dermatitis
e. Ichthyosis
f. Hyperkeratosis
g. Dialysis
h. Burn scars/Skin Grafts

BOOSTRIX® see TETANUS/DIPHTHERIA/ACELLULAR PERTUSSIS (TDaP)

BRETHINE® see TERBUTALINE SULFATE

BRIMONIDINE (Max 11 refills)
ALPHAGAN®
0.2% OPHTHALMIC SOLUTION -10ML ($3.99)

BROMOCRIPTINE MESYLATE (Max 11 refills)
PARLODEL®
2.5MG TABLET ($0.46)
(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.)

BUPIVACAINE HCL
MARCAINE®
0.5% INJECTION - 10ML VIAL ($1.16)
0.25% INJECTION - 10ML VIAL ($1.03)
(Note: Clinic use only. Take from stock. May not be given KOP.)

BUTORPHANOL TARTRATE - CIV
STADOL®
2MG/ML IM INJECTION - 1ML VIAL ($2.62)
(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.)

CALAMINE LOTION
LOTION – 6OZ ($1.22)
(Note: Take from stock.)
CALAN® SR see VERAPAMIL HCL

CALAN® see VERAPAMIL HCL

CALCITRIOL (Max 11 refills)
  ROCALTROL®
  0.25MCG CAPSULE ($0.35)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

CALCIUM CARBONATE (Max 11 refills)
  OS-CAL®
  500MG ELEMENTAL CALCIUM/1.25GM CARBONATE SALT TAB ($0.02)
  (Note: Take from stock.)
  ALCALAK®
  420MG CHEW TABLET – 500/BOX ($7.63)
  (Note: For nursing protocol use only. No refills allowed.)

CALCIUM CARBONATE/VITAMIN D (Max 11 refills)
  OSCAL 250 + VITAMIN D®
  250MG ELEMENTAL CALCIUM/125 IU VITAMIN D TABLET ($0.01)
  (Note: Take from stock.)

CALCIUM GLUCONATE
  10% INJECTION – 10ML VIAL ($3.10)
  (94MG CALCIUM GLUCONATE EACH VIAL)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

CALCIUM POLYCARBOPHIL (Max 5 refills)
  FIBERCON®
  625MG TABLET ($0.04)
  (Note: Not allowed as floor stock except cards of 14 for nursing protocol orders only. No refills allowed on nursing protocol orders.)

CARBAMAZEPINE (Max 11 refills)
  TEGRETOL®
  200MG TABLET ($0.50)
  (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.)

CARBAMIDE PEROXIDE
  DEBROX®
  6.5% OTIC SOLUTION – 15ML ($0.86)
  (Note: Clinic use only, should be taken from stock, and may not be given KOP.)
CARBIDOPA/LEVODOPA (Max 11 refills)
SINEMET® 25-250
CARBIDOPA 25MG/LEVODOPA 250MG TABLET ($0.17)

CARDIZEM® see DILTIAZEM HCL

CARVEDILOL (Max 11 refills)
COREG®
3.125MG ($0.03), 6.25MG ($0.03), 12.5MG ($0.03), 25MG ($0.03) TAB

CASTOR OIL
CASTOR OIL - 120ML ($1.22)
(Note: Take from stock.)

CATAPRES® see CLONIDINE HCL

CATHFLO ACTIVASE® see ALTEPLASE

CEFAZOLIN SODIUM
ANCEF®
1GM INJECTION – 10ML VIAL ($0.65)
Preparation Standard:
< 2gm in 100mL D2W over 30-60 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

CEFTAZIDIME
FORTAZ®
500MG INJECTION ($5.13)
1GM INJECTION ($3.05)
IV Preparation Standard:
< 2gm in 100mL D2W over 40 minutes
> 2gm in 150mL D2W over 60 minutes.
(Note: Clinic use only. Take from stock. 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®
250MG INJECTION ($0.60)
(Note: Clinic use only. Take from stock. May not be given KOP. Use restricted to treatment of GC)
1 GM INJECTION ($0.78)
(Note: Clinic use only. Take from stock. 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®
   500MG CAPSULE ($0.07)

CHARCOAL
   ACTIDOSE® WITH SORBITOL
   50GM ACTIVATED CHARCOAL / 54GM SORBITOL LIQUID - 8OZ ($16.77)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

CHLORDIAZEPoxide - CIV
   LIBRiUM®
   10MG ($0.11), 25MG ($0.13) CAPSULE
   (Note: May not be given KOP. Restricted to facilities for detoxification. Take from stock. May only be ordered by a physician or a DEA/DPS registered midlevel provider.)

CHLORHExIDINE GLUCONATE
   PERIDEX®
   0.12% ORAL RINSE - 16OZ ($2.18)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Restricted to floor stock.)

CHLORPHENIRAMINE MALEATE
   CTM, CHLOR-TRIMETON®
   4MG TABLET ($0.02)
   (Note: Take from stock.)

CHLORPROMAZINE HCL (Max 11 refills)
   THORAZiNE®
   50MG ($4.79), 100MG ($6.84), 200MG ($9.77) TABLET
   (Note: May not be given KOP.)

CHLOR-TRIMETON® see CHLORPHENIRAMINE

CHOLESTYRAMINE (Max 11 refills)
   QUESTRAN® LIGHT
   4GM POWDER PKT W/ASPARTAME - 60/BOX ($1.82 each)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
CIBALITH-S® see LITHIUM CITRATE

CIPRO® see CIPROFLOXACIN

CIPROFLOXACIN

CIPRO®

500MG TABLET ($0.10)
(Not: 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 RMFs.)

CITALOPRAM HBR (Max 11 refills)

CELEXA®

10MG ($0.02), 20MG ($0.03), 40MG ($0.03) TABLET
(Note: May not be given KOP. 10mg restricted to TJJD only.)

CLARITIN® see LORATADINE

CLEAR EYES® see NAPHAZOLINE

CLEOCIN®, CLEOCIN-T® see CLINDAMYCIN

CLINDAMYCIN HCL

CLEOCIN®

150MG CAPSULE ($0.07)

CLINDAMYCIN PHOSPHATE

CLEOCIN®, CLEOCIN-T®

1% TOPICAL SOLUTION – 60ML ($50.95)
(Not: Topical solution is restricted to TJJD facilities and may not be given KOP.)

150MG/ML - 6ML VIAL ($2.59)

IV Preparation Standard:
> 600mg in 150mL D5W over 60 minutes. Maximum rate of infusion 30mg/minute.
900MG/50ML D5W PREMIX ($7.82)
(Not: Injection is clinic use only. Take from stock. May not be given KOP.)

CLOBETASOL

TEMOVATE®

0.05% OINTMENT - 15GM ($67.88)
CLONIDINE HCL
CATAPRES®
0.1MG TABLET ($0.02)
(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
PLAVIX®
75MG TABLET ($0.09)
(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, 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 - 10ML ($14.38)
1% CREAM - 15GM TUBE ($1.06)

CLOZAPINE
CLOZARIL®
25MG ($46), 100MG ($1.02) TABLET
(Note: May not be given KOP. Floor stock restricted to BC-Pamio, JM, J4 and SV. Non-formulary approval is still required for use and recommended monitoring must be followed (Pharmacy Policy 55-20).)

CLOZARIL® see CLOZAPINE
COAL TAR
PC-TAR®
1% SHAMPOO - 6OZ ($3.73)
(Note: Should be ordered for 1 bottle to last 90 days.)

COGENTIN® see BENZTROPINE MESYLATE

COLACE® see Docusate Sodium

COLLAGENASE
SANTYL®
250UNITS/GM - 30GM OINTMENT ($170.29)
(Note: Clinic use only. Take from stock. May not be given KOP. Use is restricted to wound care facilities.)

COMPAXINE® see PROCHLORPERAZINE

COMPOUND W® see SALICYLIC ACID

CONDYLOX® see PODOFILOX

**CONTACT LENS CARE PRODUCTS**

<table>
<thead>
<tr>
<th>CONTACT TYPE</th>
<th>CLASS</th>
<th>PRODUCT (DAYS SUPPLY)</th>
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<tbody>
<tr>
<td>RGP</td>
<td>SOAKING/DISINFECTING/PROTEIN REMOVER/CLEANER SOLUTION ($7.66)</td>
<td>BOSTON SIMPLUS MULTI-ACTION SOLUTION® 3.5OZ (30)</td>
</tr>
<tr>
<td>RGP, S</td>
<td>CONTACT REWETTING &amp; LUBRICANT SOLUTION ($2.81)</td>
<td>CLERZ PLUS® - 5ML (30)</td>
</tr>
<tr>
<td>S</td>
<td>SOFT CONTACT LENS MULTI PURPOSE SOLUTION ($3.04)</td>
<td>OPTI-ONE MULTIPURPOSE SOLUTION® 12OZ (90) : ONE SOLUTION FOR RINSING, DISINFECTING, STORAGE, &amp; REWETTING</td>
</tr>
<tr>
<td>RGP, S</td>
<td>CONTACT LENS CASE ($0.86)</td>
<td></td>
</tr>
</tbody>
</table>

RGP = RIGID GAS PERMEABLE
S = SOFT LENSES
ORDERING CONTACT LENS PRODUCTS

Option 1 (soft lenses) – Contact lens case must be ordered separately if needed*

Option 2 (rigid gas permeable lenses) – Contact lens case must be ordered separately if needed*

<table>
<thead>
<tr>
<th>OPTIONS FOR PROVIDING A 12 MONTH SUPPLY OF PRODUCTS</th>
<th>DAYS SUPPLY</th>
<th>ORDER QTY</th>
<th>REFILLS</th>
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<tbody>
<tr>
<td><strong>OPTION 1 (SOFT LENSES)</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>OPTI-ONE MULTIPURPOSE SOLUTION®</td>
<td>90</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>CLERZ-PLUS 5ML®</td>
<td>30</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>CONTACT LENS CASE*</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>OPTION 2 (RIGID GAS PERMEABLE LENSES)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BOSTON SIMPLUS MULTI-ACTION SOLUTION®</td>
<td>30</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>CLERZ-PLUS 5ML®</td>
<td>30</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>CONTACT LENS CASE*</td>
<td></td>
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</tr>
</tbody>
</table>

*Contact lens case may be ordered from the pharmacy warehouse if needed. Stat orders are not available.

