

CMC FORMULARY

22ND EDITION
2016



**CORRECTIONAL
MANAGED CARE**

FORMULARY

22nd Edition

2016

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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UNIT RESTRICTION LIST FOR FLOOR STOCK PURPOSES

Dialysis Units:	GC, E2, HP
Female Units:	BB, GC, GR, GV, HB, HT, LC, LJ, LM, LT, MV, N1, N2, SV, T1, WM, XQ, County Jails
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, XM, XN, SAFP facilities, State Jails, County 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, XQ
State Jails:	AJ, BH, BJ, BL, BX, CL, FB, HF, HJ, HM, LJ, LN, LT, RL, RZ, TI, WI, WM, WR
County Jails:	A1, A2, A3
Hospital Galveston:	No P-list restrictions. All medications administered from stock.

SAFP = Substance Abuse Felony Punishment

CONVERSIONS AND CALCULATIONS

WEIGHT MEASURE	LIQUID MEASURE
1 kg (kilogram) = 1000 gm (grams) 1 gm = 1000 mg (milligrams) 1 mg = 1000 mcg or μg (micrograms)	METRIC=APOTHECARY 1 mL (milliliter) = 1 cc 30 mL = 1 oz 15 mL = 1/2 oz 15 mL = 1 tablespoon (tbsp.) 5 mL = 1 teaspoon (tsp.) 2.5 mL = 1/2 tsp. 960 mL = 1 quart 1 L (liter) = 1000 mL (milliliters)
METRIC=APOTHECARY 60 mg or 65 mg = 1 gr (grain) 125 mg = 2 gr 200 mg = 3 gr 300 mg or 325 mg = 5 gr 600 mg or 650 mg = 10 gr 0.4 mg or 400 mcg = 1/150 gr 0.6 mg 600 mcg = 1/100 gr 15 gm = 1/2 oz 30 gm = 1 oz 60 gm = 2 oz 240 gm = 8 oz = 1/2 lb 480 gm = 16 oz = 1 lb 1 kg = 2.2 lb (pounds)	

To convert from grams to milligrams multiply by 1000, milligrams to grams \div by 1000

To convert from kilograms to pounds multiply by 2.2, pound to kilograms \div by 2.2

To convert from grains to milligrams multiply by 60, milligrams to grains \div 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? $60 \times 5 = 300$ divided by 100 = 3 mL

Formula for Calculating Drip Rate of IV Fluids:

$\frac{\text{total volume}}{\text{total hours}} = \text{mL/hr}$ Example: $\frac{1000 \text{ mL}}{8 \text{ hr}} = 125 \text{ mL/hr}$

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

Example: $\frac{125 \text{ mL/hr} \times 10 \text{ gtts/mL}}{60 \text{ min}} = \frac{125 \times 10}{60} = \frac{1250}{60} = 20.8$ or 21 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 Hospital Galveston.

Non-formulary approval at the unit level is obtained by completing an electronic non-formulary request form and forwarding it to the assigned clinical pharmacist for a consultation. If the unit

provider disagrees with the clinical pharmacist's recommendation, approval may be requested from the Regional Medical Director. Non-formulary procedures for UTMB clinic/discharge patients can be found under subsection NON-FORMULARY APPROVAL PROCESS FOR DISCHARGE /CLINIC PATIENTS.

OVERVIEW OF HOSPITAL GALVESTON PROCESS

Offenders transferring from Hospital Galveston (HG) to Texas Department of Criminal Justice (TDCJ) units will have all active medication orders entered into the Pearl 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 utmbcmc.pharmacyHG@utmb.edu for an advanced approval for non-formulary medications that will need to be continued at the unit level.

NON-FORMULARY APPROVAL PROCESS/UNIT LEVEL

The unit practitioner is responsible for evaluating the patient and determining if the medication needs to be continued beyond 10 days. If the HG physician obtained advanced approval for a non-formulary medication, a copy of the approval will be sent to the TDCJ facility. If an approval was not obtained, the TDCJ facility will submit a non-formulary request using the usual procedure.

MEDICATION NOT RECEIVED FROM HOSPITAL GALVESTON

If the patient arrives at the unit **without non-formulary medications**, unit personnel should re-enter the non-formulary medication for 10 days with no refills into the system & **TYPE “HG-SEND”** in the SPECIAL INSTRUCTIONS field. This will trigger the CMC pharmacist to allow an automatic 10-day approval of the non-formulary medication and the order will be sent. This will also give providers additional time to assess the patient and request non-formulary approval for the continuation of therapy if needed.

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

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

PAROLE AND DISCHARGE PATIENTS

If a patient is to directly 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 and telephone number
 - c. Prescriber
 - d. Patient name, number, allergies, and date of birth
 - e. Medication requested including strength, dosage form, quantity, and directions for use.
 - f. Indication (diagnosis) for medication
 - g. Rationale for urgent need
 - h. Texas Tech Unit - Source of purchase (i.e., outside pharmacy) including company name, contact person and telephone number

3. The pharmacist will review the request and provide an alternative recommendation if applicable. If a formulary alternative is not available and the need is urgent as determined by a practitioner, the Pharmacist will authorize a purchase from an outside pharmacy.
 - 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. One package (e.g., eye drop, inhaler, bottle) may be approved for medications that come in unbreakable packaging.
 - 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. The On-call Pharmacist will approve a 5-day supply or up to a 7-day supply of medication for holiday weekends. One package (e.g., eye drop, inhaler, bottle) may be approved for medications that come in unbreakable packaging.
 - 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

- 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

manufacturer of a product under review for formulary inclusion or exclusion

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

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

included in the special instructions field of the medication order. All other uses require non-formulary approval.

5. Non-formulary Agents – Medications not included in the CMC Formulary. Approval must be obtained 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. Each agency reserves the right to limit the number of industry vendors that any single company has visiting a facility.
 - C. Industry vendors are not permitted inside facilities without permission from the agency Medical Directors or their designee (see VII for designees). Industry vendors shall be accompanied by authorized personnel at all times.
 - D. Industry vendors are prohibited from entering patient care areas for promotional purposes.
 - E. Industry vendors shall not attend programs or meetings in which specific patients are discussed or when quality assurance or risk management issues are presented.
 - F. Security
 - 1. Industry vendors must observe all security precautions on a facility being visited.
 - 2. Security precautions may vary depending on the facility.
 - 3. Representatives must have a driver's license with picture identification to enter a facility.
- VII. Educational Activities
 - A. Exhibits by pharmaceutical 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
(§35.05)

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

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

PROCEDURE:

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

- II. Some medications cannot or should not be crushed (Attachment A: Tables 1 and 2).
 - A. Medications not suitable for crushing include:
 1. Medications surrounded by a protective coating (e.g., enteric-coated).
 2. Medications formulated to provide delayed or continuous release of active ingredients. Many dosage forms can be identified by abbreviations such as TR (timed release), SA (sustained action), SR (sustained release), ER (extended release), CR (controlled release), LA (long acting), and XL or XR (extended release).
 3. Medications designed to be absorbed in the mouth or to have a local healing effect (e.g., lozenges, 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

PRODUCT	DOSAGE	COMMENTS/REASON
Alendronate (Fosamax®)	Tablet	Mucous Membrane Irritant
Aspirin (Ecotrin®, Enseals®)	Tablet	Enteric Coated
Aspirin/Dipyridamole (Aggrenox®)	Capsule	Extended Release
Bisacodyl (Dulcolax®, Correctol®)	Tablet ²	Enteric Coated
Bupropion (Wellbutrin® SR & XL, Budeprion® SR, Buproban®, Zyban®)	Tablet	Extended Release, Anesthetizes Mucosa
Carbamazepine (Tegretol® XR)	Tablet	Extended Release
Ciprofloxacin (Cipro XR®)	Tablet	Extended Release
Clotrimazole (Mycelex® Troches)	Troches ²	Troche
Dabigatran (Pradaxa®)	Capsule	75% Increase Bioavailability
Darifenacin (Enablex®)	Tablet	Extended Release
Didanosine EC (Videx® EC)	Capsule	Enteric Coated
Diltiazem (Dilacor® XR, Cardizem CD®)	Capsule	Extended Release
Divalproex Sodium (Depakote®, Depakote ER)	Tablet	Enteric Coated, Extended Release
Erythromycin (E-Mycin®, Ery-Tab®, E.E.S.®, Eryc®)	Tablet	Enteric Coated
Felodipine (Plendil®)	Tablet	Extended Release
Ferrous Sulfate (Feosol®)	Tablet	Enteric Coated
Finasteride (Proscar®, Propecia®)	Tablet	Film Coated
Fluoxetine (Prozac® Weekly)	Capsule	Delayed Release
Glipizide (Glucotrol® XL)	Tablet	Extended Release
Guaifenesin (Mucinex®)	Tablet	Extended Release
Hyoscyamine (Symax-SR®, Levbid®)	Capsule, Tablet ³	Slow Release
Lithium Carbonate (Eskalith CR®, Lithobid®)	Tablet	Extended Release
Lopinavir/ritonavir 200mg/50mg (Kaletra®)	Tablet	Film Coated
Mesalamine (Asacol®, Lialda®)	Tablet	Enteric Coated
Methylphenidate (Ritalin® SR, Concerta®, Metadate® ER, Methylin® ER)	Tablet	Extended Release
Morphine Sulfate (MS Contin®)	Tablet	Extended Release
Mycophenolate (CellCept®, Myfortic®)	Capsule, Tablet	Mucous Membrane Irritant, Teratogenic, Enteric Coated Tablet
Niacin (Niaspan®)	Tablet	Extended Release
Nifedipine (Adalat CC®, Procardia XL®)	Tablet	Extended Release
Nitroglycerin (Nitrostat® SL)	Tablet ⁴	Sublingual
Oxybutynin (Ditropan® XL)	Tablet	Extended Release
Paliperidone (Invega®)	Tablet	Extended Release
Pantoprazole (Protonix®)	Tablet	Enteric Coated

PRODUCT	DOSAGE	COMMENTS/REASON
Pentoxifylline (Trental®)	Tablet	Extended Release
Phenytoin (Dilantin Kapseals®)	Capsule	Extended Release
Potassium Chloride/Gluconate (Klor-Con®, Slow-K®)	Capsule	Extended Release
Propranolol (Inderal® LA, InnoPran® XL)	Capsule	Extended Release
Ranolazine (Ranexa®)	Tablet	Extended Release
Ritonavir (Norvir®)	Tablet	Decreased Bioavailability
Sevelamer (Renagel®)	Tablet	Tablets expand when exposed to liquid
Sulfasalazine (Azulfidine® EN-tabs®)	Tablet	Enteric Coated
Tamsulosin (Flomax®)	Capsule	Slow Release
Theophylline (Uniphyll®, Theochron®)	Tablet,	Extended Release
Valproic Acid (Depakene®)	Capsule	Slow Release, Mucous Membrane Irritant
Venlafaxine (Effexor XR®)	Tablet	Extended Release

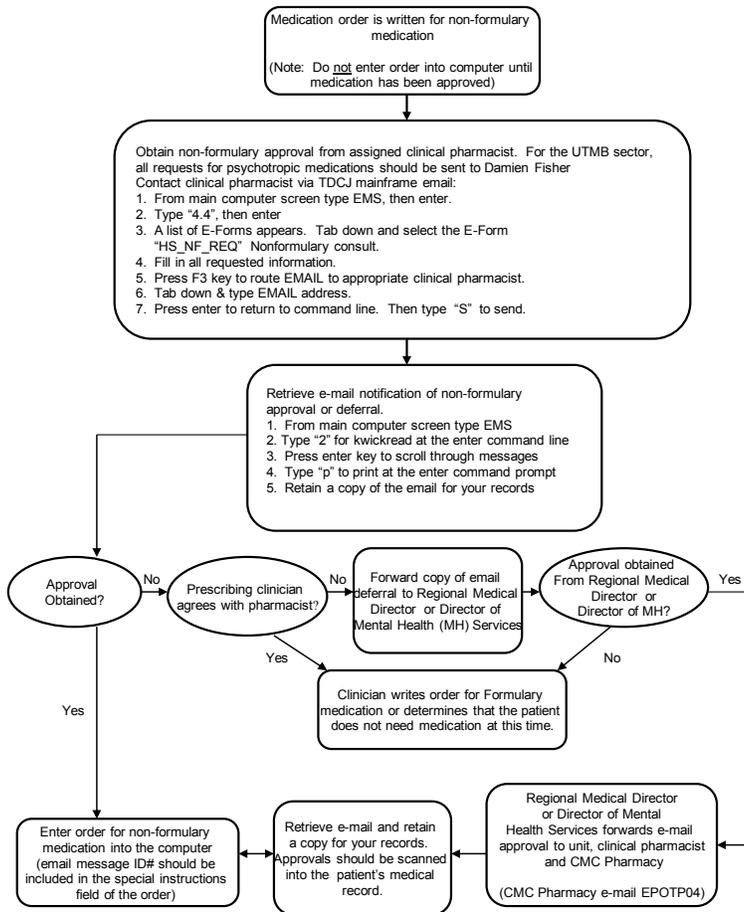
The recommendations are specific to the drug product listed by proprietary name. Other immediate release forms of the drugs listed may be available and can be crushed, opened or chewed. (1) Antacids or milk may prematurely dissolve the coating of the tablet (2) Troches are made to slowly dissolve in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

Table 2: Solid Dosage Forms that Should not be Crushed, Opened or Chewed

PRODUCT	DOSAGE	COMMENTS/REASON
Amphetamine/Dextroamphetamine (Adderall XR®)	Capsule ¹	Extended Release
Atomoxetine (Strattera®)	Capsule	Ocular Irritant
Carbamazepine (Equetro®, Carbatrol®)	Capsule ¹	Extended Release
Dextroamphetamine (Dexedrine Spansule®)	Capsule ¹	Slow Release
Divalproex Sodium (Depakote Sprinkles®)	Capsule ¹	Extended Release
Docosate Calcium/Sodium (Surfak®, Colace®)	Capsule ²	Liquid Filled, Bad Taste
Duloxetine (Cymbalta®)	Capsule ³	Enteric-Coated Pellets
Esomeprazole (Nexium®)	Capsule ¹	Delayed Release
Etravirine (Intelence®)	Tablet ⁴	Do not crush
Ibuprofen (various)	Tablet	Bad Taste
Indinavir (Crixivan®)	Capsule ¹	Bad Taste
Isosorbide Mononitrate (Imdur®)	Tablet ⁵	Extended Release
Isotretinoin (Amnesteem®, Claravis®)	Capsule ²	Mucous Membrane Irritant, Liquid Filled
Lansoprazole (Prevacid®)	Capsule ¹	Delayed Release
Levetiracetam (Keppra®)	Tablet	Bitter Taste
Lisdexamphetamine (Vyvanse®)	Capsule ⁴	Extended Release
Methylphenidate (Metadate CD®, Ritalin LA®)	Capsule ¹	Extended Release
Metoprolol Succinate (Toprol XL®)	Tablet ⁵	Extended Release
Nifedipine (Procardia®)	Capsule ⁶	Liquid Filled
Omeprazole (Prilosec®)	Capsule ¹	Delayed Release
Pancrelipase (Creon®)	Capsule ¹	Enteric Coated
Piroxicam (Feldene®)	Capsule	Mucous Membrane Irritant
Theophylline (Theo-24®)	Capsule ¹	Extended Release
Tipranavir (Aptivus®)	Capsule	Liquid Filled, Taste
Topiramate (Topamax®)	Tablet, Capsule ¹	Bad Taste
Venlafaxine (Effexor XR®)	Capsule ¹	Extended Release
Verapamil (Calan® SR, Isoptin® SR, Verelan® PM, Covera® HS)	Tablet ⁵ , Capsule ¹	Extended Release

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



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).

USE CRITERIA FOR PRIOR AUTHORIZATION AND RESTRICTED AGENTS

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Absorbace (Eucerin®)	RMF or Dialysis
Acetaminophen/Codeine (Tylenol 3®)	Restricted to 21 days. Minimum of 30 days between orders without non-formulary approval.
Adenosine (Adenocard®) injection	EMS or RMF
Albumin, Human (Plasbumin-25®)	RMF for paracentesis
Albuterol (Ventolin®) nebulizer solution	<ul style="list-style-type: none"> • Acute asthma management. Orders should not exceed 7 days. • May be ordered for a maximum of 30 days for COPD
Alteplase (Cathflo Activase®)	Dialysis for catheter restoration
Amiodarone (Cordarone®) injection	EMS or RMF
Aripiprazole (Abilify®)	<p>TJJD only. Prior authorization criteria must be met and include:</p> <ul style="list-style-type: none"> • Intolerance to risperidone and ziprasidone • Treatment failure on risperidone and ziprasidone • Contraindication to risperidone and ziprasidone
Atomoxetine (Strattera®)	<p>TJJD only. Prior authorization criteria must be met and include: ADHD plus</p> <ul style="list-style-type: none"> • 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®)	<ul style="list-style-type: none"> • HIV+ dosed 1200 milligrams q week for MAC primary prophylaxis when CD4 < 50 • Gonorrhea (GC) <ul style="list-style-type: none"> - 1200mg x 1 dose in combination with ceftriaxone 250 mg IM x 1 dose • Pregnant patients <ul style="list-style-type: none"> - Treatment of chlamydia dosed 1200 milligrams x 1 dose
Baclofen (Lioresal®)	<ul style="list-style-type: none"> • Spinal cord injury • Multiple Sclerosis • Muscular dystrophy • Spastic hemiplegia • Amyotrophic lateral sclerosis • Cerebral palsy
Birth control (Low-Ogestrel®, Norinyl®, Zovia®)	Females

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Body Lotion (Lubriscot [®])	<ul style="list-style-type: none"> • Eczema • Dermatitis • Psoriasis • Chronic stasis dermatitis • Ichthyosis • Hyperkeratosis • Dialysis • Burn Scars/Skin Grafts
Ceftazidime (Fortaz [®] , Tazicef [®])	RMF (inpatient use only) or TJJD patient
Ceftriaxone (Rochephin [®])	<ul style="list-style-type: none"> • 250mg - 250mg IM x 1 dose for GC (gonorrhea) in combination with azithromycin 1200 mg x 1 dose • 1 gram – RMF (inpatient use only), Infirmary unit (inpatient use only), and TJJD
Chlordiazepoxide (Librium [®])	Restricted to detoxification for TDCJ and TJJD only.
Ciprofloxacin (Cipro [®])	RMF (inpatient use only)
Clonazepam (Klonopin [®])	<p>0.5mg - County Jails only. Prior authorization criteria must be met and include:</p> <ul style="list-style-type: none"> • New intake, allowed up to 30 days for tapering over to a formulary agent.
Clonidine (Catapres [®])	<ul style="list-style-type: none"> • Hypertensive emergency • Management of opioid withdrawal • Intake to taper
Clopidogrel (Plavix [®])	<ul style="list-style-type: none"> • Intolerant or allergic to aspirin and needs cardioprotection or prevention • Failed aspirin therapy (Event while on aspirin such as MI, stroke, TIA) • Acute coronary syndromes (e.g., MI, unstable angina, or PCI with or without stent placement) and treatment is in combination with aspirin • Brachytherapy • Intermittent claudication and failed trial or remained symptomatic while on aspirin plus dipyridamole • Dialysis vascular graft.
Collagenase (Santyl [®])	Wound care facility
Dextrose 10% Water 1000ml (D10W)	Restricted to Estelle, Michael and Young facilities for use until TPN is available.

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Diazepam (Valium [®])	<ul style="list-style-type: none"> • Spinal Cord Injury • Multiple Sclerosis • Muscular Dystrophy • Spastic Hemiplegia • Amyotrophic Lateral Sclerosis • Cerebral Palsy • County Jails only-Restricted to withdrawal protocol.
Dicyclomine (Bentyl [®])	20mg-County Jails only-Restricted to withdrawal protocol, allowed for up to 7 days.
Doxercalciferol (Hectoral [®])	Dialysis
Elvitegravir – Cobicistat – Emtricitabine – Tenofovir (Genvoya [®])	New intake patient with current therapy
Enteral feeding (Osmolite [®])	RMF and Dialysis
Epinephrine (Epipen [®])	EMS and TJJJ emergency boxes and patients at TJJJ halfway houses
Epoetin Alfa (Procrit [®])	Dialysis
Estrogens (Premarin [®])	Females
Fluconazole (Diflucan [®])	<ul style="list-style-type: none"> • 150mg – single dose for vaginal candidiasis • 100mg & 200mg – HIV-positive patients, for treatment or prevention of opportunistic infections
Flumazenil (Romazicon [®])	Emergency use only
Glucose Tolerance test (Glucola [®])	Diagnostic use in females
Heparin	1,000 U/ML – 30ML: Dialysis
Hepatitis A vaccine (Havrix [®])	<ul style="list-style-type: none"> • 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 [®])	<p>Patient is not immune (P&P B-14.07) plus one of the following</p> <ul style="list-style-type: none"> • 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

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Human Papillomavirus – HPV (Gardasil®)	Females ages 9 through 26 with no previous vaccination.
Hydroxyzine Pamoate (Vistaril®)	Restricted to TJJJ 50mg-County Jails only-Restricted to withdrawal protocol, allowed for up to 7 days.
Influenza vaccine (Flulaval®)	Infection Control P&P B-14.07 <ul style="list-style-type: none"> • ≥ 50 years old • Certain chronic diseases (heart disease, asthma, COPD, diabetes, renal disease, hepatic disease, neurologic disease, and hematologic disease) • Immunosuppressed (including immunosuppression caused by HIV, most cancers, ESRD, sickle cell, medications) • Pregnancy during the influenza season • < 18 years old and on chronic aspirin therapy • Morbidly obese BMI ≥ 40
Imipramine (Tofranil®)	TJJJ for enuresis
Ipratropium bromide (Atrovent®) nebulizer solution	<ul style="list-style-type: none"> • Acute asthma management. Orders should not exceed 7 days. • May be ordered for a maximum of 30 days for COPD
Iron sucrose (Venofer®)	Dialysis
Labetalol injection	EMS use only for treatment of HTN emergencies per protocol
Lidocaine	<ul style="list-style-type: none"> • 2% jelly – emergency use only • 5% ointment – OB/GYN services at GC or GV
Lorazepam (Ativan®) injection	Injection <ul style="list-style-type: none"> • Treatment of acute seizures uncontrolled by other measures. • Short-term treatment of agitation at inpatient psychiatric facilities. 1mg Tablet <ul style="list-style-type: none"> • County Jails only-Restricted to withdrawal protocol.
Medroxyprogesterone (Provera®, Depo-Provera®)	Females
Meningococcal Vaccine (Menomune®, Menactra®)	Anatomic or functional asplenic patients who have no history of prior immunization or require a booster
Meropenem (Merrem®)	RMF (inpatient use only)

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Methocarbamol (Robaxin [®])	One 7 day supply/injury; min. 30 days b/t orders
Miconazole vaginal suppositories (Monistat [®])	Females
MMR vaccine (M-M-R [®] -II)	<ul style="list-style-type: none"> • ≤18 years old without documentation of series completion • Born after 1956 & did not attend public school in Texas • Immigrants that have not completed the series
Morphine sulfate (MS Contin [®])	<ul style="list-style-type: none"> • Elixir and extended release tablets – RMF inpatient or Hospice (may not exceed 21 day supply) • Injection – one time orders for pain associated with acute trauma or severe medical condition
Multivitamin	<ul style="list-style-type: none"> • HIV-positive + CD4 count < 100 + <u>not</u> on enteral feeding • County Jails only-Restricted to withdrawal protocol. Use limited to 10 days.
Nephro-Vite [®]	Dialysis
Nitroglycerin (Nitrobid [®])	Clinic use only for short term relief of angina
Paricalcitol (Zemplar [®])	Dialysis
Penicillin G Benzathine (Bicillin LA [®])	Syphilis
Petrolatum (Vaseline [®])	Phototherapy at E2
Phenobarbital (Luminal [®])	32.4mg-County jails only. Prior authorization criteria must be met and include: <ul style="list-style-type: none"> • New intake, allowed up to 30 days for tapering over to a formulary agent.
Phenytoin (Dilantin [®])	<ul style="list-style-type: none"> • Oral suspension restricted to RMFs • Injection restricted to Emergency Medical Services (EMS).
Pneumococcal vaccine (Pneumovax-23 [®])	<ul style="list-style-type: none"> • Age ≥ 65 years • Certain chronic disease patients (e.g., heart disease, COPD, diabetes) • Patients with disease associated with increased risk (splenic dysfunction, anatomic asplenia, Hodgkin'sDisease, multiple myeloma, cirrhosis, alcoholism, renal failure, CSF leaks) or immunosuppression (HIV, most cancers, sickle cell disorder)
Polio vaccine (Ipo [®])	Patients under 18 years old
Potassium Chloride injection	Infirmiry or RMF
Prenatal vitamins	Pregnancy

Prior Authorization Agent / Restricted Agent	Criteria (Should be typed in Special Instructions)
Rilpivirine (Edurant [®])	New intake patient with current therapy
Sevelamer (Renagel [®])	<ul style="list-style-type: none"> • Chronic kidney disease • Dialysis
Stavudine (Zerit [®]) 20mg	HIV positive + dialysis/renal impairment patients
Surgical lubricant (Surgilube [®]) 4.24 oz tube	RMF
Terbutaline injections (Brethine [®])	Female patients at CYMF and Crain
Tetanus-Diphtheria (Tenivac [™])	<ul style="list-style-type: none"> • ≤ 18 years old without documentation of completion • No history of prior immunization within the last 10 years • Prophylaxis for wound management
Tetanus-Diphtheria-Acellular Pertussis Tdap (Boostrix [®])	<ul style="list-style-type: none"> • Pregnancy • Td booster indicated and not previously vaccinated
Tiotropium 18mcg (Spiriva [®])	<ul style="list-style-type: none"> • Inadequate response to ipratropium 2 puffs QID • Moderate COPD • Severe COPD • Very severe COPD
Ulipristal (Ella [®])	Female unit/patient for emergency contraception
Varicella Vaccine (Varivax [®])	<ul style="list-style-type: none"> • ≤ 18 years old without documentation of previous disease or immunization • Post-exposure prophylaxis with approval from Office of Public Health • HIV positive patients without documented immunity and CD4 count > 200
Vasopressin (Pitressin [®]) injection	RMF

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
Mini-Bag Plus Admixture System <ul style="list-style-type: none"> • Mini-Bag Plus 0.9% NaCl 100mL bag • Mini-Bag Plus D5W 100mL bag 	Ampicillin (NS only) Cefazolin Ceftazidime** Ceftizoxime* Meropenem ** Nafcillin Oxacillin* Penicillin G Potassium
Mini-Bag Vial-Mate Adaptor	Doxycycline* Erythromycin Lactobionate* Vancomycin

NS=normal saline

*Non-formulary approval required

**Restricted to Regional Medical Facilities

Antibiotics that cannot be used with the admixture systems include amphotericin, 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.

Index of Disease Management Guidelines

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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Disease Management Guidelines for Youth

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

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

1

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:
 - The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell transfusion; and
 - Reducing the risk of alloimmunization and/or other red blood cell transfusion-related risks is a goal.
- Transferrin saturation \geq 20%
 (transferrin saturation = serum iron/iron binding capacity)
- Serum ferritin \geq 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

2

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

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

3

Check Hgb at 2 weeks

4

Maintenance Dose

- Titrate dose as needed to maintain Hgb sufficient to:
 - Not exceed 11 g/dL or
 - Not increase Hgb > 2 g/dL during ANY 4 week period.
 - If the 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 (folic 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

Baseline Parameters:	Follow-Up Parameters:
<ul style="list-style-type: none"> •Hgb, Hct, and platelets •CMP (including BUN, uric acid, Cr, Phos and K) •Transferrin saturation and serum ferritin •Blood pressure 	<ul style="list-style-type: none"> •Hgb every 4 weeks with maintenance therapy •Hgb 4 weeks after ANY dose adjustment •Hct and platelets regularly •Transferrin saturation and serum ferritin every 1-3 months. Supplement iron if transferrin saturation < 20% or ferritin < 100 ng/mL •Blood pressure monthly (MUST remain adequately controlled to continue therapy) •CMP regularly (including BUN, uric acid, Cr, Phos, and K)

Table 3: Contraindications

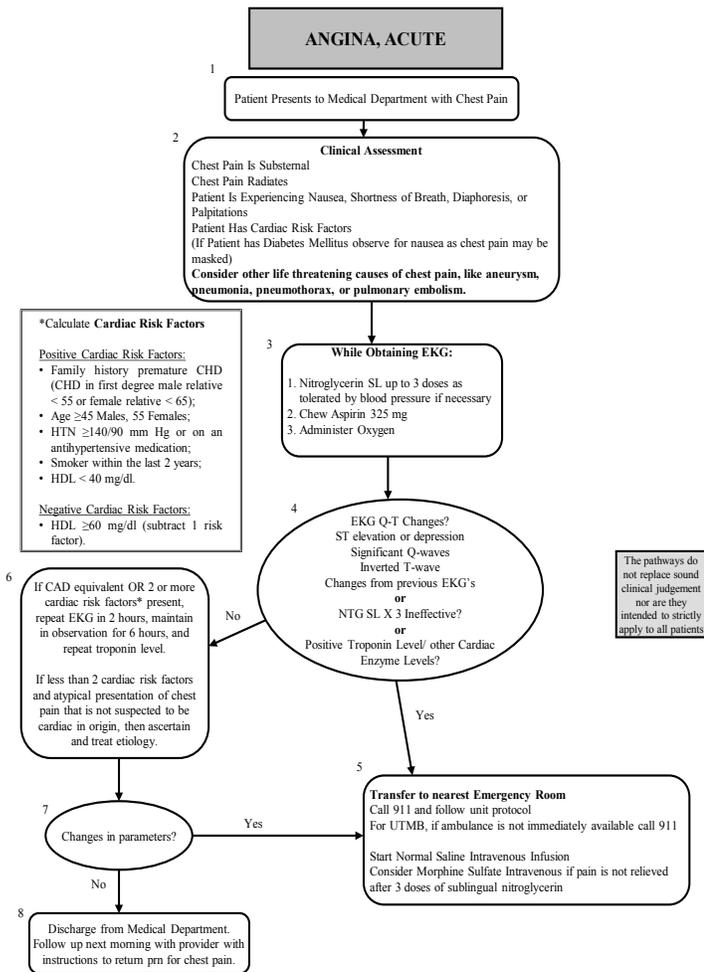
1. Uncontrolled hypertension
2. Known hypersensitivity to mammalian cell-derived products
3. Known hypersensitivity to albumin (Human)

Table 4: WarningsThe 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.

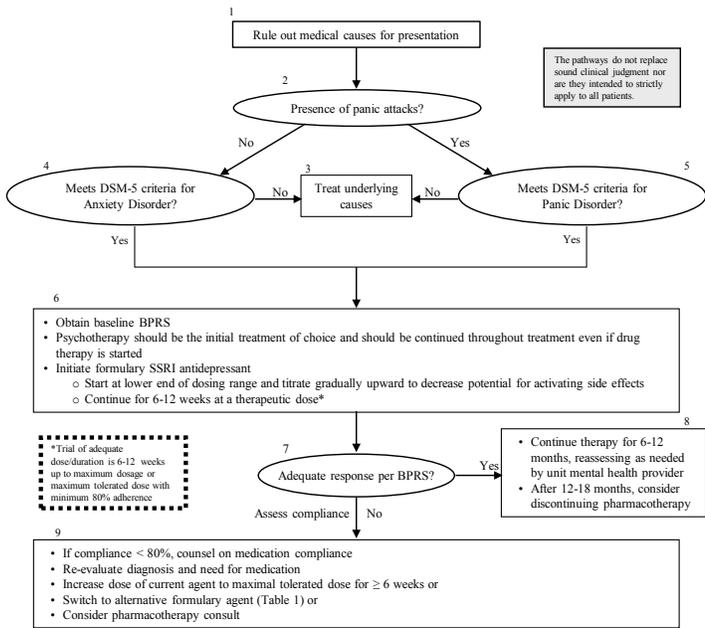
ESA labels now recommend:

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.



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved February 2001;
Reviewed 11/02, 1/07, 1/15; Revised 4/03, 3/08, 5/11, 7/11.

ANXIETY and PANIC DISORDER



*Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee,
Approved 1/99, revised 5/02, 2/03, 4/03, 9/05, 7/08, 7/11, 9/11, 3/14.*

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

Drug Class	Generic Name	Brand Name	May Consider First If	Initial Dose (Dose Range) mg/day	Therapeutic Range ng/mL	Monitoring
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram 20mg, 40mg tablet	Celexa®	Atypical features or dysthymia	20 (20 – 40)	N/A	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present If QTc is > 450msec for males or > 470msec for females, do not initiate citalopram. If pt is on citalopram and QTc is > 500msec, consider alternative treatment.
	Fluoxetine 20mg capsule	Prozac®	Atypical features or dysthymia	20 (20 – 60)		
	Sertraline 50mg, 100mg tablet	Zoloft®	Significant anxiety	50 (50 – 200)		
Tricyclic Antidepressant* (TCA)	Nortriptyline 25mg, 50mg, 75mg capsule	Pamelor®	Melancholic features	25 – 50 (75 – 150)	50 - 150	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Liver function test at baseline Nortriptyline dose > 100 mg/day – EKG at baseline and as clinically indicated, and blood level within 2 weeks, then as clinically indicated
Other*	Trazodone 50mg, 100mg tablet	Desyrel®	Atypical features or dysthymia	100 – 150 (300 – 600)	N/A	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Priapism

*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.

Brief Psychiatric Rating Scale (BPRS)

Patient Name _____ Patient Number _____ Date _____

Facility _____ Practitioner _____

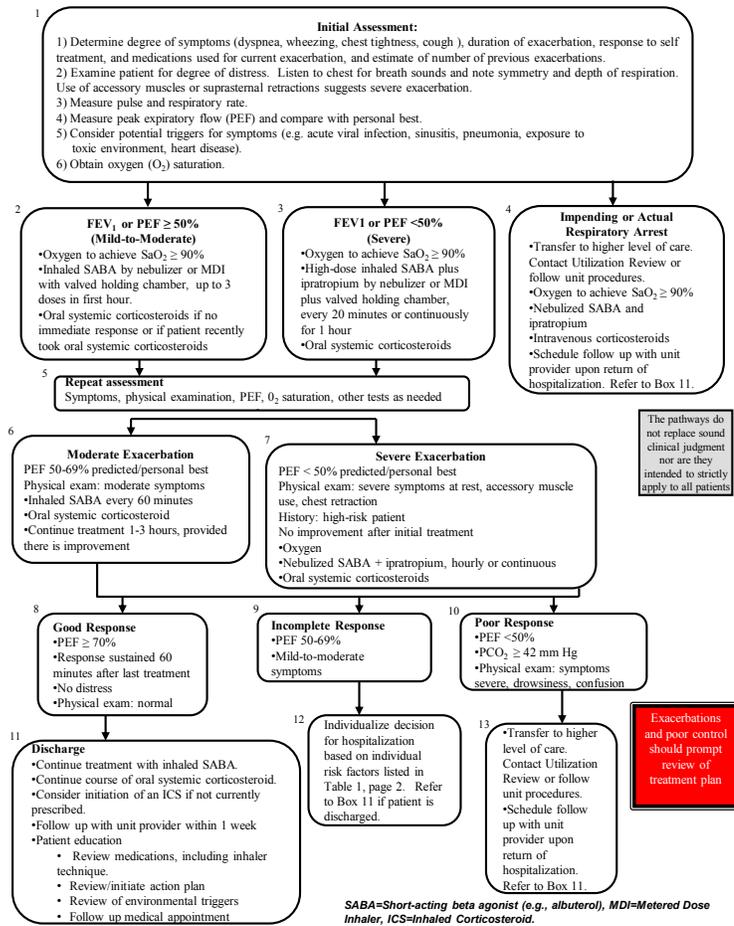
Enter the score for the term that best describes the patient's condition.

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.

Asthma – Acute: Unit Level Management



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved January 1999. Reviewed 4/02, 4/03, 3/05, 9/09, 1/11, 1/13. Revised 10/03, 5/14.

Table 1: Risk Factors for Death from Asthma*
<p>Asthma History</p> <ul style="list-style-type: none"> •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 <p>Social History</p> <ul style="list-style-type: none"> •Illicit drug use •Major psychosocial problems <p>Co-morbidities</p> <ul style="list-style-type: none"> •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

Medication	Adult Dose	Comments
Albuterol nebulizer Solution (0.083%, 2.5mg/3ml)	2.5-5mg every 20 minutes for 3 doses, then 2.5-10mg every 1-4 hours as needed, or 10-15mg/hour continuously	Use large volume nebulizers for continuous administration. May mix with ipratropium nebulizer solution.
Albuterol MDI (90mcg/puff)	4-8 puffs every 20 minutes up to 4 hours, then every 1-4 hours as needed.	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.
Ipratropium bromide nebulizer solution (0.25mg/ml)	0.5mg every 20 minutes for 3 doses then as needed.	May mix in same nebulizer with albuterol. Should not be used as first-line therapy; should be added to SABA therapy for severe exacerbations.
Ipratropium bromide MDI (18mcg/puff)	8 puffs every 20 minutes as needed up to 3 hours	
Ipratropium with albuterol nebulizer solution (each 3ml vial contains 0.5mg ipratropium bromide and 2.5mg albuterol)	3 ml every 20 minutes for 3 doses, then as needed	May be used for up to 3 hours in the initial management of severe exacerbations.
Prednisone (5mg, 10mg, and 20mg tablets)	40-80mg/day in 1 or 2 divided doses until PEF reaches 70% of predicted or personal best	For outpatient "burst," use 40-60mg in single or 2 divided doses for total of 3 to 10 days.

Notes:

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

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

- I. Treatment Goals
- Correction of significant hypoxemia, in moderate or severe exacerbations, by administering supplemental oxygen.
 - 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.
 - 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)

	Symptoms and Signs	Initial PEF (or FEV ₁)	Clinical Course
Mild	Dyspnea only with activity	PEF \geq 70 percent predicted or personal best	<input type="checkbox"/> Usually cared for at home <input type="checkbox"/> Prompt relief with inhaled SABA <input type="checkbox"/> Possible short course of systemic corticosteroids
Moderate	Dyspnea interferes with or limits usual activity	PEF 50-69 percent predicted or personal best	<input type="checkbox"/> Usually requires office or ED visit <input type="checkbox"/> Relief from frequent inhaled SABA <input type="checkbox"/> Oral systemic corticosteroids; some symptoms last 1-2 days after treatment is begun
Severe	Dyspnea at rest; interferes with conversation	PEF < 50 percent predicted or personal best	<input type="checkbox"/> Usually requires ED visit and likely hospitalization <input type="checkbox"/> Partial relief from frequent inhaled SABA <input type="checkbox"/> Oral systemic corticosteroids; some symptoms last for >3 days after treatment is begun
Subset: Life threatening	Too dyspneic to speak; perspiring	PEF < 25 percent predicted or personal best	<input type="checkbox"/> Requires ED/hospitalization; possible ICU <input type="checkbox"/> Minimal or no relief from frequent inhaled SABA <input type="checkbox"/> Intravenous corticosteroids
Key: ED, emergency department; FEV ₁ , forced expiratory volume in 1 second; ICU, intensive care unit; PEF, peak expiratory flow; SABA, short-acting beta ₂ -agonist			

- III. Monitoring
- 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.
 - 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.
 - 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 hospitalizations. Patients given systemic corticosteroids should continue oral systemic corticosteroids for 3 – 10 days. The need for further corticosteroid therapy should be assessed at a follow up visit. For corticosteroid courses of less than 1 week, there is no need to taper the dose. For 10-day courses, there remains no need to taper especially if patients are concurrently taking inhaled corticosteroids.
 - E. Inhaled corticosteroids (ICS) should be considered at discharge in addition to oral corticosteroids. Long-term ICS therapy reduces exacerbations in patients who have persistent asthma. Patients already taking ICS should continue it following discharge.
- V. Patient Education
- A. Advise patient to keep follow up appointments
 - B. Review medications (e.g., dosing, purpose, side effects) and proper inhaler technique
 - C. Advise patient on when to seek medical care if asthma worsens
 - D. Review asthma triggers
 - E. Review or develop a written plan for managing either relapse of the exacerbation or recurrent symptoms

Asthma (Adults and Children ≥ 12 years)

1

1. Obtain thorough history and perform physical exam
2. Review history of symptoms witnessed or addressed by healthcare staff
3. Document peak expiratory flow. Spirometry is suggested when available.
4. Consider transferring the patient to a 24 hour unit if the patient has a history of intubation.
5. Assess the patient's knowledge and skills for self-management
6. Classify asthma severity to select the most appropriate therapy by assessing **impairment & risk**

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

2

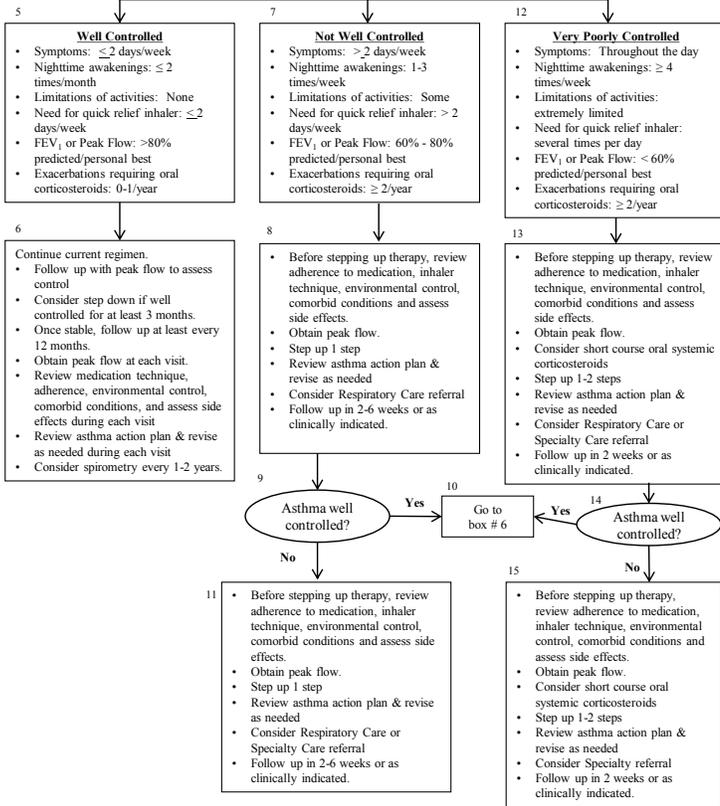
Components of Severity		Classification			
		Intermittent	Persistent Mild	Persistent Moderate	Persistent Severe
Impairment	Symptoms	≤ 2 days/week	> 2 days/week but not daily	Daily	Throughout the day
	Nighttime awakenings	≤ 2 times/month	3-4 times/month	> 1 time/week but not nightly	Often 7 times/week
	SABA for symptom control (not prevention EIB)	≤ 2 days/week	> 2 days/week but not > 1 time/day	Daily	Several times per day
	Interference with normal activity	None	Minor limitations	Some limitation	Extremely limited
	Lung function	<ul style="list-style-type: none"> • Normal FEV₁ between exacerbations • FEV₁ > 80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ ≥ 80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ > 60% but < 80% predicted • FEV₁/FVC reduced 5% 	<ul style="list-style-type: none"> • FEV₁ < 60% predicted • FEV₁/FVC reduced > 5%
Risk	Exacerbations requiring oral systemic corticosteroids	0-1/year	≥ 2/year		
		Consider severity and interval since last exacerbation. Frequency and severity may fluctuate over time for patients Relative annual risk of exacerbations may be related to FEV ₁			
Treatment	Long-Term Control Medication (see table 9 for alternatives)	STEP 1 None	STEP 2 Low dose inhaled corticosteroid Beclomethasone HFA 1 puff BID	STEP 3 Medium dose ICS Beclomethasone HFA 2 puffs BID	STEP 4 or STEP 5 Medium dose ICS + LABA Beclomethasone HFA 3 puffs BID Plus Salmeterol* 1 puff bid
		STEP 4 or STEP 5 High dose ICS + LABA* Beclomethasone HFA high dose; 4 puffs bid Plus Salmeterol* 1 puff bid			
	Quick Relief Medication	Short-acting Beta2-agonist as needed for symptoms for all patients for all steps of therapy Albuterol HFA 2 puffs QID prn			

SABA=short-acting beta2-agonist, LABA=long-acting beta2-agonist, ICS=inhaled corticosteroid, EIB=exercise induced bronchospasm
*Non-formulary approval required.



Exacerbations and poor control should prompt review of treatment plan

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



Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. September 1996. Reviewed 3/05. Revised 4/98, 1/99, 4/02, 4/03, 10/03, 7/09, 1/10, 1/13, 1/15. Revised to include children 11/06.

I. Definition: Asthma is a chronic disorder of the airways that is complex and characterized by variable and recurring symptoms (e.g., cough, wheezing, shortness of breath, chest tightness, and sputum production), airflow obstruction, bronchial hyperresponsiveness and underlying inflammation. In some patients, airflow obstruction may be only partially reversible and permanent structural changes in the airways may occur. Structural changes are associated with progressive loss of lung function overtime that is not prevented or fully reversible by current therapies. The interaction of these features determines severity and response to treatment.

II. Diagnosis is based on the following:

- A. History
1. Family history of asthma, allergy, sinusitis, rhinitis, eczema or nasal polyps
 2. Age of onset and diagnosis
 3. Recurrent symptoms such as wheeze, cough, chest tightness, shortness of breath, or difficulty breathing
 4. Pattern of symptoms
 - a. Perennial, seasonal, or both
 - b. Continual, episodic, or both
 5. Precipitating factors that cause symptoms to occur or worsen
 - a. Exercise
 - b. Allergen (e.g., mold, pollen, dust mites, animal fur)
 - c. Irritant (e.g., smoke, chemicals)
 - d. Viral infection
 - e. Changes in weather
 - f. Menstrual cycles
 - g. Strong emotional expression (e.g., stress, laughing or crying hard)
 - h. Drugs (e.g., aspirin, NSAIDS, or beta-blockers)
 6. Symptoms occur or worsen at night and awaken the patient
 7. History of exacerbations
 - a. Usual prodromal signs and symptoms
 - b. Rapidity of onset, duration & frequency
 - c. Severity (e.g., need for hospitalization) and life-threatening exacerbations (e.g., intubation)
 - d. Number and severity of exacerbations in last year
 - e. Usual management of exacerbations
 8. Comorbid conditions that may aggravate asthma (e.g., rhinitis, GERD, obesity, obstructive sleep apnea)
- B. Physical exam focusing on the upper respiratory tract, chest, and skin
1. Hyper-expansion of the chest
 2. Wheezing during normal breathing or prolonged forced exhalation. Usually high pitched whistling sounds when breathing out.
 3. Increased nasal secretion, mucosal swelling, and/or nasal polyps.
 4. Atopic dermatitis, eczema, or any other manifestations of an allergic skin condition.
 5. Note: Physical examination in patients with asthma is often normal. Lack of wheezing or normal chest examination does not exclude asthma.
- C. Airflow obstruction is at least partially reversible
1. Spirometry is used to demonstrate obstruction and assess reversibility.
 2. Considered reversible if either an increase in FEV₁ of ≥12 percent from baseline or by an increase ≥10 percent of predicted FEV₁ after inhalation of a short-acting bronchodilator.
 3. Spirometry typically measures the maximal volume of air forcibly exhaled from the point of maximal inhalation (FVC) and the volume of air exhaled during the first second of this maneuver (FEV₁).
- D. Exclusion of other diagnoses
1. Adults - COPD, heart failure, pulmonary embolism, mechanical obstruction such as tumor, vocal cord dysfunction, cough secondary to medications such as ACE inhibitors, or pulmonary infiltration.
 2. Children – Vocal cord dysfunction, bronchiectasis, cystic fibrosis, congenital heart disease, alpha-1-antitrypsin deficiency, inhaled foreign body, chronic upper airway cough syndrome

III. Classification of severity

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

Table 1: Impairment and Risk

Impairment	Risk
<ul style="list-style-type: none"> • Frequency and intensity of symptoms • Functional limitations 	<ul style="list-style-type: none"> • Likelihood of exacerbation • Progressive loss of lung function • Risk of adverse effects from medications
<ul style="list-style-type: none"> • Nighttime awakenings • Need for short-acting beta agonist for quick relief of symptoms • School/work days missed • Ability to engage in normal daily activities • Lung function measured by spirometry 	<ul style="list-style-type: none"> • Exacerbations requiring oral corticosteroids • Two or more emergency room visits or hospitalizations for asthma in last year • History of intubation or ICU admission especially in last 5 years • Patients report that they feel in danger or frightened by their asthma • Psychosocial factors (e.g., depression, stress) • Severe airflow obstruction by spirometry • Attitudes and beliefs about taking medications

- B. Level of severity is determined by assessment of both impairment and risk. Assess impairment by patient's recall of previous 2–4 weeks and spirometry. Assign severity to the most severe category in which any feature occurs.
- C. Respiratory Care may be consulted to assist with asthma classification and patient education.

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

Components of Severity		Intermittent	Persistent Mild	Persistent Moderate	Persistent Severe
Impairment	Symptoms	≤ 2 days/week	> 2 days/week but not daily	Daily	Throughout the day
	Nighttime awakenings	≤ 2 times/month	3-4 times/month	> 1 time/week but not nightly	Often 7 times/week
	SABA for symptom control (not prevention EIB)	≤ 2 days/week	> 2 days/week but not > 1 time/day	Daily	Several times per day
	Interference with normal activity	None	Minor limitations	Some limitation	Extremely limited
Normal FEV ₁ /FVC: 8-19 yr = 85% 20-39 yr = 80% 40-59 yr = 75% 60-80 yr = 70%	Lung function	<ul style="list-style-type: none"> • Normal FEV₁ between exacerbations • FEV₁ > 80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ ≥ 80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ > 60% but < 80% predicted • FEV₁/FVC reduced 5% 	<ul style="list-style-type: none"> • FEV₁ < 60% predicted • FEV₁/FVC reduced > 5%
	Risk	Exacerbations requiring oral systemic corticosteroids	0-1/year	≥ 2/year	
		Consider severity & interval since last exacerbation. Frequency & severity may fluctuate over time.			
		Relative annual risk of exacerbations may be related to FEV ₁			
Step for initiating treatment		Step 1	Step 2	Step 3	Step 4 or 5 (consider short course oral corticosteroids to gain control)
Evaluate level of asthma control and step up or step down therapy as needed					

*Adapted from Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma
SABA=short-acting beta2-agonist, EIB=exercise induced bronchospasm

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

Table 3: Classification of Asthma Severity*

	Intermittent	Persistent Mild	Persistent Moderate	Persistent Severe
Lowest level of treatment required to maintain control	Step 1	Step 2	Step 3 – 4	Step 5 - 6

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

IV. Assessing asthma control

- A. Level of control is based on the most severe impairment or risk category.
 - 1. Impairment is assessed based on the patient’s recall of events during the previous 2-4 weeks and by spirometry or peak flow measures.
 - 2. Risk is assessed based on events over the last year
- B. Patients who have asthma that is well controlled at the time of a clinical assessment must be monitored over time and treatment should be adjusted accordingly, since asthma can vary in intensity over time.
- C. Depending on level of asthma control, the patients is assigned to one of six treatment steps.
- D. Therapy is stepped up or stepped down based on how well asthma is controlled and level of severity assessed for both impairment and risk
- E. Any exacerbation should prompt review of maintenance treatment.
- F. **Note:** For treatment purposes, patients who had ≥ 2 exacerbations requiring oral systemic corticosteroids in the past year may be considered the same as patients who have not-well-controlled asthma, even in the absence of impairment levels consistent with not-well-controlled asthma.

Table 4: Assessing Asthma Control and Adjusting Therapy*

Components of Severity		Well Controlled	Not Well Controlled	Very Poorly Controlled
Impairment	Symptoms	≤ 2 days/week	> 2 days/week	Throughout the day
	Nighttime awakenings	≤ 2 times/month	1-3 times/week	≥ 4 times/week
	SABA for symptom control (not prevention EIB)	≤ 2 days/week	> 2 days/week	Several times per day
	Interference with normal activity	None	Some limitations	Extremely limited
	FEV ¹ or peak flow	$> 80\%$ predicted/personal best	60-80% predicted/personal best	$< 60\%$ predicted/personal best
Risk	Exacerbations	0-1/year		≥ 2 /year
		Consider severity & interval since last exacerbation.		
	Treatment-related adverse effects	Not correlated to level of control but should be considered in assessment of therapy.		
Recommended Action		<ul style="list-style-type: none"> • Maintain current treatment step • Follow up every 6-12 months as needed • Consider step down if well controlled for at least 3 months 	<ul style="list-style-type: none"> • Step up 1 step and • Reevaluate in 2-6 weeks or as clinically indicated. 	<ul style="list-style-type: none"> • Consider short course of oral systemic corticosteroids • Step up 1-2 steps • Reevaluate in 2 weeks or as clinically indicated

*Adapted from Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma
 SABA=short-acting beta2-agonist, EIB=exercise induced bronchospasm

V. Treatment Principles

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

VI. Treatment

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

Table 5: Stepping Down Treatment

Regimen	Action
low dose ICS	• Reduced dose by 25-50% at 3 month intervals
Medium dose or high dose ICS	• Reduced dose by 25-50% at 3 month intervals
ICS + LABA	• Reduce dose ICS by 50% and continue LABA • If patient remains controlled, reduce to low dose ICS and discontinue LABA
ICS + LABA + OCS	• Continue ICS + LABA and reduce dose of OCS

ICS=inhaled corticosteroid, OCS=oral corticosteroid, LABA=long-acting beta2 agonist

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

Table 6: Quick Relief Medications

Drug	Type of Medication	Adult Dose	Child ≤ 12 Dose	Adverse Effects
Albuterol (Proventil HFA®) 90mcg/puff 200 puffs/inhaler	Quick relief Short-acting beta ₂ -agonist	Quick relief: 2 puffs qid prn (up to 2 puffs every 4 hrs.) Exacerbation: 4-8 puffs every 20 for up to 4 hours then every 1-4 hours prn	Quick relief: 2 puffs qid prn (up to 2 puffs every 4 hrs.) Exacerbation: 4-8 puffs every 20 minutes for 3 doses then every 1-4 hours prn	Tachycardia, tremor, headache
Prednisone (Deltasone®) 5mg, 10mg, 20mg tablets	Quick relief – used short-term for establishing control when initiating therapy or during moderate to severe exacerbations Oral corticosteroid	40-60mg/day x 3-10 days	1-2mg/kg/day maximum 60mg/day x 3-10 days	Hyperglycemia, increased appetite, fluid retention, weight gain, facial flushing, mood alteration, hypertension, ulcer

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

Table 7: Long-term Control Medications - Inhaled

Drug	Type of Medication	Adult Dose	Child ≤ 11 Dose	Adverse Effects
Beclomethasone HFA (Qvar®) 80mcg/puff 120 puffs/inhaler	Long-term control ICS	Low dose: 80mcg-240mcg • 160mcg = 1 puff bid Medium dose: >240mcg-480mcg • 320mcg = 2 puffs bid • 480mcg = 3 puffs bid High dose: >480mcg • 640mcg = 4 puffs bid	Low dose: 80-160 mcg • 160mcg = 1 puff bid Medium dose: >160-320mcg • 320mcg = 2 puffs bid High dose: >320mcg • 480mcg = 3 puffs bid	Cough, dysphoria, oral thrush Systemic adverse effects may occur at high doses (see oral corticosteroids below for list)
Fluticasone HFA (Flovent®) 44mcg, 110mcg or 220mcg/puff (non-formulary) 120 puffs/inhaler	Long-term control ICS	Low dose: 88-264mcg • 88mcg = 1 puff (44mcg inhaler) bid Medium dose: >264-440mcg • 440mcg = 2 puffs (110mcg inhaler) bid High dose: >440mcg • 880mcg = 2 puffs (220mcg inhaler) bid	Low dose: 88-176mcg • 88mcg = 1 puff (44mcg inhaler) bid Medium dose: >176-352mcg • 220mcg = 1 puff (110mcg inhaler) bid High dose: >352mcg • 440mcg = 1 puff (220mcg inhaler) bid	Cough, dysphoria, oral thrush Systemic adverse effects may occur at high doses (see oral corticosteroids below for list)
Salmeterol Diskus (Serevent®) 50mcg/puff powder for inhalation (non-formulary) 60 puffs/inhaler	Long-term control LABA	1 puff bid Notes: • Must be used in combination with ICS • Do NOT wash mouthpiece	1 puff bid Notes: • Must be used in combination with ICS • Do NOT wash mouthpiece • Child ≥ 4 years	Tachycardia, tremor, hypokalemia, QTc prolongation, diminished bronchoprotective effect may occur within 1 week Uncommon, severe, life-threatening or fatal exacerbation
Mometasone/formoterol (Dulera®) 100/5mcg, 200/5mcg (non-formulary) 120 puffs/inhaler	Long-term control Combination ICS & LABA	Medium dose: • 2 puffs (100/5mcg inhaler) bid • Maximum 4 inhalations High dose: • 2 puffs (200/5mcg inhaler) BID • Maximum 4 inhalations Note: Do NOT use in combination with another LABA such as salmeterol.	Not approved for use in children ≤ 11 years	See adverse effects for ICS and LABA

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

Table 8: Long-term Control Medications - Oral

Drug	Type of Medication	Adult Dose	Child \leq 11 Dose	Adverse Effects
Montelukast (Singulair®) 10mg tablet, 5mg chewable tablet (non-formulary)	Long-term control LTRA	\geq 15 years - Adult: 10mg orally once daily in the evening	6-14 years: 5mg chewable one daily in the evening	None usually Headache, cough, upper respiratory infection, pharyngitis, abdominal pain
Prednisone (Deltasone®) 5mg, 10mg, 20mg tablets	Long-term control OCS	5-60mg daily or every other day Note: • Use lowest effective dose	0.25-2mg/kg daily or every other day Note: • Use lowest effective dose	Short-term: Hyperglycemia, increased appetite, fluid retention, weight gain, facial flushing, mood alteration, hypertension, ulcer Long-term: adrenal suppression, dermal thinning, hypertension, diabetes, Cushing's syndrome, cataracts, muscle weakness, osteoporosis, immunosuppression

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

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

Table 9: Stepwise Approach to Managing Asthma Long-term

	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	
	Intermittent Asthma	Persistent Asthma					
Quick Relief Medication	<ul style="list-style-type: none"> SABA as needed for symptoms for all patients for all steps of therapy. Intensity of treatment depends on severity of symptoms: up to 3 treatments every 20 minutes as needed. Short course of oral systemic corticosteroids may be needed. Caution: Use of SABA > 2 days/week for symptom relief (not to prevent EIB) generally indicates inadequate control and the need to step up treatment. 						
Long-Term Control Medication	Preferred Treatment	SABA as needed	Low dose ICS Beclomethasone HFA	Medium dose ICS Beclomethasone HFA	Medium dose ICS + LABA* Beclomethasone HFA Plus Salmeterol*	High dose ICS + LABA* Beclomethasone HFA Plus Salmeterol*	High dose ICS* + LABA* + OCS Fluticasone* HFA plus Salmeterol* plus prednisone Consider specialty referral
	Alternative Treatment		LTRA* Montelukast*	Low dose ICS + LABA* Beclomethasone HFA plus Salmeterol* Or Low dose ICS + LTRA* Beclomethasone HFA plus Montelukast	Medium dose ICS + LABA* Combination inhaler mometasone/formoterol* 100/5mcg Or Medium dose ICS + LTRA* Beclomethasone HFA Plus Montelukast*	High dose ICS* + LABA* Fluticasone HFA Plus Salmeterol* Or Combination inhaler mometasone/formoterol* 200/5mcg Consider specialty referral	High dose ICS* + LABA* + OCS Combination inhaler mometasone/formoterol* 200/5mcg plus prednisone Consider specialty referral

* Non-formulary medication
 SABA=short-acting beta₂ agonist, LABA=long-acting beta₂ agonist, ICS=inhaled corticosteroid, OCS=oral corticosteroid, LTRA=leukotriene receptor antagonist, EIB=exercise induced bronchospasm

VII. Follow-Up

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

VIII. Referrals

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

IX. Peak Flow Monitoring

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

Patient Education**Teach patients how to manage their asthma.**

- I. Basic facts about the disease
 - A. What is asthma
 - B. Consequences of poor control
 - C. What to expect during an asthma exacerbation
- II. Use of medication
 - A. Difference between quick relief and long-term control medications and when to use them
 - B. Proper inhaler technique (technique varies between inhalers)
 - C. Importance of adherence for control
- III. Self-monitoring to assess level of asthma control and recognize signs of worsening asthma based on symptoms.
- IV. Use of a written asthma action plan
 - A. How to adjust medications in response to worsening asthma
 - B. When to seek medical care if symptoms fail to respond to quick relief medication
- V. Avoidance of environmental triggers that worsen asthma

Figure 1: Inhaler Use

Priming HFA inhaler

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

Cleaning HFA inhaler:

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

Instructions for taking a dose from your HFA inhaler:

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

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

Important points:

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

Figure 1

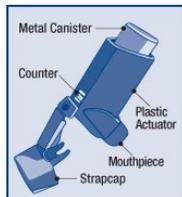


Figure 2

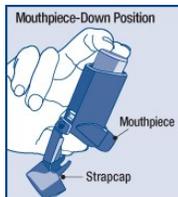


Figure 3



Asthma Action Plan

Patient Name: <insert>

Patient MRN: <insert>

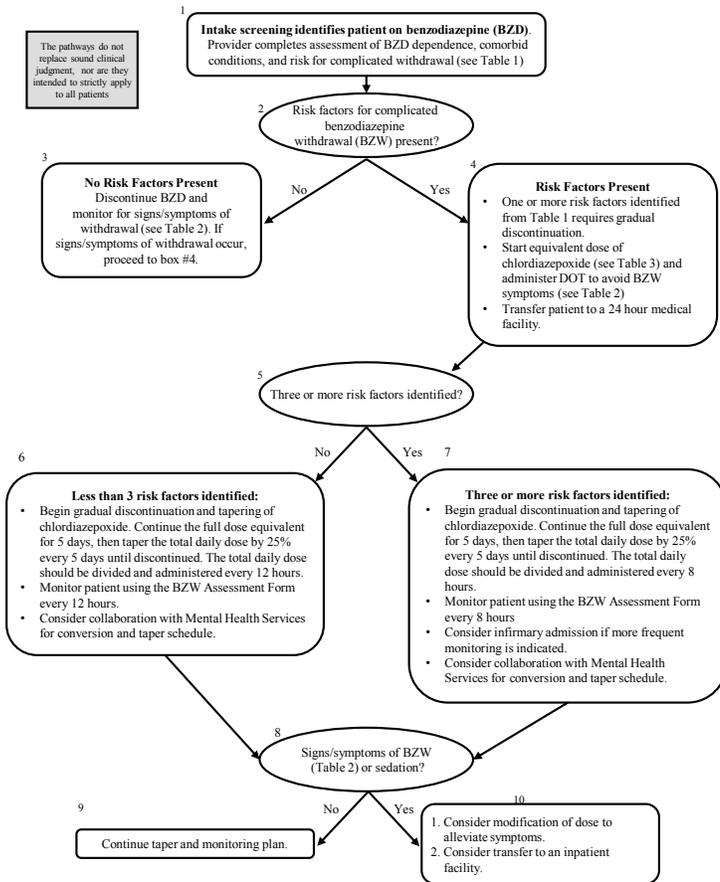
Completed by: <insert>

Date: <insert>

Long-term Control Medicines	How to Take	Other Instructions
1.		
2.		
3.		
4.		
Quick Relief Medicine	How to Take	Other Instructions
		Take only if needed and in the yellow and red zones or before exercise.
Special instructions when I feel  good,  not good, and  awful.		
Green Zone	<p>I feel good.</p> <ul style="list-style-type: none"> No cough, wheeze, chest tightness, or shortness of breath during the day or night Can do usual activities. 	<p>PREVENT asthma symptoms everyday.</p> <ul style="list-style-type: none"> Take my long-term control medicines every day. Before exercise, take ___ puffs of _____ Avoid known triggers when possible
Yellow Zone	<p>I do <u>not</u> feel good.</p> <ul style="list-style-type: none"> Cough, wheeze, chest tightness, shortness of breath, or Waking at night due to asthma symptoms, or Can do some, but not all, usual activities. 	<p>CAUTION. I should continue taking my long-term control asthma medicines every day AND:</p> <ul style="list-style-type: none"> Take ___ puffs of quick relief medicine. If you still do not feel good within 20-30 minutes, you should take ___ puffs. If you do not feel better within one hour, go to the Red Zone. If you do feel better, Continue using quick relief medicine every 4 hours as needed for 24 hours. Increase _____ Drop a sick call request.
Red Zone	<p>I feel awful.</p> <ul style="list-style-type: none"> Very short of breath, or Quick relief medicine has not helped, or Cannot sleep because of trouble breathing, or Cannot do usual activities because of trouble breathing 	<p>MEDICAL ALERT! Get help!</p> <ul style="list-style-type: none"> Take quick relief medicine. _____ puffs every _____ minutes Get help immediately if you are having difficulty walking or talking due to shortness of breath or lips or fingernails are gray or blue. Increase _____

BENZODIAZEPINE DISCONTINUATION

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



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved January 2000. Reviewed 8/03, 1/10, 5/12, 5/14. Revised 1/07, 3/08, 3/09, 11/09, 9/14.

Table 1 – Risk Factors for Complicated BZW

- Long duration of daily BZD use (≥ 4 weeks)
- Higher dose/frequency (> 1.25x's FDA approved daily maximum)
- Use of BZD with short half-life
- Comorbid medical conditions exacerbated by adrenergic state (i.e. COPD, DM, HTN, CAD, and history of CVA)
- History of seizure disorder
- Comorbid psychiatric illness
- History of complicated BZD or alcohol withdrawal
- Concomitant dependence to barbiturates, opioids, or alcohol

Table 2 – Signs and Symptoms of BZW

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

Anxiety	Nausea
Agitation	Vomiting
Convulsions	Blood Pressure lability
Tremor	Delirium
Tachycardia	Hallucinations
Perspiration	

Table 3 – BZD Equivalents (Estimates) & Withdrawal Data

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

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

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

Table 4. Example Taper Schedule: Patient arrives on lorazepam 8 mg/day and switched to chlordiazepoxide 80 mg/day. Total daily dose should be divided and administered every 8 or 12 hours depending on risk stratification.

1 mg lorazepam = 10mg chlordiazepoxide, therefore 8mg lorazepam = 80mg chlordiazepoxide

Approximate Chlordiazepoxide Dose Reductions*	Dose with Formulary Chlordiazepoxide 10 mg Capsules
80 mg/day	Eight 10 mg capsules x 5 days
60 mg/day	Six 10 mg capsules x 5 days
40 mg/day	Four 10 mg capsules x 5 days
30 mg/day	Three 10 mg capsules x 5 days
20 mg/day	Two 10 mg capsules x 5 days
10 mg/day	One 10 mg capsule x 5 days

*Dose reductions are approximate to 25%.

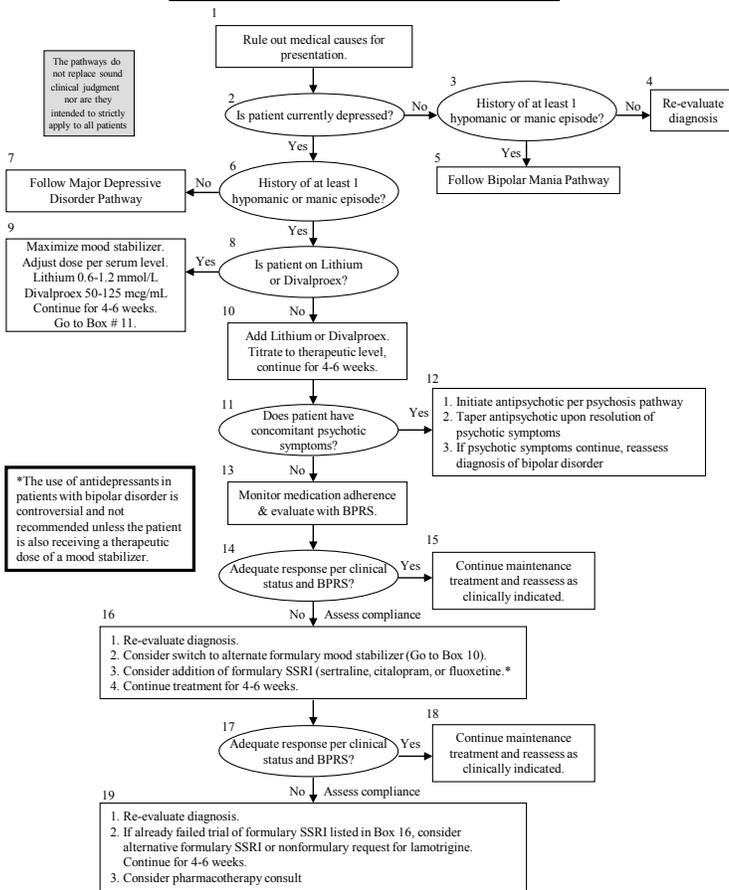
Benzodiazepine Withdrawal (BZW) Assessment Form Page 1		Name: _____ TDCJ # _____						
	Date							
	Time							
	Initials of Staff Assessing							
Perspiration	0 no sweating 1 palms moist 2 palms/fore-head moist 3 sweat beads on face 4 drenching sweats							
Tremor	0 none 1 none 2 mild visible tremor 3 moderate-arms out 4 severe- arms at side							
Restlessness/agitation	0 none 1 uneasy 2 restless 3 excitable-purposeless activity 4 pacing-unable to sit							
Level of Consciousness	0 unimpaired 1 alert-obey commands 2 confused-responds to speech 3 stuporous-responds to pain 4 semi-comatose 5 comatose							

Benzodiazepine Withdrawal (BZW)		Name _____					
Data Collection Form Page 2		TDCJ # _____					
Nausea or Vomiting	0	none					
	1	mild					
	2	moderate					
	3	severe					
4	very severe						
Baseline (Admission)							
Blood Pressure							
Pulse							
Temperature							
Respirations							

Pearls:

- Monitor BZW Observation parameters based on setting guidelines
- Baseline (on admission) vital sign observation: those assessed prior to initiating tapering regimen
- Hyperthermia: any temperature exceeding 99.5 degrees F or 37.5 degrees C
- Tachycardia: heart rate > 90 BPM or an increase of ≥ 20 BPM from baseline heart rate on admission
- Blood pressure lability: change in systolic or diastolic of 20mm Hg from baseline on admission
- Severe 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 DEPRESSION



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

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, TSH, and T4 at baseline.
 - 2. Repeat every 6 – 12 months.
- C. Trough Serum Drug Levels
 - 1. Obtain 5 – 10 days after lithium initiation.
 - 2. Monitor every 2 – 6 months once patient and levels are stabilized.
 - 3. Monitor weekly if patient begins to destabilize.
 - 4. Levels should be drawn 5-10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase/decrease lithium renal clearance (e.g., ACE inhibitors, calcium-channel blockers, diuretics, NSAIDs, SSRIs, theophylline), or if there is a change in renal function.
 - 5. Therapeutic Range: 0.6-1.2 mmol/L for maintenance, 0.8 – 1.2 mmol/L for acute stabilization. Determine by serum trough level in the morning, 10 – 12 hours after last dose.

II. Divalproex

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

III. Lamotrigine (Requires Nonformulary Approval for use)

- A. Dosing
 - 1. Monotherapy (No concurrent enzyme-inducing or enzyme-inhibiting medications)
 - a. 25 mg/day for 2 weeks, then 50 mg/day for 2 weeks, then 100 mg/day for 1 week; thereafter, daily dose may be increased to 200 mg/day.
 - 2. Adjunctive therapy in patient receiving enzyme-inducing medications (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

Medication: Daily Dose Range	Contraindications	Toxicity Starting At Trough Serum Levels of:	Signs/symptoms of toxicity (dose-related)	Signs/symptoms of toxicity (NOT dose-related)
<p>Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses.</p> <p>Dose to stay between 0.6 mEq/L and 1.2 mEq/L.</p> <p>It is advised to not order doses > 1200 mg daily</p>	<ul style="list-style-type: none"> • Hypersensitivity to lithium • Severe cardiovascular or renal disease • Severe debilitation • Dehydration • Sodium depletion • Pregnancy Category D 	<p>> 1 – 1.2 mmol/L</p> <p>Patients who are sensitive to lithium may manifest toxicity at serum levels < 1 mmol/L.</p> <p><i>Note: A rise in white blood cell count is to be expected.</i></p>	<p>Lithium toxicity can be FATAL.</p> <p>Acute:</p> <ul style="list-style-type: none"> • Apathy • Coarsening hand tremor that spreads to other parts of body while patient sitting still • Confusion / Drowsiness • Dysarthria • Diarrhea, nausea, vomiting • Giddiness <p>Acute To Severe:</p> <ul style="list-style-type: none"> • Blurred vision • Deep tendon reflexes increased • Muscle rigidity / fasciculations • Mild ataxia • Profound lethargy • Tinnitus • Vertical nystagmus • Vomiting <p>Severe Intoxication:</p> <ul style="list-style-type: none"> • Arrhythmias • Impaired consciousness • Increased fasciculations and ataxia • CV collapse with oliguria and anuria • Coarse / irregular limb tremors or muscle contractions • Choreoathetoid movements • Cogwheel rigidity • Coma • Generalized tonic-clonic seizures 	<p>Not applicable</p>
<p>Divalproex: 20mg/kg/day, given in divided doses</p> <p>Dose to stay between 50 mcg/mL and 125 mcg/mL.</p> <p>It is not recommended to exceed 60mg/kg/day</p>	<ul style="list-style-type: none"> • Hypersensitivity to VPA • Hepatic dysfunction • Urea cycle disorder • Pregnancy Category D 	<p>> 100-125 mcg/mL</p>	<p>Acute</p> <ul style="list-style-type: none"> • Somnolence • Heart block • Deep coma • Hyperbilirubinemia • Lethargy • Vomiting • Changes in mental status • Thrombocytopenia • Prolongation of bleeding time • Hepatotoxicity 	<ul style="list-style-type: none"> • Pancreatitis - DO NOT RECHALLENGE • Hyperammonemic encephalopathy • Hepatotoxicity, severe or fatal • Stevens-Johnson Syndrome • Toxic Epidermal Necrolysis • Polycystic ovarian syndrome (PCOS)

Medication: Daily Dose Range	Contraindications	Toxicity Starting At Trough Serum Levels of:	Signs/symptoms of toxicity (dose-related)	Signs/symptoms of toxicity (NOT dose-related)
Lamotrigine: 25 – 400 mg/day (Dosing depends on concomitant medication due to significant drug interactions)	<ul style="list-style-type: none"> Hypersensitivity to Lamotrigine Pregnancy Category C 	Therapeutic plasma concentration has not been established.	<ul style="list-style-type: none"> Rash (maculopapular and erythematous) Tourette's Syndrome in children Blood dyscrasias 	<ul style="list-style-type: none"> Fever Lymphadenopathy Multiorgan dysfunction Stevens-Johnson Syndrome Toxic Epidermal Necrolysis

Table 2: SSRI Antidepressants

Medication	Initial Dose (Dose Range) mg/day	Significant Drug Interactions	Monitoring
Citalopram (Celexa®) 20mg, 40mg tablet	20 (20 – 40)	<ul style="list-style-type: none"> QTc prolonging agents Serotonergic agents Agents that may increase citalopram levels: azole antifungals, carbamazepine Antiplatelet/ anticoagulant agents 	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior EKG for citalopram if risk factors for QTc prolongation are pre If QTc is > 450msec for males or > 470msec for females, do not initiate citalopram. If pt is on citalopram and QTc is > 500msec, consider alternative treatment.
Fluoxetine (Prozac®) 20mg capsule	20 (20 – 60)	<ul style="list-style-type: none"> Serotonergic agents Agents that may increase fluoxetine levels: carbamazepine, haloperidol, propranolol Thioridazine- levels increased by fluoxetine Antiplatelet/ anticoagulant agents 	
Sertraline (Zoloft®) 50mg, 100mg tablet	50 (50 – 200)	<ul style="list-style-type: none"> Serotonergic agents Agents that may increase sertraline levels: haloperidol, propranolol Antiplatelet/ anticoagulant agents 	

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 _____

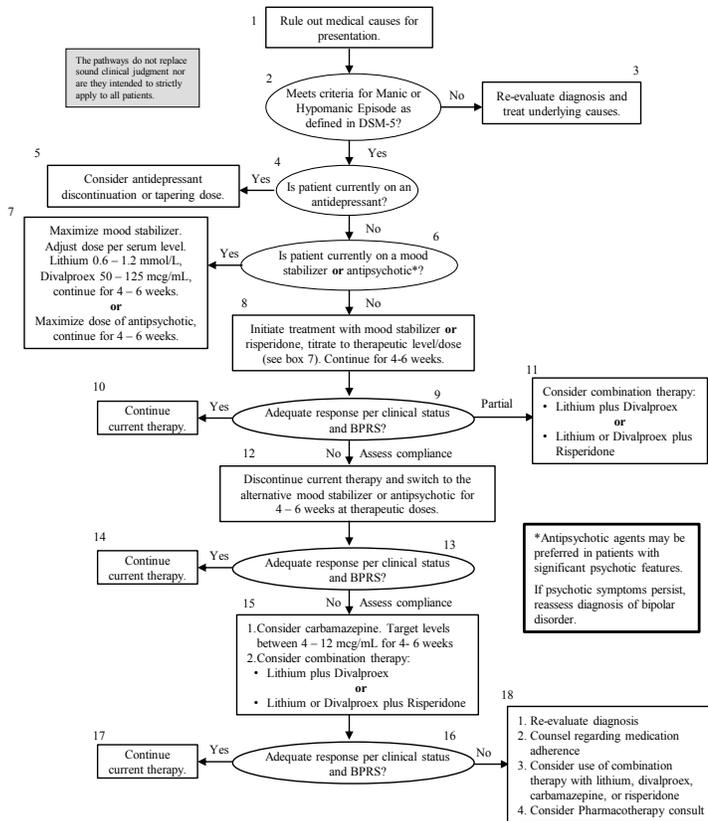
Enter the score for the term that best describes the patient's condition.

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, 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.

BIPOLAR DISORDER: MANIA



Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 1/99; revised 5/02, 1/10, 3/12, 1/15; reviewed 4/03, 9/05.

Recommended Laboratory Monitoring

- I. Lithium**
- A. Cardiac – obtain ECG at baseline if patient is > 40 or has pre-existing heart disease
 - B. Metabolic
 - 1. Obtain electrolytes, BUN, SCr, TSH, and T4 at baseline.
 - 2. Repeat every 6 – 12 months.
 - C. Trough Serum Drug Levels
 - 1. Obtain 5 – 10 days after lithium initiation.
 - 2. Monitor every 2 – 6 months once patient and levels are stabilized.
 - 3. Monitor weekly if patient begins to destabilize.
 - 4. Levels should be drawn 5-10 days (or more often if clinically indicated) after a dosage change, with the addition or deletion of drugs that increase/decrease lithium renal clearance (e.g., ACE inhibitors, calcium-channel blockers, diuretics, NSAIDs, SSRIs, theophylline), or if there is a change in renal function.
 - 5. Therapeutic Range: 0.6-1.2 mmol/L for maintenance, 0.8 – 1.2 mmol/L for acute stabilization. Determine by serum trough level in the morning, 10 – 12 hours after last dose.
- II. Divalproex**
- A. Hematologic
 - 1. CBC with differential – obtain at baseline, then monthly for first 2 months, then every 6 months thereafter.
 - 2. Platelets – obtain at baseline, then every 6 - 12 months thereafter.
 - B. Chemistry – obtain LFTs at baseline, then monthly for first 2 months, then yearly thereafter. If LFTs are elevated on repeat testing, consider obtaining ammonia level and monitor for cognitive dysfunction.
 - C. Serum Drug Level
 - 1. Obtain 1-3 weeks following initiation, change in dose, addition of other CNS agents to the patient's regimen, or observed signs/symptoms of toxicity. Then obtain every 6 – 12 months thereafter.
 - 2. Therapeutic Range: 50 – 125 mcg/mL, dose not to exceed 60 mg/kg/day.
 - 3. Standard draw time is 12 hours after the last dose.
- III. Carbamazepine**
- A. Cardiac – obtain ECG at baseline if patient is > 40 or has pre-existing heart disease
 - B. Hematologic
 - 1. CBC with differential – obtain baseline, then monthly for first 2 months, then every 6 months thereafter
 - 2. Platelets – obtain at baseline, then every 6 months thereafter
 - C. Hepatic – obtain LFTs at baseline then yearly thereafter
 - D. Metabolic – obtain serum sodium at baseline, 3 months, then annually.
 - E. Serum Drug Level
 - 1. Initial level should be drawn within first 7 – 10 days of therapy.
 - 2. Obtain every 4 weeks while titrating to therapeutic levels, then every 6 months.
 - 3. Therapeutic Range: 4-12 mcg/mL.
 - 4. Onset of auto-induction occurs in about 3 days from first dose, with maximum effect at about 30 days.
 - 5. Draw serum trough levels just prior to the next dose.
 - F. Genetic testing – recommended for people with Asian ancestry
 - 1. Serious skin reactions (e.g., Stevens Johnson Syndrome) are more common in people with the HLA-B 1502 variant, a mutation found primarily in Asians. Reactions have been fatal.
 - 2. Carbamazepine should not be prescribed for patients with Asian ancestry unless no other reasonable alternative exists. If so, patients must undergo genetic testing for the mutation before being prescribed carbamazepine. Providers must obtain approval from their Regional Medical Director prior to ordering the test.
 - 3. 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.
 - 4. 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.

