

FEDERAL BUREAU OF PRISONS HEALTH SERVICES

NATIONAL FORMULARY Part I

Winter 2018



APPROVED

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FORMULARY DRUG MONOGRAPHS BY GENERICBEMR RX REPORT, SALLYPORT

Formulary Changes, Winter 2018 Meeting

*** The prescribing of medications against the restrictions, without an approved non-formulary request, is considered an unauthorized use of government funds. The procurement of non-formulary medications or the procurement of formulary medications used outside of formulary restrictions is considered an unauthorized procurement. The prescriber is responsible for justifying the non-formulary request. ***

The following is a summary of the major changes as a result of the Winter 2018 BOP Formulary meeting; please refer to the Winter 2018 National P&T minutes for additional information and detailed discussion regarding all of the changes. Revisions or changes from the previous year are highlighted in Yellow throughout the document.

| | |
|--|---|
| bictegravir, emtricitabine, and tenofovir alafenamide (BIKTARVY™) | ADD |
| Cefdinir (Omnicef™) | ADD |
| Cefixime (Suprax™) | DELETE |
| Didanosine | DELETE |
| Fosamprenavir | DELETE |
| Haemophilus influenza type b conjugate vaccine (ActHIB™, Hiberix™) | ADD ActHIB™ |
| Lopinavir/Ritonavir | DELETE |
| Meningococcal vaccines (Menactra™, Menveo™) | ADD Menveo™ ADD Bexsero™ |
| Metoprolol Succinate ER (Toprol XL™) | ADD with inclusionary diagnosis |
| Nelfinavir | DELETE |
| Nevirapine | DELETE |
| Rosuvastatin (Crestor™) | ADD |
| Sacubitril-Valsartan (Entresto™) | ADD with inclusionary diagnosis |
| Saquinavir | DELETE |
| Stavudine | DELETE |

National BOP Formulary Mission / Procedural Statement

Purpose:

The formulary system, as defined in the "ASHP Statement on the Formulary System", is a method for evaluating and selecting suitable drug products for the formulary of an organized health-care setting.

The BOP formulary is a list of medications that are considered by the organization's professional staff to ensure high quality, cost-effective drug therapy for the population served. Participants of the Pharmacy, Therapeutics and Formulary Meeting are responsible for the development, maintenance and approval recommendations of the formulary to the BOP Medical Director. Periodically, medications are reassessed and extensively reviewed for inclusion, exclusion, or restrictions in the formulary as applicable per current evidence-based practices and security concerns. Regular maintenance of the BOP formulary ensures optimal treatment options are uniformly consistent and readily available.

The primary goals of BOP Formulary Management are to optimize therapeutic outcomes, optimize cost effectiveness of medications, and to ensure drug usage is conducive within the correctional environment.

Expectations:

1. ALL BOP institutions, including Medical Centers, are expected to abide by the formulary as outlined in the BOP Pharmacy Services Program Statement. It is expected that persons in the review process will NOT be circumvented in the event of a short term absence for non-urgent requests.
2. ALL comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
3. It is expected that non-urgent non-formulary medications will not be initiated until AFTER authorization is received, even if the medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.
4. Prescribers (BOP Physician / MLP / Dentist/ Clinical Pharmacist) are expected to thoroughly justify the request including why the formulary agent cannot be used, and provide pertinent laboratory information. It is expected that non-formulary use criteria will be thoroughly addressed point by point and that all non-formulary justifications/criteria are met.
5. Clinical Directors are expected to support the BOP National Formulary and ensure compliance at their respective institution. The CD is expected to review all requests ensuring that appropriate justification and corresponding non-formulary use criteria are met. It is expected that the CD will allow the pharmacist to appropriately comment and provide pertinent information on the request even if not supportive. It is expected that the CD will disapprove, at the local level, any request which does not meet the non-formulary use criteria.
6. Institution Chief Pharmacists are expected to review all medication orders for formulary compliance. This will include reviewing all non-formulary requests for completeness and appropriate justification, and, if applicable, commenting on information provided by the prescriber regarding non-formulary use criteria. The pharmacist is also expected to provide pertinent information regarding patient compliance for formulary agents, drug cost information, and other comments as they pertain to the request.