CONTACT LENSREWETTING SOLUTION see CONTACT LENS CARE PRODUCTS

CONTACT LENS CLEANER see CONTACT LENS CARE PRODUCTS

CORDARONE® see AMIODARONE

COREG® see CARVEDILOL

CORTISPORIN® see NEOMYCIN/POLYMYXIN/BACITRACIN/HYDROCORTISONE

CORTISPORIN® OTIC see NEOMYCIN/POLYMYXIN/HYDROCORTISONE

COUMADIN® see WARFARIN SODIUM

CREON 12® see PANCRELIPASE

CRIXIVAN® see INDINAVIR

CRYSELLE® see NORGESTREL/ETHINYL ESTRADIOL

CTM see CHLORPHENIRAMINE MALEATE
CYANOCOBALAMIN, VITAMIN B-12 (Max 11 refills)
1000MCG/ML INJECTION - 1ML VIAL ($1.68)
(Note: Clinic use only. Take from stock. May not be given KOP.)

CYCLOGLY see CYCLOPENTOLATE HCL

CYCLOPENTOLATE HCL
CYCLOGLY
1% OPHTHALMIC SOLUTION - 15ML ($9.68)

CYCLOSPORE (Max 11 refills)
NEORAL
25MG ($0.67), 100MG ($2.37) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

CYPROHEPTADINE
PERIACIN
4MG TABLET ($0.40)

D-T TOXOIDS see TETANUS & DIPHTHERIA TOXOIDS

D4T see STAVUDINE

DACRIOSE see OPHTHALMIC IRRIGATING SOLUTION

DAPSONE (Max 11 refills)
AVLOSOULON
100MG TABLET ($1.01)

DARAPRIM see PYRIMETHAMINE

DARUNAVIR (Max 11 refills)
PREZISTA
600MG ($18.18), 800MG ($36.36) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

DDAVP see DESMOPRESSIN

DDI see DIDANOSINE

DEBROX see CARBAMIDE PEROXIDE

DECADRON see DEXAMETHASONE
DELTASONE® see PREDNISONE

DEPAKOTE® see DIVALPROEX SODIUM

DEPO-PROVERA® see MEDROXYPROGESTERONE

DESMOPRESSIN (Max 5 refills)
DDAVP®
  0.2MG TABLET ($0.86)
  (Note: May not be given KOP. Restricted to TJJD use only)

DESYREL® see TRAZODONE HCL

DEXAMETHASONE
DECADRON®
  4MG/ML – 1ML VIAL ($0.45)
  (Note: Clinic use only. Take from stock. May not be given KOP).
  4MG TABLET ($0.10)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Tablet restricted to Carol Young Medical Facility as floor stock only. Non-formulary approval still required for use.)

DEXTROAMPHETAMINE/AMPHETAMINE see AMPHETAMINE SALTS

DEXTROSE
DEXTROSE 5% in WATER INJECTION
  100ML ($1.16), 250ML, ($0.68), 500ML ($0.75), 1000ML ($1.08)
DEXTROSE 5% in WATER INJECTION MINI-BAG – 50ML ($1.16)
DEXTROSE 5% in NS INJECTION - 500ML ($1.07), 1000ML ($0.93)
DEXTROSE 5% in 1/4 NS INJECTION - 1000ML ($1.16)
DEXTROSE 5% in 1/2 NS INJECTION - 1000ML ($0.94)
DEXTROSE 5% LACTATED RINGERS - 1000ML ($0.93)
DEXTROSE 10% in WATER INJECTION - 1000ML ($1.48)
DEXTROSE 50% INJECTION SYRINGE - 50ML ($4.84)
DEXTROSE 40% GEL 37.5GM TUBE – 3 TUBES/BOX
  GLUTOSE 15% ($2.79/TUBE)
  (Note: Clinic use only. Take from stock. May not be given KOP. D10W 1000ml restricted to Estelle, Michael and Young facilities.)

DIAMOX® see ACETAZOLAMIDE
DIAZEPAM - CIV (Max 5 refills)  
VALIUM®  
5MG TABLET ($0.04)  
(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®  
250MG ($0.23), 500MG ($0.46) CAPSULE

DIDanosine EC (DDI) (Max 11 refills)  
VIDEX-EC®  
250MG ($4.41), 400MG ($6.89) 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 (Max 11 refills)  
LANOXIN®  
0.125MG ($1.83), 0.25MG ($1.83) TABLET

DILACOR® XR see DILTIAZEM HCL

DILANTIN® see PHENytoin SODIUM

DILTIAZEM (Max 11 refills)  
CARDIZEM®  
60MG ($0.08), 90MG ($0.09) TABLET  
DILACOR® XR (extended release once-daily dosage form)  
180MG ($0.51), 240MG ($0.56) CAPSULE
DIPHENDRamine HCl (Max 11 refills, capsule only)
   BENADRYL®
   25MG ($0.01), 50MG CAPSULE ($0.01)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
   Elixir 12.5MG/5ML - 480ML ($1.76)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
   50MG/ML INJECTION - 1ML VIAL ($0.59) (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®
   75MG TABLET ($0.10)
   (Note: Use should be limited to combination therapy with ASA for intermittent claudication.)

DITROPA® see OXYBUTYNIN

DIVALPROEX SODIUM (Max 11 refills)
   DEPAKOTE®
   250MG ($0.15), 500MG ($0.31) TABLET
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

DOCUSATE SODIUM (Max 5 refills)
   COLACE®
   100MG CAPSULE ($0.01)

DOLUTEGRAVIR (Max 11 refills)
   TIVICAY®
   50MG TABLET ($38.45)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

DOMEBORO OTIC® see ACETIC ACID/ALUMINUM ACETATE

DOPAMINE
   DOPAMINE 400MG IN 5% DEXTROSE 250ML ($6.53)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

DORZOLAMIDE
   TRUSOPT®
   2% OPHTHALMIC SOLUTION – 10ML ($8.27)

DOUBLE ANTIBIOTIC OINTMENT see BACITRACIN/POLYMIXIN B

371
DOXERCALIFEROL (Max 11 refills)

HECTORAL®

2.5MCG CAPSULE ($31.50)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Restricted to dialysis units.)

D-T TOXOIDS see see TETANUS & DIPHTHERIA TOXOIDS

DULCOLAX® see BISACODYL

DUOFILM® see SALICYLIC ACID

DURAGESIC® see FENTANYL

DYAZIDE® see TRIAMTERENE/HCTZ

DYNAPEN® see DICLOXACILLIN SODIUM

ECOTRIN® see ASPIRIN, ENTERIC-COATED

EDURANT® see RILPI\VIRINE

EFAVIRENZ (Max 11 refills)

SUSTIVA®

600MG TABLET ($23.97)
(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 ($6.78)
(Note: Clinic use only. Take from stock. May not be given KOP.)

ELIMITE® see PERMETHRIN

ELLA® see ULIPRISTAL

ELOCON® see MOMETASONE FUROATE

372
ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR

STРИБИЛД®
150MG/150MG/200MG/300MG TABLET ($76.62)
(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: New intake patient currently prescribed Stribild at intake.)

ENGEX® B see HEPATITIS B VACCINE, RECOMBINANT

ENTECAVIR
BARACLUD®
0.5MG ($38.49), 1MG ($38.49) 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 utmbcmc.pharmacyID@utmb.edu for UTMB units and assigned clinical pharmacist for TTUHSC units.)

ENTERAL FEEDING
OSMOLITE® 1 CAL
8 OZ RTU CAN ($0.80)
(Note: May not be given KOP. Take from stock. Restricted to regional medical facilities and dialysis units. Enteral feeding formulation may be therapeutically interchanged if unavailable.)

ENULOSE® see LACTULOSE

EPINEPHRINE HCL
ADRENALIN®
1:1000 (1MG) INJECTION - 1ML AMPULE ($1.11)
1:10,000 (0.1MG) INJECTION - 10ML SYRINGE ($3.83)
EPIPEN®
1:1000 (0.3MG/0.3ML) INJECTION – 2 SYRINGES/PK ($187.65/SYR)
(Note: Clinic use only. Take from stock. May not be given KOP. Epipen restricted to EMS and TJJD for emergency boxes only.)

EPIPEN® see EPINEPHRINE

EPIVIR® see LAMIVUDINE
EPOETIN ALFA (Max 2 refills)
    PROCIRIT®
    10,000 UNIT/ML INJECTION - 2ML VIAL ($389.96)
(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. Physicians and Mid-level Providers who order ESA for oncology patients must complete the required training and enroll in the ESA APPRISE (Assisting Providers and cancer Patients with Risk Information for the Safe use of ESAs) Oncology Program. Providers must review the appropriate medication guide and counsel each patient on the risks and benefits of ESA. Providers must document the risk and benefit discussion through completion of an ESA APPRISE Patient and Healthcare Professional Acknowledgment Form in the EMR. The ESA Medication Guide must be provided to patients at the initiation of therapy and again if the Medication Guide is materially revised or updated regardless of indication.

ERYTHROCIN® see ERYTHROMYCIN BASE, ERYTHROMYCIN STEARATE

ERYTHROMYCIN BASE
    ERYTHROCIN®
    500MG TABLET ($8.38)

ERYTHROMYCIN STEARATE
    ERYTHROCIN®
    250MG TABLET ($4.66)

ERYTHROMYCIN
    ILOTYCIN®
    0.5% OPHTHALMIC OINTMENT - 3.5GM ($4.00)

ERYTHROPOIETIN see EPOETIN ALFA

ESKALITH® see LITHIUM CARBONATE

ESTROGENS, BIRTH CONTROL
    see ETHYNODIOL DIACETATE / ETHINYL ESTRADIOL (ZOVIA®)
    see NORETHINDRONE / ETHINYL ESTRADIOL (ORTHO-NOVUM®, NORINYL®)
    see NORGESTREL / ETHINYL ESTRADIOL (LOW-OGESTREL®, LO-OVRAL®)
ESTROGENS, CONJUGATED (Max 11 refills, tablets only)
PREMARIN®
0.625MG ($3.10), 1.25MG ($3.10) TABLET
(Note: Restricted to use in female patients only.)
25MG/5ML INJECTION – 5ML VIAL ($171.69)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to use in female patients only.)

ESTROGENS, CONJUGATED, VAGINAL (Max 11 refills)
PREMARIN VAGINAL CREAM®
0.625MG/GRAM – 30 GRAM TUBE ($205.81)
(Note: Restricted to use in female patients only.)

ETHAMBUTOL HCL (Max 11 refills)
MYAMBUTOL®
400MG TABLET ($0.98)
(Note: May not be given KOP.)

ETHANOL see ALCOHOL, ETHYL

ETHYNODIOL DIACETATE/ETHINYL ESTRADIOL (Max 11 refills)
ZOVIA – 1/50E®
1/50-28 TABLET ($16.79/pack)
(Note: Restricted to female patients.)