Table 1: Mood Stabilizers

Medication: Daily Dose Range	Contraindications	Toxicity Starting At Trough Serum Levels of:	Signs/symptoms of toxicity (dose-related)	Signs/symptoms of toxicity (NOT dose-related)
<p>Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses.</p> <p>Dose to stay between 0.6 mEq/L and 1.2 mEq/L.</p> <p>It is advised to not order doses > 1200 mg daily</p>	<ul style="list-style-type: none"> • Hypersensitivity to lithium • Severe cardiovascular or renal disease • Severe debilitation • Dehydration • Sodium depletion • Pregnancy Category D 	<p>> 1 – 1.2 mmol/L</p> <p>Patients who are sensitive to lithium may manifest toxicity at serum levels < 1 mmol/L.</p> <p><i>Note: A rise in white blood cell count is to be expected.</i></p>	<p>Lithium toxicity can be FATAL.</p> <p>Acute:</p> <ul style="list-style-type: none"> • Apathy • Coarsening hand tremor that spreads to other parts of body while patient sitting still • Confusion / Drowsiness • Dysarthria • Diarrhea, nausea, vomiting • Giddiness <p>Acute To Severe:</p> <ul style="list-style-type: none"> • Blurred vision • Deep tendon reflexes increased • Muscle rigidity / fasciculations • Mild ataxia • Profound lethargy • Tinnitus • Vertical nystagmus • Vomiting <p>Severe Intoxication:</p> <ul style="list-style-type: none"> • Arrhythmias • Impaired consciousness • Increased fasciculations and ataxia • CV collapse with oliguria and anuria • Coarse / irregular limb tremors or muscle contractions • Choreoathetoid movements • Cogwheel rigidity • Coma • Generalized tonic-clonic seizures 	Not applicable
<p>Divalproex: 20mg/kg/day, given in divided doses</p> <p>Dose to stay between 50 mcg/mL and 125 mcg/mL.</p> <p>It is not recommended to exceed 60mg/kg/day</p>	<ul style="list-style-type: none"> • Hypersensitivity to VPA • Hepatic dysfunction • Urea cycle disorder • Pregnancy Category D 	<p>> 100-125 mcg/mL</p>	<p>Acute</p> <ul style="list-style-type: none"> • Somnolence • Heart block • Deep coma • Hyperbilirubinemia • Lethargy • Vomiting • Changes in mental status • Thrombocytopenia • Prolongation of bleeding time • Hepatotoxicity 	<ul style="list-style-type: none"> • Pancreatitis - DO NOT RECHALLENGE • Hyperammonemic encephalopathy • Hepatotoxicity, severe or fatal • Stevens-Johnson Syndrome • Toxic Epidermal Necrolysis • Polycystic ovarian syndrome (PCOS)

Drug: Daily Dose Range	Contraindications	Toxicity Seen Starting At Trough Serum Levels of:	Signs/symptoms of toxicity (dose-related)	Signs/symptoms of toxicity (NOT dose-related)
Carbamazepine: 600 – 1600 mg, given in divided doses Dose to stay between 4 mcg/mL and 12 mcg/mL.	<ul style="list-style-type: none"> Hypersensitivity to carbamazepine or TCAs Bone marrow depression In combination with or within 14 days of MAOIs Pregnancy Category D 	> 12 mcg/mL	<ul style="list-style-type: none"> Abnormal reflex response Acetonuria Agitation / restlessness Ataxia / dizziness Blurred vision / diplopia/mydriasis Cardiac dysrhythmias Coma Cyanosis Disorientation Extreme lethargy or drowsiness Flushing Glycosuria Involuntary muscle movements Nausea / vomiting Nystagmus Opisthotonos Tremor Urinary retention 	<ul style="list-style-type: none"> Arrhythmias Blood cell dyscrasias Chest pain CHF Nausea / vomiting Photosensitivity SIADH (Syndrome of Inappropriate ADH Secretion) Stevens-Johnson Syndrome Toxic epidermal necrolysis

Antipsychotic Monitoring Parameters

Table 2: Metabolic and Endocrine Monitoring Guidelines

Parameter	Baseline	Q 6 Months	Annually
Weight-Height-BMI	X	X	
Blood Pressure, Pulse	X	X	
Fasting Plasma Glucose	X	X	
Fasting Lipid Profile	X		X
Complete Metabolic Panel	X		X
TSH	X	As clinically indicated	
EKG ¹	As clinically indicated		
Prolactin ²	As clinically indicated		

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

Additional Monitoring Parameters for Specific Agents

- Ziprasidone (Geodon®) - EKG at baseline then annually or as clinically indicated
- Quetiapine (Seroquel®) - Ophthalmic exam checking for cataracts every 6 months

Table 3: Outcome and Adverse Effect Monitoring

Assessment	Baseline	Follow-up
AIMS (Abnormal Involuntary Movement Scale) • Acute EPS - Akathisia • Tardive Dyskinesia	X	Baseline and at least every 6 months
Mental Status Exam	X	Baseline and at least every 6 months
BPRS (Brief Psychiatric Rating Scale)	X	• Baseline and at least every 6 months • Medication is started, changed or discontinued

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

Agent	Formulary Status	Traditional Equivalents (approx. mg)	Dose Range (mg/day)	Adverse Effects				
				Weight Gain	EPS	Sedation	Anticholinergic	Orthostasis
Aripiprazole (Abilify®)	NF	7.5	10 – 30	0/+	0/+	+	0/+	0/+
Asenapine (Saphris®)	NF	?	5-20	++	+	++	+	+
Olanzapine (Zyprexa®)	NF	5	5 – 20	+++	0/+	++	++	+
Quetiapine (Seroquel®)	NF	125	300 – 800	++	0/+	+/+++	++	+
Risperidone (Risperdal®)	F	2	0.5-6	+	0/+++ [§]	++	+	++
Ziprasidone (Geodon®)	NF	60	120 -160	0/+	++	++	+	++

[§] dose-dependent

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- ___ 21. BIZARRE BEHAVIOR - Reports of behaviors which are odd, unusual, or psychotically criminal. Not limited to interview period. Include inappropriate sexual behavior and inappropriate affect.
- ___ 22. SELF-NEGLECT - Hygiene, appearance, or eating behavior below usual expectations, below socially acceptable standards or life threatening.
- ___ 23. DISTRACTIBILITY - Degree to which observed sequences of speech and actions are interrupted by stimuli unrelated to the interview. Distractibility is rated when the individual shows a change in the focus of attention as characterized by a pause in speech or a marked shift in gaze. Individual's attention may be drawn to noise in adjoining room, books on a shelf, interviewer's clothing, etc.

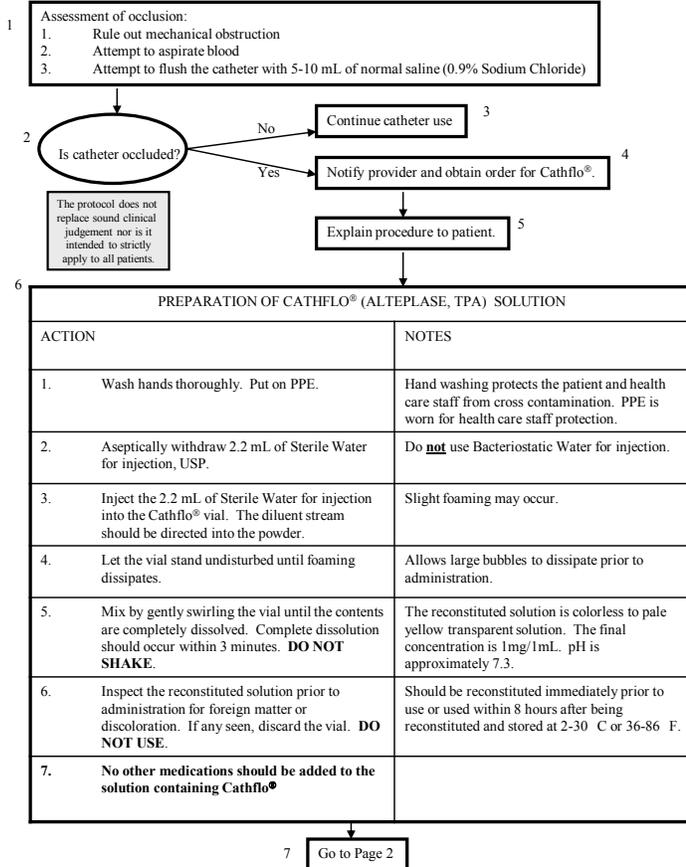
ABNORMAL INVOLUNTARY MOVEMENT SCALE

Complete examination procedure outlined in the instructions before making rating. Rate highest severity observed.
 Movements occurring upon activation rate one less than those occurring spontaneously.
 0 = None 1 = Minimal 2 = Mild 3 = Moderate 4 = Severe

Date of Evaluation									
1	Muscles of facial expression e.g. movements of forehead, eyebrows, preorbital area, cheeks, include frowning, blinding, smiling, grimacing								
2	Lips and perioral area e.g. puckering, pouting, 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:								

CATHETER RESTORATION FOR HEMODIALYSIS PATIENTS

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

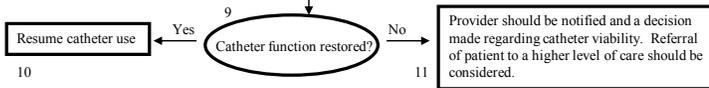


Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. January 2005. Reviewed 1/08, 01/11, 09/14.

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

Catheter Restoration for Hemodialysis Patients
Page 2

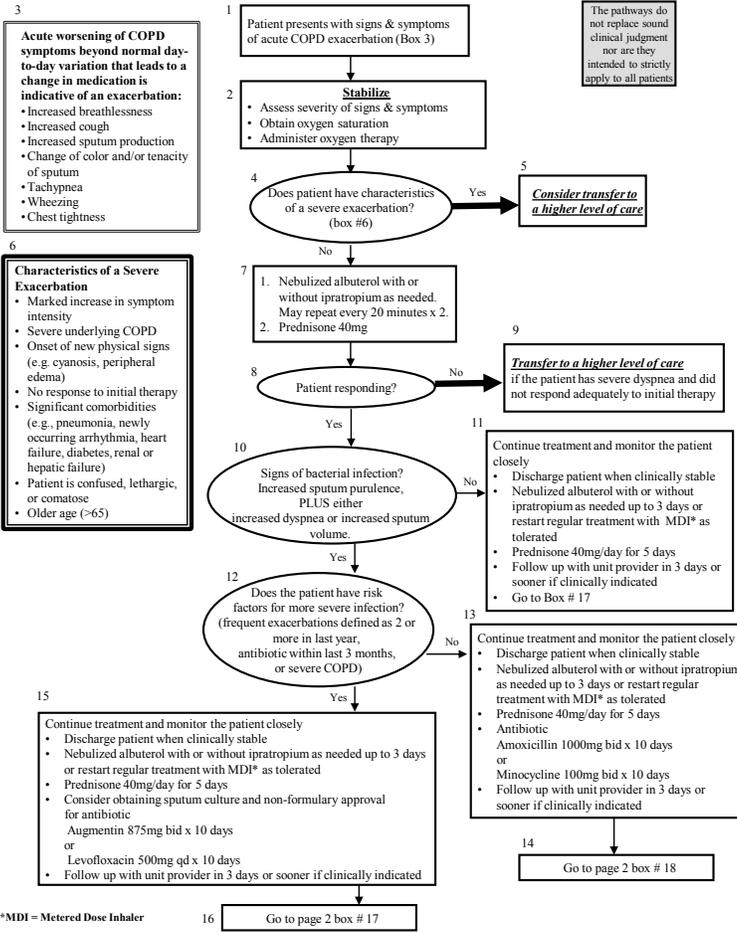
INSTILLATION OF CATHFLO® (ALTEPLASE, TPA) SOLUTION	
ACTION	NOTES
1. Inspect the reconstituted solution prior to administration for foreign matter or discoloration.	If any seen, discard the vial. DO NOT USE.
2. Aseptically withdraw the reconstituted solution from the vial.	Dose to be determined by the provider. The usual dose is 2mg (2mL) for patients ≥ 30 kg.
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.
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.
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 <u>not</u> functional, go to step 6	Vigorous suction should not be applied during attempts to assess catheter function, because of the risk of damage or collapse.
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 <u>not</u> 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 <u>must</u> 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).	
9. Discard any unused Cathflo® solution.	
10. Document administration in the patient medial record.	Documentation should include drug, dose, route, time administered, patient response, & signature and title of person administering the drug.



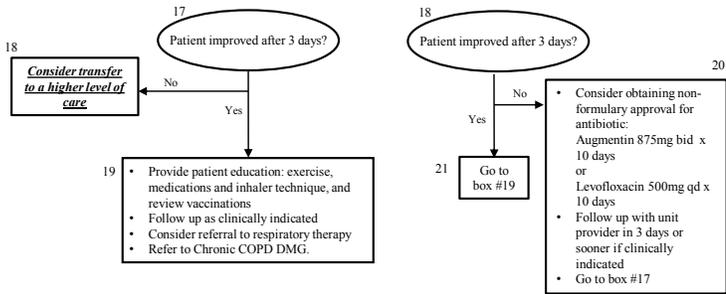
Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. January 2005. Reviewed 1/08, 01/11, 09/14.

- 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 \geq 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



ACUTE EXACERBATION COPD



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

I. Definition of acute exacerbation

- "An acute event characterized by a worsening of the patient's respiratory symptoms (dyspnea, cough, sputum production) that is beyond normal day-to-day variations and leads to a change in medication." (GOLD 2015 Guidelines)
- COPD exacerbations are important events because of the following:
 - Negatively impact quality of life
 - May take several weeks for symptom improvement and lung function to recover
 - Accelerate rate of lung function decline
 - Associated with significant mortality, particularly if results in hospitalization

II. Risk factors for COPD exacerbation

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

III. Diagnosis

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

Table 1. Symptoms of COPD Exacerbation

Cardiac	<ul style="list-style-type: none"> • Chest tightness • Tachycardia
Musculoskeletal	<ul style="list-style-type: none"> • Decreased exercise tolerance
Psychiatric	<ul style="list-style-type: none"> • Confusion • Depression • Insomnia or sleepiness
Pulmonary	<ul style="list-style-type: none"> • Change in volume, color, or tenacity of the sputum • Cough • Dyspnea • Tachypnea • Wheezing
Systemic	<ul style="list-style-type: none"> • Fatigue • Fever • Malaise

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

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

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

Classification	Clinical History/Physical Findings	Outcome
Level I	<ul style="list-style-type: none"> • Mild-moderate chronic COPD by history • Hemodynamically stable (SBP > 90mmHg) 	<ul style="list-style-type: none"> • Generally may be treated as an outpatient
Level II	<ul style="list-style-type: none"> • Moderate-severe chronic COPD by history • Presence of comorbidities (e.g., heart failure, arrhythmias, pneumonia) • Hemodynamically stable (SBP > 90mmHg) • Use of accessory respiratory muscles, tachypnea, and persistent symptoms after initial therapy is likely 	<ul style="list-style-type: none"> • Requires hospitalization
Level III	<ul style="list-style-type: none"> • Severe chronic COPD by history • Presence of comorbidities (e.g., heart failure, arrhythmias) • Hemodynamically unstable (SBP < 90mmHg) • Use of accessory respiratory muscles, tachypnea, and persistent symptoms after initial therapy is likely 	<ul style="list-style-type: none"> • Requires hospitalization and may lead to respiratory failure and ICU level care

V. Treatment

- A. More than 80% of exacerbations can be managed on an outpatient basis with pharmacologic therapy including bronchodilators, corticosteroids and antibiotics.
- B. Supplemental oxygen should be titrated to improve hypoxemia with a target saturation of 88-92%.
- C. Nebulizer treatment may be more convenient for sicker patients but a systematic review found no significant differences in FEV1 between metered dose inhalers and nebulizers.
- D. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015 guidelines recommend a dose of prednisone 40mg daily for 5 days although it is noted that there is insufficient data to provide firm conclusions on the optimal duration of corticosteroid therapy for an acute COPD exacerbation.
1. Corticosteroids shorten recovery time, improve lung function and arterial hypoxemia, reduce the risk of early relapse, treatment failure and length of hospital stay.
- E. Antibiotics should be given to patients that meet the below criteria:
1. Have three cardinal symptoms - increase in dyspnea, sputum volume, and sputum purulence
Or
 2. Have two of the cardinal symptoms if increased sputum purulence is one of the two symptoms
- F. Sputum cultures are recommended if the patient has a history of frequent exacerbations (> 2/year), does not respond to initial antibiotic therapy, has severe airflow limitation, and/or exacerbations requiring mechanical ventilation.

Table 3. Treatment

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

*Counsel patients to complete the prescribed course of antibiotic even if they begin to feel better to avoid treatment failure and antibiotic resistance

Table 4. Follow up after initial treatment

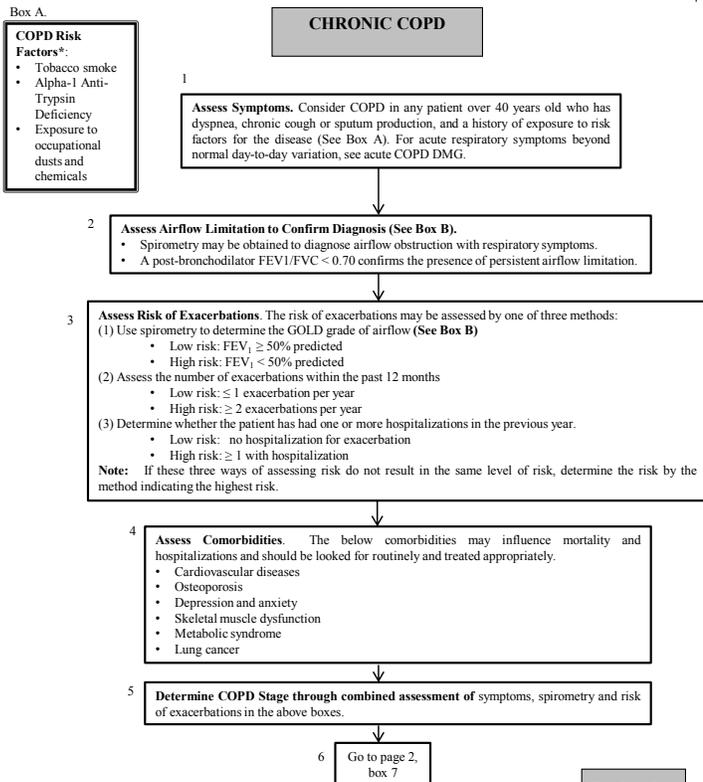
Responds to initial treatment	Failure to respond to initial treatment	Continued Symptoms at Follow-up Visit (3 days later or sooner if clinically indicated)	Post Hospital Discharge
<ul style="list-style-type: none"> ○ Restart bronchodilator MDI prn if tolerated ○ Restart maintenance therapy ○ Finish the courses of oral steroid and antibiotic(s) if applicable ○ Follow up in 3 days or sooner if clinically indicated, then as needed 	<ul style="list-style-type: none"> ○ Continue nebulized bronchodilators ○ Transfer to a higher level of care 	<ul style="list-style-type: none"> ○ Continue nebulized bronchodilators ○ Consider switching to broad spectrum antibiotics if started on narrow spectrum antibiotic ○ Consider extending duration of oral prednisone ○ Follow up in 3 more days or sooner if clinically indicated, or transfer to a higher level of care if necessary 	<ul style="list-style-type: none"> ○ Generally, follow up on the next clinic day or sooner if clinically indicated

VII. Refer to Chronic COPD Disease Management Guideline

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

VIII. Prognosis

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



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Box B. Classification of Severity of Airflow Limitation

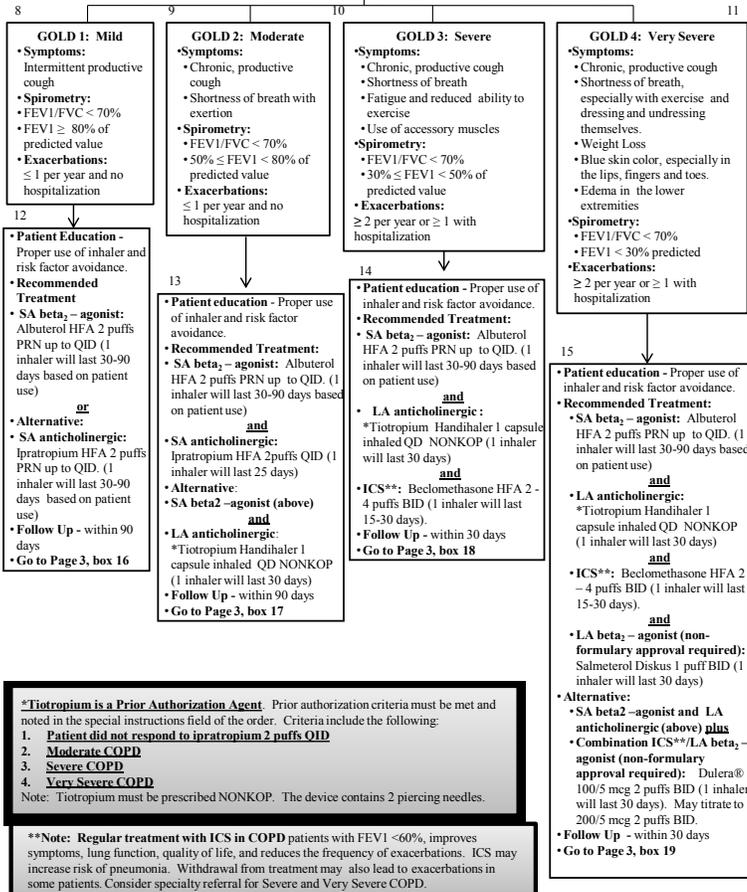
GOLD 1	Mild	FEV ₁ ≥ 80 % predicted
GOLD 2	Moderate	50% ≤ FEV ₁ < 80% predicted
GOLD 3	Severe	30% ≤ FEV ₁ < 50% predicted
GOLD 4	Very Severe	FEV ₁ < 30% predicted

Prepared By The Correctional Managed Care Pharmacy & Therapeutic Committee, September 1996, Revised 8/98, 12/98, 4/02, 4/03, 10/03, 11/06, 3/10, 7/12, 11/15. Reviewed 3/05, 1/09.

CHRONIC COPD

7
Continued from Page 1

•SA = short acting
•LA = long acting
•ICS = inhaled corticosteroid
•PRN = when necessary



***Tiotropium is a Prior Authorization Agent.** Prior authorization criteria must be met and noted in the special instructions field of the order. Criteria include the following:

1. **Patient did not respond to ipratropium 2 puffs QID**
2. **Moderate COPD**
3. **Severe COPD**
4. **Very Severe COPD**

Note: Tiotropium must be prescribed NONKOP. The device contains 2 piercing needles.

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

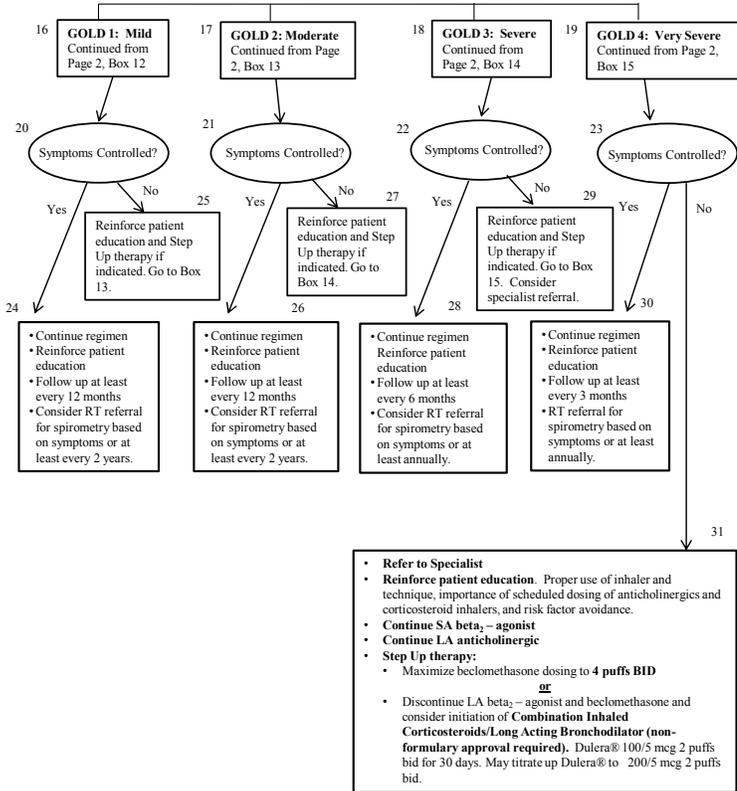


Figure 1: Inhaler Use

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

Priming HFA inhaler

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

Cleaning HFA inhaler:

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

Instructions for taking a dose from your HFA inhaler:

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

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

Important points:

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

Figure 1

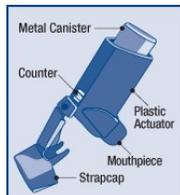


Figure 2

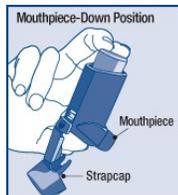


Figure 3



CHRONIC COPD

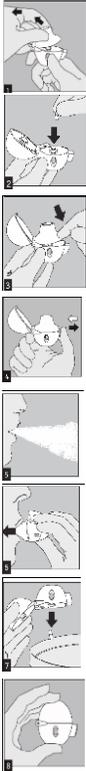
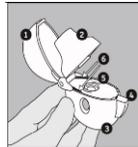


Figure 2: Inhaler Technique Tiotropium

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

Notes:
 Do not store capsules in the inhaler
 Do not open capsule package until you are ready to use the inhaler

- Inhaler parts:
1. Dust cap
 2. Mouthpiece
 3. Base
 4. Piercing Button
 5. center chamber
 6. Air intake vents



CHRONIC COPD



Figure 3: Salmeterol Diskus

1. **Open your Diskus:** Hold the Diskus in your left hand and place the thumb of your right hand in the thumb grip. Push the thumb grip away from you as far as it will go until the mouthpiece shows and snaps into place. (Picture A)
2. **Slide the lever until you hear it click.** Hold the Diskus in a level, flat position with the mouthpiece towards you. Slide the lever away from mouthpiece as far as it will go until it clicks. The number on the counter will count down by 1. The Diskus is now ready for use. (Picture B)
3. **Inhale your medication.** Before you breath in your dose, breathe out as long as you can while you hold the Diskus level and away from your mouth. **Do not** breath into the mouthpiece. Put the mouthpiece to your lips. Breathe in quickly and deeply through the Diskus. **Do not** breath in through your nose. Remove the Diskus from your mouth and hold your breath for about 10 seconds, or for as long as is comfortable for you. Breathe out slowly as long as you can. (Pictures C and D)
4. **Close the Diskus.** Place your thumb in the thumb grip and slide it back towards you as far as it will go. Make sure the Diskus clicks shut and you cannot see the mouthpiece. The Diskus is now ready for your next scheduled dose in about 12 hours. (Picture E)

Important Notes: To avoid accidentally wasting a dose:

- **Do not** close the Diskus
- **Do not** tilt the Diskus
- **Do not** move the lever on the Diskus



I. Definitions (adapted from the 2015 GOLD guidelines)

- A. **Chronic obstructive pulmonary disease (COPD)** is a "disease state characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lungs to noxious particles or gases."
- B. **Exacerbation** of COPD is "an acute event characterized by a worsening of the patient's respiratory symptoms that is beyond normal day-to-day variations and leads to a change in medication. The most common causes appear to be respiratory tract infections (viral or bacterial)."

II. Diagnosis

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

III. Classification

Table 1.

COPD Stage	Spirometry	Exacerbations per year	Characteristics
GOLD 1: Mild	FEV ₁ ≥ 80% predicted	≤ 1 per year and no hospitalization	<ul style="list-style-type: none"> • Intermittent productive cough • Low risk of exacerbations
GOLD 2: Moderate	50% ≤ FEV ₁ < 80% predicted	≤ 1 per year and no hospitalization	<ul style="list-style-type: none"> • Chronic, productive cough • Shortness of breath with exertion • Low risk of exacerbations, occasional flare ups
GOLD 3: Severe	30% ≤ FEV ₁ < 50% predicted	≥ 2 per year or ≥ 1 with hospitalization	<ul style="list-style-type: none"> • Chronic, productive cough • Shortness of breath with exertion • Fatigue and reduced ability to exercise • Use of accessory muscles • High risk of exacerbations, repeated and sometimes severe flare ups
GOLD 4: Very Severe	FEV ₁ < 30% predicted	≥ 2 per year or ≥ 1 with hospitalization	<ul style="list-style-type: none"> • Chronic, productive cough • Shortness of breath, especially with exercise and dressing and undressing • Weight Loss • Blue skin color, especially in the lips, fingers and toes • Edema in the lower extremities • High risk of exacerbations and life threatening

- IV. Patient Evaluation
- A. Obtain thorough medical history
 1. Risk factors (smoking, occupational or environment exposures)
 2. Past medical history of respiratory problems such as asthma, allergies, infections, etc.
 3. Family history of respiratory disease
 4. History of symptom development and impact on activities and function
 5. History of exacerbations/hospitalizations
 6. Presence of co-morbidities such as cardiovascular disease, osteoporosis, depression and anxiety, skeletal muscle dysfunction, metabolic syndrome, diabetes, GERD, infections and malignancies (lung cancer)
 7. Past and current treatments
 - B. Physical Exam- Rarely diagnostic but important
- V. Goals of therapy
- A. Prevent disease progression
 - B. Relieve symptoms
 - C. Improve exercise intolerance
 - D. Prevent complications
 - E. Prevent exacerbations
 - F. Reduce mortality
 - G. Prevent or minimize adverse effects of therapy
- VI. Treatment
- A. Non-pharmacologic Treatment
 1. Risk factor avoidance (e.g., smoking cessation)
 2. Exercise
 3. Oxygen- Consider if patient has stage 4 COPD with chronic respiratory failure:
 - PaO₂ < 7.3 kPa (55mmHg) or SaO₂ < 88% with or without hypercapnia or PaO₂ between 7.3kPa-8kPa (60mmHg) 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 Beta₂-agonists are used as needed or on a regular basis to prevent or reduce symptoms. Anticholinergics are used daily. Long acting inhaled bronchodilators are more effective at producing maintained symptom relief than short-acting bronchodilators. Combining bronchodilators of different pharmacological classes may improve efficacy and decrease the risk of side effects compared to increasing the dose of a single bronchodilator.
 2. Glucocorticosteroids- In COPD patients with FEV₁ < 60% predicted, regular use of inhaled corticosteroids has been shown to improve symptoms, lung function, quality of life, and reduces the frequency of exacerbations. There is an increased risk of pneumonia with inhaled corticosteroid therapy. Withdrawal from treatment with ICS may lead to exacerbations in some patients. Regular treatment with inhaled corticosteroids improves symptoms and reduces the frequency of exacerbations in COPD but does not modify the occurrence of long term decline in pulmonary function or the rate of mortality in COPD patients.
 3. Vaccinations:
 - a. **Influenza vaccination** can reduce serious illness and death in COPD patients and is recommended per Infection Control Policy B-14.07.
 - b. **Pneumococcal polysaccharide** vaccine is recommended for COPD patients (See Infection Control Policy B-14.07).
- VII. Follow Up
- A. Inquire about changes in symptoms at each visit including cough and sputum, breathlessness, fatigue, activity limitation, and sleep disturbances
 - B. Review current treatment including medication dosages, adherence, inhaler technique, effectiveness of the current regimen at controlling symptoms, and adverse effects
 - C. Evaluate the frequency, severity, and likely causes of exacerbations
 - D. Monitor comorbidities which can potentially complicate management of COPD

Table 2. Treatment

Regimen	Mild	Moderate	Severe	Very Severe
Recommended	SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed	SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed <u>and</u> SA anticholinergic: Formulary: Ipratropium bromide HFA 2 puffs QID	SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed <u>and</u> LA anticholinergic: Prior Authorization Agent: Tiotropium Bromide Handihaler 1 capsule inhaled daily NONKOP <u>and</u> ICS: Formulary: Beclomethasone HFA 2 – 4 puffs bid	SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed <u>and</u> LA anticholinergic: Prior Authorization Agent: Tiotropium Bromide Handihaler 1 capsule inhaled daily NONKOP <u>and</u> ICS: Formulary: Beclomethasone HFA 2 puffs bid up to 4 puffs bid <u>and</u> LA beta ₂ -agonist: Non Formulary: Salmeterol 50mcg Diskus 1 inhalation bid
Alternative	SA anticholinergic as needed: Formulary: Ipratropium bromide HFA 2 puffs QID as needed	SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed <u>and</u> LA anticholinergic: Prior Authorization Agent: Tiotropium Bromide Handihaler 1 capsule daily NONKOP		SA beta ₂ -agonist as needed: Formulary: Albuterol HFA 2 puffs QID as needed <u>and</u> LA anticholinergic: Prior Authorization Agent: Tiotropium Bromide Handihaler 1 capsule inhaled daily NONKOP <u>and</u> Combination LA beta ₂ -agonist and ICS: Dulera® 100/5 mcg 2 puffs bid. May increase to Dulera® 200/5 mcg 2 puffs bid.

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

CHECKLIST FOR SECONDARY PREVENTION OF CORONARY ARTERY DISEASE

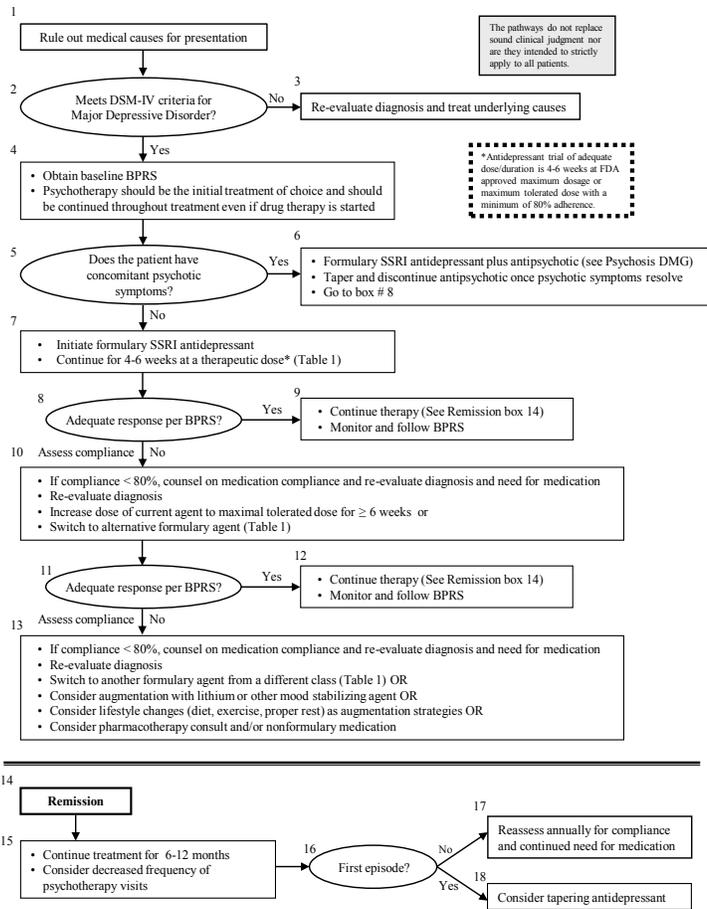
Page 2

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

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 B-blocker therapy include allergies and certain heart rhythm abnormalities.
5. Contraindications to aldosterone blockade include allergies, renal dysfunction, and hyperkalemia (K >5.0mEq/L).
6. Contraindications to influenza vaccine include egg allergy.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved May 2008. Revised 9/09, 05/2012.

MAJOR DEPRESSIVE DISORDER



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

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

Drug Class	Generic Name	Brand Name	May Consider First If	Initial Dose (Dose Range) mg/day	Therapeutic Range ng/mL	Monitoring
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram 20mg, 40mg tablet	Celexa®	Atypical features or dysthymia	20 (20 – 40)	N/A	<ul style="list-style-type: none"> 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®	Atypical features or dysthymia	20 (20 – 60)		
	Sertraline 50mg, 100mg tablet	Zoloft®	Significant anxiety	50 (50 – 200)		
Tricyclic Antidepressant* (TCA)	Nortriptyline 25mg, 50mg, 75mg capsule	Pamelor®	Melancholic features	25 – 50 (75 – 150)	50 - 150	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Liver function test at baseline Nortriptyline dose > 100 mg/day – EKG at baseline and as clinically indicated, and blood level within 2 weeks, then as clinically indicated
Other*	Trazodone 50mg, 100mg tablet	Desyrel®	Atypical features or dysthymia	100 – 150 (300 – 600)	N/A	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Priapism

*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.

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

1

- 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 Ace-Inhibitor** (Enalapril 2.5mg QD) if no contraindications (see Table 1).
 - Start statin therapy if LDL is >100mg/dl. (Pravastatin 10 to 80mg 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 Ace-Inhibitor, microalbumin annually.
If microalbumin > 30, consider non-dihydropyridine CCB (verapamil or diltiazem). Ace-inhibitor or CCB usage precludes necessity for annual microalbumin.

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

- 2
- 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

3

Controlled?

No

Yes

- 4
- 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.

5

- Estimate the average amount of regular insulin needed before each meal for the past 2 weeks. Convert to fixed amount of regular insulin before each meal.
- Monitor for hypoglycemia by obtaining FS AC and HS as clinically indicated – minimum of 4 times a week before different meals.
- Return to clinic every month until stable, then follow up in Chronic Care Clinic.
- Obtain A1c every 3 months
- Obtain Complete Metabolic Panel (CMP), Hepatic Function Panel (LFP), Lipid panel, and UA annually
- Conduct foot & eye exam annually

6

Is patient experiencing hypoglycemia \geq twice a week? (FS <60mg/dl)?

No

Yes

7

Controlled?

No

9

- 8
- Adjust insulin to prevent hypoglycemia
 - Consider referral to specialist

- Reevaluate compliance with medications, exercise and diet.
- Reevaluate regular sliding scale and NPH doses.
- Consider referral to specialist.

***Glycemic Control Statement:**

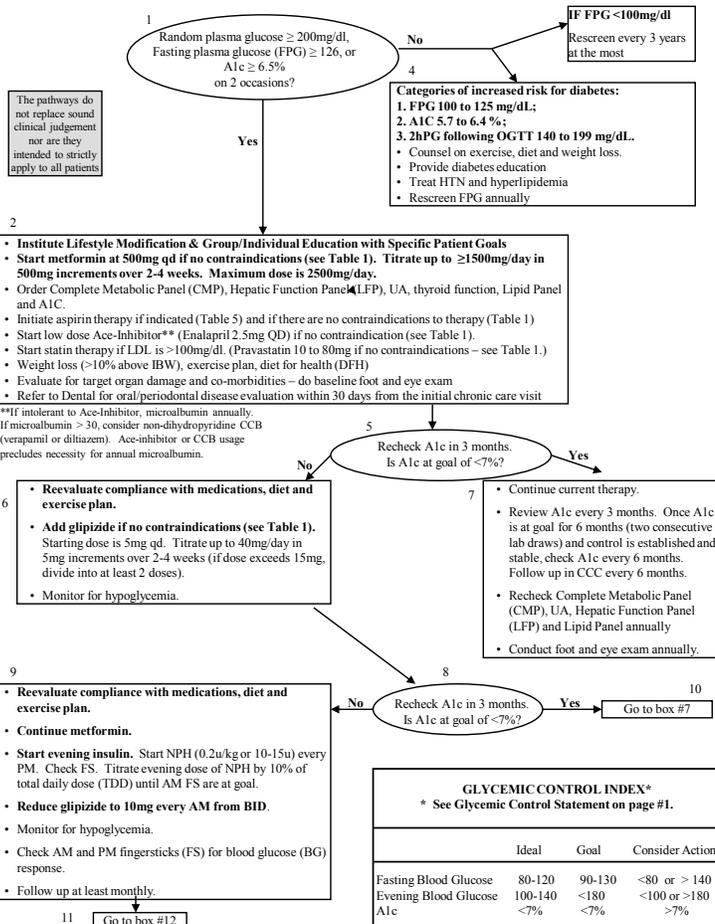
Less stringent A1C goals than the general goal of < 7 % may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, or extensive comorbid conditions and those with longstanding diabetes in whom the general goal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

GLYCEMIC CONTROL INDEX*

	Ideal	Goal	Consider Action
Fasting Blood Glucose	80-120	90-130	<80 or > 140
Evening Blood Glucose	100-140	<180	<100 or >180
A1c	<7%	<7%	>7%

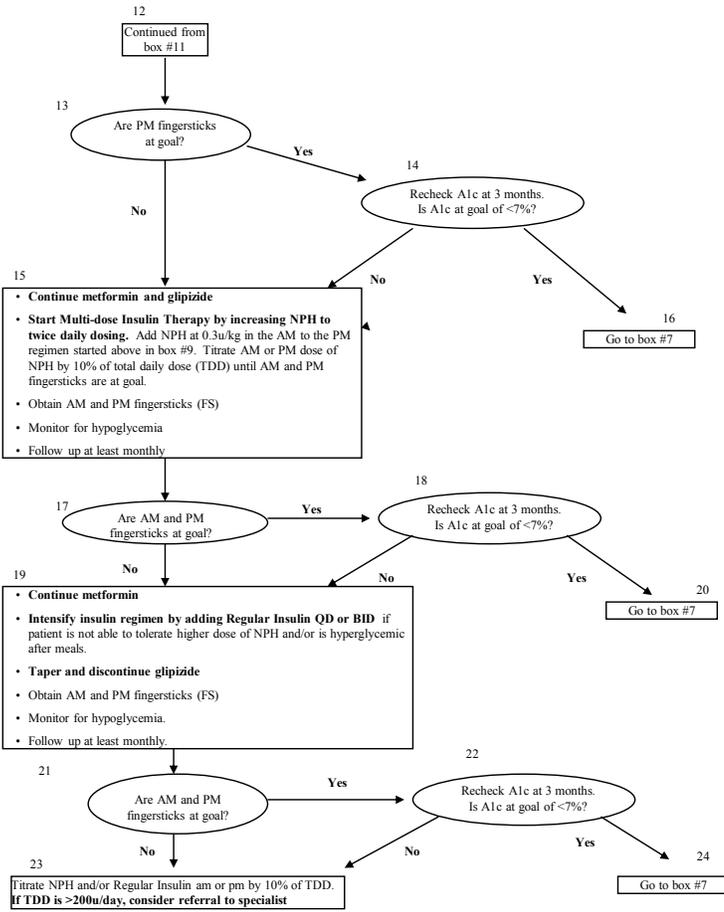
Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, March 1997, Revised 9/97,6/01, 4/03, 3/04, 9/06, 9/07, 7/08, 3/10, 11/14, Reviewed 3/13.

TYPE 2 DIABETES MELLITUS



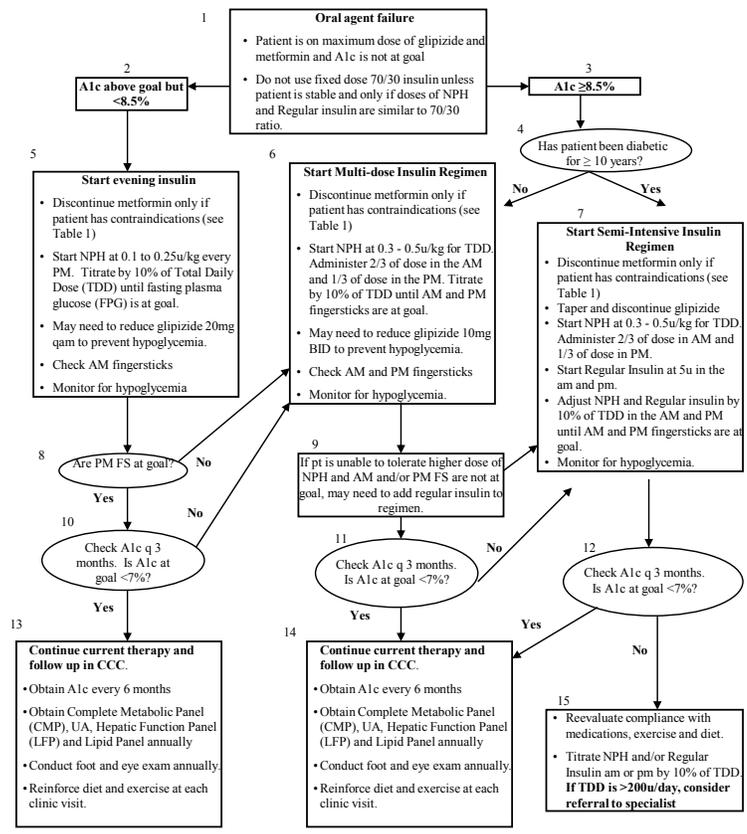
GLYCEMIC CONTROL INDEX*			
* See Glycemic Control Statement on page #1.			
	Ideal	Goal	Consider Action
Fasting Blood Glucose	80-120	90-130	<80 or > 140
Evening Blood Glucose	100-140	<180	<100 or >180
A1c	<7%	<7%	>7%

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. 3/97, Revised 9/97, 6/01, 4/03, 3/04, 9/06, 9/07, 7/08, 3/10, 3/13, 11/14.



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



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, 3/10, 3/13, 11/14.

DIABETES DISEASE MANAGEMENT GUIDELINES

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, if 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 ($\geq 120\%$ desirable body weight/IBW or BMI ≥ 25 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 ($\geq 140/90$)
 - 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. Extremity 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 and current treatment of diabetes and results
 5. Prior or current infections, frequency
 6. Severity and cause of acute complications of DM (hypoglycemia/ketoacidosis)
 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. Extremities: 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.

CRITERIA FOR DIABETES MELLITUS DIAGNOSIS			
Lab:	Normal:	Categories of increased risk for diabetes:	Diabetes:
Fasting Plasma Glucose (FPG)*	< 100 mg/dL	100 to 125 mg/dL	≥ 126mg/dL
2hPG following OGTT**	< 140 mg/dL	140 to 199 mg/dL	≥ 200mg/dL
HbA1c (A1C)*	< 5.7 %	5.7 to 6.4 %	≥ 6.5 %

*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 90-130mg/dL and PM fingersticks <180mg/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 commiserate 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 hours 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 ketoacidosis 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, then as needed.
 - 5. Transportation: No restriction unless severe/brittle diabetic that would necessitate nursing/EMS care/monitoring during transport.

EDUCATION FOR PATIENTS AND PRACTITIONERS

- I. Who is educated?
 - A. Unit Practitioners – updated on diabetes so accurate and easy to understand information is provided to patients.
 - B. All diabetic patients
 1. Type 1 diabetics - absolute deficiency in insulin secretion.
 2. Type 2 diabetics - 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 dietitians 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, lightheadedness, shakiness, blurry vision
 - b. Treatment - Counsel patient to ingest 15 grams of carbohydrates (i.e. 1 slice of bread, 4-5 small pieces of candy, ½ can of soda, 4oz 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, sinus 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 – Done every 3 months (if not at goal) or every 6 months (if at goal). A1c signifies overall control patient's diabetes.
 2. Finger sticks – Ordered 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 he or she 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 supple by drinking plenty of water. Never put lotion or moisturizers between the toes.
 3. Wash feet daily with lukewarm water and soap.
 4. Dry feet well, especially between the toes.
 5. Check feet daily (including bottoms and between toes) for sores, redness, and swelling.
 6. Change into clean socks daily.
 7. Keep feet warm and dry.
 8. Never walk barefoot.
 9. Keep toenails trimmed.
 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.

Pharmacologic Therapy

Table 1. Contraindications to medications commonly used in Diabetes Management

Medication	Absolute Contraindications
Metformin	<ul style="list-style-type: none"> •Renal impairment (i.e. SCr \geq1.4mg/dL in females and \geq1.5mg/dL in males •Metabolic acidosis, acute or chronic, including ketoacidosis •Iodinated contrast media, intravascular use in radiologic studies •Hypersensitivity to metformin
Glipizide	<ul style="list-style-type: none"> •Diabetic ketoacidosis •Hypersensitivity to glipizide
Insulin	<ul style="list-style-type: none"> •Hypersensitivity to any component of the formulation
Enalapril	<ul style="list-style-type: none"> •ACE-inhibitor induced andioedema •Hereditary or idiopathic andioedema •Pregnancy •Hypersensitivity to enalapril or other ACE inhibitors
Aspirin	<ul style="list-style-type: none"> •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
Statins (e.g., Pravastatin and Atorvastatin)	<ul style="list-style-type: none"> •Active liver disease •Unexplained persistent elevations of serum transaminases •Pregnancy •Hypersensitivity to statins or any component of the formulation

Table 2. Comparison of Agents

Intervention	Decrease in A1c (%)*	Advantages	Disadvantages
Lifestyle monotherapy	1-2	Low cost, many benefits	Fails in 1 year
Metformin	1.5	Weight neutral, inexpensive	GI side effects, rare lactic acidosis
Glipizide	1.5 - 2.5	Inexpensive	Weight gain, hypoglycemia
Insulin	1.5	No dose limit, improved lipid profile, inexpensive	Injections, monitoring, hypoglycemia, weight gain

*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*

Insulin	Onset of Action	Peak Action	Effective Duration
Regular Insulin	30 to 60 min	2 to 3 hours	8-10 hours
NPH Insulin	2 to 4 hours	4 to 10 hours	12 to 18 hours
70/30 Insulin	30 to 60 min	3 to 12 hours	12 to 18 hours

*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.

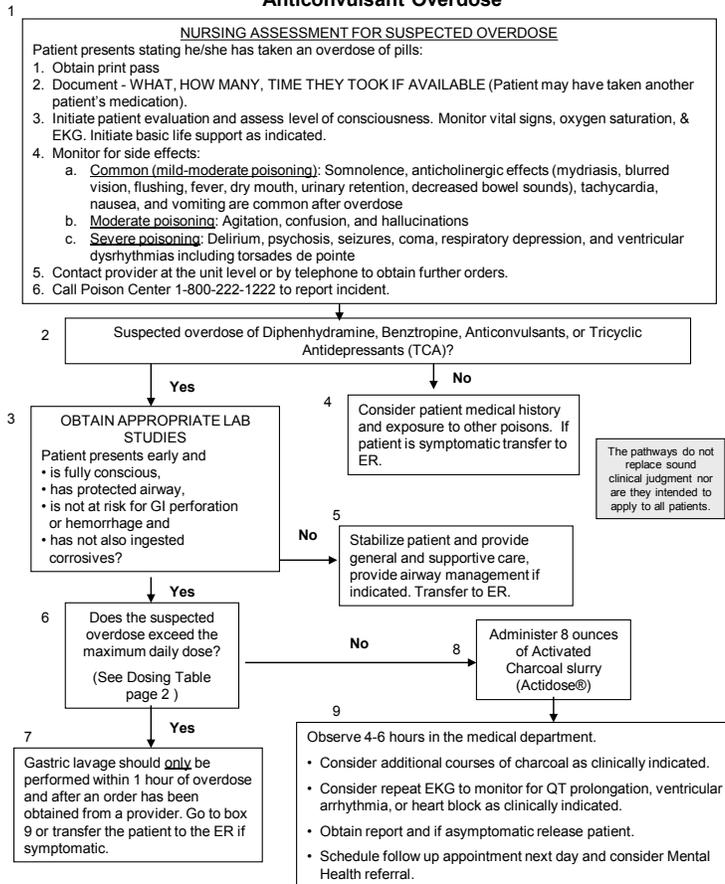
Table 4. Sample Regular Insulin Sliding Scale

Blood glucose range (mg/dL)	Units of regular insulin to be administered
150 to 200	2
201 to 250	4
251 to 300	6
301 to 350	8
351 to 400	10
401 to 450	12
451 to 500	14
>501	Check for ketones, Contact unit provider

Table 5. Indications for Daily Aspirin Therapy*

Indication	Comments
Primary Prevention	
<ul style="list-style-type: none"> Men > 50 years of age with diabetes and at least 1 additional major cardiac risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). 	Consider aspirin therapy (75 to 162 mg/day).
<ul style="list-style-type: none"> Women > 60 years of age with diabetes and at least 1 additional major cardiac risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). 	Consider aspirin therapy (75 to 162 mg/day).
<ul style="list-style-type: none"> Lower risk individuals, such as men < 50 years of age or women < 60 years of age without other major risk factors. 	There is not sufficient evidence to recommend aspirin.
<ul style="list-style-type: none"> Not recommended for patients < 21 years 	Risk of Reye's syndrome.
Secondary Prevention	
<ul style="list-style-type: none"> Patients with diabetes and a history of CVD. 	Use aspirin therapy (75 to 162 mg/day).
<ul style="list-style-type: none"> Patients with diabetes, CVD, and documented aspirin allergy. 	Use clopidogrel (75 mg/day).
<ul style="list-style-type: none"> Patients with diabetes, CVD, and an Acute Coronary Syndrome. 	Combination therapy with aspirin (75 to 162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to 1 year after the event.

**Initial Assessment of Suspected Overdose
Management of TCA, Diphenhydramine, Benztropine &
Anticonvulsant Overdose**



Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved March 2011. Reviewed November 2014.

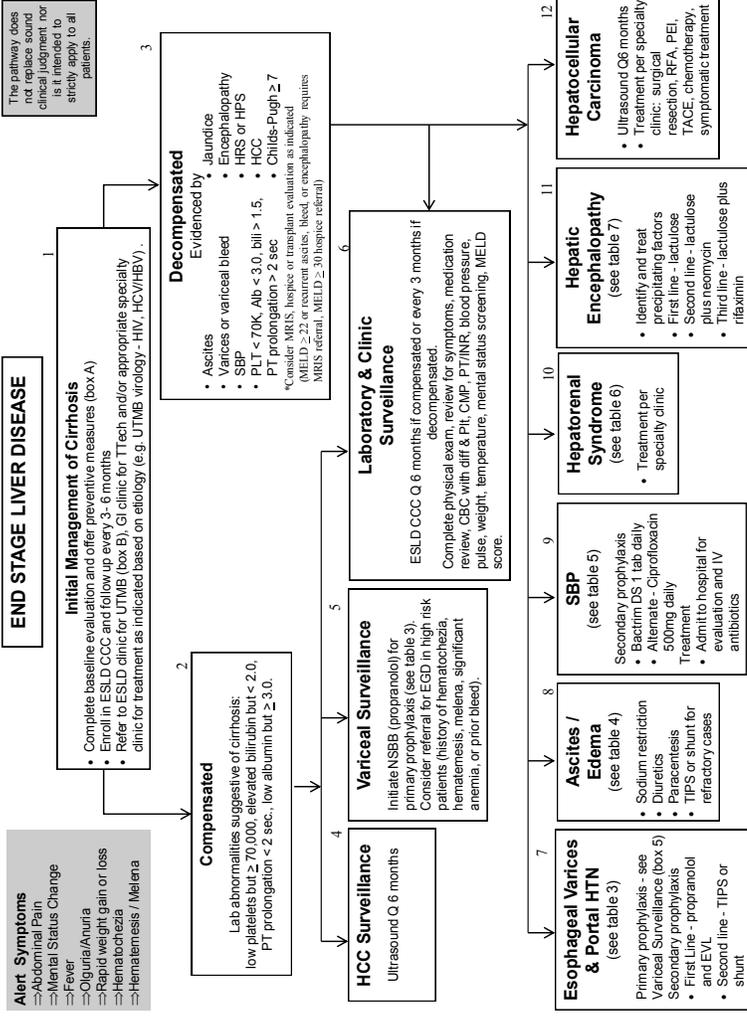
Therapeutic and Toxic Doses

Diphenhydramine, Benzotropine & TCA Therapeutic and Toxic Doses			
Drug	Usual Therapeutic Dosing	Maximum Daily Dose	Common Dose of Severe Toxicity
Benzotropine	1-4 mg/day	8 mg/day	-
Diphenhydramine	25-50 mg q 4-8h	400 mg divided	> 1 g
Desipramine	100-200 mg/day	300 mg/day	10-20 mg/kg
Doxepin	75-150 mg/day	300 mg/day	10-20 mg/kg
Imipramine	75-150 mg/day	200-300 mg/day	10-20 mg/kg
Nortriptyline	75-150 mg/day	150 mg/day	10-20 mg/kg

Divalproex Therapeutic and Toxic Doses				
Drug	Usual Therapeutic Dosing	Maximum Daily Dose	Common Dose of Severe Toxicity	Usual Toxic Serum Level
Valproic Acid	15-60 mg/kg/day	60 mg/kg	>28 g	>450mcg/mL

Phenytoin Therapeutic and Toxic Doses				
Drug	Usual Therapeutic Dosing	Maximum Daily Dose	Common Dose of Severe Toxicity	Usual Toxic Serum Level
Phenytoin	300-400 mg/day	1,000 mg divided	>20 mg/kg	>20 mcg/mL

Carbamazepine Therapeutic and Toxic Doses				
Drug	Usual Therapeutic Dosing	Maximum Daily Dose	Common Dose of Severe Toxicity	Usual Toxic Serum Level
Carbamazepine	Up to 1200 mg/day, divided	1600 mg divided	>1600 mg	>12 mcg/mL



CCC - chronic care clinic, EVL - endoscopic variceal ligation, ICC - hepatocellular carcinoma, IBS - hepatopulmonary syndrome, IE - hepatic encephalopathy, IRS - hepatorenal syndrome, MELD - model for end-stage liver disease, NSBB - non-selective beta blocker, PH - percutaneous ethanol injection, RFA - radiofrequency ablation, SBP - spontaneous bacterial peritonitis, TACE - transarterial chemoembolization, TIPS - transjugular intrahepatic portosystemic shunt.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. Approved 7/2013.

Box A. Initial Management

Baseline Evaluation

- Complete H&P
- Vitals including weight
- Labs: CBC with diff and plts, PT/INR, CMP, 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

- Hematochezia/Hematemesis

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

	POINTS*		
	1	2	3
Encephalopathy	None	Grade 1-2 (or precipitant-induced)	Grade 3-4 (or chronic)
Ascites	None	Mild / Moderate (diuretic - responsive)	Severe (diuretic - refractory)
Bilirubin (mg/dL)	< 2	2 - 3	> 3
Albumin (g/dL)	> 3.5	2.8 - 3.5	< 2.8
PT (sec prolonged) or INR	< 4 < 1.7	4 - 6 1.7 - 2.3	> 6 > 2.3

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

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

Grade 0	No detectable symptoms
*Minimal (or covert) Encephalopathy (MHE)	Mildest form of the HE continuum. Subtle neurocognitive abnormalities primarily affect attention, vigilance, response inhibition, and executive function which are not recognizable on standard neurological or mental status examination, but are evident on psychometric testing. MHE may predict the development of overt HE and is associated with poor survival.
Grade 1	Trivial lack of awareness Euphoria or anxiety Shortened attention span Impaired performance of addition
Grade 2	Lethargy or apathy Minimal disorientation for time or place Subtle personality change Inappropriate behavior Impaired performance of subtraction
Grade 3	Somnolence to semi-stupor, but responsive to verbal stimuli Confusion Gross disorientation
Grade 4	Coma (unresponsive to verbal or noxious stimuli)

* Not an official stage on the West Haven Scale.

TABLE 3: ESOPHAGEAL VARICES & PORTAL HYPERTENSION	
EVALUATION & TREATMENT	<ul style="list-style-type: none"> • Nonselective beta-blockers (propranolol) are the preferred pharmacologic agent for prevention of bleeding and should be continued indefinitely. <ul style="list-style-type: none"> ◦ 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 <ul style="list-style-type: none"> ◦ Small varices - propranolol ◦ Medium/large varices - propranolol. Endoscopic variceal ligation (EVL) may be preferred in patients at high risk of hemorrhage or those who have contraindications or intolerance to beta-blockers. (Decision to perform EVL would be made by ESLD specialty clinic). • Secondary Prophylaxis <ul style="list-style-type: none"> ◦ 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): <ul style="list-style-type: none"> ◦ 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	<p>Surveillance</p> <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 gm/dL indicates portal hypertension with 97% accuracy. <ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> ◦ For minimal to mild edema: <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none"> – Furosemide 40mg with Spironolactone 100mg. Also useful in patients who do not respond to or have hyperkalemia with spironolactone monotherapy. – Titrate diuretic therapy every 5-7 days. This 40:100 ratio of furosemide:spironolactone can be increased to 80mg furosemide plus 100mg spironolactone, and further increased to 80mg BID furosemide plus 100mg BID spironolactone. – Amiloride 10-40mg daily may be substituted for spironolactone if tender gynecomastia is present, but may be less effective. Nonformulary approval is required. – If the above program does not work, metolazone 5 mg can be added once per week, increasing to 5mg M-W-F, then 5 mg M-F, and 5mg daily. Renal function and electrolytes must be monitored closely when using > 2 diuretics. Consider BMP every 1-2 weeks until stable, then monthly. – Monitor for diuretic complications (BMP every 1-2 weeks during titration) which include uncontrolled or recurrent encephalopathy, serum sodium < 120 mmol/L despite fluid restriction, Scr > 2.0 mg/dL, K > 6.0. – TED hose (knee-high) may be considered for lower leg edema. Patients with thigh swelling or who demonstrate pitting over the thighs need thigh-high TED hose. If the hose will not stay up or if there is abdominal wall swelling, consider referral to Brace & Limb for fitted compression garments (hose up to the waist). Compression hose and garments may help prevent hospitalization for chronic edema and cellulitis. • Tense ascites (massive and/or painful) - consider large volume paracentesis (LVP) followed by sodium restriction and diuretic therapy. Caution as LVP and aggressive diuresis can precipitate HRS.

Continued on page 4

TABLE 4: ASCITES / EDEMA CONTINUED	
EVALUATION & TREATMENT	<ul style="list-style-type: none"> • Refractory Edema or Ascites <ul style="list-style-type: none"> ◦ 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	<ul style="list-style-type: none"> • 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 acidosis. • Diagnosis is confirmed by paracentesis with ≥ 250 PMNs/mm³ and/or positive ascitic bacterial culture. • Acute treatment requires hospitalization and IV antibiotic (cefotaxime or ceftriaxone). • Outpatient prophylaxis of SBP <ul style="list-style-type: none"> ◦ All patients with a history of prior SBP should receive indefinite prophylaxis with one of the following: <ul style="list-style-type: none"> – First line - sulfamethoxazole/trimethoprim DS one tab daily – Second line - ciprofloxacin 500mg po once daily. (Reserved for sulfa allergy or renal insufficiency.)
MONITORING	Signs/symptoms and vitals (temperature) at each encounter. CMP and CBC every 90 days or more frequently if clinically indicated.
TABLE 6: HEPATORENAL SYNDROME (HRS)	
TREATMENT	<ul style="list-style-type: none"> • HRS 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. <ul style="list-style-type: none"> ◦ Sepsis ◦ Volume depletion ◦ Vasodilators ◦ Organic renal failure • There are two types of HRS <ul style="list-style-type: none"> ◦ 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	<ul style="list-style-type: none"> • 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, dehydration, psychoactive medications, constipation, poor compliance with medications). HE is a clinical diagnosis and serum ammonia levels are not routinely indicated. • Pharmacologic Prophylaxis (indefinite) <ul style="list-style-type: none"> ◦ 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 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. <ul style="list-style-type: none"> ◦ 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 infirmity 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

Medication	Formulary Status	Indication	Dosing	Side Effects / Comments
Amiloride 5mg tab	NF	Ascites / edema	5mg to 10mg once daily	Hyperkalemia, hyponatremia, acidosis, GI upset
Ciprofloxacin 500mg tab	NF	SBP Prophylaxis	500mg once daily	Rash, nausea, vomiting, diarrhea Reserved for sulfa allergy or renal insufficiency.
Furosemide 20mg, 40mg tab	F	Ascites / edema	40mg to 160mg daily. Doses over 80mg daily should be divided twice daily.	Electrolyte disturbances including hypokalemia and hyponatremia, increased serum creatinine, photosensitivity, rash, dizziness, hypotension, hyperuricemia
Lactulose 10gm/15ml syr	F	Hepatic Encephalopathy	Start at 30 mL BID - TID. Titrate to achieve 3-4 loose stools per day.	Can cause electrolyte imbalance, abdominal discomfort, cramping, nausea, flatulence.
Metolazone 5mg tab	F	Ascites / edema	Titrate slowly up to 5mg daily	Electrolyte disturbances including hypokalemia and hyponatremia, increased serum creatinine, photosensitivity, rash, dizziness, hypotension, hyperuricemia
Neomycin 500mg tab	NF	Hepatic Encephalopathy	500mg to 1000mg BID	Nausea, nephrotoxicity, ototoxicity. Avoid in AKI or CKD.
Propranolol 10mg, 20mg, 40mg tab	F	Esophageal varices	Initial dose 20mg BID. Titrate to a maximally tolerated dosage (heart rate 55-60 beats/minute).	Hypotension, bradycardia, fatigue. Caution in decompensated CHF, sinus bradycardia, heart block, severe asthma or COPD.
Rifaximin 200mg tab	NF	Hepatic Encephalopathy	600mg (3 x 200mg tabs) po BID	Reserved for breakthrough HE despite optimized lactulose and neomycin.
Spironolactone 25mg tab	F	Ascites / edema	100mg to 400mg daily	Gynecomastia, hyperkalemia, rash, renal dysfunction
Sulfamethoxazole / trimethoprim 800mg/160mg tab	F	SBP Prophylaxis	1 double strength tablet once daily	GI upset, rash, urticaria, blood dyscrasia, hyperkalemia, crystalluria

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

Medication	Formulary Status	Dosing / Comments
Acetaminophen	F	May be used up to a maximum daily dose of 2,600mg.
Acetaminophen / codeine	F*	Up to 2,600mg acetaminophen daily. Impaired hepatic conversion of codeine (prodrug) to its active form may result in decreased analgesic effect.
Morphine sulfate	F*	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.
NSAIDS	F	NSAIDS should generally be avoided in patients with cirrhosis due to increased risk of variceal hemorrhage, impaired renal function, risk of hepato-renal syndrome, and 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.
Benzodiazepines	F*	Should generally be avoided in cirrhosis as benzodiazepines may trigger or aggravate hepatic encephalopathy.
Anticonvulsants Carbamazepine Divalproex Phenytoin Primidone	F	Phenytoin, carbamazepine, and divalproex are all extensively metabolized by the liver, highly protein bound, and potentially hepatotoxic. They should generally be avoided in cirrhosis due to increased risk of toxicities, including thrombocytopenia. Divalproex is contraindicated with severe hepatic impairment. Primidone is also heavily metabolized by the liver and can accumulate in cirrhosis precipitating hepatic encephalopathy. If anticonvulsant therapy is indicated, levetiracetam may be considered. Levetiracetam requires dose adjustment in renal impairment.

*Formulary restrictions apply

Information for the Provider

I. Screening for Cirrhosis

A. Key History Questions

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

B. Key Physical Findings

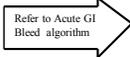
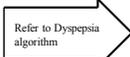
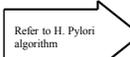
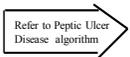
1. Always list age, height, weight, and BMI at each visit. Check last visit and note change.
2. Skin/Hands/Nails: jaundice, thin skin, bruises, petechiae, palmar and peri-nail bed erythema, curved nails, Dupuytren's contractures, spider angiomas, venous pattern over abdomen (caput medusa), especially 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 penile or scrotal edema. May have pitting over abdomen.
8. Ascites: best test is shifting dullness.
9. Encephalopathy: asterixis, accentuated by closing eyes with arms outstretched. Minimal encephalopathy: tremor of hands when out stretched with eyes closed.

C. Key Laboratory Findings

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

Gastrointestinal Pathways

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

Present?	Symptom / Disease
<input type="checkbox"/> Yes <input type="checkbox"/> No	Acute GI Bleed 
<input type="checkbox"/> Yes <input type="checkbox"/> No	Heartburn 
<input type="checkbox"/> Yes <input type="checkbox"/> No	Reflux 
<input type="checkbox"/> Yes <input type="checkbox"/> No	H. Pylori Positive 
<input type="checkbox"/> Yes <input type="checkbox"/> No	Ulcer 

*Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved September 2010, Revised 11/2015, Reviewed 03/2012*

ACUTE GI BLEED TRIAGE

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

2

Signs of hypovolemia?

(SBP<100, RR>20/min, HR>100 bpm, orthostatic hypotension)
OR

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.

Yes

No

3

Unstable patient and/or apparent GI bleed

- Activate EMS/911 system
- Establish IV access and NS infusion
- Administer oxygen by nasal cannula or mask

4

Stable patient with possible GI bleed

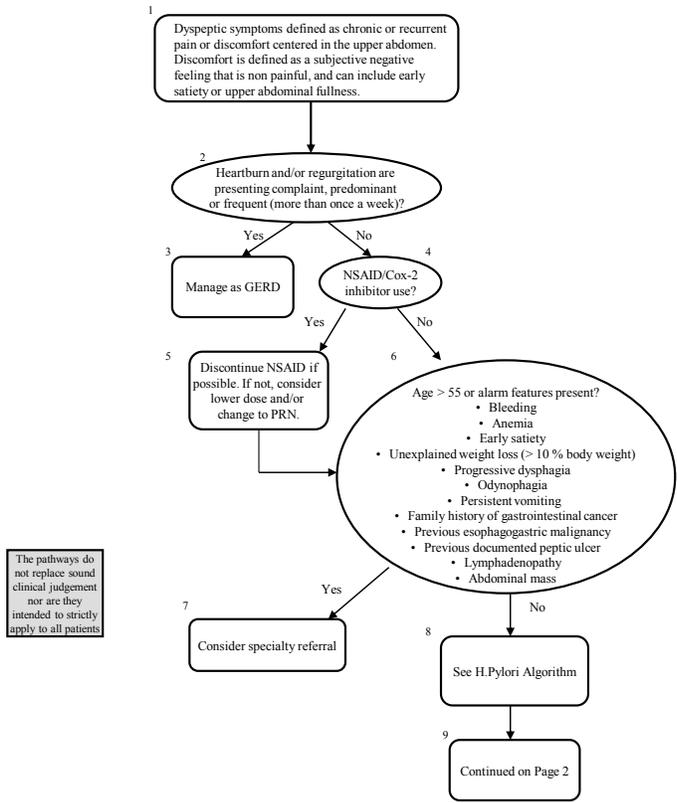
Based on clinical presentation, further evaluation and/or observation may be indicated as follows:

- 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

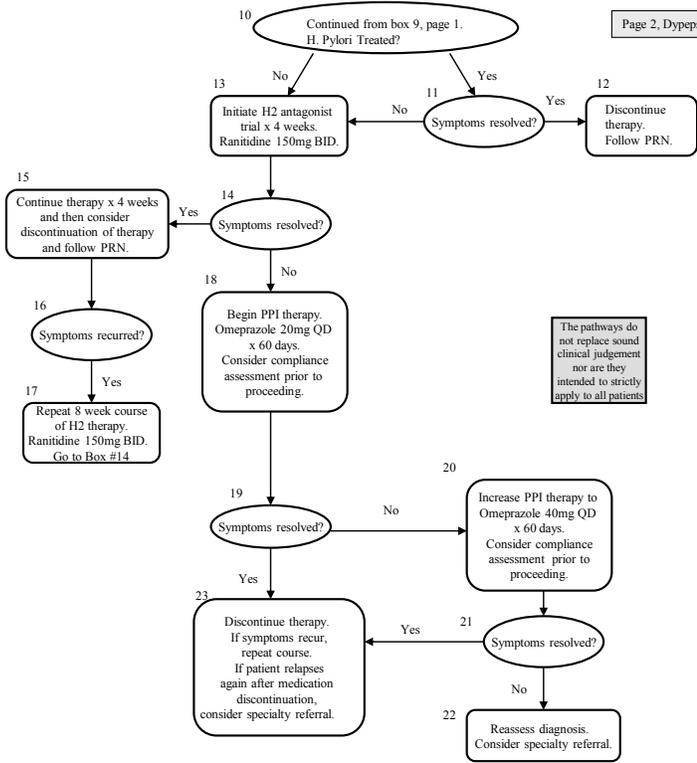
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients

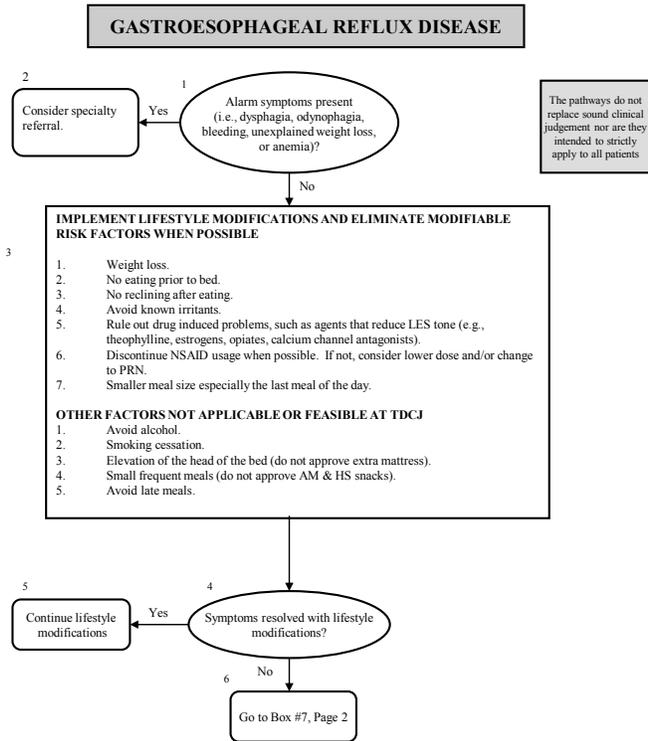
Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee,
Approved May 2012; Reviewed 11/2015.

DYSPEPSIA

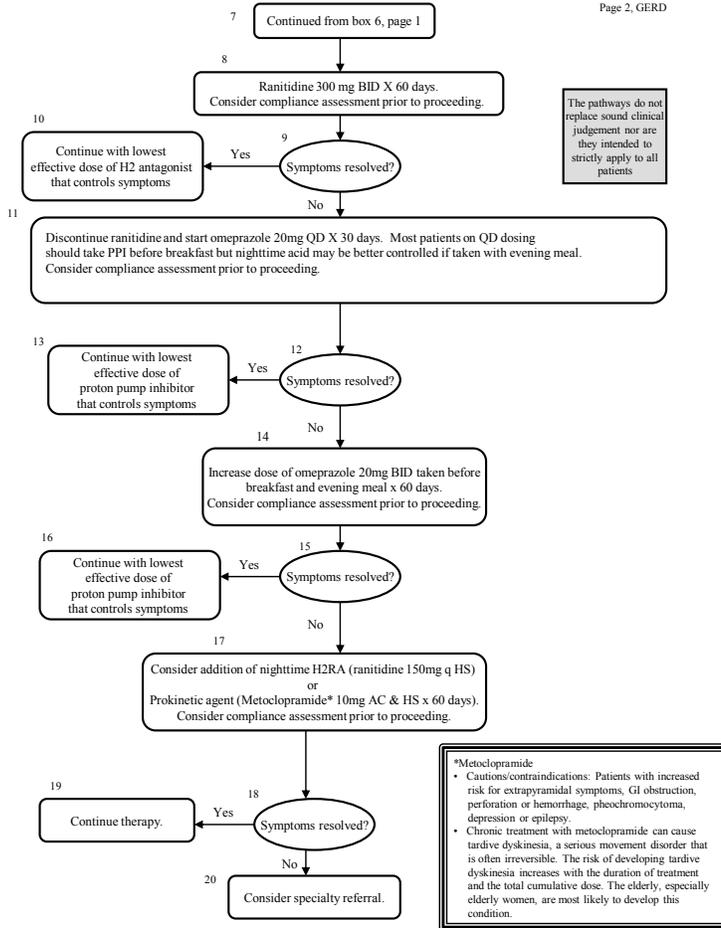


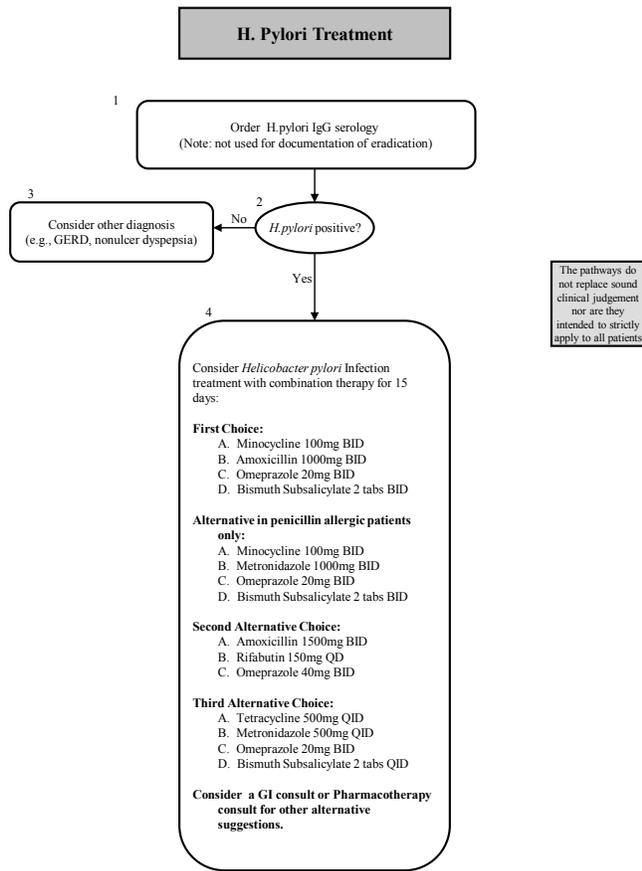
*Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved August 1995, Revised 6/99, 4/03, 1/07, 9/10. Reviewed 3/12, 11/2015.*





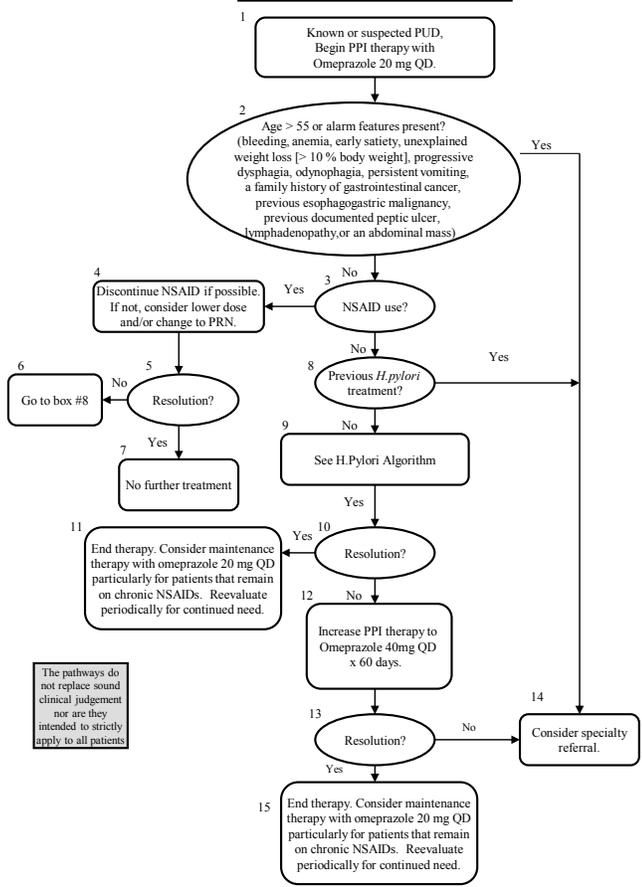
Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.
 Approved August 1995; Revised 8/98, 6/99, 11/01, 4/03, 9/06, 9/10; Reviewed 3/12, 11/2015.