7. Institution Administration (HSA, Associate Warden, and Warden) are expected to support and ensure compliance with the BOP National Formulary. Administrative decisions regarding medical care are expected to be consistent with the BOP National Formulary and not conflict with the medically necessary provision of medications and restrictions set forth in the BOP National Formulary.
8. Consultant Physicians are expected to utilize and stay within the guidelines of the BOP National Formulary when making recommendations and to provide specific and adequate justification if formulary medications cannot be utilized.
9. Court Orders: Court orders recommending or ordering specific treatments should be referred to the appropriate BOP attorney(s). All such orders/recommendations are still subject to the non-formulary approval process.
10. It is expected that all institution inventories and ordering procedures will be conducive to acceptable inventory practices (e.g. two week par levels on the shelf maintained with weekly medication ordering).

Compliance:

1. Completion and appropriateness of non-formulary medication requests are a review element of the Clinical Director (CD) Peer Review Process.
2. The Medical Director may request Regional Medical Director follow-up and/or issue a memo to the CD requesting a response and corrective action if problems are identified. This may be prompted by consistent failure of the institution staff to appropriately initiate or complete all elements of the non-formulary request, particularly the required supporting documentation.
3. The Medical Director may issue memos to the institution Warden regarding persistent problems or concerns with respect to the institution's compliance with this process.

Continuity of Care Provision:

There are times when inmates are processed into a facility after normal working hours, weekends, and holidays. In those cases where continuity of care is medically necessary because:

1. There is not a formulary substitute, or
2. Changing to a formulary substitute will not allow for appropriate follow up monitoring until the next workday, **AND**
3. Not providing the medication would pose a significant risk to the patient,

An allowance is given to dispense/administer a non-formulary medication for four days while waiting for non-formulary approval. This four day allowance is to only be utilized for urgent continuity of care purposes, and not for initiating routine/non-emergency non-formulary medications without appropriate approval.

This provision is not a substitute for adequate follow up, monitoring, and initiation of non-formulary medications for patients maintained within the facility for chronic ongoing conditions. It is the prescriber's responsibility to ensure appropriate non-formulary submission prior to the expiration of a current non-formulary request.

Medication orders that do not meet the above continuity of care elements should not be written, entered into the pharmacy software system, or dispensed prior to the appropriate non-formulary approval.

DEFINITIONS / RULES

FORMULARY RULES

BRAND NAME PRODUCTS ARE FOR REFERENCE ONLY
THE LEAST EXPENSIVE GENERIC EQUIVALENT IS TO BE UTILIZED WHEN AVAILABLE, OTHERWISE NON-FORMULARY APPROVAL IS REQUIRED
USE AGAINST SPECIFIC RESTRICTIONS REQUIRES NON-FORMULARY APPROVAL
USE OF FORMULATION NOT SPECIFICALLY INCLUDED (E.G. EXTENDED RELEASE, NASAL, TOPICAL, OPHTHALMIC, RAPID DISSOLVE TABLET, COMBINATION PRODUCT, ETC.) IS NOT AUTHORIZED; REQUIRES NON-FORMULARY APPROVAL

COMPOUNDING

This is defined as the combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the needs of an individual patient. All compounded prescription drugs are deemed "new drugs" within the meaning of the Federal Food, Drug, and Cosmetic Act (FDCA).

ALL compounded medications will be considered non-formulary and will go through the same non-formulary and addition to formulary processes as individual, commercially available entities.

DEA CONTROLLED SUBSTANCES

**** ALL CONTROLLED SUBSTANCES ARE RESTRICTED TO PILL LINE ****
** IMMEDIATE RELEASE, NON-ENTERIC COATED, ORAL CONTROLLED SUBSTANCES ARE TO BE CRUSHED PRIOR TO ADMINISTRATION **** IMMEDIATE RELEASE CONTROLLED SUBSTANCE CAPSULES SHOULD BE PULLED APART AND ADMINISTERED IN POWDER FORM **

DIRECTLY OBSERVED THERAPY

A single dose of medication is administered at Pill Line by a qualified employee, and that dose is consumed in the presence of the employee.

EPINEPHERINE AUTO-INJECTOR (EPIPEN™)

Epipen™ may be issued to inmates with known anaphylaxis utilizing the procedure outlined below.