EUCERIN® see ABSORBASE

FENTANYL
DURAGESIC®
25MCG/HR ($4.38), 100MCG/HR ($14.38) PATCH
(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®
325MG TABLET ($0.01)

FIBERCON® see CALCIUM POLYCARBOPHIL

375
FLEETS PHOSPHO SODA® see SODIUM PHOSPHATE ORAL SOLUTION

FLAGYL® see METRONIDAZOLE

FLUCONAZOLE (Max 11 refills)
DIFLUCAN®
   100MG ($1.38), 150MG ($2.14), 200MG ($2.26) 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. 100mg and 200mg tablets restricted to treatment of HIV-related opportunistic infections.
   b. 150mg tablets restricted to single dose therapy for vaginal candidiasis.)

FLULAVAL® see INFLUENZA VIRUS VACCINE

FLUMAZENIL
ROMAZICON®
   0.1MG/ML IV INJECTION - 5ML VIAL ($3.79)
(Note: Restricted to emergency use only. Clinic use only. Take from stock. May not be given KOP.)

FLUCINONIDE (Max 2 refills 60gm cream only)
LIDEX®
   0.05% OINTMENT - 15GM ($23.50)
   0.05% CREAM - 15GM ($10.88), 60GM ($20.88)

FLUORETS® see FLUORESCIN SODIUM STRIPS

FLUORESCIN SODIUM STRIPS
FLUORETS®
   1MG OPHTHALMIC STRIPS – 100/BOX ($0.13 each strip)
(Note: Clinic use only. Take from stock. May not be given KOP.)

FLUOXETINE (Max 11 refills)
PROZAC®
   10MG ($0.03), 20MG ($0.02) CAPSULE
(Note: May not be given KOP. 10mg restricted to TJJD only.)
FLUPHENAZINE HCL (Max 11 refills)
PROLIXIN®
  2.5MG ($0.19), 5MG ($0.25), 10MG ($0.32) TABLET
  2.5MG/ML INJECTION - 10ML VIAL ($82.20)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP.)

FLUPHENAZINE DECANOATE (Max 11 refills)
PROLIXIN D®
  25MG/ML INJECTION - 5ML VIAL ($68.87)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP.)

FLURBIPROFEN
OCUFEN®
  0.03% OPHTHALMIC SOLUTION - 2.5ML ($2.60)

FOLIC ACID (Max 11 refills)
FOLVITE®
  1MG TABLET ($0.01)

FOLINIC ACID see LEUCOVORIN CALCIUM

FOLVITE® see FOLIC ACID

FORTAZ® see CEFTAZIDIME

FOSAMPRENAVIR (Max 11 refills)
LEXIVA®
  700MG TABLET ($14.64)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

FUROSEMIDE (Max 11 refills, tablet)
LASIX®
  20MG ($0.01), 40MG ($0.01) TABLET
  10MG/ML INJECTION - 4ML VIAL ($2.98)
(Note: Injection for clinic use only, should be taken from stock and may not be given KOP.)

GARDASIL® see HUMAN PAPILLOMAVIRUS

GEL-KAM® see STANNOUS FLUORIDE

377
GEMFIBROZIL (Max 11 refills)
    LOPID®
    600MG TABLET ($0.08)

GENOPTIC® see GENTAMICIN

GENTAMICIN
    GARAMYCIN®, GENOPTIC®, GENTAK®
    0.3% OPHTHALMIC OINTMENT - 3.5GM ($8.47)
    0.3% OPHTHALMIC SOLUTION - 5ML ($3.18)

GENTAMICIN
    40MG/ML INJECTION - 2ML VIAL ($0.60)
    IV Preparation Standard:
    ≤ 100mg in 100mL D,W over 60 minutes
    >100mg in 150mL D,W over 60 minutes.
    (Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

GENTIAN VIOLET
    2% SOLUTION - 60ML ($10.34)
    (Note: Clinic use only. Take from stock. May not be given KOP.)

GEODON® see ZIPRASIDONE

GLIPIZIDE (Max 11 refills)
    GLUCOTROL®
    5MG ($0.03), 10MG ($0.04) TABLET

GLUCAGON® see GLUCAGON

GLUCAGON
    GLUCAGEN®
    1MG HYPOKIT ($183.38)
    (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®
100GM GLUCOSE - 10 OZ BOTTLE ($5.66)
(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

GOLYTELY® see ELECTROLYTE ORAL SOLUTION

GUANFACINE (Max 11 refills)
TENEX®
1MG ($0.06), 2MG ($0.09) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

HALDOL® see HALOPERIDOL, HALOPERIDOL LACTATE

HALDOL D® see HALOPERIDOL DECANOATE

HALOPERIDOL (Max 11 refills)
HALDOL®
1MG ($0.32), 5MG ($0.69), 10MG ($0.65) TABLET

HALOPERIDOL LACTATE (Max 11 refills, oral concentrate only)
HALDOL®
2MG/ML ORAL CONCENTRATE - 120ML ($3.30)
5MG/ML INJECTION - 1ML VIAL ($0.85)
(Note: May not be given KOP. Injection for clinic use only and should be taken from stock.)

HALOPERIDOL DECANOATE (Max 11 refills)
HALDOL®
100MG/ML INJECTION - 5ML VIAL ($183.36)
(Note: May not be given KOP. Injection for clinic use only and should be taken from stock.)

HAVRIX® see HEPATITIS A VACCINE

HC RECTAL CREAM see HYDROCORTISONE CREAM

HECTORAL® see DOXERCALCIFEROL

HEMORRHOIDAL-HC® see HYDROCORTISONE
HEMORROIDAL (Max 11 refills)
ANUSOL®, TUCKS®
OINTMENT - 30GM ($3.51)
SUPPOSITORY - 12/BOX ($0.09/suppos)
(Note: Take from stock. Ointment contains pramoxine HCL 1% and zinc oxide 12.5%. Suppositories contain phenylephrine HCL 0.25% as active ingredients.)

HEP-LOCK® see HEPARIN SODIUM

HEPARIN SODIUM
HEP-LOCK®
100U/ML - 3ML SYRINGE ($0.35)
HEPARIN
1,000U/ML - 30ML VIAL ($3.62)
5,000U/ML – 1ML VIAL ($0.91)
(Note: Clinic use only. Take from stock. May not be given KOP. 1,000U/ML-30ML restricted to dialysis centers.)

HEPATITIS A VACCINE, INACTIVATED (Max 1 refill)
HAVRIX®
1,440 EL.U/ML – 1ML VIAL ($59.62)
(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:
a. HIV-positive patients who are not immune (P&P B-14.07)
b. Chronic hepatitis C patients who are not immune (P&P B-14.07)
c. Chronic hepatitis B patients who are not immune (P&P B-14.07)
d. End stage liver disease)
HEPATITIS B VACCINE, RECOMBINANT (Max 2 refills)

**ENGERTIX®**

- 20MCG/ML - 1ML VIAL ($49.12)

(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
  c. Dialysis (Dialysis patients should be given 2 doses [40mcg] per administration)
  d. Offenders who are subject to a blood borne exposure as outlined in Infection Control Policy B-14.06
  e. Offender workers in job classifications that have potential for occupational exposure as outlined in Correctional Managed Healthcare Policy B-14.4
  f. ≤ 18 year old without documentation of series completion
  g. End stage liver disease

HUMAN PAPILLOMAVIRUS VACCINE (HPV) (Max 2 refills)

**GARDASIL®**

- 0.5ML SINGLE DOSE VIAL ($137.52)

(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.)

HYDRAZINE (Max 11 refills)

**APRESOLINE®**

- 25MG ($0.04), 50MG ($0.05) TABLET

HYDROCHLOROTHIAZIDE (Max 11 refills)

**HYDRODIURIL®**

- 12.5MG CAPSULE ($0.04)
- 25MG ($0.02), 50MG ($0.03) TABLET
HYDROCORTISONE
ANUSOL-HC®
1% HEMORRHOIDAL-HC RECTAL CREAM – 30GM ($5.07)
25MG HEMORRHOIDAL-HC RECTAL SUPPOSITORY–12/BOX ($8.81)
EACH
(Note: Max 11 refills on hemorrhoidal cream & suppositories.)
HYTONE®
1% CREAM – 30GM ($1.18), U/D PACKET ($0.05)

HYDROCORTISONE SODIUM SUCCINATE
SOLU-CORTEF®
100MG INJECTION - 2ML VIAL ($3.50)
250MG INJECTION - 2ML VIAL ($11.23)
IV Preparation Standard:
50-100mg in 100mL D5W over 40 minutes
>100mg in 250mL D5W over 60 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

HYDRODIURIL® see HYDROCHLOROTHIAZIDE

HYDROGEN PEROXIDE
3% SOLUTION - 473ML ($0.59)
(Note: Clinic use only. Take from stock. May not be given KOP.)

HYDROXYZINE PAMOATE (Max 2 refills)
VISTARIL®
25MG ($0.05), 50MG ($0.08) CAPSULE
(Note: May not be given KOP. Restricted to TJJD only.)

HYTONE® see HYDROCORTISONE CREAM

HYTRIN® see TERAZOSIN

IBUPROFEN (Max 2 refills)
MOTRIN®
200MG ($0.02), 400MG ($0.04), 600MG ($0.05), 800MG ($0.06) TABLET
(Note: The 200mg 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.)

ILOTYCIN® see ERYTHROMYCIN

IMDUR® see ISOSORBIDE MONONITRATE

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IMIPRAMINE HCL (Max 11 refills)

TOFRANIL®

25MG ($0.12), 50MG ($0.17) TABLET

(Note: May not be given KOP. Restricted to TJJD for treatment of enuresis.)

IMODIUM® see LOPERAMIDE HCL

IMURAN® see AZATHIOPRINE

INDERAL® see PROPRANOLOL

INDINAVIR (Max 11 refills)

CRIXIVAN®

400MG ($2.37) CAPSULE

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

INFLIXIMAB

REMICADE®

100MG IV INJECTION ($868.28)

(Note: Floor stock restricted to GC and E2 facilities. 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

FLULAVAL®

5ML MULTI-DOSE VIAL - 10 DOSES/VIAL ($67.60)

(Note: Clinic use only. Take from stock. May not be given KOP. Seasonally available. Follow Infection Control P&P B-14.51 when selecting patients. Criteria include:

a. ≥ 50 years old
b. Certain chronic diseases (heart disease, asthma, COPD, diabetes, renal disease, hepatic disease, neurologic disease, 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. American Indian or Alaska Native
g. Morbidly obese BMI ≥ 40)

INFUVITE® see MULTIVITAMIN

INH see ISONIAZID

383
INSULIN, HUMAN (Max 11 refills)
NOVOLIN®
  NPH 100 UNITS/ML - 10ML VIAL ($97.36)
  REGULAR 100 UNITS/ML - 10ML VIAL ($97.36)
  70/30 (70% NPH/30% REG) 100 UNITS/ML - 10ML VIAL ($97.36)
  (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.)