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Peptic Ulcer Disease (PUD)



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.
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GOUT

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

1

Establish Diagnosis of Gout

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

Criteria for clinical diagnosis of gout:
 In the absence of the means to identify urate crystals or in the presence of a negative polarized light microscopy, a provisional diagnosis of gout is made by a combination of clinical and historical criteria. There are no validated clinical diagnostic criteria. Criteria that may be useful include:

1. Serum uric acid level >7.0mg/dL
2. Maximum inflammation with symptoms of pain, swelling, redness, and warmth within 24 hours
3. History of one or more episodes of monoarticular arthritis followed by period(s) of completely free symptoms
4. Unilateral first metatarsophalangeal joint attack
5. Presence of a visible or palpable lesion, which by location or appearance is likely to be a tophus
6. Consider risk factors: family history, age, weight, male gender (See Table 1)

2

Baseline Recommendations

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

3 **Clinical Features**

4 **Asymptomatic**

5

- Sudden onset of pain
- Erythema
- Swelling involving joints

6

Established diagnosis of gouty arthritis and one or more of the following:

- **Tophus or tophi** by clinical exam or imaging study
- **Frequent attacks** of acute gouty arthritis (≥2 attacks/year)
- **CKD Stage 2** (Glomerular Filtration Rate (GFR) between 60 to 89) or worse (GFR < 60)
- **Recurrent urolithiasis**

7

Therapy not warranted in asymptomatic patients

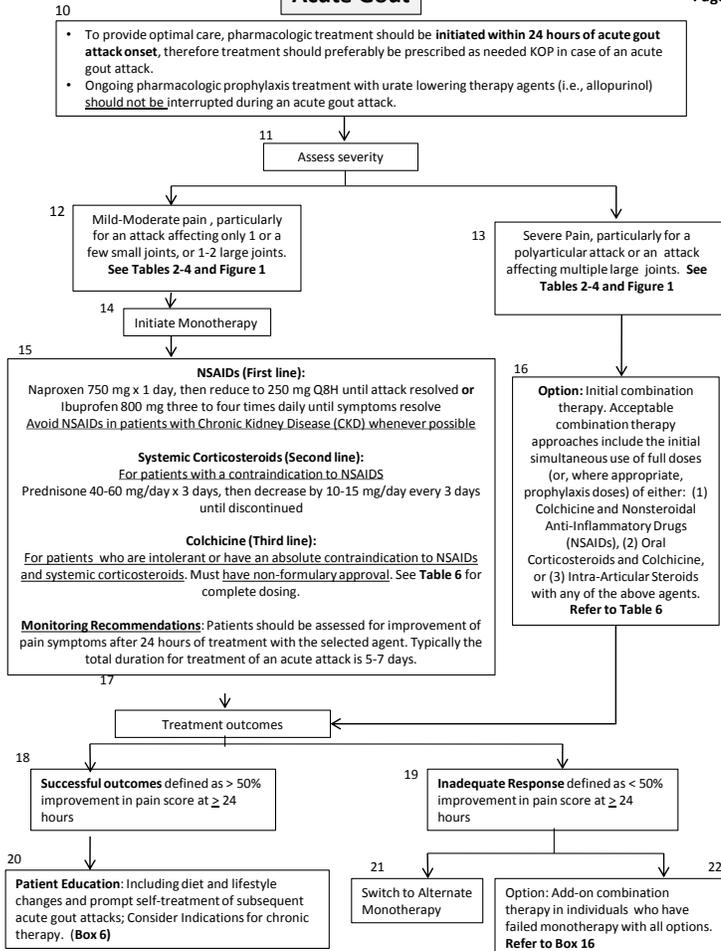
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See **Acute Gout** (Page 2)

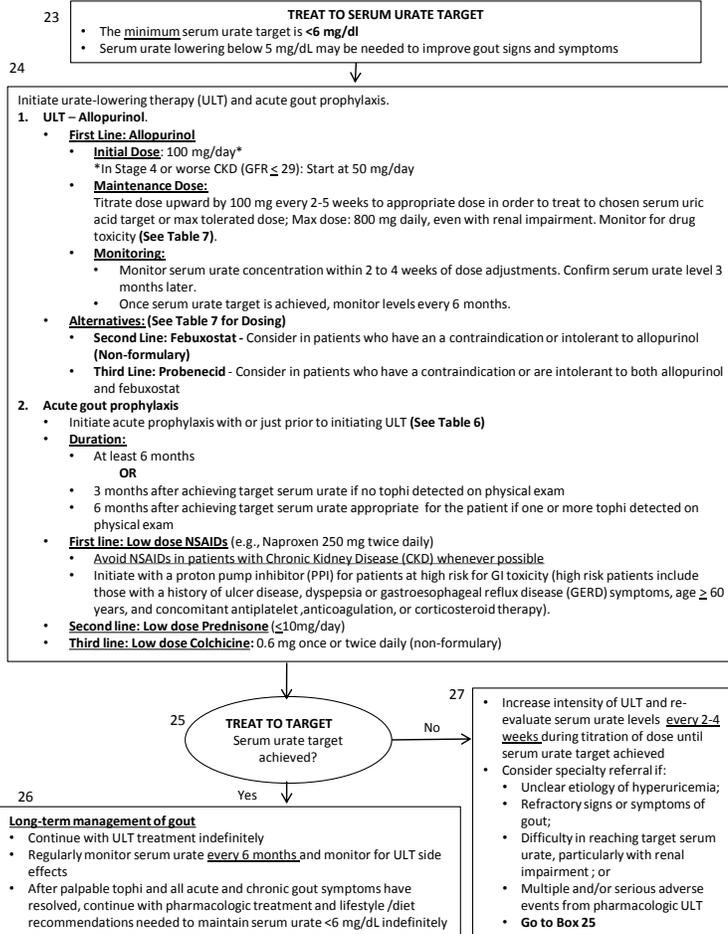
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Meets indication for **Chronic Gout Prophylaxis** (Page 3)

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, January 2015.

I. Risk Factors that promote hyperuricemia

Table 1

Risk Factors	
Comorbidities	<ul style="list-style-type: none"> • Hypertension • Obesity • Metabolic syndrome • Type 2 Diabetes Mellitus • Hyperlipidemia • Chronic Kidney Disease
Medications	<ul style="list-style-type: none"> • Diuretics (Loop and Thiazides) • Niacin • Aspirin (75 to 325 mg/day) • Pyrazinamide
Diet	<ul style="list-style-type: none"> • Excessive alcohol intake (particularly beer) (≥ 2 servings/day for a male and ≥ 1 serving/day for a female) • Organ meats high in purine content (e.g., sweetbreads, liver, kidney) • Beverages containing high fructose corn syrup • Overeating
Other	<ul style="list-style-type: none"> • Adult males (often between the ages of 30-45) • ≥ 65 years of age (regardless of gender)

II. Acute Gout

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

Table 2: Severity of Acute Gouty Arthritis Attack

Intensity of attack based on self-reported pain (0-10 visual analog scale)	
Mild	≤ 4
Moderate	5-6
Severe	≥ 7

Figure 1: Visual Analog Scale (VAS)

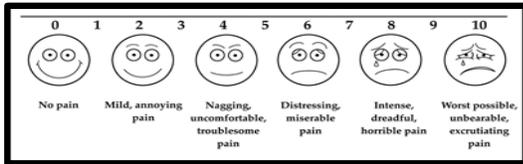


Table 3

Duration of the gouty arthritis attack since onset	
Early	<12 hours after attack onset
Well-Established	12 to 36 hours after attack onset
Late	>36 hours after attack onset

Table 4

Extent of acute gouty arthritis attack Based on number of active joints
One or a few small joints
1 or 2 large* joints <i>*defined as: ankle, knee, wrist, elbow, hip, shoulder</i>
Polyarticular <ul style="list-style-type: none"> 4 or more joints, with arthritis involving more than 1 region <ul style="list-style-type: none"> Regions defined as: forefoot (metatarsophalangeal joints, toes), midfoot (tarsal joints), ankle/hindfoot, knee, hip, fingers, wrist, elbow, shoulder, other Acute gout attack involving 3 separate large joints is considered as a form of polyarticular gout

B. Recommendations for combination therapy for acute gout treatment

Table 5

Recommendations for Combination Therapy Approach to Acute Gouty Arthritis
<ul style="list-style-type: none"> Initial combination therapy is an appropriate option for an acute, severe gout attack, particularly with involvement of multiple large organs or polyarticular arthritis. Acceptable combination therapy approaches include the initial simultaneous use of full doses (or, where appropriate, prophylaxis doses) of either: <ul style="list-style-type: none"> (1) Colchicine and Nonsteroidal Anti-Inflammatory Drugs (NSAIDs); (2) Oral Corticosteroids and Colchicine; or (3) Intra-Articular Steroids with any of the above agents. For some patients not responding adequately to initial pharmacologic monotherapy, adding a second appropriate agent is an acceptable option.

Acute Gout Treatment			
Drug	Dosage Forms	Dosing	Side Effects/ Contraindications/Monitoring
Colchicine			
Colchicine (Colcrys®) +Probenecid (Colbenemid®) Status: Non-Formulary	0.6 mg tablet	Initial: 1.2 mg orally (two 0.6 mg tablets) followed by 0.6 mg in 1 hour (Max 1.8 mg over 1 hour) Prophylaxis: 0.6 mg orally once or twice daily beginning 12 hours after initial dose; Max 1.2 mg/day If CrCl below 30 ml/min: 0.3 mg/day (half-tablet) orally initially; may increase dose to a max of 1.2 mg/day with close monitoring for toxicity	Common Side Effects: • Nausea, vomiting, abdominal pain, diarrhea (Approximately 80% of patients at high doses > 1.8 mg) Colchicine toxicity: • Myelosuppression, rhabdomyolysis or myopathy, reversible peripheral neuropathy, liver failure, and death possible if overdosed Contraindications: • Do not repeat course more than once every 2 weeks in individuals with severe hepatic or renal impairment (CrCl below 30 mL/min) • Concomitant use of p-glycoprotein or strong CYP3A4 inhibitors in patients with hepatic or renal impairment (see Table 8)
NSAIDs			
Naproxen (Naprosyn®, others) Status: Formulary	250 mg, 500 mg tablet	750 mg x 1 day, then reduce to 250 mg orally every 8 hours until attack resolved	Common Side Effects: • Nausea, take with food Contraindications: • Allergic reaction following NSAIDs or aspirin use
Ibuprofen (Motrin®) Status: Formulary	200 mg, 400 mg, 600 mg, 800 mg tablet	800 mg orally three to four times a day until symptoms resolve	Precautions: • Avoid NSAIDs in patients with Chronic Kidney Disease (CKD) whenever possible • Consider bleeding risk in patients being treated with anticoagulants or those with active peptic ulcer disease
Meloxicam (Mobic®) Status: Formulary	7.5 mg, 15 mg	7.5 mg orally once daily; max 15 mg once daily	• CVD risk (mostly with celecoxib)
Indomethacin (Indocin®) Status: Non-Formulary	25 mg, 50 mg tablet	50 mg orally three times a day until pain is tolerable, then taper down to avoid risk of rebound attack	• Indomethacin was 1 st NSAID approved and is the traditional drug of choice; however, it is more toxic than ibuprofen (Increased risk for GI toxicity) and has risk of psychiatric side effects including confusion, depression, psychosis
Celecoxib (Celebrex®) Status: Non-Formulary	50 mg, 100 mg, 200 mg, 400 mg capsule	800 mg orally immediately, followed by 400 mg 12 hours later, then 400 mg every 12 hours for 7 days	
Sulindac (Clinoril®) Status: Non-Formulary	150 mg, 200 mg tablet	300-400mg orally once daily	

Table 6

Acute Gout Treatment, Continued			
Steroids: Can be given PO, IM, IV, intra-articular			
Prednisone (orally) Status: Formulary	5 mg, 10 mg, 20 mg tablet	40-60 mg/day x 3 days, then decrease by 10-15 mg/day every 3 days until discontinued	Acute Steroid Use Side Effects: Increased blood glucose, elevated blood pressure, nervousness, insomnia, increased appetite, edema.
Methylprednisolone sodium succinate (Solu-Medrol®) Status: Formulary	125 mg injection – 2 ml vial	Initial 10 to 40 mg IM; may be repeated as clinically indicated <u>(Option in patients with active acute gout affecting 1 or 2 large joints defines as: ankle, knee, wrist, elbow, hip, shoulder)</u>	Injection: Slight risk of infection, risk of joint damage with repeat injections
Triamcinolone Acetonide Status: Formulary	10 mg/ml- 5 mL vial 40 mg/mL- 1 mL vial	60 mg IM, then oral prednisone as above	

Table 7

Chronic Gout Treatment			
Drug	CMC Formulary Strengths	Dosing	Side Effects/Contraindications/Monitoring
Allopurinol (Zyloprim®) Status: Formulary	100 mg, 300 mg tablet	Mild: 100-300 mg/day orally as a single or divided doses (2-3 times daily) Moderate to severe: 400-600 mg/day orally in divided doses (2-3 times daily); Max dose 800 mg/day Stage 4 or worse CKD (CrCl <29 mL/min): Start at 50 mg/day; gradually titrate up every 2-5 weeks to appropriate maintenance dose (refer to mild and moderate/severe maintenance doses)	Common Side Effects <ul style="list-style-type: none"> Precipitation of acute gout attacks Nausea Skin rash Precautions <ul style="list-style-type: none"> Allopurinol hypersensitivity syndrome (AHS) - severe rash, fever, eosinophilia, hepatitis, and renal failure. Starting at lower doses can reduce the risk of AHS. Consider HLA-B*5801 screening in those populations at high risk for developing AHS: Koreans with Stage 3 or worse CKD (GFR < 59), and those of Han Chinese or Thai descent. Monitoring <ul style="list-style-type: none"> Check LFTs at 2 and 4 months and periodically thereafter.
Febuxostat (Uloric®) Status: Non-formulary	40 mg, 80 mg tablet	Initial: 40 mg orally once daily Maintenance: May increase to 80 mg orally once daily in patients who do not achieve a serum uric acid level below 6 mg/dL after 2 weeks.	<ul style="list-style-type: none"> May be safer in severe renal impairment and has decreased risk for hypersensitivity reactions but extremely costly. Common Side Effects <ul style="list-style-type: none"> Precipitation of acute gout attacks Rash Nausea Monitoring <ul style="list-style-type: none"> Liver enzyme elevations (requires LFT monitoring at 2 and 4 months, and then periodically thereafter)
Probenecid Status: Formulary	500 mg tablet	250 mg orally BID for one week, followed by 500 mg BID thereafter; If symptoms persist, may incrementally increase by 500 mg every 4 weeks as tolerated; MAX 2000 mg/day.	<ul style="list-style-type: none"> Uricosurics require adequate renal function. They are not commonly used, but may be used in younger patients with good renal function (CrCl greater than 50 mL/min). Common Side Effects: <ul style="list-style-type: none"> Precipitation of acute gout attacks Rash GI intolerance Uric acid stone formation Contraindications: <ul style="list-style-type: none"> Renal impairment (CrCl below 50 mL/min) Kidney stones

Table 8

Drug Interactions	
Allopurinol	<ul style="list-style-type: none"> • Azathioprine, 6-mercaptopurine, cyclophosphamide, cyclosporine - Allopurinol may increase toxicity of these agents • Ampicillin and amoxicillin - Allopurinol may result in a higher probability of rash associated with these agents • Captopril and enalapril - May result in hypersensitivity reactions including Stevens-Johnson Syndrome in combination • Didanosine - contraindicated; allopurinol may increase serum concentrations • Pegloticase - May result in an increased risk of anaphylaxis and infusion reactions in combination • Warfarin - Increased bleeding risk in combination
Colchicine	<ul style="list-style-type: none"> • Strong CYP3A4 inhibitors (increase colchicine concentrations): atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, and other • P-gp inhibitors (increase colchicine concentrations): vinca alkaloids, amiodarone, azole antifungals, clarithromycin, cyclosporine, diltiazem, erythromycin, quinidine, tacrolimus, verapamil, and others. • Dose adjustments: <ul style="list-style-type: none"> • Strong CYP3A4 inhibitors; Gout flare: 1.2 mg oral for 1 dose, do not repeat dose earlier than 3 days. • P-gp inhibitors; Gout flare: 0.6 mg oral for 1 dose, do not repeat dose earlier than 3 days. • CYP3A4 or P-gp inhibitors; Gout Prophylaxis: Avoid use, but if unavoidable, consider reduction of daily dose of 0.3 mg orally every other day to 0.3 mg orally once a day.
Febuxostat	<ul style="list-style-type: none"> • Azathioprine and 6-mercaptopurine - contraindicated; febuxostat may increase plasma concentrations

A. Causes of Gout

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

B. Risk Factors

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

C. Gout Attacks

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

D. Treatment goals

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

E. Acute gout treatment

- Pain and inflammation associated with acute gout attacks are treated using either an NSAID, colchicine, or steroids.
- The pain and inflammation of an acute gout attack usually reaches its peak of intensity within 12 to 24 hours and generally resolves completely within a few days to several weeks, even if untreated.
- Treat acute gout attacks within 24 hours of the onset of symptoms to receive the greatest benefit. Continue with treatment until symptoms resolve (usually within 5-7 days)
- NSAID counseling
 - Take with food to avoid upset stomach.
 - May cause bleeding in the stomach or intestine. Risk is higher in patients older than 60 years of age, history of stomach ulcer, using certain medications (steroids and blood thinners), individuals who smoke or drink regularly, or those with poor health.
 - May increase the risk of heart attack or stroke. Risk higher in patients with heart disease or long-term use of NSAIDs. Seek medical attention immediately if signs of a heart attack or stroke occur.
- Prednisone
 - May cause fluid retention, upset stomach (take with food), mood or behavior changes, increased appetite, weight gain, increase in blood glucose sugars, and high blood pressure.
 - Do not stop taking suddenly if using longer than 2 weeks. Must taper slowly to avoid withdrawal symptoms.
- Colchicine counseling
 - At the first sign of an attack take 2 tablets. Can take an additional tablet in one hour. Do not exceed more than 3 tablets in 24 hours.
 - Do not take 2nd dose if upset stomach, nausea, or diarrhea occurs.

F. Chronic gout

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

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

Lifestyle Recommendations for gout patients	
Exercise regularly	Engage in moderate-intensity physical activities for at least 30 minutes most days of the week
Maintain a healthy body weight	Obese patients are four times as likely to develop gout than someone with ideal body weight. Encourage weight loss for obese patients to achieve BMI that promotes general health
Stay well hydrated	Many dietitians recommend consuming at least 64 ounces of water daily, and more if the patient is exercising

Table 10

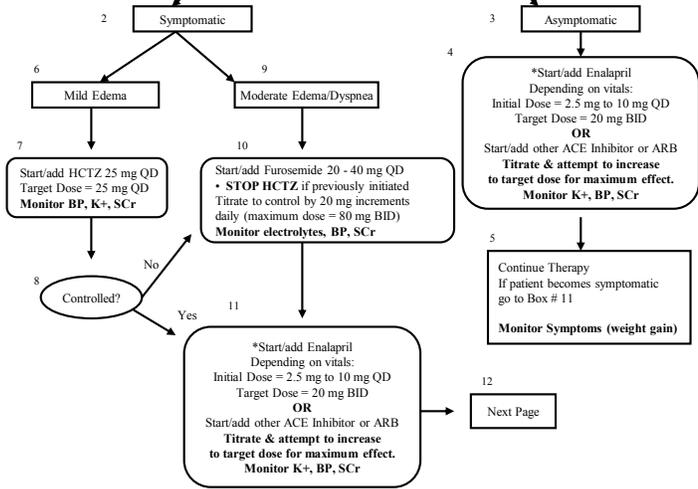
Diet Recommendations for Gout Patients		
Avoid	Limit	Encourage
<ul style="list-style-type: none"> • Organ meats high in purine content (e.g., sweetbreads, liver, kidney) 	Serving size of: <ul style="list-style-type: none"> • Beef, Lamb, Pork • Seafood with high purine content (e.g., sardines, shellfish) 	<ul style="list-style-type: none"> • Low-fat or non-fat dairy products
<ul style="list-style-type: none"> • High fructose corn syrup-sweetened sodas, other beverages, or foods 	<ul style="list-style-type: none"> • Servings of naturally sweet fruit juices • Table sugar, sweetened beverages and desserts • Table salt, including in sauces and gravy 	<ul style="list-style-type: none"> • Vegetables
<ul style="list-style-type: none"> • Alcohol overuse (Defined as more than 2 servings per day for a male and 1 serving per day for a female) • Any alcohol use in gout during periods of frequent gout attacks, or advanced gout under poor control 	<ul style="list-style-type: none"> • Alcohol (Particularly beer, but also wine and spirits) 	

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.

Chronic Heart Failure (Left Ventricular Systolic Dysfunction)

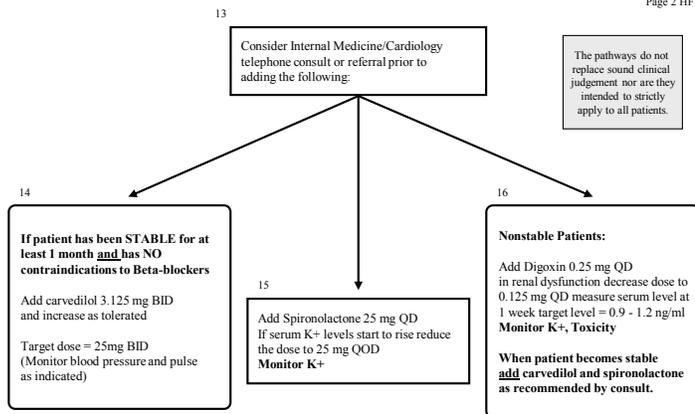
- 1) Control HTN, DM, and hyperlipidemia
- 2) Weight reduction in obese (educate on exercise)
- 3) Low sodium diet
- 4) Pneumococcal and flu vaccination
- 5) Smoking cessation
- 6) Discontinuation of alcohol
- 7) Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial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

Criteria:
 A. Simple heart failure - diagnosis code on problem list
 B. 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
 and
 Isosorbide mononitrate 30 mg QD; Target dose = 60 mg QD

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



Healthcare providers Education

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 (<3grams)
- Encourage exercise (as tolerated) to prevent or reverse physical unconditioning
- Influenza and pneumococcal vaccines to decrease risk of serious respiratory infections
- Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit.
- Medications to be **AVOIDED** include:
 - Non-steroidal anti-inflammatory drugs-can decrease the effectiveness of ACE inhibitors and diuretics and can worsen renal and cardiac function.
 - Anti-arrhythmics-heart failure patients can experience cardiodepressant and proarrhythmic effects.
 - Calcium Antagonists-lack of evidence supporting efficacy; safety concerns

Medications:

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)
- Dosage titration: Begin initial dose monitoring potassium, SCr changes, and blood pressure. Increase dose to target based on toleration by the patient.
- Monitor: 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)
- Dosage titration: Start patient at 25 mg. There is no proven benefit to increasing this dose.
- Monitor: 1) BP for symptomatic hypotension; 2) K⁺ for hypokalemia
- NOTE: It does not reduce fluid as efficiently as furosemide.
If continuance of symptoms DC and start furosemide.

Furosemide - loop diuretic

- Benefit: Manage fluid overload to reduce or minimize symptoms
 - When to use: In NYHA Class I-IV If HCTZ fails, replace with furosemide.
If symptomatic, add to captopril or other ACE inhibitors to decrease fluid overload
 - Dosage and titration: Titrate dose to symptoms - stabilize patient and maintain patient on smallest dose
 - Monitor: 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
- Monitor: 1) BP for hypotension; 2) pulse for symptomatic bradycardia < 60 BPM; 3) fluid retention or worsening heart failure during uptitration
- NOTE: ****Use in STABLE patients ONLY**
****Advise patients**
 - 1) Side effects may occur early in therapy but they do not generally prevent long-term use
 - 2) Improvements in symptoms may not be seen for 2-3 months
- Contraindications include: **** Asthma, Type 1 diabetes, bronchospasm, or acutely ill patients****

Digoxin

- Benefit: Unknown
- When to use: In NYHA Class II-IV in patients with atrial fibrillation
- Dosage and titration: Maintain Serum levels between 0.8ng/ml-2.0ng/ml
- Monitor: 1) K+ for hypokalemia or hyperkalemia (can cause digoxin toxicity); 2)Mg+ hypomagnesemia (can maintain hypokalemia)
- Side 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)**

Spirolactone

- 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 hyperkalemia 2) signs of gynecomastia-make patients aware of the side effect
- 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
- Wollen 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)

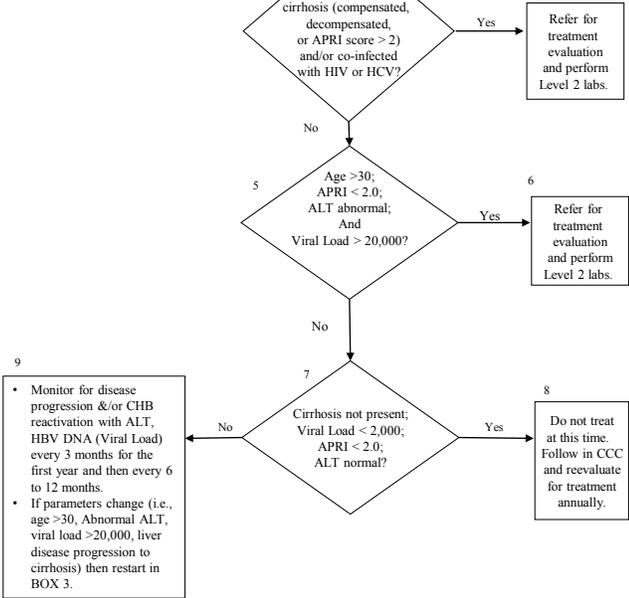
Exercise – Consult your doctor. Regular exercise, such as walking, will improve cardiovascular fitness and help strengthen the heart muscle. A strong heart does not have to work as hard to pump blood through the body.

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 nor is it intended to strictly apply to all patients

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



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

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

	Pre Rx	Month of Treatment				Continued Treatment			6 mos. Post Rx
		3	6	9	12	Q3 mos.	Q6 mos.	Q12 mos.	
CBC + diff	X	X	X	X	X	X			X
PT/PTT	X	X	X	X	X	X			X
Liver tests**	X	X	X	X	X	X			X
Free T4, T4, TSH	X	X	X	X	X	X			X
alpha-fetoprotein (AFP)	X		X		X		X		X
Creatinine (if on adefovir, entecavir, or tenofovir)	X	X						X***	
HBV-DNA	X		X		X		X		X
HBeAg/anti-HBe (if initially HBeAg positive)	X		X		X		X		X
HBsAg (if HBeAg neg and HBV-DNA < 2,000)	X		X		X		X		X

** liver test: ALT, AST, bilirubin (conjugated & unconjugated), albumin, Alkaline phosphatase, LDH
 *** Monitoring should be more frequent in those at higher risk of renal dysfunction.

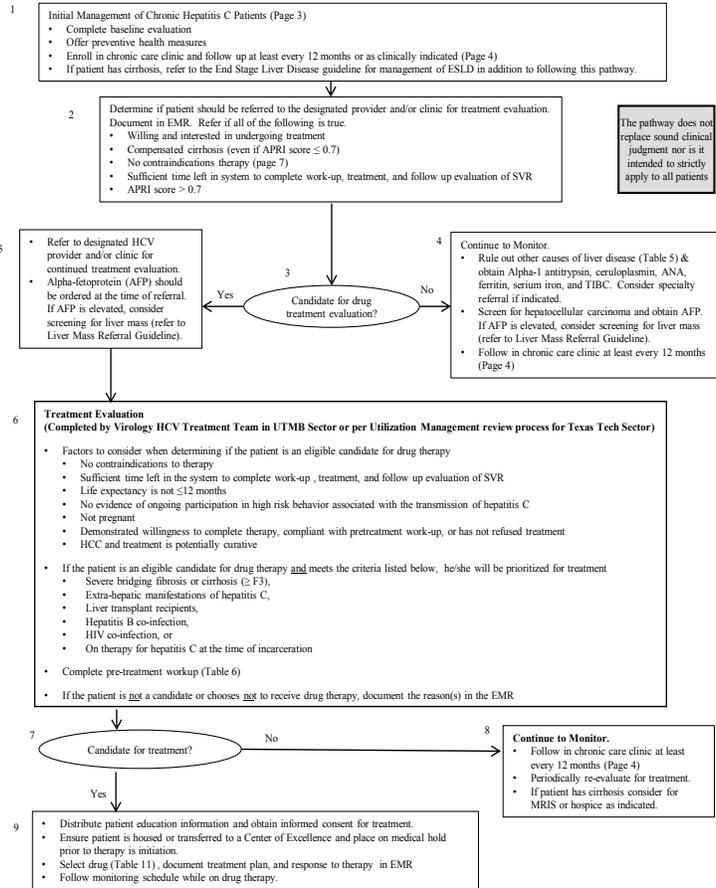
Table 2: Monitoring Schedule on Peg-IFN alfa

Treatment Week	Pre Rx	Week of Treatment					3 mos. Post Rx	6 mos. Post Rx
		2	4	8	12	16		
CBC + diff	X	X	X	X	X	X	X	X
PT/PTT	X	X	X	X	X	X	X	X
Liver tests**	X	X	X	X	X	X	X	X
Free T4, T4, TSH	X				X		X	X
alpha-fetoprotein (AFP)	X							X
HBV-DNA	X					X	X	
HBeAg/anti-HBe (if initially HBeAg positive)	X					X	X	X
HBsAg (if HBeAg neg and HBV-DNA < 2,000)	X					X		
Beck Depression Index	X	Monthly while on treatment					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



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, Approved July 2008; Reviewed 5/11; Revised 9/13, 1/15.

1. APRI (AST to Platelet Ratio Index) – A non-invasive method for the assessment of fibrosis in chronic liver disease. It is the ratio of the AST level, expressed as a percentage of the upper limit of normal, divided by the platelet count in thousands per cubic millimeter. It is a good predictor of liver fibrosis but cannot replace the liver biopsy in all cases. The APRI may be less predictive when there are co-morbid conditions other than liver disease that may affect the platelet count or AST level.

Table 1: APRI Calculation
$[(AST \div ULN) \div Platelet\ Count] \times 100$
<ul style="list-style-type: none"> • Use most recent lab results. ULN = upper limit of normal for the AST level and platelet count is in 1,000/mm³ • Available on CMCWEB under Tools and in the EMR under Guidelines • APRI ≥ 0.7 associated with significant fibrosis (F2) • APRI ≥ 1 associated with severe fibrosis (F3) • APRI ≥ 2 associated with cirrhosis (F4)

2. Cirrhosis - Cirrhosis or advanced liver disease is a chronic disease of the liver in which liver tissue is replaced by connective tissue or scar tissue, resulting in the loss of liver function.
 - Compensated cirrhosis - Compensated cirrhosis is characterized by laboratory evidence of liver dysfunction such as low albumin but ≥ 3.0 , low platelet count but $\geq 70,000$, elevated bilirubin but < 2.0 , and/or prolonged prothrombin time but less than 2 seconds greater than control in the absence of clinical complications associated with cirrhosis.
 - Decompensated cirrhosis - Decompensated cirrhosis is characterized by the presence of one or more of the clinical complications of chronic liver disease including ascites, encephalopathy, spontaneous bacterial peritonitis, variceal bleeding, jaundice, and/or impaired hepatic synthetic function (e.g., hyperbilirubinemia and hypoalbuminemia). Laboratory results consistent with decompensated cirrhosis are albumin < 3.0 , bilirubin > 2 , platelet count $< 70,000$, or prothrombin time > 2 seconds longer than control

Table 2: Child Turcotte-Pugh (CTP) Calculator			
	Points		
	1	2	3
Encephalopathy	None	Grade 1-2 (or precipitant-induced)	Grade 3-4 (or chronic)
Ascites	None	Mild / Moderate (diuretic-responsive)	Severe (diuretic-refractory)
Bilirubin (mg/dL)	< 2	2 – 3	> 3
Albumin (g/dL)	> 3.5	2.8 – 3.5	< 2.8
PT (second prolonged) or INR	< 4 < 1.7	4 – 6 1.7 – 2.3	> 6 > 2.3

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

3. FRT (Fibrous Routine Test) - A non-invasive method for the assessment of fibrosis in chronic liver disease utilizing routine laboratory markers (age, albumin, APRI and AFP).

Table 3: FRT Calculation
$3.31 + (age \times 0.09) + (APRI \times 1.5) + (AFP \times 0.4) - (Alb \times 0.14)$
<ul style="list-style-type: none"> • Use most recent lab results • FRT > 4 predictive Metavir score F2 – F4 (portal fibrosis with rare bridges – cirrhosis)

Definitions Cont.

4. Liver biopsy scoring schemas

Stage	Batts-Ludwig	Metavir	Ishak
No fibrosis	Stage 0	F0	0 = no fibrosis
Mild portal fibrosis	Stage 1	F1	1 = Fibrous expansion some portal areas +/-septa 2 = fibrous expansion most portal areas +/-
Moderate periportal fibrosis or portal-portal septa	Stage 2	F2	3 = Fibrous expansion most portal areas with occasional portal-portal bridging
Severe bridging fibrosis	Stage 3	F3	4 = Fibrous expansion portal areas + marked bridging 5 = Marked bridging + occasional nodules
Cirrhosis	Stage 4	F4	6 = cirrhosis, probable or definite

5. Response to therapy

- End of treatment response (ETR) - Undetectable HCV RNA level at the conclusion of a course of drug therapy
- Sustained virologic response (SVR) - Undetectable HCV RNA level 12 weeks after the conclusion of a course of drug therapy
- Relapse - Reappearance of serum HCV RNA after achieving an undetectable level at the conclusion of a course of drug therapy
- Null response - Failure to reduce HCV RNA by at least 2 logs after treatment. Considered a non-responder.
- Partial response - At least a 2 log drop in HCV RNA, but inability to fully remove the virus from the blood after treatment. Considered a non-responder.

Initial Management

1. Baseline evaluation

- History including probable date of HCV infection, alcohol use, co-infection with HIV or hepatitis B, drug use, symptoms of liver disease, and previous treatment for HCV.
- Physical including signs of advanced liver disease, evidence of other causes of liver disease, and extra-hepatic manifestations of HCV (e.g., leukocytoclastic vasculitis, cryoglobulinemia, porphyria cutanea tarda, membranoproliferative glomerulonephritis, and type 2 diabetes)
- Laboratories
 - CBC with differential & platelets
 - Prothrombin time, INR
 - ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine
 - HIV
 - Anti-HBsAB, anti-HBc, HBsAg, anti-HAV

2. Offer preventive health measures

- Vaccinations if indicated
 - Hepatitis B vaccine if hepatitis serum markers are negative
 - Hepatitis A vaccine if the anti-HAV test is negative
- Patient education
 - Natural history of disease
 - Behaviors to avoid (e.g., alcohol)
 - Avoiding transmission (e.g., sharing needles, tattooing, or grooming items such as razors & toothbrushes; unprotected sex)
 - Potential treatments
- Additional care if cirrhosis present
 - Pneumococcal vaccine
 - Annual influenza vaccination
 - Refer to the End Stage Liver Disease (ESLD) guideline for complete recommendations on management

3. Enroll in chronic care clinic and follow up at least every 12 months or as clinically indicated

4. Job assignments

- Patients with chronic HCV should be restricted from plumber's helper or bar trap cleaner job assignments unless they have been vaccinated against hepatitis A or have been documented as positive anti-HAV antibody.
- Other restrictions should be made on a case-by-case basis if clinically indicated.

Chronic Care Clinic Follow Up

1. Evaluate for clinical signs and symptoms of liver disease.
2. Laboratories
 - ALT, AST, bilirubin, albumin, CBC with differential & platelets, PT, INR
 - Other laboratories as clinically indicated
3. Calculate APRI and record in results entry of EMR
4. If cirrhotic
 - Refer to the ESLD guideline for recommendations on management and consider referral to ESLD clinic
 - Patients with decompensated cirrhosis and MELD score ≥ 22 or recurrent ascites, bleed or encephalopathy requires MRIS referral
 - Patients with MELD ≥ 30 should be referred to hospice
 - Patients unable to care for themselves in general population should be considered for sheltered housing or assisted living
5. Evaluate patient to determine if he/she is a candidate for drug treatment and document in the medical record.
 - If not a candidate initially
 - Re-evaluate the patient at least annually and refer the patient for evaluation of drug treatment if clinically indicated.
 - Rule out other causes of liver disease & obtain Alpha-1 antitrypsin, ceruloplasmin, ANA, ferritin, serum iron, and TIBC. Consider specialty referral if indicated.

Signs & Symptoms	Lab Test	Disease
Shortness of breath, cough, wheezing, early COPD ≤ 45 , frequent lung infections, necrotizing panniculitis (looks like raised red spots on the skin)	↓ Alpha-1 antitrypsin	Alpha-1 antitrypsin deficiency
Swelling arms & legs; jaundice; joint pain; bruising; difficulty speaking, walking, & swallowing; drooling; shaking; rash	↓ Ceruloplasmin	Wilson Disease
Joint pain, irregular heart rhythm, skin color changes (bronze, ashen-gray green), hair loss, enlarged liver or spleen, fatigue	↑ Ferritin, serum iron, TIBC	Iron overload
Associated with other autoimmune diseases, jaundice, abdominal discomfort, enlarged liver, pruritus, spider angiomas, joint pain	↑ Antinuclear antibody (ANA)	Autoimmune hepatitis

- Screen for hepatocellular carcinoma (HCC) and obtain AFP. If AFP is elevated, consider screening for liver mass (refer to Liver Mass Referral Guideline).
- Refer the patient to the designated HCV provider and/or clinic for treatment evaluation if all of the following are true:
 - Patient is willing and interested in undergoing treatment
 - Compensated cirrhosis
 - No contraindications therapy
 - Sufficient time left in system to complete work-up and treatment
 - APRI score $> 0.7^*$
 - * May consider referring patients with an APRI score ≤ 0.7 if there is clinical or laboratory evidence of a failing liver, or the patient has co-morbid conditions that might cause elevation of the platelet count or unusually low AST levels resulting in an unreliable APRI Score.
 - * Refer patients with cirrhosis even if APRI score ≤ 0.7 .
- 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).

Drug Treatment Evaluation

1. Patients should be evaluated for drug therapy by a provider experienced in the treatment of chronic hepatitis C. This is completed by the Virology HCV Treatment Team in the UTMB Sector or per the Utilization Management review process for the Texas Tech Sector
2. If the patient is not a candidate for drug therapy, document the reason(s) in the medical record.
3. If the patient chooses to not receive drug therapy, document the reason(s) in the medical record.
4. If no contraindications to drug therapy are present and the patient is a potential candidate for drug therapy, complete pre-treatment evaluation.

Table 6: Pre-treatment Workup

- Physical examination if not done in last 12 months
- If not done in preceding 12 weeks: ALT, AST, alkaline phosphatase, bilirubin, albumin, BUN, creatinine, CBC with differential, platelets, TSH, PT, INR, calculated GFR
- A1C if diabetic and not done in preceding 6 months
- HCV RNA and genotype
- Screen for HCC: Alpha-fetoprotein (AFP)
- Rule out other causes liver disease: Alpha-1 antitrypsin, ceruloplasmin, ANA, ferritin, serum iron, TIBC
- Obtain liver ultrasound if FRT > 5, clinical evidence of cirrhosis, or as clinically indicated
- Obtain liver biopsy if HIV co-infected, hepatitis B co-infected, liver mass detected on imaging, low ceruloplasmin (<20), or as clinically indicated
- Pregnancy test if female
- Chest x-ray and EKG if over 40, cardiac disease, or clinically indicated
- Review previous HCV treatment history and clinical outcome
- If peginterferon eligible
 - Visual acuity. Fundoscopic exam if higher risk for retinopathy (ophthalmologic disorder, hypertension, diabetes, and age > 50).
- Mental health evaluation

Candidate for Drug Therapy

1. Treatment is generally not recommended and is postponed for patients with no or mild fibrosis (F0-F2), since decompensated cirrhosis is unlikely to develop in the subsequent few years and newer medications are expected to become available that will be safer, simpler to use, and more effective
2. There are factors to consider when determining if the patient is an eligible candidate for drug therapy.
 - No contraindications to therapy
 - Sufficient time left in the system to complete work-up, treatment, and follow up evaluation of SVR
 - Life expectancy is not ≤ 12 months
 - No evidence of ongoing participation in high risk behavior associated with the transmission of hepatitis C
 - Pregnancy
 - Demonstrated willingness to complete therapy and compliance with pretreatment work-up or refusal of treatment
 - HCC and treatment is potentially curative
3. If the patient is an eligible candidate for drug therapy and meets the criteria listed below, he/she will be prioritized for treatment
 - Severe bridging fibrosis or cirrhosis ($\geq F3$),
 - Extra-hepatic manifestations of hepatitis C,
 - Liver transplant recipients,
 - Hepatitis B co-infection,
 - HIV co-infection, or
 - On therapy for hepatitis C at the time of incarceration

Mental Health Evaluation for Peginterferon Treatment

1. Patients with active untreated psychiatric disorders should be stabilized before beginning therapy with peginterferon.
2. It is reasonable to postpone treatment following a psychiatric hospitalization or suicidal behavior in order to ensure stability.
3. Patients with a significant history of psychiatric illness prior to treatment or a history of severe depressive symptoms during previous peginterferon treatment require regular mental health evaluations during treatment.
4. Predictors of developing depression while on peginterferon include prior history of psychiatric illness, female gender, poor social supports, low educational status, and ongoing depressive symptoms at the start of treatment
5. Patients should receive a mental health screening prior to initiating therapy and should be screened for psychiatric adverse effects monthly while on therapy.
 - If significant depressive or other psychiatric symptoms are detected, the provider should obtain a history of symptoms including onset, duration, nature, precipitating factors, mitigating factors, and level of distress of the symptoms.
 - The frequency of clinical evaluation should be increased to once weekly if symptoms develop.
 - The dose of peginterferon should be reduced to 135 mcg per week if depressive symptoms are moderate. The dose may be reduced as low as 90 mcg per week if necessary. If symptoms improve and are stable for 4 weeks, the reduced dose may be continued or the normal dose can be restarted and the patient monitored closely.
 - Peginterferon should be discontinued if depressive symptoms are severe. The presence of hopelessness or suicidal ideation should result in immediate assessment of risk of harm to self and others.
6. Antidepressant therapy should be considered if mild symptoms of depression emerge during treatment, since symptoms may progress to major depression if left untreated and should be considered for patients with pre-treatment depressive symptoms.

Initiation of Therapy

1. Distribute patient education materials to patient
2. Obtain informed consent and document in the medical record
3. Patients should be housed at a Center of Excellence while on therapy.
4. Patients must be placed on medical hold while on therapy.(refer to Standard Operating Procedure: Placing Patients on Medical Hold During Hepatitis C Treatment)
5. Monitor the patient per monitoring schedule while on drug therapy

Note: Modifiable or treatable contraindications should be controlled or resolved and the patient reconsidered for treatment whenever possible.

Table 7: Peginterferon	
Absolute Contraindications	Relative Contraindications
<ul style="list-style-type: none"> Decompensated cirrhosis Potentially life-threatening non-hepatic disease such as far advanced AIDS, malignancy, severe COPD or severe heart failure Uncontrolled autoimmune disorders Autoimmune hepatitis Uncontrolled hyperthyroidism Solid organ transplant Ongoing alcohol or injection drug use Suicidal ideation or other uncontrolled neuropsychiatric disorder Poorly controlled seizure disorder Previously demonstrated hypersensitivity to the drug 	<ul style="list-style-type: none"> Neutropenia or thrombocytopenia Poorly controlled HIV infection on HAART Poorly controlled diabetes (A1C \geq 9)

Table 8: Ribavirin	
Absolute Contraindications	Relative Contraindications
<ul style="list-style-type: none"> Pregnancy (during treatment and for 6 months afterward; also applies to partners of males who are treated) Hemoglobinopathies (e.g., sickle cell, thalassemia major) Hemolytic or other severe anemias Ischemic cardiovascular or cerebrovascular disease Renal insufficiency with serum creatinine > 2.0 Co-administration with didanosine Previously demonstrated hypersensitivity to the drug 	

Table 9: Ledipasvir/Sofosbuvir	
Contraindications	Relative Contraindications
<ul style="list-style-type: none"> Previously demonstrated hypersensitivity to the drug Concomitant usage with <ul style="list-style-type: none"> Anticonvulsant: Carbamazepine, Oxcarbazepine, Phenytoin, Phenytoin Antimycobacterials: Rifampin, Rifabutin, Rifapentine St. John's wort HIV medications: <ul style="list-style-type: none"> Combination elvitegravir, cobicistat, emtricitabine, and tenofovir Tipranavir/ritonavir Simeprevir Rosuvastatin 	<ul style="list-style-type: none"> Concomitant usage with <ul style="list-style-type: none"> Acid reducing agents: <ul style="list-style-type: none"> Antacids (e.g., aluminum and magnesium hydroxide)¹ H2-antagonists (e.g., ranitidine)² Proton pump inhibitors (e.g., omeprazole)³ Digoxin⁴ HIV medications: <ul style="list-style-type: none"> Efavirenz, Emtricitabine, Tenofovir⁵ Tenofovir plus Kaletra, Atazanavir/ritonavir, or Darunavir/ritonavir⁶

- Separate antacid and ledipasvir/sofosbuvir administration by 4 hours
- Administer H2-receptor antagonist simultaneously with ledipasvir/sofosbuvir or 12 hours apart
- Proton pump inhibitor doses comparable to omeprazole 20mg or lower may be administered simultaneously with ledipasvir/sofosbuvir.
- Co-administration of ledipasvir/sofosbuvir with digoxin may increase the concentration of digoxin. Therapeutic concentration monitoring of digoxin is recommended
- Monitor for tenofovir-associated adverse reactions in patients receiving ledipasvir/sofosbuvir concomitantly with the combination of efavirenz, emtricitabine and tenofovir
- Consider alternative HCV or antiretroviral therapy to avoid increases in tenofovir exposures. If co-administration is necessary, monitor for tenofovir-associated adverse reactions.

Table 10: Sofosbuvir	
Contraindications	Relative Contraindications
<ul style="list-style-type: none"> Previously demonstrated hypersensitivity to the drug Concomitant usage with <ul style="list-style-type: none"> Anticonvulsant: carbamazepine, oxcarbazepine, phenobarbital, phenytoin Antimycobacterials: rifampin, rifabutin, rifapentine St. John's wort HIV medications: Tipranavir/ritonavir 	

Drug Selection

1. Selection of drug regimen is based on patient specific characteristics including genotype, prior HCV treatment history, co-morbidities, and peginterferon eligibility.
2. The treatment regimens listed below are no longer recommended unless completing a course of treatment that has been previously initiated.
 - Monotherapy with peginterferon
 - Dual therapy with peginterferon plus ribavirin
 - Triple therapy with peginterferon, ribavirin, plus boceprevir or telaprevir
3. Antiretroviral regimen changes may be necessary prior to initiating HCV drug treatment due to drug-drug interactions.
 - Sofosbuvir may not be used with Tiplranavir/ritonavir
 - Ledipasvir/Sofosbuvir should be used cautiously with (1) efavirenz, emtricitabine, and tenofovir, and (2) tenofovir plus Kaletra, atazanavir/ritonavir, or darunavir/ritonavir. It should not be used with (1) combination elvitegravir, cobicistat, emtricitabine, and tenofovir, and (2) tiplanavir/ritonavir.
4. Discontinuation of therapy
 - If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold ($>1 \log_{10}$ IU/mL) on repeat testing at week 6, then discontinue treatment.

Table 11: Drug Selection

Patient Characteristics	Preferred Regimen	Alternative Regimen if PEG ineligible
Genotype 1 Treatment naïve, no cirrhosis and VL < 6 million	Ledipasvir/Sofosbuvir for 8 weeks	Not applicable
Genotype 1 Treatment naïve +/- cirrhosis or Treatment experienced without cirrhosis	Ledipasvir/Sofosbuvir for 12 weeks	Not applicable
Genotype 1 Treatment experienced with cirrhosis	Ledipasvir/Sofosbuvir + RBV for 12 weeks	Not applicable
Genotype 2	Sofosbuvir + RBV for 12 weeks	Not applicable
Genotype 2, cirrhotic	Sofosbuvir + RBV +PEG for 12 weeks	Sofosbuvir + RBV for 16 weeks
Genotype 3	Sofosbuvir + RBV +PEG for 12 weeks	Sofosbuvir + RBV for 24 weeks
Genotype 4	Ledipasvir/Sofosbuvir for 12 weeks	None
Genotype 5	Sofosbuvir + RBV +PEG for 12 weeks	None
Genotype 6	Ledipasvir/Sofosbuvir for 12 weeks	None

RBV=Ribavirin
PEG=Peginterferon

Dose Modification 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
- Ribavirin and Sofosbuvir cannot be used as monotherapy

Table 12: Hematological Dose Modification Guide

Lab Value	Action
ANC < 750 cells/mm ³	<ul style="list-style-type: none"> • Dose reduction: Peginterferon 135 micrograms once week • Continue dose Ribavirin • Continue dose direct-acting antiviral
ANC < 500 cells/mm ³	Discontinue all treatment until ANC values return to more than 1,000 cells/mm ³ . Reinstigate Peginterferon at reduced dose: 90 mcg once weekly and monitor ANC.
Platelets < 50,000 cells/mm ³	<ul style="list-style-type: none"> • Peginterferon 90 micrograms once weekly • Continue dose Ribavirin • Continue dose direct-acting antiviral
Platelets < 25,000 cells/mm ³	Discontinue all treatment
Hemoglobin 8.5 – 10 g/dL patient no cardiac disease	<ul style="list-style-type: none"> • Continue Peginterferon • Dose reduction: Ribavirin 600 mg/day • Continue dose direct-acting antiviral
Hemoglobin < 8.5 g/dL patient no cardiac disease	<ul style="list-style-type: none"> • Continue Peginterferon • Discontinue ribavirin until resolved¹ • May need to discontinue direct-acting antiviral²
Hgb ≥ 2g/dL reduction in 4 weeks patient with stable cardiac disease	<ul style="list-style-type: none"> • Continue Peginterferon • Dose reduction: Ribavirin 600 mg/day • Continue dose direct-acting antiviral
Hemoglobin < 12 g/dL after 4 weeks at reduced dosage patient with stable cardiac disease	<ul style="list-style-type: none"> • Continue Peginterferon • Discontinue ribavirin until resolved¹ • May need to discontinue direct-acting antiviral²

1. Once ribavirin is discontinued due to a laboratory abnormality or clinical adverse reaction, an attempt may be made to restart at 600 mg daily and further increase the dose to 800 mg daily. However, it is not recommended that ribavirin be increased to the original dose (1000 mg or 1200 mg).
2. Direct-acting antiviral for hepatitis C (e.g., sofosbuvir) may need to be discontinued. Consult experienced physician.

Table 13: Depression Dose Modification Guide*

Depression Severity	Dose Reduction
Mild	None
Moderate	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.
Severe	Discontinue Peginterferon immediately and refer to mental health.

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

Table 14: ALT Dose Modification Guide

Lab Value	Dose Reduction	Discontinue When
ALT > 2x baseline	Peginterferon 135 micrograms q week	Continued ALT increase despite dose reduction, elevation of bilirubin, or evidences of hepatic decompensation
10-fold increase in ALT at week 4		Promptly discontinue therapy
Any increase in ALT of less than 10-fold at week 4 if accompanied by any weakness, nausea, vomiting, or jaundice, or accompanied by increased bilirubin, alkaline phosphatase, or INR		Promptly discontinue therapy

Table 15: Renal Impairment Dose Modification

Creatinine clearance	Peginterferon	Ribavirin	Ledipasvir/Sofosbuvir	Sofosbuvir
30 to 50 mL/min	180 mcg once weekly	Alternating doses, 200 mg and 400 mg every other day	1 tablet once daily	400 mg once daily
< 30 mL/min	135 mcg once weekly	200 mg once daily	Data not available	Data not available
Hemodialysis	135 mcg once weekly	200 mg once daily	Data not available	Data not available

Peginterferon Alfa-2a Drug Information

Table 16: Peginterferon Alfa-2a	
Brand name	Pegasys®
Formulation	<ul style="list-style-type: none"> • 180 mcg per 0.5 mL • 135 mcg per 0.5 mL
Dose	<ul style="list-style-type: none"> • 180 micrograms subcutaneously once weekly regardless of weight • Administered by subcutaneous injection in the abdomen or thigh
Mechanism of Action	Not fully understood. Inducer of the innate antiviral immune response
Adverse effects*	<ul style="list-style-type: none"> • May aggravate neuropsychiatric, autoimmune, ischemic and infectious disorders • Most common: <ul style="list-style-type: none"> • Flu-like symptoms such as fatigue, pyrexia, myalgia, headache and rigors • Anorexia • Nausea, vomiting, and diarrhea • Arthralgias • Injection site reactions • Alopecia • Pruritus • Serious adverse effects: <ul style="list-style-type: none"> • Infection (e.g., sepsis, osteomyelitis, endocarditis, pyelonephritis, pneumonia) • Psychiatric reactions (e.g., depression, suicidal ideation, hallucinations, aggression, irritability, anxiety and insomnia) • Hepatic dysfunction • Fatty liver • Cholangitis • Aplastic anemia • Hemolytic anemia • Neutropenia • Thrombocytopenia • Elevated ALT • Peripheral neuropathy • Autoimmune disorders: myositis, hepatitis, thrombocytopenia purpura, psoriasis, interstitial nephritis, thyroiditis, and systemic lupus erythematosus • Cardiovascular disorders: hypertension, arrhythmias, chest pain and myocardial infarction • Endocrine disorders: hypothyroidism, hyperthyroidism, diabetes mellitus • Ophthalmologic disorders: decrease of loss of vision, retinopathy including macular edema, retinal artery or vein thrombosis, retinal hemorrhages and cotton wool spots, optic neuritis, papilledema and serous retinal detachment • Pulmonary disorders: dyspnea, pulmonary infiltrates, pneumonia, bronchiolitis obliterans, interstitial pneumonitis, pulmonary hypertension and sarcoidosis <p>*Note: refer to the manufacturer's product information for a complete list</p>

Ribavirin Drug Information

Table 17: Ribavirin	
Brand Name	Rebetol®, Ribasphere®
Special Notes	<ul style="list-style-type: none"> • Not effective as monotherapy • Pregnancy category X • Do not use in pregnancy and for 6 months after treatment • Must have a negative pregnancy test prior to therapy and monthly pregnancy tests
Formulation	200 mg capsule
Weight Based Dose	<p>Weight < 75 kg</p> <ul style="list-style-type: none"> • 400mg orally in the morning • 600mg orally in the evening <p>Weight ≥ 75 kg</p> <ul style="list-style-type: none"> • 600mg orally twice daily
Mechanism of Action	Not fully understood. Inhibits autonomous HCV RNA replication.
Adverse effects*	<ul style="list-style-type: none"> • Serious adverse effects: <ul style="list-style-type: none"> • Birth defects and fetal death • Hemolytic anemia resulting in worsening of cardiac disease and myocardial infarction • Severe hypersensitivity reactions including urticaria, angioedema, bronchoconstriction, and anaphylaxis, and serious skin reactions such as Stevens-Johnson Syndrome
Drug interactions*	<ul style="list-style-type: none"> • Azathioprine due to reports of severe pancytopenia and myelotoxicity • Didanosine due to reports of fatal hepatic failure, as well as peripheral neuropathy, pancreatitis, and symptomatic hyperlactatemia/lactic acidosis • Zidovudine due to reports of severe neutropenia and anemia

*Note: refer to the manufacturer's product information for additional information and a complete list

Ledipasvir/Sofosbuvir Drug Information

Table 18: Ledipasvir/Sofosbuvir									
Brand Name	Harvoni®								
Special Notes	<ul style="list-style-type: none"> • Store only in original container • Treatment is <u>not</u> guided by on treatment HCV RNA response • Used as sole therapy to treat Genotype 1 chronic hepatitis C 								
Formulation	Fixed-dose combination tablet Ledipasvir 90mg/Sofosbuvir 400mg								
Dose	1 tablet orally once daily with or without food								
Mechanism of Action	<ul style="list-style-type: none"> • Direct-acting antiviral • Ledipasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication • Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication 								
Duration of Therapy	<table border="0"> <tr> <td>Treatment naive, no cirrhosis and VL < 6 million</td> <td>8 Weeks</td> </tr> <tr> <td>Treatment naive +/- cirrhosis</td> <td>12 Weeks</td> </tr> <tr> <td>Treatment experienced without cirrhosis</td> <td>12 Weeks</td> </tr> <tr> <td>Treatment experienced with cirrhosis</td> <td>24 Weeks (note: 12 weeks if used in combination with ribavirin)</td> </tr> </table>	Treatment naive, no cirrhosis and VL < 6 million	8 Weeks	Treatment naive +/- cirrhosis	12 Weeks	Treatment experienced without cirrhosis	12 Weeks	Treatment experienced with cirrhosis	24 Weeks (note: 12 weeks if used in combination with ribavirin)
Treatment naive, no cirrhosis and VL < 6 million	8 Weeks								
Treatment naive +/- cirrhosis	12 Weeks								
Treatment experienced without cirrhosis	12 Weeks								
Treatment experienced with cirrhosis	24 Weeks (note: 12 weeks if used in combination with ribavirin)								
Adverse effects*	<ul style="list-style-type: none"> • Fatigue (most common) • Headache (most common) • Nausea • Diarrhea • Insomnia • Bilirubin elevations of greater than 1.5 times upper limit of normal • Transient, asymptomatic lipase elevations of greater than 3 times upper limit of normal 								
Drug interactions*	<ul style="list-style-type: none"> • Acid reducing agents: <ul style="list-style-type: none"> • Antacids (e.g., aluminum and magnesium hydroxide)¹ • H2-antagonists (e.g., ranitidine)² • Proton pump inhibitors (e.g., omeprazole)³ • Digoxin⁴ • HIV medications: <ul style="list-style-type: none"> • Efavirenz, Emtricitabine, and Tenofovir⁵ • Tenofovir plus Kaletra, Atazanavir/ritonavir, or Darunavir/ritonavir⁶ • Tipranavir/Ritonavir⁷ • Elvitegravir, cobicistat, emtricitabine, and tenofovir⁷ • Anticonvulsants: Carbamazepine, Oxcarbazepine, Phenytoin⁷ • Antimicrobials: Rifampin, Rifabutin, Rifapentine⁷ • St. John's wort⁷ • Simeprevir⁷ • Rosuvastatin⁷ 								

1. Separate antacid and ledipasvir/sofosbuvir administration by 4 hours
2. Administer H2-receptor antagonist simultaneously with ledipasvir/sofosbuvir or 12 hours apart
3. Proton pump inhibitor doses comparable to omeprazole 20mg or lower may be administered simultaneously with ledipasvir/sofosbuvir.
4. Co-administration of ledipasvir/sofosbuvir with digoxin may increase the concentration of digoxin. Therapeutic concentration monitoring of digoxin is recommended
5. Monitor for tenofovir-associated adverse reactions in patients receiving ledipasvir/sofosbuvir concomitantly with the combination of efavirenz, emtricitabine and tenofovir
6. Consider alternative HCV or antiretroviral therapy to avoid increases in tenofovir exposures. If co-administration is necessary, monitor for tenofovir-associated adverse reactions.
7. Co-administration not recommended.

*Note: refer to the manufacturer's product information for additional information and a complete list

Sofosbuvir Drug Information

Table 19: Sofosbuvir	
Brand Name	Sovaldi®
Special Notes	<ul style="list-style-type: none"> • Cannot be used as monotherapy • Store only in original container • Treatment is <u>not</u> guided by on treatment HCV RNA response
Formulation	400 mg tablet
Dose	400 mg orally once daily with or without food
Mechanism of Action	<ul style="list-style-type: none"> • Direct-acting antiviral • Inhibitor of the HCV NSSB RNA-dependent RNA polymerase
Adverse effects*	<ul style="list-style-type: none"> • Fatigue • Headache • Hyperbilirubinemia
Drug interactions*	Co-administration <u>not</u> recommended. <ul style="list-style-type: none"> • Anticonvulsant: Carbamazepine, Oxcarbazepine, Phenobarbital, Phenytoin • Antimycobacterials: Rifampin, Rifabutin, Rifapentine • St. John's wort • HIV medications: Tipranavir/Ritonavir

* Note: refer to the manufacturer's product information for additional information and a complete list

Chronic Hepatitis C Treatment Checklist			
Note: Ensure all information is available and criteria for treatment has been met prior to requesting approval to begin drug therapy.			
Patient Name: _____		Unit: _____	
Patient TDCJ #: _____		Weight: _____	
Indication for Treatment:			
		Result	Date
<input type="checkbox"/>	HCV RNA	IU/mL	
<input type="checkbox"/>	HCV genotype	(Circle one) 1 2 3 4 6 untypeable	
<input type="checkbox"/>	Liver ultrasound (if obtained)		
<input type="checkbox"/>	Liver biopsy (if obtained)	(Circle degree of fibrosis) None / Portal / Periportal / Bridging / Cirrhosis	
<input type="checkbox"/>	APRI Score		
<input type="checkbox"/>	FRT Score		

Requested Treatment:
<input type="checkbox"/> Ledipasvir/Sofosbuvir for 8 weeks
<input type="checkbox"/> Ledipasvir/Sofosbuvir for 12 weeks
<input type="checkbox"/> Ledipasvir/Sofosbuvir + Ribavirin for 12 weeks
<input type="checkbox"/> Sofosbuvir + Ribavirin + Peginterferon for 12 weeks
<input type="checkbox"/> Sofosbuvir + Ribavirin for 12 weeks
<input type="checkbox"/> Sofosbuvir + Ribavirin for 16 weeks

Prior Treatment for HCV:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes, answer the following:
Drug Names and Dosages: _____			
Start Date: _____ Stop Date: _____ Reason Discontinued: _____			
Treatment Response:			
<input type="checkbox"/> Relapser			
<input type="checkbox"/> Partial responder			
<input type="checkbox"/> Null responder			
<input type="checkbox"/> SVR			

Medical Clearance (check all that apply)	
<input type="checkbox"/>	Informed consent obtained
<input type="checkbox"/>	Sufficient time left on sentence to complete treatment
<input type="checkbox"/>	No evidence of ongoing participation in high risk behaviors (e.g., alcohol or drug use, tattooing)
<input type="checkbox"/>	Compliant with pretreatment work-up and pretreatment workup complete
<input type="checkbox"/>	No evidence of decompensated cirrhosis (ascitis, esophageal varices, jaundice, encephalopathy)
<input type="checkbox"/>	No contraindications to sofosbuvir
<input type="checkbox"/>	No contraindications to ledipasvir/sofosbuvir
<input type="checkbox"/>	No contraindications to peginterferon
<input type="checkbox"/>	No contraindications to ribavirin
<input type="checkbox"/>	If HIV co-infected, viral load undetectable and CD4 > 200
<input type="checkbox"/>	Physical exam performed in last 12 months

Week of Treatment	Base-line	2	4	8	12	Post Treatment
Date						
Clinical Evaluation ¹	√	√	√	√	√	12 weeks post treatment
Mental Health screening	√	Monthly while on therapy				
HCV genotype	√					
HCV RNA PCR ²	√		√ ⁹		√	12 weeks post treatment
Urine Pregnancy Test ³	√		√	√	√	Monthly x 6 months
CBC with diff ⁴	√	√	√	√	√	
CMP ⁵	√	√	√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	
TSH	√				√	
PT/INR	√	√	√	√	√	
Medication Adherence		√	√	√	√	
Weight	√	√	√	√	√	
A1C ⁶	√					
HIV	√					
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√					
EKG ⁷	√					
Chest x-ray ⁷	√					
Antinuclear antibody (ANA)	√					
Ferritin, Serum iron, TIBC	√					
Alpha-fetoprotein (AFP)	√					
Alpha-1 antitrypsin	√					
Ceruloplasmin	√					
Visual acuity	√					
Fundoscopic exam ⁸	√	As clinically indicated				
Liver imaging studies	√					

- Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
- HCV RNA PCR quantitative
- Urine pregnancy test = Females should be tested monthly during treatment and during the 6 months after treatment is stopped if childbearing potential
- CBC = Complete blood count with differential
- CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
- Obtain for diabetic patients
- Obtain if over 40, preexisting cardiac disease is present, or as clinically indicated.
- Perform in patients at higher risk for retinopathy including patients with history of ophthalmologic disorder, hypertension, diabetes, and older patients (age > 50 years).
- If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

Monitoring Schedule for **Ribavirin plus Sofosbuvir – 12 WEEK SCHEDULE**

Week of Treatment	Base-line	2	4	8	12	Post Treatment
Date						
Clinical Evaluation ¹	√	√	√	√	√	12 weeks post treatment
HCV genotype	√					
HCV RNA PCR ²	√		√ ⁷		√	12 weeks post treatment
Urine Pregnancy Test ³	√		√	√	√	Monthly x 6 months
CBC with diff ⁴	√	√	√	√	√	
CMP ⁵	√	√	√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	
PT/INR	√	√	√	√	√	
Medication Adherence		√	√	√	√	
Weight	√	√	√	√	√	
HIV	√					
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√					
EKG ⁶	√					
Chest x-ray ⁶	√					
Antinuclear antibody (ANA)	√					
Ferritin, Serum iron, TIBC	√					
Alpha-fetoprotein (AFP)	√					
Alpha-1 antitrypsin	√					
Ceruloplasmin	√					
Liver imaging studies	√					

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 if over 40, preexisting cardiac disease is present, or as clinically indicated.
7. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

Monitoring Schedule for Ribavirin plus Sofosbuvir – 16 WEEK SCHEDULE

Week of Treatment	Base-line	2	4	8	12	16	Post Treatment
Date							
Clinical Evaluation ¹	√	√	√	√	√	√	12 weeks post tx
HCV genotype	√						
HCV RNA PCR ²	√		√ ⁷			√	12 weeks post tx
Urine Pregnancy Test ³	√		√	√	√	√	Monthly x 6 months
CBC with diff ⁴	√	√	√	√	√	√	
CMP ⁵	√	√	√	√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	√	
PT/INR	√	√	√	√	√	√	
Medication Adherence		√	√	√	√	√	
Weight	√	√	√	√	√	√	
HIV	√						
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√						
EKG ⁶	√						
Chest x-ray ⁶	√						
Antinuclear antibody (ANA)	√						
Ferritin, Serum iron, TIBC	√						
Alpha-fetoprotein (AFP)	√						
Alpha-1 antitrypsin	√						
Ceruloplasmin	√						
Liver imaging studies	√						

- Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
- HCV RNA PCR quantitative
- Urine pregnancy test = Females should be tested monthly during treatment and during the 6 months after treatment is stopped if childbearing potential
- CBC = Complete blood count with differential
- CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
- Obtain if over 40, preexisting cardiac disease is present, or as clinically indicated.
- If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

Monitoring Schedule for Ribavirin plus Sofosbuvir – 24 WEEK SCHEDULE

Week of Treatment	Base-line	2	4	8	12	16	20	24	Post Treatment
Date									
Clinical Evaluation ¹	√	√	√	√	√	√	√	√	12 weeks post tx
HCV genotype	√								
HCV RNA PCR ²	√		√ ⁷					√	12 weeks post tx
Urine Pregnancy Test ³	√		√	√	√	√	√	√	Monthly x 6 months
CBC with diff ⁴	√	√	√	√	√	√	√	√	
CMP ⁵	√	√	√	√	√	√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	√	√	√	
PT/INR	√	√	√	√	√	√	√	√	
Medication Adherence		√	√	√	√	√	√	√	
Weight	√	√	√	√	√	√	√	√	
HIV	√								
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√								
EKG ⁶	√								
Chest x-ray ⁶	√								
Antinuclear antibody (ANA)	√								
Ferritin, Serum iron, TIBC	√								
Alpha-fetoprotein (AFP)	√								
Alpha-1 antitrypsin	√								
Ceruloplasmin	√								
Liver imaging studies	√								

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 if over 40, preexisting cardiac disease is present, or as clinically indicated.
7. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

Monitoring Schedule for Ledipasvir/Sofosbuvir – 8 WEEK SCHEDULE

Week of Treatment	Base-line	2	4	8	Post Treatment
Date					
Clinical Evaluation ¹	√	√	√	√	12 weeks post treatment
HCV genotype	√				
HCV RNA PCR ²	√			√	12 weeks post treatment
CBC with dif ³	√				
CMP ⁴	√		√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	
PT/INR	√				
Medication Adherence		√	√	√	
HIV	√				
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√				
Antinuclear antibody (ANA)	√				
Ferritin, Serum iron, TIBC	√				
Alpha-fetoprotein (AFP)	√				
Alpha-1 antitrypsin	√				
Ceruloplasmin	√				
Liver imaging studies	√				

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
3. CBC = Complete blood count with differential
4. CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN

Monitoring Schedule for Ledipasvir/Sofosbuvir – 12 WEEK SCHEDULE

Week of Treatment	Base-line	2	4	8	12	Post Treatment
Date						
Clinical Evaluation ¹	√	√	√	√	√	12 weeks post treatment
HCV genotype	√					
HCV RNA PCR ²	√		√ ⁵		√	12 weeks post treatment
CBC with diff ³	√					
CMP ⁴	√		√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	
PT/INR	√					
Medication Adherence		√	√	√	√	
HIV	√					
Anti-HBsAB, anti-HBc, HBsAg, anti-HAV	√					
Antinuclear antibody (ANA)	√					
Ferritin, Serum iron, TIBC	√					
Alpha-fetoprotein (AFP)	√					
Alpha-1 antitrypsin	√					
Ceruloplasmin	√					
Liver imaging studies	√					

1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
3. CBC = Complete blood count with differential
4. CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
5. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

Monitoring Schedule for **Ledipasvir/Sofosbuvir** – 24 WEEK SCHEDULE

Week of Treatment	Base-line	2	4	8	12	16	20	24	Post Treatment
Date									
Clinical Evaluation ¹	√	√	√	√	√	√	√	√	12 weeks post treatment
HCV genotype	√								
HCV RNA PCR ²	√		√ ⁵					√	12 weeks post treatment
CBC with diff ³	√								
CMP ⁴	√		√	√	√	√	√	√	
Calculated Glomerular filtration rate (GFR)	√		√	√	√	√	√	√	
PT/INR	√								
Medication Adherence		√	√	√	√	√	√	√	
HIV	√								
Anti-HBsAB, anti-HBc., HBsAg, anti-HAV	√								
Antinuclear antibody (ANA)	√								
Ferritin, Serum iron, TIBC	√								
Alpha-fetoprotein (AFP)	√								
Alpha-1 antitrypsin	√								
Ceruloplasmin	√								
Liver imaging studies	√								

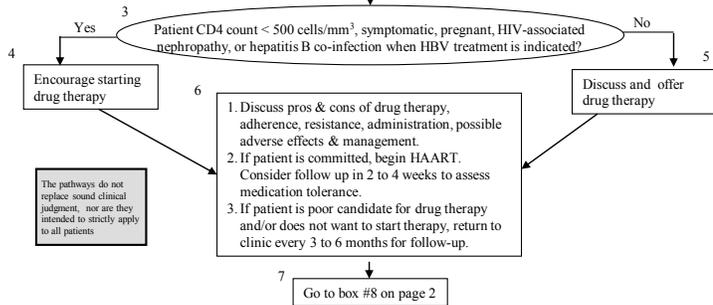
1. Clinical evaluations should be scheduled a few days after laboratory results are expected to be available.
2. HCV RNA PCR quantitative
3. CBC = Complete blood count with differential
4. CMP = complete metabolic panel includes albumin, alkaline phosphatase, ALT, AST, bilirubin, calcium, carbon dioxide, chloride, potassium, sodium, glucose, creatinine, protein, BUN
5. If viral load is detectable at week 4 of treatment, repeat the viral load after 2 additional weeks of treatment (treatment week 6). If it has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6, then discontinue treatment

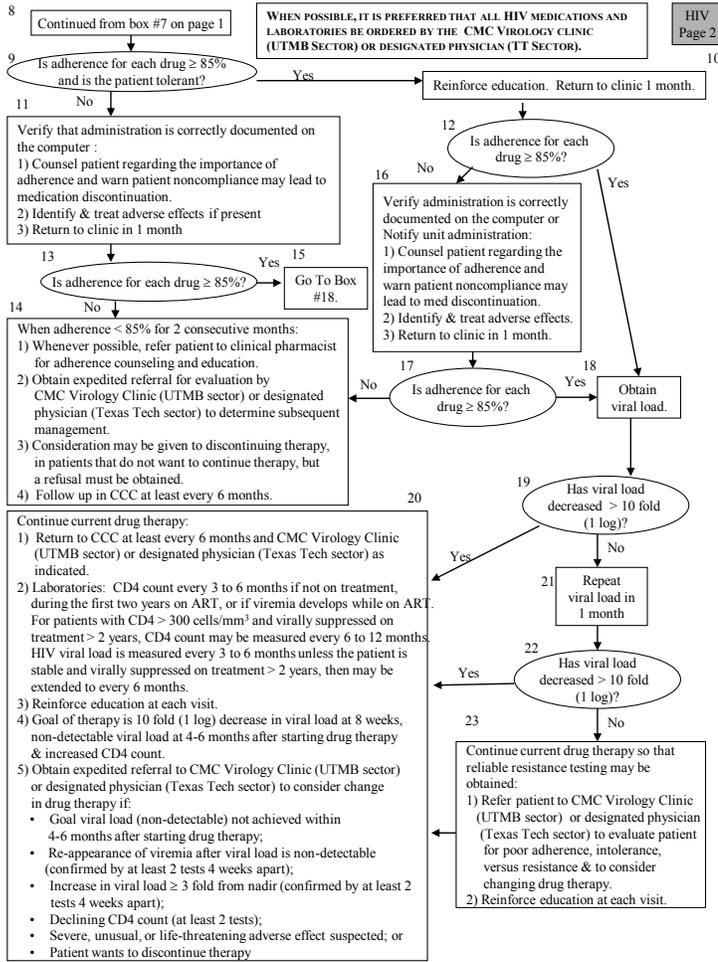
HIV DISEASE MANAGEMENT

1

- Initial evaluation of HIV+ patients to be done at the intake facility by facility provider:
- 1) Obtain medical history including sexual history, social history, medication history, & history of opportunistic infections.
 - 2) Complete physical examination: vitals, weight, general exam, neurologic examination, and pelvic exam with PAP and GC/chlamydia tests. Perform pelvic exam every 6 months for HIV+ female patients.
 - 3) Obtain baseline laboratories: CBC with differential, Chemistry profile to include LFTs, serum creatinine, fasting blood sugar and lipid profile, Hepatitis serology (HbsAg, Anti-HBs, anti-HBc total antibody, anti-HCV and anti-HAV total antibody), Syphilis screen (RPR), Urinalysis, calculated estimate of glomerular filtration rate (GFR) (available in Tools on the CMC Web), CD4+ lymphocyte analysis, HIV RNA viral load, Varicella-Zoster Immune Status, Chest X-ray, PPD skin test.
 - 4) Screen patients for risk of chronic kidney disease by obtaining urinalysis, calculating GFR, and assessing risk. Risk factors include family history of renal disease, African American, CD4 <200 cells/mm³, VL > 4000 copies/ml, certain diseases (diabetes, HTN, hepatitis C co-infection), & concomitant use of nephrotoxic agents. If 1+ proteinuria or calculated GFR < 60 ml/min/1.73m², consider further evaluation. If normal & high risk based on risk factors, reassess and recheck annually. If normal & patient does not have risk factors, reassess annually in chronic care clinic (CCC).
 - 5) Update vaccines: influenza vaccine annually; pneumococcal vaccine with single revaccination 5 years after the first dose; hepatitis A & B vaccine if not already immune; varicella vaccine if CD4 > 200 and patient born after 1979 with no history of disease, vaccination, or evidence of immunity.
 - 6) Initiate prophylactic medication(s) for opportunistic infection(s) as indicated in box A page 3 & box B page 4.
 - 7) Refer to dental for oral/periodontal evaluation within 30 days from initial chronic care visit.
 - 8) Refer all HIV + patients regardless of CD4 count to the CMC Virology Clinic offered via DMS (UTMB sector) or designated physician (Texas Tech sector) for evaluation for antiretroviral treatment (ART). Expedited referrals should be obtained for patients that are symptomatic or have a CD4 count < 200 cells/mm³. If patient refuses, contact the CMC Virology Clinic (UTMB sector) or designated physician (Texas Tech sector) for drug therapy and ITP recommendations.

- 2 Follow-up for HIV+ Patients:
- 1) Evaluate in chronic care clinic at least every 6 months.
 - 2) Refer patients with CD4 count < 100 cells/mm³ to Ophthalmology for a retinal examination to rule out HIV retinopathy & CMV retinitis.
 - 3) Laboratories: CD4 count every 3 to 6 months if patient meets the following criteria: not on treatment, during the first two years on ART, or if viremia develops while on ART. For patients with CD4 > 300 cells/mm³ and virally suppressed on treatment > 2 years, CD4 count may be measured every 6 to 12 months. HIV viral load is measured every 3 to 6 months unless the patient is stable and virally suppressed on treatment > 2 years, then can be extended to every 6 months. Obtain CBC with differential every 3 to 6 months and Chemistries including LFTs, serum creatinine, blood sugar, lipid profile at least annually.
 - 4) Consider discontinuing prophylactic medication(s) for opportunistic infection(s) as indicated in box A & B, pages 3-4.





Box A: Primary Prophylaxis of Opportunistic Infections				
Initiate based on CD4 count	Organism	Recommended Regimen	Alternative Regimen	Discontinuation Criteria*****
All (regardless of CD4 count)	M. tuberculosis PPD ≥ 5 mm	INH 5mg/kg/day (max 300mg) or 900mg twice a week x 9 months	Rifampin 600mg po qd or Rifabutin 300mg po qd x 4 months	
	S. pneumoniae	Pneumococcal vaccine (repeat one time only in 5 years)		
	Influenza virus	Influenza vaccine (one dose annually)		
	Hepatitis A virus*****	Hepatitis A vaccine to all susceptible patients (2 dose series)		
	Hepatitis B virus*	Hepatitis B vaccine (3 dose series)		
< 200**	Pneumocystis jirovecii	TMP-SMX DS Once daily or three times weekly	Dapsone 100mg qd or Atovaquone 1500mg qd (nonformulary approval is required)	CD4 count > 200 for > 3 months (restart if CD4 count < 200)
< 100***	Toxoplasma gondii	TMP-SMX DS Once daily or three times weekly	Dapsone 100mg qd + pyrimethamine 50mg q week + leucovorin 25mg q week	CD4 count > 200 for > 3 months (restart if CD4 count < 100-200)
< 50	M. avium complex	Azithromycin 1200 mg q week	Clarithromycin 500mg bid or rifabutin 300mg qd	CD4 count > 100 for ≥ 3 months (restart if CD4 count < 50)

* 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

*****in response to ART and virally suppressed

Box B: Secondary Prophylaxis of Opportunistic Infections				
Indication	Organism	Recommended Regimen	Alternative Regimen	Discontinuation Criteria****
Prior PCP	<i>Pneumocystis jirovecii</i>	TMP-SMX DS qd	TMP-SMX DS three times weekly, Dapsone 100mg qd or Atovaquone 1500mg daily (Nonformulary approval required)	CD4 count > 200 for ≥ 3 months (restart if CD4 count < 200 or PCP recurrence)
Prior toxoplasmic encephalitis	<i>Toxoplasma gondii</i>	Sulfadiazine 1000mg to 2000mg po bid + Pyrimethamine 25-50mg po qd + Leucovorin 10-25mg po qd	Clindamycin 600mg po q 6 hr + Pyrimethamine 25-50mg po qd + Leucovorin 10-25mg po qd	CD4 count > 200 for > 6 months* (restart if CD4 count < 200)
Prior disseminated disease	<i>M. avium</i> complex	Clarithromycin 500mg po bid + Ethambutol 15mg/kg po qd +/- Rifabutin 300mg po qd	Azithromycin 500mg po qd + Ethambutol 15mg/kg po qd +/- Rifabutin 300mg po qd	CD4 count > 100 for > 6 months* (restart if CD4 count < 100)
Prior end-organ disease	Cytomegalovirus (CMV)	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	Foscarnet IV 90mg/kg/day, Cidofovir 5mg/kg IV q 2 weeks, or Valganciclovir 900mg po qd	CD4 count > 100 for > 3-6 months** (restart if CD4 count < 100)
Prior disease	<i>Cryptococcus neoformans</i>	Fluconazole 200mg po qd	Itraconazole 200mg po qd, or Amphotericin 0.6-1mg/kg IV weekly ~ 3 times weekly	CD4 count ≥ 100 for > 3 months* (restart if CD4 count < 100)
Prior disease	<i>Histoplasma capsulatum</i>	Itraconazole 200mg po bid	Amphotericin 1mg/kg IV weekly or Fluconazole 800mg qd	Histoplasma antigen < 2ng/mL, CD4 count > 150 for ≥ 6 months* (restart CD4 count ≤ 150)
Prior disease	<i>Coccidioides immitis</i>	Fluconazole 400mg po qd	Itraconazole 200mg po bid or Amphotericin 1mg/kg IV weekly	
Bacteremia	<i>Salmonella</i> species	Ciprofloxacin 500mg po bid x several months		CD4 count > 200
Frequent/severe recurrences	Herpes simplex virus***	Acyclovir 400mg po bid	Valacyclovir 500mg po bid or famciclovir 250mg bid	
Frequent/severe recurrences	<i>Candida</i> *** (oropharyngeal, vulvovaginal, esophageal)	Fluconazole 100-200mg po qd	Itraconazole 200mg po qd	

*if completed ≥ 12 months of treatment and asymptomatic
 **if initial treatment completed, asymptomatic, & regular ophthalmology exams
 ***recommended only if subsequent episodes are frequent or severe
 ****in response to ART and virally suppressed

Patient and Provider Education

- I. Who is educated?
 - A. Health Services Personnel – updated on HIV so accurate and easy to understand information is provided to patients
 - B. All offenders with HIV
- II. Who educates?
 - A. Unit team will delegate educational responsibility - physicians and mid-level providers have the final responsibility to ensure education occurs
 - B. Educator must document education in patient' s chart
- III. When does education take place?
 - A. Upon identification of having HIV
 - B. Individual education at clinic visit
 - C. Group education if available
- IV. What is included in education?
 - A. Health Services Personnel
 - 1. Pathophysiology & diagnostic criteria
 - 2. Monitoring parameters
 - 3. Pharmacologic treatments
 - 4. Adverse event monitoring & management
 - 5. Drug resistance & importance of adherence
 - 6. Opportunistic infections & prophylactic therapy
 - 7. Goals of therapy
 - B. Patients
 - 1. Pathophysiology
 - 2. Routes of transmission
 - 3. Complications/risks of disease
 - 4. Pharmacologic treatments
 - 5. Monitoring parameters – frequency & importance
 - 6. Drug resistance & importance of adherence
 - 7. Individual treatment plan
 - 8. Dental hygiene to include daily brushing in the morning and evening and flossing once daily

Table 1: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)

Medication	Dosage	Drug Interactions*	Adverse Effects*
Abacavir (ABC, Ziagen®)	300mg BID or 600mg QD		Hypersensitivity reaction characterized by fever, nausea, vomiting, malaise, anorexia, respiratory symptoms, +/- rash. Should not be restarted if occurs. Record in medical record as allergy; Lactic acidosis with hepatic steatosis.
Didanosine EC (ddl, Videx EC ®)	> 60kg 400mg QD or < 60kg 250mg QD CrCl >60kg <60kg 30-59 200mg QD 125mg QD 10-29 125mg QD 100mg QD <10 or HD 125mg QD 75mg QD Best if taken on empty stomach	Tenofovir, methadone	Peripheral neuropathy, rare pancreatitis, nausea, diarrhea Lactic acidosis with hepatic steatosis.
Emtricitabine (FTC, Emtriva ®) Nonformulary	200mg QD CrCl Dose 30-49 200mg q 48 15-29 200mg q 72 <15 or HD 200mg q 96		Nausea, vomiting, diarrhea, headache, hyperpigmentation of palms & soles Lactic acidosis with hepatic steatosis.
Lamivudine (3TC, Epivir ®)	150mg BID or 300mg QD CrCl Dose 30-49 150mg QD 15-29 100mg QD 5-14 50mg QD <5 or HD 25mg QD		Minimal effects Lactic acidosis with hepatic steatosis.
Stavudine (d4T, Zerit ®)	> 60kg 40mg BID < 60kg 30mg BID CrCl >60kg <60kg 26-50 20mg q 12 15mg q 12 10-25 or HD 20mg q 24 15mg q 24	Zidovudine, methadone	Peripheral neuropathy, lipodystrophy, hyperlipidemia, pancreatitis Lactic acidosis with hepatic steatosis.
Zalcitabine (ddC, Hivid ®) Nonformulary	0.75mg TID CrCl Dose 10-40 0.75mg BID <10 0.75mg qd HD no data		Peripheral neuropathy, stomatitis Lactic acidosis with hepatic steatosis.
Zidovudine (AZT, ZDV, Retrovir ®)	300mg BID CrCl < 15 or HD 100mg TID or 300mg QD	Stavudine, ribavirin	Initial GI upset, headache, nail discoloration, fatigue, anemia, neutropenia, myopathy Lactic acidosis with hepatic steatosis.
Tenofovir** (TDF, Viread ®)	300mg QD best if taken with food CrCl Dose 30-49 300mg q 48 10-29 300mg twice a week HD 300mg q 7 days	Didanosine, atazanavir	GI upset, flatulence, headache, asthenia, renal insufficiency Lactic acidosis with hepatic steatosis.