1. Epipen™ is to be entered into BEMR as a pill line item with the recommended sig: - "Inject as directed for severe allergic reaction ** must present this device to pill-line daily for integrity inspection**"
2. The inmate will present the Epipen™ at pill line every day to insure the seal is intact and that no manipulation has occurred.
3. Health services staff will document the encounter in the Medication Administration Record daily.
4. The inmate should be counseled regarding the potential consequences and adverse actions that may occur if tampering is evident or the product is lost or manipulated.

FDA MEDICATION GUIDES AND SIDE EFFECTS STATEMENT

**FDA MEDICATION GUIDES AND DISPLAY OF THE SIDE EFFECTS STATEMENT ARE REQUIRED WITH PRESCRIPTIONS DISPENSED PURSUANT TO INMATES BEING RELEASED, OR SENT TO A RESIDENTIAL REENTRY CENTER (RRC) (E.G. HALF-WAY HOUSE) FDA WEBSITE: <http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>

FDA Medication Guides and display of the side effects statement **ARE NOT** required to be provided to the patient when the inmate is:

1. Confined within a BOP institution.
2. Being transferred within BOP (intra-system) or to another correctional entity (inter-system).

FDA Medication Guides and display of the side effects statement ARE required to be provided to the patient when the inmate is:

1. Being released to the community. (including writs and furloughs)
2. Sent to a Residential Reentry Center (RRC) (e.g. Half-Way House).

OVER THE COUNTER MEDICATIONS

Formulary OTC Medications may only be prescribed as a maintenance medication associated with ongoing follow up in a related chronic care clinic and supported by an appropriate and commensurate indication. Refer to the [Formulary OTC Prescribing Criteria Matrix](#).

MEDICAL CENTER ONLY

A restriction placed on some medication requiring that the use of this drug only be within a Federal Medical Center.

MEDICATION RESTRICTIONS

Prescribing restrictions placed on certain medications. Variance from restrictions requires non-formulary authorization.

PILL LINE ONLY

A restriction placed on controlled substances, psychotropics, TB medications, and some other drugs, requiring that a single dose of the drug be administered to an inmate by a qualified employee at a designated time and place. The administration of that dose must be recorded on a Medication Administration Record (MAR) by the employee. A report of medications that are pill line only is available in BOP electronic medical record. There are some medications that are designated as pill line only for certain indications ([see page 11](#)).

MLP REQUIRES COSIGN

A restriction placed on some medications requiring that a physician sign the medical record each time this drug is prescribed. Subsequent medication orders for this drug must also include the signature of a physician.

PLACEBOS - STATEMENT ON USE

Placebos will not be utilized within the Federal Bureau of Prisons.

References:

AMA "Placebo Use in Clinical Practice" statement:

<https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf> "In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient".

ASHP "Ethical Use of Placebos in Clinical Practice" (1116) statement

<https://www.ashp.org/-/media/assets/policy-guidelines/docs/policy-positions/policy-positions-ethics.ashx?la=en&hash=EC9E91D6DE66E75BFE873695D19047B991F9B59C> "To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; ..."

NON-SUBSTITUTABLE PRODUCTS

| <u>GENERIC DRUG NAME</u> | <u>REQUIRED BRAND PRODUCT</u> |
|-----------------------------|-------------------------------|
| ESTROGENS, CONJUGATED | Premarin™ (Wyeth-Ayerst) |
| PURIFIED PROTEIN DERIVATIVE | Tubersol™ |
| NIACIN (NF) | Niaspan™ (NF) |

LOOK ALIKE / SOUND ALIKE MEDICATIONS

Both the Joint Commission (JC) and the Accreditation Association for Ambulatory Care (AAAHC) require health care organizations to identify look-alike / sound alike medications utilized at their site. A Look Alike / Sound Alike medication list is available from ISMP (Institute of Safe Medicine Practices)

Each BOP institution needs to incorporate Look-Alike / Sound-Alike drugs into the agenda of the local Pharmacy & Therapeutics Committee Meetings, and review them on an annual basis. The discussions, decisions, and respective local policy must follow the requirements set forth by accrediting bodies (JC, AAAHC).

This responsibility is deferred to the local level due to the varying missions of our institutions (e.g. Medical Referral Center, ambulatory institution, Detention Centers, implementation of levels of care) and not all institutions carry exactly the same items from the BOP National Formulary.

RESOURCES The Joint Commission www.jointcommission.org

Institute of Safe Medicine Practices www.ismp.org

[ISMP's List of Confused Drug Names](#)

RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

REMS is defined by the FDA as a program to manage a known or potential serious risk associated with a drug or biologic product. Medications with REMS require differing levels of monitoring and control with the most extreme requiring written contracts between the pharmacy/physician and the manufacturer.