INVIRASE® see SAQUINAVIR

IPRATROPIUM BROMIDE HFA (Max 11 refills)
ATROVENT HFA®
  HFA ORAL INHALER 200 ACTUATIONS/17MCG EACH ($221.20)
  0.02% NEBULIZER SOLUTION - 2.5ML ($0.11) (No refills)
  (Note: Nebulizer for clinic use only, should be taken from stock, and may not be given
  KOP. Nebulizer restricted to acute asthma management. Orders for nebulizer should
  not exceed 72 hours.)

IRON SUCROSE
VENOFER®
  20MG/ML – 5ML SINGLE DOSE VIAL ($29.00)
  (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
  300MG TABLET ($0.13)
  (Note: May not be given KOP.)

ISOPTOATROPINE® see ATROPINE SULFATE

ISOPTOTEARS® see METHYLCELLULOSE

ISOSORBIDE MONONITRATE (Max 11 refills)
ISMN, IMDUR®
  30MG ($0.20), 60MG ($0.21) EXTENDED RELEASE TABLET

KALETRA® see LOPINAVIR/ritonavir

KAYEXALATE® see POLYSTYRENE SODIUM SULFONATE

K-DUR® see POTASSIUM CHLORIDE

384
KCL see POTASSIUM CHLORIDE
KEFLEX® see CEPHALixin
KENALOG® see TRIAMCINOLONE
KENALOG IN ORABASE® see TRIAMCINOLONE DENTAL PASTE
KEPPRA® see LEVETIRACETAM

LABETALOL
  NORMODYNE®
  5MG/ML – 40ML MDV ($2.73)
  (Note: Restricted to EMS for treatment of HTN emergencies per protocol.)

LACTATED RINGERS
  INJECTION 1000ML ($0.97)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

LACTULOSE (Max 11 refills)
  ENULOSE®
  10GM/15ML SYRUP - 473ML ($4.69)
  (Note: Take from floor stock.)

LAMIVUDINE (3TC) (Max 11 refills)
  EPIVIR®
  150MG ($2.28), 300MG ($6.73) TABLET
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LANOXIN® see DIGOXIN

LASIX® see FUROSEMIDE

LATANOPROST (Max 11 refills)
  XALATAN®
  0.005% OPHTHALMIC SOLUTION - 2.5ML ($5.72)
  (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
5MG TABLET ($0.54)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LEVETIRACETAM (Max 11 refills)
KEPPRA®
500MG ($0.11), 1000MG ($0.23) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LEVODOPA/CARBIDOPA see CARBIDOPA/LEVODOPA

LEVOTHYROXINE SODIUM (Max 11 refills)
SYNTHROID®
0.025MG ($0.31), 0.05MG ($0.35), 0.1MG ($0.39), 0.15MG ($0.48) TABLET

LEXIVA® see FOSAMPRENAVIR

LIBRIUM® see CHLORDIAZEPoxide

LIDEX® see FLUOCINONIDE

LIDOCAINE HCL
XYLOCAINE®
2% VISCOS ORAL SOLUTION - 100ML ($1.41)
2% JELLY - 30ML ($5.20)
5% OINTMENT – 1.25OZ ($211.99)
1% LOCAL INJECTION (10MG/ML) - 20ML VIAL ($0.78)
2% LOCAL INJECTION (20MG/ML) - 20ML VIAL ($0.91)
1% WITH EPINEPHRINE 1:100,000 – 20ML VIAL ($1.19)
(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 OB/GYN services and may not be given KOP.)

LIORESAL® see BACLOFEN

LIPITOR® see ATORVASTATIN

LISINOPRIL (Max 11 refills)
PRINIVIL®, ZESTRIL®
2.5MG ($0.01), 5MG ($0.02), 10MG ($0.02), 20MG ($0.02), 40MG ($0.05) TABLET
LITHIUM CARBONATE (Max 11 refills)
   ESKALITH®
   300MG CAPSULE ($0.02)
   (Note: May not be given KOP.)

LITHIUM CITRATE (Max 11 refills)
   CIBALITH-S®
   300MG/5ML SYRUP - 500ML ($16.05)
   (Note: May not be given KOP.)

LO/OVRAL-28® see NORGESTREL/ETHINYL ESTRADIOL

LONITEN® see Minoxidil

LOPERAMIDE HCL (Max 2 refills)
   IMODIUM®
   2MG CAPSULE ($0.16)

LOPID® see Gemfibrozil

LOPINAVIR/РИTONAVИR (Max 11 refills)
   KALETRA®
   200MG/50MG FILM-COATED TABLET ($6.35)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LOPRESSOR® see Metoprolol Tartrate

LORATADINE (Max 2 refills)
   CLARITIN®
   10MG TABLET ($0.05)

LORAZEPAM - CIV
   ATIVAN®
   2MG/ML INJECTION - 1ML VIAL ($0.98)
   (Note: Clinic use only. Take from stock. 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 non­formulary approval.)

LOTIRIMIN® see Clotrimazole

LOW-ОGESTREL® see Norgestrel/Ethinyl Estradiol
LUBRICANT EYE OINTMENT (Max 11 refills)
LUBRIFRESH PM®
OPHTHALMIC OINTMENT - 3.5GM ($2.21)

LUBRICANT, SURGICAL
SURGILUBE®
4.24 OZ TUBE ($2.36)
3GM FOILPACK ($0.10)
(Note: Clinic use only. Take from stock. May not be given KOP. Tube restricted to regional medical facilities.)

LUBRIFRESH PM® see LUBRICANT EYE OINTMENT

LUBRISOFT® see BODY LOTION

MACRODANTIN ® see NITROFURANTOIN

MAGNESIUM CITRATE
SOLUTION - 300ML ($1.03)
(Note: Clinic use only. Take from stock. May not be given KOP.)

MAGNESIUM HYDROXIDE
MILK OF MAGNESIA®
2400MG/30ML SUSPENSION - 30ML UNIT DOSE ($0.67)
(Note: Take from stock.)

MAGNESIUM SULFATE
50% INJECTION (500MG/ML) - 2ML VIAL ($1.13)
(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
0.5ML SC INJECTION ($56.08)
(Note: Restricted form 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. ≤ 18 years old without documentation of completion
  b. Immigrants that have not completed the series
  c. Born after 1956 and did not attend public school.)
MECLIZINE HCL (Max 2 refills)
   ANTIVERT®
   25MG TABLET ($0.20)

MEDROXYPROGESTERONE
   DEPO-PROVERA®
   150MG/ML INJECTION - 1ML VIAL ($52.81) (Max 3 refills)
   PROVERA®
   2.5MG ($0.10), 10MG ($0.10) 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)
   3MG TABLET ($0.05)
   (Note: May not be given KOP. Restricted to TJJD only.)

MELOXICAM (Max 2 refills)
   MOBIC®
   7.5 MG ($0.02), 15MG ($0.02) TABLET

MENINGOCOCCAL VACCINE, POLYSACCHARIDE
   MENOMUNE®
   50MCG/0.5ML SDV ($109.76)
   (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.)

MENTHOLATUM RUB
   VICKS VAPORUB®
   OINTMENT – 50GM ($2.96)
   (Note: Clinic use only. Take from stock. May not be given KOP. Restricted to TJJD facilities.)

MENOMUNE® see MENINGOCOCCAL VACCINE

MEPHYTON® see PHYTONADIONE

MERREM® see MEROPENEM
MEROPENEM
MERREM®
1GM IV INJECTION – 30ML VIAL ($7.72)
IV Preparation Standard:
1gm in NS or D5W 100ML over 30 minutes
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to regional medical facilities for inpatient use only.)

METFORMIN (Max 11 refills)
GLUCOPHAGE®
500MG ($0.02), 1000MG ($0.03) TABLET

METHIMAZOLE (Max 11 refills)
TAPAZOLE®
5MG TABLET ($0.18)

METHOCARBAMOL
ROBAXIN®
750MG TABLET ($0.08)
(Note: Tablets restricted to one 7-day supply per injury. A minimum 30 day period between orders is required. Allowed KOP at 8-hour units, may not be given KOP at all other units.)

METHYLCELLULOSE
ISOPTOTEARS®
0.5% OPHTHALMIC SOLUTION - 15ML ($16.98)

METHYLDOPA
ALDOMET®
250MG TABLET ($0.17)
(Note: Floor stock restricted to Carol Young Medical Facility. Non-formulary approval is still required for use.)

METHYLPHENIDATE- CII
RITALIN®
5MG ($0.62), 10MG ($0.87) TABLET
RITALIN LA®
10MG ($5.65), 20MG ($5.70), 30MG ($5.78), 40MG ($5.94) 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.)

390
METHYLPREDNISOLONE SODIUM SUCCINATE
SOLU-MEDROL®
125MG INJECTION – 2ML VIAL ($5.00)
IV Preparation Standard:
3gm in 100mL D5W over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)

METHYLSALICYLATE/MENTHOL BALM
ANALGESIC BALM
30GM TUBE ($1.66)
(Note: May not be given KOP. Restricted to TJJD.)

METOCLOPRAMIDE HCL (Max 2 refills)
REGLAN®
10MG TABLET ($0.04)

METOLAZONE (Max 11 refills)
ZAROXOLYN®
5MG TABLET ($1.30)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

METOPROLOL TARTRATE (Max 11 refills)
LOPRESSOR®
25MG ($0.03), 50MG ($0.02), 100MG ($0.03) TABLET
5MG/5ML INJECTION - 5ML VIAL ($0.47)
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

METRONIDAZOLE HCL
FLAGYL®
250MG ($0.22), 500MG ($0.39) TABLET
500MG in NS READY-TO-USE 100ML BAG ($0.87)
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.)

MICRONAZOLE
MONISTAT-7®
100MG VAGINAL SUPPOSITORY - 7 SUPP/BOX ($2.76/BOX)
(Note: Restricted to female patients. Generally dosed 1 suppository inserted vaginally q hs x 7 days.)