*not a complete list of drug interactions or adverse effects

**nucleoside reverse transcriptase inhibitor (NRTI)

HD=hemodialysis

Table 2: Combination Products

Medication	Dosage	Drug Interactions*	Adverse Effect*
Combivir® (zidovudine 300 mg & lamivudine 150mg) Nonformulary	1 tablet BID Do not use if CrCl < 50	Same as single entity drugs	Same as single entity drugs
Epzicom® (lamivudine 300mg & abacavir 600mg) Nonformulary	1 tablet QD Do not use if CrCl < 50	Same as single entity drugs	Same as single entity drugs
Truvada® (emtricitabine 200mg & tenofovir 300mg) Nonformulary	1 tablet QD CrCl _____ Dose 30-49 1 tab q 48hr < 30 do not use	Same as single entity drugs	Same as single entity drugs
Atripla® (emtricitabine 200mg, tenofovir 300mg, & efavirenz 600mg) Nonformulary	1 tablet QD Do not use if CrCl < 50	Same as single entity drugs	Same as single entity drugs
Complera® (emtricitabine 200mg, tenofovir 300mg, & rilpivirine 25mg) Nonformulary	1 tablet QD with food Do not use if CrCl < 50	Rifampin, carbamazepine, primidone, phenobarbital, phenytoin, H ₂ - antagonists (ranitidine), proton pump inhibitors (omeprazole), dexamethasone	Diarrhea, rash, headache, insomnia, hepatitis B exacerbation, renal insufficiency Lactic acidosis with hepatic steatosis.
Stribild® (emtricitabine 200mg, tenofovir 300mg, elvitegravir 150mg, & cobicistat 150mg) Prior Authorization	1 tablet QD with food Do not use if CrCl < 70	Ergotamine, rifampin, cisapride, primidone, midazolam, lovastatin, Maraviroc, triazolam	Nausea, diarrhea, abnormal dreams, headache, insomnia, upper respiratory infection, renal insufficiency Lactic acidosis with hepatic steatosis.
Trizivir® (zidovudine 300 mg, lamivudine 150mg, & abacavir 300mg) Nonformulary	1 tablet BID Do not use if CrCl < 50	Same as single entity drugs	Same as single entity drugs
Triumeq® (dolutegravir 50mg, abacavir 600 mg, & lamivudine 300 mg) Nonformulary	1 tablet QD with or without food. Triumeq is not for people with known HIV resistance to abacavir, lamivudine or any of the approved integrase inhibitors.	Same as single entity drugs	Same as single entity drugs

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; BID = twice daily; coBI = cobicistat; d4T = stavudine;
ddI = didanosine; EC = enteric coated; EFV = efavirenz; EVG = elvitegravir; FTC = emtricitabine;
HSR = hypersensitivity reaction; MI = myocardial infarction; RPV = rilpivirine; TDF = tenofovir;
TID = three times a day; WHO = World Health Organization; ZDV = zidovudine

*not a complete list of drug interactions or adverse effects

Table 3: Protease Inhibitors (PIs)

Medication	Dosage*	Drug Interactions**	Adverse Effects**
Atazanavir (ATV, Reyataz®)	400mg QD best if taken with food <u>Boosted or With Tenofovir or EFV</u> ATV 300 + RTV 100 QD	Clarithromycin, diltiazem, lovastatin, rifabutin, rifapentine, ergotamine, H2-antagonists (ranitidine), proton pump inhibitors (omeprazole), elvitegravir, tenofovir	Diarrhea, nausea, prolongation of the PR interval, hyperbilirubinemia, jaundice hyperglycemia, fat redistribution, increase bleeding in hemophilia
Darunavir (DRV, Prezista®)	<u>Treatment Naïve patient</u> DRV 800 + RTV 100 QD <u>Treatment Experienced patient</u> DRV 600 + RTV 100 BID (<u>must</u> be given with RTV)		Skin rash, SJS, hepatotoxicity, diarrhea, nausea, headache, elevated transaminase hyperglycemia, fat redistribution, increase bleeding in hemophilia
Fosamprenavir (FPV, Lexiva®)	1400mg BID <u>Boosted</u> f-APV 1400 + RTV 100-200 QD f-APV 700 + RTV 100 BID <u>With EFV</u> f-APV 700 + RTV 100 BID f-APV 1400 + RTV 300 QD	Lovastatin, rifampin, rifabutin, rifapentine, ergotamine	Diarrhea, nausea, vomiting, rash hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Indinavir (IDV, Crixivan®)	800mg q 8 hr drink plenty of fluids, best if taken on empty stomach, best if separate dosing with ddI by 1 hr <u>Boosted</u> IDV 800 + RTV 100-200 q 12 hr	Carbamazepine, lovastatin, rifampin, rifabutin, rifapentine, ergotamine	Nephrolithiasis, GI intolerance, nausea, metallic taste hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Lopinavir 200mg + Ritonavir 50mg (LPV/r, Kaletra®)	2 tabs BID or 4 tabs QD <u>With EFV or NVP</u> 3 tabs BID	Lovastatin, rifampin, rifabutin, rifapentine, ergotamine	Nausea, vomiting, diarrhea, asthenia, elevated LFTs hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Nelfinavir (NFV, Viracept®)	1250mg BID best if taken with meal or snack	Atorvastatin, lovastatin, rifampin, rifabutin, rifapentine, ergotamine	Diarrhea hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Ritonavir (RTV, Norvir®)	600mg q 12 hr food may decrease GI upset Usually given as 100 to 400 mg once or twice daily to boost effected drug levels	Lovastatin, amiodarone, quinidine, clozapine, rifabutin, rifapentine, ergotamine, desipramine, theophylline	Nausea, vomiting, diarrhea, paresthesias, pancreatitis, taste perversion, elevated LFTs hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Saquinavir (SQV, Invirase®)	SQV 1000 + RTV 100 BID (<u>must</u> be given with RTV) Take with meals or within 2 hours after a meal	Lovastatin, rifampin, rifabutin, rifapentine, ergotamine	Nausea, vomiting, diarrhea, rash, elevated LFTs hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia
Tipranavir (TPV, Aptivus®) Nonformulary	500mg + RTV 200mg BID (<u>must</u> be given with RTV) Best if taken with food.	Lovastatin, rifampin, amiodarone, quinidine, ergotamine, fluticasone	Hepatotoxicity, rash, hyperlipidemia hyperglycemia, fat redistribution, lipid abnormalities, increased bleeding in hemophilia

*dosage if used as the only PI in the drug regimen, dosages are often adjusted if used in combination with other agents

**not a complete list of drug interactions or adverse effects

Table 4: Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Medication	Dosage	Drug Interactions*	Adverse Effects*
Delavirdine (DLV, Rescriptor®) Nonformulary	400mg TID	Lovastatin, rifampin, rifapentine, rifabutin, H-2 antagonists (ranitidine), proton pump inhibitors (omeprazole), ergotamine, dapson, phenytoin, warfarin, carbamazepine, quinine, clarithromycin	Rash, elevated LFTs, headache
Efavirenz (EFV, Sustiva ®)	600mg q HS best if taken on empty stomach	Rifampin, rifabutin, rifapentine, ergotamine, clarithromycin	Rash, CNS symptoms (e.g., dizziness, insomnia, vivid dreams), elevated LFTs, false positive cannabinoid test, avoid in pregnancy
Etravirine (ETR, Intelence®) Nonformulary	200mg BID best if taken with food	Phenytoin, carbamazepine, other NNRTIs, PIs (except DRV/RTV, SQV/RTV, and LPV/RTV with caution), clarithromycin, rifampin, warfarin	Rash, nausea
Nevirapine (NVP, Viramune ®)	200mg QD x 14 days then 200mg BID or 400mg QD	Ketoconazole, rifampin, phenytoin, carbamazepine	Rash, elevated LFTs, hepatitis
Ripivirine (RPV, Edurant ®) Prior Authorization	25 mg QD with a meal	Acid suppression therapy, rifampin, rifabutin, carbamazepine, primidone, phenobarbital, phenytoin	Rash, depression, insomnia, headache, hepatotoxicity

Table 5: Integrase Inhibitors

Medication	Dosage	Drug Interactions*	Adverse Effect*
Dolutegravir (DTG, Tivicay®)	50mg QD With certain resistance or drug interactions 50mg BID	Inducers (efavirenz, boosted fosamprenavir, boosted tipranavir, rifampin)	Nausea, headache, diarrhea
Elvitegravir (EVG, Stribild®) Only as Stribild®	(EVG 150 mg + COBI 150 mg + TDF 300 mg + FTC 200 mg) Tablet once daily with food	Ergotamine, rifampin, cisapride, primidone, midazolam, lovastatin, maraviroc, triazolam	Nausea, diarrhea, abnormal dreams, headache, insomnia, upper respiratory infection, renal insufficiency Lactic acidosis with hepatic steatosis.
Raltegravir (RAL, Isentress®)	400mg BID With rifampin 800mg BID	rifampin	Nausea, headache, diarrhea, pyrexia, fatigue, elevated CPK

Table 6: CCR5 Antagonist

Medication	Dosage	Drug Interactions	Adverse Effect*
Maraviroc (MVC, Selzentry®) Nonformulary	Tropism testing is required before use <u>With Protease Inhibitors except tipranavir, delavirdine, itraconazole, ketoconazole, clarithromycin</u> 150mg BID <u>With all NRTI, Efavirtide, TPV, NVP</u> 300mg BID <u>With EFV, rifampin, carbamazepine, phenytoin</u> 600mg BID	Potent CYP3A inhibitors such as protease inhibitors, delavirdine, itraconazole, ketoconazole, clarithromycin Potent CYP3A inducers such as efavirenz, rifampin, carbamazepine, phenytoin	Abdominal pain, cough, dizziness, musculoskeletal symptoms, pyrexia, rash, upper respiratory track infections, hepatotoxicity, orthostasis

Table 7: Fusion Inhibitors

Medication	Dosage	Drug Interactions*	Adverse Effect*
Enfuvirtide (T20, Fuzeon®) Nonformulary	90mg SQ BID		Local injection site reaction (e.g., pain erythema, induration, nodules, cysts), increased rate of pneumonia, hypersensitivity reaction (rechallenge is not recommended)

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; BID = twice daily; cobv = cobicistat; d4T = stavudine; ddI = didanosine; EC = enteric coated; EFV = efavirenz; EVG = elvitegravir; FTC = emtricitabine; HSR = hypersensitivity reaction; MI = myocardial infarction; RPV = rilpivirine; TDF = tenofovir ; TID = three times a day; WHO = World Health Organization; ZDV = zidovudine

*not a complete list of drug interactions or adverse effects

I. Background

A. More than 50% of people do not know they are HIV-infected until they become symptomatic (an indicator of advanced disease).

HIV
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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 Lentivirus 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 use - 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 set point = longer time it will take for an individual's disease to progress over time

B. Intermediate

1. T cell destruction by HIV begins to weaken the immune system over time (in contrast to the acute stage, where the immune system "keeps pace" by producing an equivalent amount of CD4 cells).

2. In general if untreated, there is an 8-10 year period during which an HIV+ individual undergoes a gradual decline in immune function (monitored by laboratory testing of CD4 count) and increase in HIV viral load (monitored by laboratory testing of viral load).

3. Often no symptoms exhibited during this stage

4. Factors which influence how long individuals will remain in this stage before progressing to advanced disease:

a. How high the viral load is at 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, diarrhea, recurrent vaginal candidiasis, thrush, herpes zoster, recurrent infections, anemia, weight loss

3. Actual diagnosis of AIDS is made when the CD4 count falls below 200 cells/cmm 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

1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
2. Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.
3. Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).

VI. Treatment

- A. Recommendations for ART therapy
 1. ART therapy is recommended for all HIV-infected individuals to reduce the risk of disease progression
 2. Primary Care providers should refer patients to CMC Virology Clinic (UTMB Sector) or designated physician (Texas Tech Sector) for recommendations and initiation of therapy.
 3. Strength of evidence for the recommendation varies by pretreatment CD4 cell count as follows:

Table 8: Indication for drug therapy*

CD4 Count	Recommendation
< 350 cells/mm ³	Strong
350 to 500 cells/mm ³	Strong
> 500 cells/mm ³	Moderate

B. Table 9: Antiretroviral Regimens or Components That Should Not Be Offered At Any Time*

	Rationale	Exception
<i>Antiretroviral Regimens Not Recommended</i>		
Monotherapy with NRTI (All)	<ul style="list-style-type: none"> • Rapid development of resistance • Inferior ARV activity when compared with combination of three or more ARV agents 	• No exception
Dual-NRTI regimens (All)	<ul style="list-style-type: none"> • Rapid development of resistance • Inferior ARV activity when compared with combination of three or more ARV agents 	• No exception
Triple-NRTI regimens (All) except for ABC/ZDV/3TC (B1) or possibly TDF + ZDV/3TC (B11)	<ul style="list-style-type: none"> • High rate of early virologic nonresponse seen when triple-NRTI combinations, including ABC/TDF/3TC and TDF/ddI/3TC, were used as initial regimen in ART-naïve patients. • Other triple-NRTI regimens have not been evaluated. 	• ABC/ZDV/3TC (B1) and possibly TDF + ZDV/3TC (B11) in patients in whom other combinations are not desirable

*adapted from Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.

Antiretroviral Components <u>Not</u> Recommended as Part of an Antiretroviral Regimen*		
ATV + IDV (AIII)	<ul style="list-style-type: none"> Potential additive hyperbilirubinemia 	<ul style="list-style-type: none"> No exception
ddl + d4T (AII)	<ul style="list-style-type: none"> High incidence of toxicities: peripheral neuropathy, pancreatitis, and hyperlactatemia Reports of serious, even fatal, cases of lactic acidosis with hepatic steatosis with or without pancreatitis in pregnant women 	<ul style="list-style-type: none"> No exception
ddl + TDF (AII)	<ul style="list-style-type: none"> Increased ddl concentrations and serious ddl-associated toxicities Potential for immunologic nonresponse and/or CD4 cell count decline High rate of early virologic failure Rapid selection of resistance mutations at failure 	<ul style="list-style-type: none"> Clinicians caring for patients who are clinically stable on regimens containing TDF + ddl should consider altering the NRTIs to avoid this combination.
2-NNRTI combination (AI)	<ul style="list-style-type: none"> When EFV combined with NVP, higher incidence of clinical adverse events seen when compared with either EFV- or NVP-based regimen. Both EFV and NVP may induce metabolism and may lead to reductions in ETR exposure; thus, they should not be used in combination with ETR. 	<ul style="list-style-type: none"> No exception
EFV in first trimester of pregnancy or in women with significant childbearing potential (AIII)	<ul style="list-style-type: none"> Teratogenic in nonhuman primates 	<ul style="list-style-type: none"> When no other ARV options are available and potential benefits outweigh the risks (BIII)
FTC + 3TC (AIII)	<ul style="list-style-type: none"> Similar resistance profiles No potential benefit 	<ul style="list-style-type: none"> No exception
ETR + unboosted PI (AII)	<ul style="list-style-type: none"> ETR may induce metabolism of these PIs; appropriate doses not yet established 	<ul style="list-style-type: none"> No exception
ETR + RTV-boosted ATV or FPV (AII)	<ul style="list-style-type: none"> ETR may alter the concentrations of these PIs; appropriate doses not yet established 	<ul style="list-style-type: none"> No exception
ETR + RTV-boosted TPV (AII)	<ul style="list-style-type: none"> ETR concentration may be significantly reduced by RTV-boosted TPV 	<ul style="list-style-type: none"> No exception
NVP in ARV-naïve women with CD4 count >250 cells/mm ³ or men with CD4 count >400 cells/mm ³ (BI)	<ul style="list-style-type: none"> High incidence of symptomatic hepatotoxicity 	<ul style="list-style-type: none"> If no other ARV option available and if used, patient should be monitored closely
d4T + ZDV (AII)	<ul style="list-style-type: none"> Antagonistic effect on HIV-1 	<ul style="list-style-type: none"> No exception
Unboosted DRV, SQV, or TPV (AII)	<ul style="list-style-type: none"> Inadequate bioavailability 	<ul style="list-style-type: none"> No exception

*Acronyms: 3TC = lamivudine, ABC = abacavir, ATV = atazanavir, d4T = stavudine, ddl = didanosine, DRV = darunavir, EFV = efavirenz, ETR = etravirine, FPV = fosamprenavir, FTC = emtricitabine, IDV = indinavir, NVP = nevirapine, RTV = ritonavir, SQV = saquinavir, TDF = tenofovir, TPV = tipranavir, ZDV = zidovudine

*adapted from Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents.

Lamivudine may substitute for emtricitabine or vice versa

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 to 12 months based on patient status.
7. +/- 30% change is considered a significant change

B. Viral Load

1. Indicator of the magnitude of viral replication & response to drug therapy, i.e., virological response
2. Specifically, it is a measure of viral replication and is reported as number of viral copies/ml of blood
3. Used to monitor a patient's response to drug therapy
4. Decisions should be based on 2 measurements obtained 1-2 weeks apart due to technical & biological variations
5. Do not obtain within 4 weeks of intercurrent illness or immunization
6. Monitor at baseline, 2-8 weeks after initiating or changing therapy, and every 3 to 6 months thereafter based on status
7. > 0.5 log or 3-fold change in viral load is considered significant
8. Should see 1 log (10-fold) decrease in viral load within 8 weeks (may take as long as 16 weeks if very high) of initiating drug therapy and should be undetectable within 4-6 months

C. Resistance Testing

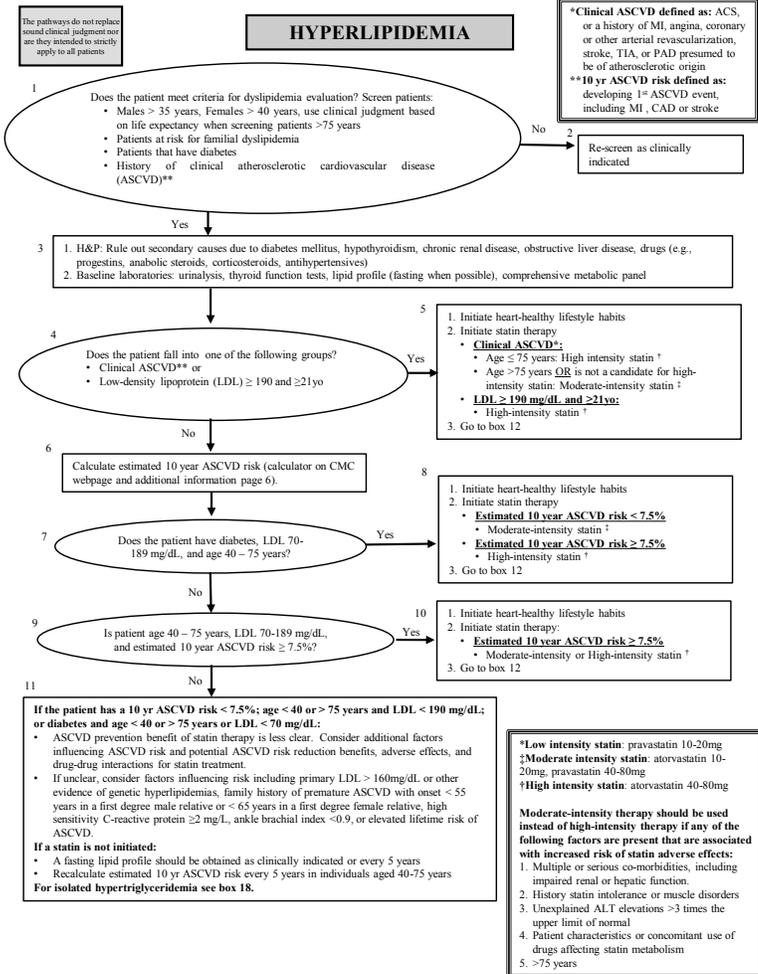
1. Should be performed by experienced provider (e.g., Infectious Diseases Specialist) since requires expert interpretation
2. Absence of resistance should be interpreted cautiously in conjunction with previous drug use history
3. Should be performed at baseline, while on antiretroviral therapy or immediately (within 4 weeks) after discontinuation of therapy
4. Should not be performed if viral load < 1,000 copies/mL because amplification of virus is unreliable

D. HLA-B*5701 screening – 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: VL > 200 copies/mL after 24 weeks of therapy
 - b. Virologic rebound is the confirmed detectable HIV RNA (to >200 copies/mL) after virologic suppression. This excludes isolated episodes of viremia (i.e. single level 50-1000)
3. Immunologic Failure
 - a. Failure to increase CD4 count by 25-50 cells/mm³ above baseline over 1 year
 - b. CD4 count decreases below baseline
 - c. Immunologic failure may not warrant drug therapy change if viral load is undetectable
 - d. In the setting of virologic suppression, there is no consensus on how to define or treat immunologic failure
4. Clinical Progression
 - a. Occurrence or recurrence of HIV-related illness after 3 months excluding immune reconstitution which is generally seen within first 3 months of starting therapy
 - b. Clinical progression may not warrant drug therapy change if viral load is undetectable



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.
 Approved February 1998. Revised April 4/00, 7/02, 4/03, 3/05, 7/09, 3/12, 1/13, 11/14. Reviewed 2/03, 1/12.

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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 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).

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Goal therapeutic response met?

- Low intensity statin*: LDL lowering of <30%
- Moderate intensity statin †: LDL lowering of 30% to 49%
- High intensity statin ‡: LDL lowering of ≥50%

LDL levels and percent reduction are to be used to assess response to therapy and adherence.

Yes

No

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If LDL levels are <40mg/dL on two consecutive readings, decreasing the statin dose may be considered.

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Assess for intolerance to statin therapy. Reinforce medication adherence.

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Follow-up in 1 year.

1. Reinforce continued adherence.
2. Monitor lipid profile (TC, LDL, HDL, TG) every 12 months
2. Monitor LFT and creatine phosphokinase as clinically indicated (see box 11)
3. Continue Lifestyle Modifications and reinforce at follow up

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1. **Adherence to lifestyle modifications and to statin therapy should be re-emphasized before the addition of a non-statin drug is considered.**

2. If clinically indicated, may consider increasing statin dose; however, there is no evidence that titration of statin therapy to achieve specific LDL levels or percent reduction improved ASCVD outcomes.

3. If high risk patients on high intensity statin have inadequate LDL lowering response, may consider addition of non-statin cholesterol lowering drug(s) if the ASCVD risk-reduction benefit outweighs potential risk for adverse effects.

High risk groups:

- Individuals with clinical ASCVD who are <75 years
- Individuals with baseline LDL ≥190 mg/dL.
- Individuals 40-75 years with diabetes

There is limited data supporting the routine use of non-statin drugs combined with statin therapy to reduce further ASCVD events.

Follow up as clinically indicated or at least annually.

*Low intensity statin: pravastatin 10-20mg
 †Moderate intensity statin: atorvastatin 10-20mg, pravastatin 40-80mg
 ‡High intensity statin: atorvastatin 40-80mg

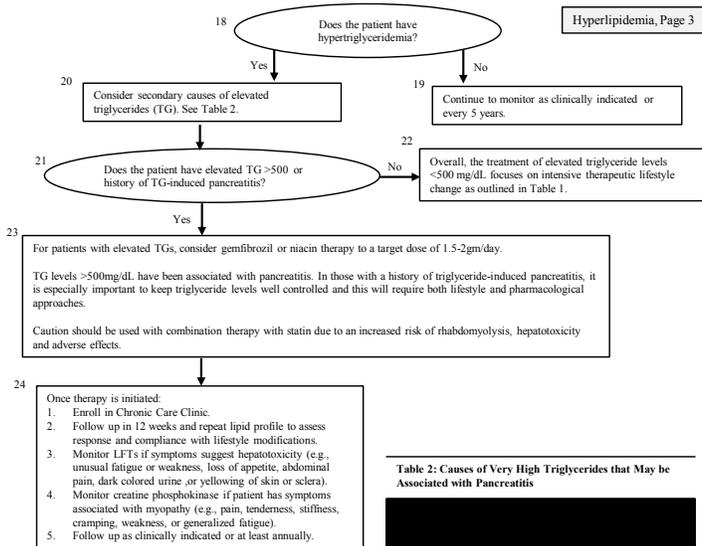


Table 2: Causes of Very High Triglycerides that May be Associated with Pancreatitis

Acquired disorders of metabolism:
Hypothyroidism
Pregnancy
Poorly controlled insulinopenic diabetes

Diet:
High saturated fat diet

Table adapted from the American Heart Association

Table 1: Effects of Nutrition Practices on Triglyceride Lowering

Nutrition Practice	TG-Lowering Response
Weight loss (5% to 10% of body weight)	20%
Decrease carbohydrates 1% energy replacement with MUFA/PUFA	1-2%
Eliminate trans fat 1% energy replacement with MUFA/PUFA	1%

PUFA, polyunsaturated fatty acid; MUFA, monounsaturated fatty acid
Table adapted from the American Heart Association

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Table 3: Formulary Statin Therapy as recommended by ACC/AHA

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL on average by approximately $\geq 50\%$	Daily Dose lowers LDL on average by 30% to $< 50\%$	Daily dose lowers LDL on average by $\leq 30\%$
Atorvastatin 40-80mg	Atorvastatin 10-20mg Pravastatin 40-80mg	Pravastatin 10-20mg

- Atorvastatin is associated with drug interactions due to its effects on the cytochrome P450 enzymatic pathway; however, pravastatin is not metabolized extensively via this pathway and is associated with fewer drug interactions.
- There is less statin toxicity (CK elevations and rhabdomyolysis) with pravastatin therapy when compared with atorvastatin.

Table 4: Lipid-Lowering Agents

Drug Class	Starting Dose	Effect on Lipids	ADR	Contraindications
1. Statins		LDL \downarrow 18-55%	myopathy	absolute: liver disease
Pravastatin	See page 1 †	HDL \uparrow 5-15%	\uparrow LFT	relative: certain drugs ‡
Atorvastatin	See page 1 †	TG \downarrow 7-30%		
2. BAS		LDL \downarrow 15-30%	GI upset	absolute: TG > 400mg/dl &
Cholestyramine	4gm QID	HDL \uparrow 3-5%	constipation	dysbetalipoproteinemia
		TG \uparrow or no change	\downarrow absorption drugs	relative: TG > 200mg/dl
3. Nicotinic Acid		LDL \downarrow 5-25%	flushing	absolute: chronic liver disease,
Niacin	500mg TID	HDL \uparrow 15-35%	hyperglycemia	severe gout
Niacin TR	500mg BID	TG \downarrow 20-50%	hyperuricemia	relative: PUD, diabetes,
			GI upset	hyperuricemia
			hepatotoxicity	
4. Fibrin Acid		LDL \downarrow 5-20%	dyspepsia	absolute: severe renal or
Gemfibrozil	600mg BID	HDL \uparrow 10-20%	gallstones	liver disease
		TG \downarrow 20-50%	myopathy	
			unexplained non-CHD deaths	

† The starting dose is dependent upon statin indication
‡ cyclosporine, macrolide antibiotics, azole antifungals, protease inhibitors, cytochrome P450 inhibitors (use fibrates with caution)

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

Hyperlipidemia Management

EDUCATION FOR PATIENTS AND PRACTITIONERS

I. Who is educated?

- A. Unit Practitioners- updated on hyperlipidemia so accurate and easy to understand information is provided to patients
- B. All patients with hyperlipidemia, including all patients with increased risk of atherosclerotic cardiovascular disease (ASCVD):
 1. Clinical ASCVD, defined as a acute coronary syndrome (ACS), or a history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral artery disease (PAD) presumed to be of atherosclerotic origin
 2. LDL \geq 190 mg/dL and age \geq 21 years of age
 3. Diabetes 40-75 years of age and LDL 70-189 mg/dL
 4. Age 40-75 years and \geq 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 dietitians will provide counseling on diet & how to choose the correct foods from the meal line. If dietitian is unavailable, the Unit Team designee will complete counseling.

III. When does education take place?

- A. Upon identification as high risk OR for secondary prevention
- B. Group education: provides general information about hyperlipidemia, risk factors, weight, diet and exercise
- C. Individual education: occurs at clinic visit and provides individual risk assessment, goal setting, information about compliance with diet and exercise program and will supplement information provided by group education

IV. What is included in hyperlipidemia education?

- A. Health Services Personnel
 1. Pathophysiology & diagnostic criteria for hyperlipidemia
 2. Identification & management of secondary causes of hyperlipidemia
 3. Non-pharmacologic and pharmacologic treatments
 4. Follow-up evaluations
 5. Adverse event monitoring
- B. Hyperlipidemia patients
 1. Pathophysiology
 2. Individual treatment plan
 3. Lifestyle modifications
 4. Monitoring parameters- frequency and importance
 5. Complications/risks 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)
 4. Patient History of
 - a. CHD
 - b. Hypertension (HTN)
 - c. DM
 - d. Cerebrovascular disease (CVD)
 - e. Peripheral vascular disease (PVD)
 - f. Pancreatitis
 - g. Peptic ulcer disease (PUD)
 - h. Gout or hyperuricemia
 - i. Thyroid disease
 - j. Chronic renal insufficiency (CRI)
 - k. Liver disease
 - l. Tobacco and alcohol use
 5. Diet History
 6. Activity Level
 7. Medication profile
 8. Previous lipid levels
 9. Physical Exam
 - a. Height
 - b. Weight
 - c. Xanthomas
 - d. Evidence of atherosclerosis
- 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 presumed to be of atherosclerotic origin
 2. LDL \geq 190 mg/dL and \geq 21 years of age
 3. Diabetes in individuals 40-75 years old with LDL 70-189mg/dL
 4. Individuals with no diabetes 40-75 years of age and LDL-C 70-189 mg/dL with estimated 10 year ASCVD risk \geq 7.5% or 5 to <7.5%
 - Available evidence indicates a clear net absolute benefit of initiation of statin therapy at a baseline estimated 10-year ASCVD risk of 7.5%.
 - Available evidence indicates that when baseline ASCVD risk is 5.0% to <7.5%, there is still net absolute benefit with statin therapy; however, the tradeoffs between the ASCVD risk-reduction benefit and adverse effects are less clear.
 5. Additional factors influencing ASCVD risk include primary LDL $>$ 160mg/dL or other evidence of genetic hyperlipidemias, 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 \geq 2 mg/L, ankle brachial index $<$ 0.9, or elevated lifetime risk of ASCVD.
 6. 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 Lloyd-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 race/ethnic 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 without ASCVD who has 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 race/ethnic groups, though as mentioned above, these estimates may represent under- and overestimates 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 $>$ 320mg/dL, HDL $<$ 20 or $>$ 100 mg/dL, or systolic blood pressure $<$ 90 or $>$ 200 mmHg.
 - e. The ASCVD risk calculator evaluates smoking status prior to estimating risk. This question is a "yes" or "no" answer which should be selected based upon current smoking status.

C. Who To Test

1. Primary Prevention

Initial Screening:

PATIENTS	INITIAL SCREENING
Males >35 years	TC, HDL, LDL, TG
Females >40 years	TC, HDL, LDL, TG
> 75 years	Use clinical judgment based on life expectancy, TC, HDL, LDL, TG

Patients at risk for familial dyslipidemia or that have a diagnosis of diabetes should be screened with a fasting lipid profile (TC, HDL, LDL, TG).

2. Secondary Prevention: All patients under 75 years old with known ASCVD should have a fasting lipid profile.

D. Secondary Causes of Lipid Abnormalities

1. Drugs:

- a. Alpha-agonists & antagonists- decrease TC & TG, increase HDL cholesterol
- b. Alpha-interferon – increase TG
- c. Amiodarone – increase LDL
- d. Anabolic steroids – increase TG
- e. Atypical antipsychotics – increase TG
- f. Beta-blockers- increase TG; decrease HDL-cholesterol
- g. Bile acid resins – increase TG
- h. Cyclosporine- increase LDL-cholesterol
- i. Ethanol- increase TG
- j. Glucocorticoids- increase TC & TG
- k. Isotretinoin- increase TC & TG; decrease HDL-cholesterol
- l. Oral contraceptives- increase TC, TG & HDL-cholesterol
- m. Protease inhibitors – increase TG
- n. Raloxifen – increase TG
- o. Sirolimus – increase TG
- p. Tamoxifen – increase TG
- q. Thiazide diuretics- increase TC, TG & HDL-cholesterol

2. Effects of Various Conditions

Secondary Cause	Elevated LDL-C	Elevated Triglycerides
Diet	Saturated or trans fats, weight gain, anorexia	Weight gain, very low-fat diets, high intake of refined carbohydrates, excessive alcohol intake
Diseases	Biliary obstruction, nephrotic syndrome	Nephrotic syndrome, chronic renal failure, lipodystrophies
Disorders and altered states of metabolism	Hypothyroidism, obesity, pregnancy*	Diabetes (poorly controlled), hypothyroidism, obesity, pregnancy*

*Treatment with statins niacin, and ezetimibe are contraindicated during pregnancy and lactation.
Table adapted from ACC/AHA

E. Factors That Alter Lipid Levels

1. Fasting

TC levels and HDL-cholesterol can be measured in the non-fasting patient. TG concentrations, however, are affected by recent food intake, and will affect the calculation of LDL-cholesterol by the Friedewald equation: $LDL = [TC] - [HDL] - [TG/5]$. Therefore patients should be fasting for at least 12 hours prior to having blood drawn for lipid profile testing.

2. Elevated TG

If the TG concentration is > 400 mg/dl, a calculated LDL may be inaccurate. In this instance, a direct LDL measurement may be appropriate.

3. Illness

Recent myocardial infarction, stroke, surgery, trauma, or infection may transiently lower cholesterol.

MANAGEMENT

- A. General Approach: Clinical decisions should be based on 2 lipid profiles, performed 1 to 8 weeks apart
- B. Non-Pharmacologic Therapy
 - 1. Diet
 - 2. Exercise
 - 3. Weight reduction in obese patients
 - 4. Stop smoking
 - 5. Decrease alcohol consumption
- C. Pharmacotherapy
 - 1. Dietary changes and exercise should be attempted prior to initiation of drug therapy in select patients where ASCVD prevention benefit of statin therapy may be less clear. In patients who are at particularly high risk, diet therapy and drug therapy may be initiated concurrently.
 - 2. The first-line agents to treat hyperlipidemia are the HMG-CoA Reductase Inhibitors ("Statins"). In the past, niacin and bile acid sequestrants were used, but the shift has been to the statins. This has provided for a more aggressive approach to managing hyperlipidemia. The statins are usually well tolerated and convenient to take.
 - 3. Isolated hypertriglyceridemia may be treated with gemfibrozil or nicotinic acid (see table 4 for a comparison of lipid lowering agents). Triglyceride (TG) levels ≥ 500 mg/dl have been associated with pancreatitis. Do not routinely offer fibrates in combination with a statin and do not offer nicotinic acid, bile acid sequestrants, or omega 3 fatty acid compounds alone or in combination with a statin. There is limited data supporting the routine use of non-statin drugs combined with statin therapy to reduce further ASCVD events.
- D. Follow-up
 - 1. History
 - a. Diet Compliance
 - b. Compliance with exercise program
 - c. Medication compliance and presence of symptoms suggesting adverse drug reactions (if indicated)
 - d. Current medications or pertinent changes in other drug therapy
 - e. Re-evaluation of the modifiable risk factors
 - f. Presence of muscle aches in large muscle groups
 - 2. Physical Examination
 - a. Weight
 - b. Blood Pressure
 - 3. Laboratory tests
 - a. Fasting lipid profile
 - b. LFTs as clinically indicated for patients on statins
 - c. Creatine kinase (CK) if symptoms of myositis
 - 4. Adverse event monitoring (including but not limited to)
 - a. Significant elevations of liver enzymes (>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

**PATIENT EDUCATION
HYPERLIPIDEMIA CLINIC**

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 deposits build up in the carotid arteries in the neck, this could lead to a stroke. Lowering of elevated cholesterol levels has been proven to decrease your risk of death from CHD, decrease the incidence of atherosclerosis and stroke. Cholesterol is a waxy compound that the body needs and uses for many important functions. The liver makes some of the cholesterol from fat in the diet. The fat in the diet comes from meat, eggs and dairy products. There are two types of cholesterol: LDL cholesterol (which has been called "bad cholesterol") and HDL cholesterol (which has been called "good cholesterol"). The LDL-cholesterol is the type of cholesterol that is associated with atherosclerosis and heart disease. The HDL-cholesterol seems to protect the body from developing heart disease. A simple blood test can determine what a person's cholesterol level is. Changes in diet are often the most effective way to lower or maintain a healthy cholesterol level. One of the most important changes to make is to lower the amount of fat in the diet. Food packages, from the commissary, now have the percentage of fat and grams of fat on the label, which makes it easier to keep track of the amount of fat in the diet. Weight loss, even in the slightly overweight patient, can make a big difference in cholesterol level. The Diet for Health, when followed properly, should help with weight loss. A routine exercise program not only helps with weight loss, but also helps to lower overall risk of heart disease. Drug therapy is not a substitute for diet and exercise, but should be considered to be an extension of the therapy. In some patients who are at high risk, diet, exercise and drug therapy may need to be started at the same time.

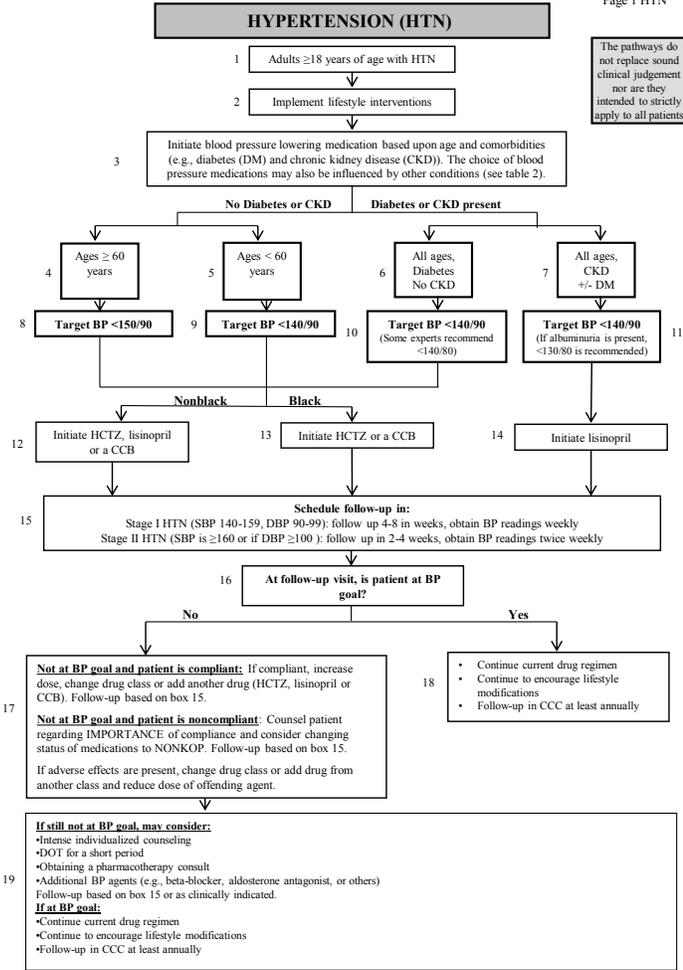
HIGH TRIGLYCERIDES

Studies have shown that 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 triglycerides can sometimes cause the blood to thicken causing a problem with clotting. High triglyceride levels usually respond well to non-drug therapy, such as changes in diet and increased exercise. Triglyceride is ingested in the diet from fats and sugars, is also made in the body in the liver and is important in the body for energy and fuel storage. High triglyceride levels may be caused by overproduction in the liver or decreased removal by the body. Triglyceride levels have been shown to be increased in certain disease states, in times of extreme stress, and by certain drugs.

Reducing other risks of cardiovascular disease

A healthy diet, regular exercise, and weight loss in overweight people can improve overall health and decrease the risk of heart disease as well as lowering lipid levels. In addition to hyperlipidemia, there are other risk factors for heart disease that should be controlled:

1. Control high blood pressure
2. Control high blood sugar
3. Stop smoking
4. Limit alcohol intake
5. Reduce stress



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

Table 1: CLASSIFICATION OF HYPERTENSION

BP Classification	SBP mmHg ¹	DBP mmHg ²	Lifestyle Modification	Initial Therapy
Normal	<120	and <80	Encourage	No antihypertensive indicated
Prehypertension	120-139	or 80-89	Yes	No antihypertensive indicated
Stage 1 Hypertension	140-159	or 90-99	Yes	See algorithm on page 1
Stage 2 Hypertension	≥160	or ≥100	Yes	See algorithm on page 1

1. SBP = systolic blood pressure

2. DBP = diastolic blood pressure

Table 2: Drug Selection in Patients with or without compelling conditions

A. When hypertension is the main condition:

- | | |
|---|--|
| <ul style="list-style-type: none"> • Black patients • Nonblack patients | <ul style="list-style-type: none"> • CCB or HCTZ • Lisinopril, CCB or HCTZ |
|---|--|

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	Spirolactone 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

*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*

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. A large adult cuff should be kept in all clinics.
- 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

Initial Blood Pressure (mm Hg)*

Systolic	Diastolic	Follow-up Recommended**
<120	<80	Recheck as clinically indicated
120-139	80-89	Confirm within 1 year
140-159	90-99	Evaluate/Refer within 2 months
≥160	≥100	<ul style="list-style-type: none"> • Evaluate or refer to source of care immediately or within 1 month. • For those with higher pressures (e.g., 180/120mm Hg), evaluate and treat per Hypertensive Emergency/Urgency pathway.

*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 advise on therapeutic lifestyle modifications.

Medical History

- Known duration and levels of elevated blood pressure.
- Patient history or symptoms of CHD, heart failure, cerebrovascular disease, peripheral vascular disease, renal disease, diabetes mellitus, dyslipidemia, gout, or sexual dysfunction.
- Family history of high blood pressure, premature CHD, stroke, diabetes, dyslipidemia, or renal disease.
- Symptoms suggestive of hypertension (headache, nose bleeds, dizziness, abnormal physical exam).
- History of recent changes in weight, leisure time physical activity, and smoking or tobacco use.
- Dietary assessment including intake of sodium, alcohol, saturated fat and caffeine.
- History of all prescribed and OTC medication, herbal remedies, and illicit drugs.
- Results and adverse effects of past antihypertensive therapy.
- Psychosocial and environmental factors that may influence hypertensive control.

Cardiovascular Risk Factors

- Hypertension
- Obesity (Body Mass Index ≥ 30kg/m²)
- Physical Inactivity
- Dyslipidemia
- Diabetes Mellitus
- Microalbuminuria or estimated GFR < 60 ml/min
- Age (>55 male, > 65 females)
- Family history of premature cardiovascular disease (male < 55 or females < 65)

Physical Exam

- Two or more blood pressure readings separated by 2 minutes with the patient supine or seated.
- Verification in the contralateral arm (if values are different, the higher value should be used).
- Measurement of weight, height, and waist circumference.
- Fundoscopic examination for hypertensive retinopathy (i.e., arteriolar narrowing, focal arteriolar constrictions, arteriovenous crossing changes, hemorrhages and exudates, disc edema).
- Examination for the neck for carotid bruits, distended veins, or enlarge thyroid gland.
- Examinations of the heart for abnormalities in the rate and rhythm, increase size, precordial heave, clicks, murmurs and third and fourth heart sounds.
- Examination of the lungs for rales and evidence for bronchospasm.
- Examination of the abdomen for bruits, enlarged kidney, masses and abnormal aortic pulsation.
- Examinations of the extremities for diminished or absent peripheral arterial pulsations, bruits, and edema.
- Neurological assessment.

Routine Laboratory Test

Routine laboratory 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

Background:
 Prehypertension is defined as having a systolic blood pressure within the range of **120-139 mmHg** and/or a diastolic blood pressure of **80-89 mmHg**.

Several reputable studies support the prehypertension categorization through the following findings:

- *Framingham Heart Study found that 55-year old adults (who were then normotensive in the study) have a **90% probability of developing HTN in their lifetime** and a 60% probability of receiving anti-HTN meds.
- *Framingham Heart Study found that individuals with blood pressure values in the range of 130-139/85-89 mmHg have a **2-fold** increased risk of cardiovascular disease (CVD) versus a person with BP <120/80
- *Meta-analysis of 61 studies indicated that risk of death from CVD and stroke increases linearly with increasing BP beginning as low as 115/75 mmHg and for each increment of 20/10 mmHg the risk of CVD **DOUBLES**
- *According to Greenlund et al. (2004), persons with prehypertension were found to have a **higher prevalence of other risk factors for heart disease and stroke** (hyperlipidemia, obesity, diabetes) vs. normotensive persons.

Aggressive Management of the Prehypertensive Patient:
 The main purpose of the prehypertension category is to identify persons who are at risk of developing hypertension and hypertension-related long-term complications in the future. It is important that healthcare providers identify prehypertensive patients early and manage their condition aggressively. **EDUCATION IS THE KEY HERE! This is the opportunity to counsel patients on the serious complications of HTN and to promote healthy habits and lifestyle changes so that an actual diagnosis of HTN may be avoided.**

Therapeutic Lifestyle Modifications:**
 There is no evidence yet to support the use of medications to treat prehypertension. Lifestyle modifications are currently the gold standard in the management of the condition. Suggested modifications and the extent of systolic blood pressure reduction are as follows:

Modification	Recommendation	Approximate SBP Reduction
Weight reduction	Encourage patient to maintain normal body weight (BMI 18-24.9)	5-20mmHg/10kg weight loss
Diet	Consider DFH and encourage adherence. Discourage commissary foods.	8-14mmHg
Dietary sodium restriction	Encourage patient to reduce dietary sodium intake to no more than 2.4g sodium or 6g NaCl.	2-8mmHg
Physical activity	Encourage patient to engage in aerobic physical activity to lower BP: 3 to 4 sessions a week, lasting on average 40 minutes per session, and involving moderate physical activity.	4-5mmHg

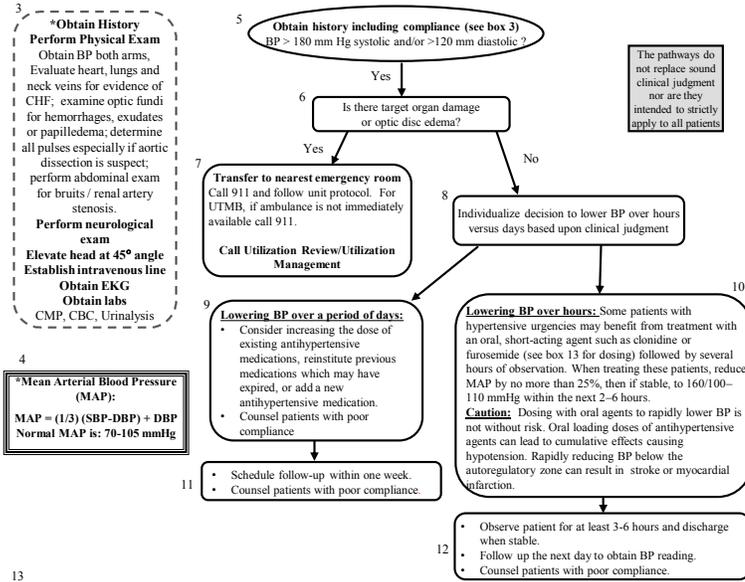
**Set realistic goals for your patients and discuss the value of self-rewarding and goal setting. Encourage patients to make gradual changes to their lifestyle, as they are more likely to comply with one change at a time.

HYPERTENSION EMERGENCY

Hypertensive emergencies are characterized by severe 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, intracranial hemorrhage, unstable angina pectoris, acute myocardial infarction, acute left ventricular failure with pulmonary edema, dissecting aortic aneurysm, acute renal failure or eclampsia. Most hypertensive emergencies are treated initially with parenteral agents. Blood pressure reduction does not need to reach the normal range immediately. The initial goal of therapy is to reduce the mean arterial blood pressure (MAP) (see box 4) by no more than 25% (within minutes to 1 hour), then, if stable, toward 160/100 to 110 mm Hg within 2 to 6 hours, avoiding excessive falls in pressure that may precipitate renal, cerebral, or coronary ischemia.

HYPERTENSION URGENCY

Hypertensive urgencies are those situations with severe elevations in BP without progressive target organ damage. Examples include upper levels of Stage 2 hypertension associated with severe headache, shortness of breath, epistaxis, 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.



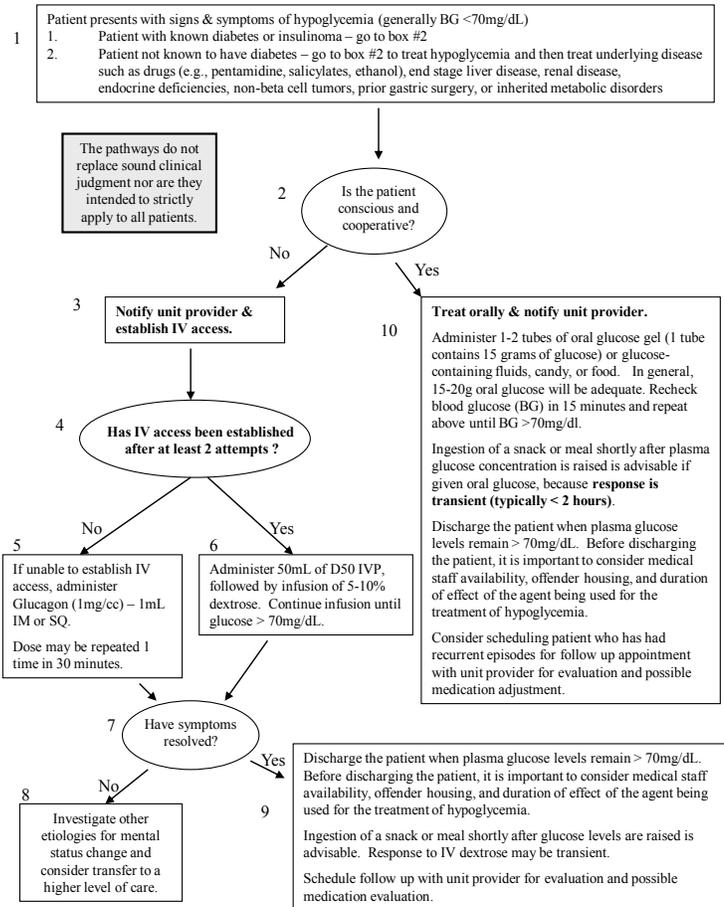
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients

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 mortality and risk of rebound hypertension with clonidine withdrawal in non-adherent patients.

Furosemide dosing in hypertensive urgency: May be dosed as 20-40mg every 2-3 hours. Furosemide is useful in patients with volume overload, but the risk of volume depletion in patients with reduced or normal volume status should be considered.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee. Approved August 1995; Reviewed 1/08, 5/11; Revised 10/98, 4/02, 4/03, 3/04, 5/14

HYPOGLYCEMIA



Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, January 2006. Reviewed 5/10, 1/13.

Hypoglycemia

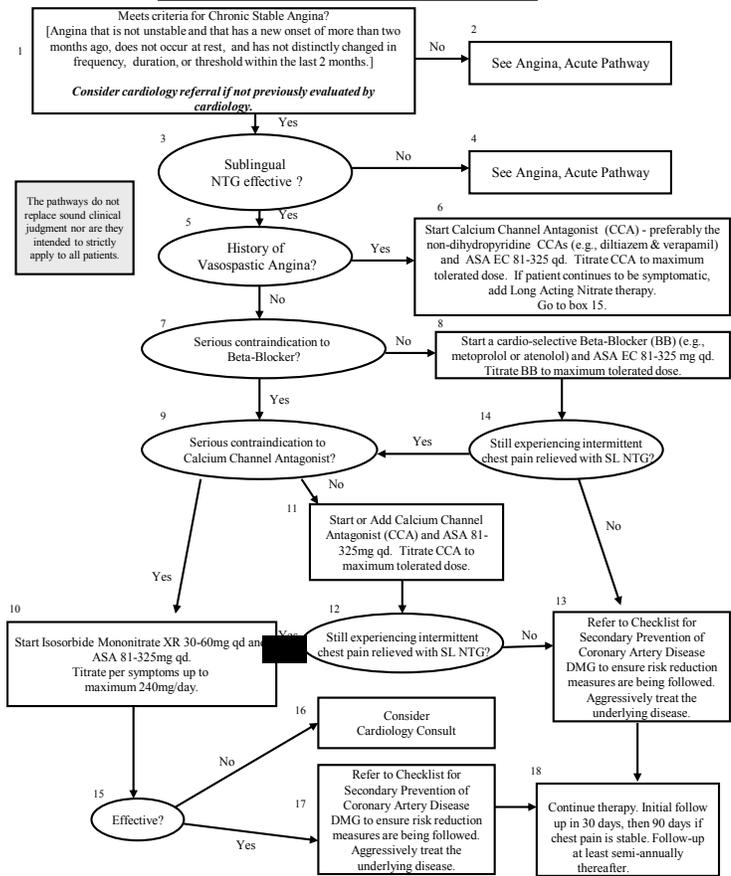
- I. Definition – Blood glucose < 70mg/dL. However, glucose thresholds for hypoglycemia-induced symptoms and physiologic responses may vary between patients. Therefore, an important framework for making the diagnosis of hypoglycemia is *Whipple's triad*:
 - (1) symptoms consistent with hypoglycemia,
 - (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

Ischemic Heart Disease, Stable



Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. Approved February 2001; Reviewed 11/02, 1/08, Revised 4/03, 9/09, 7/11, 1/15.

Definition of chronic stable angina

A clinical syndrome characterized by discomfort in the chest, jaw, shoulder, back, or arms, typically elicited by exertion or emotional stress and relieved by rest or nitroglycerin.

Goals of Treatment:

- Relief of symptoms
- Prevention or slowing of disease progression
- Prevention of future cardiac events, i.e. myocardial infarction, unstable angina, need for revascularization
- Improvement in survival

Mainstay of therapy in symptomatic treatment

- Short acting nitroglycerin - 1st line therapy
- Cardioselective beta blockers (BB) - 2nd line therapy
 - Atenolol 50-100mg/day
 - Metoprolol 100-450mg/day in 2-3 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 and diltiazem should not be used in combination with beta-blockers (see drug interaction alert).**
 - Amlodipine 5-10mg/day (Dihydropyridine CCA)
 - Diltiazem XR 180-360mg/day (Non-dihydropyridine CCA)
 - Verapamil 240-480mg/day in 3-4 divided doses (Non-dihydropyridine CCA)
- 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
- Ranolazine - 4th line agent for patients with stable ischemic heart disease; should be used in combination with other established anti-anginal medications such as amlodipine, beta-blockers or nitrates; preferably, should only be recommended by a cardiologist. (see other educational information below).

Note: Three anti-anginal drugs (excluding short acting NTG) may actually provide less symptomatic protection than two drugs. Thus, the dose of one drug should be optimized before adding another one, and it is advisable to switch drug combinations before attempting a three drug regimen.

Contraindications

- Beta-blockers
 - Sinus bradycardia (HR <50 bpm)
 - Second or third degree heart block
 - Overt cardiac failure
 - Hypersensitivity to BB's
- Calcium channel antagonists
 - Sick sinus syndrome
 - Second or third degree heart block
 - Hypotension (systolic <90mmHg)
 - Hypersensitivity to CCA's
 - ❖ Diltiazem: acute MI or pulmonary congestion
 - ❖ Verapamil: severe left ventricular dysfunction, cardiogenic shock, atrial flutter or fibrillation
 - ❖ Amlodipine: use with caution in patients with heart failure
- Aspirin
 - Hypersensitivity to NSAIDs
 - Syndrome of asthma, rhinitis, and nasal polyps
 - Inherited or acquired bleeding disorders

Drug interaction alert:

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

Counseling on the use of nitrates

- Patients should be counseled to come down to medical if chest pain or discomfort is unimproved or worsening five minutes after one nitroglycerin dose has been taken.
- If the sublingual nitroglycerin (NTG) is potent, a slight tingling sensation should be felt under the tongue. Tablets that crumble easily should not be used. The sublingual mucosa should be moist for adequate dissolution and absorption of the 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.
- Isosorbide mononitrate XR should be dosed 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.

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 Guideline):

- Aspirin 81-325mg for all patients
- Beta-blockers for all patients
- Statins for all patients to achieve target LDL <100mg/dl, <70mg/dl for high-risk patients
- Angiotensin Converting Enzyme (ACE) Inhibitor (see below)

Role of ACEI per 2007 Chronic Angina ACC/AHA guidelines:

- ACE inhibitors are recommended for patients with chronic stable angina and a history of myocardial infarction, left ventricular ejection fraction (LVEF) < 40 percent, hypertension, diabetes, or chronic kidney disease
- ACE inhibitors may be considered for lower risk patients with mildly reduced or normal LVEF in whom risk factors are well controlled and revascularization has been performed.

Ranolazine Healthcare Provider Education

- Ranolazine is an anti-angina medication that was recently included in the current stable ischemic heart diseases guideline.
- The proposed ranolazine mechanism of action is the inhibition of pathologic increases in late Na⁺ current induced during myocardial ischemia. Because of Na⁺/Ca²⁺ coupling, this would be expected to reduce ischemia-induced calcium overload, resulting in more normal diastolic relaxation and decreased wall tension. Improved diastolic function decreases oxygen demand and increases coronary blood supply.
- Ranolazine is approved for treatment of patients with chronic angina who have not achieved an adequate response with other antianginal drugs.
- Dosing is 500 mg PO BID initially; may increase to 1,000 mg PO BID, if needed.
- Place in therapy: 4th line agent for patients with stable ischemic heart disease; should be used in combination with other established anti-anginal medications such as amlodipine, beta-blockers or nitrates.
- Due to the risk of QTc prolongation, it should not be used with medications that have high QTc prolongation risk. Preferably, ranolazine should only be recommended by a cardiologist.

Formulary Substitutions for Commonly Prescribed Non-Formulary Medications

Patients should be evaluated for use of formulary agents whenever possible. Clinicians should consider past history of response, contraindications, co-morbidities, medication compliance, and potential for adverse effects and/or drug-drug interactions when making treatment decisions. When medications are changed, patients should be monitored more closely for signs of worsening symptoms and adverse effects. The recommendations listed below are not intended to replace sound clinical judgment.

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Hypertensive Medications				
Felodipine (Plendil®)	2.5 - 10 mg qd	Amlodipine (Norvasc®) 5 mg, 10 mg tablets	2.5 - 10 mg qd	5 mg qd to 5 mg qd
Isradipine (DynaCirc CR®)	5 - 20 mg qd			5 mg qd to 5 mg qd
Nicardipine SR (Cardene SR®)	30 - 60 mg BID			30 mg BID to 5 mg qd
Nifedipine (Procardia XL®)	30 - 120 mg qd			30 mg qd to 5 mg qd
Nisoldipine (Sular®)	10 - 40 mg qd			10 mg qd to 5 mg qd
Benazepril (Lotensin®)	10 - 40 mg qd			10 mg qd to 10 mg qd
Captopril (Capoten®)	25 - 50 mg bid-tid			25 mg bid to 10 mg qd
Fosinopril (Monopril®)	10 - 40 mg qd			10 mg qd to 10 mg qd
Enalapril (Vasotec®)	2.5 - 40 mg qd			5 mg qd to 10 mg qd
Moexipril (Univasc®)	7.5 - 30 mg qd			7.5mg qd to 10 mg qd
Perindopril (Aceon®)	4 - 8 mg qd			4 mg qd to 10 mg qd
Quinipril (Accupril®)	10 - 40 mg qd			10 mg qd to 10 mg qd
Ramipril (Altace®)	2.5 - 20 mg qd			2.5 mg qd to 10 mg qd
Trandolapril (Mavik®)	1 - 8 mg qd			2 mg qd to 10 mg qd
Aliskiren (Tekturna®)	150 - 300 mg qd			150 mg qd to 10 mg qd
Azilsartan (Edarbi®)	40 - 80 mg qd			40 mg qd to 10 mg qd
Candesartan (Atacand®)	8 - 32 mg qd			8 mg qd to 10 mg qd
Eprosartan (Teveten®)	400 - 800 mg qd			400 mg qd to 10 mg qd
Irbesartan (Avapro®)	150 - 300 mg qd			150 mg qd to 10 mg qd
Losartan (Cozaar®)	50 - 100 mg qd			50 mg qd to 10 mg qd
Olmesartan (Benicar®)	20 - 40 mg qd			20 mg qd to 10 mg qd
Teimisartan (Micardis®)	20 - 80 mg qd			20 mg qd to 10 mg qd
Valsartan (Diovan®)	80 - 320 mg qd			80 mg qd to 10 mg qd

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Hypertensive Medications Continued				
Acebutolol (Sectral®)	100 - 1200 mg in divided doses	Atenolol (Tenormin®) 25 mg, 50 mg tablets	25 - 100 mg qd	Nonformulary to Atenolol; Metoprolol; Propranolol; Carvedilol; Sotalol 100 mg bid to 25 mg qd : 25 mg bid: 20 mg bid: 3.125mg bid:80mg bid
Betaxolol (Betopic®)	5 - 20 mg qd	Metoprolol (Lopressor®) 25 mg, 50 mg, 100 mg tablets; 5mg/5mL injection—5mL vial	50 - 100 mg in single-divided doses	5 mg qd to 25 mg bid : 25 mg bid : 20mg bid: 3.125mg bid:80mg bid
Bisoprolol (Zebeta®)	2.5 - 10 mg qd	Propranolol (Inderal®) 10 mg, 20 mg, 40 mg tablets	40 - 160 mg in divided doses	2.5 mg qd to 25 mg qd : 25 mg bid : 20 mg bid: 3.125mg bid:80mg bid
Carteolol (Cartrol®)	2.5 - 10 mg qd	Coreg (Carvedilol®) 3.125mg, 6.25mg, 12.5mg, 25mg tablets	3.125-25 mg bid	2.5 mg qd to 25 mg qd : 25 mg bid : 20 mg bid: 3.125mg bid:80mg bid
Metoprolol succinate (Toprol XL®)	25 - 100 mg qd	Sotalol (Betapace®) 80mg, 120mg, 160mg tablets	80-160 mg bid	25 mg qd to 25 mg qd : 25 mg bid : 20 mg bid: 3.125mg bid:80mg bid
Nadolol (Corgard®)	40 - 120 mg qd			
Penbutolol (Levatol®)	10 - 40 mg qd			
Pindolol (Visken®)	5 - 20 mg divided bid			
Propranolol long-acting (Inderal LA®)	60 - 180 mg qd			
Timolol (Blocadren®)	10 - 20 mg divided bid			
Prazosin (Minipress®)	3 - 20 mg in 2 - 3 doses/day	Terazosin (Hytrin®) 1 mg, 2 mg, 5 mg, 10 mg capsules	1 - 20 mg q hs	10 mg bid to 25 mg qd : 25 mg bid : 20 mg bid:3.125mg bid:80mg bid 1 mg tid to 1 mg q hs
Doxazosin (Cardura®)	1 - 16 mg q hs			
Clonidine (Catapres®)	0.1 - 0.8 mg tid	Guanfacine (Tenex®) 1 mg, 2 mg tablets	1 - 3 mg qd	1 mg q hs to 1 mg q hs 0.1 mg tid to 1 mg qd

Formulary Substitutions page 2

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Hyperlipidemic Medications				
Fluvastatin (Lescol®)	20-80 mg qd	Pravastatin (Pravachol®) 10 mg, 20 mg, 40 mg tablets	10-80 mg qd	Nonformulary to Pravastatin : Atorvastatin 80 mg qd to 40 mg qd : 10 mg qd 80 mg qd to 80 mg qd : 20 mg qd 2 mg qd to 40 mg qd : 10 mg qd 20 mg qd to 40 mg qd : 10 mg qd 5 mg qd to 80 mg qd : 20 mg qd
Lovastatin (Mevacor®)	10-80 mg qd	Atorvastatin (Lipitor®) 10 mg, 20 mg, 40 mg tablets	10-80 mg qd	
Pitavastatin (Livalo®)	1-4 mg qd			
Simvastatin (Zocor®)	5-80 mg qd			
Rosuvastatin (Crestor®)	5-40 mg qd			
Fenofibrate (Tricor®)	48-145 mg qd	Gemfibrozil (Lopid®) 600 mg tablets	600 mg bid	48-145 mg qd to 600 mg bid
Colestipol (Colestid®)	5-30 g/day given once or in 2-4 doses	Cholestyramine (Questran®) 4g powder	4-24 g/day given once or in divided doses	5g qd to 4g qd
Anti-diabetic Medications				
Aspart (Novolog®)		Regular (Novolin R®) 100 units/ml vial, 10 ml		Unit to unit conversion
Lispro (Humalog®)				
Glisine (Apidra®)				
Regular (Humulin R®)				
Glargine (Lantus®)		NPH (Novolin N®) 100 units/ml vial, 10 ml		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.
Detemir (Levemir®)				unit to unit conversion
NPH (Humulin®)				Unit to unit conversion
NPH 50/ Regular 50 (Humulin 50/50®)				
Lispro Protamine 50/ Lispro 50 (Humalog Mix 50/50®)		NPH 70/Regular 30 (Novolin 70/30®) 100 units/ml, 10 ml		NPH and Regular Insulin
Lispro Protamine 75/ Lispro 25 (Humalog Mix 75/25®)		Regular (Novolin R®)		
Aspart Protamine 70/ Aspart 30 (Novolog Mix 70/30®)		NPH (Novolin N®)		Novolin 70/30 or NPH and Regular Insulin Formulary Substitutions page 3

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Diabetic Medications Continued				
Glimepiride (Amaryl®)	1 - 8 mg qd			2 mg qd to 5 mg qd
Glyburide (Diabeta®)	5 – 20 mg in single or divided doses			5 mg qd to 5 mg qd
Glyburide micronized (Glynase PresTab®)	1.5 - 12 mg in single or divided doses	Glipizide (Glucotrol®) 5mg, 10mg tablets	5-40mg daily in single or divided doses	3 mg to 5 mg qd
Tolazamide	100 mg qd – 500 mg bid			250 mg qd to 5 mg qd
Tolbutamine	500 – 2000 mg daily in 1 - 3 divided doses			500 mg BID to 5 mg qd
Respiratory Medications				
Tiotropium (Spiriva®)	1 capsule qd	Ipratropium (Atrovent®) 17 mcg, 200 puffs	2 puffs qid	1 capsule qd to 2 puffs qid
Atrovent / Ipratropium (Combivent®)	2 puffs qid	Albuterol (Ventolin®) 90 mcg, 200 puffs	2 puffs qid prn SOB	
		Ipratropium (Atrovent®)	2 puffs qid	
Budesonide (Pulmicort Turbuhaler®)	180 – 1200 mcg/day divided bid	Beclothemethasone HFA (QVAR®)	80 - 480 mcg/day divided bid	Convert based on whether the patient was dosed at low, medium, or high dose; then convert to Qvar® dosing listed below: Low dose (puffs) = 1 puff bid; Medium dose (puffs) = 2-3 puffs bid; High dose (puffs) = 4 puffs bid.
Fluticasone (Aerospan®)	500 – 2000 mcg/day divided bid			
Mometasone (Asmanex Twisthaler®)	200 – 400 mcg/day given once daily or divided bid			
Triamcinolone (Azmacort®)	300 – 1500 mcg/day divided 2 – 4 times/day			
Fluticasone (Flovent MDI®)	88 – 440 mcg/day divided bid			

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

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	
Anti-Retroviral Medications (Continued)				
Zidovudine+Lamivudine (Combivir®)	300mg bid +150mg bid	Zidovudine (retrovir, AZT) 300 mg tablet +Lamivudine (EpiVir®, 3TC) 150mg, 300mg tablets	300mg bid+150mg bid	Approximate Equivalent (Non-formulary to Formulary)
Efavirenz+Emtricitabine+tenofovir (Atripla®)	600mg+200mg+300mg qd	Efavirenz (Sustiva®) 600mg tablet +Lamivudine (EpiVir®, 3TC) 300 mg tablet +Tenofovir (Viread®, TDF) 300mg tablet	600mg qd+300mg qd+300mg qd	Atripla® to Efavirenz 600mg+3TC 300mg+TDF 300mg
Emtricitabine+tenofovir (Truvada®)	200mg+300mg qd	Lamivudine (EpiVir®, 3TC) 300 mg tablet +Tenofovir (Viread®, TDF) 300mg tablet	300mg qd+300mg qd	Truvada® to 3TC 300mg+TDF 300mg
Abacavir + Lamivudine (Epizcom®)	600mg+300mg qd	Abacavir (Ziagen®, ABC) 600mg tablet+Lamivudine (EpiVir®, 3TC) 300mg tablet	600mg+300mg qd	Epizcom to 600mg abacavir + 300mg lamivudine
Abacavir+Lamivudine+Zidovudine (Trizivir®)	300mg+150mg+300mg po bid	Abacavir (Ziagen®, ABC) 300mg tablet+Lamivudine (EpiVir®, 3TC) 300mg tablet+Zidovudine (Retrovir®, AZT) 300 mg tablet	300mg+150mg+300mg po bid	Trizivir® to abacavir 300mg+Lamivudine 150mg+zidovudine 300mg
Emtricitabine+Rilpivirine+Tenofovir (Complera®)	200+25mg +300mg qd	Lamivudine(EpiVir®, 3TC) 300mg tablet+Rilpivirine (Edurant®, RPV) 25mg tablet+Tenofovir (Viread®, TDF) 300mg tablet	300mg+25mg+300mg po qd	RPV available through prior authorization: Complera to 3TC 300mg +RPV 25mg+TDF 300mg

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Retroviral Medications (Continued)				
Abacavir+Dolutegravir+Lamivudine (Triumeq®)	600mg+50 mg+300mg qd	Abacavir (Zigen®, ABC) 600mg tablet+Dolutegravir (Tivicay®, DTG) 50mg tablet+Lamivudine (Epivir®, 3TC) 300mg tablet	600mg+50 mg+300mg qd	Triumeq to ABC 600mg + DTG 50mg + 3TC 300mg
Very High Potency Topical Steroids				
Betamethasone dipropionate, augmented (Diprolene®) 0.05%		Clobetasol propionate (Temovate®) 0.05% ointment 15 gm tube		
Diflorasone diacetate (ApexCon®) 0.05%				
Halobetasol propionate 0.05% (Ultravate®)				
High Potency Topical Steroids				
Amcinonide (Cyclocort®) 0.1%		Fluocinonide (Lidex®) 0.05% cream 60 gm tube		
Betamethasone dipropionate (Diprolene®) 0.05%		0.05% ointment 15 gm tube		
Betamethasone valerate (Valesone®) 0.1%		0.05% cream 15 gm tube		
Diflorasone diacetate (Florone®) 0.05%				
Halcinonide (Halog®) 0.1%				

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	
Intermediate Potency Topical Steroids				
Betamethasone valerate (Psorion Cream®) 0.05%		Triamcinolone acetonide (Kenalog®)		
Clo cortolone pivalate (Cloderm®) 0.01%		0.025% ointment 15 gm tube		
Fluocinolone acetonide (Fluorosyn®) 0.025%		0.025% cream 15 gm tube		
Flurandrenolide (Cordran®) 0.05%		0.1% cream 15 gm tube		
Fluocisone propionate (Cultivate®) 0.05%				
Hydrocortisone butyrate (Locoid®) 0.1%				
Hydrocortisone valerate (Westcort®) 0.2%				
Mometasone furoate (Elocon®) 0.1%				
Prednicarbate (Dermatop®) 0.1%				
Low Potency Topical Steroids				
Alcometasone dipropionate (Acloivate®) 0.05%		Mometasone (Elocon®) 0.1% 60mL solution		
Desonide (DesOwen®) 0.05%		Hydrocortisone (Hytone®) 1% 30 gm tube, unit dose packets		
Fluocinolone (Synalar®) 0.01% 60 mL solution		Hydrocortisone (Anusol-HC®) 1% hemorrhoidal-HC rectal cream — 30 gm tube		
		Hydrocortisone (Anusol-HC®) suppository 25 mg		

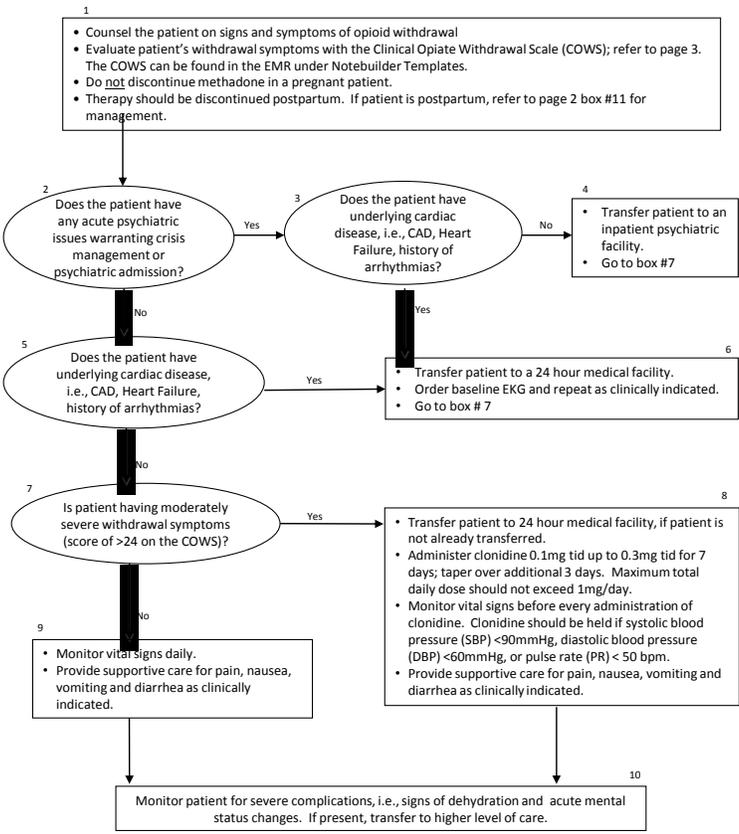
Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	Approximate Equivalent (Non-formulary to Formulary)
Anti-Glaucoma Medications				
Bimatoprost (Lumigan®) 0.03% Ophthalmic Solution	1 gtt in affected eye q pm	Latanoprost (Xalatan®) 0.005% Ophthalmic Solution	1 gtt in affected eye(s) q pm	
Travoprost (Travatan®) 0.004% Ophthalmic Solution	1 gtt in affected eye q pm			
Betaxolol (Betoptic®) 0.5% Ophthalmic Solution	1-2 gtt in affected eye bid			
Levobunolol (Betagan®) 0.25% and 0.5% Ophthalmic Solution	0.25% - 1-2 gtt in affected eye bid 0.5% - 1-2 gtt in affected eye qd 1 gtt in affect eye bid	Timolol (Timoptic®) 0.5% Ophthalmic Solution	1 gtt in affected eye bid	
Metipranolol (OptiPranolol®) 0.3% Ophthalmic Solution	1 gtt in affected eye qd			
Timolol (Timoptic-XE®) 0.25% and 0.5% Ophthalmic Gel Forming Solution				
Apraclonidine (Iopidine®) 1% ophthalmic solution	1 gtt in affected eye tid	Brimonidine (Alphagan®) 0.2% ophthalmic solution— 10mL	1 gtt in affected eye tid	
Brinzolamide (Azopt®) 1% Ophthalmic Suspension	1 gtt in affected eye tid	Dorzolamide (Trusopt®) 2% Ophthalmic Solution	1 gtt in affected eye tid	
Dorzolamide 2 % Ophthalmic + Timolol 0.5% Ophthalmic Solution (Cosopt®)	1 gtt in affected eye bid	Dorzolamide (Trusopt®) 2% Ophthalmic Solution + Timolol (Timoptic®) 0.5% Ophthalmic Solution	1 gtt in affected eye bid and 1 gtt in affected eye bid	

Non-Formulary Medication		Formulary Medication		Comments
Name of Medication	Dose Range and Frequency	Name of Medication and Dosages Available	Dose Range and Frequency	
Miscellaneous				
Calcium carbonate (Titracac®) 420mg chewable tablet	1 tablet qid	Calcium carbonate (Tums®) 500mg chewable tablet	1 tablet qid	Titracac contains 168mg elemental calcium
Ferrous gluconate (Fergon®) 325mg tablet	2 tablets qd	Ferrous sulfate (Feosol®) 325mg tablet	1 tablet qd	Tums contains 200mg elemental calcium Fergon tablet contains 36mg elemental iron
Docusate calcium (Surfak®) 240mg capsule	240mg qd	Docusate sodium (Colace®) 100 capsule	100mg bid or 200mg qd	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



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, October 2008. Reviewed 01/11. Revised 9/2014

OPIOID DISCONTINUATION POSTPARTUM

- 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

If discharge methadone total daily dose is >40mg:	If discharge methadone total daily dose is ≤40mg:																																				
<ul style="list-style-type: none"> • Decrease dose by 20mg/day until 40mg is reached. • Then, decrease dose by 5mg/day until it is discontinued. 	<ul style="list-style-type: none"> • Decrease dose by 5mg/day until it is discontinued. 																																				
<p>Example: 100mg/day</p> <table style="width: 100%; border: none;"> <tr><td style="width: 50%;">80mg</td><td style="width: 50%;">Day 1</td></tr> <tr><td>60mg</td><td>Day 2</td></tr> <tr><td>40mg</td><td>Day 3</td></tr> <tr><td>35mg</td><td>Day 4</td></tr> <tr><td>30mg</td><td>Day 5</td></tr> <tr><td>20mg</td><td>Day 6</td></tr> <tr><td>15mg</td><td>Day 7</td></tr> <tr><td>10mg</td><td>Day 8</td></tr> <tr><td>5mg</td><td>Day 9</td></tr> <tr><td>Discontinue</td><td>Day 10</td></tr> </table>	80mg	Day 1	60mg	Day 2	40mg	Day 3	35mg	Day 4	30mg	Day 5	20mg	Day 6	15mg	Day 7	10mg	Day 8	5mg	Day 9	Discontinue	Day 10	<p>Example: 40mg/day</p> <table style="width: 100%; border: none;"> <tr><td style="width: 50%;">35mg</td><td style="width: 50%;">Day 1</td></tr> <tr><td>30mg</td><td>Day 2</td></tr> <tr><td>25mg</td><td>Day 3</td></tr> <tr><td>20mg</td><td>Day 4</td></tr> <tr><td>15mg</td><td>Day 5</td></tr> <tr><td>10mg</td><td>Day 6</td></tr> <tr><td>5mg</td><td>Day 7</td></tr> <tr><td>Discontinue</td><td>Day 8</td></tr> </table>	35mg	Day 1	30mg	Day 2	25mg	Day 3	20mg	Day 4	15mg	Day 5	10mg	Day 6	5mg	Day 7	Discontinue	Day 8
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Clinical Opiate Withdrawal Scale

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

Patient Name: _____
 Current Vitals (BP, RR, HR): _____
 Observer: _____

Patient MRN #: _____
 Date: _____ Time: _____

Signs and Symptoms	Score
Resting Pulse Rate: (record beats per minute) <i>Measured after patient is sitting or lying down for one minute</i> 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	

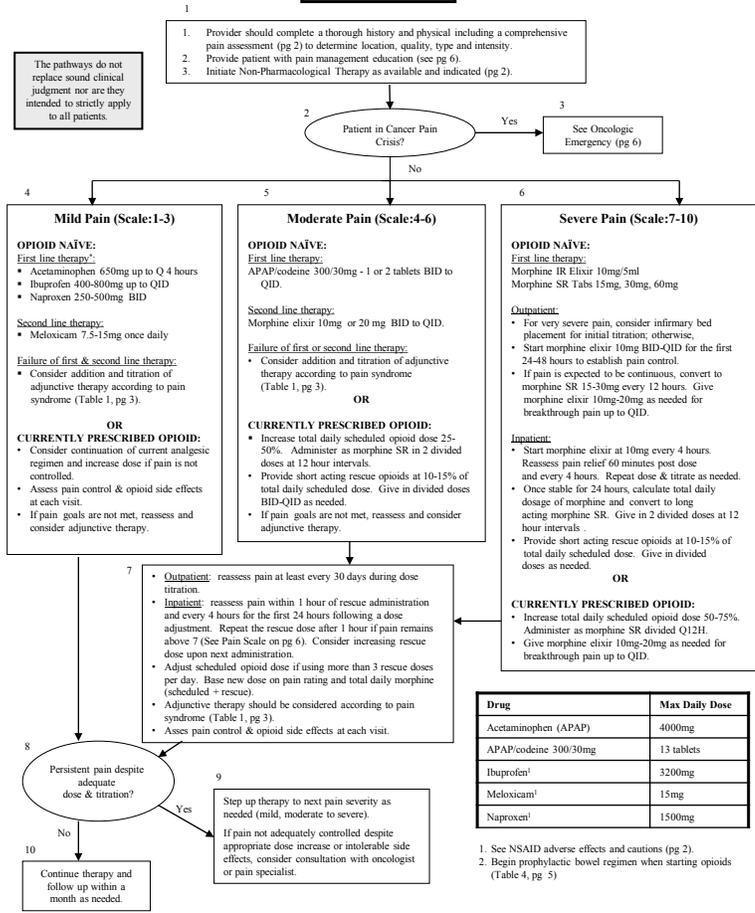
COWS cont.