Institution pharmacists/physicians should not sign any agreements without first being reviewed by the BOP Chief Pharmacist or designee. The BOP Chief Pharmacist/designee will consult with the BOP Office of General Counsel as appropriate. A list of current REMS drugs can be found at:

<http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>

BOP institutions with patients requiring "specialty pharmacy restricted REMS medications" (e.g., Revlimid™) should contact their Regional Chief Pharmacist or the Chief of Pharmacy Logistics Support for guidance. Institutions may be directed to obtain some complex REMS medications from a single BOP Pharmacy. Institutions and providers should not obtain REMS medications from a non-BOP pharmacy until all internal processes are exhausted and Central Office Pharmacy staff has instructed them to do so.

KEEP ON PERSON (KOP), I.E. SELF-CARRY MEDICATIONS

Medications are generally excluded (i.e., not self-carry eligible) if:

1. Potential for abuse or misuse. (e.g., controlled substances)
2. Injectable drugs.
3. Psychiatric medications. (unless deemed to be very safe when taken in excessive amounts)
4. Most antipsychotics.
5. Close monitoring is required. (e.g., TB meds)
6. Caustic or harmful agents. (e.g., podofilox)
7. Require refrigeration.
8. Packaging can be misused. (e.g., glass container, inhalers with piercing devices)
9. Cost.

NON-CONTROLLED SUBSTANCES RESTRICTED TO PILL LINE

REFER TO BEMR RX DRUG FILE REPORT FOR AN ALL INCLUSIVE LISTING

ANTIEPILEPTIC DRUGS used for treatment of psychiatric disorders

- CARBAMAZEPINE
- DIVALPROEX
- GABAPENTIN - all uses
- LAMOTRIGINE
- LEVETIRACETAM - all non-seizure indications
- OXCARBAZEPINE
- TOPIRAMATE
- VALPROIC ACID

OXYBUTYNIN

PSYCHOTROPIC MEDICATIONS

TRICYCLIC ANTIDEPRESSANTS

****ALL ITEMS ON THIS PAGE ARE RESTRICTED TO PILL LINE ADMINISTRATION.
THE PHARMACY AND THERAPEUTICS COMMITTEE AT EACH INSTITUTION SHALL DETERMINE WHICH
ADDITIONAL MEDICATION ITEMS ARE TO BE PLACED ON PILL LINE. HEALTH CARE
PROFESSIONALS MAY ALSO PLACE SPECIFIC PATIENT ORDERS ON PILL LINE. ****

****ANY MEDICATIONS USED TO TREAT TUBERCULOSIS (INCLUDING QUINOLONES AND
OTHER ANTIBIOTICS NOT LISTED ABOVE) MUST BE GIVEN BY DIRECTLY OBSERVED
THERAPY**

NON-FORMULARY CLINICAL CRITERIA/JUSTIFICATION REQUIREMENTS, ALGORITHMS, AND TREATMENTS

Acitretin (Soriatane™)

1. Patients need to have a significant BSA involvement, failed appropriate topical agents, and either failed methotrexate or is a poor candidate for methotrexate.
2. The patient has a teledermatology consult in BEMR with the BOP National Dermatology Consultant
3. Female patients must meet all criteria of the "Do our P.A.R.T" program; however, alternative medications should be sought due to the teratogenicity and long-term effects of acitretin.

Adalimumab (Humira™) - See [Immunomodulator TNF Inhibitors](#)

Adult Attention Deficit Hyperactivity Disorder Medications/ Treatment: atomoxetine (Strattera™), methylphenidate (Ritalin™), amphetamine/dextroamphetamine (Adderall™/Dexedrine™)