MICROSULFON® see SULFADIAZINE

391
MILK OF MAGNESIA see MAGNESIUM HYDROXIDE

MINOCIN® see MINOCYCLINE

MINOCYCLINE
MINOCIN®
100MG CAPSULE ($0.20)

MINOXIDIL (Max 11 refills)
LONITEN®
2.5MG ($0.12), 10MG ($0.20) TABLET

M-M-R VACCINE see MEASLES/MUMPSS/RUBELLA VACCINE, LIVE

MOBIC® see MELODICAM

MOMETASONE FUROATE
ELOCON®
0.1% TOPICAL SOLUTION – 60ML ($11.18)

MONISTAT® see MICONAZOLE

MORPHINE SULFATE - CII
10MG/ML INJECTION - 1ML VIAL ($1.95)
10MG/5ML ELIXIR – 5ML UNIT DOSE ($1.54)
MS CONTIN®
15MG ($0.71), 30MG ($1.35) 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 > 21 days. A minimum 30 day period between orders is required for use beyond 21 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 - 10ML VIAL ($7.16)
(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 OPHTHALMIC OINTMENT

M.V.I. ADULT™ see MULTIVITAMIN

MYAMBUTOL® see ETHAMBUTOL HCL

MYCOBUTIN® see RIFABUTIN

MYCOPHENOLATE MOFETIL (Max 11 refills)
CELLCEPT®
  250MG CAPSULE ($42)
  500MG TABLET ($0.84)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

MYCOSTATIN® see NYSTATIN

MYLICON® see SIMETHICONE

MYSOLINE® see PRIMIDONE

NAFCILL® see NAFCILLIN SODIUM

NAFCILLIN

NAFCILL®
  1GM INJECTION VIAL ($5.60)
IV Preparation Standard:
  ≤ 1gm in 100mL D₂W over 30 minutes
  > 1gm in 100mL D₂W over 40 minutes.
(Note: Clinic use only. Take from stock. May not be given KOP.)
NALOXONE HCL
NARCAN®
0.4MG/ML INJECTION - 1ML VIAL ($12.14)
(Note: Clinic use only. Take from stock. May not be given KOP)

NAPHAZOLINE HCL
NAPHC®. CLEAR EYES®
0.012% OPHTHALMIC SOLUTION - 15ML ($2.57)

NAPHAZOLINE/PHENIRAMINE
NAPHC®. OPCON-A®
NAPHAZOLINE 0.025%/PHENIRAMINE 0.3%
OPHTHALMIC SOLUTION - 15ML ($4.29)

NAPHC® see NAPHAZOLINE HCL
NAPHCON-A® see NAPHAZOLINE/PHENIRAMINE

NAPROSYN® see NAPROXEN

NAPROXEN (Max 2 refills)
NAPROSYN®
250MG ($0.03), 500MG ($0.05) TABLET

NARCAN® see NALOXONE HCL

NATALINS® FA see PRENATAL-FOLIC ACID

NAVANE® see THIOTHIXENE HCL

NELFINAVIR (Max 11 refills)
VIRACEPT®
625MG TABLET ($7.11)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

NEOMYCIN/BACITRACIN/POLYMYXIN
NEOSP®
OPHTHALMIC OINTMENT - 3.5GM ($5.73)
TOPICAL OINTMENT 1GM PACKET ($0.08)
(Note: 1gm packet for clinic use only, should be taken from stock and may not be given KOP.)
NEOMYCIN/BACITRACIN/POLYMYXIN/HYDROCORTISONE
CORTISPORIN®
OPHTHALMIC OINTMENT - 3.5GM ($9.86)

NEOMYCIN/POLYMYXIN/DEXAMETHASONE
MAXITROL®
OPHTHALMIC SUSPENSION - 5ML ($5.58)
OPHTHALMIC OINTMENT - 3.5GM ($5.80)

NEOMYCIN/POLYMYXIN/HYDROCORTISONE
CORTISPORIN®
OTIC SUSPENSION - 10ML ($8.00)

NEOMYCIN/GRAMICIDIN/POLYMYXIN
NEOSPORIN®
OPHTHALMIC SOLUTION - 10ML ($19.18)

NEORAL® see CYCLOSPORINE

NEOSPORIN® see NEOMYCIN/GRAMICIDIN/POLYMYXIN
see also NEOMYCIN/BACITRACIN/POLYMYXIN

NEPHRO-VITE® see VITAMIN B COMPLEX & VITAMIN C WITH FOLIC ACID

NEVIRAPINE (Max 11 refills)
VIRAMUNE®
200MG TABLET ($0.12)
(Note: May not be given KOP.)

NIACIN (Max 11 refills)
NIASPAN ER®
500MG ($2.12), 1000MG ($3.74) TABLET
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

NIASPAN ER® see NIACIN

NITRO-DUR® see NITROGLYCERIN

NITRO-BID® see NITROGLYCERIN
NITROFURANTOIN
MACRODANTIN®
50MG CAPSULE ($0.62)

NITROGLYCERIN (Max 1 refill SL tablets, 11 refills patches)
NITROSTAT®
0.4MG SUBLINGUAL TABLET - 25 PER BOTTLE ($10.76 PER BOTTLE)
(Note: Sublingual tablets should be ordered as 1 bottle to last 6 months.)
NITROBID®
2% TOPICAL OINTMENT - 60GM ($58.00)
(Note: The ointment is restricted to clinic use only, should be taken from stock and may not be given KOP.)
NITRO-DUR®
0.2MG/HR ($0.40), 0.4MG/HR ($0.42) 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®, NORINYL®
1/35-28 TABLET ($58.14)
(Note: Restricted to female patients)

NORGESTREL/ETHINYL ESTRADIOL (Max 11 refills)
LO/OVRAL®, LOW-OGESTREL®, CRYSELLE®
0.3/30-28 TABLET ($16.88)
(Note: Restricted to female patients)
NORINYL® see NORETHINDRONE/ETHINYL ESTRADIOL

NORMAL SALINE see SODIUM CHLORIDE 0.9%

NORMODYNE® see LABETALOL

NORTRIPTYLINE HCL (Max 11 refills)
PAMELOR®
25MG ($0.10), 50MG ($0.12), 75MG ($0.17) CAPSULE
(Note: May not be given KOP. Restricted to TDCJ, non-formulary approval required for use at TJJD facilities.)

NORVASC® see AMLODIPINE

396
NORVIR® see RITONAVIR
NOVOLIN® see INSULIN, HUMAN
NYDRAZID® see ISONIAZID

NYSTATIN
MYCOSTATIN®
100,000 UNITS/ML ORAL SUSPENSION - 60ML ($6.99)

OCEAN NASAL MIST® see SODIUM CHLORIDE
OCUFEN® see FLURBIPROFEN

OMEPRAZOLE (Max 11 refills)
PRILOSEC®
20MG CAPSULE ($0.06)

OMNIPEN-N® see AMPICILLIN
OPCON-A® see NAPHAZOLINE/PHENIRAMINE

OPHTHALMIC IRRIGATING SOLUTION
DACRIOSE®
IRRIGATING EYE WASH - 120ML ($1.31)

OPTI-FREE SUPRA CLENS® see CONTACT LENS CARE PRODUCTS
OPTI-ONE MULTIPURPOSE SOLUTION® see CONTACT LENS CARE PRODUCTS

ORABASE/BENZOCAINE
ORABASE® WITH BENZOCAINE
PASTE - 12GM ($4.06)

ORTHO-NOVUM® see NORETHINDRONE/ETHINYL ESTRADIOL
OS-CAL® see CALCIUM CARBONATE
OS-CAL 250 + VITAMIN D® see CALCIUM CARBONATE/VITAMIN D
OSMOLITE® 1 CAL see ENTERAL FEEDING
OXYBUTYNIN (Max 11 refills)
DITROPA®
5MG TABLET ($0.29)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PAMELOR® see NORTRIPTYLINE HCL

PANCRELIPASE (Max 11 refills)
CREON 12®
LIPASE 12,000U/AMYLASE 38,000U/PROTEASE 60,000U PER CAPSULE ($218.84 per 100 count bottle)

PARICALCITOL
ZEMPLAR®
5MCG/ML - 1ML VIAL ($9.26)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to dialysis centers.)

PARLODEL® see BROMOCRIPTINE MALEATE

PC-TAR® see COAL TAR

PEGASYS® see PEGINTERFERON

PEGINTERFERON ALFA-2A (Max 11 refills)
PEGASYS®
180MCG/0.5ML – 0.5ML SYRINGE ($771.95)
(Note: May not be given KOP. Non-formulary approval required by HCV group from pharmacy at utmbcmc.pharmacyID@utmb.edu for UTMB units and Utilization Management at (806)356-5350 for TTUHSC units.)

PENICILLIN VK
VEETIDS®
500MG TABLET ($0.13)

PENICILLIN G BENZATHINE
BICILLIN LA®
1.2MU/2ML SYRINGE ($70.87)
(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®

5MU INJECTION VIAL ($3.37)

IV Preparation Standard:

2MU in 100mL D5W over 20 minutes

>2MU in 100mL D5W over 40 minutes.

(Note: Clinic use only. Take from stock. May not be given KOP.)

**PEPTO-BISMOL®** see BISMUTH SUBSALICYLATE

**PERIACTIN®** see CYPROHEPTADINE

**PERIDEX®** see CHLORHEXIDINE GLUCONATE ORAL RINSE

**PERMETHRIN**

NIX®

1% LOTION – 2OZ ($5.45)

ELIMITE®

5% CREAM – 60GM ($75.58)

**PERPHENAZINE** (Max 11 refills)

TRILAFON®

4MG ($1.57), 8MG ($1.91), 16MG ($2.57) TABLET

(Note: May not be given KOP.)

**PERSANTINE®** see DIPYRIDAMOLE

**PETROLATUM**

VASELINE®

JELLY - 13OZ ($2.29)

(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to use at phototherapy centers.)

PFIZERPEN® see PENICILLIN G POTASSIUM

**PHENAZOPYRIDINE HCL**

PYRIDIUM®

200MG TABLET ($1.46)

PHENERGAN® see PROMETHAZINE HCL

**PHENYLEPHRINE HCL**

SUDAFED-PE®

10MG TABLET ($0.01)
PHENYTOIN (Max 11 refills)
   DILANTIN®
   125MG/5ML SUSPENSION - 8OZ ($17.88)
   (Note: Restricted to regional medical facilities. Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PHENYTOIN SODIUM (Max 11 refills, capsule)
   DILANTIN®
   100MG EXTENDED RELEASE CAPSULE ($0.24)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)
   50MG/ML INJECTION – 5ML VIAL ($1.04)
   (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®
   1MG/ML INJECTION - 2ML AMPULE ($7.99)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

PHYTONADIONE (VITAMIN K-1)
   AQUAMPHYTON®
   10MG/ML INJECTION - 1ML AMPULE ($27.56)
   (Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)
   MEPHYTON®
   5MG TABLET ($0.01)
   (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PITRESSIN® see VASOPRESSIN

PLASBUMIN-25® see ALBUMIN, HUMAN

PLAVIX® see CLOPIDOGREL

400
PNEUMOCOCCAL VACCINE (POLYVALENT)
PNEUMOVAX 23®
25MCG/0.5ML INJECTION - 0.5ML SINGLE DOSE VIAL ($67.71)
(Note: Clinic use only. Take from stock. May not be given KOP. Follow Infection
Control P&P for selecting patients. Criteria include:
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, CHF,
Cardiomyopathies)
c. Immunosuppressed patients (HIV positive, most cancers)

PNEUMOVAX 23® see PNEUMOCOCCAL VACCINE

PODOCON-25® see PODOPHYLLUM RESIN

PODOFILOX
CONDYLOX®
0.5% TOPICAL SOLUTION - 3.5ML ($40.87)
(Note: Clinic use only. Take from stock. May not be given KOP.)