Signs and Symptoms	Score
Runny nose or tearing: not accounted for by cold symptoms or allergy 0 = none present 1 = nasal stuffiness or unusually moist eyes 2 = nose running or tearing 4 = nose constantly running or tears streaming down cheeks	
GI upset: over last ½ hour 0 = no GI symptoms 1 = stomach cramps 2 = nausea or loose stool 3 = vomiting or diarrhea 5 = multiple episodes of diarrhea or vomiting	
Tremor: observation of outstretched hands 0 = no tremor 1 = tremor can be felt, but not observed 2 = slight tremor observable 4 = gross tremor or muscle twitching	
Yawning: observation during assessment 0 = no yawning 1 = yawning once or twice during assessment 2 = yawning three or more times during assessment 4 = yawning several times/minute	
Anxiety or irritability 0 = none 1 = patient reports increasing irritability or anxiousness 2 = patient obviously irritable or anxious 4 = patient so irritable or anxious that participation in the assessment is difficult	
Gooseflesh skin 0 = skin is smooth 3 = piloerection of skin can be felt or hairs standing up on arms 5 = prominent piloerection	
Total Score	

*COWS adapted from National Institute on Drug Abuse. <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



Drug	Max Daily Dose
Acetaminophen (APAP)	4000mg
APAP/codeine 300/30mg	13 tablets
Ibuprofen ¹	3200mg
Meloxicam ¹	15mg
Naproxen ¹	1500mg

1. See NSAID adverse effects and cautions (pg 2).
 2. Begin prophylactic bowel regimen when starting opioids (Table 4, pg 5)

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 under-treatment of pain
- IV. Management
- A. Treat underlying causes
- B. Non-Pharmacologic Interventions
1. Consider assistive devices for bed, bath, and walking if indicated
 2. Consider physical therapy (PT) if indicated. PT techniques may be useful in teaching patients to control pain, by moving in a safe and structure 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 renally excreted (eg. Meloxicam)
 - c. Adverse effects - Toxicity of some anti-cancer treatment may increase the risk profile of NSAIDS
 - i. Renal - Discontinue NSAID if BUN or creatinine doubles or if hypertension develops or worsens
 - ii. GI – If patient develops gastric upset or nausea, consider discontinuing NSAID, changing agents, or adding protective therapy such as ranitidine or omeprazole. If patient develops ulcer or gastrointestinal hemorrhage, discontinue NSAID.
 - iii. Cardiac - Discontinue NSAID if hypertension develops or worsens
 - d. Monitoring
 - i. Baseline blood pressure, BUN, creatinine, CBC, fecal occult blood
 - ii. Repeat as clinically indicated every 3 months
 - e. Caution – NSAIDS are antipyretics and may mask fever. Use caution in patients on myelosuppressive chemotherapy. NSAIDS may have antiplatelet effects that can increase the risk of bleeding in patients who are thrombocytopenic or on myelosuppressive chemotherapy and likely to become thrombocytopenic. Consider non-NSAIDS such as acetaminophen.
3. Adjunctive therapy
- a. Consider addition of adjunctive therapy according to pain syndrome
 - b. Titrate dose to adequate response or intolerable side effects.

Table 1: Adjunctive Therapy

Pain Descriptor	Cancer Pain Syndrome (Drug Class)	Selected Drugs	Additional Information
Aching, dull, localized tenderness	Bone (NSAIDs)	Ibuprofen 400-800 mg QID	-Max daily dose 3200 mg -May cause GI upset
		Meloxicam 7.5-15 mg QD	-Max daily dose 15 mg -May cause GI upset
		Naproxen 250-500 mg BID	-BID dosing -Max daily dose 1500 mg -May cause GI upset
Deep, boring, referred, poorly localized	Visceral (Corticosteroids) *Also used for spinal cord and nerve compression	Prednisone 10 – 80 mg daily	-May increase blood glucose -May cause GI upset -Increased appetite -May cause CNS symptoms -May cause osteopenia
Burning, tingling	Neuropathic (Tricyclic Antidepressants) *Refer to Neuropathic Pain DMG	Nortriptyline 25– 150 mg divided doses or HS	-Less sedating -Less anti-cholinergic effects -Max daily dose 150 mg
Shooting, lancinating, chronic neuralgias	Neuropathic (Anticonvulsants) *Refer to Neuropathic Pain DMG	Carbamazepine 200–400 mg BID – QID	-Sedating -Max daily dose 1600 mg
		Gabapentin 100mg TID titrate to 300-900 mg TID	-Generally requires doses \geq 1600mg/day -Potential for abuse (sedation & dizziness) -Drug of choice for lancinating pain -Non-formulary medication -Max daily dose 3600 mg -Dosage base on renal function
Colic-cramping abdominal pain, bladder spasms	Smooth muscle spasms (Anticholinergics)	Oxybutynin 5-10 mg TID	-Used for bladder spasms and retention -Max daily dose 30 mg

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 24 hour opioid requirement is stable.
4. Provide rescue doses of short acting opioids for pain not relieved by sustained release opioids including breakthrough pain or acute exacerbations of pain, activity, or position related pain or pain 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 Titrations

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 SR BID (30mg) + 3 x 10mg breakthrough doses = 60mg or new opioid dose of 30mg SR BID. As an alternative to calculating the total daily dose needed use 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:

$$\frac{\text{Equianalgesic dose (route) current opioid}}{24 \text{ hour dose (route) current opioid}} = \frac{\text{Equianalgesic dose (route) new opioid}}{24 \text{ hour dose (route) new opioid}}$$

3. To convert from one opioid to another:
 - a. Total the amount of current opioid (s) taken in a 24 hour period that effectively controls pain.
 - b. Calculate the equianalgesic dose of the new opioid (Table 2)
 - c. If patient was effectively controlled, reduce the dose by 25-50% to allow for incomplete cross tolerance between different opioids. During the first 24 hours, titrate rapidly to analgesic effect. If previous dose was ineffective, may begin with 100% of equianalgesic dose or increase that by 25%.
 - d. Lastly divide the total daily dose of new opioid needed by the number of doses per day to determine the individual dose (e.g., new 24 hour morphine dose of 60mg, may be given as 10mg elixir Q 4 hrs or morphine SR 30mg Q 12 hrs).

Table 2. Equianalgesic Opioid Dose Conversions

Opioid	Oral Dose (mg)	Parenteral (IV/SC) Dose	Conversion Factor IV to PO	Duration of Action (hrs)	Comments
Morphine	30	10	3	IR: 4hrs SR: 12hrs	
Oxycodone	20	NA	NA	IR: 4hrs SR: 12hrs	
Codeine	200	130	1.5	3-4hrs	
Hydrocodone	30-200	NA	NA	3-5hrs	
Methodone	3-20	10	2	4-8hrs	<ul style="list-style-type: none"> • Extremely long half life and should be used with caution to avoid accumulation. • Equianalgesic dosing with methodone is dose-dependent and subject to significant inter-patient variability. It is generally not recommended for pain management and should be used cautiously to avoid overdose.
Hydromorphone	7.5	1.5	5	2-3hrs	
Tramadol	50-100	NA	NA	3-7hrs	<ul style="list-style-type: none"> • Weak opioid agonist. Recommended max dose is 400mg daily to avoid CNS toxicity. • Risk of over dosage or suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs. • Requires dose adjustment in renal & hepatic impairment.

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. PRN morphine may be needed particularly during the first 8-24 hours after converting to the patch
8. Dose adjustments should be based on the average amount of additional (rescue) opioid required over the 72 hour period.

Converting to Fentanyl patch

- * Calculate the total 24 hour morphine dose.
- * Table 3 displays the range of 24-hour 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.

Table 3: Fentanyl Conversion

Oral Morphine (mg/24hours)	Parenteral Morphine (mg/24 hours)	Transdermal Fentanyl Equivalent (mcg/hr)
25-65	8-22	25
65-115	23-37	50
116-150	38-52	75
151-200	53-67	100
201-225	68-82	125
226-300	83-100	150

Table 4: Management of Opioid Side Effects

Adverse Event	Action
Constipation	<ul style="list-style-type: none"> ☐ Anticipate and treat prophylactically. Goal is 1 BM every 1-2 days. ☐ Encourage increased fluids, fiber and physical activity. [calcium polycarbophil / fiber tabs – 2 to 4 tabs BID] ☐ As a preventive measure a bowel regimen should be prescribed with the initial opioid prescription consisting of at least a stool softener and a laxative. (docusate 100mg BID & bisacodyl 10-15mg HS) ☐ For acute treatment of constipation, additional agents may be provided as needed. <ul style="list-style-type: none"> - milk of magnesia 15-60 ml daily or - lactulose 15-30 ml BID or - If no bowel movement in 3 days, consider magnesium citrate or enema - Last line – consider use of prokinetic agent (metoclopramide 10-20mg qid)
Dizziness	<ul style="list-style-type: none"> ☐ Usually resolves as body adjusts to medication. ☐ Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.
Nausea	<ul style="list-style-type: none"> ☐ Take medication with food. ☐ Encourage patient to contact PCP if condition persists more than 1 week or is bothersome.
Respiratory Depression	<ul style="list-style-type: none"> ☐ Infrequent, but requires immediate medical attention. ☐ May occur from drug accumulation as a result of overaggressive titration.
Sedation	<p>Sedation Scale. (Level 3 or higher – consider intervention)</p> <p>4 = Somnolent, minimal or not response to physical stimulation 3 = Frequently drowsy, easily arousable, drifts off to sleep during conversation 2 = Slightly drowsy 1 = Awake and alert</p> <ul style="list-style-type: none"> ☐ Sedation can be reduced or avoided with slow titration. Consider dose reduction with slower titration. ☐ Rule out other causes such as concomitant CNS depressants, CNS pathology, hypercalcemia, dehydration, sepsis, or hypoxia.
Sweating	<ul style="list-style-type: none"> ☐ Relatively uncommon. Consider dose reduction with slower titration.
Vomiting	<ul style="list-style-type: none"> ☐ May resolve as body adjusts to medication. Hold the next dose. Increase fluids as appropriate. Progressive alimantation. ☐ Consider short term use of meclizine, metoclopramide or prochlorperazine.
Itching	<ul style="list-style-type: none"> ☐ Itching is often self limiting but may be dose related. Consider antihistamine. ☐ Rule out allergies (e.g., developmental reaction: hives)
Urinary Hesitation	<ul style="list-style-type: none"> ☐ Go back to previously tolerated dose with gradual titration. ☐ Consider fecal impaction as a potential cause for urinary retention.

Table 5: Mosby Pain Rating Scale

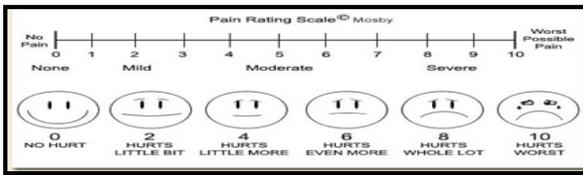


Table 6: Non-Communicative Rating Scale

Verbal/Vocal	Body Movement	Facial	Touching
0 Positive	0 Moves easily	0 Smiling	0 No touching
2-4 Whimper/moans	5 Neutral, shifting, pacing	2-4 Neutral	5 Rubbing, patting
5-7 Repetitive comment, crying	10 Tense, not moving	5-7 Frown, grimace	10 Clenched, tight muscles
8-10 Screaming		8-10 Clenched teeth	

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.

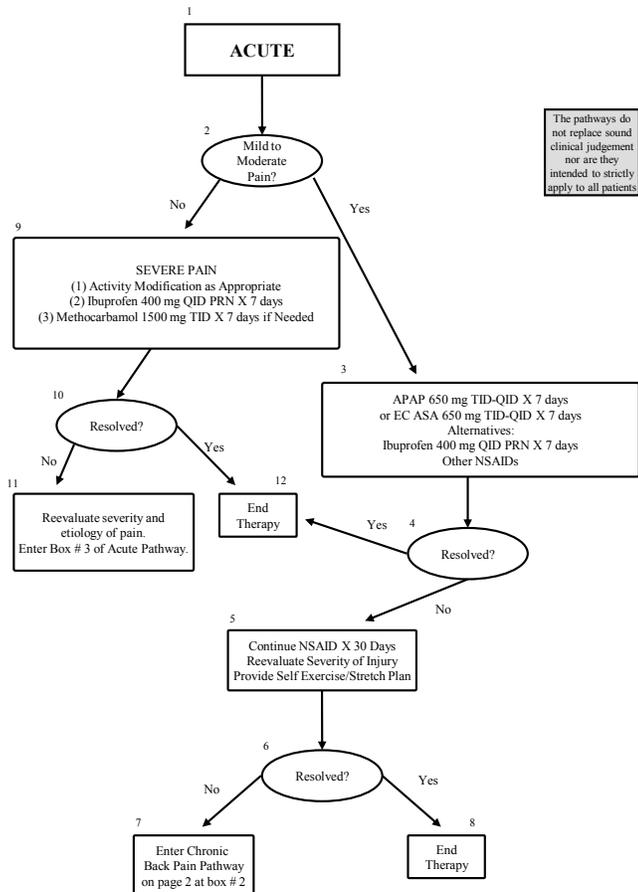
F. Referrals

1. Consider referral or consultation with pain specialist if pain is not controlled despite adequate dose, titration, and use of adjunctive therapies.
2. **Oncologic Emergency** - Severe uncontrolled pain is a medical emergency and should be evaluated & treated promptly (e.g., surgery, steroids, radiotherapy, antibiotics). Potential causes are listed below.
 - a. Metastases – brain, epidural, leptomeningeal
 - b. Infection
 - c. Bone fracture or impending fracture of weight bearing bone
 - d. Obstructed or perforated viscous
3. Consider mental health referral if patient appears to be depressed.

G. Monitoring and Assessment

1. Assess the four A's at each clinic visit.
 - a. Adverse effects
 - b. Adherence to treatment & signs of aberrant drug related behavior
 - c. Activity – functional status, both physical and psychosocial
 - d. Analgesic efficacy – pain, functioning, effectiveness
2. Use pain rating scales to assess intensity of pain (Table 5 and 6)
3. Prior to changing therapy
 - a. Compare pain assessment scores for changes
 - b. Ensure analgesics are given as prescribed
 - c. Evaluate need for adjunctive 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.

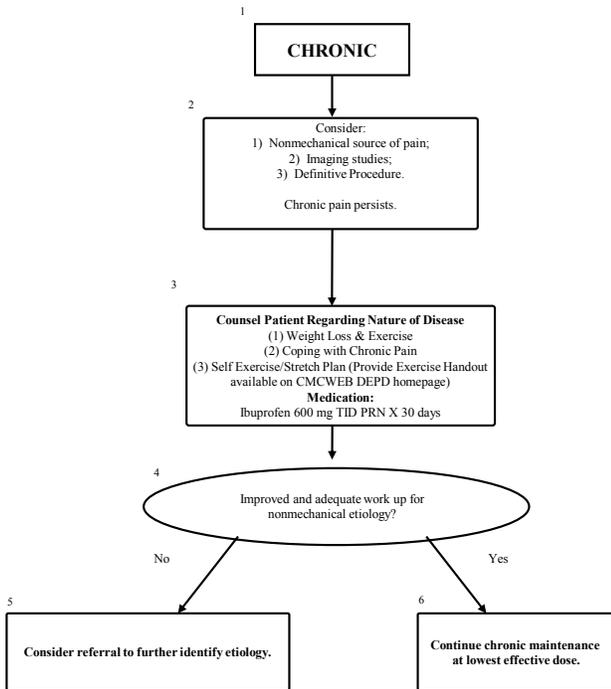
PAIN, BACK



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 September 1995.
Reviewed 3/05, 1/08; Revised 8/98, 4/02, 4/03, 5/11; 11/14.

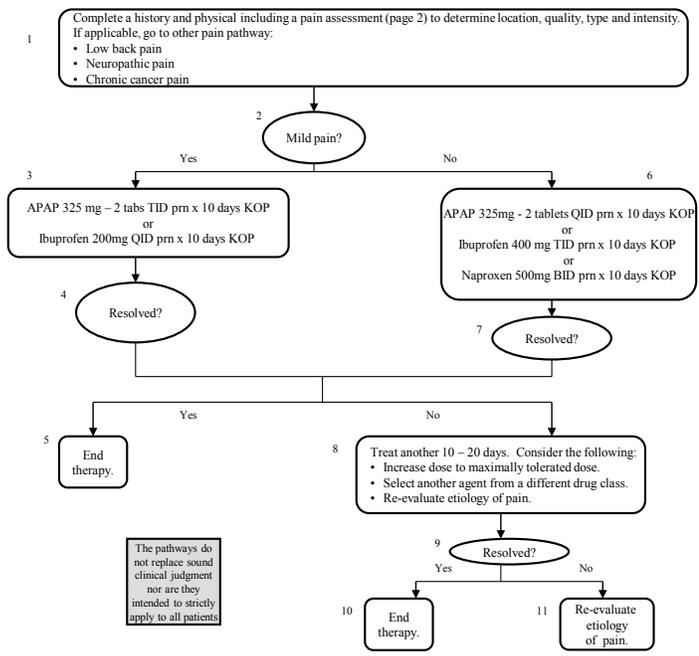
PAIN, BACK Page #2



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.

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Reviewed 3/05, 1/08; Revised 8/98, 4/02, 4/03, 5/11; 11/14.

TREATMENT OF MILD TO MODERATE PAIN



Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996.
Revised 8/98, 12/98, 9/10, 1/13. Reviewed 3/01, 4/03, 1/07.

- 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 /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. 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

Formulary Medications	Usual Directions †	Max Daily Dose	Drug Class
Acetaminophen (APAP) 325mg *	1-2 tablets 2-4 times daily	4,000mg/day	
Ibuprofen 200mg *	1 tablet 2-4 times daily	3,200mg/day	NSAID – propionic acid
Ibuprofen 400mg	1 tablet 2-4 times daily	3,200mg/day	NSAID – propionic acid
Ibuprofen 600mg	1 tablet 2-4 times daily	3,200mg/day	NSAID – propionic acid
Ibuprofen 800mg	1 tablet 2-4 times daily	3,200mg/day	NSAID – propionic acid
Naproxen 250mg	1 tablet 2-3 times daily	1,500mg/day	NSAID – propionic acid
Naproxen 500mg	1 tablet 2 times daily	1,500mg/day	NSAID – propionic acid
Meloxicam 7.5mg	1-2 tablets once daily	15mg/day	NSAID - oxicam

*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

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

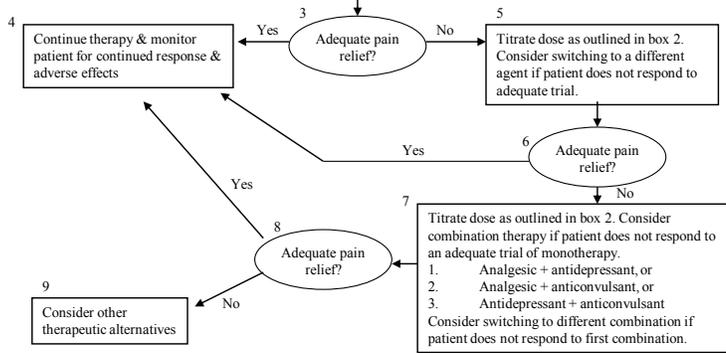
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Initial treatment:

1. Provide patient education
2. Pharmacologic Treatment – Monotherapy preferred

Drug	Class	Initial Dose	Titration	Target Dose
Acetaminophen	Analgesic	325mg tid prn	325mg q week	Max dose=4g/day
Ibuprofen	Analgesic	200mg bid-tid prn	200mg q week	Max dose=3.2g/day
Naproxen	Analgesic	250mg bid prn	250mg q week	500mg bid
Nortriptyline	Antidepressant	25mg q hs	25mg q month	75-150mg/day
Carbamazepine*	Anticonvulsant	200mg qd	200mg q month	1000-1600mg/day
Divalproex Sodium	Anticonvulsant	250 mg qd	250mg q month	500-1250 mg/day
Phenytoin	Anticonvulsant	100mg qd	100mg q month	300-500mg/day
Pyridoxine**	Other	50mg qd	-	Max dose=100mg/day

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



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

- 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=ddl, 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
 2. History of present illness (C.O.L.D.E.R.)
 - 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

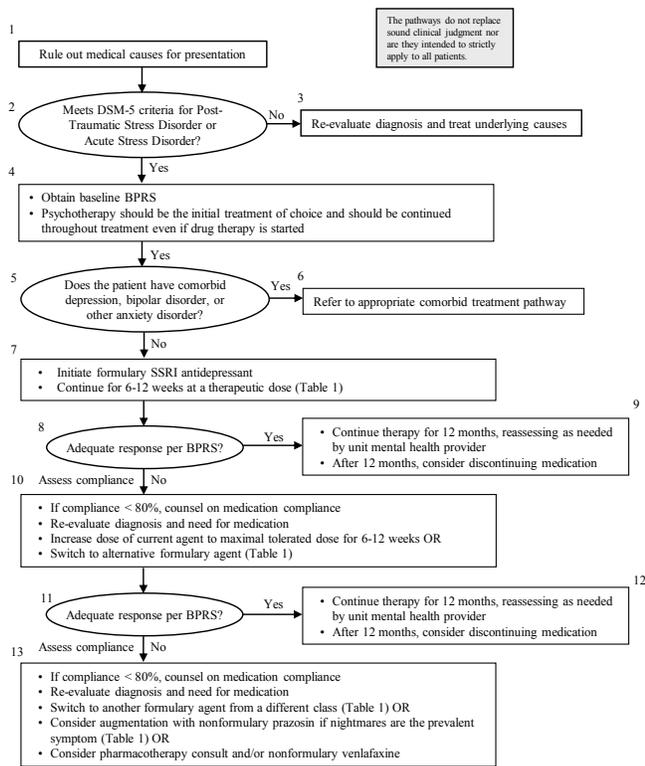
Small Fiber Neuropathy	Large Fiber Neuropathy
Normal muscle-stretch reflexes	Reduced or absent muscle-stretch reflexes
Normal muscle strength	Normal or slightly reduced muscle strength
Normal proprioception & vibration sensation	Reduced proprioception & vibration sensation
Reduced distal pinprick sensation	Reduced pinprick & touch sensation

*adapted from Mendell JR, et al. NEJM 2003;348:1243-1255.

- 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. If so, patients must undergo genetic testing for the mutation before being prescribed carbamazepine. Providers must obtain approval from their Regional or District Medical Director prior to ordering the test.
 - c. The risks versus benefits of carbamazepine therapy should be weighed in patients that test positive and discussed with the Regional or District Medical Director prior to initiating therapy.
 - d. Carbamazepine therapy may be continued in intake Asian patients or Asian patients already taking the medication for ≥ 3 months if they have not experienced adverse effects.
 - C. Patient Education
 - 1. Pathophysiology
 - 2. Treatment goals
 - 3. Treatment expectations
 - 4. Treatment plan
 - D. Consider specialty referral for patients that do not respond to an adequate trial of pharmacologic therapy or that might require additional diagnostic evaluation

POST TRAUMATIC STRESS DISORDER and ACUTE STRESS DISORDER



*Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved May 2002, revised 2/03, 9/05, 7/08, 5/11, 3/14.*

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

Drug Class	Generic Name	Brand Name	Initial Dose (Dose Range) mg/day	Therapeutic Range ng/mL	Monitoring
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram 20mg, 40mg tablet	Celexa®	20 (20 – 40)	N/A	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present If QTc is > 450msec for males or > 470msec for females, do not initiate citalopram. If pt is on citalopram and QTc is > 500msec, consider alternative treatment.
	Fluoxetine 20mg capsule	Prozac®	20 (20 – 60)		
	Sertraline 50mg, 100mg tablet	Zoloft®	50 (50 – 200)		
Tricyclic Antidepressant* (TCA)	Nortriptyline 25mg, 50mg, 75mg capsule	Pamelor®	25 – 50 (75 – 150)	50 - 150	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Liver function test at baseline Nortriptyline dose > 100 mg/day – EKG at baseline and as clinically indicated, and blood level within 2 weeks, then as clinically indicated
Other†	Prazosin 1mg capsule	Minipres®	Initial dose 1mg HS, titrate gradually up to 15mg HS based upon response	N/A	<ul style="list-style-type: none"> Monitor supine, standing, and sitting BP, orthostatic hypotension When discontinuing, taper over 1 week or more

*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 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 _____

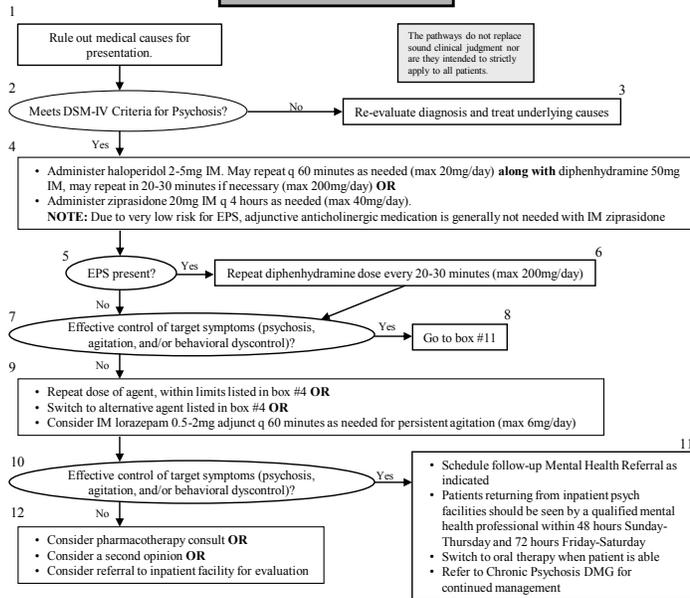
Enter the score for the term that best describes the patient's condition.

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.
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- ___ 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.

ACUTE PSYCHOSIS



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.

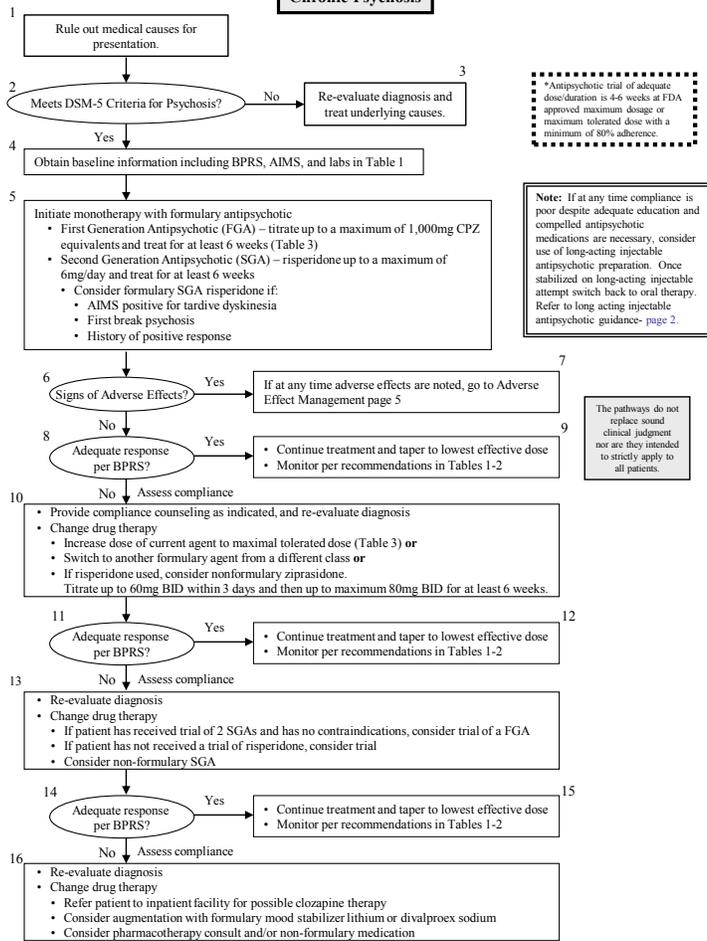
- Mental Status: Alert and oriented, motor activity, speech, excess sedation
- Extrapyramidal Symptoms (EPS): Dystonia, parkinsonism, akathisia, tremor, dyskinesia
- Behavior: Psychosis (ie. hallucinations, delusions, disorganized speech/behavior), assaultive, agitated
- Neuroleptic Malignant Syndrome (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 ER
- 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

Chronic Psychosis



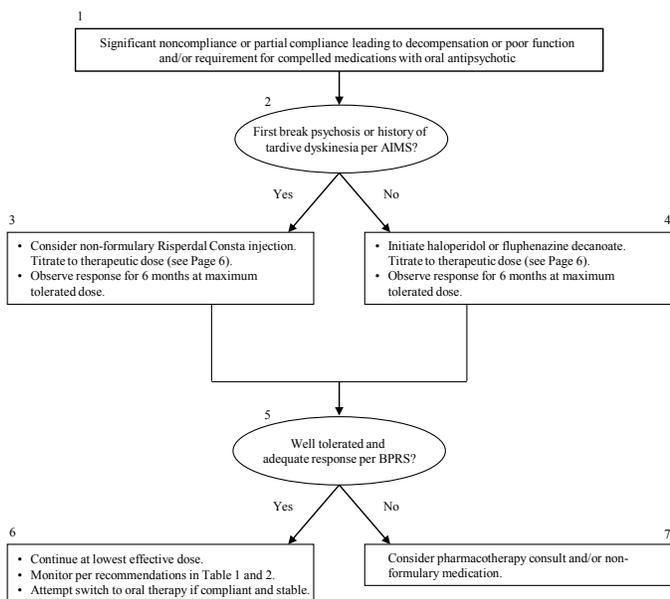
*Antipsychotic trial of adequate dose/duration is 4-6 weeks at FDA approved maximum dosage or maximum tolerated dose with a minimum of 80% adherence.

Note: If at any time compliance is poor despite adequate education and compelled antipsychotic medications are necessary, consider use of long-acting injectable antipsychotic preparation. Once stabilized on long-acting injectable attempt switch back to oral therapy. Refer to long acting injectable antipsychotic guidance- page 2.

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, 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



Antipsychotic Monitoring Parameters

Table 1: Metabolic and Endocrine Monitoring Guidelines

Parameter	Baseline	Q 6 Months	Annually
Weight, Height, BMI	X	X	
Blood Pressure, Pulse	X	X	
Fasting Plasma Glucose	X	X	
Fasting Lipid Profile	X		X
Complete Metabolic Panel	X		X
TSH	X	As clinically indicated	
EKG ¹	As clinically indicated		
Prolactin ²	As clinically indicated		

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

Additional Monitoring Parameters for Specific Agents

- Ziprasidone (Geodon®) - 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

Assessment	Baseline	Follow-up
AIMS (Abnormal Involuntary Movement Scale) •Acute EPS - Akathisia •Tardive Dyskinesia	X	Baseline and at least every 6 months
Mental Status Exam	X	Baseline and at least every 6 months
BPRS (Brief Psychiatric Rating Scale)	X	Baseline and at least every 6 months Medication is started, changed or discontinued

Table 3: Antipsychotic Dosages and Adverse Effects

Agent	Formulary Status	Potency	Traditional Equivalents (approx.mg)	Dose Range (mg/day)	Adverse Effects				
					Weight Gain	EPS	Sedation	Anticholinergic	Orthostasis
Conventionals									
Chlorpromazine (Thorazine®)	F	Low	100	300-800	+++	++	+++	+++	+++
Fluphenazine (Prolixin®)	F	High	2	1-40	?	++++	++	++	++
Haloperidol (Haldol®)	F	High	2	1-100	++	++++	+	+	+
Perphenazine (Trilafon®)	F	Mid	8	12-64	?	+++	++	++	++
Thioridazine* (Mellaril®)	NF	Low	100	20-800	?	+	+++	++++	+++
Thiothixene (Navane®)	F	High	4	6-60	?	+++	++	++	++
Trifluoperazine (Stelazine®)	F	High	5	2-40	?	+++	++	++	++
Atypicals									
		5HT₂/D₂							
Aripiprazole (Abilify®)	NF	++++/++++#	7.5	10 – 30	+/0	0/+	+	+/0	+/0
Asenapine (Saphris®)	NF	?	?	5-20	++	+	++	+	+
Clozapine (Clozaril®)	NF	+++/+	50	75 – 900	++++	0	+++	++++	++++
Iloperidone (Fanapt®)	NF	++++/++++	?	12-24	+	+	++	+	++
Lurasidone (Latuda®)	NF	?	?	40-80	+	+	++	+/0	+/0
Olanzapine (Zyprexa®)	NF	+++//++	5	5 – 20	+++	0/+	++	++	+
Paliperidone (Invega®)	NF	++++/++++	3	3 – 12	+	0/+++	++	+	++
Quetiapine (Seroquel®)	NF	+/+	125	300 – 800	++	0/+	+/+++	++	+
Risperidone (Risperdal®)	F	++++/++++	2	0.5-6	+	0/+++	++	+	++
Ziprasidone (Geodon®)	NF	++++/++++	60	120-160	+/0	++	++	+	++

*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

Side Effect	Recommended Management Strategies
EPS	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Diagnosis supported by AIMS? • Switch to a SGA • Consider pharmacotherapy consult for treatment options
Neuroleptic Malignant Syndrome	<ul style="list-style-type: none"> • 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.

Quick Reference Guide for Initiating Long-Acting Injectable Antipsychotics

Haloperidol Decanoate (Haldol-D®)

General information

- Formulary strength available: 100mg/ml solution for injection
- The first dose should be no more than 100mg
 - If > 100mg is needed, administer the remainder 3-7 days later
 - All future injections can be administered in doses up to 300mg at a time
- Inject in the gluteal muscle by z-track administration
- Dosing interval: 4 weeks
- Maximum approved dose = 450mg q4weeks

Loading dose method (preferred)

- Month 1: Initiate haloperidol decanoate at 20 times the oral haloperidol dose
 - Discontinue oral haloperidol at time of first injection
- Month 2: Haloperidol decanoate 15 times the oral haloperidol dose
- Month 3 and thereafter: Haloperidol decanoate 10 times the oral haloperidol dose

Traditional dosing method

- Initiate haloperidol decanoate at 10-15 times the oral haloperidol dose
- Continue oral haloperidol for 1 month, then discontinue

Fluphenazine Decanoate (Prolixin D®)

General information

- Formulary strength available: 25mg/ml solution for injection
- Inject in the gluteal muscle by z-track administration
- Dosing interval: 2-3weeks
- Maximum approved dose = 100mg q2weeks
- Accumulation may occur over time; consider dose reduction after 6 months of treatment

Dosing method

- Initiate fluphenazine decanoate at 1.2-1.6 times the oral fluphenazine dose
 - Round to the nearest 12.5mg
- Continue oral fluphenazine for 1-4 weeks, then discontinue

Risperdal Consta®

General information

- Requires nonformulary approval
- Oral test dose is required if the patient has no documented history of risperidone use
 - Administer 1-2mg oral risperidone for 2 days prior to injection
- Inject in the deltoid or gluteal muscle
- Dosing interval: 2 weeks
- Maximum approved dose = 50mg q2weeks

Dosing method

- Initiate Risperdal Consta 25mg q2weeks
- Continue oral antipsychotic for 3 weeks, then discontinue
- Adjust dose no sooner than q4weeks, as needed

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

Date of Evaluation										
1	Muscles of facial expression e.g. movements of forehead, eyebrows, preorbital area, cheeks, include frowning, blinding, smiling, grimacing									
2	Lips and perioral area e.g. puckering, pouting, 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:**

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Facility _____ Practitioner _____

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- ___ 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.

**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

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

Table 1: Antidepressants

DRUG	FORMULARY AGENT	USUAL DOSE (MG/DAY)	APPROXIMATE EQUIVALENT DOSE (MG) †
Tricyclic Antidepressants (TCAs)			
Amitriptyline (Elavil®)	N	100-300	100
Amoxapine (Asendin®)	N	100-400	100
Clomipramine (Anafranil®)	N	100-250	100
Desipramine (Norpramin®)	N	100-300	100
Doxepin (Sinequan®)	N	100-300	100
Imipramine (Tofranil®)	Y (TJJD only)	100-300	100
Maprotiline (Ludiomil®)	N	100-225	100
Nortriptyline (Pamelor®)	Y	50-150	50
Protriptyline (Vivactil®)	N	15-60	20
Trimipramine (Surmontil®)	N	100-300	100
Selective Serotonin Reuptake Inhibitors (SSRIs)			
Citalopram (Celexa®)	Y	20-40	20
Escitalopram (Lexapro®)	N	10-20	10
Fluoxetine (Prozac®)	Y	20-80	20
Fluvoxamine (Luvox®)	N	100-300	100
Paroxetine (Paxil®)	N	20-50 CR = 25-75	20 CR = 25
Sertraline (Zoloft®)	Y	50-200	50
Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)			
Venlafaxine (Effexor®)	Y (TJJD only)	75-375 XR = 37.5-225	150 XR = 75
Duloxetine (Cymbalta®)	N	40-60	30
Milnacipran (Savella®)*	N	100-200	N/A
Levomilnacipran (Fetzima®)	N	40-120	N/A
Desvenlafaxine (Pristiq®, Khedezla®)	N	50	N/A

DRUG	FORMULARY AGENT	USUAL DOSE (MG/DAY)	APPROXIMATE EQUIVALENT DOSE (MG) †
Monoamine Oxidase Inhibitors (MAOIs)			
<i>(the following are inexact estimates for approximate equivalent dosing)</i>			
Isocarboxazid (Marplan®)	N	10-30	10
Phenelzine (Nardil®)	N	15-90	15
Tranlycypromine (Parnate®)	N	10-60	10
Selegiline (Emsam®)	N	6-12 (transdermal)	6
Other			
<i>(the following are inexact estimates for approximate equivalent dosing)</i>			
Bupropion (Wellbutrin®)	N	300-450 SR = 150-400 XL = 150-450	150 SR = 150 XL = 150
Mirtazapine (Remeron®)	N	15-45	15
Trazodone (Desyrel®)	Y	150-600	50
Nefazodone (Serzone®)	N	300-600	100
Vilazodone (Viibryd®)*	N	20-40	N/A
Vortioxetine (Brintellix®)*	N	5-20	N/A

†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

FROM (DRUG #1)	TO (DRUG #2)	STRATEGY
TCA or Others	TCA	Discontinue Drug #1 by taper while initiating the new TCA <i>OR</i> Discontinue Drug #1 by taper and then initiate therapy with the new TCA <i>OR</i> Discontinue Drug #1 and start Drug #2 the next day
TCA or Others	SSRI	Discontinue Drug #1 by taper over 3 days while initiating the SSRI <i>OR</i> Discontinue Drug #1 by taper over 3 days and then initiate therapy with the SSRI
TCA or Others	Others	Discontinue Drug #1 and start Drug #2 the next day <i>OR</i> Discontinue Drug #1 by taper and start Drug #2 gradually

FROM (Drug #1)	TO (Drug #2)	STRATEGY
TCA	MAOI	Discontinue the TCA by taper (doses >100mg/day). After a 2-week washout, start MAOI
TCA or Others	Others	Discontinue Drug #1 and start Drug #2 the next day <i>OR</i> Discontinue Drug #1 by taper and start Drug #2 gradually
TCA	MAOI	Discontinue the TCA by taper (doses >100mg/day). After a 2-week washout, start MAOI
SSRI (with the exception of fluoxetine)	SSRI	Discontinue the SSRI and start the new SSRI the next day <i>OR</i> 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 <i>OR</i> 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 or Other	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: Antipsychotics

DRUG	FORMULARY AGENT	USUAL DOSE (MG/DAY)	APPROXIMATE EQUIVALENT DOSE (MG)
High-Potency First Generation Agents			
Pimozide (Orap®)	N	1-10	2
Fluphenazine (Prolixin®)	Y	0.5-20	2
Haloperidol (Haldol®)	Y	0.5-20	2
Mid-Potency First Generation Agents			
Loxapine (Loxitane®)	N	25-250	10
Perphenazine (Trilafon®)	Y	16-64	10
Thiothixene (Navane®)	Y	5-40	4
Trifluoperazine (Stelazine®)	Y	2-40	5
Low-Potency First Generation Agents			
Chlorpromazine (Thorazine®)	Y	200-1000	100
Thioridazine (Mellaril®)	N	200-800	100
Second Generation Agents			
Aripiprazole (Abilify®)	N	10-30	7.5
Clozapine (Clozaril®)	N	75-900	50
Olanzapine (Zyprexa®)	N	5-20	5
Quetiapine (Seroquel®)	N	50-800	75
Risperidone (Risperdal®)	Y	0.5-6	2
Ziprasidone (Geodon®)	N	40-160	60
Paliperidone (Invega®)	N	3-12	4
Asenapine (Saphris®)*	N	10-20	N/A
Iloperidone (Fanapt®)*	N	12-24	N/A
Lurasidone (Latuda®)*	N	40-80	N/A

*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.^{13,18-22} 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

STRATEGY	ADVANTAGE	DISADVANTAGE	RECOMMENDED FOR:
Abrupt Switching	Low risk of drug interactions	Withdrawal reactions	Patients with serious adverse event(s)
Gradual Switching	Low risk of withdrawal reactions, few drug interactions	Danger of symptom exacerbation	Patients with low risk of relapse
Cross-tapering	Safest to prevent relapse	Drug interactions complicated	Recently stabilized patients

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

FROM (DRUG #1)	TO (DRUG #2)	STRATEGY
Typical agent, Risperidone, or Olanzapine	Ziprasidone*	<ul style="list-style-type: none"> • Ziprasidone 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily • Abrupt discontinuation: Drug #1 discontinued the day before starting ziprasidone <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> • Ziprasidone 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily • Immediate dose reduction with cross-taper: Dose of Drug #1 reduced 50% for first week and then Drug #1 discontinued <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> • Ziprasidone 40mg bid x 2 days followed by doses ranging up to 160mg/day divided twice daily • 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
Typical agent	Olanzapine	<ul style="list-style-type: none"> • Olanzapine 10mg daily (<i>starting dose</i>) • Abrupt discontinuation: Drug #1 discontinued the day before starting olanzapine <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> • Olanzapine 10mg daily (<i>starting dose</i>) • Dose reduction with overlap: Dose of Drug #1 given in decreasing doses for 2 weeks then discontinued

FROM (Drug #1)	TO (Drug #2)	STRATEGY
Typical or atypical agent	Aripiprazole	<ul style="list-style-type: none"> Aripiprazole 15mg daily (<i>starting dose</i>) Abrupt discontinuation: Drug #1 discontinued the day before starting aripiprazole <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> Aripiprazole 15mg daily (<i>starting dose</i>) Dose reduction with overlap: Dose of Drug #1 reduced by 50% for the first week, reduced another 50% during week 2, and then discontinued <p style="text-align: center;"><i>OR</i></p> <ul style="list-style-type: none"> 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

DRUG	FORMULARY AGENT	USUAL DOSE (MG)	USUAL DOSING INTERVAL	MAXIMUM DOSE
Haloperidol decanoate (Haldol-D®)	Y	50-200	Q 4wks	450mg Q 4 wks
Fluphenazine decanoate (Prolixin-D®)	Y	25-50	Q 2-3wks	100mg Q 2wks
Risperidone long acting (Risperdal Consta®)	N	25-50	Q 2wks	50mg Q 2wks
Paliperidone long acting (Invega Sustenna®)	N	78-234	Q 4wks	234mg Q 4wks
Aripiprazole long acting (Abilify Maintena®)	N	300-400	Q 4wks	400 Q 4wks

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.

AGENTS USED IN THE TREATMENT OF BIPOLAR DISORDER

Table 7: Agents Used to Treat Bipolar Disorder

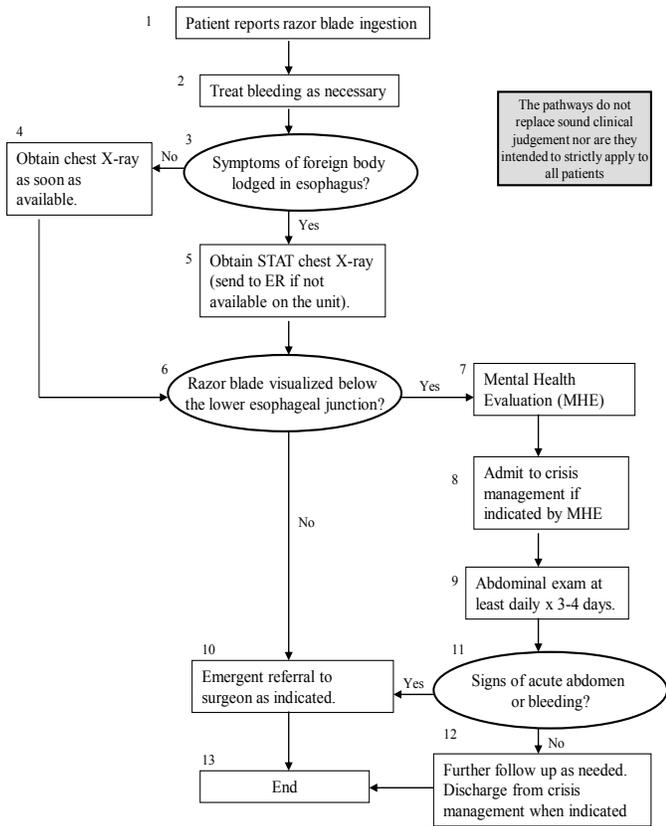
DRUG	FORMULARY AGENT	USUAL DOSE (MG/DAY)	TARGET DRUG CONCENTRATION
Lithium	Y	900-2400	0.6 – 1.2 mmol/L
Olanzapine and Fluoxetine (Symbyax®)	N	6/25-18/75	N/A
Anticonvulsant Agents			
Oxcarbazepine (Trileptal®)	N	1200-2400	N/A
Carbamazepine (Tegretol®)	Y	400-1600	4-12 mcg/mL
Lamotrigine (Lamictal®)	N	100-400	N/A
Valproic Acid (Depakene®)	N	1000-2800 (20 mg/kg/d)	50-125 mcg/mL
Divalproex Sodium (Depakote®)	Y	1000-2800 (20 mg/kg/d) (ER = 25 mg/kg/d)	50-125 mcg/mL
Second Generation Antipsychotics			
Olanzapine (Zyprexa®)	N	5-20	N/A
Quetiapine (Seroquel®)	N	400-800	N/A
Risperidone (Risperdal®)	Y	1-6	N/A
Ziprasidone (Geodon®)	N	80-160	N/A
Aripiprazole (Abilify®)	N	10-30	N/A
Asenapine (Saphris®)	N	10-20	N/A
Lurasidone (Latuda®)	N	40-80	N/A

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.

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved July 2006. Revised 1/10, 9/11, 7/12, 1/15.

Management of Razor Blade Ingestion



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 7/2006. Reviewed 3/09, 3/12.

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.

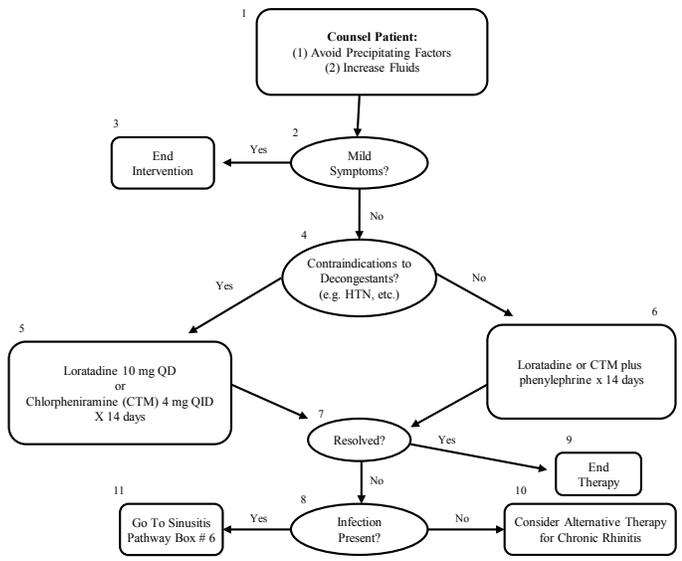
When an offender gives a history of razor blade ingestion, treat clinically significant bleeding if present. A chest x-ray should be obtained and should be adequate to visualize the entire esophagus. This may require 2 films.

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.

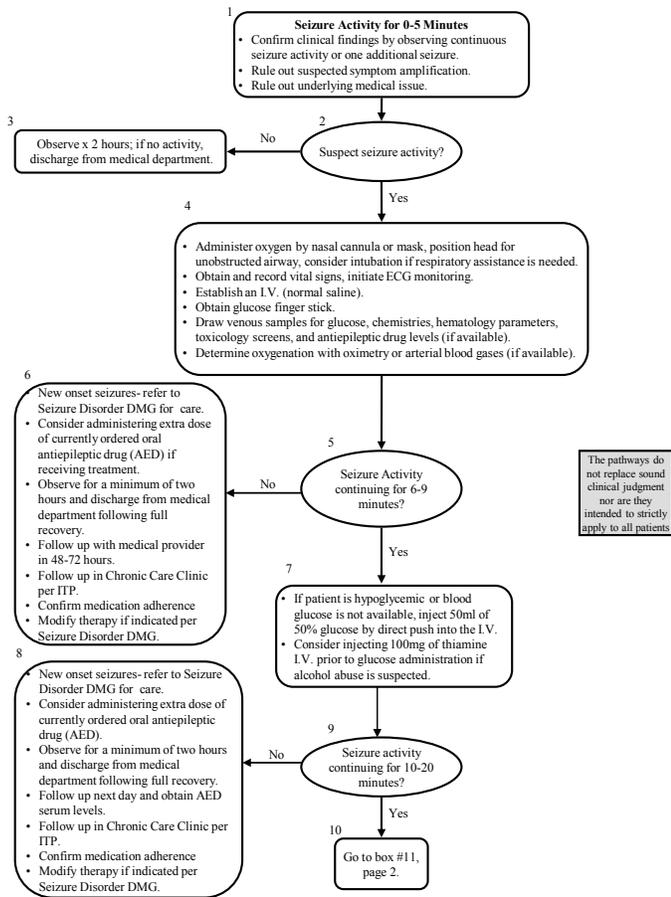
RHINITIS



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, September 1996;
Reviewed 5/11, 11/14; Revised 8/98, 12/98, 3/01, 4/03, 3/07, 5/07, 1/10.

Acute Seizures



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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.

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Seizure activity continuing for 30 minutes?

No

Yes

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- New onset seizures- refer to Seizure Disorder DMG for care.
- Confirm medication adherence and reinforce education if receiving AED therapy.
- Consider administering extra dose of currently ordered oral antiepileptic drug (AED) before discharging the patient.
- Observe for a minimum of two hours and discharge from medical department following full recovery.
- 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.

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

Transfer to the nearest Emergency room
Follow current unit protocol.

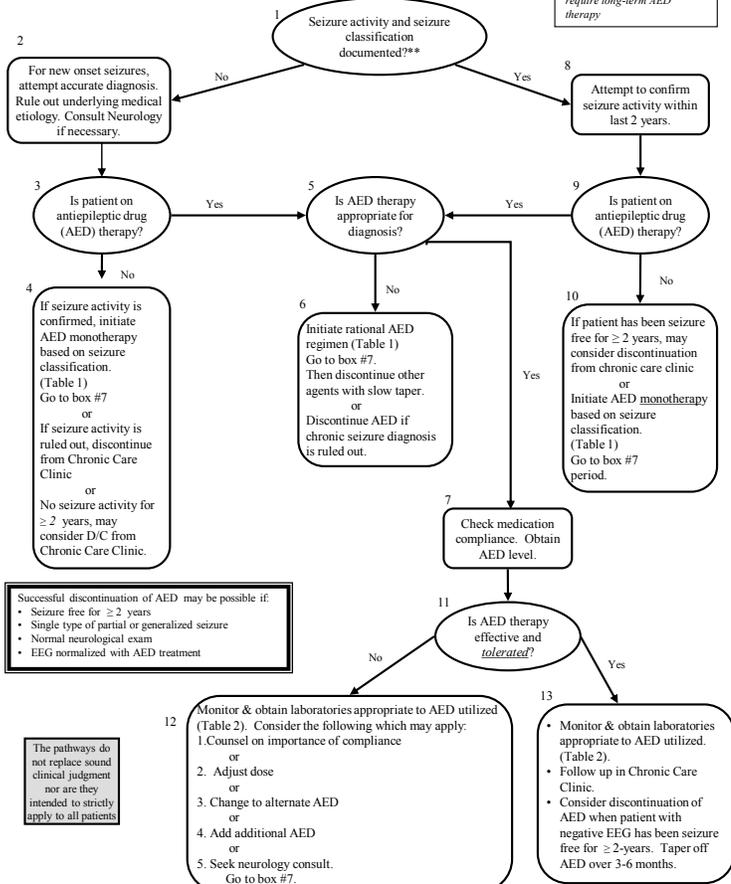
Follow up with the patient within 1 week upon return from the emergency room or hospital.

- 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.

Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, March 1998, Reviewed 3/01, 4/03, 1/07, 1/13. Revised 7/07, 10/08, 9/10.

Seizure Disorder

** One seizure event is not necessarily diagnostic for a seizure disorder and may not require long-term AED therapy



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

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, March 1998, Reviewed 3/01, 4/03. Revised 11/05, 3/07, 3/08, 10/08, 9/10, 1/13.

Table 1: Most Commonly Used Drugs for Specific Seizure Disorders

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				
Simple Partial	Complex Partial	Generalized Tonic-Clonic	Absence	Preferred with Clinical Evidence of Cirrhosis
Carbamazepine Phenytoin Primidone Divalproex Sodium	Carbamazepine Levetiracetam Phenytoin Primidone Divalproex Sodium	Carbamazepine Levetiracetam Phenytoin Primidone Divalproex Sodium	Divalproex Sodium Ethosuximide	Levetiracetam
Non-Formulary Medications				
Simple Partial	Complex Partial	Generalized Tonic-Clonic	Absence	Preferred with Clinical Evidence of Cirrhosis
Gabapentin Lamotrigine Oxcarbazepine Phenobarbital Tiagabine Topiramate Zonisamide	Gabapentin Lamotrigine Oxcarbazepine Phenobarbital Tiagabine Topiramate Zonisamide	Gabapentin Lamotrigine Oxcarbazepine Phenobarbital Topiramate Zonisamide	Clonazepam Lamotrigine Topiramate Zonisamide	Gabapentin

Table 2: Monitoring Parameters for Commonly Prescribed Formulary Anticonvulsants

Carbamazepine						
Parameter	Baseline	1 week	2 week	Q 2 week for 2 months	1 month	Annually
CBC with platelets	X			X		X or as clinically indicated
Complete Metabolic Panel	X				X	X or as clinically indicated
EKG	X (>40 years old or as clinically indicated)					
Blood levels		X	X		X	X or as clinically indicated

Phenytoin					
Parameter	Baseline	1 week	1 month	Annually	
CBC with platelets	X				as clinically indicated
Complete Metabolic Panel	X				X or as clinically indicated
EKG	X (>40 years old or as clinically indicated)				
Blood levels		X	X		X or as clinically indicated

Divalproex Sodium						
Parameter	Baseline	1 week	2 week	Q 2 week for 2 months	1 month	Annually
CBC with platelets	X			X		X or as clinically indicated
Complete Metabolic Panel	X				X	X or as clinically indicated
PT/PTT, INR	X					X
Blood levels		X	X			X or as clinically indicated

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.

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 somatosensory 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 psychotic episodes
 - Patients with complex partial seizures are generally amnesic 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, Phenobarbital, 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 and clonic phase
 - 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)**- Phenobarbital, Topiramate, Gabapentin, Lamotrigine, Oxcarbazepine
 - 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 slumping to the ground
 - These patients often wear protective head-ware to prevent trauma
 - **Drugs of Choice (formulary)**- Divalproex Sodium, Levetiracetam, Primidone
 - **Other options (nonformulary)**- Topiramate, Phenobarbital, Oxcarbazepine
 - Juvenile Myoclonic Epilepsy (JME) - Myoclonic seizures precede generalized tonic-clonic seizure; generally occur upon awakening; sleep deprivation and alcohol commonly precipitate; lifelong treatment required. **Drug of Choice (formulary)**—Divalproex Sodium; **Other options (nonformulary)**- Lamotrigine
 - Infantile Spasms - Begins in the 1st 6 months of life; occur in clusters, several times a day; parents describe symptoms that sound like colic; 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 3: Antiepileptic Drug Selection

Generic Name	Trade Name	Mechanism of Action	Usual Adult Dose	FDA Approved Indications
Carbamazepine	Tegretol®	Inhibits voltage-dependent Na channels	800-1200 mg divided tid-qid	Complex partial seizures, generalized tonic-clonic, mixed seizure patterns
Ethosuximide	Zarontin®	Inhibits NADPH-linked aldehyde reductase	20-40 mg/kg/day divided bid	Absence
Phenobarbital (nonformulary)	Luminal®	Enhances GABA	50-100 mg bid-tid	Adjunctive therapy for generalized tonic-clonic and partial seizures
Phenytoin	Dilantin®	Inhibits voltage-dependent Na channels	300 mg/day or 5-6mg/kg/day in 3 divided doses (range 200-1200mg/day)	Generalized tonic-clonic, complex partial seizures, prevention of seizures following head trauma/neurosurgery
Primidone	Mysoline®	Enhances GABA	750-1500 mg/day in divided doses tid-qid	Monotherapy or adjunctive use for generalized tonic-clonic, psychomotor, and focal seizures
Divalproex Sodium	Depakote®	Enhances GABA; may also block Na ion channels	1000-2500mg/day divided bid-qid (15-60mg/kg/day)	Monotherapy and adjunctive therapy for complex partial seizures; monotherapy for absence seizures; adjunctive therapy for mixed seizure types that include absence seizures
Gabapentin (nonformulary)	Neurontin®	Unclear, but differs from other available anticonvulsants	900-1800 mg/day divided tid	Adjunctive therapy for partial seizures with and without secondary generalized seizures
Lamotrigine (nonformulary)	Lamictal®	Inhibits voltage-dependent Na channels and glutamate	100-500mg/day in 1-2 divided doses	Adjunctive therapy for partial seizures and generalized seizures of Lennox-Gastaut syndrome, generalized tonic clonic seizures
Lacosamide (nonformulary)	Vimpat®	Enhances slow activation of voltage-gated Na ⁺ channels	200-400mg/day	Partial seizures
Levetiracetam	Keppra®	Unknown	1000-3000 mg/day divided bid	Adjunctive therapy for partial and generalized tonic clonic seizures; adjunctive therapy for juvenile myoclonic epilepsy
Oxcarbazepine (nonformulary)	Trileptal®	Inhibits voltage-dependent Na channels	600mg bid	Monotherapy or adjunctive therapy for partial seizures
Parampanel (nonformulary)	Fycompa®	Selective, noncompetitive AMPA receptor antagonist	4-12mg/day	Adjunct therapy of partial seizures with or without secondary generalized seizures
Pregabalin C-V (nonformulary)	Lyrica ®	binds with the alpha2- delta site – an aspect of voltage gated calcium channels	75mg bid up to 600mg/day divided as BID	Adjunctive therapy for partial seizures in adults
Tiagabine (nonformulary)	Gabitril®	Inhibits reuptake of GABA into presynaptic nerve terminals	4-56 mg/day divided bid-qid	Adjunctive therapy for partial seizures
Topiramate (nonformulary)	Topamax®	GABA agonist and non-NMDA glutamate receptor antagonist	200-400 mg/day	Adjunctive or mono therapy for partial seizures and generalized tonic-clonic seizures; treatment of seizures associated with Lennox-Gastaut syndrome
Vigabatrin (nonformulary)	Sabril ®	increases the levels of GABA, by inhibiting GABA transaminase	500-1500mg/day (adults)	Infantile spasms; adult complex partial seizures unresponsive to safer alternatives
Zonisamide (nonformulary)	Zonegran®	Inhibits voltage-dependent Na channels & voltage-dependent Ca currents; binds to GABA receptors and facilitates dopamine and serotonin neurotransmission	100-400 mg/day qd or divided bid	Adjunctive therapy for partial seizures

Principles of Treatment with Confirmed Seizure Disorder

1. Monotherapy—**always** preferred
2. Polytherapy (2 agents)—assess patient compliance prior to addition of second agent. Noncompliance may be the single most common reason for treatment failure. If indicated, add an AED with a different mechanism of action provided doses of the first anticonvulsant have been maximized. If possible, begin to slowly (generally over several weeks) reduce the dose of the first drug. This is especially important if the patient has not responded to the first AED.
3. Polytherapy (≥3 agents)—although rarely needed, add a third AED if: a) a combination of anticonvulsants is tolerated and significantly reduces seizure frequency or severity, b) the two anticonvulsants have been maximized. Reassess and discontinue unnecessary anticonvulsants as soon as possible.
4. Do not abruptly discontinue any anticonvulsant as this may precipitate status epilepticus.
5. Consider patient co-morbidities and possible drug interactions upon initiation of therapy, during therapy, and upon drug discontinuation. Many of the antiepileptic agents may increase or decrease metabolism of other medications.
6. Benefits versus risks must be weighed during pregnancy. The fewest number of antiepileptic agents (and lowest dose) that control seizures should be used. The second-generation antiepileptics (levetiracetam, gabapentin, lamotrigine, tiagabine, topiramate, oxcarbazepine) are rated as Pregnancy Category C, which means that risk cannot be ruled out. Human studies are lacking, and animal studies are either positive for fetal risk or lacking. However, potential benefits may justify potential risks. The first generation antiepileptics (phenytoin, phenobarbital, primidone, carbamazepine, valproic acid) are rated as Pregnancy Category D. This means there is positive evidence of risk. Investigational or post-marketing data show risk to the fetus. However, potential benefits may outweigh potential risks. The drug may be acceptable if safer drugs cannot be used or are ineffective.

Potential Reasons for Treatment Failure

1. Incorrect diagnosis
2. Inappropriate anticonvulsant selected
3. Inappropriate dose
4. Subtherapeutic levels
5. Poor patient adherence
6. Refractory seizures

Contraindications (C/I)/Cautions/Monitoring Parameters

1. Carbamazepine
 - Black box warning—Aplastic anemia and agranulocytosis have been reported. Consider obtaining complete hematologic testing at baseline. Monitor patient closely if patient has low or decreased WBC or platelet count during the course of therapy. Consider discontinuation of therapy if patient has any evidence of significant bone marrow depression.
 - C/I—hypersensitivity to carbamazepine, tricyclic antidepressants, or any component of the formulation; with or within 14 days of MAOI use; bone marrow depression; pregnancy
 - Use with caution in patients with increased intraocular pressure
 - May possibly activate latent psychosis and confusion or agitation in the elderly population
 - Severe dermatological reactions have been rarely reported including toxic epidermal necrolysis and Steven-Johnson syndrome
 - Hyponatremia has been reported in association with carbamazepine use either alone or in combination with other drugs
 - Consider obtaining urinalysis, BUN determinations, and electrolytes at baseline, then at one month, and annually or as clinically indicated.
 - Consider performing baseline liver function tests, repeat at one month, and annually or as clinically indicated. Discontinue drug immediately if LFTs > 3 times normal limit.
 - Consider obtaining baseline and periodic eye examinations
 - Consider obtaining CBC with platelets at baseline, then twice monthly first two months, and annually or as clinically indicated
 - Consider EKG at baseline for patients > 40 years old and as clinically indicated
 - Monitoring of blood levels is useful for verifying compliance and determining cause of toxicity when more than 1 agent is used. Consider obtaining carbamazepine level weekly for two weeks, then at one month and annually or as clinically indicated.
 - Therapeutic blood level- 4-12mcg/ml. Toxic concentration->15mcg/ml
 - **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.
2. Phenytoin
 - C/I- hypersensitivity to hydantoin; sinus bradycardia, sino-atrial block, second and third degree AV block or in patients with Adams-Stokes syndrome; pregnancy
 - Use with caution in patients with hypotension and severe myocardial insufficiency
 - Hepatic failure—discontinue therapy if LFTs increase >3 times normal limit
 - Steven-Johnson syndrome—discontinue therapy if signs or symptoms of severe rash develops
 - Hyperglycemia due to inhibitory effect on insulin
 - Peripheral neuropathy
 - Consider alternative anticonvulsant if lymph node enlargement occurs (may represent hypersensitivity reaction)
 - Hydantoin facies (thickening of subcutaneous tissues, enlargement of nose and lips)
 - Acne, hirsutism, and gingival hyperplasia (suggest good oral hygiene) may occur
 - Osteomalacia—treat with vitamin D if alkaline phosphatase increases and 25-hydroxycholecalciferol decreases
 - Folate deficiency causing megaloblastic anemia (rare)
 - Consider obtaining CBC at baseline and as clinically indicated. Signs of marked depression of the blood count indicate the need for drug withdrawal.
 - Consider obtaining blood chemistries with emphasis on hepatic and renal function at baseline, then at one month, and annually or as clinically indicated
 - Consider EKG at baseline for patients > 40 years old and annually or as clinically indicated
 - Consider obtaining phenytoin level in one week, then in one month, and annually or as clinically indicated
 - Therapeutic blood level (total phenytoin)-10-20mcg/ml. Toxic concentration-30-50mcg/ml

Contraindications (CI)/Cautions/Monitoring Parameters Continued

3. Divalproex Sodium
- Black box warning—fatal hepatotoxicity
 - Black box warning—fatal hemorrhagic pancreatitis
 - Black box warning—teratogenic
 - CI- 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 first two months, and annually or as clinically indicated. Consider obtaining protime, INR, PPT at baseline and annually.
 - 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

**= all AEDs carry an FDA mandated warning for the potential of increased risk of suicidal thoughts or behavior vs. placebo (0.43 versus 0.22%)

Table 4

DRUG	ADRS	DRUG INTERACTIONS (DI)/COMMENTS
Gabapentin	Weight gain, peripheral edema	• DI - No known interactions with other AEDs
Lamotrigine	Dose-dependent: ataxia, blurred or double vision, dizziness, GI upset, insomnia. Non-dose-dependent: skin rash. Other: hypersensitivity including risk of hepatic and renal failure and DIC	• DI - 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.
Levetiracetam	Dose-dependent: dizziness, fatigue, irritability, sedation.	• DI - 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.
Oxcarbazepine	Dose-dependent: GI (Nausea & vomiting), CNS (dizziness, somnolence), diplopia. Non-dose-dependent: hyponatremia, skin rash.	• DI - oral contraceptives, diuretics, AEDs, dihydropyridine calcium channel blockers. • 50% dose reduction recommended in renal insufficiency. • Kinetic changes not observed in cirrhosis. • Does not undergo autoinduction. • Crosses placenta and breast milk. Pregnancy Category C.

Table 4 continued

DRUG	ADRS	DRUG INTERACTIONS (DI)/COMMENTS
Tiagabine	Dose-dependent: dizziness, weakness, depression, HA, sedation, difficulty with concentration. Non-dose dependent: exacerbation of generalized seizures.	<ul style="list-style-type: none"> • DI - AEDs. • Hepatic metabolism-impairment may require dosage reduction or longer dosing intervals. • Pregnancy Category C. Excreted in breast milk.
Topiramate	Dose-dependent-sedation, confusion, mental slowing, word-finding difficulties, anorexia, paresthesias. Non-dose-dependent: weight loss. Other: nephrolithiasis	<ul style="list-style-type: none"> • DI - oral contraceptives, AEDs, carbonic anhydrase inhibitors, CNS depressants. • Administer with caution in patients with hepatic impairment. • CrCl <70ml/min- 50% of usual dose recommended. • Pregnancy Category C. Unknown if excreted in breast milk. • Counsel pt to drink plenty of fluids.
Zonisamide	Dose-dependent: ataxia, somnolence, fatigue, anorexia, weight loss, irritability, dizziness. Non-dose-dependent- kidney stones, liver toxicity, leukopenia. Others: rash, hypohidrosis predominately children	<ul style="list-style-type: none"> • DI - topiramate (additive toxicity); enzyme-inducing AED reduce half-life 50%; cyclosporine, ketoconazole, miconazole inhibit metabolism. • Renal and hepatic impairment dose adjustment unknown. • Sulfonamide derivative. Contraindication in sulfa allergic patients. • Counsel patient to drink plenty of fluids. • Crosses placenta and breast milk. Pregnancy Category C.

Pseudoseizures

1. Definition- "Psychogenic seizures are episodes involving affective, autonomic, or sensorimotor manifestations that are precipitated by emotional distress." Other terms used to refer to these events include nonepileptic seizures, hysterical seizure, 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 Pseudoseizure - Gates et al successfully identified 96% of pseudoseizures using the following criteria.
 - Strongly suggestive
 - Prolonged duration of event (10-30)
 - 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 cautions that the diagnosis of pseudoseizure 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.

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 dose should be tapered over 6 months) and tailored to the specific drug, dosage, and serum concentrations for each patient.

Table 5

Factors Against Drug Withdrawal	Factors in Favor of Drug Withdrawal
<ul style="list-style-type: none"> • Adolescent-onset epilepsy • Adult-onset epilepsy • Partial epilepsy • Juvenile myoclonic epilepsy • Presence of underlying neurological condition • Abnormal EEG (children) 	<ul style="list-style-type: none"> • Childhood-onset epilepsy • Elderly-onset epilepsy • Idiopathic generalized epilepsy • Benign epilepsy with centrotemporal spikes • Normal EEG (children) • Childbearing potential and planning pregnancy • Co-morbidity with concurrent treatments

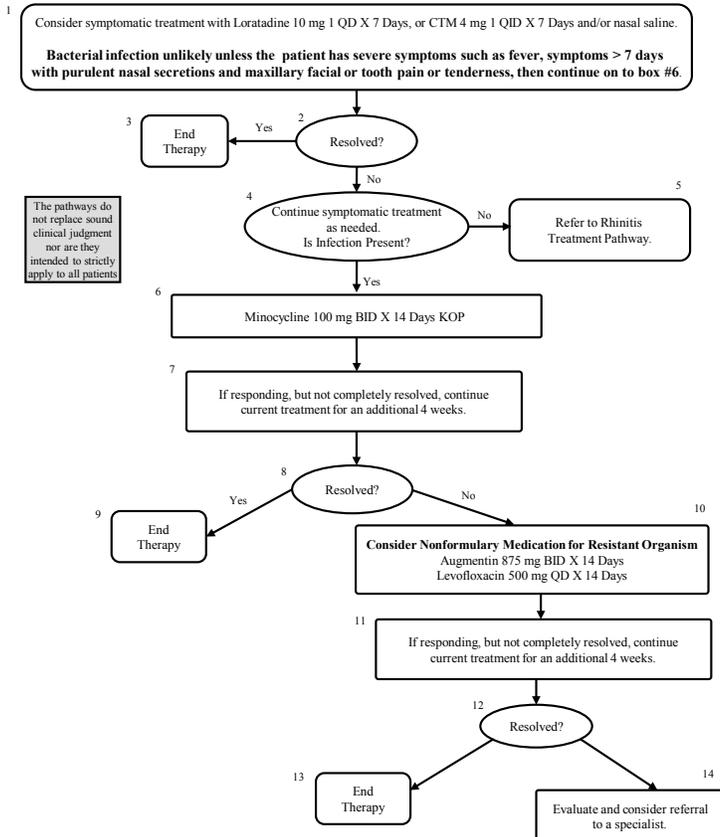
Adapted from Speechio et al.

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

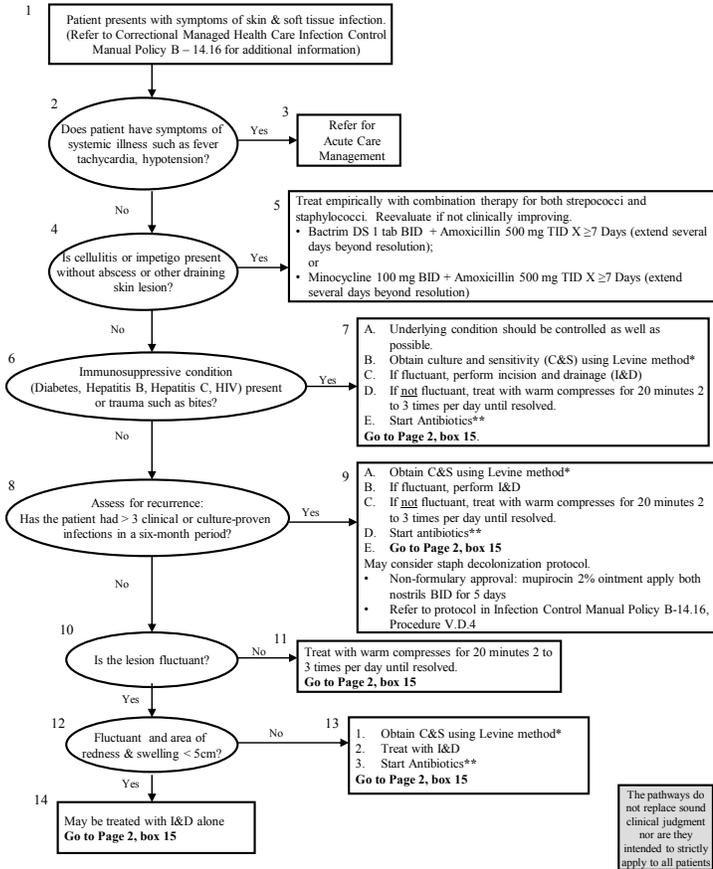
Tapering schedule: Decrease phenobarbital dose by 30mg a month over 1-6 month period. Example: Patient is receiving 120mg/day 1 st month, patient receives 90mg/day 2 nd month, patient receives 60mg/day 3 rd month, patient receives 30mg/day 4 th month, patient receives 0mg/day
Labs: If patient has undetectable 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. He/she must determine if the underlying disorder has returned or if the seizures were the result of withdrawing the phenobarbital too quickly. Phenobarbital should be tapered more slowly if the latter is true.

SINUSITIS



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



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

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee.
Approved 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

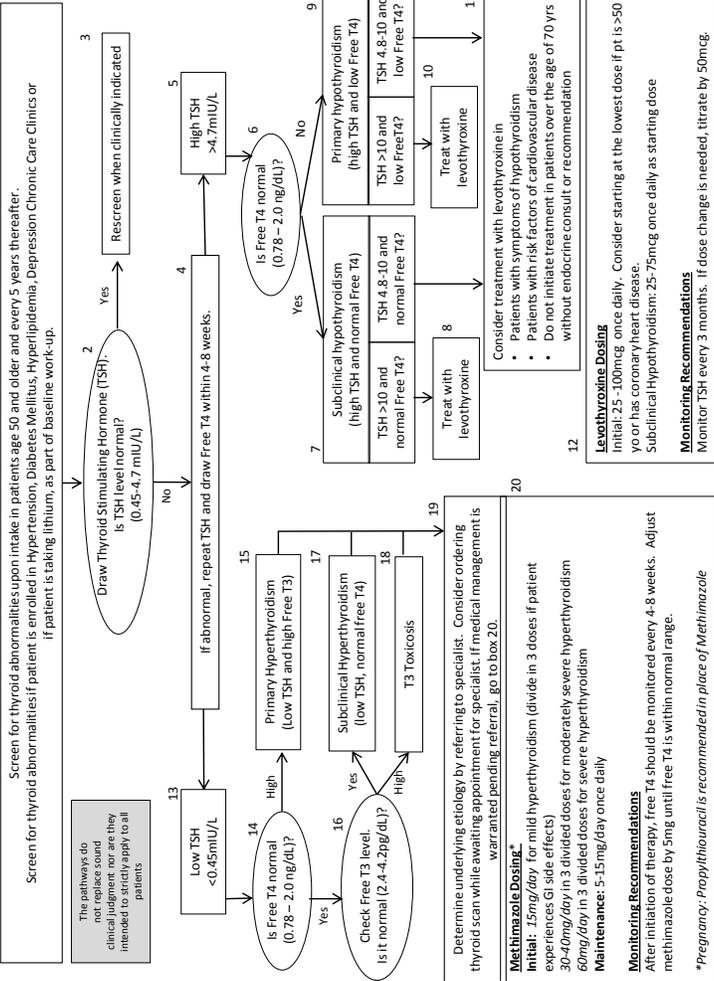
****Antibiotic Selection**

- 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
- Empiric therapy to avoid: rifampin alone, fluoroquinolone, cephalosporin, clindamycin, or erythromycin.

***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 moistened with sterile water to increase the chances of recovering organisms from the site.
- C. Collect in a zig-zag motion – the swab should be moved across the wound surface in a zig-zag motion, at the same time, being rotated between the fingers.
- D. Send to lab – immediately following the collection, the swab should be returned to its container (placed into the transport medium) and accurately labeled.

THYROID DISORDERS



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 1.

Hypothyroidism	Hyperthyroidism
<ul style="list-style-type: none"> • Constipation • Cold sensitivity • Dry skin • Hair loss or change in texture • Fatigue • Myalgia/arthralgia • Hoarseness • Weight gain despite poor appetite • Bradycardia • Cognitive deficits/depression • Thyroid enlargement/nodules • Carpal tunnel syndrome • Sleep apnea • Females may present with menorrhagia, amenorrhea, and galactorrhea 	<ul style="list-style-type: none"> • Anxiety • Weakness • Tremors • Palpitations • Heat intolerance • Increased perspiration • Weight loss

C. Lab Evaluation – see pathway for frequency

1. TSH
2. Free T4
3. Free T3

D. Physical Exam (Intake and CCC)

1. Vitals
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 2.

	Criteria for Thyroid Disorder Diagnosis	
	TSH	Free T4
Normal*	0.35 – 5.5 mIU/L	0.78 – 2.2 ng/dL
Subclinical Hypothyroidism	5.6 - 9.9 mIU/L	0.78 – 2.2 ng/dL
Primary Hypothyroidism	>10 mIU/L	0.78 ng/dL
Subclinical Hyperthyroidism	<0.35 mIU/L	0.78 – 2.2 ng/dL
Primary Hyperthyroidism	<0.35 mIU/L	>2.2 ng/dL

*Values based on UTMB CMC's normal range of values

III. Plan/Treatment

A. Hypothyroidism – Treatment is recommended in those diagnosed with primary hypothyroidism (>10mIU/L TSH). Treatment is considered in patients with subclinical hypothyroidism if the patient is symptomatic of hypothyroidism or has cardiovascular risk factors (e.g. elevated LDL).