1. Failure of non-pharmacologic / Education & Counseling / Psychology Referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for minimum of 6 months.
2. Failure of ALL formulary noradrenergic re-uptake inhibitors after ADEQUATE trials for a minimum 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medication trials must occur and be documented within the BOP.
 - a. desipramine/imipramine
 - b. nortriptyline
 - c. venlafaxine
3. Submitted documentation must include/show the following:
 - a. Copy of full psychiatric and psychological behavioral function evaluations
 - b. Evidence (with specific examples) of inability to function in the correctional environment (e.g. incident reports)
 - c. Doses of formulary medications have been maximized
 - d. Six week minimum trial of medication occurred at maximized dose
 - e. Copy of Medication Administration Records (MARs) showing compliance at maximized dose for minimum six week trial
 - f. lab reports of plasma drug levels for desipramine/imipramine and nortriptyline
 - g. History of drug abuse including type of drug (e.g. stimulants, opiates, benzodiazepines, etc.)
4. Additional Notes:
 - a. Only approved on **pill line**.
 - b. **Long acting stimulants** will NOT be approved.
 - c. Contingent to formulation compatibility, stimulant medications will be **crushed** prior to administration.
 - d. Stimulant medications (including atomoxetine) will be our last drug of choice and will only be approved if **function is significantly impaired**.
 - e. The use of stimulant in persons with a history of stimulant **drug abuse** will not be approved.
 - f. See [Bupropion \(Wellbutrin™\)](#) for ADHD use criteria.

Albiglutide (Tanzeum™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Alfuzosin (Uroxatral™)

1. Documentation of significant symptomatic hypotension, orthostatic hypotension, or syncope while receiving terazosin, doxazosin or tamsulosin.
2. Failure of doxazosin 8mg, terazosin 20mg, or tamsulosin 0.8mg daily for a minimum of 6 weeks.

Alirocumab (Praluent™) - See [PCSK9 Inhibitors](#)

Alogliptin (Nesina™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Amantadine (Symmetrel™)

1. Parkinson's Disease / syndrome
2. Drug induced extrapyramidal reactions not responsive to trihexyphenidyl or benztropine.
3. Institutional influenza outbreak - approval will be considered on a case by case basis **AFTER** discussion with the National Infectious Disease Coordinator or Chief Physician. Upon determining appropriateness per the CDC guidelines the institution will be advised to apply for non-formulary approval.

Anticoagulants: apixaban (Eliquis™), dabigatran (Pradaxa™), edoxaban (Savaysa™), rivaroxaban (Xarelto™)

1. Patients being treated for atrial fibrillation with an INR that is unable to be stabilized on warfarin therapy despite being enrolled into an anticoagulation clinic
2. Patients previously stabilized on a direct thrombin inhibitor or Factor Xa inhibitor with an appropriate diagnosis. NOTE: NFR for new intakes may be approved for 90 days at care level 1 and 2 institutions and for 30 days at care level 3 and 4 institutions pending appropriate assessment and conversion to warfarin.
3. The expectation is that patients will be converted to warfarin within the time frames listed in the non-formulary use criteria.

Antiepileptic Medications: ethosuximide (Zarontin™), felbamate (Felbatol™), zonisamide (Zonegran™)

Approval of any non-formulary antiepileptic medications will be considered on an individual basis. When requesting approval please provide information necessary for evaluation of the request. This will include:

1. Previous medications, doses, and documented compliance; blood levels when appropriate.
2. EEG or clinical evidence of failure to achieve seizure-free state.
3. Documented adverse effects of formulary medications.
4. Results of any neurologic consultations.

Please be aware that many of the antiepileptic agents have potentially life-threatening side effects under certain conditions, or in some individuals. The prescriber should take special care:

1. To assess and follow the inmate for potential adverse side-effects.
2. Be aware of any potential drug-drug interactions.
3. Adjust dose no more quickly than recommended by the manufacturer.
4. Monitor compliance.

Antifungals - Oral for onychomycosis: itraconazole (Sporanox™), ketoconazole (Nizoral™), griseofulvin, fluconazole (Diflucan™), terbinafine (Lamisil™)

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation.
2. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil™) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Antihistamines - oral: diphenhydramine (Benadryl™), hydroxyzine (Atarax™, Vistaril™), loratadine (Claritin™), cetirizine (Zyrtec™), cyproheptadine (Periactin™), and fexofenadine (Allegra™)