PODOPHYLLOM RESIN
PODOCON-25®
25% RESIN - 15ML ($87.04)
(Note: Clinic use only. Take from stock. May not be given KOP.)

POLIO VIRUS VACCINE, INACTIVATED
IPOL®
0.5ML INJECTION – 5ML MDV – 10 DOSES/VIAL ($256.66)
(Note: May not be given KOP. Prior authorization required for use. Criteria: patients <
18 years old. All other uses require non-formulary approval.)

POLYSPORIN® see BACITRACIN/POLYMYXIN B

POLYSTYRENE SODIUM SULFONATE
KAYEXALATE®
SUSPENSION 15G/60ML - 16OZ ($30.40)
(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 60mL)

POLYTRIM® see TRIMETHOPRIM/POLYMYXIN B
POLYVINYL ALCOHOL (Max 11 refills)
ARTIFICIAL TEARS
1.4% OPTHALMIC SOLUTION - 15ML ($1.36)

POTASSIUM CHLORIDE (Tablets max 11 refills)
K-DUR®
10MEQ ($0.28), 20MEQ ($0.28) EXTENDED RELEASE TABLET
20MEQ/1000ML D5W INJECTION ($1.95)
20MEQ/1000ML 1/2NS D5W INJECTION ($1.29)
(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 ($0.36), 20MG ($0.37), 40MG ($0.54) TABLET

PRED FORTE® see PREDNISOLONE ACETATE

PREDNISOLONE ACETATE
PRED FORTE®
1% OPTHALMIC SUSPENSION - 5ML ($40.24)
PRED MILD®
0.12% OPTHALMIC SUSPENSION - 5ML ($68.27)

PREDNISONE (Max 11 refills 5mg tablets only)
DELTASONE®
5MG ($0.11), 10MG ($0.12), 20MG ($0.14) TABLET

PRENATAL-FOLIC ACID (Max 11 refills)
NATALINS FA®
TABLET ($0.46)
(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.)

PREMARIN® see ESTROGENS, CONJUGATED

PREZISTA® see DARUNAVIR

PRILOSEC® see OMEPRAZOLE

402
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

PROBENECID (Max 11 refills)
   BENEMID®
      500MG TABLET ($0.49)

PROCHLORPERAZINE
   COMPAZINE®
      10MG TABLET ($0.06)
      (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PROCRIT® see EPOETIN ALPHA

PROGRAF® see TACROLIMUS

PROLIXIN® see FLUPHENAZINE HCL

PROLIXIN D® see FLUPHENAZINE DECANOATE

PROMETHAZINE HCL
   PHENERGAN®
      25MG TABLET ($0.05)
      25MG SUPPOSITORY - 12/BOX ($100.77/BOX)
      25MG/ML INJECTION - 1ML VIAL ($0.67)
      (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 ($5.59)
      (Note: Clinic use only. Take from stock. May not be given KOP.)

PROPRANOLOL HCL (Max 11 refills)
   INDERAL®
      10MG ($0.02), 20MG ($0.02), 40MG ($0.02) TABLET
PROTAMINE SULFATE
50MG INJECTION - 5ML VIAL ($6.97)
(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 ($1.77)
(Note: May not be given KOP.)

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: May not be given KOP.)

PZA see PYRAZINAMIDE

QUESTRAN LIGHT® see CHOLESTYRAMINE

QVAR® see BECLOMETHASONE

RALTEGRAVIR (Max 11 refills)
ISENTRESS®
400MG TABLET ($17.57)
(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 ($0.02)

REGLAN® see METOCLOPRAMIDE HCL

REMICADE® see INFliximab
RENAGEL® 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 RBAVIRIN

RIBAVIRIN (Max 11 refills)
RIBASPHERE®
200MG CAPSULE ($0.48)
(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 utmbcmcreummKNOWNEMAIL for UTMB units and Utilization Management at (806)356-5350 for TTUHSC units.)

RIFABUTIN (Max 11 refills)
MYCOBUTIN®
150MG CAPSULE ($16.21)
(Note: May not be given KOP.)

RIFADIN® see RIFAMPIN

RIFAMPIN (Max 11 refills)
RIFADIN®
300MG CAPSULE ($0.48)
(Note: May not be given KOP.)

RILPIVIRINE (Max 11 refills)
EDURANT
25MG TABLET ($24.00)
(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: New intake patient currently prescribed Edurant or Complera at intake.)
RINGERS INJECTION, LACTATED see LACTATED RINGERS

Risperdal® see Risperidone

**Risperidone** (Max 11 refills)

**Risperdal®**
- 0.5MG TABLET ($0.06)
  (Note: May not be given KOP. Restricted to TJJD.)
- 1MG ($0.07), 2MG ($0.08), 3MG ($0.09), 4MG ($0.11) TABLET
  (Note: May not be given KOP.)

Ritalin® see methylphenidate

Ritalin LA® see methylphenidate

**Ritonavir** (Max 11 refills)

**NORVIR®**
- 100MG TABLET ($8.02)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

Robaxin® see methocarbamol

Rocaltral® see calcitriol

Rocephin® see ceftriaxone

Romazicon® see flumazenil

**Salicylic Acid**

**Compound W®, Duofilm®**
- 17% TOPICAL SOLUTION - 0.3 OZ ($4.73)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

Saline solution - see soft contacts saline solution

Saline see sodium chloride

Salt Water Gargle see sodium chloride gargle

Santyl® see collagenase
SAQUINAVIR (Max 11 refills)
INVIIRASE®
  500MG TABLET ($7.65)
  (Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

SELENIUM SULFIDE
SELSUN®
  2.5% SUSPENSION - 120ML ($8.57)
  (Note: Orders should be written for 1 bottle to last 90 days.)

SELSUN® see SELENIUM SULFIDE

SERTRALINE (Max 11 refills)
ZOLOFT®
  25mg ($0.03), 50MG ($0.04), 100MG TABLET ($0.05)
  (Note: May not be given KOP.)

SEVELAMER (Max 11 refills)
RENADEL®
  800MG TABLET ($4.98)
  (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 ($33.44/BOX)
  (Note: Clinic use only. Take from stock. May not be given KOP.)

SILVER SULFADIAZINE
SILVADENE®
  1% CREAM - 50GM ($9.17), 400GM ($38.57)
  (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 ($1.36/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 ($15.75), 2MG ($31.50) TABLET  
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

SMZ/TMP see SULFAMETHOXAZOLE/TRIMETHOPRIM

SOAKING SOLUTION see CONTACT LENS CARE PRODUCTS

SODIUM BICARBONATE  
SODIUM BICARBONATE  
1mEq/ML INJECTION (8.4%) - 50ML SYRINGE ($4.98)  
(Note: Clinic use only. Take from stock. May not be given KOP.)

SODIUM CHLORIDE  
0.45% INJECTION - 1000ML ($1.20)  
0.9% INJECTION – 100ML ($1.08), 250ML ($0.70)  
500ML ($0.78), 1000ML ($1.00)  
0.9% MINI-BAG – 100ML ($2.34)  
0.9% IRRIGATION SOLUTION - 250ML ($1.04)  
0.9% BACTERIOSTATIC INJECTION - 30ML VIAL ($0.74)  
0.9% BACTERIOSTATIC FREE INJ - 10ML VIAL ($0.60)  
0.9% INHALANT SOLUTION - 3ML VIAL ($0.09)

OCEAN® (Max 2 refills)  
NASAL SPRAY - 45ML ($0.58)

MURO 128® (Max 11 refills)  
2% OPHTHALMIC SOLUTION - 15ML ($11.23)  
5% OPHTHALMIC SOLUTION - 15ML ($3.65)  
5% OPHTHALMIC OINTMENT - 3.5GM ($4.00)

GARGLE  
PACKETS - 1000/BOX ($2.08/box)  
(Note: Injection, irrigating solution, bags, and inhalation are for clinic use only, should be taken from stock, and may not be given KOP. Gargle should be taken from stock.)

SODIUM PHOSPHATE  
FLEET'S® ENEMA  
ENEMA - 133ML ($0.71)  
(Note: Take from stock.)

SOFT CONTACT PRODUCTS see CONTACT LENS CARE PRODUCTS

SOLU-CORTEF® see HYDROCORTISONE SODIUM SUCCINATE
SOLU-MEDROL® see METHYLprednisolone Sodium Succinate

SOTALOL (Max 11 refills)
BETAPACE®
  80MG ($0.10), 120MG ($0.11), 160MG ($0.14) TABLET

SPIRIVA® HANDIHALE see Tiotropium

SPIRONOLACTONE (Max 11 refills)
ALDACTONE®
  25MG TABLET ($0.07)

STADOL® see Butorphanol Tartrate

STANNOUS FLUORIDE
GEL-KAM®
  0.4% GEL – 4.3OZ ($10.27)

STAVUDINE (D4T) (Max 11 refills)
ZERIT®
  20MG ($0.76), 30MG ($0.83), 40MG ($0.67) CAPSULE
(Nota: Allowed KOP at 8-hour units, may not be given KOP at all other units. 20mg dose usually reserved for dialysis patients or patients with renal impairment.)

STELAZINE® see trifluoperazine HCl

STRATTERA see Atomoxetine

STRIIBILD® see elvitegravir/cobicistat/emtricitabine/tenofovir

SUDAFED-PE® see Phenylephrine

SULAMYD® see Sulfacetamide Sodium

SULFACETAMIDE SODIUM
SULAMYD®
  10% OPHTHALMIC SOLUTION - 15ML ($13.34)

SULFADIAZINE (Max 11 refills)
MICROSULFON®
  500MG TABLET ($3.36)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

409
SULFAMETHOXAZOLE/TRIMETHOPRIM (Max 11 refills, tablets only)

BACTRIM® DS
SMZ 800MG/TMP 160MG DOUBLE STRENGTH TABLET ($0.09)
SMZ 400MG/TMP 80MG per 5ML INJECTION - 10ML VIAL ($4.21)

IV Preparation Standard:
5mL in 150mL 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 ($0.06)

SUNSCREEN

SUNSCREEN
SPF 30 LOTION - 240ML ($2.61)
(Note: One bottle must last 90 days. May be supplied as a different size depending on product availability.)