1. Pharmacological Therapy: Levothyroxine (Synthroid, Levoxy) is drug of choice.

Table 3.

	Primary Hypothyroidism	Patients with Primary Hypothyroidism with CHD	Patients with Primary Hypothyroidism >50 yo	Subclinical Hypothyroidism
Starting dose	25mcg to 100mcg once daily	25mcg once a day	25mcg once a day	25mcg to 75mcg once a day

CMC Formulary Levothyroxine Strengths: 25mcg, 50mcg, 100mcg, 150mcg

2. Treatment goals include:

- Symptom relief
 - Target TSH within normal value range (0.35 – 5.5 mIU/L)
 - Free T4 within normal value range (0.78 – 2.2ng/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.
- If TSH is suppressed (<0.35mIU/L) - consider dose reduction by 25 – 50mcg. Excess replacement increases the risk of osteoporosis and arrhythmias, especially in the elderly.
 - If TSH is wnl- dose has been established. Monitor TSH at 6 months and then every 12 months thereafter.
 - If TSH is elevated (>5.5mIU/L) – consider dose increase by 25- 50mcg.
4. Clinical pearls on levothyroxine
- 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.
 - Patients should take levothyroxine 4 hours apart from antacids, iron and calcium supplements.
 - Patients should take levothyroxine with a full glass (8oz) of water ONLY.

Table 4.

Agents Impacting Levothyroxine Therapy or the Hypothalamic-Pituitary Axis (HPA)		
Interferes with absorption of levothyroxine	Increases clearance of levothyroxine	Direct and indirect effects on the HPA
<ul style="list-style-type: none"> •Bile acid sequestrants •Sucralfate •Kayexalate •Oral bisphosphonates •Proton pump inhibitors •Multivitamins (containing ferrous sulfate or calcium carbonate) •Ferrous sulfate •Phosphate binders •Calcium salts •Ciprofloxacin •H2 receptor antagonists <p>Diet:</p> <ul style="list-style-type: none"> •Ingestion with a meal •Grapefruit juice •Espresso coffee •High fiber diet •Soy 	<ul style="list-style-type: none"> •Phenobarbital •Primidone •Phenytoin •Carbamazepine •Rifampin •Sertaline •Quetiapine •Stavudine •Nevirapine 	<p>Decreases TSH secretion</p> <ul style="list-style-type: none"> •Dopamine •Dopaminergic agonists (bromocriptine, cabergoline) •Glucocorticoids •Thyroid hormone analogues •Metformin •Opiates <p>Increases TSH secretion</p> <ul style="list-style-type: none"> •Dopamine receptor blockers (metoclopramide) •Hypoadrenalism •Amphetamines •Ritonavir •St. John's Wort

5. Hypothyroidism during pregnancy
 a. TSH goals vary depending on the trimester

Table 5.

	First Trimester	Second Trimester	Third Trimester
TSH Goal	0.1-2.5 mIU/L	0.2-3.0 mIU/L	0.3-3.0 mIU/L

- 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 6.

Dosing	Initial Dose	Maintenance
Drug of Choice: Methimazole Formulary strength: 5mg	15mg/day for mild hyperthyroidism (divide in 3 doses if patient experiences GI side effects) 30-40mg/day in 3 divided doses for moderately severe hyperthyroidism 60mg/day in 3 divided doses for severe hyperthyroidism	5-15mg once daily
In pregnancy: Propylthiouracil Nonformulary	50-150mg (depending on severity) 3 times daily	50mg 2-3 times daily for a total of 12-18 months, then taper or discontinue if TSH is normal at that time.

Table 7.

Side Effects of Methimazole	Side Effects of Propylthiouracil
<ul style="list-style-type: none"> •Agranulocytosis •Leukopenia •Thrombocytopenia •Aplastic Anemia •Hepatitis 	<p><u>BBW-Severe liver injury and acute liver failure have been reported</u></p> <ul style="list-style-type: none"> • Agranulocytosis • Leukopenia • Thrombocytopenia • Aplastic anemia • Hepatitis • Acute renal failure, glomerulonephritis

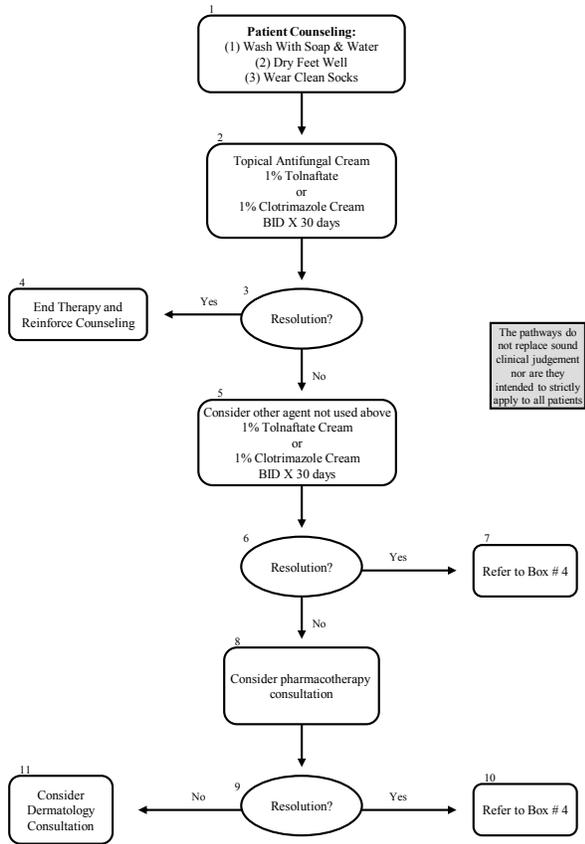
Table 8.

Drug Interactions			
Methimazole may increase the levels of the following agents	Methimazole may decrease the levels of the following agents	Propylthiouracil* may increase the levels of the following agents	Propylthiouracil may decrease the levels of the following agents
<ul style="list-style-type: none"> • Arpiprazole • Cardiac glycosides • Clozapine • Lomitapide • Pimozide • Theophylline derivatives 	<ul style="list-style-type: none"> •Sodium Iodide •Vitamin K antagonists 	<ul style="list-style-type: none"> •Cardiac glycosides •Clozapine •Theophylline derivatives 	<ul style="list-style-type: none"> •Sodium Iodide •Vitamin K antagonists

*Propylthiouracil levels may be altered if taken with food. Either always take with food or always take without food.

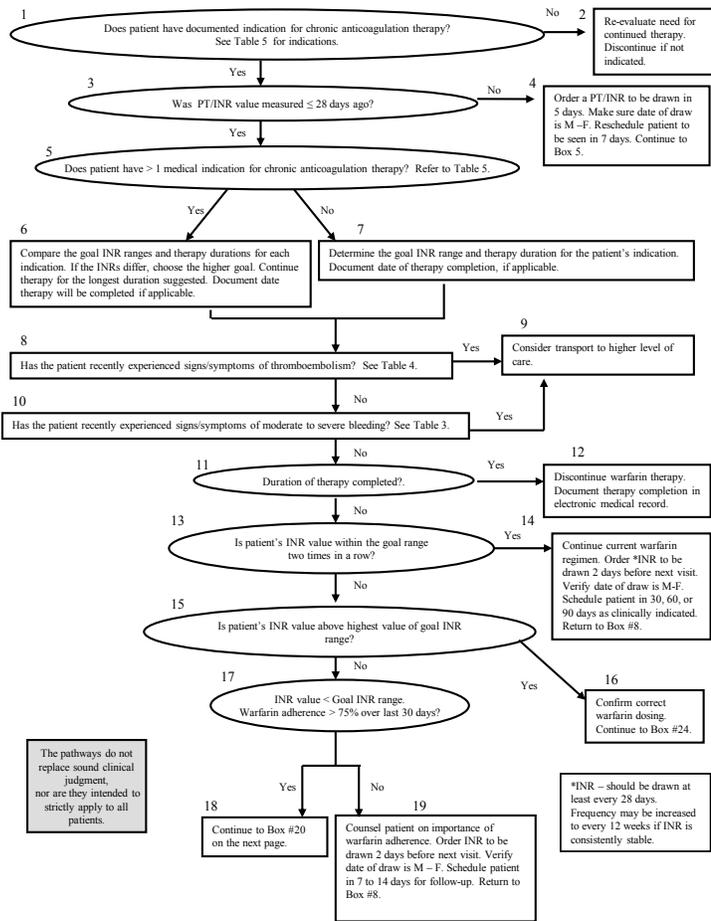
2. Lithium and Hyperthyroidism
 - a. Perform thyroid physical examination upon intake.
 - b. Obtain TSH and antithyroid peroxidase antibody titers prior to initiation of lithium treatment.
 - i. If thyroid function is abnormal at the initial evaluation, lithium can still be given, but the thyroid dysfunction should be treated. Please refer to Thyroid Disorders pathway.
 - ii. If thyroid function is normal at baseline, it should be re-evaluated every 6 to 12 months while on lithium treatment.
 - c. Monitor TSH and Free T4 in patients taking lithium as recommended in the Thyroid Disorders pathway.
3. Treatment goals include:
 - a. Symptom relief
 - b. TSH within normal value range (0.35 – 5.5 mIU/L)
 - c. Free T4 within normal value range (0.78 – 2.2ng/dL)
4. Monitoring recommendations
 - a. Baseline tests: prothrombin, CBC, and liver function enzymes.
 - b. Free T4 level should be drawn 4 weeks after initiating methimazole, and every 3 months thereafter until patient is euthyroidic.
 - c. TSH should be monitored at 6 months and then every 6 months until 18 months of therapy are complete. TSH may remain suppressed for several months after starting therapy and is therefore not a good parameter to guide medication adjustment.
 - d. Patients should report signs/symptoms of liver injury when using methimazole or propylthiouracil including: anorexia, pruritis, right upper quadrant pain
 - e. Liver function tests should be monitored frequently while taking PTU
 - f. Continue to monitor for presence of nodules or goiters in hyperthyroid patients and refer to specialist if needed.
5. Hyperthyroidism during pregnancy
 - a. Refer to OBGYN for management of hyperthyroidism in pregnant patients

TINEA PEDIS



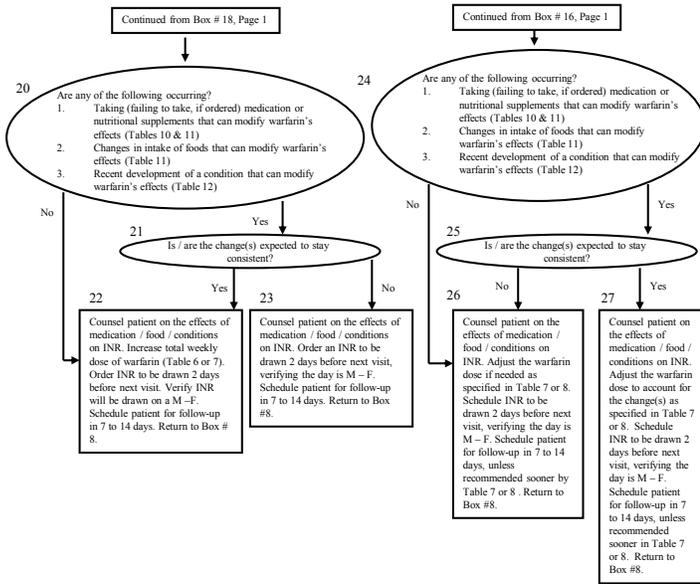
Prepared By The Correctional Managed Care Pharmacy & Therapeutics Committee, September 1996, Revised 8/98, 12/98, 3/01, 7/04. Reviewed 4/03, 1/07, 5/10, 1/13.

Chronic Anticoagulation Using Warfarin



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

*INR - should be drawn at least every 28 days. Frequency may be increased to every 12 weeks if INR is consistently stable.



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

I. Treatment Principles

A. Primary vs. Secondary Prevention

1. Primary prevention: Circumventing a thrombotic event before it happens
2. Secondary prevention: Avoiding a recurrence of a thrombotic event in a patient who has already experienced one

B. Negative Consequences of NOT Providing Venous Thromboembolism (VTE) Prophylaxis

1. Symptomatic deep venous thrombosis (DVT) or pulmonary embolism (PE)
2. Fatal PE
3. Costs of tests used to diagnose symptomatic patients
4. Risks and costs of treating unprevented VTE
5. Increased risk of recurrence
6. Development of chronic post-thrombotic syndrome

C. Risk Factors Associated With Deep Venous Thrombosis (DVT)

TABLE 1

Risk Factors Associated With Deep Venous Thrombosis	
<ul style="list-style-type: none"> • Cancer: currently on treatment, treatment within past 6 months, or not receiving curative treatment • Paralysis, paresis, or any other factor that leads to a severe decrease in ability to move about • Confined to bed for > 3 days • Major surgery (esp. orthopedic) in the last 12 weeks that required general or regional anesthesia lasting > 30 minutes • Heparin-Induced Thrombocytopenia (HTT) • Pharmacotherapy <ul style="list-style-type: none"> ○ Estrogenic oral contraceptive agents ○ Post-menopausal hormone therapy ○ Cancer treatments <ul style="list-style-type: none"> ▪ Hormonal ▪ Radiotherapy ▪ Chemotherapy 	<ul style="list-style-type: none"> • History of VTE • Age > 60 years • Fracture of hip / pelvis / leg(s) • Indwelling central venous catheter • Major medical illness (e.g. HF, MI, TIA, ischemic stroke) • Hypercoagulable States <ul style="list-style-type: none"> ○ Cancer ○ Activated Protein C Resistance Factor / Factor V Leiden mutation ○ Prothrombin 20210A mutation, ○ Protein C or S deficiency ○ Antithrombin deficiency ○ Factor VIII or XI excess(> 90th percentile) ○ Antiphospholipid Antibody Syndrome ○ Dysfibrinogenemia ○ Hyperhomocysteinemia ○ Excess of Inhibitor of Plasminogen Activator ○ Inflammatory Bowel Disease <ul style="list-style-type: none"> ▪ Ulcerative Colitis ▪ Crohn's Disease / Crohn's Colitis ○ Nephrotic Syndrome ○ Pregnancy and post-partum period

D. Risk Factors Associated With Pulmonary Embolism (PE)

1. History of PE or DVT
2. Recent surgery or immobilization (e.g., plaster cast)
3. Resting heart rate consistently > 100 beats per minute
4. Cancer / malignancy
5. Age > 60 years

E. Risk Factors Associated with Developing A Severe Bleed While On Warfarin Therapy

TABLE 2

Factors That Increase Risk of Developing A Severe Bleed During Warfarin Therapy	
<ul style="list-style-type: none"> • Age > 65 years • Diabetes mellitus • Cerebrovascular disease • Anemia • Female gender • Alcohol abuse 	<ul style="list-style-type: none"> • History of GI bleeds, peptic ulcerations, etc. • Hypertension • Renal insufficiency • Antiplatelet therapy • History of recent or past bleeding event • Drug abuse

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

Signs & Symptoms Of Possible Acute, Severe Bleed	
<ul style="list-style-type: none"> • Severe headache that fails to resolve • Decrease \geq 10 mmHg in systolic BP or an $\uparrow \geq$ 10 beats per minute or more in pulse rate when rising from a lying down position to a standing position • Dyspnea • Decrease in supine blood pressure • Hematemesis • Hemoptysis <ul style="list-style-type: none"> o Fainting upon rising from a lying position or from a sitting position 	<ul style="list-style-type: none"> • Hypovolemic shock • Tachycardia at rest or with mild exertion (skin may be cool and clammy) • Hematuria • Melena • Menorrhagia • Hematochezia as indicated by 1 or more of the following: <ul style="list-style-type: none"> o Bright red colored stool o Mahogany colored stool o Pure blood o Blood mixed with formed stool o Bloody diarrhea

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
<ul style="list-style-type: none"> • Tenderness localized to deep venous system (e.g., calf) • Difference in calf circumference > 3 cm when compared to asymptomatic leg (measure 10 cm (4 in) below the tibial tuberosity) • Pitting edema present on symptomatic leg only • Collateral superficial veins, non-varicose • Elevated D-dimer reading 	<ul style="list-style-type: none"> • Hemoptysis • Chest pain • Recent onset and/or worsening dyspnea • Any clinical signs or symptoms of VTE • 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 conditions 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, **STEMI** = ST-segment Elevation Myocardial Infarction, **MI** = Myocardial Infarction, **VKA** = Vitamin K Antagonist (ie. warfarin), **ASA** = Aspirin

Medical Condition	Specific Indication	Target INR	INR Range	Duration of Therapy	Comments/Notes
Atrial Fibrillation <i>or</i> Atrial Flutter	➤ Age < 75 years, no risk factors	NA	NA	NA	Aspirin 81 – 325 mg daily
	➤ Plus: • History of ischemic stroke • History of systemic embolism • History of poor left ventricular systolic function and/or HF • Age ≥ 75 years • DM • HTN	2.5	2.0 – 3.0	Indefinite	
	➤ Mitral Valve Stenosis ➤ Planned conversion to sinus rhythm	2.5	2.0 – 3.0	Start 3 weeks before elective cardioversion and continue for 4 weeks after successful cardioversion	
Antiphospholipid Antibody Syndrome <i>or</i> Presence of Lupus Inhibitor	➤ Patients with no additional risk factors	2.5	2.0 – 3.0	Indefinite	
	➤ Patients with recurrent thromboembolic events at INR of 2.0 – 3.0 or with additional risk factors	3.0	2.5 – 3.5	Indefinite	
Cerebral Venous Sinus Thrombosis		2.5	2.0 – 3.0	Up to 12 months	
CTPH		2.5	2.0 – 3.0	Indefinite	
DVT <i>or</i> PE	➤ 1 st episode, secondary to reversible risk factor	2.5	2.0 – 3.0	3 months	
	➤ 1 st isolated distal DVT				
	➤ 1 st episode, idiopathic	2.5	2.0 – 3.0	At least 3 months; consider long-term therapy	Depending on bleeding risk
	➤ Recurrent	2.5	2.0 – 3.0	Indefinite	
	➤ Cancer	2.5	2.0 – 3.0	Until cancer resolves or Indefinitely	LMWH recommended for the first 3 – 6 months.
Mitral Annular Calcification	➤ Complicated by systemic embolism, ischemic stroke, or TIA <i>without</i> AF	NA	NA	NA	Aspirin 81 mg/day
	➤ Recurrent episodes despite aspirin therapy ➤ With AF	2.5	2.0 – 3.0	Indefinite	
Mitral Valve Stenosis	➤ Preprocedural TEE showing left atrial thrombus	3.0	2.5 – 3.5	Until thrombus resolution is documented by repeat TEE	Percutaneous mitral balloon valvotomy (PMBV) can only be performed if no thrombus present on TEE.

Medical Condition	Specific Indication	Target INR	INR Range	Duration of Therapy	Comments/Notes
Mitral Valve Prolapse	➤ With TIA or ischemic stroke	NA	NA	NA	Aspirin 81 mg/day
	➤ With: <ul style="list-style-type: none"> • AF • Documented systemic embolism • Recurrent TIA with aspirin therapy 	2.5	2.0 – 3.0	Indefinite	
MI	➤ Post-MI, high risk <ul style="list-style-type: none"> • Large anterior MI • Significant HF • Intracardiac thrombus • AF • History of thromboembolic event 	2.5	2.0 – 3.0	At least 3 months post-MI	Combination with aspirin 81 mg/day
Rheumatic Mitral Valve Disease	➤ AF <ul style="list-style-type: none"> • Systemic embolism • Left atrial thrombus • NSR with atrial diameter ≥ 55 mm 	2.5	2.0 – 3.0	Indefinite	
	➤ AF with systemic embolism and/or left atrial thrombus while at therapeutic INR	3.0	2.5 – 3.5	Indefinite	
Valves, Heart, Mechanical	➤ AORTIC Position in NSR w/o left atrial enlargement <ul style="list-style-type: none"> • Bileaflet • Tilting disk 	2.5	2.0 – 3.0	Indefinite	
	➤ MITRAL Position <ul style="list-style-type: none"> • Bileaflet • Tilting disk 	3.0	2.5 – 3.5	Indefinite	
	➤ ANY Position <ul style="list-style-type: none"> • Caged ball • Caged disk • AF • Anterior-apical STEMI • Left atrial enlargement • Hypercoagulable state • Low ejection fraction 	3.0	2.5 – 3.5	Indefinite	Combine with aspirin 81 mg/day in patients with multiple risk factors for thromboembolism and atherosclerotic disease.
	➤ Systemic embolism despite previously therapeutic INR: <ul style="list-style-type: none"> • Target 2.5 (2.0 – 3.0) • Target 3.0 (2.5 – 3.5) 	3.0 3.5	2.5 – 3.5 3.0 – 4.0	Indefinite	Combine with aspirin 81 mg/day or upward titrate warfarin dose and INR.
Valves, Heart, Bioprosthetic	➤ AORTIC Position with: <ul style="list-style-type: none"> • NSR • No other VKA indication 	NA	NA	NA	Aspirin 81 mg/day.
	➤ ANY Position with: <ul style="list-style-type: none"> • History of systemic embolism 	2.5	2.0 – 3.0	First 3 months following valve insertion	ASA 81 mg/day afterwards in patients with NSR and no other indications for warfarin therapy.
	➤ ANY Position with: <ul style="list-style-type: none"> • AF • Hypercoagulable state • Low ejection fraction • Any additional thromboembolic risk 	2.5	2.0 – 3.0	Indefinite	Consider addition of aspirin 81 mg/day in patients with atherosclerotic disease.

- 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 15%	2 days before next visit	7 – 14 days

- 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 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					
Bleeding Severity	Patient INR	Vitamin K ₁ (oral dose)	Warfarin Adjustment	Schedule next INR to be drawn in:	Schedule for reevaluation in:
Without signs & symptoms of serious bleeding, and without urgent or recent surgery	More than therapeutic up to 5	None	Hold 1 dose or Decrease total weekly dose by 5% - 15%.	2 days before next visit	7 - 14 days
	>5 - 8.9	None	Hold 1- 2 doses. Decrease total weekly dose by 10% to 20%.	Within next 1 - 2 days.	1 - 2 days. Unit evaluation of signs of excess bleeding should be frequently performed.
		2.5 mg	Hold 1 dose. Decrease total weekly dose by 10% to 20%.	Within next 1 - 2 days.	1 - 2 days. Unit evaluation of signs of excess bleeding should be frequently performed.
	9 - 10	2.5 - 5 mg, based on patient risk for bleeding	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.	Within next 1 - 2 days.	As soon as possible. If INR still higher than desirable, may administer another dose of Vitamin K ₁ , 2.5 mg by mouth 24 hours after first dose.
	>10	Hold warfarin, give Vitamin K, and consider transport to higher level of care.			
Serious Bleeding	Any INR	Hold warfarin, give Vitamin K, and consider transport to higher level of care.			

E. Factors That Can Result In A Subtherapeutic or Supratherapeutic Warfarin Level or Alter Warfarin's Effect

TABLE 9

Drugs That Can Change Warfarin's Effects and/or INR	
Drugs That ↑ Warfarin's Effects and/or INR (SUPRAtherapeutic)	Drugs that ↓ Warfarin Effects and/or INR (SUBtherapeutic)
Acetaminophen or aspirin > 1.3 g (1300 mg) per day X 7 days or more	Aminoglutethimide
Allopurinol	Antithyroid agents: propylthiouracil
Amiodarone	Azathioprine
Androgens: testosterone, oxandrolone, methyltestosterone	Bile acid sequestrants: cholestyramine resin
Cephalosporins: cephalexin, cefazolin, cefadroxil, ceftriaxone	Bosentan
Antiplatelet agents: aspirin, clopidogrel, ticlopidine, prasugrel	CYP2C9 inducing drugs : carbamazepine, phenobarbital, phenytoin, primidone, rifampin, rifapentine, ritonavir
CYP 2C9 inhibiting drugs : amiodarone, chloramphenicol, cimetidine, lovastatin, isoniazid, fluoxetine, fluvoxamine, metronidazole, fluconazole, voriconazole, zafirlukast	Penicillin-based antibiotics: dicloxacillin, nafcillin
Antihyperlipidemic agents: gemfibrozil, clofibrate, fenofibrate	Hormonal Contraceptives: norethindrone / ethinyl estradiol, norgestrel / ethinyl estradiol, ethynodiol diacetate / ethinyl estradiol
NSAID Agents: aspirin, ibuprofen, indomethacin, naproxen, meloxicam	Hormone Therapy: estrogens, conjugated; synthetic estrogens
Macrolide antibiotics: clarithromycin, erythromycin	Sulfasalazine
Levothyroxine	Chronic daily ethanol use
Anticonvulsants: phenytoin, valproic acid	Griseofulvin
Omeprazole	Antipsychotic Agents: haloperidol, clozapine
Quinidine	Spirolactone
Quinolone antibiotics: ciprofloxacin, levofloxacin	Sucralfate
Salicylates: aspirin, salsalate	Trazodone
Selective serotonin reuptake inhibitors: citalopram, fluoxetine, paroxetine, sertraline	
Sulfonamide derivatives: trimethoprim / sulfamethoxazole	
Tetracycline derivatives: tetracycline, doxycycline	

TABLE 10: Foods That Alter the Effects of Warfarin	
Foods That ↑ Warfarin's Effects and/or INR	Foods that ↓ Warfarin Effects and/or INR = Foods High in Vitamin K
Beverages: Juice, cranberry	Fats & Dressings: Margarine Mayonnaise Oil, canola Oil, vegetable Oil, soybean Oil, olive Foods containing Olestra® synthetic fats
	Vegetables: Asparagus Avocado Broccoli Brussel sprouts Cabbage Cabbage, red Collard greens Endives, raw Green scallions, raw Kale, raw leaf Lettuce, raw Mustard greens Parsley Peas, green, cooked Spinach, raw leaf Turnip greens, raw Watercress, raw
Over-the-Counter Supplements: Vitamin E	Over-the-Counter Supplements: Vitamin supplements containing Vitamin K Vitamin C, high-dose Nutritional supplement beverages (e.g. Osmolite®)

TABLE 11: Factors That May Change Warfarin's Effects	
Factors That Can ↑ Warfarin's Effects	Factors That Can ↓ Warfarin Effects
<ul style="list-style-type: none"> ● Blood dyscrasias ● Cancer ● Collagen vascular disease ● Congestive Heart Failure (CHF) ● Diarrhea ● Dietary deficiencies / poor nutritional state ● Elevated temperature / fever ● Hepatic Disorders: <ul style="list-style-type: none"> • Infectious hepatitis • Jaundice ● Hyperthyroidism ● Prolonged hot weather → dehydration ● Steatorrhea ● Vitamin K deficiency 	<ul style="list-style-type: none"> ● Diet high in Vitamin K ● Edema ● Hereditary coumarin resistance ● Hyperlipidemia ● Hypothyroidism ● Nephrotic syndrome

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?

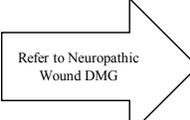
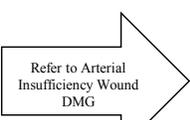
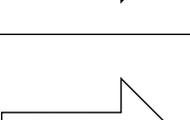
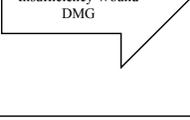
1. Clinical warfarin therapy management sessions
2. When patient is stable, following a thromboembolic event or a hemorrhagic event.
3. Group education if available

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

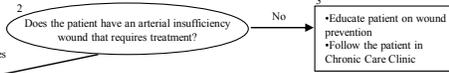
The pathways do not replace sound clinical judgment nor are they intended to strictly apply to all patients.

Wound / Patient Characteristics	Present?	If yes,
<ul style="list-style-type: none"> • Mobility impaired • Low Braden Score • Bony prominence • Located in areas of pressure • Malnourished • Moisture exposure 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<ul style="list-style-type: none"> • Callous formation • Dry skin • Decreased sensation • Located in plantar aspect of foot • Diabetes 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<ul style="list-style-type: none"> • Located in lower extremities, below the ankle • Decreased peripheral pulses • Smooth/round edges • Wounds are usually small and deep. • Wound bed is dry or pale pink. • "Punched out" lesions • Poor hair and nail growth • Distal wounds • ABI <0.9 • Intermittent claudication 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<ul style="list-style-type: none"> • Located in gaited area, mostly in the medial malleolus • Positive peripheral pulses • Larger, irregular borders • Wounds are usually large and superficial. • Wound bed is beefy, red and moist. • Painful • Surrounding skin usually has stasis dermatitis and hemosiderin. • ABI >0.9 • Presence of scar tissue increases risk of re-ulceration. • Varicosities 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<ul style="list-style-type: none"> • Caused by incisional wound dehiscence or laceration • Occurred post-op 	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee, November 2005. Revised 1/07, 11/07, 5/10, 7/12, 3/14. Reviewed 1/08.

- 1 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 ASA 81mg to 325mg for the treatment 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 sound clinical judgment nor are they intended to strictly apply to all patients.

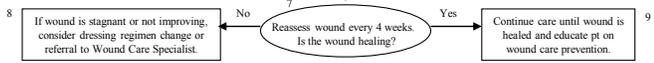


- 4 Precautions:
- Avoid compression therapy
 - Avoid elevation of lower extremities
 - Avoid sharp debridement of chronic dry, eschar-covered, uninfected ulcers in pts with low ABIs.

5 Treat wound according to wound bed description. Most arterial insufficiency wounds will be dry. Go to "Dry Wound Bed".

6

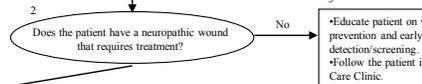
Wound Bed	Epithelization	Granulation	Local infection/critical colonization	Necrotic/Slough
Objective	Protect newly formed tissue	Support granulation and tissue growth	Debridement and decrease bacterial burden	Debridement
OFFLOAD	Use offloading equipment i.e., heel protectors, pressure relieving overlay, crutches and trapezes			
CLEANSE	Wash with soap and water or a commercial wound cleanser		Flush with 250cc's of normal saline or sterile water	
PROTECT PERIWOUND	Consider using skin prep, hydrocolloid window padding dressing, or foam with silicone adhesive.			
Wet Wound Bed	Primary Dressing	•Hydrocolloid •Foam	•Cadexomer Iodine •Silver alginate	•Wet to moist (WTM) dressings •Collagenase (Santyl®) •Silver alginate •Cadexomer Iodine
	Secondary Dressing	n/a	•Foam •Hydrocolloid •Permeable dressing	•Foam •Gauze
Moist Wound Bed	Primary Dressing	•Hydrocolloid	•Silver dressing •Cadexomer Iodine	•Silver dressing •Cadexomer Iodine •WTM dressings
	Secondary Dressing	n/a	•Foam	•Foam •Gauze
Dry Wound Bed	Primary Dressing	•Hydrogel •Cadexomer Iodine	•Hydrogel	•Hydrogel •Silver with hydrogel •Collagenase (Santyl®)
	Secondary Dressing	•Hydrocolloid	•Hydrocolloid	•Foam •Hydrocolloid •Gauze



NEUROPATHIC WOUNDS

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



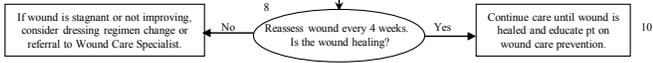
- 3
- Educate patient on wound prevention and early detection/screening.
 - Follow the patient in Chronic Care Clinic.

- 4 Assess wound for:
- Calluses
 - Infection
 - Cellulitis
 - Gangrene

- 5 Consider evaluation for osteomyelitis:
- X-ray if indicated
 - Bone scan if indicated
 - Ortho referral if indicated

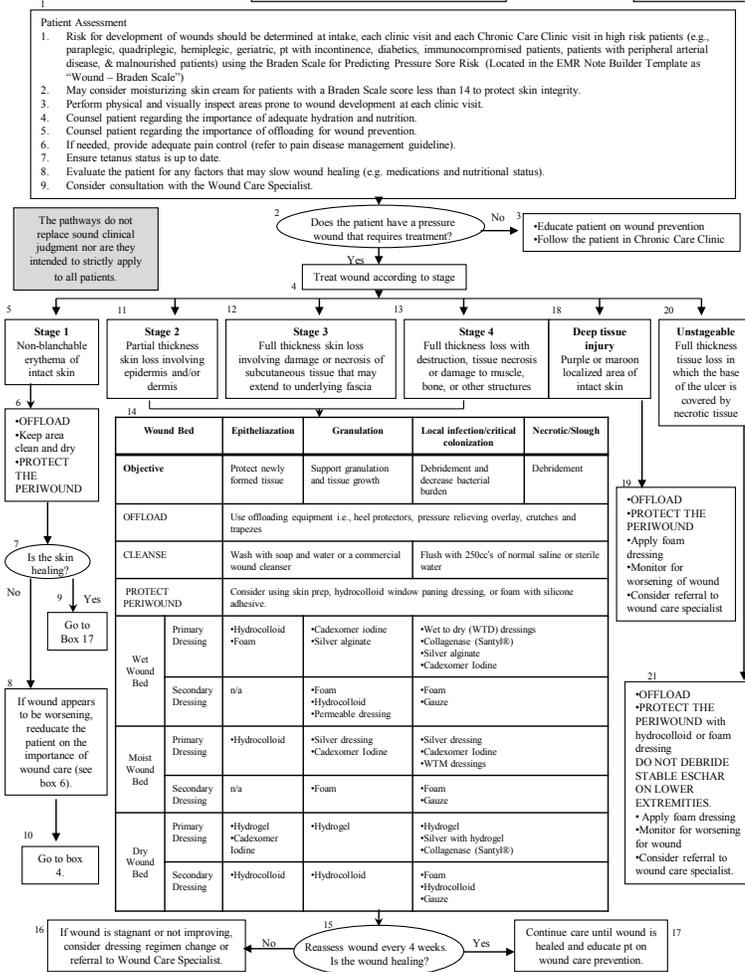
6 Treat wound according to wound bed description. Most neuropathic wounds will be dry. Go to "Dry Wound Bed". Debridement is the mainstay of therapy.

Wound Bed	Epithelialization	Granulation	Local infection/critical colonization	Callous/Necrotic/Slough
Objective	Protect newly formed tissue	Support granulation and tissue growth	Debridement and decrease bacterial burden	Debridement
OFFLOAD	Use offloading equipment i.e., heel protectors, pressure relieving overlay, crutches and trapezes			
CLEANSE	Wash with soap and water or a commercial wound cleanser		Flush with 250cc's of normal saline or sterile water	
PROTECT PERIWOUND	Consider using skin prep, hydrocolloid window padding dressing, or foam with silicone adhesive.			
Wet Wound Bed	Primary Dressing	•Hydrocolloid •Foam	•Cadexomer Iodine •Silver alginate	•Wet to moist (WTM) dressings •Collagenase (Santyl®) •Silver alginate •Cadexomer Iodine
	Secondary Dressing	n/a	•Foam •Hydrocolloid •Permeable dressing	•Foam •Gauze
Moist Wound Bed	Primary Dressing	•Hydrocolloid	•Silver dressing •Cadexomer Iodine	•Silver dressing •Cadexomer Iodine •WTM dressings
	Secondary Dressing	n/a	•Foam	•Foam •Gauze
Dry Wound Bed	Primary Dressing	•Hydrogel •Cadexomer Iodine	•Hydrogel	•Hydrogel •Silver with hydrogel •Collagenase (Santyl®)
	Secondary Dressing	•Hydrocolloid	•Hydrocolloid	•Foam •Hydrocolloid •Gauze

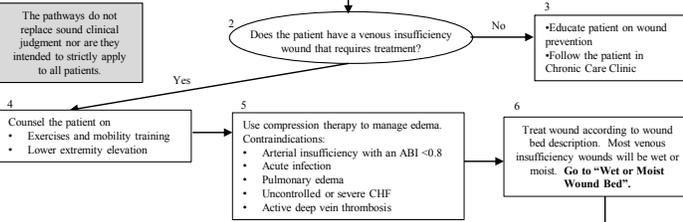


9 If wound is stagnant or not improving, consider dressing regimen change or referral to Wound Care Specialist.

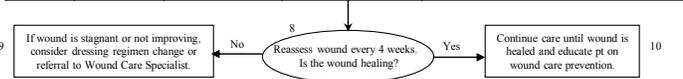
10 Continue care until wound is healed and educate pt on wound care prevention.

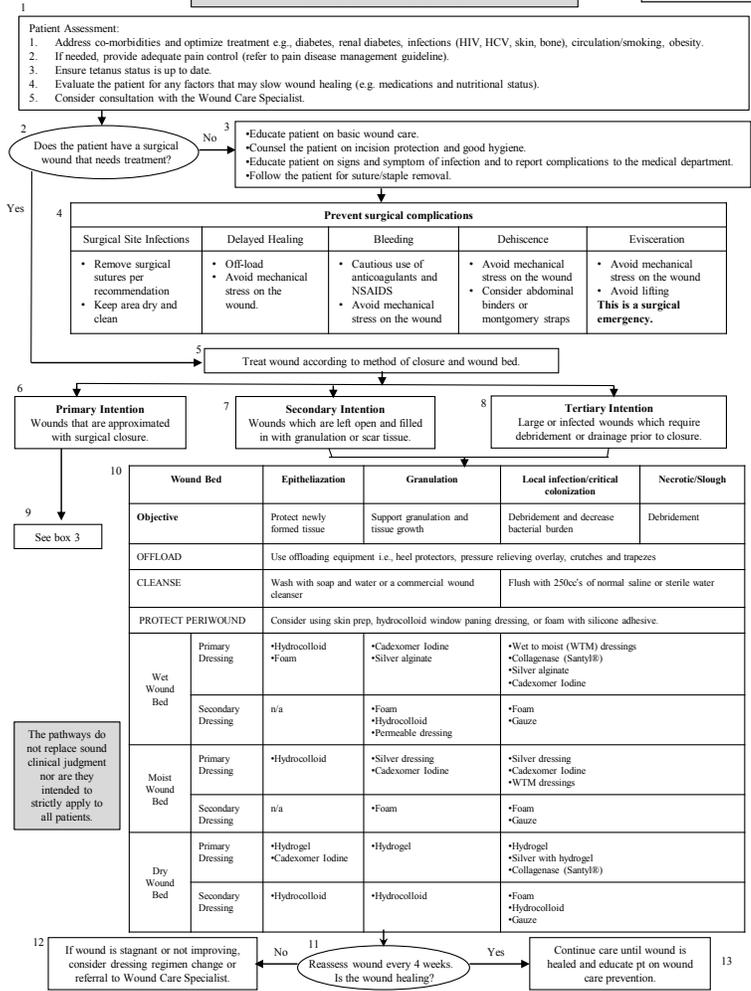


1 Patient Assessment:
 1. Obtain ABI to rule out arterial insufficiency. Refer to Arterial Insufficiency disease management guidelines.
 2. May consider moisturizing skin cream for stasis dermatitis.
 3. Manage underlying diseases that can increase risk of venous insufficiency disease (e.g. hypertension and diabetes mellitus)
 4. If needed, provide adequate 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.



Wound Bed	Epithelialization	Granulation	Local infection/critical colonization	Necrotic/Slough
Objective	Protect newly formed tissue	Support granulation and tissue growth	Debridement and decrease bacterial burden	Debridement
OFFLOAD	Use offloading equipment i.e., heel protectors, pressure relieving overlay, crutches and trapezes			
CLEANSE	Wash with soap and water or a commercial wound cleanser		Flush with 250cc's of normal saline or sterile water	
PROTECT PERIWOUND	Consider using skin prep, hydrocolloid window panning dressing, or foam with silicone adhesive.			
Wet Wound Bed	Primary Dressing	•Hydrocolloid •Foam	•Cadexomer Iodine •Silver alginate	•Wet to moist (WTM) dressings •Collagenase (Santyl®) •Silver alginate •Cadexomer Iodine
	Secondary Dressing	n/a	•Foam •Hydrocolloid •Permeable dressing	•Foam •Gauze
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Purpose

1. To define different kinds of wounds and how to individualize treatment regimen per wound type
2. To define specific language for the assessment of wounds
3. To provide preventative measures and prevention education for each high-risk population
4. To provide education on specific treatment measures

Definitions/Description

- I. Arterial Insufficiency Wounds
 - A. Definition: Wound caused by the partial or complete blockage of arterial blood flow to the internal organs, arms or leg as a result of atherosclerosis. Intermittent claudication (defined as pain, fatigue or cramping in the leg muscles occurring with activity) is a common symptom of arterial insufficiency. ABI is <0.9.
 - B. Description of wound: Arterial insufficiency wounds will appear small and "punched out," with round and smooth margins. Wounds are usually deep, and the wound bed is dry, pale pink or grey.
- II. Neuropathic Wounds
 - A. Definition: Wound caused by peripheral neuropathy and constant pressure or repeated trauma to lower extremities, otherwise known as diabetic foot ulcers in diabetics.
 - B. Description of wound: Wound usually located on the plantar aspect of the foot on a pressure point. It will be painless, surrounded by a callous and have even wound margins. Wound bed is usually deep and dry.
- III. Pressure wounds
 - A. Definition: Wound caused by localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure or pressure combined with shear and/or friction.
 - B. Description of wound: Wound usually located on a pressure point and is defined by the level of tissue involved.
- IV. Venous insufficiency wounds
 - A. Definition: Wound caused by improper functioning of the venous valves, usually of the legs. It is the most common type of leg ulcers, accounting for 80-85% of all cases.
 - B. Description of wound: Wound usually located on the Gaiter area, where area has been exposed to trauma and/or skin is the weakest (e.g. scar sites of skin graft). Wound will be superficial, irregular in shape, and painful. Wound bed is beefy, red and wet.
- V. Surgical Wounds
 - A. Definition: Wound caused by a precise, planned break in the skin integrity or sutured laceration.
 - B. Description of wound: Wounds occurring post-surgery based on type of closure.

Prevention of Wounds

- I. Manage underlying risk factors
 - A. Arterial Insufficiency Wounds:
 1. Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy.
 2. Improve tissue perfusion by avoiding tobacco, caffeine, and wearing constrictive garments, not crossing legs and staying hydrated.
 3. Consider antiplatelet medication for peripheral arterial disease.
 4. Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.
 - B. Neuropathic Wounds
 1. Assess patient for neuropathy by testing for sensory function using a 5.07/10gm monofilament
 - a. Demonstrate sensation on forearm or hand.
 - b. Place monofilament perpendicular to test site on plantar aspect of foot.
 - c. Bow into C-shape for one second.
 - d. Test minimum of four sites, avoiding calluses, scar and ulcers.
 2. Optimize glycemic control in diabetics
 3. Counsel patient to off-load lower extremities to prevent repetitive pressure and trauma to feet.
 4. Counsel patient to visually inspect feet for lesions, ulcers and calluses.
 5. Manage the risk factors for peripheral arterial disease, e.g. hypertension, hyperlipidemia, smoking.
 6. Refer for proper fitting footwear.
 7. Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.
 - C. Pressure Wounds
 1. Assess patient's risk for the development of wounds at intake, each clinic visit and Chronic Care Clinic visit in high risk patients using the Braden Scale (Located in the EMR Note Builder Template as "Wound – Braden Scale")
 2. High risk patients are:
 - a. Paraplegics, quadriplegics, hemiplegics
 - b. Geriatric patients
 - c. Patients with incontinence
 - d. Diabetics
 - e. Immunocompromised patients
 - f. Patients with peripheral arterial disease
 - g. Malnourished patients
 3. Physically and visually inspect areas prone to wound development at each clinic visit.
 4. Maintain skin integrity by keeping area clean and dry.
 - a. Gentle cleansing for bed bound and/or incontinent patients.
 - b. Prevent excessive moisture by changing incontinent patient frequently and using moisture barrier creams.
 - c. Consider moisturizing skin cream for patients with a Braden Scale score of less than 14.
 5. Off-load
 - a. Reposition at least every 2 hours or as indicated. Use turning sheets, trapeze or lifts to reposition to prevent shear and drag.
 - b. Elevate head of bed no more than 30 degrees.
 - c. Raise heels off the bed by placing pillows under legs allowing the heels to hang off the edge or use heel protectors.
 - d. Use pressure reducing devices, e.g. foam mattresses, as available.

6. Optimize glycemic control in diabetics.
 7. Manage the risk factors for peripheral arterial disease, e.g. hypertension, hyperlipidemia, smoking.
 8. Treat underlying disease to improve immune system in immunocompromised patients.
 9. Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.
- D. Venous Insufficiency Wounds
1. Optimize management of hypertension, hyperlipidemia and diabetes through therapeutic lifestyle changes and pharmacotherapy
 2. Counsel patient to implement therapeutic lifestyle changes with diet and exercise to maintain normal body mass index (BMI).
 3. Counsel patient to decrease salt consumption.
 4. Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.
 5. Counsel patient that compression therapy is the mainstay of prevention and treatment.
- E. Surgical wounds
1. Counsel patient to avoid mechanical stress on the incision.
 2. Counsel patient on conducting daily inspections of skin and to notify a health care provider if any lesions start to form.
- II. Screen for medications that may impede wound healing
- A. Anticoagulants – forms hematomas
 - B. Aspirin – suppresses inflammation
 - C. NSAIDs – suppress inflammation, protein synthesis and epithelialization
- III. Evaluate nutritional status
- A. Counsel patient on the importance of adequate hydration and nutrition.
 - B. Assure adequate protein intake.
 - C. Consider an appetite stimulant if unintentional weight loss leads to loss of lean body mass. Evaluate for underlying cause of weight loss.

Assessment of Wounds

- I. Determine the mechanism of injury. CONSIDER obtaining the appropriate diagnostic work-up.
 - A. Arterial insufficiency wounds
 1. Ankle-Brachial Index (ABI) Measurement is a non-invasive tool necessary for screening arterial insufficiency. Refer to Vascular Surgery Lab.
 - a. How ABI is performed:
 - i. Equipment: blood pressure and handheld Doppler device with a vascular probe
 - ii. ABI = Ankle Systolic BP / Brachial Systolic BP
 - iii. Using a BP cuff and Doppler, measure the systolic BP in the right dorsalis pedis and right posterior tibial arteries. Use the higher SBP to calculate the ABI for the right leg.
 - iv. Using a BP cuff and Doppler, measure the systolic BP in the left dorsalis pedis and left posterior tibial arteries. Use the higher SBP to calculate the ABI for the left leg.
 - v. Using a BP cuff, measure the systolic BP in the brachial artery in both arms. Use the higher SBP for the ABI formula to calculate the ABI in both the right and left legs.
 - b. ABI Interpretation
 - i. ABI > 1.2 is not a valid test. Refer to vascular surgery due to possible stiffening of vessels secondary to diabetes or hypertension.
 - ii. ABI 0.9 to 1.2 is normal
 - iii. ABI 0.6 to 0.8 is borderline perfusion. Manage wound according to Arterial Insufficiency DMG.
 - iv. ABI of < 0.5 is critical ischemia and requires immediate referral to vascular surgery
 - B. Neuropathic wounds
 1. Check ABI to screen for arterial insufficiency, which commonly co-exists with peripheral neuropathy.
 2. Screen for infection with wound culture, and screen for osteomyelitis with x-ray.
 3. Classify the wound according to the Wagner Grading System
 - a. Grade 0 – No open foot lesions
 - b. Grade 1 – Presence of superficial ulcer, partial or full thickness
 - c. Grade 2 – Ulcer extends to ligaments, tendon, joint capsule or deep fascia without abscess or osteomyelitis
 - d. Grade 3 – Presence of deep ulcer with abscess, osteomyelitis or joint sepsis
 - e. Grade 4 – Gangrene localized to the forefoot or heel
 - f. Grade 5 – Extensive gangrene
 - C. Pressure wounds
 1. Screen for infection with wound culture, and screen for osteomyelitis with x-ray.
 2. Stage the wound based upon the level of tissue involved. ONLY pressure wounds are staged.
 - a. Stage I – non-blanchable erythema
 - b. Stage II – partial thickness skin loss involving the epidermis and possibly the dermis
 - c. Stage III – full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down but not through underlying fascia
 - d. Stage IV – full thickness skin loss involving damage to muscle, bone, or supporting structures.
 - e. Deep Tissue Injury - Purple or maroon localized area of intact skin
 - f. Unstageable - Full thickness tissue loss in which the base of the ulcer is covered by necrotic tissue
 - D. Venous insufficiency wounds
 1. Screen for concomitant arterial insufficiency by checking the ABI. Compression should not be used with ABI < 0.8.
 2. Screen for DVT (deep vein thrombosis) by checking ultrasonography.
 - E. Surgical wounds – screen for infection with wound culture, and screen for osteomyelitis with x-ray.
- II. Identify any underlying co-morbidities – diabetes, hypertension, hyperlipidemia or chronic infections.
- III. Review medication profile.
 - A. Optimize control of underlying comorbidities.
 - B. Identify medications that may impair wound healing.
- IV. Review vitals, including weight.

V. Wound documentation (document using the EMR Note Builder Template "Wound – Wound Care Assessment Form")

- A. Type of wound
- B. Location of wound
- C. Measurement of wound
 - 1. What is the size of the wound (measure in centimeters)?
 - a. Measure actual ulcer. Do not include the periwound in the measurement.
 - b. Measure the longest length (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
 - 3. Type
 - a. Serous – inflammatory phase of wound healing
 - b. Sanguineous – from bleeding
 - c. Purulent – from infection
 - 4. Consistency of drainage: thick or thin
- G. Note odor

Treatment of Wounds

Step 1: Cleanse the wound, then pat dry.

- A. Superficial wounds – cleanse with soap and water or use a commercial cleanser
- B. Deeper wounds – flush with 250cc's of normal saline or sterile water
- C. Do not use iodine or betadine as these are cytotoxic to healing skin.
- D. Do not soak the wound.

Step 2: Protect the periwound (skin surrounding the edges of the wound). Options include:

- A. Copolymer skin prep – do not use with silicone adhesive
- B. Hydrocolloid window padding
- 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 highly 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 10, section II.C. and D.)
 - 1. Silver infused sheets or gel for dry or moist wounds
 - 2. Silver with alginate for wet wounds
- E. Cadexomer iodine dressing (refer to Management of Infection on page 10, section II.C. and D.)
- F. Chemical debrider - collagenase for debridement of calloused and necrotic wounds (refer to Debridement on page 10, section IV.B.)

Step 4: Apply secondary dressing to wound bed. Options include:

- A. Gauze dressing – use with hydrogel, wet to moist dressings or chemical debrider
- B. Foam dressing – use with silver dressing or cadexomer iodine
- C. Hydrocolloid dressing – use with silver dressing or cadexomer iodine
- D. Permeable dressing – use with hydrogel, wet to moist dressing or chemical debrider

Debridement

I. Purpose

- A. Decreases bacterial load and reduces risk of infection, as devitalized material is a medium for infection and supports the growth of organisms that retard wound healing
- B. Increases effectiveness of topical treatments
- C. Decreases wound odor

II. Indication – for removal of necrotic tissue, debris, callus, foreign material, eschar and slough.

III. Contraindications

- A. Red, granular wounds
- B. Heel 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 with moisture-retentive dressing (example: Alginate dressings and hydrogel dressings)
 1. Indicated for non-infected wounds with necrotic tissue
 2. Advantages
 - a. Moist wound healing
 - b. Dressing changes are fast/easy and can be every 72 to 96 hours
 3. Disadvantage – patients often complain of odor.
 - B. Enzymatic debridement - uses prescribed enzymes to debride necrotic tissue with moisture –retentive dressing (example: collagenase with hydrocolloid dressing; do not use iodine or silver containing dressings as silver and iodine deactivates the collagenase)
 1. Indicated for infected and non-infected wounds with necrotic tissue
 2. Advantages
 - a. Moist wound healing
 - b. Dressing changes are fast/easy
 3. Disadvantage – dressing changes are up to BID to TID
 - C. Mechanical debridement - uses force to remove devitalized tissue (example: gauze (wet to moist) dressings)
 1. Advantages
 - a. Dressing changes are fast/easy
 - b. Decreases odor
 - c. Decreases drainage in highly exudative wounds
 2. Disadvantages
 - a. Nonselective debridement
 - b. Painful
 - c. Periwound maceration
 - 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: Existence of non-replicating bacteria within a wound. All chronic wounds are contaminated.
 2. Management: irrigate or cleanse with sterile water or normal saline
 - B. Colonization
 1. Description: Presence of replicating bacteria, but does not adversely affect the individual (no odor, no drainage).
 2. Management: irrigate or cleanse with sterile water or normal saline
 - C. Critical colonization
 1. Description: Theoretical point when the bacteria becomes a bioburden. Wound may start exuding serous fluid, have an odor and/or have friable or red granulation tissue.
 2. Management: Consider a wound culture using the Levine technique, and topical antimicrobial treatment (e.g. antimicrobial dressings such silver or cadexomer iodine dressings or triple antibiotic cream).
 - D. Infection
 1. Description: When bacteria invade the body tissue of the host. A wound culture will have bacterial levels greater than 10^5 organisms per gram. Wound healing becomes stalled or reverses. Wound will be warm to touch, edematous and erythematous. Bacteria may gain access to systemic circulation. Patient may start exhibiting systemic symptoms of infection.
 2. Management: Consider clinical work-up for infection (monitor vitals, obtain labs such as CBC and cultures via the Levine technique, and order appropriate x-rays if needed). Use appropriate systemic antibiotics plus topical antimicrobial treatment (e.g. antimicrobial dressings such silver or cadexomer iodine dressings or triple antibiotic cream).
 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 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.

Braden Scale For Predicting Pressure Sore Risk
 Located in the EMR Note Builder template as "Wound-Braden Scale"

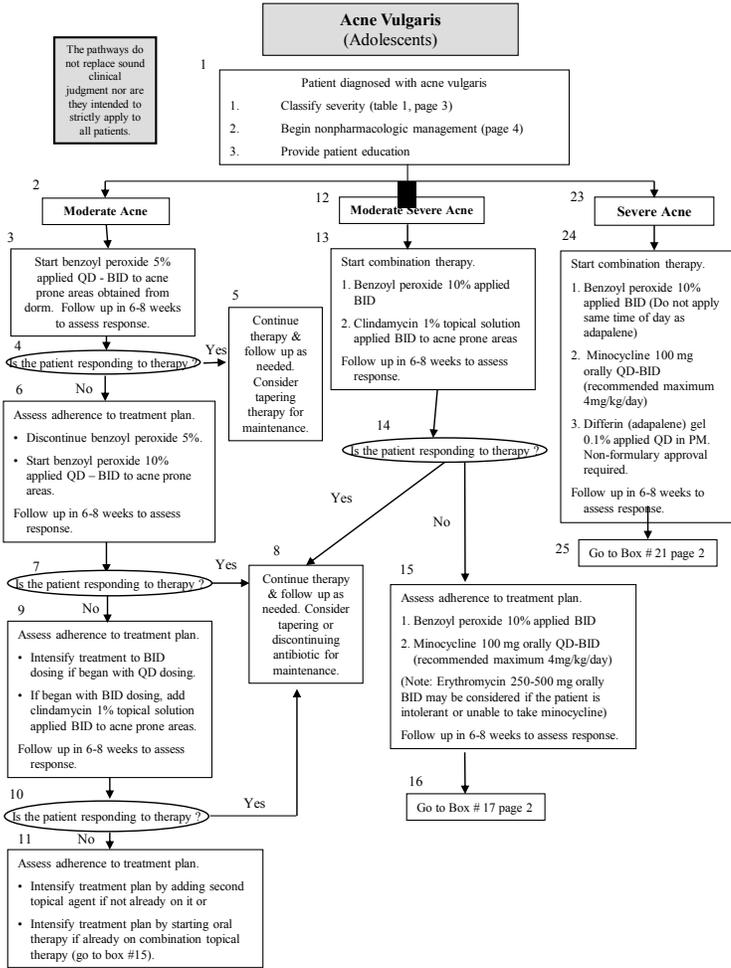
Directions: Assessment should be done upon intake, every clinic visit, and Chronic Care Clinic visit for high risk patients (defined on page 3).
 Note: Patients with a total score of 16 or less are considered to be at risk for developing pressure ulcers (15-16 = low risk, 13-14 = moderate risk, 12 or less = high risk).

	Date of Assessment			
Sensory Perception Ability to respond meaningfully to pressure-related discomfort.	1. Completely Limited. Unresponsive (does not moan, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation or limited ability to feel pain over most of body.	2. Very Limited. Responds only to painful stimuli. Can't communicate discomfort except by moaning or restlessness or has a sensory impairment which limits ability to feel pain or discomfort over ½ of body.	3. Slightly Limited. Responds to verbal commands, but can't always communicate discomfort or the need to be turned or has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities.	4. No Impairment. Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort.
Moisture Degree to which skin is exposed to moisture	1. Constantly Moist Skin is kept moist almost constantly by perspiration urine, etc. Dampness is detected every time patient is moved or turned.	2. Very Moist Skin is often, but not always moist. Linen must be changed at least once a shift.	3. Occasionally Moist Skin is occasionally moist requiring an extra linen change once a day.	4. Rarely Moist Skin is usually dry, linen only requires changing at routine intervals.
Activity Degree of physical activity	1. Bedfast. Confined to bed.	2. Chairfast. Ability to walk severely limited or non-existent. Can't bear own weight, and/or must be assisted into chair or wheelchair.	3. Walks Occasionally. Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.	4. Walks Frequently. Walks outside room at least twice a day & inside room at least once every 2 hours during waking hours.
Mobility Ability to change & control body position	1. Completely Immobile. Does not make slight changes in body or extremity position without assistance.	2. Very Limited. Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.	3. Slightly Limited. Makes frequent though slight changes in body or extremity position independently.	4. No Limitation. Makes major & frequent changes in position without assistance.
Nutrition Usual food intake pattern	1. Very Poor. Never eats a complete meal. Rarely eats more than 1/3 of food offered. Eats 2 servings or less of protein (meat or dairy) per day. Takes fluids poorly. Doesn't take a liquid dietary supplement or is NPO and/or maintained on clear liquids or IV for more than 5 days.	2. Probably Inadequate. Rarely eats a complete meal & generally eats only ½ of food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement or receives less than optimum amount of liquid diet or tube feeding.	3. Adequate. Eats over ½ of most meals. Eats a total of 4 servings of protein per day. Occasionally will refuse a meal, but will usually take a supplement when offered or is on a tube feeding or TPN regimen which probably meets most of nutritional needs.	4. Excellent Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat & dairy products. Occasionally eats between meals. Does not require supplementation.
Friction & Shear	1. Problem. Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair requiring frequent repositioning with maximum assistance. Spasticity, contractures or agitation leads to almost constant friction.	2. Potential Problem. Moves feebly or requires minimum assistance. During a move, skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down.	3. No Apparent Problem. Moves in bed and in chair independently & has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair.	
Total Score				

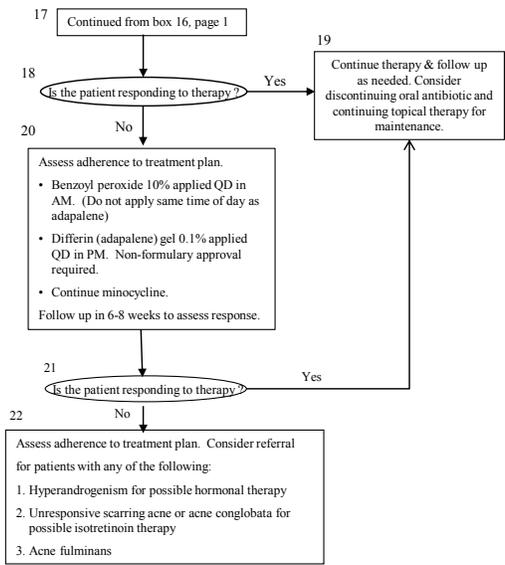
Patient Name: _____ TDCJ#: _____
 Date and time of evaluation: _____
 Admit Date: _____
 Patient Diagnosis: _____
 Braden Score: _____
 Location of Wound: 1. _____
 2. _____
 3. _____

DESCRIPTION OF WOUND	WOUND 1	WOUND 2	WOUND 3
SKIN AROUND WOUND			
Skin color around wound			
1. Normal			
2. Bright red or blanches to touch			
3. Dark red or purple, non-blanchable			
4. White or gray pallor, macerated			
5. Irritated, dermatitis or reaction			
Peripheral tissue edema (press 5 seconds)	WOUND 1	WOUND 2	WOUND 3
1. Minimal swelling around wound			
2. Non-pitting edema, skin shiny and taunt			
3. Pitting edema			
Peripheral tissue firmness (induration)	WOUND 1	WOUND 2	WOUND 3
1. Minimal firmness			
2. Cannot gently pinch tissue			
3. Firmness extends to surrounding tissue			
DRAINAGE OF THE WOUND			
Exudate type	WOUND 1	WOUND 2	WOUND 3
1. None			
2. Sanguinous (bloody)			
3. Serous (clear)			
4. Serosanguinous (watery pink)			
5. Purulent			
6. Odor			
Exudate amount	WOUND 1	WOUND 2	WOUND 3
1. None or dry wound tissue			
2. Scant or moist wound tissue			
3. Small or wet wound tissue			
4. Moderate or saturated wound tissue			
5. Large or draining obvious			

DESCRIPTION OF WOUND	WOUND 1	WOUND 2	WOUND 3
ARCHITECTURE OF UNHEALED WOUND			
Measurements in centimeters (cm)			
1. Length (vertical dimension) in cm			
2. Width (horizontal dimension) in cm			
3. Depth (deepest, do not include tunnel) in cm			
WOUND BED CHARACTERISTICS	WOUND 1	WOUND 2	WOUND 3
Necrotic type			
1. None visible			
2. Non-adherent yellow slough			
3. Loosely adherent yellow slough			
4. Adherent soft, eschar			
5. Firmly adherent, hard eschar			
Granulation tissue type	WOUND 1	WOUND 2	WOUND 3
1. Skin intact			
2. Bright, beefy red			
3. Pink or dull, dusky red			
4. Combination of #2 and #3			
5. Obscured			
Undermining/Tunneling Wound	Location of undermining/tunneling (use clock as reference)	Depth of tunnel in cm	
For example, right ischial wound with tunnel	Tunnel at 3 o'clock	3 cm	
GOALS	GOALS MET	NOT MET	
1. Facilitate granulation and re-epithelialization through use of clean technique during cleansing and dressing change			
2. Promote granulation tissue of wound bed			
3. Soften and remove non-viable tissue			
4. Patient will express understanding and importance of the educational information presented			
PLAN:			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			



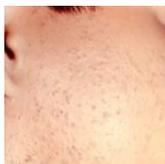
Prepared by the Correctional Managed Care Pharmacy and Therapeutics Committee. November 2006. Revised 10/09, 4/12, 1/14.



- I. Definitions
- A. Acne vulgaris – Disorder of the skin characterized by open or closed comedones. Inflammatory lesions may also be present such as papules, pustules or nodules. It commonly occurs on the face, arms, chest and back.
 - B. Closed comedones (whiteheads) – Sebaceous follicle plugged with sebum, dead cells and bacteria with a thin overlying epidermal membrane.
 - C. Open comedones (blackheads) – Sebaceous follicle plugged with sebum, dead cells and bacteria.
 - D. Acne conglobata – Chronic and severe form of acne vulgaris that is more common in males than females with a usual age of onset between 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 1.

Severity	Description
Mild	Comedones present. Small and few (<10) papules and pustules may be present.
Moderate	Moderate numbers of comedones (10-40) and papules and pustules (10-40) are present. Mild disease of the trunk may also be present.
Moderately Severe	Many comedones (40-200) and papules and pustules (40-100), occasional deeper nodular inflamed lesions (≤ 5). Widespread often involving the face and trunk.
Severe	Many comedones, papules, and pustules present. Nodulocystic acne and acne conglobata with many large and painful nodular or pustular lesions.



Mild acne



Moderate



Moderately severe



Severe

- IV. Management – Goals of therapy include controlling flares, decreasing lesions, and preventing scar formation. Acne may get worse with treatment before it gets better.

A. Non-pharmacologic Treatment

1. Gently wash skin twice a day with water and mild soap
2. Avoid scrubbing 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 2.

Agent	Dose	Adverse Effects	Comments
Benzoyl Peroxide 5-10%	Apply QD-BID	Skin irritation, erythema, dryness, scaling	Effective for inflammatory lesions. Bactericidal & mild keratolytic. May bleach clothing & bedding.
Clindamycin 1% Topical Solution	Apply BID	Skin irritation, may stain clothing	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.
Adapalene 0.1% gel (Differin®)	Apply q HS. May use every other day to minimize irritation	Skin irritation, erythema, dryness, scaling, photosensitivity	Non-formulary medication. Maximum response usually requires 12 weeks. Not recommended in pregnancy. Apply sparingly.

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 3.

Agent	Dose	Adverse Effects	Comments
Erythromycin	250mg - 500mg BID Best taken on an empty stomach or immediately before meals.	GI upset	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.
Minocycline	100mg QD-BID (recommended maximum 4mg/kg/day) May be taken with food.	Common: Dizziness, headache, fatigue, photosensitivity Rare, Serious: drug hypersensitivity syndrome, Stevens-Johnson syndrome, lupuslike syndrome, pseudotumor cerebri, cutaneous and/or mucosal hyperpigmentation	Do not use in pregnancy or children <8 years of age. Response may take 6 weeks and full effect may take up to 3 months.

Table 4.

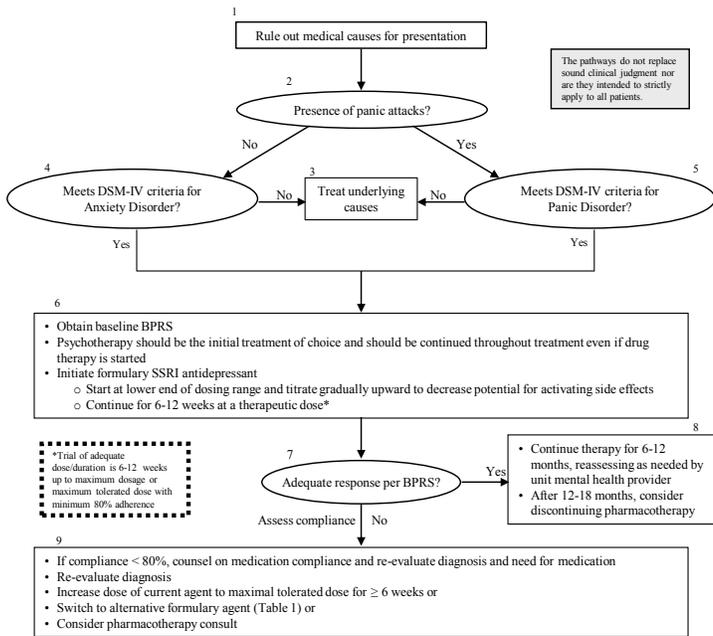
Agent	Dose	Adverse Effects	Comments
Isotretinoin* (Accutane®) Must enroll in iPLEDGE program to prescribe*	0.5 to 1 mg/kg day in 2 divided doses given with food for 15-20 weeks or until total cyst count decreases by 70%, whichever is sooner. If necessary, a second course may be offered after at least 8 weeks of completing first course.	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	<ul style="list-style-type: none"> •Nonformulary medication. •Relapse rates higher for patients < 16 years at initial treatment, for patients with very severe acne that involves the trunk, and for adult women. •Reserved for patients with severe acne that does not respond to combination oral and topical therapy. •Only treatment that leads to remission that may be permanent •Do not use in pregnancy
Oral Contraceptives	1 tablet QD	Nausea, weight gain, thrombosis, edema	<ul style="list-style-type: none"> •Consider for women with signs of hyperandrogenism, failed conventional therapy, or quickly relapse after isotretinoin. •Especially useful in patients that desire contraception or have irregular menstrual cycles or hirsutism. •Effects seen within 6 to 9 months •Do not use in pregnancy
Spironolactone	50 to 100mg QD	Teratogenic , drowsiness, GI upset, hyperkalemia	<ul style="list-style-type: none"> •May be added to oral contraceptive therapy if not effective after several months of therapy •Do not use in pregnancy

*Must meet and follow criteria in iPLEDGE program to prescribe. For more information go to www.ipledgeprogram.com or call 1-866-495-0654.

Patient Education

1. Cause of acne
2. Goals of Therapy
 - a. Decrease and/or resolve lesions
 - b. Control and/or prevent flares
 - c. Prevent scar formation
3. General Information
 - a. Acne is not the result of poor hygiene and excessive skin washing and scrubbing may actually worsen acne.
 - b. Face Washing: Gently wash affected areas with warm soapy water, rinse with warm water thoroughly, then use a final rinse with cool water. Do this twice a day in the morning and night as well as after heavy perspiration.
 - c. Blemishes and pimples should not be squeezed. This can worsen acne and lead to scarring.
 - d. Skin care: Do not pick or squeeze acne lesions. Remember that pimples are temporary, but picking lesions can result in scars and scars are permanent.
4. Treatment Plan
 - a. General information
 - Medications used to treat acne do not work immediately. It may take 6-8 weeks to see visible improvements and may take up to 3 months to see maximum effects with some treatments.
 - Acne may get worse with treatment before it gets better.
 - Topical medications should be applied to dry skin, applied sparingly (pea-size amount is usually sufficient to cover the face), and should be applied to all acne prone areas and not just visible blemishes.
 - Certain medications (e.g., adapalene, isotretinoin, certain oral antibiotics) may increase the patient's risk for sunburns. Avoiding excessive exposure to sunlight is recommended.
 - Shampoo hair regularly. If hair is oily, wash hair daily.
 - Avoid greasy hair-care products. Oily hair-care products such as oil-containing gels and pomades, can drip onto skin and clog pores.
 - Water-based lotions and cosmetics are less comedogenic than oil-based products.
 - Wet face prior to shaving and shave lightly.
 - b. Information on specific therapy prescribed
5. Importance of Adherence

ANXIETY and PANIC DISORDER
(Adolescents)



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

Drug Class	Generic Name	Brand Name	Initial Dose (Dose Range) mg/day	Monitoring
Selective Serotonin Reuptake Inhibitors (SSRIs)	Citalopram 20mg, 40mg tablet	Celexa®	20 (20 – 40)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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.

Brief Psychiatric Rating Scale (BPRS)

Patient Name _____ Patient Number _____ Date _____

Facility _____ Practitioner _____

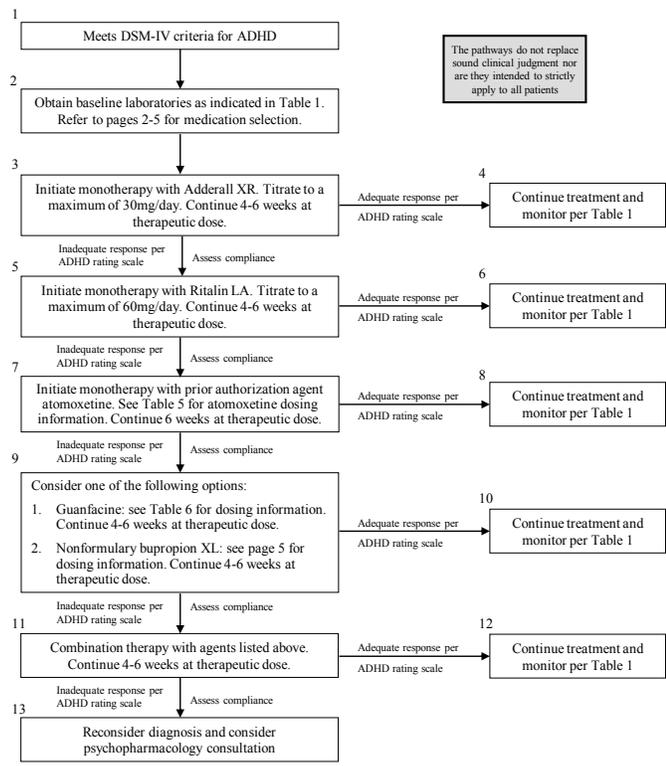
Enter the score for the term that best describes the patient's condition.

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.

**ATTENTION DEFICIT HYPERACTIVITY DISORDER
(Adolescents)**



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, 1/30/12, 2/11/13.

Table 1: Monitoring Guidelines

Parameter Frequency	Baseline	Each Visit
ADHD rating scale ¹	X	X
Height, weight, BMI	X	X
Blood pressure & pulse	X	X
EKG ²	As clinically indicated	

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

Generic Name	Brand Name	Form	Strengths
Mixed amphetamine salts	Adderall®	Tablet	5mg, 10mg
	Adderall XR®	Capsule	10mg, 20mg, 30mg
Methylphenidate	Ritalin®	Tablet	5mg, 10mg
	Ritalin LA®	Capsule	10mg, 20mg, 30mg, 40mg
Guanfacine	Tenex	Tablet	1mg, 2mg

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

Vyvanse	Focalin XR	Ritalin LA	Concerta	Ritalin IR	Daytrans Transdermal	Dexedrine	Adderall IR	Adderall XR
Lisdexamfetamine	Dex-MPH	MPH	MPH	MPH	MPH	Dextro-amphetamine	MAS	MAS
NF	NF	F	NF	F	NF	NF	F	F
20 mg	*	*	18 mg	10-15mg	10-15mg	5-10mg	5-10mg	10mg
30 mg	5 mg	10 mg	18-27 mg					
40 mg	5-10 mg	10-20 mg	27-36 mg	20-30mg	20mg	15-20mg	15-20mg	20mg
50 mg	10-15 mg	20-30 mg	36- 45 mg					
60 mg	20 mg	30-40 mg	45- 54 mg	30-45mg	30mg	20-30mg	20-30mg	30mg

*MPH: Methylphenidate
 MAS: Mixed amphetamine salts
 NF: Non-formulary
 F: Formulary

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

Generic Name	Brand Name	Form	Strength	Prior Authorization Criteria
Atomoxetine	Strattera®	Capsule	25mg, 40mg, 60mg, 80mg, 100mg	ADHD and <ul style="list-style-type: none"> • Failure on adequate dose and trial of both formulary stimulants • Intolerance to both formulary stimulants • Contraindication to use of both formulary stimulants • Significant history of substance abuse • Comorbid anxiety disorder

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

Atomoxetine Dosing	Weight ≤ 70 kg	Weight > 70 kg
Starting dose	0.5mg/kg/day x 3 days	40mg/day x 3 days
Target dose	1.2mg/kg/day	80mg/day
Max dose	1.4mg/kg/day or 100mg/day, whichever is less	100mg/day

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

Week	Weight < 45kg		Weight > 45kg	
	Clonidine <i>(Nonformulary)</i>	Guanfacine <i>(Formulary)</i>	Clonidine <i>(Nonformulary)</i>	Guanfacine <i>(Formulary)</i>
Baseline				
1-2	0.05mg q HS	0.5mg q HS	0.1mg q HS	1mg q HS
2-4	0.05mg BID	0.5mg BID	0.1mg BID	1mg BID
3-6	0.05mg TID	0.5mg TID	0.1mg TID	1mg TID
4-8	0.05mg QID	0.5mg QID	0.1mg QID	1mg QID

Total daily dose ranges:

- Clonidine 0.05-0.4 mg/day
- Guanfacine 0.5-4 mg/day

Student Name: _____ Student Number: _____ DOB: _____

Completed by: _____ Date Completed: _____ Facility: _____

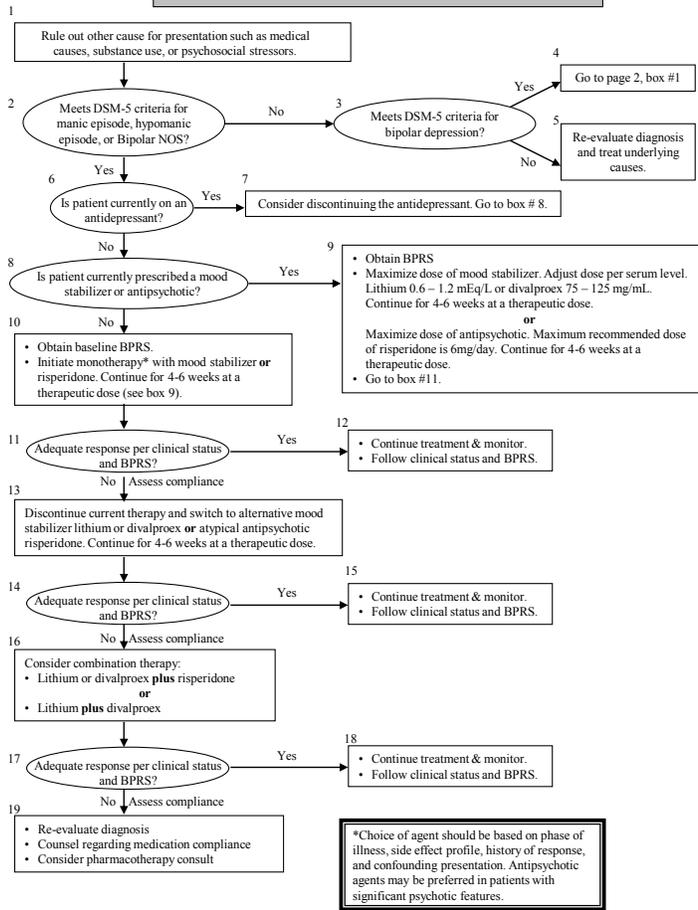
INATTENTION		Not at all	Just a little	Pretty Much	Very Much
1.	Fails to pay attention to details or makes careless errors.				
2.	Doesn't stay on task for school work or chores.				
3.	Doesn't listen when spoken to directly.				
4.	Doesn't follow through on instructions.				
5.	Has difficulty organizing task or activities.				
6.	Often avoids or dislikes activities that require sustained mental effort.				
7.	Often loses things necessary for tasks or activities.				
8.	Is often easily distracted by things around him/her.				
9.	Is often forgetful in daily activities.				
TOTAL					

IMPULSIVITY/HYPERACTIVITY		Not at all	Just a little	Pretty Much	Very Much
1.	Often fidgets with hands or feet or squirms in seat.				
2.	Often leaves seat in classroom or other situations in which it is inappropriate.				
3.	Often runs about or climbs excessively in situations in which it is inappropriate.				
4.	Has difficulty playing or engaging in leisure activities quietly.				
5.	Is often "on the go" or acts as if "driven by a motor"				
6.	Often talks excessively.				
7.	Often blurts out answers before questions have been completed.				
8.	Often has difficulty awaiting turn.				
9.	Often interrupts or intrudes on others.				
TOTAL					

OPPOSITIONAL BEHAVIOR		Not at all	Just a little	Pretty Much	Very Much
1.	Often loses temper.				
2.	Often argues with adults.				
3.	Often actively defies adults' requests or rules.				
4.	Often deliberately annoys people, peers refuse to play with him/her because he/she does mean or silly things.				
5.	Often blames others for his/her mistakes.				
6.	Is often touchy or easily annoyed by others.				
7.	Is often angry or resentful for long periods of time.				
8.	Often does mean or spiteful things to others.				
TOTAL					

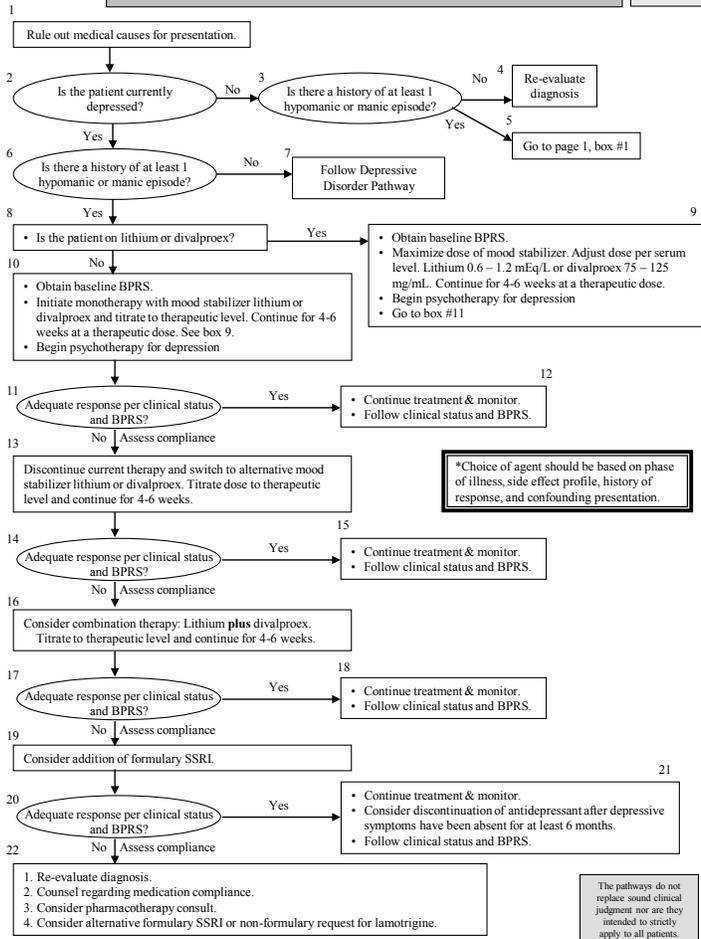
COMMENTS: _____

BIPOLAR DISORDER ADOLESCENTS: MANIA



*Choice of agent should be based on phase of illness, side effect profile, history of response, and confounding presentation. Antipsychotic agents may be preferred in patients with significant psychotic features.