SURGILUBE® see LUBRICANT, SURGICAL

SUSTIVA ® see EFAVIRENZ

SYMMETREL® see AMANTADINE HCL

SYNTHROID® see LEVOTHYROXINE SODIUM

TACROLIMUS (Max 11 refills)

PROGRAF®
0.5 MG ($0.95), 1MG ($1.90), 5MG ($9.20) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

TAPAZOLE® see METHIMAZOLE

TDaP see TETANUS/DIPHTHERIA/ACELULAR PERTUSSIS

TDF see TENOFOVIR

TEGRETOL® see CARBAMAZEPINE

TEMOVATE® see CLOBETASOL

TENEX® see GAUNFACTINE
TENIVAC™ see TETANUS & DIPHTHERIA TOXOIDS

TENOFVIR (TDF) (Max 11 Refills)
  VIREAD®
    300MG TABLET ($27.22)
    (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 ($0.07), 2MG ($0.07), 5MG ($0.07), 10MG ($0.07) CAPSULE

TERBUTALINE SULFATE
  BRETHINE®
    1MG/ML INJECTION - 1ML VIAL ($1.06)
    (Note: Clinic use only. Take from stock. May not be given KOP. Use restricted to female patients at Carol Young and Crain facilities.)

TETANUS/DIPHTHERIA TOXOIDS
  D-T TOXOIDS, TENIVAC™
    0.5ML SINGLE DOSE VIAL ($14.83)
    (Note: Clinic use only. Take from stock. May not be given KOP. Follow Infection Control P&P for selecting patients. Criteria include:
    a. ≤ 18 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 (TdP)
  BOOSTRIX®
    0.5ML SINGLE DOSE VIAL ($35.17)
    (Note: May not be given KOP. Clinic use only. Floor stock restricted to the Carol Young facility. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: Post-partum female who has been accepted into the Baby and Mother Infant Bonding Initiative (BAMBI) program.)

TETRAHYDROZOLINE HCL
  VISINE®
    0.05% OPHTHALMIC SOLUTION - 15ML ($1.00)
THIAMINE HCL (VITAMIN B-1) (Max 11 refills, tablet only)
100MG TABLET ($0.01)
100MG/ML - 2ML VIAL ($5.38)
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

THIOTHIXENE (Max 11 refills)
NAVANE®
2MG ($0.63), 5MG ($0.96), 10MG ($1.67) CAPSULE
(Note: May not be given KOP.)

THORAZINE® see CHLORPROMAZINE HCL

TIMOLOL MALEATE (Max 11 refills)
TIMOPTIC®
0.5% OPHTHALMIC SOLUTION - 5ML ($3.24)

TINACTIN® see TOLNAFTATE

TIOTROPIUM (Max 11 refills)
SPIRIVA® HANDIHALER
18MCG CAPSULE, 30/BOX ($275.78/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 Severe COPD
c. Classified as Very severe COPD)

TIVICAY® see DOLUTEGRAVIR

TOBRAMYCIN
TOBREX®
0.3% OPHTHALMIC SOLUTION - 5ML ($2.25)
40MG/ML INJECTION – 2ML VIAL ($0.65)
(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% SOLUTION - 10ML ($2.01)
1% CREAM - 15GM ($1.11)

t-PA (TISSUE-TYPE PLASMINOGEN ACTIVATOR) see ALTEPLASE

TRAZODONE HCL (Max 11 refills)
DESYREL®
50MG ($0.02), 100MG ($0.03) TABLET
(Note: May not be given KOP.)

TRI-CHLOR® see TRICHLOROACETIC ACID

TRIAMCINOLONE
KENALOG®
0.025% OINTMENT - 15GM ($3.37)
0.025% CREAM - 15GM ($2.11)
0.1% CREAM - 15GM ($2.47)
10MG/ML INJECTION - 5ML VIAL ($10.33)
40MG/ML INJECTION - 1ML VIAL ($8.00)
KENALOG IN ORABASE®
0.1% DENTAL PASTE – 5GM ($40.78)
(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 ($0.17)

TRICHLOROACETIC ACID
TRI-CHLOR®
80% SOLUTION – 15ML ($52.62)
(Note: Clinic use only. Take from stock. May not be given KOP.)

TRIFLUOPERAZINE HCL (Max 11 refills)
STELAZINE®
2MG ($0.76), 5MG ($0.96), 10MG ($1.44) TABLET
(Note: May not be given KOP.)

TRIFLURIDINE
VIROPTIC®
1% OPHTHALMIC SOLUTION - 7.5ML ($109.25)
TRILAFON® see PERPHENAZINE

TRIMETHOPRIM/POLYMyxIN B
POLYTRIM®
1MG/10,000U OPHTHALMIC SOLUTION - 10ML ($2.86)

TRUSOPT® see DORZOLAMIDE

TUBERCULIN INJECTION (PURIFIED PROTEIN DERIVATIVE)
PPD, APLISOL®
10TESTS/1ML INJECTION - 1ML VIAL ($35.79)
50TESTS/5ML INJECTION - 5ML VIAL ($132.64)
(Note: Clinic use only. Take from stock. May not be given KOP.)

TUCKS® OINTMENT see HEMORRHoidal OINTMENT

TYLENOL® see ACETAMINOPHEN

TYLENOL® W/CODEINE see ACETAMINOPHEN/CODEINE

TYLENOL #3® see ACETAMINOPHEN WITH CODEINE

ULIPRISTAL
ELLA®
20MG TABLET ($32.95)
(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.)

URECHOLINE® see BETHANECOL

VALIUM® see DIAZEPAM

VANCOCIN® see VANCOMYCIN HCL

VANCOMYCIN HCL
VANCOCIN®
1G INJECTION VIAL ($2.41)
IV Preparation Standard:
<500mg in 100mL D5W over 60-90 minutes
>500mg in 150mL D5W over 90-120 minutes.
(Note: Recommended dosage is 1gm Q12 Hours in patients with normal renal function. Clinic use only. Take from stock. May not be given KOP.)
VARICELLA VACCINE (Max 1 refill)

VARIVAX®
1350 PFU/0.5ML – VIAL ($100.69)
(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. 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 Preventive Medicine
  b. ≤ 18 years old without documentation of previous disease or immunization)

VASELINE® JELLY see PETROLATUM

VASOPRESSIN

PITRESSIN®
20U/ML – 1ML VIAL ($3.51)
(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to regional medical facilities.)

VEETIDS® see PENICILLIN VK

VENLAFAXINE HCL (Max 11 refills)

EFFEXOR® XR
75MG ($0.16), 150MG ($0.19) EXTENDED RELEASE CAPSULE
(Note: May not be given KOP. Restricted to TJJD only.)

VENOFER® see IRON SUCROSE

VENTOLIN® see ALBUTEROL SULFATE

VERAPAMIL HCL (Max 11 refills, tablet & caplet)

CALAN®
80MG ($0.10), 120MG ($0.12) IMMEDIATE RELEASE TABLET
2.5MG/ML INJECTION - 2ML VIAL ($23.21)
CALAN SR®
180MG ($0.17), 240MG ($0.16) SUSTAINED RELEASE CAPLET
(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

VICKS VAPORUB® see CAMPHOR/EUCALYPTUS/MENTHOL

VICTRELIS® see BOCEPRAVIR

VIDEX-EC® see DIDANOSINE
VIRACEPT® see NELFINAVIR
VARAMUNE® see NEVIRAPINE
VIREAD® see TENOFOVIR
VIOPTIC® 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 ($0.07)
   (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

WARFARIN SODIUM (Max 11 refills)
   COUMADIN®
   2.5MG TABLET ($0.09)
   (Note: May not be given KOP.)

WATER FOR INJECTION
   WATER FOR INJECTION, STERILE - 10ML ($0.77)
   WATER FOR INJECTION, BACTERIOSTATIC - 30ML ($0.89)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

WATER FOR IRRIGATION
   WATER FOR IRRIGATION, STERILE – 250ML ($1.25)
   (Note: Clinic use only. Take from stock. May not be given KOP.)

WELLCOVORIN® see LEUCOVORIN CALCIUM
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<th>Brand Name</th>
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<td>(AZT, ZDV) Max 11 refills</td>
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<td>RETROVIR®</td>
<td>300MG TABLET ($0.27)</td>
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<td></td>
<td>(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)</td>
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<tr>
<td>ZIPRASIDONE HCL</td>
<td>Max 11 refills, capsule</td>
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<td>GEODON®</td>
<td>20MG ($1.29), 40MG ($1.29), 60MG ($1.51), 80MG ($1.51) CAPSULE</td>
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<td>(Note: May not be given KOP. Restricted to TJJD. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: a. Intolerance to risperidone. b. Treatment failure on risperidone. c. Contraindication to risperidone. d. BMI ≥ 90th percentile.)</td>
</tr>
<tr>
<td>ZIPRASIDONE MESYLATE</td>
<td>GEODON®</td>
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<tr>
<td></td>
<td>20MG/ML – 1ML VIAL ($17.46)</td>
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<td>(Note: Clinic use only. Take from stock. May not be given KOP. See the Acute Psychosis pathway for injection dosing recommendations.)</td>
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<td>ZITHROMAX®</td>
<td>see AZITHROMYCIN</td>
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WETTING & SOAKING SOLUTION® see CONTACT LENS PRODUCTS

XALATAN® see LATANOPROST

XYLOCAINE® see LIDOCAINE HCL

ZANTAC® see RANITIDINE

ZAROXOLYN® see METOLAZONE

ZDV see ZIDOVUDINE

ZEMPLAR® see PARICALCITOL

ZERIT® see STAVUDINE

ZESTRIL® see LIXISINOPRIL

ZIAGEN® see ABACAVIR
ZOVIAM® see ETHYLODIOL DIACETATE/ETHINYL ESTRADIOL

ZOVIARAX® see ACYCLOVIR

ZYLOPRIM® see ALLOPURINOL
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.

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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

04:04.92 Miscellaneous Derivatives
cyproheptadine

04:08 Second Generation Antihistamines
loratadine

ANTI-INFECTIVES

08:00 Antibacterials

08:12 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
erythromycin
Penicillins

Natural Penicillins
penicillin G benzathine
penicillin G potassium
penicillin VK

Penicillinase-Resistant Penicillins
dicloxacillin
nafcillin

Aminopenicillins Penicillins
amoxicillin
ampicillin

08:12.18 Quinolones
ciprofloxacin

08:12.20 Sulfonamides
sulfadiazine
sulfamethoxazole/trimethoprim
sulfasalazine

08:12.24 Tetracyclines
minocycline

08:12.28 Miscellaneous Antibacterials
cimidamycin
vancomycin

08:14 Antifungals
08:14.08 Azoles
fluconazole

08:14.28 Polyenes
nystatin

08:16 Antimycobacterial Agents
08:16.04 Antituberculosis Agents
ethambutol
isoniazid
pyrazinamide
rifabutin
rifampin
08:16.92 Miscellaneous Antimycobacterials
dapsone

08:18 Antivirals
08:18.04 Adamantanes
amantadine

08:18.08 Antiretroviral Agents
Integrase Inhibitor
raltegravir

Integrase Strand Transfer Inhibitor
dolutegravir
evlitegravir/Cobicistat/Emtricitabine/Tenofovir

Nucleoside reverse transcriptase inhibitors
abacavir
didanosine
lamivudine
stavudine
zidovudine

Nucleotide reverse transcriptase inhibitors
tenofovir

Non-nucleoside reverse transcriptase inhibitors
efavirenz
nevirapine
rilpivirine

Protease Inhibitors
atazanavir
darunavir
fosamprenavir
indinavir
lopinavir/ritonavir
nefivinavir
ritonavir
saquinavir

08:18.20 Interferons
peginterferon alfa-2b
08:18.32 Nucleosides and Nucleotides
acyclovir
entecavir
ribavirin

08:18.40 HCV Protease Inhibitors
bocepravir

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
bethanecol
physostigmine

12:08 Anticholinergic Agents
12:08.04 Antiparkinson Agents
benztropine

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

20:12.20 Thrombolytic Agents
alteplase

20:16 Hematopoietic Agents
epoetin alfa

20:28 Antihemorrhagic Agents
20:28.08 Antiheparin Agents
protamine

24:00 CARDIOVASCULAR DRUGS
24:04 Cardiac Drugs
24:04.04 Antiarrhythmic Agents
adenosine
amiodarone

24:04.08 Cardiotonic Agents
digoxin

24:06 Antilipemic Agents
24:06.04 Bile Acid Sequestrants
cholestyramine

24:06.06 Fibrin Acid Derivative
gemfibrozil
24:06.08 HMG-CoA Reductase Inhibitor (Statins)
   atorvastatin
   pravastatin

24:06.92 Miscellaneous
   Niacin

24:08 Hypotensive Agents
24:08.16 Central Alpha Agonists
   clonidine
   guanfacine
   methyldopa

24:08.20 Direct Vasodilators
   hydralazine
   minoxidil

24:12 Vasodilating Agents
24:12.08 Nitrates and Nitrites
   isosorbide mononitrate
   nitroglycerin

24:12.92 Miscellaneous Vasodilating Agents
   dipyridamole

24:20 Alpha-Adrenergic Blocking Agents
   terazosin

24:24 Beta-Adrenergic Blocking Agents
   atenolol
   carvedilol
   labetalol
   metoprolol
   propranolol
   sotalol

24:28 Calcium-Channel Blocking Agents
24:28.08 Dihydropyridines
   amlodipine

24:28.92 Miscellaneous Calcium-Channel Blocking Agents
   diltiazem
   verapamil

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### Renin-Angiotensin-Aldosterone System Inhibitors

#### Angiotensin-Converting Enzyme Inhibitors
- lisinopril

#### Mineralcorticoid (Aldosterone) Receptor Antagonists
- spironolactone

### CENTRAL NERVOUS SYSTEM AGENTS

#### Analgesics and Antipyretics

##### Nonsteroidal Anti-Inflammatory Agents
- Acetylated salicylates
  - aspirin
- Propionic Acids
  - ibuprofen
  - naproxen
- Oxicams
  - meloxicam

##### Opiate Agonists
- acetaminophen / codeine
- fentanyl
- morphine

##### Opiate Partial Agonists
- butorphanol

##### Miscellaneous Analgesics & Antipyretics
- acetaminophen

#### Opiate Antagonists
- naloxone

#### Anticonvulsants

##### Barbiturates
- primidone

##### Hydantoins
- phenytoin
Miscellaneous Anticonvulsants
- Carbamazepine
- Divalproex sodium
- Levetiracetam
- Magnesium sulfate

28:16 Psychotherapeutic Agents
28:16.04 Antidepressants
Selective Serotonin & Norepinephrine Reuptake Inhibitors
- Venlafaxine

Selective Serotonin Reuptake Inhibitors
- Citalopram
- Fluoxetine
- Sertraline

Serotonin Modulators
- Trazodone

Tricyclics and Other Norepinephrine Reuptake Inhibitors
- Imipramine
- Nortriptyline

28:16.08 Antipsychotics
Atypical Antipsychotics
- Aripiprazole
- Clozapine
- Risperidone
- Ziprasidone

Typical Antipsychotics
- Chlorpromazine
- Fluphenazine
- Haloperidol
- Perphenazine
- Thiothixene
- Trifluoperazine

28:20 Anorexigenic Agents and Respiratory & Cerebral Stimulants
28:20.04 Amphetamines
- Amphetamine salts
- Methylphenidate
28:20.92 Miscellaneous
ammonia

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

36:00 DIAGNOSTIC AGENTS
36:58 Ocular
fluorescein strips

36:84 Tuberculosis
tuberculin PPD

40:00 ELECTROLYTIC, CALORIC & WATER BALANCE
40:08 Alkalinizing Agents
sodium bicarbonate

40:10 Ammonia Detoxicants
lactulose
Replacement Preparations
- calcium carbonate
- calcium gluconate
- dextrose / lactated ringers
- potassium chloride
- ringers-lactated
- sodium chloride

Ion-removing Agents
Potassium-Removing Agents
- polystyrene sodium sulfonate

Phosphate-Removing Agents
- sevelamer

Caloric Agents
- dextrose
- enteral feeding

Diuretics
- Loop Diuretics
  - furosemide

  - Potassium-sparing diuretics
    - triamterene / hydrochlorothiazide

  - Thiazide Diuretics
    - hydrochlorothiazide

  - Thiazide-like Diuretics
    - metolazone

Irrigating Solutions
- sodium chloride
- sterile water

Uricosuric Agents
- probenecid
52:00 EYE, EAR, NOSE, & THROAT (EENT) PREPARATIONS

52:04 Anti-Infectives

52:04.04 Antibacterials
bacitracin / polymyxin ophth
erythromycin ophth
gentamicin ophth
neomycin / polymyxin / bacitracin ophth
neomycin / polymyxin / bacitracin / hydrocortisone ophth
neomycin / polymyxin / dexamethasone ophth
neomycin / polymyxin / gramicidin ophth
neomycin / polymyxin / hydrocortisone otic
sulfacetamide ophth
tobramycin ophth
trimethoprim / polymyxin ophth

52:04.20 Antivirals
trifluridine ophth

52:04.92 Miscellaneous Anti-Infectives
acetic acid / aluminum acetate otic
carbamide peroxide otic
chlorhexidine

52:08 Anti-Inflammatory Agents

52:08.03 Corticosteroids
prednisolone ophth

52:08.20 Nonsteroidal Anti-inflammatory Agents
flurbiprofen ophth

52:12 Contact Lens Solutions
contact lens enzymatic solution
contact rewetting and lubricant solution
gas permeable lens multi-action solution
soft contact lens multi-purpose solution

52:16 Local Anesthetics
antipyrine / benzocaine otic
benzocaine (orabase)
lidocaine viscous
proparacaine ophth
52:24 **Mydriatics**
atropine ophth
cyclopentolate ophth

52:28 **Mouth Washes & Gargles**
hydrogen peroxide

52:32 **Vasoconstrictors**
naphazoline / pheniramine 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**
acetzolamide
dorzolamide ophth

52:40.28 **Prostaglandin Analogs**
latanoprost

52:92 **Miscellaneous EENT Drugs**
lubricant ophth oint
methylcellulose ophth
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

56:16 **Digestants**
  lipase / protease / amylase (pancrelipase)

56:22 **Antiemetics**
  56:22.08 **Antihistamines**
  meclizine
  prochlorperazine

56:28 **Antiulcer Agents and Acid Suppressants**
  56:28.12 **Histamine H2-Antagonists**
  ranitidine

  56:28.36 **Proton-pump Inhibitors**
  omeprazole

56:32 **Prokinetic Agents**
  metoclopramide
HORMONES & SYNTHETIC SUBSTITUTES

Adrenals
dexamethasone
hydrocortisone
methylprednisolone
prednisone
triamcinolone

Contraceptives
ethynodiol diacetate / ethinyl estradiol
norethindrone / ethinyl estradiol
norgestrel / ethinyl estradiol
ulipristal

Estrogen

Conjugated estrogens

Antidiabetic Agents

Biguanides
metformin

Insulins
insulin, human - NPH
insulin, human – regular
insulin, human – 70/30

Sulfonylureas
glipizide

Antihypoglycemic Agents

Glycogenolytic Agents
glucagon

Pituitary
desmopressin
vasopressin

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
  rh(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 polysaccharide 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
   alcohol, ethyl
   selenium sulfide
   silver sulfadiazine

84:06 Anti-Inflammatory Agents
   clobetasol propionate
   fluocinonide
   hydrocortisone
   mometasone furoate
   triamcinalone
   triamcinalone/orabase

84:08 Antipruritics & Local Anesthetics
   lidocaine
   phenazopyridine
   pramoxine/zinc oxide (hemorrhoidal)

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
   absorbase

84:28 Keratolytic Agents
   benzoyl peroxide
   podophyllum resin
   salicylic acid

84:32 Keratoplastic Agents
   coal tar

84:80 Sunscreen Agents
   sunscreen, SPF 30

435
84:92 Miscellaneous
collagenase
lubricant, surgical
podoflox
phenylephrine suppositories (hemorrhoidal)
trichloroacetic acid

86:00 SMOOTH MUSCLE RELAXANTS
86:12 Genitourinary Smooth Muscle Relaxants
oxybutynin

88:00 VITAMINS
88:08 Vitamin B Complex
cyanocobalamin
folic acid
nephro-vite
pyridoxine
thiamine

88:16 Vitamin D
calcitriol
doxercalciferol
paricalcitol

88:24 Vitamin K
phytonadione

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
Disease-modifying Antirheumatic Drugs
infliximab

Immunosuppressive Agents
azathioprine
cyclosporine
mycophenolate mofetil
sirolimus
tacrolimus

Other
melatonin

PHARMACEUTICAL AIDS
glucose tolerance test
petrolatum jelly