Prepared By The Texas Youth Commission October 2001. Revised 5/02, 2/04, 3/06. Youth Services Pharmacy and Therapeutics Committee. Revised 10/10, 4/12, 4/15.



It is important to rule out other causes of behavior changes before diagnosing bipolar disorder.

- Adjustment disorder
- Drug-induced including drug and/or alcohol misuse
- General medical condition (e.g., stroke, hyperthyroidism, hypothyroidism, Cushing's syndrome)
- Other psychiatric disorder (e.g., depression, ADHD)
- Traumas such as sexual, emotional and physical abuse if the patients exhibits disinhibition, hypervigilance or hypersexuality.
- Bipolar disorder should not be diagnosed solely on the basis of a depressive episode in an adolescent with a history of depression or a family history of bipolar disorder

The DSM-5 criteria used to diagnose adults may be used when diagnosing adolescents:

- A distinct period of abnormally and persistently elevated, expansive or irritable mood and persistently increased goal directed activity or energy, lasting at least 1 week and present most of the day, nearly every day
- During the period of mood disturbance and increased energy or activity, 3 or more of the following symptoms are present to a significant degree and represent a noticeable change from usual behavior (4 if the mood is only irritable):
 1. inflated self-esteem or grandiosity
 2. decreased need for sleep
 3. more talkative than usual or pressure to keep talking
 4. flight of ideas or subjective experience that thoughts are racing
 5. distractibility
 6. increase in goal-directed activity or psychomotor agitation
 7. excessive involvement in pleasurable activities that have a high potential for painful consequences

DSM-5 criteria should be used when making a diagnosis of bipolar in children and adolescents. The diagnosis should be updated as necessary with use of appropriate episode specifiers (e.g., most recent episode manic, depressed, mixed, etc.) including severity/psychotic/remission specifiers (e.g., mild, moderate, severe with psychotic features, partial remission, full remission).

- Bipolar I Disorder – criteria have been met for at least 1 manic episode and the occurrence of the manic and major depressive episode is not better explained by another psychotic disorder
- Bipolar II Disorder – criteria have been met for a current or past hypomanic episode and a current or past major depressive 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.

Table 1: Formulary Agents

Drug Class	Generic Name	Brand Name	Form	Strength
Antimanic	Lithium carbonate	Eskalith® Cibalith-S®	Capsule Syrup	300mg 300mg/5ml
Anticonvulsant	Divalproex Sodium	Depakote®	EC Tablet	250mg, 500mg
Anticonvulsant	Carbamazepine	Tegretol®	Tablet	200mg
Antipsychotic	Risperidone	Risperdal®	Tablet	0.5mg, 1mg, 2mg, 3mg, 4mg

Table 2: Prior Authorization Agents

Drug Class	Generic Name	Brand Name	Form	Strength	Prior Authorization Criteria
Antipsychotic	Aripiprazole	Abilify®	Tablet	2mg, 5mg, 10mg, 15mg, 20mg, 30mg	<ul style="list-style-type: none"> • Intolerant to formulary 2nd generation AP • Treatment failure on formulary 2nd generation AP • Contraindication to formulary 2nd generation AP BMI >90%
Antipsychotic	Ziprasidone	Geodon®	Capsule	20mg, 40mg, 60mg, 80mg	

Lithium General Information

Therapeutic effects of lithium are seen 10-14 days after a therapeutic level has been achieved. It may take up to 6 weeks to see full effects of a given dosage. Laboratory measures and serum lithium levels should be reassessed quarterly during maintenance treatment. 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. **NSAIDs (e.g., ibuprofen) should be not be used in combination with lithium if possible due to a 15-30% increase in serum lithium level.** The lithium serum level should be obtained immediately before the next dose and at least 12 hours after the last dose. A therapeutic serum level is 0.6 to 1.2 mEq/L.

Common side effects: sedation, thirst, urinary frequency

Other side effects: hypothyroid, confusion, toxicity, acne, increased WBC's

Table 3: Frequency of Lithium Monitoring

Parameter	Baseline	4 weeks	Every 3 Months	Every 6 Months
EKG*	As clinically indicated			
CBC, BUN/Cr, Electrolytes, TSH	X			X
Initial Lithium levels	5-10 days after each dose change			
Maintenance Lithium levels		X	X	

*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 1,000mg/day, whichever is smaller. At baseline, CBC, liver function tests, and platelet counts should be obtained. Dose may be titrated on a weekly basis until 12-hour post-dose serum concentrations reach 75 to 125 mg/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 4: Frequency of Divalproex Monitoring

Parameter	Baseline	1 month	2 months	Every 6 Months	Every 12 months
CBC with differential	X	X	X	X	
LFTs	X	X	X		X
Platelet	X				X
Initial divalproex levels	1-3 weeks after each dose change				
Maintenance divalproex levels			X		X

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.

Common side effects: drowsiness, increased appetite, fatigue, abdominal pain, heart burn, bowel changes, weight gain

Rare side effects: abnormal movements, gynecostasia, galactorrhea

Table 5: Risperidone Titration

	Risperidone	Day 1-4	Day 5-8	Day 9-12
Upward Titration	Daily Dose	0.5-1 mg	1.5-2 mg	3-4 mg
	Divide:	Single Dose or 0.5/0.5	Single Dose or 0.5-1/1	Single Dose or 1-2/2

Table 6: Antipsychotic Monitoring Parameters

Parameter Frequency	Baseline	4 weeks	8 weeks	12 weeks	6 Months	Annually
Personal Family History	X					X
Weight-Height-BMI (overweight 25.0-29.9; obese \geq 30.0)	X	X	X	X	X	X
Blood Pressure, Pulse	X			X	X	X
Fasting Plasma Glucose	X			X	X	X
Fasting Lipid Profile	X			X	X	X
CBC, LFT, BUN/Cr, Electrolytes	X			X	X	X
AIMS	X			X		X
TSH	X	As clinically indicated				
HgbA1c	X	As clinically indicated				
EKG ¹	As clinically indicated					
Prolactin ²	As clinically indicated					

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

- Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease.
- Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunction.
 - Routine screening for hyperprolactinemia is **not** recommended unless symptoms are present
 - The normal range of prolactin is 10-20mcg/L in males and 10-25mcg/L in females
 - Symptoms typically do not appear until levels reach 60-100mcg/L
 - Patients should be referred to medical to rule-out other etiologies of hyperprolactinemia

Lamotrigine General Information

The 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 \geq 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 should be taken in combination with divalproex by using one half the starting dose and monitoring levels.

Table 7

Drug: Daily Dose Range	Contraindications	Toxicity Seen Starting At Trough Serum Levels of:	Signs & Symptoms of Toxicity (dose-related)	Signs & Symptoms of Toxicity (NOT dose-related)
<p>Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses.</p> <p>Target level: 0.6 – 1.2 mEq/L</p> <p>Doses should not generally exceed 1200mg/day</p>	<ul style="list-style-type: none"> Hypersensitivity to lithium Severe cardiovascular or renal disease Severe debilitation Dehydration Sodium depletion Pregnancy Category D 	<p>> 1 – 1.2 mmol/L</p> <p>Patients who are sensitive to lithium may manifest toxicity at serum levels < 1 mmol/L.</p> <p><i>Note: A rise in white blood cell count is to be expected.</i></p>	<p>Lithium toxicity can be FATAL</p> <p>Acute:</p> <ul style="list-style-type: none"> Apathy Coarsening hand tremor that spreads to other parts of body while patient sitting still Confusion Drowsiness Dysarthria GI symptoms (diarrhea, N & V, etc.) Giddiness <p>Acute To Severe:</p> <ul style="list-style-type: none"> Blurred vision Deep tendon reflexes increased Muscle rigidity / fasciculations Mild ataxia Profound lethargy Tinnitus Vertical nystagmus Vomiting <p>Severe Intoxication:</p> <ul style="list-style-type: none"> Arrhythmias Impaired consciousness Increase in fasciculations and ataxia CV collapse with oliguria and anuria Coarse / irregular limb tremors Coarse muscle contractions Choreoathetoid movements Cogwheel rigidity Coma Generalized tonic-clonic seizures 	Not applicable
<p>Divalproex Sodium: 20mg/kg/day or 1,000mg/day given in divided doses up to 60mg/kg/day</p> <p>Target level: 75-125mg/mL</p>	<ul style="list-style-type: none"> Hypersensitivity to valproate Hepatic dysfunction Urea cycle disorder Pregnancy Category D 	> 100 – 125 mcg/mL	<ul style="list-style-type: none"> Somnolence Lethargy Mental status change Coma Hyperbilirubinemia Hepatotoxicity Heart block Vomiting Thrombocytopenia Prolongation of bleeding time Alopecia 	<ul style="list-style-type: none"> Pancreatitis – Do not rechallenge Hyperammonemic encephalopathy Hepatotoxicity, severe or fatal Stevens-Johnson Syndrome Toxic epidermal necrolysis Polycystic ovarian syndrome
<p>Lamotrigine: Dosing depends on concomitant drug therapy due to drug interactions</p>	<ul style="list-style-type: none"> Hypersensitivity to lamotrigine Pregnancy Category C 	Therapeutic plasma concentration has not been established.	<ul style="list-style-type: none"> Rash, maculopapular and erythematous Tourette's syndrome Blood dyscrasias 	<ul style="list-style-type: none"> Fever Lymphadenopathy Multi-organ dysfunction Stevens-Johnson Syndrome Toxic epidermal necrolysis

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.

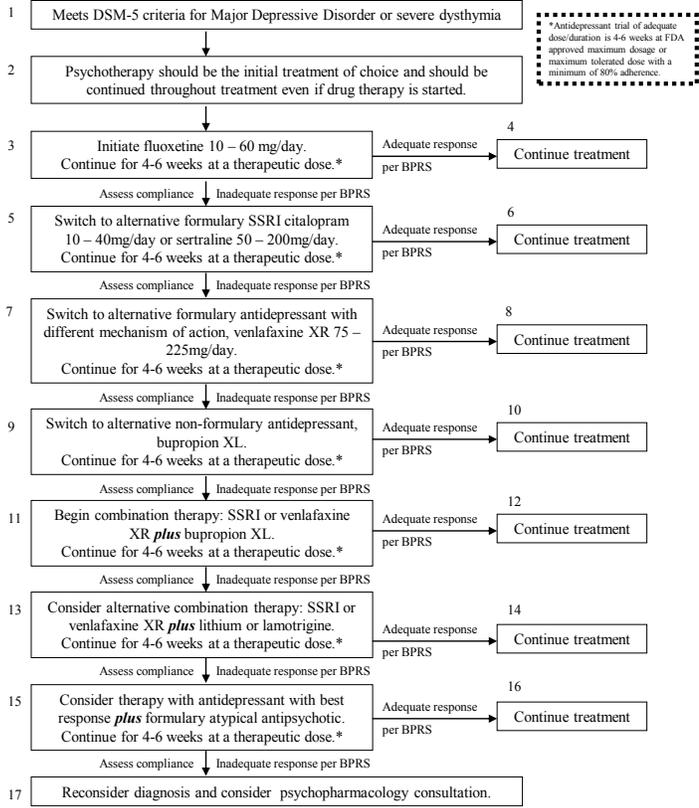
0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

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.

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

DEPRESSIVE DISORDERS (Adolescents)



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. Revised by Youth Services Pharmacy & Therapeutics Committee 7/10, 8/11, 4/12, 1/15 (note: original pathway developed by TDCJ Pharmacy & Therapeutics Committee 4/98, revised 7/98 then as above by TYC)

Medication Selection

Patients should be evaluated for use of formulary agents 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: Formulary Agents

Drug Class	Generic Name	Brand Name	May Consider First If	Initial Dose (Dose Range) mg/day	Monitoring
Selective Serotonin Reuptake Inhibitor (SSRI)	Citalopram 20mg, 40mg tablet	Celexa®	Atypical features or dysthymia	20 (20 – 40)	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present
	Fluoxetine 10mg, 20mg capsule	Prozac®	Atypical features or dysthymia	20 (20 – 60)	
	Sertraline 25mg, 50mg, 100mg tablet	Zoloft®	Significant anxiety	50 (50 – 200)	
Serotonin Norepinephrine Reuptake Inhibitor (SNRI)	Venlafaxine XR 75mg, 150mg capsules	Effexor XR®		75 (75-225)	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Blood pressure and pulse
Other*	Trazodone 50mg, 100mg tablet	Desyrel®	Atypical features or dysthymia	100 – 150 (300 – 600)	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Priapism

*Not recommended as first line or second line therapy for treatment of depression in children or adolescents

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.

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 0.6 to 1.2 mEq/L.

Common side effects: sedation, thirst, urinary frequency

Other side effects: hypothyroid, confusion, toxicity, acne, increased WBCs

Table 2: Frequency of Lithium Monitoring

Parameter	Baseline	4 weeks	Every 6 months
EKG	As clinically indicated		
CBC, Scr, BUN, Electrolytes, TSH	X		X
Lithium level		X	X

*Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease

Monitoring Parameters for Antipsychotics

Table 3: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents in Children and Adolescents

Parameter & Frequency	Baseline	4 weeks	8 weeks	12 weeks	6 Months	Annually
Weight, Height, BMI (overweight 25.0-29.9; obese \geq 30.0)	X	X	X	X	X	X
Blood Pressure, Pulse	X			X	X	X
Fasting Plasma Glucose	X			X	X	X
Fasting Lipid Profile	X			X	X	X
CBC, LFT, BUN/Cr, Electrolytes	X			X	X	X
TSH	X	As clinically indicated				
EKG ¹	As clinically indicated					
Prolactin ²	As clinically indicated					

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

- Providers should consider obtaining an EKG at baseline and periodically when there is a personal or family history of cardiovascular disease.
- Providers should consider obtaining a prolactin level if the patient is complaining of gynecomastia, galactorrhea, irregular or absent menses, or sexual dysfunction.
 - Routine screening for hyperprolactinemia is **not** recommended unless symptoms are present
 - The normal range of prolactin is 10-20mcg/L in males and 10-25mcg/L in females
 - Symptoms typically do not appear until levels reach 60-100mcg/L
 - Patients should be referred to medical to rule-out other etiologies of hyperprolactinemia

Table 4: Adverse Effect Monitoring

Assessment	Baseline	Follow-up
AIMS (Abnormal Involuntary Movement Scale) •Acute EPS – Akathisia, dystonia, pseudoparkinsons •Tardive Dyskinesia	X	Baseline, at 3 months, then annually

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.

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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.

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- ___ 1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.
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TYPE 1 DIABETES MELLITUS
(Children & Adolescents)

- 1. Institute Lifestyle Modifications & Group/Individual Education with Specific Patient Goals**
- 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.
 - Obtain fasting lipid profile at baseline after glycemic controlled achieved if
 - ≥ 10 years:
 - If normal (LDL <100mg/dl), repeat every 5 years.
 - 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 if no contraindications – Table 8) if
 - LDL ≥130mg/dl and patient has at least 1 cardiovascular risk factor.
 - LDL ≥160mg/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. If abnormal, recheck annually. Statins not recommended in children < 10 years of age.
 - Determine if blood pressure 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 (Refer to Table 8 for ACEI contraindications). Refer to Hypertension disease management guidelines for children & adolescents.
 - 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* if microalbuminuria present (Enalapril 2.5mg QD) and obtain creatinine and estimate GFR annually.
 - Institute lifestyle modifications (i.e., exercise, diet, smoking cessation and weight loss) if BMI >80th percentile.
 - Administer annual influenza vaccine. If pneumococcal vaccine was not previously given in their lifetime, administer one time only.
 - Refer to Dental for oral/periodontal disease evaluation within 30 days from the initial chronic care visit if not completed at intake.
 - 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 (See Table 9).
• Obtain fasting finger sticks 3 times a day before meals and at bedtime for 2 weeks.
• Follow up in 2 weeks.**
- * If intolerant to ACE-inhibitor, obtain microalbumin annually. If microalbumin > 30, consider non-dihydropyridine CCB (verapamil or diltiazem)

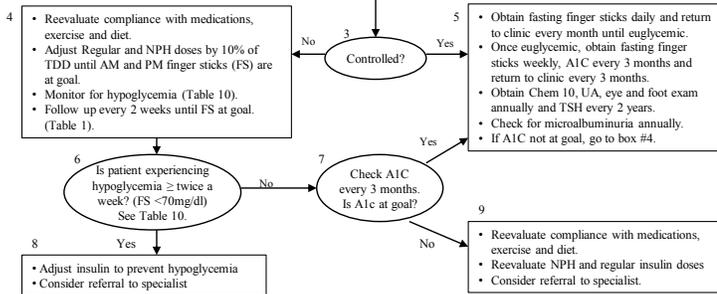


Table 1: Glycemic Control Goals

Age	Premeal BG	Bedtime/Overnight BG	A1C	Consider Action
6-12 yrs	90-180	100-180	< 8%	Glucose < 90 or > 180 and/or A1C >8%
13-19 yrs	90-130	90-150	< 7.5%	Glucose < 90 or > 150 and/or A1C >8%

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, November 2006, Revised 11/07, 4/11, 5/13

TYPE 2 DIABETES MELLITUS (Children & Adolescents)

Diabetes Page 2

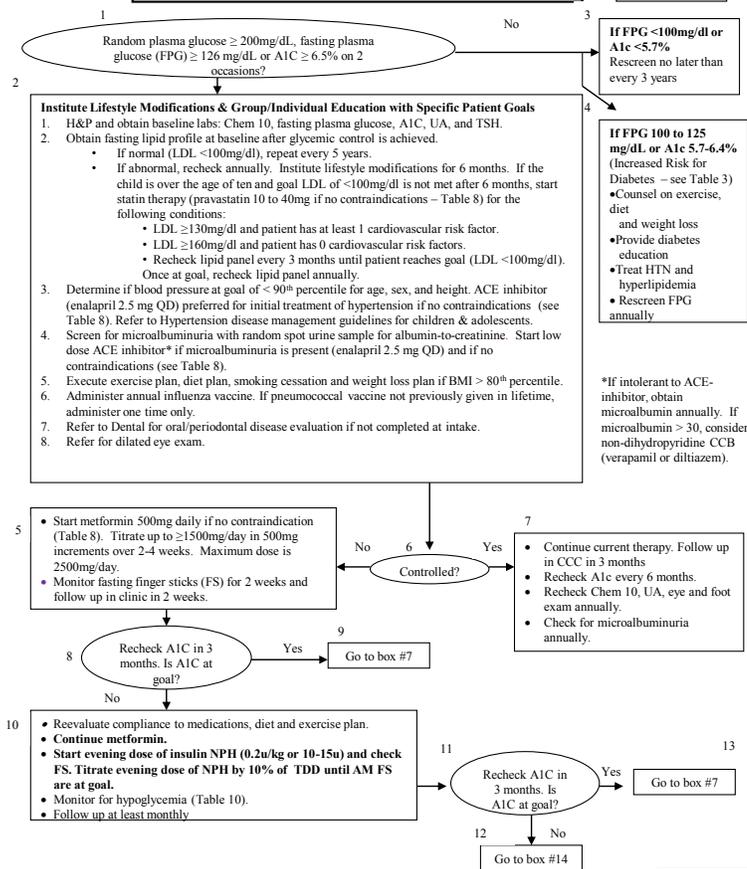
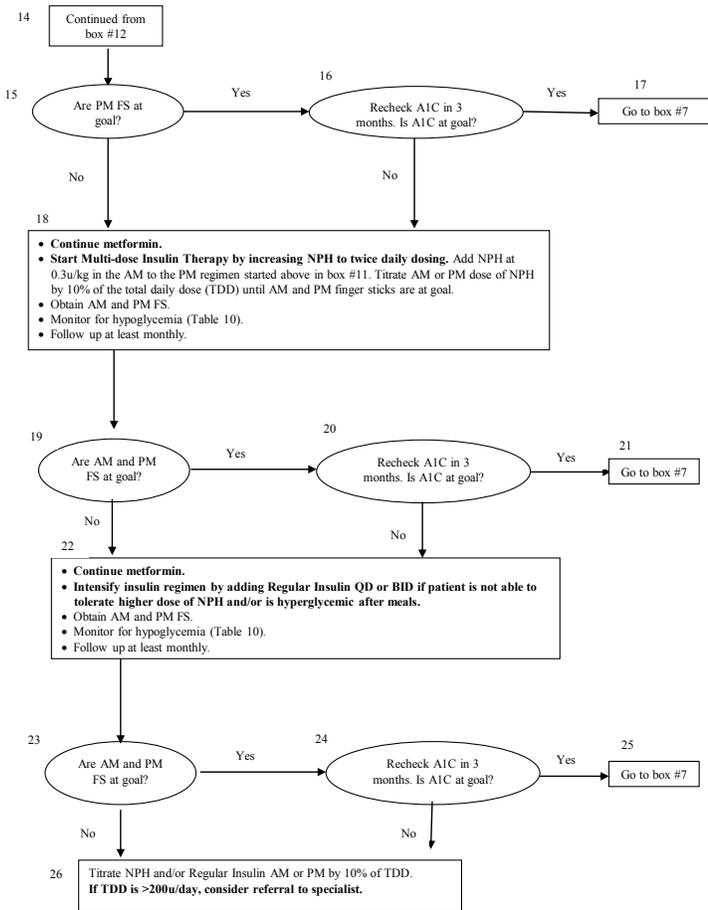


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Prepared by The Correctional Managed Care Pharmacy and Therapeutics Committee, November 2006. Revised 11/07, 4/11, and 5/13.

- 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 2: Screening Criteria

Criteria	Findings
Overweight	BMI > 85th percentile for age and sex, > 85th percentile weight for height, or weight > 120% of ideal for height
Plus any two of the following risk factors	<ul style="list-style-type: none"> • Family history of type 2 diabetes in first or second-degree relative • Race/ethnicity – Native American, African American, Latino, Asian American, Pacific Islander • Signs of insulin resistance or conditions associated with insulin resistance (e.g., acanthosis nigricans, hypertension, dyslipidemia, polycystic ovarian syndrome, or small-for-gestational age birth weight) • Maternal history of diabetes or gestational diabetes

- 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

FPG	100 – 125mg/dl
2-hr plasma glucose on the 75g OGTT	140-199mg/dl
A1c	5.7-6.4%

V. Diagnosis

- A. Most children with type 1 diabetes present with a short duration of symptoms (several week history) such as polyuria, polydipsia, polyphagia, weight loss, hyperglycemia, glycosuria, ketonemia, and/or ketonuria.
- B. Most children with type 2 diabetes are overweight or obese and present with glycosuria without ketonuria, absent or mild polyuria and polydipsia, and little or no weight loss. They are usually diagnosed after the age of 10 and in middle to late puberty with a family history of diabetes. Acanthosis nigricans and polycystic ovarian syndrome are common.
- C. Diagnostic criteria (Table 4)
 1. If the patient is asymptomatic and if random plasma glucose is ≥ 200 mg/dl, FPG is ≥ 126 mg/dl, or 2-hr plasma glucose ≥ 200 mg/dl, results should be confirmed with a second test on a different day for confirmation.
 2. If the patient is symptomatic and random plasma glucose is ≥ 200 mg/dl, diagnosis does not require a repeat value on another day.
 3. A1c $\geq 6.5\%$. Confirmation by repeat testing preferred. A1C may not be an effective test in special patient populations with affected hemoglobin disorders

Table 4: Diagnostic Criteria

Criteria	Findings
Symptoms of diabetes	Symptoms of diabetes and plasma glucose ≥ 200 mg/dl
Fasting plasma glucose (FPG)	FPG ≥ 126 mg/dl with no caloric intake within last 8 hours
Oral glucose tolerance test (OGTT) 2-hr plasma glucose	2-hr plasma glucose ≥ 200 mg/dl during OGTT.
Hemoglobin A1C	A1C $\geq 6.5\%$

VI. Evaluation

- A. Medical history
 1. Age and characteristics of diabetes onset (e.g. DKA, asymptomatic lab findings)
 2. Symptoms of diabetes
 3. Recent or current infection or illnesses
 4. Growth records & weight history
 5. Eating, diet, and exercise patterns
 6. Family history of diabetes
 7. Risk factors for atherosclerosis such as smoking, hypertension, obesity, dyslipidemia, and family history
 8. Previous management of diabetes
 9. Previous episodes of ketoacidosis and hypoglycemia
 10. Previous testing or treatment of chronic diabetes complications
 11. Medications that may affect glucose levels (e.g. atypical antipsychotics, steroids)
 12. Social history – alcohol, tobacco, and recreational drug use
 13. Review of systems should include gastrointestinal function (including symptoms of celiac disease) and symptoms of other endocrine disorders such as hypothyroidism and Addison's disease

- 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

Test	Frequency of Monitoring
Fasting plasma glucose	<ul style="list-style-type: none"> • Baseline • As clinically indicated to monitor/adjust medications
A1C*	<ul style="list-style-type: none"> • Baseline • Every 6 months if stable and meeting treatment goals • Every 3 months if not meeting treatment goals
Fasting lipid profile	<ul style="list-style-type: none"> • At baseline, after glycemic control is achieved • Type 1 diabetes <ul style="list-style-type: none"> ○ ≥ 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 if no contraindications – Table 8) if <ul style="list-style-type: none"> ▪ LDL ≥ 130mg/dl and patient has at least 1 cardiovascular risk factor ▪ LDL ≥ 160mg/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 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 diabetics). 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 A1C (see Table 1 for goals).
 2. Decrease risk for acute and chronic complications of diabetes
 3. Maintain normal growth and weight
 4. Control of co-morbidities such as hypertension and hyperlipidemia
- B. Annual influenza vaccination. If pneumococcal vaccine not previously given in their lifetime, administer one time only.
- C. Microalbuminuria - ACE inhibitor preferred for patients with persistently elevated microalbuminuria (refer to Table 6).

Table 6: Definition of abnormalities in albumin excretion

Category	Spot collection ($\mu\text{g}/\text{mg}$ of creatinine)
Normal	< 30
Microalbuminuria	30-299
Macroalbuminuria (clinical)	≥ 300

- 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 7: Treatment of Hyperlipidemia

Value	Management*	Goal
LDL 100-129mg/dl	<ul style="list-style-type: none"> • Optimize glycemic control and initiate lifestyle changes including diet, weight loss if overweight and exercise 	LDL < 100mg/dl
LDL 130-150mg/dl plus 1 cardiovascular risk factor	<ul style="list-style-type: none"> • Optimize glycemic control and initiate lifestyle changes including diet, weight loss if overweight and exercise • Consider drug therapy based on patient's risk factors for CVD if goal LDL not met after 6 months of lifestyle changes. 	LDL < 100mg/dl
LDL > 160mg/dl	<ul style="list-style-type: none"> • Optimize glycemic control and initiate lifestyle changes including diet, weight loss if overweight and exercise • Initiate drug therapy with statin agent if not contraindicated (refer to table 8) if goal LDL not met after 6 months of lifestyle changes. 	LDL < 100mg/dl

*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 ($BG \geq 200\text{mg/dl}$ 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

Drug	Dose	Comments
Metformin	500mg qd-bid Max 2500mg/day	<ul style="list-style-type: none"> Contraindications: Impaired renal function, radiocontrast media, hypoxemic conditions, hepatic disease, metabolic acidosis, hypersensitivity to metformin Pregnancy category B
Insulin	0.5 to 1 units/kg/day	<ul style="list-style-type: none"> Contraindication: Hypersensitivity to insulin Insulin requirements may decrease in newly diagnosed patients during the honeymoon phase Insulin requirements may increase during puberty to as much as 1.5 units/kg/day Pregnancy category B
Enalapril	2.5mg qd Max 40mg/day	<ul style="list-style-type: none"> Contraindications: ACE-inhibitor induced angioedema, hereditary or idiopathic angioedema, pregnancy, hypersensitivity to enalapril or other ACE inhibitors Pregnancy category D
Pravastatin	Max 80mg/day • 10-13 years – 20mg/day • 14-18 years - 40mg/day	<ul style="list-style-type: none"> Contraindications: Active liver disease, unexplained persistent elevations of serum transaminases, pregnancy, hypersensitivity to statins or any component of the formulation Pregnancy category X

Table 9: Pharmacokinetics of Insulin*

Insulin	Onset of Action	Peak Action	Effective Duration
Regular Insulin	30 to 60 min	2 to 3 hours	8 to 10 hours
NPH Insulin	2 to 4 hours	4 to 10 hours	12 to 18 hours
70/30 Insulin	30 to 60 min	3 to 12 hours	8 to 18 hours

*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:

- 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
- 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

Recommendations	Comment
Glucose 15-20g	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.
Glucagon	Treat individuals at significant risk of severe hypoglycemia
Hypoglycemia Unawareness	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.

Table 11: Correlation of A1C with average glucose

A1c (%)	Mean plasma glucose	
	Mg/dl	Mmol/L
6	126	7.0
7	154	8.6
8	183	10.2
9	212	11.8
10	240	13.4
11	269	14.9
12	298	16.5

Table 12: Sample Regular Insulin Sliding Scale

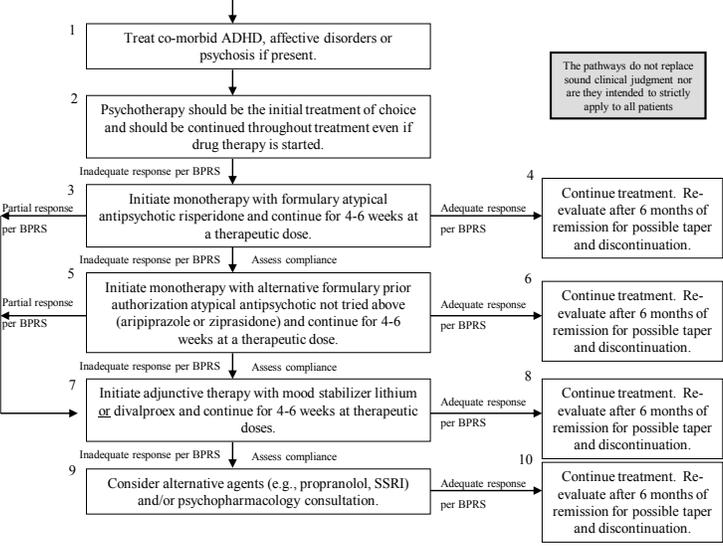
Blood glucose range (mg/dl)	Units of regular insulin to be administered
150-200	2
201-250	4
251-300	6
301-350	8
351-400	10
401-451	12
>500	Check for ketones. Contact unit provider.

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 dietitians will provide counseling on diet and how to choose the correct foods from the meal line, otherwise, diet counseling will be completed by the diabetes educator.
- III. When does education take place?
 - A. Within the patient's first week of stay on unit assignment OR at the initial visit to clinic, whichever is sooner.
 - B. Education will be reinforced at each clinic visit.
- IV. What is included in diabetes education? (to include health services personnel and diabetic patients)
 - A. Pathophysiology of Type 1 versus Type 2 diabetes
 - B. Non-pharmacologic treatment plan & importance of lifestyle modifications
 - Physical activity:
 1. Recommend at least 150 min/week of moderate-intensity aerobic physical activity (50-70% of maximum heart rate)
 2. In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week.
 - C. Signs, symptoms, and treatment for acute and chronic complications (i.e., hypoglycemia, hyperglycemia, and DKA if type 1)
 - D. Monitoring parameters – frequency and importance
 - E. Complications of diabetes (i.e. retinopathy, neuropathy, nephropathy, cardiovascular, cerebrovascular, and peripheral vascular disease)
 - F. Proper techniques of administering insulin for all patients on insulin (i.e. proper self-administration, insulin preparation, mixing, and administration sites)
 - G. Patient self-monitoring to include foot, skin, and wound care
 - Foot/skin care tips:
 1. Watch for pain, numbness, and/or wounds that will not heal.
 2. Keep skin supple by drinking plenty of water. Never put lotion or moisturizers between the toes.
 3. Wash feet daily with lukewarm water and soap.
 4. Dry feet well, especially between the toes.
 5. Check feet daily (including bottoms and between toes) for sores, redness, and swelling.
 6. Change into clean socks daily.
 7. Keep feet warm and dry.
 8. Never walk barefoot.
 9. Keep toenails trimmed.
 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)

**EXPLOSIVE/REACTIVE AGGRESSION
(Adolescents)**

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.



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

Risperidone	Day 1-4	Day 5-8	Day 9-12
Daily Dose	0.5-1 mg	1.5-2 mg	3-4 mg
Divide:	Single Dose or 0.5/0.5	Single Dose or 0.5-1/1	Single Dose or 1-2/2

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

Drug Class	Medication	Strength
1 st Generation Antipsychotics	Chlorpromazine	50mg, 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
	Thiothixene	2mg, 5mg, 10mg capsule
	Trifluoperazine	2mg, 5mg, 10mg tablet
2 nd Generation Antipsychotics	Risperidone	0.5mg, 1mg, 2mg, 3mg, 4mg tablet
	Ziprasidone	20mg/ml injection

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

Drug Class	Medication & Strength	Prior Authorization Criteria
2 nd Generation Antipsychotic	Aripiprazole (Abilify®) 2mg, 5mg, 10mg, 15mg, 20mg, 30mg tablet	<ul style="list-style-type: none"> • Intolerant to formulary 2nd generation antipsychotic • Treatment failure on formulary 2nd generation antipsychotic
	Ziprasidone (Geodon®) 20mg, 40mg, 60mg, 80mg capsule	<ul style="list-style-type: none"> • Contraindication to formulary 2nd generation antipsychotic • BMI ≥ 90th percentile

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

Medication Tapering	Max Daily Dose	Day 1-4	Day 5-8	Day 9-12	Day 13-14
Quetiapine	200mg TID	100mg/100mg/200mg	100mg TID	100mg BID	50mg BID
Ziprasidone	80mg BID	60mg BID	40mg BID	20mg BID	
Aripiprazole	30mg daily	20mg daily	10mg daily	5mg daily	

Tapering and discontinuing medications

It is recommended that providers consider tapering medications in patients who have experienced remission in aggressive symptoms for 6 months or longer.

- Consider reducing dose by 25% every 2 – 4 weeks
- If patient tolerates the tapering of dose, the medication should be discontinued

Antipsychotic Monitoring Parameters in Children and Adolescents Receiving Antipsychotic Pharmacotherapy**Table 5:** Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents in Children and Adolescents

Parameter	Baseline	4 wks	8 wks	12 wks	6 months	Annually
Personal Family History	X					X
Weight-Height-BMI (overweight 25-29.9; obese \geq 30)	X	X	X	X	X	X
Blood Pressure, Pulse	X			X	X	X
Fasting Plasma Glucose	X			X	X	X
Fasting Lipid Profile	X			X	X	X
CBC, LFT, SCr, Electrolytes	X			X	X	X
TSH	X	As clinically indicated				
EKG ¹	As clinically indicated					
Prolactin ²	As clinically indicated					

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

Assessment	Baseline	Follow-up
AIMS (Abnormal Involuntary Movement Scale) •Acute EPS - Akathisia •Tardive Dyskinesia	X	Baseline, at 3 months, then annually
BPRS (Brief Psychiatric Rating Scale)	X	Baseline and at each visit to assess response to treatment when a medication is started, changed or discontinued

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

Parameter	Baseline	4 weeks	Every 6 Months
EKG	X		
CBC, SCr, Electrolytes, TSH	X		X
Lithium levels		X	X

Table 11: Toxicity Information

Drug: Daily Dose Range	Contraindications	Toxicity Seen Starting At Trough Serum Levels of:	Signs & Symptoms of Toxicity (dose-related)
<p>Lithium: Initially 900 – 1200 mg daily in 1 to 3 divided doses.</p> <p>Target level: 0.5-1.2mEq/L</p> <p>Doses should not generally exceed 1200mg/day</p>	<ul style="list-style-type: none"> • Hypersensitivity to lithium • Severe cardiovascular or renal disease • Severe debilitation • Dehydration • Sodium depletion • Pregnancy Category D 	<p>> 1 – 1.2 mmol/L</p> <p>Patients who are sensitive to lithium may manifest toxicity at serum levels < 1 mmol/L.</p> <p><i>Note: A rise in white blood cell count is expected.</i></p>	<p>Lithium toxicity can be FATAL.</p> <p>Acute:</p> <ul style="list-style-type: none"> • Apathy • Coarse hand tremor that spreads to other parts of body • Confusion • Drowsiness • Dysarthria • GI symptoms (diarrhea, N/V) • Giddiness <p>Acute To Severe:</p> <ul style="list-style-type: none"> • Blurred vision • Deep tendon reflexes increased • Muscle rigidity / fasciculations • Mild ataxia • Profound lethargy • Tinnitus • Vertical nystagmus • Vomiting <p>Severe Intoxication:</p> <ul style="list-style-type: none"> • Arrhythmias • Impaired consciousness, coma • Increase in fasciculations and ataxia • CV collapse with oliguria and anuria • Coarse / irregular limb tremors • Coarse muscle contractions • Choreoathetoid movements • Cogwheel rigidity • Generalized tonic-clonic seizures

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

Parameter	Baseline	1 month	2 months	Every 6 Months
CBC with differential, LFTs	X	X	X	X
Platelet	X			X
Divalproex levels			X	X

Table 13: Toxicity Information

Drug: Daily Dose Range	Contraindications	Toxicity Seen Starting At Trough Serum Levels of:	Signs & Symptoms of Toxicity (dose-related)	Signs & Symptoms of Toxicity (NOT dose-related)
Divalproex: 15mg/kg/day or 1,250mg/day given in divided doses up to 60mg/kg/day Target level: 75-115mg/mL	<ul style="list-style-type: none"> Hypersensitivity to valproate Hepatic dysfunction Urea cycle disorder Pregnancy Category D 	> 100 – 125 mcg/mL	<ul style="list-style-type: none"> Somnolence, lethargy Mental status change Coma Hyperbilirubinemia Hepatotoxicity Heart block Vomiting Thrombocytopenia Prolongation of bleeding time Alopecia 	<ul style="list-style-type: none"> Pancreatitis – Do not rechallenge Hyperammonemic encephalopathy Hepatotoxicity, severe or fatal Stevens-Johnson Syndrome Toxic epidermal necrolysis Polycystic ovarian syndrome

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

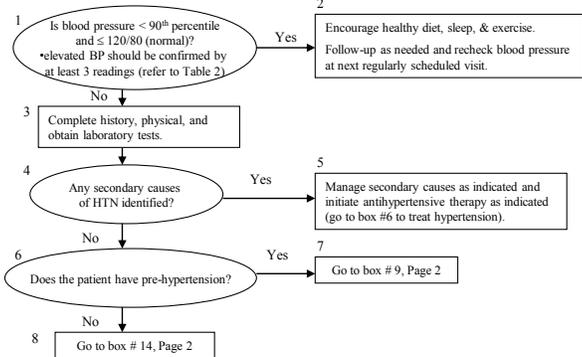
- ___ 1. SOMATIC CONCERN - Preoccupation with physical health, fear of physical illness, hypochondriasis.
- ___ 2. ANXIETY - Worry, fear, over-concern for present or future, uneasiness
- ___ 3. EMOTIONAL WITHDRAWAL - Lack of spontaneous interaction, isolation deficiency in relating to others.
- ___ 4. 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, 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.

Hypertension
(Children & Adolescents)

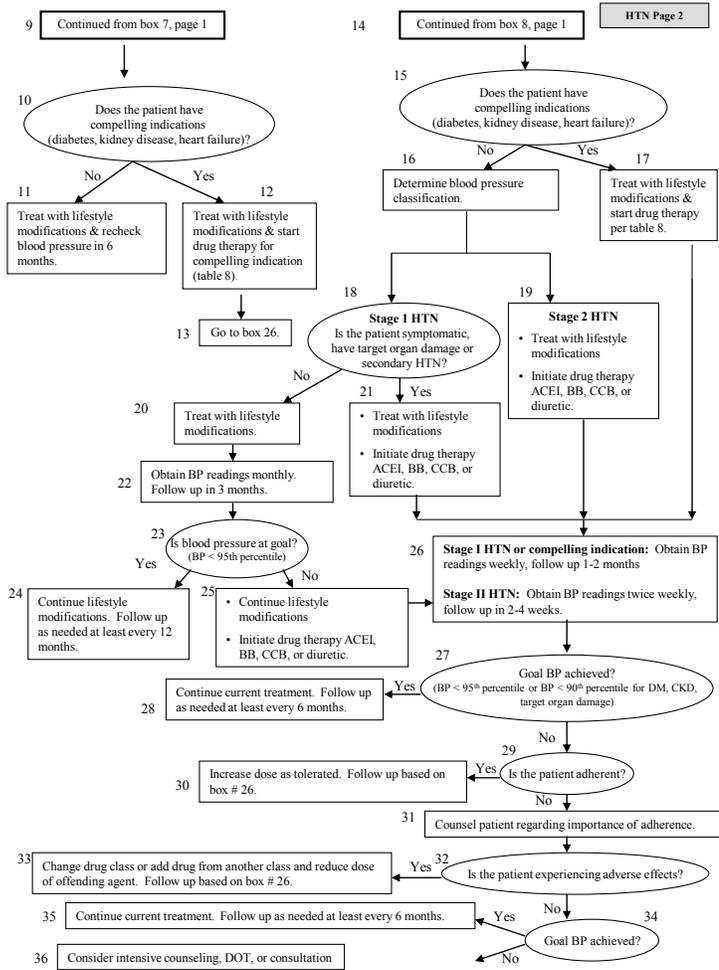
Table 1: Classification and Management of Hypertension¹

Blood Pressure Classification	SBP or DBP Percentile ²	Therapeutic Lifestyle Changes	Drug Therapy
Normal	<90 th percentile	Encourage healthy diet, sleep & exercise	None
Prehypertension	90 th to 94 th percentile or BP > 120/80mmHg even if <90 th percentile up to 94 th percentile ⁴	<ul style="list-style-type: none"> • Weight loss if overweight • Exercise program • Diet plan 	None unless compelling indications ³
Stage 1 Hypertension	95 th to 99 th percentile plus 5mmHg	<ul style="list-style-type: none"> •Weight loss if overweight •Exercise program •Diet plan 	Initiate therapy with ACEI, BB, CCB, or diuretic if <ol style="list-style-type: none"> 1. Persistent HTN with lifestyle changes 2. Compelling indication 3. Symptomatic HTN 4. Target organ damage 5. Secondary HTN
Stage 2 Hypertension	> 99 th percentile plus 5mmHg	<ul style="list-style-type: none"> •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



Prepared by the Correctional Managed Care Pharmacy & Therapeutics Committee. November 2006. Revised 4/09, 4/15.



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 \geq 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 \geq 95th percentile, should be staged to determine treatment.
- G. Follow-up based on initial blood pressure reading

Table 2

Blood Pressure (SBP or DBP)	Frequency of Follow-up
< 90 th percentile	Recheck at next regularly scheduled visit.
90 th to 94 th percentile or BP > 120/80mmHg even if <90 th percentile up to 94 th percentile	Recheck in 6 months
95 th to 99 th percentile plus 5mmHg	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.
> 99 th percentile plus 5mmHg	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.

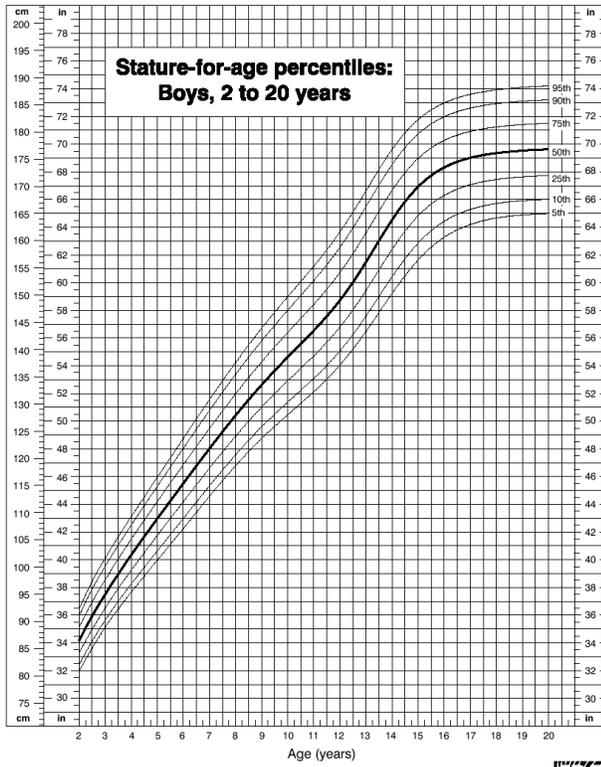
II. Patient Evaluation

- 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 | 9. Pregnancy |
| 2. Mineralocorticoid excess states | 10. Infection |
| 3. Renovascular disease | 11. Trauma |
| 4. Chronic Kidney Disease | 12. Sleep disorder |
| 5. Cushing syndrome | |
| 6. Pheochromocytoma | |
| 7. Thyroid or parathyroid disease | |
| 8. Coarctation of the aorta | |

Table 3: BP Level For Males by Age and Height

Age	BP %	SBP (mmHg) Percentile of Height							DBP (mmHg) Percentile of Height						
		5th	10th	25th	50th	75th	90th	95th	5th	10th	25th	50th	75th	90th	95th
8	90th	107	109	110	112	114	115	116	71	72	72	73	74	75	76
	95th	111	112	114	116	118	119	120	75	76	77	78	79	79	80
	99th	119	120	122	123	125	127	127	83	84	85	86	87	87	88
9	90th	109	110	112	114	115	117	118	72	73	74	75	76	76	77
	95th	113	114	116	118	119	121	121	76	77	78	79	80	81	81
	99th	120	121	123	125	127	128	129	84	85	86	87	88	88	89
10	90th	111	112	114	115	117	119	119	73	73	74	75	76	77	78
	95th	115	116	117	119	121	122	123	77	78	79	80	81	81	82
	99th	122	123	125	127	128	130	130	85	86	86	88	88	89	90
11	90th	113	114	115	117	119	120	121	74	74	75	76	77	78	78
	95th	117	118	119	121	123	124	125	78	78	79	80	81	82	82
	99th	124	125	127	129	130	132	132	86	86	87	88	89	90	90
12	90th	115	116	118	120	121	123	123	74	75	75	76	77	78	79
	95th	119	120	122	123	125	127	127	78	79	80	81	82	82	83
	99th	126	127	129	131	133	134	135	86	87	88	89	90	90	91
13	90th	117	118	120	122	124	125	126	75	75	76	77	78	79	79
	95th	121	122	124	126	128	129	130	79	79	80	81	82	83	83
	99th	128	130	131	133	135	136	137	87	87	88	89	90	91	91
14	90th	120	121	123	125	126	128	128	75	76	77	78	79	79	80
	95th	124	125	127	128	130	132	132	80	80	81	82	83	84	84
	99th	131	132	134	136	138	139	140	87	88	89	90	91	92	92
15	90th	122	124	125	127	129	130	131	76	77	78	79	80	80	81
	95th	126	127	129	131	133	134	135	81	81	82	83	84	85	85
	99th	134	135	136	138	140	142	142	88	89	90	91	92	93	93
16	90th	125	126	128	130	131	133	134	78	78	79	80	81	82	82
	95th	129	130	132	134	135	137	137	82	83	83	84	85	86	87
	99th	136	137	139	141	143	144	145	90	90	91	92	93	94	94
17	90th	127	128	130	132	134	135	136	80	80	81	82	83	84	84
	95th	131	132	134	136	138	139	140	84	85	86	87	87	88	89
	99th	139	140	141	143	145	146	147	92	93	93	94	95	96	97

CDC Growth Charts: United States



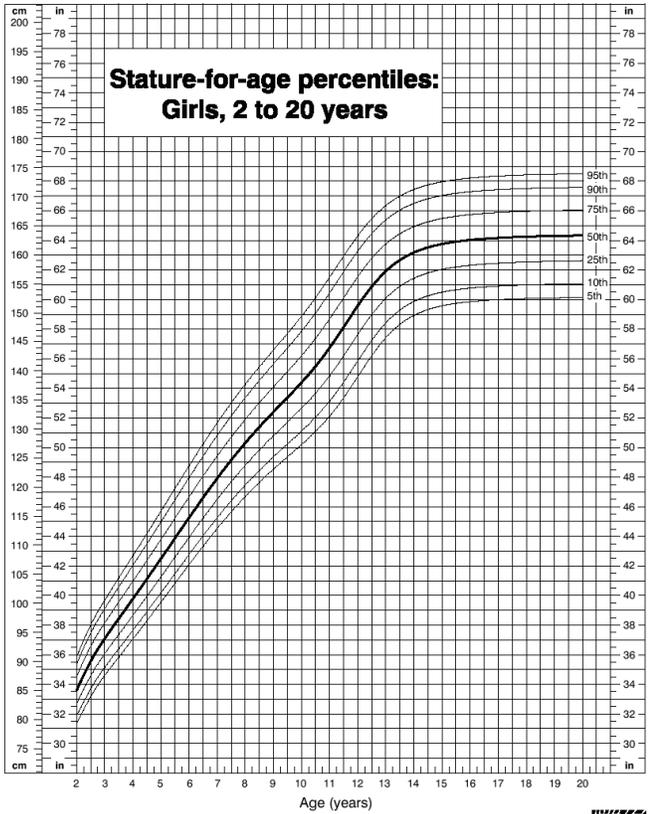
Published May 30, 2000.
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).



Table 5: BP Level For Females by Age and Height

Age	BP %	SBP (mmHg)								DBP (mmHg)							
		Percentile of Height								Percentile of Height							
		5th	10th	25th	50th	75th	90th	95th	5th	10th	25th	50th	75th	90th	95th		
8	90th	108	109	110	111	113	114	114	71	71	71	72	73	74	74		
	95th	112	112	114	115	116	118	118	75	75	75	76	77	78	78		
	99th	119	120	121	122	123	125	125	82	82	83	83	84	85	86		
9	90th	110	110	112	113	114	116	116	72	72	72	73	74	75	75		
	95th	114	114	115	117	118	119	120	76	76	76	77	78	79	79		
	99th	121	121	123	124	125	127	127	83	83	84	84	85	86	87		
10	90th	112	112	114	115	116	118	118	73	73	73	74	75	76	76		
	95th	116	116	117	119	120	121	122	77	77	77	78	79	80	80		
	99th	123	123	125	126	127	129	129	84	84	85	86	86	87	88		
11	90th	114	114	116	117	118	119	120	74	74	74	75	76	77	77		
	95th	118	118	119	121	122	123	124	78	78	78	79	80	81	81		
	99th	125	125	126	128	129	130	131	85	85	86	87	87	88	89		
12	90th	116	116	117	119	120	121	122	75	75	75	76	77	78	78		
	95th	119	120	121	123	124	125	126	79	79	79	80	81	82	82		
	99th	127	127	128	130	131	132	133	86	86	87	88	88	89	90		
13	90th	117	118	119	121	122	123	124	76	76	76	77	78	79	79		
	95th	121	122	123	124	126	127	128	80	80	80	81	82	83	83		
	99th	128	129	130	132	133	134	135	87	87	88	89	89	90	91		
14	90th	119	120	121	122	124	125	125	77	77	77	78	79	80	80		
	95th	123	123	125	126	127	129	129	81	81	81	82	83	84	84		
	99th	130	131	132	133	135	136	136	88	88	89	90	90	91	92		
15	90th	120	121	122	123	125	126	127	78	78	78	79	80	81	81		
	95th	124	125	126	127	129	130	131	82	82	82	83	84	85	85		
	99th	131	132	133	134	136	137	138	89	89	90	91	91	92	93		
16	90th	121	122	123	124	126	127	128	78	78	79	80	81	81	82		
	95th	125	126	127	128	130	131	132	82	82	83	84	85	85	86		
	99th	132	133	134	135	137	138	139	90	90	90	91	92	93	93		
17	90th	122	122	123	125	126	127	128	78	79	79	80	81	81	82		
	95th	125	126	127	129	130	131	132	82	83	83	84	85	85	86		
	99th	133	133	134	136	137	138	139	90	90	91	91	92	93	93		

CDC Growth Charts: United States



Published May 30, 2000.
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).



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
 3. 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*

Drug	Dose	Comments
Lisinopril (Prinivil®) 2.5, 5, 10, 20, and 40mg	<ul style="list-style-type: none"> • Initial: 0.07 mg/kg/day up to 5mg/day • Max: 0.6mg/kg/day up to 40mg/day • Daily administration 	<ul style="list-style-type: none"> • ACE inhibitor • FDA pediatric labeling for children ≥ 6 and creatinine clearance ≥ 30ml/min • Contraindicated in pregnancy
Atenolol (Tenormin®) 25, 50mg	<ul style="list-style-type: none"> • Initial: 0.5-1 mg/kg/day given daily or bid • Max: 2mg/kg/day up to 100mg/day 	<ul style="list-style-type: none"> • Beta-blocker • No FDA pediatric labeling • β-Receptor blockers may be considered in pregnancy. Use is controversial.†
Metoprolol (Lopressor®) 25, 50, & 100mg	<ul style="list-style-type: none"> • Initial: 1-2mg/kg day given bid • Max: 6mg/kg/day up to 200mg/day administered in 2 divided doses 	<ul style="list-style-type: none"> • Beta-blocker • FDA pediatric labeling for children ≥ 6 years old • β-Receptor blockers may be considered in pregnancy. Use is controversial.†
Propranolol (Inderal®) 10, 20 & 40mg	<ul style="list-style-type: none"> • Initial: 1-2mg/kg/day given bid or tid • Max: 4mg/kg/day up to 640mg/day 	<ul style="list-style-type: none"> • Beta-blocker • FDA pediatric labeling
Amlodipine (Norvasc®) 5 & 10mg	<ul style="list-style-type: none"> • Initial: 2.5mg/day given daily • Max: 5mg/day 	<ul style="list-style-type: none"> • Calcium channel blocker • FDA pediatric labeling for children ≥ 6 years old
Hydrochlorothiazide, HCTZ 12.5, 25 & 50mg	<ul style="list-style-type: none"> • Initial: 1mg/kg/day given daily • Max: 3mg/kg/day up to 50mg/day 	<ul style="list-style-type: none"> • Diuretic • FDA pediatric labeling
Furosemide (Lasix®) 20 & 40mg	<ul style="list-style-type: none"> Initial: 0.5-2 mg/kg/dose given daily or bid Max: 6mg/kg/day 	<ul style="list-style-type: none"> • Diuretic • No FDA pediatric labeling

Table 7 (continued): Formulary Antihypertensive Agents For Children and Adolescents*

Drug	Dose	Comments
Spirolactone (Aldactone®) 25mg	Initial: 1mg/kg/day given daily or bid Max: 3.3mg/kg/day up to 100mg/day	<ul style="list-style-type: none"> • Diuretic • No FDA pediatric labeling
Terazosin (Hytrin®) 1, 2, 5, 10mg	Initial: 1mg/day given daily Max: 20 mg/day	<ul style="list-style-type: none"> • Alpha-blocker • No FDA pediatric labeling
Minoxidil (Loniten®) 2.5 & 10mg	≥12 years initial: 5mg/day given daily to tid ≥ 12 years max: 100mg/day	<ul style="list-style-type: none"> • Vasodilator • FDA pediatric labeling • Reserved for resistant HTN
Hydralazine (Apresoline®) 25, 50mg	<ul style="list-style-type: none"> • Initial: 0.75 mg/kg/day in divided doses • Max: 7.5 mg/kg/day up to 200 mg/day • Usually in 4 divided doses 	<ul style="list-style-type: none"> • Vasodilator • FDA pediatric labeling • Reserved for resistant HTN • May be considered in pregnancy for gestational or chronic hypertension^o

*Drugs with FDA approval or have pediatric data available

†Pregnancy category C. May cause fetal bradycardia and decrease uteroplacental blood flow; may impair fetal response to hypoxic stress; risk for growth retardation when started in first or second trimester (atenolol). Limited data are available in the adolescent population.

^oPregnancy category C. Useful only in combination; may cause neonatal thrombocytopenia. Limited data are available in the adolescent population.

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 8: Drug Therapy For Co-morbidities Or Compelling Indications

Co-morbidity	Drug Choice
Diabetes	ACE inhibitor
Heart failure or LVH	ACE inhibitor
Renal Insufficiency	<ul style="list-style-type: none"> • Loop diuretic (Furosemide) or beta-blocker • ACE inhibitor use is a relative contraindication in ACE inhibitor naïve patient.
Albuminuria	ACE inhibitor
Migraine headache	Beta-blocker or calcium channel blocker
Pregnancy	<ul style="list-style-type: none"> • Methyldopa, beta blockers, vasodilators preferred. • ACE inhibitor and Angiotensin II receptor antagonist (ARB) contraindicated

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. **The provider should be contacted promptly when the resting blood pressure is: systolic BP >150 or diastolic BP >100.** 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. In select patients, consider investigating for possible illicit drug use as this is a possible cause for hypertensive urgency.
 - 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 obtain blood pressure reading. Follow up in Chronic Care Clinic per ITP. Counsel patients with poor compliance.

INSOMNIA (Adolescents)

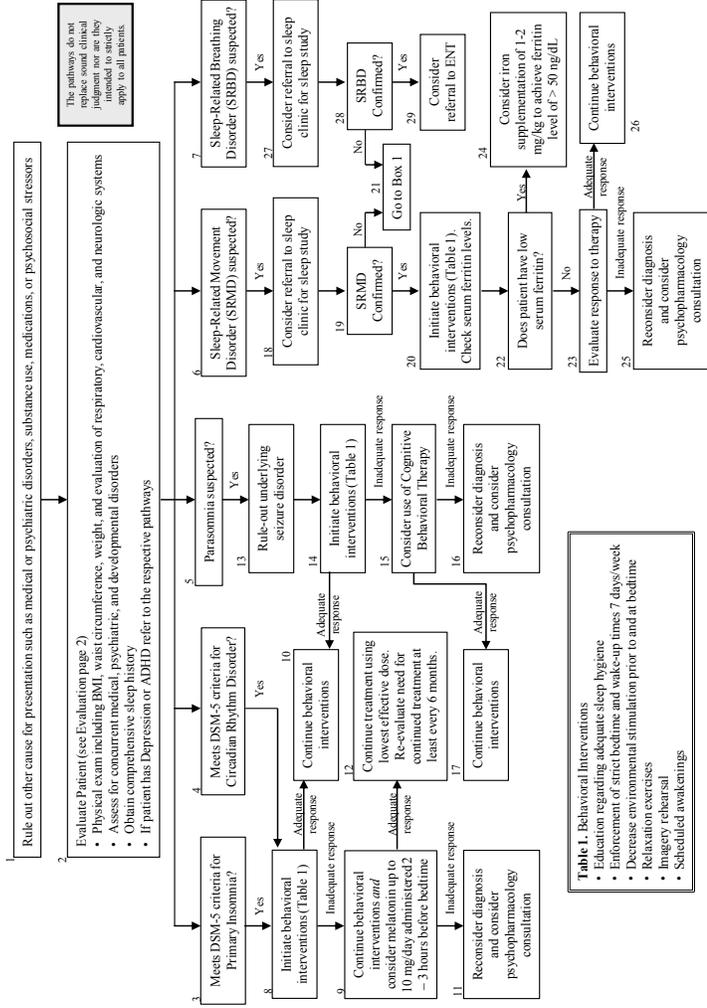


Table 1. Behavioral Interventions

- Education regarding adequate sleep hygiene
- Enforcement of strict bedtime and wake-up times 7 days/week
- Decrease environmental stimulation prior to 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 DMG)
 - 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 difficulty 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 disruption leads to excessive sleepiness or insomnia, or both.
- Sleep disturbance causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Parasomnias (DSM-5)

Non-Rapid Eye Movement Sleep Arousal Disorders

- Recurrent episodes of incomplete awakening from sleep, usually occurring during the first third of the major sleep episode, accompanied by 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 episodes.
- No or little (e.g., only a single visual scene) dream imagery is recalled.
- Amnesia for the episodes is present.
- The episodes cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- 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.

Non-pharmacological treatments are considered first line therapy

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

Pharmacological treatments are not considered first line therapy. In accordance with TJJD general administrative policy and health services policy, psychotropic or other medications may not be prescribed as a sleep aid. They may only be prescribed as second line therapy for a sleep disturbance related to a primary mental health or medical diagnosis and should be used in conjunction with behavioral interventions.

In general medications should only be used short term at the lowest effective dose and tapered whenever possible. When used long-term, use should be re-evaluated at least every 6 months to monitor for efficacy, adverse effects, and problems such as tolerance or abuse. Medication should always be used in combination with non-pharmacologic strategies.

Patients should be evaluated for use of formulary agents whenever possible. Practitioners should consider past history of response, contraindications, co-morbidities, medication compliance, and potential for adverse effects and/or drug-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

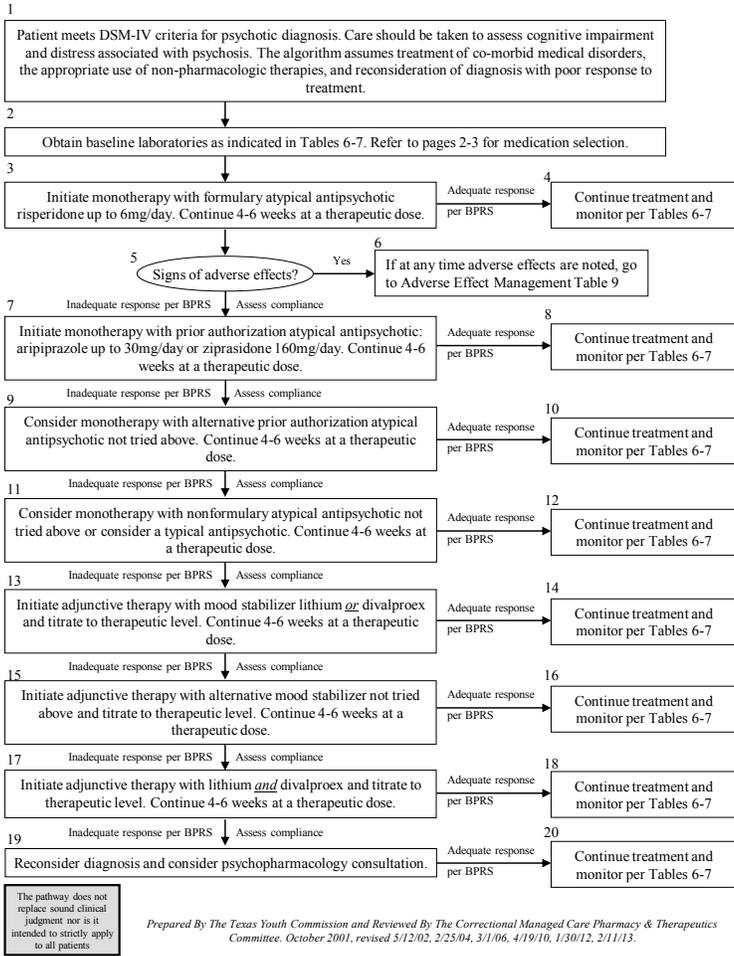
3. Guanfacine

- 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 counseled and male patients taking trazodone who experience an uncontrolled erection persisting longer than 1 hour should seek immediate medical attention. If not treated promptly, priapism may result in permanent impotence due to damage of vascular structures in the penis.

PSYCHOSIS
(Adolescents)



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

Risperidone	Day 1-4	Day 5-8	Day 9-12
Daily Dose	0.5-1 mg	1.5-2 mg	3-4 mg
Divide:	Single Dose or 0.5/0.5	Single Dose or 0.5-1/1	Single Dose or 1-2/2

Table 2: Formulary Agents

Drug Class	Medication	Strength
1 st Generation Antipsychotic	Chlorpromazine	50mg, 100mg, 200mg tablet; 25mg/ml inj
	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
	Thiothixene	2mg, 5mg, 10mg capsule
2 nd Generation Antipsychotic	Risperidone	0.5mg, 1mg, 2mg, 3mg, 4mg tablet
	Ziprasidone	20mg/ml injection
	Trifluoperazine	2mg, 5mg, 10mg tablet

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

Drug Class	Medication & Strength	Prior Authorization Criteria
2 nd Generation Antipsychotic	Aripiprazole (Abilify®) 2mg, 5mg, 10mg, 15mg, 20mg, 30mg tablet	<ul style="list-style-type: none"> • Intolerant to formulary 2nd generation antipsychotic • Treatment failure on formulary 2nd generation antipsychotic • Contraindication to formulary 2nd generation antipsychotic • BMI ≥ 90th percentile
	Ziprasidone (Geodon®) 20mg, 40mg, 60mg, 80mg capsule	

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 5 below outlines strategies for switching patients by a structured cross-titration schedule that is agent specific.

Notes:

1. If patient is on more than the maximum dose, taper down to that dose before beginning the cross titration.
2. Practitioners should be sure to complete cross-titration to ensure that the patient is not left on two antipsychotic agents indefinitely.

Table 4: Approximate Chlorpromazine Equivalent Dosage for Antipsychotic Agents

Antipsychotic Agent	Dose Equivalent to 100mg of Chlorpromazine
Chlorpromazine	100mg
Haloperidol	2mg
Perphenazine	10mg
Risperidone	2mg
Olanzapine	5mg
Quetiapine	75mg
Ziprasidone	60mg
Aripiprazole	7.5mg
Clozapine	50mg

Table 5: Schedule for Tapering Patients off Nonformulary/Prior Authorization Atypical Antipsychotics

Medication Tapering	Max Daily Dose	Day 1-4	Day 5-8	Day 9-12	Day 13-14
Quetiapine	200mg TID	100mg/100mg/ 200mg	100mg TID	100mg BID	50mg BID
Ziprasidone	80mg BID	60mg BID	40mg BID	20mg BID	
Aripiprazole	30mg daily	20mg daily	10mg daily	5mg daily	

**Antipsychotic Monitoring Parameters in
Children and Adolescents Receiving Antipsychotic Pharmacotherapy**

Table 6: Metabolic and Endocrine Monitoring Guidelines for Antipsychotic Agents in Children and Adolescents ^{1,2,3,4,5}

Parameter	Baseline	4 wks	8 wks	12 wks	6 months	Annually
Personal Family History	X					X
Weight-Height-BMI (overweight 25.0-29.9; obese >= 30.0)	X	X	X	X	X	X
Blood Pressure, Pulse	X			X	X	X
Fasting Plasma Glucose	X			X	X	X
Fasting Lipid Profile	X			X	X	X
CBC, LFT, SCr, Electrolytes	X			X	X	X
TSH	X	As clinically indicated				
EKG ¹	As clinically indicated					
Prolactin ²	As clinically indicated					

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 ^{6,7,8,9}

Assessment	Baseline	Follow-up
AIMS (Abnormal Involuntary Movement Scale) •Acute EPS - Akathisia •Tardive Dyskinesia	X	Baseline, at 3 months, then annually
BPRS (Brief Psychiatric Rating Scale)	X	Baseline and at each visit to assess response to treatment when a medication is started, changed or discontinued

Table 8: Occurrence of Adverse Effects of Antipsychotic Agents in Children and Adolescents^{10,11}

Drug	EPS	Hyper-prolactinemia	Weight Gain	Sedation	Other
Haloperidol	+++	++	+/-	+	TD, NMS
Risperidone	+	+++	++	+	Depression
Olanzapine	+/-	+/-	+++	++	Lipid and glucose dysregulation
Clozapine	-	-	+++	+++	Agranulocytosis, Seizures, lipid and glucose dysregulation
Quetiapine	-	-	+	+++	
Ziprasidone	+/-	+/-	-	++	QTc prolongation
Aripiprazole	+/-	+/-	-	+/-	EPS is typically akathisia

EPS = extrapyramidal symptoms

NMS = neuroleptic malignant syndrome

QTc = corrected QT interval

TD = tardive dyskinesia

- = absent

+/- = most probably rare

+ = rare

++ = low frequency

+++ = high frequency

Table 9: Adverse Effect Management

Side Effect	Recommended Management Strategies
EPS	<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Benzotropine 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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)

Patient Name _____ Patient Number _____ Date _____

Facility _____ Practitioner _____

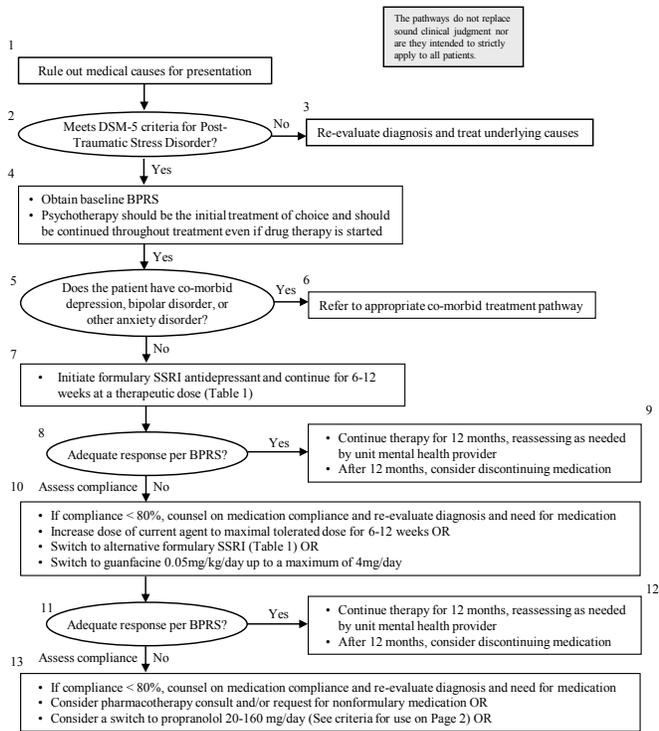
Enter the score for the term that best describes the patient's condition.

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.
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- ___ 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.
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- ___ 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.

POST-TRAUMATIC STRESS DISORDER (Adolescents)



Prepared By The Youth Services Pharmacy & Therapeutics Committee. Approved 10/2011. Revised 2/2013, 4/2014.

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

Drug Class	Generic Name	Brand Name	Initial Dose (Dose Range) mg/day	Monitoring
Selective Serotonin Reuptake Inhibitor (SSRI)	Citalopram 10mg, 20mg, 40mg	Celexa®	10mg (10 – 40)	<ul style="list-style-type: none"> Emergence of suicidal ideation or behavior Citalopram: EKG at baseline and as clinically indicated if risk factors for QTc prolongation are present
	Fluoxetine 10mg, 20mg	Prozac®	10mg (10 – 60)	
	Sertraline 50mg, 100mg	Zoloft®	50mg (50 – 200)	
Alpha antagonist	Guanfacine 1mg, 2mg	Tenex®	1mg (1 – 4)	<ul style="list-style-type: none"> Monitor supine, standing, and sitting BP especially at initiation or change in dose Monitor for orthostatic hypotension. Taper over 1 week or more when discontinuing.
Beta antagonist	Propranolol 10mg, 20mg, 40mg	Inderal®	20mg (20-160)	<ul style="list-style-type: none"> Monitor supine, standing, and sitting BP especially at initiation or change in dose Monitor for orthostatic hypotension. Taper over 1 week or more when discontinuing

Criteria for appropriate use of propranolol: ALL criteria should be met prior to initiating propranolol.

- 1) Patient has a documented diagnosis of PTSD
- 2) Patient has failed an adequate trial of SSRI therapy for PTSD
- 3) Patient is not currently receiving an antipsychotic medication

Note: Once a patient has been started on propranolol, they should be monitored for improvement in PTSD symptoms. If a clear improvement in symptoms is not evident after 4-6 weeks of treatment, propranolol should be tapered and discontinued.

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

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

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

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

Instructions for Use and Scoring:

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Brief Psychiatric Rating Scale (BPRS)

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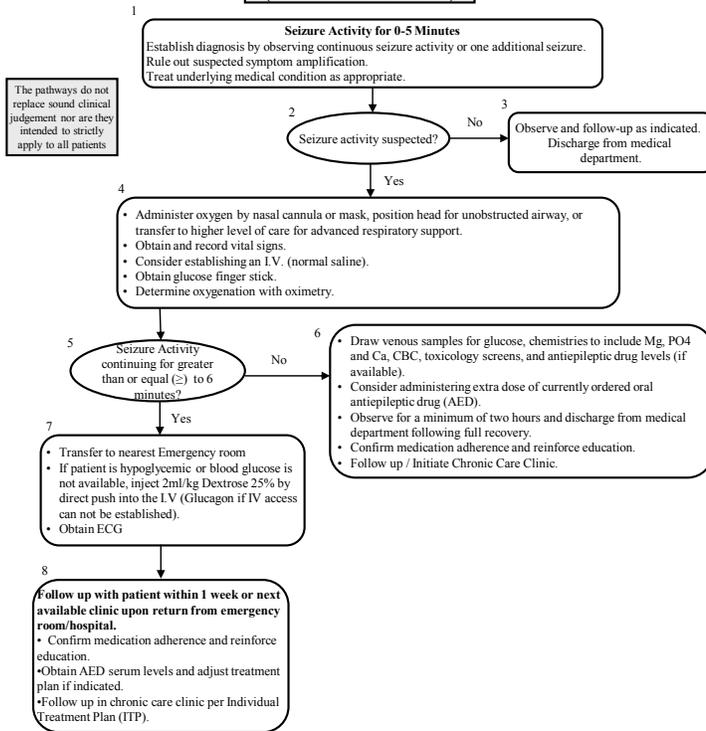
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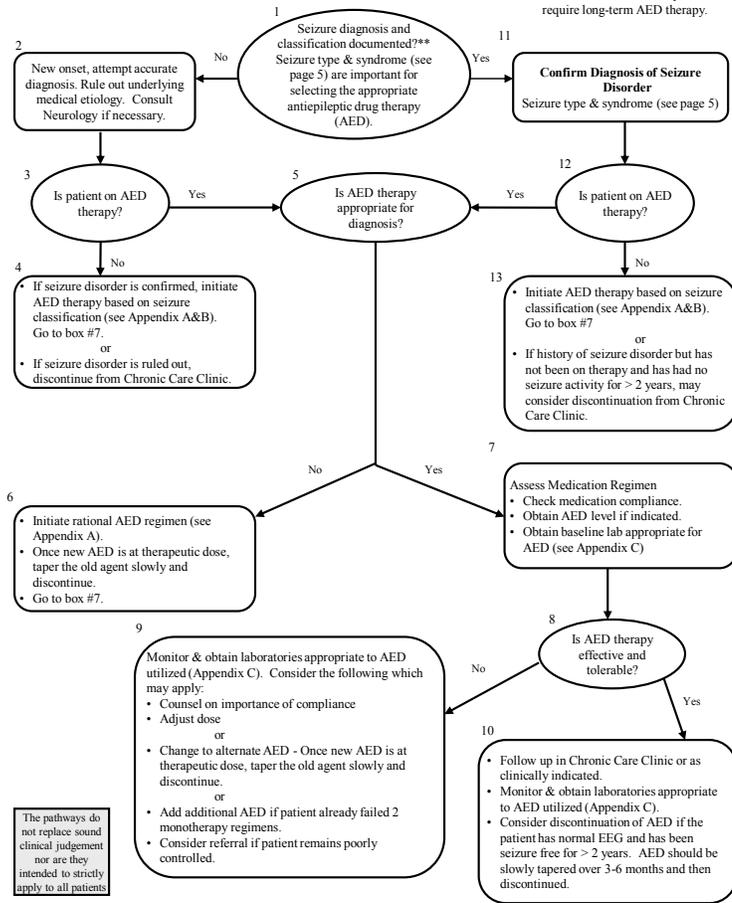
Acute Seizures (Children & Adolescents)



Prepared By The Youth Services Pharmacy & Therapeutics Committee. March 2007. Revised 10/11, 10/14.

**Seizure Disorder
(Children & Adolescents)**

**One seizure event is not necessarily diagnostic for seizure disorder and may not require long-term AED therapy.



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

Prepared By The Youth Services Pharmacy & Therapeutics Committee. March 2007. Revised 10/11, 10/14.

- 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, baclofen).
- C. **Physical Exam**
1. Identify disorders associated with seizures such as head trauma, infections which could spread to the brain, congenital abnormality, neurological disorder, alcohol or drug abuse, metabolic disorders or cancer.
 2. A complete neurologic and mental status exam should be performed.
- D. **Electroencephalographic (EEG) Studies** – Should be performed on all new onset cases. 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**
- | | |
|---|---|
| <ul style="list-style-type: none"> • Electrolytes • Blood Glucose • Liver & kidney function • Toxicology screen | <ul style="list-style-type: none"> • MRI (CT if unavailable or contraindicated) • 12 lead ECG • 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. **Principals 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 \geq 3 agents – Rarely needed. Consider only after 2 or more adequate trials of dual AEDs have failed, adherence is confirmed, and a combination of AEDs is tolerated and significantly reduces seizure frequency or severity. Consider referral prior to triple AED therapy.
5. Use of Newer AEDs
 - a. Recommended for those who have failed traditional or first generation AEDs or when traditional AEDs are unsuitable (contraindications, drug interactions, intolerance, pregnancy, etc).
 - b. Traditional AEDs have the advantage of broad familiarity, lower cost, known efficacy and long term experience.
6. Pregnancy Considerations
 - a. Category C – gabapentin, lamotrigine, levetiracetam, oxcarbazepine, 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	Factors in Favor of Drug Withdrawals
<ul style="list-style-type: none"> • Adolescent-onset epilepsy • Adult-onset epilepsy • Partial epilepsy • Juvenile myoclonic epilepsy • Presence of multiple seizure types • Presence of underlying neurological condition • Abnormal EEG 	<ul style="list-style-type: none"> • Childhood-onset epilepsy • Elderly-onset epilepsy • Idiopathic 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

Types of Epileptic Seizures	Description
Partial (focal) seizures	Begins in one hemisphere. Asymmetric clinical manifestation unless secondarily generalized.
Simple partial	Motor, sensory, autonomic, or psychic signs; consciousness is not impaired.
Complex partial	Simple partial followed by loss of consciousness or impaired consciousness at onset. Generally amnesic to events. May be misdiagnosed as psychiatric episode.
Partial Seizures evolving to secondarily generalized	Partial onset with secondary generalization
Primarily generalized seizures	Involves both hemispheres with bilateral motor manifestations and loss of consciousness.
Absence (petit mal)	Sudden onset, brief duration. May include blank stare, upward rotation of eyes, lip-smacking. Confused with daydreaming. Generally occurs in young children through adolescence. Important to differentiate from complex partial.
Myoclonic	Brief muscle contraction of face, trunk, extremities. May be isolated or repetitive.
Clonic	Repetitive jerks; cyanosis; foam at the mouth; small grunting respirations between seizures; deep respirations at the end of seizures.
Tonic	Rigid, violent, sudden muscular contractions; cry/moan; deviation of eyes and head to one side; rotation of the whole body and distortion of features; suppression of respiration; falls; tongue biting; involuntary urination.
Tonic-clonic	Also known as grand-mal. Includes both atonic and clonic phase.
Atonic	Sudden loss of postural tone lasting 1 to 2 seconds. Usually no post-ictal confusion. Violent falls.
Pseudoseizure (non-epileptic)	Episodes involving affective, autonomic, or sensorimotor manifestations that are precipitated by stress. Clinical characteristics: <ul style="list-style-type: none"> • Strongly suggestive – prolonged duration (10-30 min), preserved consciousness despite whole body jerking, bizarre and asynchronous motor movements, pelvic thrusting, not stereotypical • Strongly against – Injuries during spell, tongue laceration (esp. sides), incontinence)

Appendix B: Antiepileptic Drugs For Specific Seizures

Begin treatment with single AED using recommended initial daily dosing. Up to 80% of patients can be managed with monotherapy. Ensure proper medication adherence prior to modifying regimen.

Type of Seizure	Formulary Medications		Nonformulary Medications	
Simple Partial	Carbamazepine Divalproex Sodium Levetiracetam*	Phenytoin Primidone	Gabapentin* Lacosamide* Lamotrigine Oxcarbazepine	Perampanel*‡ Phenobarbital Tiagabine* Topiramate
Complex Partial	Carbamazepine Divalproex Sodium Levetiracetam*	Phenytoin Primidone	Gabapentin* Lacosamide* Lamotrigine Oxcarbazepine	Perampanel*‡ Phenobarbital Tiagabine* Topiramate Vigabatrin§*
Generalized Tonic-Clonic	Carbamazepine Divalproex Sodium Levetiracetam*	Phenytoin Primidone	Gabapentin* Lamotrigine Oxcarbazepine	Phenobarbital Topiramate
Absence	Ethosuximide Divalproex Sodium		Clonazepam* Lamotrigine	

*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 alternative treatments. Black box warning related to possible permanent vision loss.

‡ Schedule III controlled substance

Appendix C. Monitoring Parameters for Formulary AED

Drug	Dosage and Monitoring Parameter & Frequency
Carbamazepine	<ul style="list-style-type: none"> • 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 Steven-Johnson syndrome and toxic epidermal necrolysis is higher in this patient population. • CBC with platelets (emphasis ANC) – baseline, twice a month for first 2 months, then annually or when clinically indicated. • Chemistry (emphasis hepatic & renal function and electrolytes) – baseline, one month, then annually or when clinically indicated • Physical Findings – perform baseline and periodic eye examinations • Levels – weekly for 2 weeks, one month and then annually or when clinically indicated • Therapeutic level – 4 to 12 mcg/ml
Levetiracetam	<ul style="list-style-type: none"> • Chemistry – renal function in patients with preexisting renal impairment • Therapeutic level – not established
Phenytoin	<ul style="list-style-type: none"> • CBC – baseline and when clinically indicated • Chemistry (emphasis hepatic & renal function) – baseline, then annually or when clinically indicated • Levels – one week, one month, and then annually or when clinically indicated • Therapeutic level – 10 to 20 mcg/ml
Primidone	<ul style="list-style-type: none"> • CBC – baseline and annually or when clinically indicated • Therapeutic level – 5 to 12 mcg/ml
Valproic Acid	<ul style="list-style-type: none"> • CBC with platelets – baseline and when clinically indicated • Chemistry (emphasis hepatic function) – baseline, one month, then annually or when clinically indicated • Protome, INR, PPT at baseline and annually • Levels – weekly for 2 weeks, then annually or when clinically indicated • Therapeutic level – 50 to 100 mcg/ml

Generic Name	Usual Children, Adolescent and Adult Dose	Adverse Effects*
Formulary Agents		
Carbamazepine Tegretol®	<ul style="list-style-type: none"> • 6-12yrs: 10mg/kg/day or 100mg bid up to 1000mg/day 2-4 divided doses • >12yrs: 200mg bid, up to 1000mg/day for 12-15yrs or 1200mg/day >15yrs 2-4 divided doses 	<ul style="list-style-type: none"> • Somnolence, dizziness, fatigue, ataxia, GI upset • Serious: agranulocytosis, hepatitis & hepatic failure, hypersensitivity, rash including Stevens Johnson & toxic epidermal necrolysis, hyponatremia
Levetiracetam Keppra®	<ul style="list-style-type: none"> • 4-15yrs: 20mg/kg/day divided 2 doses up to 60mg/kg/day divided 2 doses • >16yrs: 500mg bid up to 3000mg/day divided bid 	<ul style="list-style-type: none"> • Irritability, behavioral changes, somnolence, asthenia, uncoordination
Phenytoin Dilantin®	<ul style="list-style-type: none"> • Loading dose if not already on phenytoin: 15-20mg/kg in 3 divided doses q 2-4 hours apart • Maintenance dose: Children: 4-8mg/kg/day 1-3 divided doses up to 300mg/day Adult: 300 mg/day in 1-3 divided doses up to 600mg/day 	<ul style="list-style-type: none"> • Nystagmus, blurred vision, diplopia, ataxia, dizziness, drowsiness, headache, GI upset, gingival hyperplasia, coarsening of facial features, hirsutism, acne, osteomalacia • Serious: rash including Stevens Johnson, blood dyscrasias, hepatotoxicity, systemic lupus erythematosus
Primidone Mysoline®	<ul style="list-style-type: none"> • <8yrs: 50mg/day up to 25mg/kg/day in 3-4 divided doses • ≥8 years: 250mg/day up to 750-1500 mg/day in divided doses tid-qid 	<ul style="list-style-type: none"> • Ataxia, dizziness, somnolence • Serious: megaloblastic anemia, thrombocytopenia
Valproic Acid Depakote®	<ul style="list-style-type: none"> • ≥10yrs: 10-15mg/kg/day 2-3 divided doses up to 60mg/kg/day • Usual dose 1000-2500mg/day 2-3 divided doses 	<ul style="list-style-type: none"> • GI upset somnolence, ataxia, dizziness, rash • Serious: pancreatitis, thrombocytopenia, hepatotoxicity • Patients at increased risk for hepatotoxicity include children • Female adolescents have an increased risk for development of Polycystic Ovary Syndrome • <2yrs, multiple AEDs, severe disorder with mental retardation, organic brain disease
Non-formulary Agents		
Ethosuximide Zarontin®	<ul style="list-style-type: none"> • > 6yrs: 250mg bid up to 1.5g/day in 2 divided doses 	<ul style="list-style-type: none"> • Behavioral changes, anorexia, GI upset, ataxia, dizziness, headache, somnolence, hiccups • Serious: rash including Stevens Johnson, agranulocytosis, aplastic anemia, leukopenia, pancytopenia, systemic lupus erythematosus
Gabapentin Neurontin®	<ul style="list-style-type: none"> • 5-12yrs: 10mg/kg/day up to 50mg/kg/day divided 3 doses • > 12: 300mg tid up to 1800mg/day 	<ul style="list-style-type: none"> • Somnolence, dizziness, ataxia, fatigue, weight gain, peripheral edema, behavioral changes in children
Lacosamide Vimpat®	<ul style="list-style-type: none"> • ≥ 17 yrs: 50mg bid up to 400mg/day 	<ul style="list-style-type: none"> • Dizziness, nausea, vertigo, abnormal coordination and ataxia are the most frequently reported side effects • Serious: atrial fibrillation and flutter, first degree atrioventricular block, drug hypersensitivity syndrome
Lamotrigine Lamictal®	<ul style="list-style-type: none"> • 2-12yrs & VPA: 0.2mg/kg/day up to 5mg/kg/day in 1-2 divided doses • 2-12yrs & enzyme inducer: 0.5mg/kg/day up to 8mg/kg/day in 1-2 divided doses • >12yrs & VPA: 25mg qod x 2 wk, 25mg qd x 2 wk up to 100-400mg/day in 1-2 divided doses • >12yrs & enzyme inducer or monotherapy: 50mg/day x 2 wk, 50mg bid x 2 wk up to 300-500mg/day in 2 divided doses 	<ul style="list-style-type: none"> • TICs in children, insomnia, dizziness, headache, diplopia, ataxia, nausea, vomiting, somnolence • Serious: Rash including Stevens Johnson & toxic epidermal necrolysis. Usually occurs in first 2-8 weeks. Increased risk in children, rapid dose titration, & concomitant use of valproic acid. Risk reduced with slow titration. Hypersensitivity reactions including risk of hepatic and renal failure, disseminated intravascular coagulation, arthritis.
Oxcarbazepine Trileptal®	<ul style="list-style-type: none"> • Children 8-10mg/kg/day in 2 divided doses up to 30mg/kg/day • Adult: 300mg bid up to 600mg bid 	<ul style="list-style-type: none"> • Somnolence, dizziness, drowsiness, diplopia, nausea, ataxia • Serious: Hyponatremia, skin rash.
Perampanel Fycopa® - CIII	<ul style="list-style-type: none"> • Children 12 years and older (in the absence of concomitant enzyme-inducing antiepileptic drugs (AED)), initial, 2 mg ORALLY once daily at bedtime up to 12 mg at bedtime • Children 12 years and older (with concomitant enzyme-inducing AED), initial, 4 mg ORALLY once daily at bedtime up to 12 mg at bedtime 	<ul style="list-style-type: none"> • Dizziness, somnolence, headache, fatigue, irritability, gait disturbance, falls, nausea and weight gain • Serious: neuropsychiatric effects including alteration of mood and aggression

Appendix D. (Continued)

Generic Name	Usual Children, Adolescent and Adult Dose	Adverse Effects*
Non-Formulary Agents		
Phenobarbital Luminal®	<ul style="list-style-type: none"> • 5-12yrs: 4-6mg/kg/day in 1-2 divided doses • >12yrs: 1-3mg/kg/day in 1-2 divided doses or 50-100 mg bid-tid 	<ul style="list-style-type: none"> • Drowsiness, somnolence, headache, dizziness, ataxia, cognitive effects, GI upset • Serious: rash including Stevens Johnson, agranulocytosis
Tiagabine Gabitril®	<ul style="list-style-type: none"> • <12yrs: 0.1 mg/kg/day up to 1mg/kg/day • 12-18yrs: 4-32mg/day divided bid-qid • >18yrs: 4-56 mg/day divided bid-qid 	<ul style="list-style-type: none"> • Somnolence, dizziness, tremor, headache, weakness, difficulty concentrating • Serious: Stupor or spike wave stupor
Topiramate Topamax®	<ul style="list-style-type: none"> • 2-16yrs: 0.5-1mg/kg/day up to 5.9mg/kg/day • >16yrs: 25-50mg/day up to 400-1600 mg/day 	<ul style="list-style-type: none"> • Behavioral changes especially in children, anorexia, weight loss, sleep disorders, fatigue, dizziness, headache, paresthesia • Serious: Nephrolithiasis, open angle glaucoma, and hypohidrosis especially in children
Zonisamide Zonegran®	<ul style="list-style-type: none"> • Children 2-4mg/kg/day up to 8mg/kg/day in 1-2 divided doses • > 16yrs: 100-200mg/day up to 400 mg/day 1-2 divided doses 	<ul style="list-style-type: none"> • Drowsiness, ataxia, anorexia, GI upset, headache, pruritus • Serious: Rash, renal calculi, and hypohidrosis especially in children • Do not take if history of sulfa allergy.
Vigabatrin Sabril®	<ul style="list-style-type: none"> • 10-16yrs and weight 25-60kg: 250mg bid up to 1000mg bid • 10-16yrs and weight greater than 60kg or older than 16 yrs: 500mg bid up to 1500mg bid 	<ul style="list-style-type: none"> • Drowsiness, fatigue, headache, and dizziness • Serious: Black box warning regarding possible permanent vision loss, severe hypersensitivity reactions and angioedema have been reported • Reserved for refractory cases that have failed several alternative treatments. Limited number of specialty pharmacies in the US dispense this drug as part of SHARE program. Physicians must be registered to dispense this drug.

*Not a complete list

Note: In 2008, the FDA issued a warning for a possible increased risk of suicidal ideation and behavior associated with antiepileptic drugs. This was based on a FDA review of 199 trials including 11 different antiepileptic drugs. Patients should be monitored for the emergence of suicidal thoughts or changes in behavior. Referral to mental health may be considered if appropriate.

Appendix E: Formulary AED Drug Interactions

DRUG	DRUG INTERACTIONS (DI) & COMMENTS*
Carbamazepine (CBZ)	<ul style="list-style-type: none"> • DI – levels increased by VPA, phenytoin, vigabatrin, erythromycin, fluoxetine, isoniazid, propoxyphene, & verapamil; levels decreased by phenobarbital & primidone
Levetiracetam	<ul style="list-style-type: none"> • DI - probenecid- clinical significance unknown; not metabolized thru CYP450. • Renal elimination- dose adjust in renal insufficiency • No dose adjustment for hepatic impairment.
Phenytoin	<ul style="list-style-type: none"> • DI – levels increased by VPA, topiramate, oxcarbamazepine, allopurinol, diltiazem, fluconazole, fluoxetine, ibuprofen, isoniazid, methylphenidate, metronidazole, omeprazole, propoxyphene, ritonavir, bactrim; levels decreased by CBZ, vigabatrin, antacids, rifampin, methotrexate
Primidone	<ul style="list-style-type: none"> • Potent and broad spectrum inducer of CYP • Dose adjustment is needed in renal impairment. Use with caution in patients with hepatic insufficiency.
Valproic Acid (VPA)	<ul style="list-style-type: none"> • DI – levels increased by aspirin & isoniazid; levels decreased by CBZ, phenobarbital, & phenytoin • Contraindicated hepatic disease/significant hepatic dysfunction, known urea cycle disorder

PRODUCT INFORMATION

3TC see LAMIVUDINE

ABACAVIR (Max 11 refills)

ZIAGEN®

300MG TABLET (\$7.25)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ABILIFY® see ARIPIPIRAZOLE

ABSORBASE

EUCERIN®

4OZ (\$2.12), 16OZ (\$7.48) 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 (\$0.63)

(Note: Take from stock. No refills allowed.)

ACETAMINOPHEN/CODEINE - CIII, CV

TYLENOL® #3

APAP 300MG/CODEINE 30MG TABLET – CIII (\$0.22)

APAP 300MG/CODEINE 30MG/12.5ML UD SOLUTION - CV (\$1.46)

(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 (\$2.16)

ACETIC ACID/AL ACET OTIC SOLN

DOMEBORO® OTIC

2% OTIC SOLUTION - 60ML (\$48.93)

ACTIDOSE® see CHARCOAL, ACTIVATED

ACYCLOVIR

ZOVIRAX®

400MG TABLET (\$0.06) (Max 11 refills)

800MG TABLET (\$0.25) (No refills)

ADENOCARD® see ADENOSINE

ADENOSINE

ADENOCARD®

6MG/2ML VIAL (\$3.32)

(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 (\$94.56) (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 (\$2.56/BOX)

(Note: Restricted to acute asthma management. Orders should not exceed 7 days. May be ordered for a maximum of 30 days for COPD. Must be noted in special instructions. Clinic use only. Take from stock. May not be given KOP.)

PROVENTIL-HFA®, VENTOLIN® (Max 3 refills)

METERED DOSE INHALER 90MCG/ACTUATION

200 ACTUATIONS (\$60.57, \$42.31)

(Note: Ventolin limited to Texas Tech units and requires non-formulary approval.)

ALCAINE® OPHTH SOLN see PROPARACAINE OPH SOL

ALDACTONE® see SPIRONOLACTONE

ALDOMET® see METHYLDOPA

ALCALAK® see CALCIUM CARBONATE

ALLOPURINOL (Max 11 refills)

ZYLOPRIM®

100MG (\$0.15), 300MG (\$0.40) TABLET

ALPHAGAN® see BRIMONIDINE

ALTEPLASE

(t-PA, CATHFLO ACTIVASE®)

1MG/1ML - 2ML VIAL (\$117.68)

(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 (\$1.51)

(Note: Non-formulary approval required for TJJD facilities.)

AMIODARONE (Max 11 refills, tablet only)

CORDARONE®

200MG TABLET (\$0.10)

50MG/ML INJECTION – 3ML VIAL (\$0.67)

(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 (\$0.01), 10MG (\$0.01) TABLET

AMMONIA

AROMATIC INHALANT - 0.33ML (\$2.10/BOX)

(35% ALCOHOL, 15% AMMONIA) 12 INHALANTS/BOX

(Note: Clinic use only. Take from stock. May not be given KOP.)

AMOXICILLIN

AMOXIL®

250MG (\$0.04), 500MG (\$0.06) CAPSULE

AMOXIL® see AMOXICILLIN

AMPHETAMINE/DEXTROAMPHETAMINE see AMPHETAMINE SALTS

AMPHETAMINE SALTS - CII

ADDERALL®

5MG (\$0.15), 10MG (\$0.53) TABLET

ADDERALL XR®

10MG (\$4.00), 20MG (\$6.66), 30MG (\$5.26) EXTENDED RELEASE
CAPSULE

(Note: May not be given KOP. Restricted to TJJJ only. Take from stock TJJJ
institutions only. May only be ordered by a physician.)

AMPICILLIN

OMNIPEN-N®

500MG INJECTION, IM OR IV (\$1.08)

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

ANTIVERT® see MECLIZINE HCL

ANU-MED® SUPPOSITORY see HEMORRHOIDAL SUPPOSITORY

ANUSOL-HC® CREAM see HYDROCORTISONE RECTAL CREAM

ANUSOL-HC SUPP® see HYDROCORTISONE HEMORRHOIDAL SUPPOSITORY

APRESOLINE® see HYDRALAZINE

ARIPIRAZOLE (Max 11 refills)

ABILIFY®

2MG (\$27.81), 5MG (\$27.81), 10MG (\$27.81), 15MG (\$27.81), 20MG
(\$39.33), 30MG (\$39.33) TABLET

(Note: May not be given KOP. Restricted to TJJJ. 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 and ziprasidone.
- b. Treatment failure on risperidone and ziprasidone.
- c. Contraindication to risperidone and ziprasidone.

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 (\$19.95), 300MG (\$39.51) 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 (\$0.01) TABLET

ATIVAN® see LORAZEPAM

ATOMOXETINE (Max 11 refills)

STRATTERA®

25MG (\$9.55), 40MG (\$5.08), 60MG (\$7.01), 80MG (\$5.48), 100MG

(\$5.48) CAPSULE

(Note: May not be given KOP. Restricted to T.JJD. 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 (\$0.14) TABLET

ATROPINE SULFATE

ATROPINE

0.1MG/ML INJECTION - 10ML SYRINGE (\$9.59) (No refills)

(Note: Clinic use only. Take from stock. May not be given KOP.)

ISOPTO ATROPINE®

1% OPHTH SOLUTION - 15ML (\$76.20) (Max 11 refills)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ATROVENT HFA® see IPRATROPIUM BROMIDE

AVLOSULFON® see DAPSONE

AZATHIOPRINE (Max 11 refills)

IMURAN®

50MG TABLET (\$0.47)

(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. Gonorrhea (GC)
 - 1200 milligrams x 1 dose in combination with ceftriaxone 250 mg IM x 1 dose
- c. Pregnancy
 - 1200 milligrams x 1 dose for chlamydia)

AZT see ZIDOVUDINE

AZULFIDINE® see SULFASALAZINE

B-1, VITAMIN see THIAMINE HCL

B-6, VITAMIN see PYRIDOXINE HCL

B-12, VITAMIN see CYANOCOBALAMIN

BACITRACIN/POLYMYXIN

POLYSPORIN®, DOUBLE ANTIBIOTIC OINTMENT

TOPICAL OINTMENT - 15GM TUBE (\$3.49)

POLYSPORIN®

OPHTHALMIC OINTMENT - 3.5GM TUBE (\$7.90)

BACLOFEN (Max 11 refills)

LIORESAL®

10MG (\$0.16), 20MG (\$0.25) 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 (\$174.71)

(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

BENTYL® see DICYCLOMINE

BENZAC® see BENZOYL PEROXIDE

BENZOYL PEROXIDE (Max 3 refills)

BENZAC®

10% GEL - 1.5 OZ (\$2.08)

(Note: Orders are to be given a 90 day expiration date.)

BENZTROPINE MESYLATE (Max 2 refills)

COGENTIN®

0.5mg (\$0.12), 1MG (\$0.08), 2MG (\$0.18) 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 (\$0.03)

10MG SUPPOSITORY (\$0.05)

(Note: Take from stock.)

BISMUTH SUBSALICYLATE

PEPTO BISMOL®

262MG CHEWABLE TABLET (\$0.06)

(Note: Take from stock.)

BODY LOTION

LUBRISOFT® (No refills)

19OZ LOTION - (\$1.71)

(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 (\$4.56)

BROMOCRIPTINE MESYLATE (Max 11 refills)

PARLODEL®

2.5MG TABLET (\$2.30)

(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 (\$1.70)

0.25% INJECTION - 10ML VIAL (\$1.79)

(Note: Clinic use only. Take from stock. May not be given KOP.)

BUTORPHANOL TARTRATE - CIV

STADOL®

2MG/ML IM INJECTION - 1ML VIAL (\$3.56)

(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 (\$1.20)

(Note: Take from stock.)

CALAN® SR see VERAPAMIL HCL

CALAN® see VERAPAMIL HCL

CALCITRIOL (Max 11 refills)

ROCALTROL®

0.25MCG CAPSULE (\$0.47)

(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 (\$8.44)

(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 (\$5.05)
(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 (\$0.07)
(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 (\$0.42)
(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 (\$1.09)
(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 (\$0.15)

CARDIZEM® see DILTIAZEM HCL

CARVEDILOL (Max 11 refills)

COREG®

3.125MG (\$0.02), 6.25MG (\$0.02), 12.5MG (\$0.03), 25MG (\$0.03) TAB

CASTOR OIL

CASTOR OIL - 120ML (\$0.84)
(Note: Take from stock.)

CATAPRES® see CLONIDINE HCL

CATHFLO ACTIVASE® see ALTEPLASE

CEFAZOLIN SODIUM

ANCEF®

1GM INJECTION – 10ML VIAL (\$0.79)

Preparation Standard:

≤ 2gm in 100mL D₅W over 30-60 minutes.

(Note: Clinic use only. Take from stock. May not be given KOP.)

CEFTAZIDIME

FORTAZ®

500MG INJECTION (\$4.98)

1GM INJECTION (\$4.42)

IV Preparation Standard:

≤ 2gm in 100mL D₅W over 40 minutes> 2gm in 150mL D₅W 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 (\$0.68)

(Note: Clinic use only. May not be given KOP. Prior authorization criteria must be met and noted in the special instructions field for use. Criteria is: Treatment of GC in combination with azithromycin 1200 milligrams x 1 dose.)

1 GM INJECTION (\$1.29)

(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 (\$0.09)

CHARCOAL

ACTIDOSE® WITH SORBITOL

50GM ACTIVATED CHARCOAL / 54GM

SORBITOL LIQUID - 8OZ (\$17.70)

(Note: Clinic use only. Take from stock. May not be given KOP.)

CHLORDIAZEPOXIDE - CIV

LIBRIUM®

10MG (\$0.13), 25MG (\$0.15) CAPSULE

(Note: May not be given KOP. Restricted to TDCJ and TJJJ facilities for benzodiazepine discontinuation. Take from stock. May only be ordered by a physician or a DEA/DPS registered midlevel provider.)

CHLORHEXIDINE GLUCONATE

PERIDEX®

0.12% ORAL RINSE - 16OZ (\$2.49)

(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 (\$0.03)

(Note: Take from stock.)

CHLORPROMAZINE HCL (Max 11 refills)

THORAZINE®

50MG (\$4.02), 100MG (\$3.72), 200MG (\$5.32) TABLET

(Note: May not be given KOP.)

CHLOR-TRIMETON® see CHLORPHENIRAMINE

CIBALITH-S® see LITHIUM CITRATE

CIPRO® see CIPROFLOXACIN

CIPROFLOXACIN

CIPRO®

500MG TABLET (\$0.10)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Use restricted to regional medical facilities (inpatient use only). Available as floor stock to prevent delays in therapy. Not recommended for GC or gram positive infections including *S. aureus*. Non-formulary approval still required for use at facilities other than RMFs.)

CITALOPRAM HBR (Max 11 refills)

CELEXA®

10MG (\$0.05), 20MG (\$0.05), 40MG (\$0.03) TABLET

(Note: May not be given KOP. 10mg restricted to TJJJ only.)

CLARITIN® see LORATADINE

CLEAR EYES® see NAPHAZOLINE

CLEOCIN®, CLEOCIN-T® see CLINDAMYCIN

CLINDAMYCIN HCL

CLEOCIN®

150MG CAPSULE (\$0.06)

CLINDAMYCIN PHOSPHATE

CLEOCIN®, CLEOCIN-T®

1% TOPICAL SOLUTION – 60ML (\$50.95)

(Note: Topical solution is restricted to TJJJ facilities and may not be given KOP.)

150MG/ML - 6ML VIAL (\$3.93)

IV Preparation Standard:

> 600mg in 150mL D₅W over 60 minutes. Maximum rate of infusion 30mg/minute.

900MG/50ML D₅W PREMIX (\$13.45)

(Note: Injection is clinic use only. Take from stock. May not be given KOP.)

CLONAZEPAM

KLONOPIN

0.5MG TABLET (\$0.05)

(Note: County Jails only. Take 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: New intake. Allowed up to 30 days for tapering over to a formulary agent if needed.)

CLONIDINE HCL

CATAPRES®

0.1MG TABLET (\$0.03)

(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 (\$0.07)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria includes:

- a. Intolerant or allergic to aspirin and needs cardioprotection or prevention
- b. Failed aspirin therapy [e.g., event while on aspirin such as MI, stroke, TIA]
- c. Acute Coronary Syndrome [e.g., MI, unstable angina, CABG or PCI with or without stent placement] and treatment is in combination with aspirin
- d. Brachytherapy
- e. Intermittent claudication and failed trial or remained symptomatic while on aspirin plus dipyridamole
- f. Dialysis vascular graft.

Available in stock to prevent delays in therapy. Non-formulary approval is still required for all other uses.)

CLOTRIMAZOLE

LOTRIMIN®

1% TOPICAL SOLUTION - 10ML (\$16.36)

1% CREAM - 15GM TUBE (\$1.23)

CLOZAPINE

CLOZARIL®

25MG (\$0.37), 100MG (\$0.76) 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 (\$182.45)

(Note: Clinic use only. Take from stock. May not be given KOP. Use is restricted to wound care facilities.)

COMPAZINE® see PROCHLORPERAZINE

COMPOUND W® see SALICYLIC ACID

CONDYLOX® see PODOFILOX

CONTACT LENS CARE PRODUCTS

CONTACT TYPE	CLASS	PRODUCT (DAYS SUPPLY)
RGP	SOAKING/DISINFECTING/PROTEIN REMOVER/CLEANER SOLUTION (\$7.66)	BOSTON SIMPLUS MULTI-ACTION SOLUTION® 3.5OZ (30)
RGP, S	CONTACT REWETTING & LUBRICANT SOLUTION (\$2.81)	CLERZ PLUS® - 5ML (30)
S	SOFT CONTACT LENS MULTIPURPOSE SOLUTION (\$3.03)	OPTI-ONE MULTIPURPOSE SOLUTION® 12OZ (90) : ONE SOLUTION FOR RINSING, DISINFECTING, STORAGE, & REWETTING
RGP, S	CONTACT LENS CASE (\$0.74)	

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*.

OPTIONS FOR PROVIDING A 12 MONTH SUPPLY OF PRODUCTS	DAYS SUPPLY	ORDER QTY	REFILLS
OPTION 1 (SOFT LENSES)			
OPTI-ONE MULTIPURPOSE SOLUTION®	90	1	3
CLERZ-PLUS 5ML®	30	1	11
CONTACT LENS CASE*			
OPTION 2 (RIGID GAS PERMEABLE LENSES)			
BOSTON SIMPLUS MULTI-ACTION SOLUTION®	30	1	11
CLERZ-PLUS 5ML®	30	1	11
CONTACT LENS CASE*			

*Contact lens case may be ordered from the pharmacy warehouse if needed. Stat orders are not available.

CONTACT LENS REWETTING 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

CRIVAN® see INDINAVIR

CRYSELLE® see NORGESTREL/ETHINYL ESTRADIOL

CTM see CHLORPHENIRAMINE MALEATE

CYANOCOBALAMIN, VITAMIN B-12 (Max 11 refills)
1000MCG/ML INJECTION - 1ML VIAL (\$2.38)
(Note: Clinic use only. Take from stock. May not be given KOP.)

CYCLOGYL® see CYCLOPENTOLATE HCL

CYCLOPENTOLATE HCL
CYCLOGYL®
1% OPHTHALMIC SOLUTION - 15ML (\$27.61)

CYCLOSPORINE (Max 11 refills)
NEORAL®
25MG (\$0.69), 100MG (\$2.43) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

CYPROHEPTADINE
PERIACTIN®
4MG TABLET (\$0.43)

D-T TOXOIDS see TETANUS & DIPHTHERIA TOXOIDS

D4T see STAVUDINE

DACRIOSE® see OPHTHALMIC IRRIGATING SOLUTION

DAPSONE (Max 11 refills)
AVLOSULFON®
100MG TABLET (\$1.01)

DARAPRIM® see PYRIMETHAMINE

DARUNAVIR (Max 11 refills)
PREZISTA®
600MG (\$19.61), 800MG (\$39.23) 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 (\$1.30)

(Note: May not be given KOP. Restricted to TJJD use only)

DESYREL® see TRAZODONE HCL

DEXAMETHASONE

DECADRON®

4MG/ML – 1ML VIAL (\$2.04)

(Note: Clinic use only. Take from stock. May not be given KOP).

4MG TABLET (\$0.11)

(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 (\$1.84), 250ML, (\$3.08), 500ML (\$3.20), 1000ML (\$1.83)

DEXTROSE 5% in WATER INJECTION MINI-BAG – 100ML (\$2.34)

DEXTROSE 5% in NS INJECTION - 500ML (\$3.43), 1000ML (\$3.99)

DEXTROSE 5% in 1/4 NS INJECTION - 1000ML (\$4.81)

DEXTROSE 5% in 1/2 NS INJECTION - 1000ML (\$4.19)

DEXTROSE 5% LACTATED RINGERS - 1000ML (\$4.24)

DEXTROSE 10% in WATER INJECTION - 1000ML (\$1.52)

DEXTROSE 50% INJECTION SYRINGE - 50ML (\$5.90)

DEXTROSE 40% GEL 37.5GM TUBE – 3 TUBES/BOX

GLUTOSE 15® (\$2.96/TUBE)

(Note: Clinic use only. Take from stock. May not be given KOP. D10W 1000ml restricted to Estelle, Michael and Young facilities for use until TPN is available.)

DIAMOX® see ACETAZOLAMIDE

DIAZEPAM - CIV (Max 5 refills)

VALIUM®

5MG TABLET (\$6.70)

(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
- g. County Jails only-Restricted to withdrawal protocol.)

DICLOXACILLIN SODIUM

DYNAPEN®

250MG (\$0.28), 500MG (\$0.57) CAPSULE

DICYCLOMINE

BENTYL®

20MG (\$0.04) TABLET

(Note: County Jails only – Restricted to withdrawal protocol. May be used for up to 7 days if needed.)

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 (\$6.73), 0.25MG (\$2.02) TABLET

DILACOR® XR see DILTIAZEM HCL

DILANTIN® see PHENYTOIN SODIUM

DILTIAZEM (Max 11 refills)

CARDIZEM®

60MG (\$0.23), 90MG (\$0.30) TABLET

DILACOR® XR (extended release once-daily dosage form)

180MG (\$0.49), 240MG (\$0.40) CAPSULE

DIPHENHYDRAMINE 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 (\$2.13)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

50MG/ML INJECTION - 1ML VIAL (\$0.64) (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.)

DITROPAN® see OXYBUTYNIN

DIVALPROEX SODIUM (Max 11 refills)

DEPAKOTE®

250MG (\$.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 (\$41.10)

(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 (\$8.43)

DOUBLE ANTIBIOTIC OINTMENT see BACITRACIN/POLYMYXIN B

DOXERCALCIFEROL (Max 11 refills)

HECTOROL®

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 RILPIVIRINE

EFAVIRENZ (Max 11 refills)

SUSTIVA®

600MG TABLET (\$26.29)

(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

ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR

GENVOYA®

150MG/150MG/200MG/10MG TABLET (\$80.37)

(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 Genvoya at intake.)

ENGERIX® B see HEPATITIS B VACCINE, RECOMBINANT

ENTECAVIR

BARACLUDE®

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 (\$1.02)

(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(\$1.91)

1:10,000 (0.1MG) INJECTION - 10ML SYRINGE (\$6.40)

EPIPEN®

1:1000 (0.3MG/0.3ML) INJECTION – 2 SYRINGES/PK (\$215.61/SYR)

(Note: Clinic use only. Take from stock. May not be given KOP. EpiPen restricted to EMS and TJJD institutions for emergency boxes and patients at TJJD halfway houses. Non-formulary approval required for patient orders at TDCJ and County jails.)

EPIPEN® see EPINEPHRINE

EPIVIR® see LAMIVUDINE

EPOETIN ALFA (Max 2 refills)

PROCRIT®

10,000 UNIT/ML INJECTION - 2ML VIAL (\$366.24)

(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 (\$12.53)

ERYTHROMYCIN STEARATE

ERYTHROCIN®

250MG TABLET (\$7.84)

ERYTHROMYCIN

ILOTYCIN®

0.5% OPHTHALMIC OINTMENT - 3.5GM (\$5.24)

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 (\$3.71), 1.25MG (\$3.71) TABLET

(Note: Restricted to use in female patients only.)

25MG/5ML INJECTION – 5ML VIAL (\$205.64)

(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 (\$246.50)

(Note: Restricted to use in female patients only.)

ETHAMBUTOL HCL (Max 11 refills)

MYAMBUTOL®

400MG TABLET (\$0.88)

(Note: May not be given KOP.)

ETHYNODIOL DIACETATE/ETHINYL ESTRADIOL (Max 11 refills)

ZOVIA – 1/50E®

1/50-28 TABLET (\$17.05/pack)

(Note: Restricted to female patients.)

EUCERIN® see ABSORBASE

FENTANYL

DURAGESIC®

25MCG/HR (\$4.35), 100MCG/HR (\$14.15) 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

FLEETS PHOSPHO SODA® see SODIUM PHOSPHATE ORAL SOLUTION

FLAGYL® see METRONIDAZOLE

FLUCONAZOLE (Max 11 refills)

DIFLUCAN®

100MG (\$1.28), 150MG (\$2.62), 200MG (\$2.56) 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 (\$3.08)

(Note: Restricted to emergency use only. Clinic use only. Take from stock. May not be given KOP.)

FLUOCINONIDE

LIDEX®

0.05% OINTMENT - 15GM (\$21.00)

0.05% CREAM - 15GM (\$17.58)

FLUORETS® see FLUORESCEIN SODIUM STRIPS

FLUORESCEIN SODIUM STRIPS

FLUORETS®, BIO-GLO®, FUL-GLO®

1MG OPHTHALMIC STRIPS – 100/BOX (\$0.09 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 (\$0.11), 5MG (\$0.20), 10MG (\$0.11) TABLET

2.5MG/ML INJECTION - 10ML VIAL (\$171.09)

(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 (\$101.02)

(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 (\$4.13)

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 (\$15.65)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

FUROSEMIDE (Max 11 refills, tablet)

LASIX®

20MG (\$0.02), 40MG (\$0.02) TABLET

10MG/ML INJECTION - 4ML VIAL (\$3.93)

(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

GEMFIBROZIL (Max 11 refills)

LOPID®

600MG TABLET (\$0.07)

GENOPTIC® see GENTAMICIN

GENTAMICIN

GARAMYCIN®, GENOPTIC®, GENTAK®
0.3% OPHTHALMIC OINTMENT - 3.5GM (\$5.14)
0.3% OPHTHALMIC SOLUTION - 5ML (\$3.96)

GENTAMICIN

40MG/ML INJECTION - 2ML VIAL (\$0.99)

IV Preparation Standard:

≤ 100mg in 100mL D₅W over 60 minutes

>100mg in 150mL D₅W over 60 minutes.

(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

GENTIAN VIOLET

2% SOLUTION - 60ML (\$10.34)

(Note: Clinic use only. Take from stock. May not be given KOP.)

GEODON® see ZIPRASIDONE

GLIPIZIDE (Max 11 refills)

GLUCOTROL®

5MG (\$0.01), 10MG (\$0.03) TABLET

GLUCAGEN® see GLUCAGON

GLUCAGON

GLUCAGEN®

1MG HYPOKIT (\$201.53)

(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 (\$1.00)

(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 (\$0.30), 5MG (\$0.65), 10MG (\$0.56) TABLET

HALOPERIDOL LACTATE (Max 11 refills, oral concentrate only)

HALDOL®

2MG/ML ORAL CONCENTRATE - 120ML (\$6.54)

5MG/ML INJECTION - 1ML VIAL (\$0.88)

(Note: May not be given KOP. Injection for clinic use only and should be taken from stock.)

HALOPERIDOL DECANOATE (Max 11 refills)

HALDOL D®

100MG/ML INJECTION - 5ML VIAL (\$185.20)

(Note: May not be given KOP. Injection for clinic use only and should be taken from stock.)

HARVONI® see LEDIPASVIR/SOFOSBUVIR

HAVRIX® see HEPATITIS A VACCINE

HC RECTAL CREAM see HYDROCORTISONE CREAM

HECTOROL® see DOXERCALCIFEROL

HEMORRHOIDAL-HC® see HYDROCORTISONE

HEMORRHOIDAL

PREPARATION H® (Max 11 Refills)

MAXIMUM STRENGTH CREAM 51GM (\$2.31)

ANU-MED® (No refills)

SUPPOSITORY - 12/BOX (\$0.09/suppos)

(Note: Take from stock. Cream contains pramoxine HCL 1% and phenylephrine 0.25%.
Suppositories contain phenylephrine HCL 0.25% as active ingredients.)

HEP-LOCK® see HEPARIN SODIUM

HEPARIN SODIUM

HEP-LOCK®

100U/ML - 3ML SYRINGE (\$0.47)

HEPARIN

1,000U/ML - 30ML VIAL (\$3.87)

5,000U/ML - 1ML VIAL (\$1.28)

(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®

1440 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)

ENGERIX B®

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 (\$134.91)

(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.)

HUMULIN® see INSULIN, HUMAN

HYDRALAZINE (Max 11 refills)

APRESOLINE®

25MG (\$0.03), 50MG (\$0.04) TABLET

HYDROCHLOROTHIAZIDE (Max 11 refills)

HYDRODIURIL®

12.5MG CAPSULE (\$0.02)

25MG (\$0.01), 50MG (\$0.01) TABLET

HYDROCORTISONE

ANUSOL-HC®

1% HEMORRHOIDAL-HC RECTAL CREAM – 30GM (\$5.16)
25MG HEMORRHOIDAL-HC RECTAL SUPPOSITORY–12/BOX (\$8.70
EACH)

(Note: Max 11 refills on hemorrhoidal cream. No refills allowed on suppositories.)

HYTONE®

1% CREAM – 30GM (\$2.32), U/D PACKET (\$0.06)

HYDROCORTISONE SODIUM SUCCINATE

SOLU-CORTEF®

100MG INJECTION - 2ML VIAL (\$5.42)

250MG INJECTION - 2ML VIAL (\$13.55)

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

HYDROXYZINE PAMOATE (Max 2 refills)

VISTARIL®

25MG (\$0.06), 50MG (\$0.08) CAPSULE

(Note: May not be given KOP. Restricted to TJJJ only.

50MG CAPSULE

(Note: County Jails only – Restricted to withdrawal protocol. May be used for up to 7 days if needed.)

HYTONE® see HYDROCORTISONE CREAM

HYTRIN® see TERAZOSIN

IBUPROFEN (Max 2 refills)

MOTRIN®

200MG (\$0.02), 400MG (\$0.02), 600MG (\$0.03), 800MG (\$0.04) TABLET

(Note: The 200mg tablets should be taken from stock, no refills allowed and restricted to Texas Tech TDCJ facilities, TJJJ facilities, and County jails; restricted to dental use only for UTMB TDCJ facilities.)

ILOTYCIN® see ERYTHROMYCIN

IMDUR® see ISOSORBIDE MONONITRATE

IMIPRAMINE HCL (Max 11 refills)

TOFRANIL®

25MG (\$0.20), 50MG (\$0.29) TABLET

(Note: May not be given KOP. Restricted to TJJD for treatment of enuresis.)

IMODIUM® see LOPERAMIDE HCL

IMURAN® see AZATHIOPRINE

INDERAL® see PROPRANOLOL

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 (\$955.45)

(Note: Floor stock restricted to RMFs. Designated as a Local Control and therefore must be kept and inventoried as a controlled substance (Pharmacy Policies 20-05, 20-10, 20-15). Non-formulary approval is still required prior to use. May not be given KOP.)

INFLUENZA VIRUS VACCINE, WHOLE VIRUS

FLUVIRIN®

5ML MULTI-DOSE VIAL - 10 DOSES/VIAL (\$100.00)

(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. Morbidly obese BMI ≥ 40)

INFUVITE® see MULTIVITAMIN

INH see ISONIAZID

INSULIN, HUMAN (Max 11 refills)

NOVOLIN®, HUMULIN®

NPH 100 UNITS/ML - 10ML VIAL (\$112.67, \$120.01)

REGULAR 100 UNITS/ML - 10ML VIAL (\$112.67, \$120.01)

(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. Humulin limited to Texas Tech units and requires non-formulary approval.)

INVIRASE® see SAQUINAVIR

IPRATROPIUM BROMIDE HFA (Max 11 refills)

ATROVENT HFA®

HFA ORAL INHALER 200 ACTUATIONS/17MCG EACH (\$243.10)

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 7 days. May be ordered for a maximum of 30 days for COPD. Must be noted in special instructions.)

IRON SUCROSE

VENOFER®

20MG/ML – 5ML SINGLE DOSE VIAL (\$48.00)

(Note: Clinic use only. Take from stock. May not be given KOP. Restricted to dialysis centers.)

ISENTRESS® see RALTEGRAVIR

ISONIAZID (Max 11 refills)

NYDRAZID®, INH

300MG TABLET (\$0.10)

(Note: May not be given KOP.)

ISOPTO ATROPINE® see ATROPINE SULFATE

ISOPTOTEARs® see METHYLCELLULOSE

ISOSORBIDE MONONITRATE (Max 11 refills)

ISMN, IMDUR®

30MG (\$0.16), 60MG (\$0.17) EXTENDED RELEASE TABLET

KALETRA® see LOPINAVIR/RITONAVIR

KAYEXALATE® see POLYSTYRENE SODIUM SULFONATE

K-DUR® see POTASSIUM CHLORIDE

KCL see POTASSIUM CHLORIDE

KEFLEX® see CEPHALEXIN

KENALOG® see TRIAMCINOLONE

KENALOG IN ORABASE® see TRIAMCINOLONE DENTAL PASTE

KEPPRA® see LEVETIRACETAM

KLONOPIN® see CLONAZEPAM

LABETALOL

NORMODYNE®

5MG/ML – 40ML MDV (\$2.73)

(Note: Restricted to EMS for treatment of HTN emergencies per protocol.)

LACTATED RINGERS

INJECTION 1000ML (\$5.09)

(Note: Clinic use only. Take from stock. May not be given KOP.)

LACTULOSE (Max 11 refills)

ENULOSE®

10GM/15ML SYRUP - 473ML (\$5.23)

(Note: Take from floor stock except for county jails.)

LAMIVUDINE (3TC) (Max 11 refills)

EPIVIR®

150MG (\$4.50), 300MG (\$3.50) 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 (\$4.89)

(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%

LEDIPASVIR/SOFOSBUVIR

HARVONI®

90MG-400MG TABLET (\$1052.33)

(Note: The preferred Hepatitis C therapy. Non-formulary approval required by HCV group from pharmacy at utmcmc.pharmacyID@utmb.edu. The two designated Centers of Excellence are 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.)

LEUCOVORIN CALCIUM (Max 11 refills)

WELLCOVORIN®, FOLINIC ACID

5MG TABLET (\$0.84)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

LEVETIRACETAM (Max 11 refills)

KEPPRA®

500MG (\$0.31), 1000MG (\$0.70) 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 (\$0.23), 0.05MG (\$0.27), 0.1MG (\$0.30), 0.15MG (\$0.36)
TABLET

LEXIVA® see FOSAMPRENAVIR

LIBRIUM® see CHLORDIAZEPOXIDE

LIDEX® see FLUOCINONIDE

LIDOCAINE HCL

XYLOCAINE®

2% VISCOUS ORAL SOLUTION - 100ML (\$1.85)

2% JELLY - 30ML (\$8.32)

5% OINTMENT – 1.25OZ (\$52.25)

1% LOCAL INJECTION (10MG/ML) - 20ML VIAL (\$1.07)

2% LOCAL INJECTION (20MG/ML) - 20ML VIAL (\$1.57)

1% WITH EPINEPHRINE 1:100,000 – 20ML VIAL (\$1.60)

(Note: Injection and 2% jelly for clinic use only and should be taken from stock. The 2% jelly restricted to emergency use only. Viscous solution may not be given KOP. The 5% ointment is restricted as floor stock to GC and GV for clinic use only by OBGYN services and may not be given KOP.)

LIORESAL® see BACLOFEN

LIPITOR® see ATORVASTATIN

LISINAPRIL (Max 11 refills)

PRINIVIL®, ZESTRIL®

2.5MG (\$0.01), 5MG (\$0.02), 10MG (\$0.01), 20MG (\$0.02), 40MG (\$0.03)

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 (\$11.07)

(Note: May not be given KOP.)

LO/OVRAL-28® see NORGESTREL/ETHINYL ESTRADIOL

LONITEN® see MINOXIDIL

LOPERAMIDE HCL (Max 2 refills)

IMODIUM®

2MG CAPSULE (\$0.25)

LOPID® see GEMFIBROZIL

LOPINA VIR/RITONAVIR (Max 11 refills)

KALETRA®

200MG/50MG FILM-COATED TABLET (\$6.72)

(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 (\$0.03)

LORAZEPAM - CIV

ATIVAN®

2MG/ML INJECTION - 1ML VIAL (\$1.52)

(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 non-formulary approval.)

1MG TABLET (\$0.06)

(Note: County Jails only-Restricted to withdrawal protocol.)

LOTRIMIN® see CLOTRIMAZOLE

LOW-OGESTREL® see NORGESTREL/ETHINYL ESTRADIOL

LUBRICANT EYE OINTMENT (Max 11 refills)

LUBRIFRESH PM®

OPHTHALMIC OINTMENT - 3.5GM (\$1.90)

LUBRICANT, SURGICAL

SURGILUBE®

2 OZ TUBE (\$1.48)

4.25 OZ TUBE (\$2.52)

3GM FOILPACK (\$0.10)

(Note: Clinic use only. Take from stock. May not be given KOP. 4.25 oz tube restricted to regional medical facilities.)

LUBRIFRESH PM® see LUBRICANT EYE OINTMENT

LUBRISOFT® see BODY LOTION

LUMINAL® see PHENOBARBITAL

MACRODANTIN® see NITROFURANTOIN

MAGNESIUM CITRATE

SOLUTION - 300ML (\$1.06)

(Note: Clinic use only. Take from stock. May not be given KOP.)

MAGNESIUM HYDROXIDE

MILK OF MAGNESIA®

2400MG/30ML SUSPENSION - 30ML UNIT DOSE (\$0.70)

(Note: Take from stock.)

MAGNESIUM SULFATE

50% INJECTION (500MG/ML) - 2ML VIAL (\$0.84)

(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 (\$58.78)

(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 in Texas.)

MECLIZINE HCL (Max 2 refills)

ANTIVERT®

25MG TABLET (\$0.13)

MEDROXYPROGESTERONE

DEPO-PROVERA®

150MG/ML INJECTION - 1ML VIAL (\$135.45) (Max 3 refills)

PROVERA®

2.5MG (\$0.04), 10MG (\$0.06) 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 (\$0.01), 15MG (\$0.01) TABLET

MENACTRA® see MENINGOCOCCAL VACCINE

MENINGOCOCCAL VACCINE, POLYSACCHARIDE

MENOMUNE®, MENACTRA®

50MCG/0.5ML SDV (\$98.13)

(Note: Restricted from stock. May not be given KOP. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: anatomic or functional asplenic patients who have no history of prior immunization or require a booster.)

MENTHOLATUM RUB

VICKS VAPORUB®

OINTMENT – 50GM (\$3.32)

(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 (\$14.26)

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 (\$0.02) TABLET

METHIMAZOLE (Max 11 refills)

TAPAZOLE®

5MG TABLET (\$0.06)

METHOCARBAMOL

ROBAXIN®

750MG TABLET (\$0.09)

(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 (\$24.18)

METHYLDOPA

ALDOMET®

250MG TABLET (\$0.18)

(Note: Floor stock restricted to Carol Young Medical Facility. Non-formulary approval is still required for use.)

METHYLPHENIDATE- CII

RITALIN®

5MG (\$0.63), 10MG (\$0.87) TABLET

RITALIN LA®

10MG (\$2.89), 20MG (\$5.65), 30MG (\$3.36), 40MG (\$2.60) EXTENDED
RELEASE CAPSULE

(Note: May not be given KOP. Restricted to TJJD use only. Take from stock TJJD institutions only. May only be ordered by a physician.)

METHYLPREDNISOLONE SODIUM SUCCINATE

SOLU-MEDROL®

125MG INJECTION – 2ML VIAL (\$6.04)

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 (\$0.89)

(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 (\$1.18)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

METOPROLOL TARTRATE (Max 11 refills)

LOPRESSOR®

25MG (\$0.02), 50MG (\$0.02), 100MG (\$0.03) TABLET

5MG/5ML INJECTION - 5ML VIAL (\$0.51)

(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

METRONIDAZOLE HCL

FLAGYL®

250MG (\$0.07), 500MG (\$0.18) 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.)

MICONAZOLE

MONISTAT-7®

100MG VAGINAL SUPPOSITORY - 7 SUPP/BOX (\$2.89/BOX)

(Note: Restricted to female patients. Generally dosed 1 suppository inserted vaginally q hs x 7 days.)

MICROSULFON® see SULFADIAZINE

MILK OF MAGNESIA see MAGNESIUM HYDROXIDE

MINOCIN® see MINOCYCLINE

MINOCYCLINE

MINOCIN®

100MG CAPSULE (\$0.38)

MINOXIDIL (Max 11 refills)

LONITEN®

2.5MG (\$0.09), 10MG (\$0.12) TABLET

M-M-R VACCINE see MEASLES/MUMPS/RUBELLA VACCINE, LIVE

MOBIC® see MELOXICAM

MOMETASONE FUROATE

ELOCON®

0.1% TOPICAL SOLUTION – 60ML (\$26.19)

MONISTAT® see MICONAZOLE

MORPHINE SULFATE - CII

4MG/1ML INJECTION-1ML ISECURE PREFILLED SYRINGE (\$2.01)

10MG/5ML ELIXIR – 5ML UNIT DOSE (\$0.68)

MS CONTIN®

15MG (\$0.71), 30MG (\$1.41) 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 (\$3.62)

(Note: Clinic use only. Take from stock. May not be given KOP.)

TABLET (\$0.01)

(Note: Prior authorization required for use of tablets. The following prior authorization criteria must be met and noted in the special instructions field of the order:

- a. HIV positive, CD4 count < 100 cells/mm³ and not prescribed a nutritional supplement/enteral feeding.
- b. County Jails only- Restricted to withdrawal protocols. Use limited to 10 days.)

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 (\$0.45)

500MG TABLET (\$0.39)

(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 (\$5.81)

IV Preparation Standard:

≤ 1gm in 100mL D₅W over 30 minutes

> 1gm in 100mL D₅W over 40 minutes.

(Note: Clinic use only. Take from stock. May not be given KOP.)

NALOXONE HCL

NARCAN®

0.4MG/ML INJECTION - 1ML VIAL (\$12.07)

(Note: Clinic use only. Take from stock. May not be given KOP)

NAPHAZOLINE HCL

CLEAR EYES®, NAPHCN®

0.012% OPHTHALMIC SOLUTION - 15ML (\$2.70)

NAPHAZOLINE/PHENIRAMINE

OPCON-A®, NAPHCN-A®

NAPHAZOLINE 0.025%/PHENIRAMINE 0.3%

OPHTHALMIC SOLUTION - 15ML (\$4.52)

NAPHCN® see NAPHAZOLINE HCL

NAPHCN-A® see NAPHAZOLINE/PHENIRAMINE

NAPROSYN® see NAPROXEN

NAPROXEN (Max 2 refills)
NAPROSYN®
250MG (\$0.06), 500MG (\$0.04) TABLET

NARCAN® see NALOXONE HCL

NATALINS® FA see PRENATAL-FOLIC ACID

NAVANE® see THIOTHIXENE HCL

NELFINAVIR (Max 11 refills)
VIRACEPT®
625MG TABLET (\$7.60)
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

NEOMYCIN/BACITRACIN/POLYMYXIN
NEOSPORIN®, TRIPLE ANTIBIOTIC
OPHTHALMIC OINTMENT - 3.5GM (\$42.63)
TOPICAL OINTMENT 1GM PACKET (\$0.28)
(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 (\$48.68)

NEOMYCIN/POLYMYXIN/DEXAMETHASONE
MAXITROL®
OPHTHALMIC SUSPENSION - 5ML (\$12.44)
OPHTHALMIC OINTMENT - 3.5GM (\$14.86)

NEOMYCIN/POLYMYXIN/HYDROCORTISONE
CORTISPORIN®
OTIC SUSPENSION - 10ML (\$24.81)

NEOMYCIN/GRAMICIDIN/POLYMYXIN
NEOSPORIN®
OPHTHALMIC SOLUTION - 10ML (\$37.89)

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 (\$0.68)

(Note: May not be given KOP.)

NIACIN (Max 11 refills)

NIASPAN ER®

500MG (\$4.52), 1000MG (\$8.00) 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 (\$0.76)

NITROGLYCERIN (Max 1 refill SL tablets, 11 refills patches)

NITROSTAT®

0.4MG SUBLINGUAL TABLET - 25 PER BOTTLE (\$18.53 PER BOTTLE)

(Note: Sublingual tablets should be ordered as 1 bottle to last 6 months.)

NITROBID®

2% TOPICAL OINTMENT - 60GM (\$46.39)

(Note: The ointment is restricted to clinic use only for short-term relief of angina, should be taken from stock and may not be given KOP.)

NITRO-DUR®

0.2MG/HR (\$0.45), 0.4MG/HR (\$0.76) 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 (\$18.41)
(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 (\$0.08), 50MG (\$0.12), 75MG (\$0.12) CAPSULE
(Note: May not be given KOP. Restricted to TDCJ, non-formulary approval required
for use at TJJJ facilities.)

NORVASC® see AMLODIPINE

NORVIR® see RITONAVIR

NOVOLIN® see INSULIN, HUMAN

NYDRAZID® see ISONIAZID

NYSTATIN
MYCOSTATIN®
100,000UNITS/ML ORAL SUSPENSION - 60ML (\$6.65)

OCEAN NASAL MIST® see SODIUM CHLORIDE

OCUFEN® see FLURBIPROFEN

OMEPRAZOLE (Max 11 refills)
PRILOSEC®
20MG CAPSULE (\$0.03)

OMNIPEN-N® see AMPICILLIN

OPCON-A® see NAPHAZOLINE/PHENIRAMINE

OPHTHALMIC IRRIGATING SOLUTION
DACRIOSE®
IRRIGATING EYE WASH - 120ML (\$1.35)

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)

DITROPAN®

5MG TABLET (\$0.28)

(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 (\$233.93 per 100 count bottle)

PARICALCITOL

ZEMPLAR®

5MCG/ML - 1ML VIAL (\$20.97)

(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

PEG 3350 see ELECTROLYTE ORAL SOLUTION

PEGASYS® see PEGINTERFERON

PEGINTERFERON ALFA-2A (Max 11 refills)

PEGASYS®

180MCG/0.5ML – 0.5ML SYRINGE (\$810.54)

(Note: May not be given KOP. Non-formulary approval required by HCV group from pharmacy at utmbcmc.pharmacy@utmb.edu for UTMB units and Utilization Management at (806)356-5350 for TTUHSC units.)

PENICILLIN VK

VEETIDS®

500MG TABLET (\$0.14)

PENICILLIN G BENZATHINE

BICILLIN LA®

1.2MU/2ML SYRINGE (\$89.23)

(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 (\$10.29)

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 (\$6.16)

ELIMITE®

5% CREAM – 60GM (\$55.97)

PERPHENAZINE (Max 11 refills)

TRILAFON®

4MG (\$1.07), 8MG (\$1.28), 16MG (\$2.08) TABLET

(Note: May not be given KOP.)

PERSANTINE® see DIPYRIDAMOLE

PETROLATUM

VASELINE®

JELLY - 13OZ (\$1.79)

(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 (\$2.43)

PHENERGAN® see PROMETHAZINE HCL

PHENYLEPHRINE HCL

SUDAFED-PE®

10MG TABLET (\$0.01)

PHENOBARBITAL (Max 5 refills)

LUMINAL®

32.4MG TABLET

(Note: County Jails only. Take 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: New intake. Allowed up to 30 days for tapering over to a formulary agent if needed.)

PHENYTOIN (Max 11 refills)

DILANTIN®

125MG/5ML SUSPENSION - 8OZ (\$17.31)

(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 (\$0.22)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

50MG/ML INJECTION – 5ML VIAL (\$3.04)

(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)

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

PNEUMOCOCCAL VACCINE (POLYVALENT)

PNEUMOVAX-23®

25MCG/0.5ML INJECTION - 0.5ML SINGLE DOSE VIAL (\$66.52)

(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 (\$40.74)

(Note: Clinic use only. Take from stock. May not be given KOP.)

PODOPHYLLUM 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 (\$261.28)

(Note: May not be given KOP. Prior authorization required for use. Criteria: patients < 18 years old. All other uses require non-formulary approval.)

POLYMYXIN B/TRIMETHOPRIM

POLYTRIM®

10,000U/1MG OPHTHALMIC SOLUTION – 10ML (\$1.92)

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 POLYMYXIN B/TRIMETHOPRIM

POLYVINYL ALCOHOL (Max 11 refills)

ARTIFICIAL TEARS

1.4% OPHTHALMIC SOLUTION - 15ML (\$1.61)

POTASSIUM CHLORIDE (Tablets max 11 refills)

K-DUR®, KCL

10MEQ (\$0.20), 20MEQ (\$0.19) EXTENDED RELEASE TABLET

20MEQ/1000ML D₅W INJECTION (\$5.61)

20MEQ/1000ML 1/2NS D₅W INJECTION (\$2.15)

(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 (\$0.28), 20MG (\$0.20), 40MG (\$0.24) TABLET

PRED FORTE® see PREDNISOLONE ACETATE

PREDNISOLONE ACETATE

PRED FORTE®

1% OPHTHALMIC SUSPENSION - 5ML (\$35.76)

PRED MILD®

0.12% OPHTHALMIC SUSPENSION - 5ML (\$98.45)

PREDNISONE (Max 11 refills 5mg tablets only)

DELTASONE®

5MG (\$0.12), 10MG (\$0.17), 20MG (\$0.21) TABLET

PREMARIN® see ESTROGENS, CONJUGATED

PRENATAL-FOLIC ACID (Max 11 refills)

NATALINS FA®

TABLET (\$0.04)

(Note: Contains 1mg folic acid. Prior authorization criteria must be met and noted in the special instructions field to use without non-formulary approval. Criteria: pregnancy.)

PREPARATION H® CREAM see HEMORRHOIDAL

PREZISTA® see DARUNAVIR

PRILOSEC® see OMEPRAZOLE

PRIMIDONE (Max 11 refills)

MYSOLINE®

250MG TABLET (\$0.14)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

PRINIVIL® see LISINAPRIL

PROBENECID (Max 11 refills)

BENEMID®

500MG TABLET (\$0.59)

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 (\$0.08)

25MG SUPPOSITORY - 12/BOX (\$85.80/BOX)

25MG/ML INJECTION - 1ML VIAL (\$0.78)

(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 (\$31.00)

(Note: Clinic use only. Take from stock. May not be given KOP.)

PROPRANOLOL HCL (Max 11 refills)

INDERAL®

10MG (\$0.04), 20MG (\$0.25), 40MG (\$0.42) TABLET

PROTAMINE SULFATE

50MG INJECTION - 5ML VIAL (\$3.13)

(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 (\$1.82)

(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

QVAR® see BECLOMETHASONE

RALTEGRAVIR (Max 11 refills)

ISENTRESS®

400MG TABLET (\$18.78)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

RAPAMUNE® see SIROLIMUS

RANITIDINE HCL (Max 11 refills)

ZANTAC®

150MG TABLET (\$0.06)

REGLAN® see METOCLOPRAMIDE HCL

REMICADE® see INFlixIMAB

RENAGEL® see SEVELAMER

RETROVIR® see ZIDOVUDINE

REYATAZ® see ATAZANAVIR

RHO(D) IMMUNE GLOBULIN

RHOGAM®

300MCG SYRINGE (\$65.83)

(Note: Floor stock restricted to Carol Young. Non-formulary approval still required for use).

RHOGAM® see RHO(D) IMMUNE GLOBULIN

RIBASPHERE® see RIBAVIRIN

RIBAVIRIN (Max 11 refills)
RIBASPHERE®
200MG CAPSULE (\$0.80)
(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 utmbmc.pharmacyID@utmb.edu for UTMB units and Utilization Management at (806)356-5350 for TTUHSC units.)

RIFABUTIN (Max 11 refills)
MYCOBUTIN®
150MG CAPSULE (\$18.91)
(Note: May not be given KOP.)

RIFADIN® see RIFAMPIN

RIFAMPIN (Max 11 refills)
RIFADIN®
300MG CAPSULE (\$0.72)
(Note: May not be given KOP.)

RILPIVIRINE (Max 11 refills)
EDURANT®
25MG TABLET (\$25.89)
(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 (\$0.12)
(Note: May not be given KOP. Restricted to TJJD.)
1MG (\$0.02), 2MG (\$0.05), 3MG (\$0.05), 4MG (\$0.06) 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

ROCALTROL® see CALCITRIOL

ROCEPHIN® see CEFTRIAZONE

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)

INVIRASE®

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 (\$7.64)

(Note: Orders should be written for 1 bottle to last 90days.)

SELSUN® see SELENIUM SULFIDE

SERTRALINE (Max 11 refills)

ZOLOFT®

25mg (\$0.04), 50MG (\$0.04), 100MG (\$0.04) TABLET

(Note: May not be given KOP. 25mg restricted to TJJD only.)

SEVELAMER (Max 11 refills)

RENAGEL®

800MG TABLET (\$6.00)

(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 (\$9.46), 400GM (\$37.00)

(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 (\$1.77/BOTTLE)

(Note: May be ordered PRN with a limit of one bottle of 100 to be dispensed with a 90-day expiration.)

SINEMET® see CARBIDOPA/LEVODOPA

SIROLIMUS (Max 11 refills)

RAPAMUNE®

1MG (\$28.78), 2MG (\$20.36) TABLET

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

SMZ/TMP see SULFAMETHOXAZOLE/TRIMETHOPRIM

SOAKING SOLUTION see CONTACT LENS CARE PRODUCTS

SODIUM BICARBONATE

SODIUM BICARBONATE

1mEq/ML INJECTION (8.4%) - 50ML SYRINGE (\$7.88)

(Note: Clinic use only. Take from stock. May not be given KOP.)

SODIUM CHLORIDE

0.45% INJECTION - 1000ML (\$4.46)
0.9% INJECTION – 100ML (\$1.77), 250ML (\$3.57)
500ML (\$5.09), 1000ML (\$3.82)
0.9% MINI-BAG – 100ML (\$4.97)
0.9% IRRIGATION SOLUTION - 250ML (\$2.71)
0.9% BACTERIOSTATIC INJECTION - 30ML VIAL (\$0.83)
0.9% BACTERIOSTATIC FREE INJ - 10ML VIAL (\$0.69)
0.9% INHALANT SOLUTION - 3ML VIAL (\$0.10)

OCEAN® (Max 2 refills)

NASAL SPRAY - 45ML (\$1.07)

MURO 128® (Max 11 refills)

2% OPHTHALMIC SOLUTION - 15ML (\$14.20)

5% OPHTHALMIC SOLUTION - 15ML (\$7.65)

5% OPHTHALMIC OINTMENT - 3.5GM (\$7.47)

(Note: Injection, irrigating solution, bags, and inhalation are for clinic use only, should be taken from stock, and may not be given KOP.)

SODIUM PHOSPHATE

FLEET'S® ENEMA

ENEMA - 133ML (\$0.77)

(Note: Take from stock.)

SOFOSBUVIR

SOVALDI®

400MG TABLET (\$935.40)

(Note: The preferred Hepatitis C therapy. Non-formulary approval required by HCV group from pharmacy at utmbcmc.pharmacyID@utmb.edu. The two designated Centers of Excellence are 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.)

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 (\$0.15), 160MG (\$0.14) TABLET

SOVALDI® see SOFOSBUVIR

SPIRIVA® HANDIHALER see TIOTROPIUM

SPIRONOLACTONE (Max 11 refills)
ALDACTONE®
25MG TABLET (\$0.04)

STADOL® see BUTORPHANOL TARTRATE

STANNOUS FLUORIDE
GEL-KAM®
0.4% GEL – 4.3OZ (\$10.66)

STAVUDINE (D4T) (Max 11 refills)
ZERIT®
20MG (\$0.88), 30MG (\$0.89), 40MG (\$0.93) CAPSULE
(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.
Stavudine 20mg restricted to dialysis patients or patients with renal impairment.)

STELAZINE® see TRIFLUOPERAZINE HCL

STRATTERA see ATOMOXETINE

STRIBILD® see ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR

SUDAFED-PE® see PHENYLEPHRINE

SULAMYD® see SULFACETAMIDE SODIUM

SULFACETAMIDE SODIUM
SULAMYD®
10% OPHTHALMIC SOLUTION - 15ML (\$37.75)

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.)

SULFAMETHOXAZOLE/TRIMETHOPRIM (Max 11 refills, tablets only)

BACTRIM® DS

SMZ 800MG/TMP 160MG DOUBLE STRENGTH TABLET (\$0.06)

SMZ 400MG/TMP 80MG per 5ML INJECTION - 10ML VIAL (\$8.43)

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 (\$0.15)

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 (\$1.25), 1MG (\$1.41), 5MG (\$12.51) CAPSULE

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

TAPAZOLE® see METHIMAZOLE

TDaP see TETANUS/DIPHThERIA/ACELLULAR PERTUSSIS

TDF see TENOFOVIR

TEGRETOL® see CARBAMAZEPINE

TENEX® see GAUNFACINE

TENIVAC™ see TETANUS & DIPHThERIA TOXOIDS

TENOFOVIR (TDF) (Max 11 Refills)

VIREAD®

300MG TABLET (\$29.10)

(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 (\$0.06), 2MG (\$0.03), 5MG (\$0.04), 10MG (\$0.03) CAPSULE

TERBUTALINE SULFATE

BRETHINE®

1MG/ML INJECTION - 1ML VIAL (\$1.44)

(Note: Clinic use only. Take from stock. May not be given KOP. Use restricted to female patients at Carol Young and Crain facilities.)

TETANUS/DIPHTHERIA TOXOIDS

D-T TOXOIDS, TENIVAC™

0.5ML SINGLE DOSE VIAL (\$17.08)

(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 (TDaP)

BOOSTRIX®

0.5ML SINGLE DOSE VIAL (\$35.17)

(Note: May not be given KOP. Clinic use only. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include: pregnancy and Td booster indicated and not previously vaccinated.)

TETRAHYDROZOLINE HCL

VISINE®

0.05% OPHTHALMIC SOLUTION - 15ML (\$1.00)

THIAMINE HCL (VITAMIN B-1) (Max 11 refills, tablet only)

100MG TABLET (\$0.02)

100MG/ML - 2ML VIAL (\$9.30)

(Note: Injection for clinic use only, should be taken from stock, and may not be given KOP.)

THIOTHIXENE (Max 11 refills)

NAVANE®

2MG (\$0.57), 5MG (\$0.92), 10MG (\$1.45) CAPSULE

(Note: May not be given KOP.)

THORAZINE® see CHLORPROMAZINE HCL

TIMOLOL MALEATE (Max 11 refills)

TIMOPTIC®

0.5% OPHTHALMIC SOLUTION - 5ML (\$4.77)

TINACTIN® see TOLNAFTATE

TIOTROPIUM (Max 11 refills)

SPIRIVA® HANDIHALER

18MCG CAPSULE, 30/BOX (\$265.76/BOX)

(Note: May not be given KOP. Prior authorization required. Prior authorization criteria must be met and noted in the special instructions field for use without non-formulary approval. Criteria include:

- a. Inadequate response to ipratropium HFA 2 puffs QID
- b. Classified as Moderate COPD
- b. Classified as Severe COPD
- c. Classified as Very severe COPD

TIVICAY® see DOLUTEGRAVIR

TOBRAMYCIN

TOBREX®

0.3% OPHTHALMIC SOLUTION - 5ML (\$5.53)

40MG/ML INJECTION – 2ML VIAL (\$1.33)

(Note: Injection for clinic use only, should be taken from stock and may not be given KOP. The ophthalmic solution may be given KOP.)

TOFRANIL® see IMIPRAMINE HCL

TOLNAFTATE

TINACTIN®

1% CREAM - 15GM (\$2.04), U/D PACKET (\$0.07)

(Note: U/D packets are restricted to County Jails only.)

t-PA (TISSUE-TYPE PLASMINOGEN ACTIVATOR) see ALTEPLASE

TRAZODONE HCL (Max 11 refills)

DESYREL®

50MG (\$0.05), 100MG (\$0.07) TABLET

(Note: May not be given KOP.)

TRI-CHLOR® see TRICHLOROACETIC ACID

TRIAMCINOLONE

KENALOG®

0.025% OINTMENT - 15GM (\$3.37)

0.025% CREAM - 15GM (\$2.72)

0.1% CREAM - 15GM (\$2.12)

0.1% CREAM – 80GM (\$7.08) (max 5 refills)

10MG/ML INJECTION - 5ML VIAL (\$10.33)

40MG/ML INJECTION - 1ML VIAL (\$8.00)

KENALOG IN ORABASE®

0.1% DENTAL PASTE – 5GM (\$39.48)

(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 (\$0.13)

TRICHLOROACETIC ACID

TRI-CHLOR®

80% SOLUTION – 15ML (\$54.54)

(Note: Clinic use only. Take from stock. May not be given KOP.)

TRIFLUOPERAZINE HCL (Max 11 refills)

STELAZINE®

2MG (\$0.90), 5MG (\$1.14), 10MG (\$1.59) TABLET

(Note: May not be given KOP.)

TRIFLURIDINE

VIROPTIC®

1% OPHTHALMIC SOLUTION - 7.5ML (\$109.25)

TRILAFON® see PERPHENAZINE

TRIMETHOPRIM/POLYMYXIN B see POLYMYXIN B/TRIMETHOPRIM

TRUSOPT® see DORZOLAMIDE

TUBERCULIN INJECTION (PURIFIED PROTEIN DERIVATIVE)

PPD, APLISOL®

10TESTS/1ML INJECTION - 1ML VIAL (\$56.50)

50TESTS/5ML INJECTION - 5ML VIAL (\$220.00)

(Note: Clinic use only. Take from stock. May not be given KOP.)

TYLENOL® see ACETAMINOPHEN

TYLENOL® W/CODEINE see ACETAMINOPHEN/CODEINE

TYLENOL #3® see ACETAMINOPHEN WITH CODEINE

ULIPRISTAL

ELLA®

30MG TABLET (\$33.44)

(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

VANCOGIN® see VANCOMYCIN HCL

VANCOMYCIN HCL

VANCOGIN®

1G INJECTION VIAL (\$5.70)

IV Preparation Standard:

≤500mg in 100mL D₅W over 60-90 minutes

>500mg in 150mL D₅W over 90-120 minutes.

(Note: Clinic use only. Take from stock. May not be given KOP.)

VARICELLA VACCINE (Max 1 refill)

VARIVAX®

1350 PFU/0.5ML – VIAL (\$95.68)

(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 Public Health
- b. ≤ 18 years old without documentation of previous disease or immunization
- c. HIV positive patients without documented immunity and CD4 > 200)

VASELINE® JELLY see PETROLATUM

VASOPRESSIN

PITRESSIN®

20U/ML – 1ML VIAL (\$3.75)

(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®

37.5MG (\$0.31), 75MG (\$0.09) IMMEDIATE RELEASE TABLET

(Note: May not be given KOP. Restricted to TDCJ only.)

EFFEXOR® XR

75MG (\$8.38), 150MG (\$9.13) EXTENDED RELEASE CAPSULE

(Note: May not be given KOP. Restricted to TJJJ only.)

VENOFER® see IRON SUCROSE

VENTOLIN® see ALBUTEROL SULFATE

VERAPAMIL HCL (Max 11 refills, tablet & caplet)

CALAN®

80MG (\$0.05), 120MG (\$0.13) IMMEDIATE RELEASE TABLET

2.5MG/ML INJECTION - 2ML VIAL (\$29.45)

CALAN SR®

180MG (\$0.10), 240MG (\$0.06) 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

VIDEX-EC® see DIDANOSINE

VIRACEPT® see NELFINAVIR

VIRAMUNE® see NEVIRAPINE

VIREAD® see TENOFOVIR

VIROPTIC® see TRIFLURIDINE

VISINE® see TETRAHYDROZOLINE HCL

VISTARIL® see HYDROXYZINE PAMOATE

VITAMIN B-1 see THIAMINE HCL

VITAMIN B-6 see PYRIDOXINE HCL

VITAMIN B-12 see CYANOCOBALAMIN

VITAMIN B COMPLEX & VITAMIN C WITH FOLIC ACID (Max 11 refills)

NEPHRO-VITE®

TABLET (\$0.09)

(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 (\$0.11)

(Note: May not be given KOP.)

WATER FOR INJECTION

WATER FOR INJECTION, STERILE - 10ML (\$0.79)

WATER FOR INJECTION, BACTERIOSTATIC - 30ML (\$1.24)

(Note: Clinic use only. Take from stock. May not be given KOP.)

WATER FOR IRRIGATION

WATER FOR IRRIGATION, STERILE - 250ML (\$2.82)

(Note: Clinic use only. Take from stock. May not be given KOP.)

WELLCOVORIN® see LEUCOVORIN CALCIUM

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 LISINOPRIL

ZIAGEN® see ABACAVIR

ZIDOVUDINE (AZT, ZDV) (Max 11 refills)

RETROVIR®

300MG TABLET (\$0.70)

(Note: Allowed KOP at 8-hour units, may not be given KOP at all other units.)

ZIPRASIDONE HCL (Max 11 refills, capsule)

GEODON®

20MG (\$1.28), 40MG (\$1.60), 60MG (\$1.40), 80MG (\$1.40) CAPSULE

(Note: May not be given KOP. 20mg restricted to TJJJ.)

ZIPRASIDONE MESYLATE

GEODON®

20MG/ML – 1ML VIAL (\$28.17)

(Note: Clinic use only. Take from stock. May not be given KOP. See the Acute Psychosis pathway for injection dosing recommendations.)

ZITHROMAX® see AZITHROMYCIN

ZOVIA® see ETHYNODIOL DIACETATE/ETHINYL ESTRADIOL

ZOVIRAX® see ACYCLOVIR

ZYLOPRIM® see ALLOPURINOL

THERAPEUTIC CATEGORY INDEX

The following index provides a list of Formulary items grouped by therapeutic category according to the American Hospital Formulary Service (AHFS) classification system. The major drug classification appears in all capital letters followed by sub-classification when indicated. Major drug classes are listed below with the corresponding page number(s). Drugs may be listed in more than one therapeutic category.

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- 04:00 ANTI-HISTAMINES**
- 04:04 First Generation Antihistamines**
 - 04:04.04 Ethanolamine Derivatives**
diphenhydramine
 - 04:04.12 Phenothiazine Derivatives**
promethazine
 - 04:04.20 Propylamine Derivatives**
chlorpheniramine
 - 04:04.92 Miscellaneous Derivatives**
cyproheptadine
 - 04:08 Second Generation Antihistamines**
loratadine

- 08:00 ANTI-INFECTIVES**
- 08:12 Antibacterials**
 - 08:12.02 Aminoglycosides**
gentamicin
tobramycin
 - 08:12.06 Cephalosporins**
 - 1st Generation*
cefazolin
cephalexin
 - 3rd Generation*
ceftazidime
ceftriaxone
 - 08:12.07 Miscellaneous β -Lactams**
meropenem
 - 08:12.12 Macrolides**
azithromycin
erythromycin

- 08:12.16 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**
 - clindamycin
 - 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
dapsonsone

08:18 Antivirals

08:18.04 Adamantanes
amantadine

08:18.08 Antiretroviral Agents

Integrase Inhibitor
raltegravir

Integrase Strand Transfer Inhibitor
dolutegravir
elvitegravir/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
nelfinavir
ritonavir
saquinavir

08:18.20 Interferons
peginterferon alfa-2^a

08:18.32 Nucleosides and Nucleotides

acyclovir
entecavir
ribavirin

08:18.40 HCV Antivirals

ledipasvir/sofosbuvir
sofosbuvir

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**
 - 24:06.06 **Fibric Acid Derivative**
 - gemfibrozil

 - 24:06.08 **HMG-CoA Reductase Inhibitor (Statin)**
 - 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

- 24:32** **Renin-Angiotensin-Aldosterone System Inhibitors**
 - 24:32.04** **Angiotensin-Converting Enzyme Inhibitors**
 - lisinopril

24:32.20 Mineralcorticoid (Aldosterone) Receptor Antagonists
spironolactone

28:00 CENTRAL NERVOUS SYSTEM AGENTS

28:08 Analgesics and Antipyretics

28:08.04 Nonsteroidal Anti-Inflammatory Agents

Acetylated salicylates
aspirin

Propionic Acids
ibuprofen
naproxen

Oxicams
meloxicam

28:08.08 Opiate Agonists

acetaminophen / codeine
fentanyl
morphine

28:08.12 Opiate Partial Agonists

butorphanol

28:08.92 Miscellaneous Analgesics & Antipyretics

acetaminophen

28:10 Opiate Antagonists

naloxone

28:12 Anticonvulsants

28:12.04 Barbiturates

phenobarbital
primidone

28:12.12 Hydantoins

phenytoin

28:12.92 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**
 - clonazepam
 - 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

- 40:12 Replacement Preparations**
calcium carbonate
calcium gluconate
dextrose / lactated ringers
potassium chloride
ringers-lactated
sodium chloride
- 40:18 Ion-removing Agents**
40:18.18 Potassium-Removing Agents
polystyrene sodium sulfonate
- 40:18.19 Phosphate-Removing Agents**
sevelamer
- 40:20 Caloric Agents**
dextrose
enteral feeding
- 40:28 Diuretics**
Loop Diuretics
furosemide
- Potassium-sparing diuretics*
triamterene / hydrochlorothiazide
- Thiazide Diuretics*
hydrochlorothiazide
- Thiazide-like Diuretics*
metolazone
- 40:36 Irrigating Solutions**
sodium chloride
sterile water
- 40:40 Uricosuric Agents**
probenecid

- 52:00 EYE, EAR, NOSE, & THROAT (EENT) PREPARATIONS**
- 52:04 Anti-Infectives**
- 52:04.04 Antibacterials**
bacitracin / polymyxin ophth
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
polymyxin B / trimethoprim ophth
sulfacetamide ophth
tobramycin 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**
benzocaine (orabase)
lidocaine viscous
proparacaine ophth

- 52:24 Mydriatics**
 - atropine ophth
 - cyclopentolate ophth

- 52:32 Vasoconstrictors**
 - naphazoline / pheniramine ophth
 - naphazoline ophth
 - tetrahydrozoline ophth

- 52:40 Antiglaucoma agents**
 - 52:40.04 Alpha-Adrenergic Agonists**
 - brimonidine ophth

 - 52:40.08 Beta-Adrenergic Agents**
 - timolol ophth

 - 52:40.12 Carbonic Anhydrase Inhibitors**
 - acetazolamide
 - dorzolamide ophth

 - 52.40.28 Prostaglandin Analogs**
 - latanoprost

- 52:92 Miscellaneous EENT Drugs**
 - lubricant ophth oint
 - 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

 - 56:06 Anticholinergic**
 - dicyclomine

 - 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

- 68:00 HORMONES & SYNTHETIC SUBSTITUTES**
- 68:04 Adrenals**
dexamethasone
hydrocortisone
methylprednisolone
prednisone
triamcinolone
- 68:12 Contraceptives**
ethynodiol diacetate / ethinyl estradiol
norethindrone / ethinyl estradiol
norgestrel / ethinyl estradiol
ulipristal
- 68:16 Estrogen**
68:16.04 Estrogens
conjugated estrogens
- 68:20 Antidiabetic Agents**
68:29.04 Biguanides
metformin
- 68:20.08 Insulins**
insulin, human - NPH
insulin, human – regular
- 68:20.20 Sulfonylureas**
glipizide
- 68:22 Antihypoglycemic Agents**
68:22.12 Glycogenolytic Agents
glucagon
- 68:28 Pituitary**
desmopressin
vasopressin
- 68:32 Progestins**
medroxyprogesterone
- 68:36 Thyroid & Antithyroid Agents**
68:36.04 Thyroid Agents
levothyroxine

68:36.08 Antithyroid Agents
methimazole

72:00 LOCAL ANESTHETICS

bupivacaine
lidocaine

80:00 SERUMS, TOXOIDS, & VACCINES

80:04 Serums

rho(D) immune globulin

80:08 Toxoids

tetanus-diphtheria
tetanus-diphtheria-acellular pertussis

80:12 Vaccines

hepatitis A vaccine
hepatitis B vaccine
human papillomavirus vaccine
influenza virus vaccine
measles-mumps-rubella vaccine
meningococcal polysaccharide vaccine
pneumococcal polyvalent vaccine
poliovirus vaccine, inactivated
varicella vaccine

84:00 SKIN & MUCOUS MEMBRANE AGENTS

84:04 Anti-Infectives

84:04.04 Antibacterials

bacitracin / polymyxin
clindamycin
neomycin / polymyxin / bacitracin

84:04.08 Antifungals

clotrimazole
gentian violet
miconazole
tolnaftate

84:04.12 Scabicides & Pediculicides

permethrin

- 84:04.92 Miscellaneous Local Anti-Infectives**
alcohol, ethyl
selenium sulfide
silver sulfadiazine
- 84:06 Anti-Inflammatory Agents**
fluocinonide
hydrocortisone
mometasone furoate
triamcinolone
triamcinolone / orabase
- 84:08 Antipruritics & Local Anesthetics**
lidocaine
phenazopyridine
- 84:24 Emollients, Demulcents and Protectants**
84:24.04 Basic Lotions and Liniments
calamine
body lotion
mentholatum rub
- 84:24.12 Basic Ointments and Protectants**
absorbase
- 84:28 Keratolytic Agents**
benzoyl peroxide
podophyllum resin
salicylic acid
- 84:32 Keratoplastic Agents**
coal tar
- 84:80 Sunscreen Agents**
sunscreen, SPF 30
- 84:92 Miscellaneous**
collagenase
lubricant, surgical
podofilox
phenylephrine suppositories (hemorrhoidal)
pramoxine/phenylephrine (hemorrhoidal)
trichloroacetic acid

86:00 SMOOTH MUSCLE RELAXANTS
86:12 Genitourinary Smooth Muscle Relaxants
oxybutynin

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

92:36 Disease-modifying Antirheumatic Drugs
infliximab

92:44 Immunosuppressive Agents
azathioprine
cyclosporine
mycophenolate mofetil
sirolimus
tacrolimus

92:92 **Other**
 melatonin

96:00 PHARMACEUTICAL AIDS
 glucose tolerance test
 petrolatum jelly

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