PILL LINE ONLY

1. Formulary - MRC use only, restricted to dialysis only
2. Patients taking antipsychotic medication with extrapyramidal symptoms not responsive to benztropine and trihexyphenidyl (diphenhydramine and hydroxyzine only)
3. Excessive salivation with clozapine (diphenhydramine and hydroxyzine only)
4. Chronic idiopathic urticaria (consider other formulary H2 blockers such as doxepin)
5. Chronic pruritus-associated dialysis (diphenhydramine and hydroxyzine only)
6. Non-formulary use approved via PILL LINE ONLY
7. **Urticaria:** Classified according to etiology or precipitating factor-see Clinical Update article on Urticaria. All potential precipitating factors have been considered and controlled.
8. **Urticaria:** IgE levels and/or absolute eosinophil count in conditions where this is typically seen.
9. Urticaria: Documented failure (ensuring compliance) of steroid pulse therapy (i.e. prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**

Anti-Obesity Agents: phentermine/topiramate (Qsymia™), lorcaserin (Belviq™), orlistat (Xenical™, Alli™ OTC)

Use must be approved by the BOP Chief Dietician

Apremilast (Otezla™, Celgene™)

Use for psoriasis must be in consultation with BOP teledermatologist.

Use for Psoriatic arthritis:

1. Failure of methotrexate/prednisone, gold or azathioprine.
2. Request must include a rheumatology consult report

Ascorbic Acid (Vitamin C)

Concomitant administration with an imidazole antifungal agent to improve bioavailability by increasing stomach acidity.

Apixaban (Eliquis™) - See [Anticoagulants](#)

Baclofen - See [MUSCLE RELAXANTS](#)

Becaplermin (Regranex™)

1. Patients should have a recent glycosylated hemoglobin (hemoglobin A1c or HbA1c) less than 8. If not, aggressive control of their diabetes should be attempted.
2. Patients should be non-smoking or enrolled in a smoking cessation plan.
3. Stage III or IV (International Association of Enterostomal Therapy for staging chronic wounds) lower extremity diabetic ulcers that extend through the dermis into the subcutaneous tissue or beyond.
4. The wound must have an adequate blood supply measured by Oscillometry (at least 2 units), transcutaneous oxygen pressure (TcpO2 >30 mm Hg) or bleeding with debridement.
5. The wound must be free from infection.
6. If present, lower extremity edema should be treated.
7. The patient must have failed standard therapy for at least 2 months (careful/frequent debridement, moist dressing changes and non-weight bearing).
8. The provider must see the patient on a weekly to biweekly basis for debridement and assessment of ulcer response.
9. The provider must recalculate a new amount of becaplermin gel to be applied at every visit.

Benzodiazepines: Clonazepam & Lorazepam long-term use (> 30 days)

1. Control of severe agitation in psychiatric patients
2. When lack of sleep causes an exacerbation of psychiatric illness
3. Part of a prolonged taper schedule
4. Detoxification for substance abuse
5. Failure of standard modalities for seizure disorders (4th line therapy)
6. Long-term use for terminally ill patients for palliative care (e.g. hospice patients)
7. Adjunct to neuroleptic therapy to stabilize psychosis
8. Second line therapy for anti-mania
9. Psychotic syndromes presenting with catatonia (refer to BOP Schizophrenia Clinical Practice Guideline)
10. Akathisia that is non-responsive to beta blocker at maximum dose or unsuccessful conversion to another antipsychotic agent (refer to BOP Schizophrenia Clinical Practice Guideline)
11. Nausea and Vomiting in Oncology Treatment Patients (Lorazepam only)

Brimonidine 0.1% & 0.15% ophthalmic solution (Alphagan P™)

Documented allergy or sensitivity to brimonidine 0.2 ophthalmic Solution

Budesonide/Formoterol (Symbicort™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists /Inhaled Corticosteroid (LABA/ICS)

Buprenorphine (Subutex™, Suboxone™) for detoxification

1. Will only be approved for detoxification, NOT for pain or maintenance therapy.
2. Prescribing physician MUST have buprenorphine certification and DHHS - SAMHSA waiver. These must be submitted with request.
3. Only buprenorphine/naloxone (Suboxone™) will be approved.

Bupropion (Wellbutrin™ IR, SR, and XL, Zyban™)

1. Restricted to bipolar depression and/or ADHD.
2. Evidence of proven efficacy through previous treatment with bupropion for bipolar depression and/or ADHD.
3. Patient has no history of diverting bupropion.
4. Patient has no history of seizures.
5. All approvals for bupropion will be for the IR formulation and should be administered crushed and in water.
6. BIPOLAR DEPRESSION USE: Must be maintained on a mood stabilizer and/or antipsychotic.
7. BIPOLAR DEPRESSION USE: Must have failed therapy on at least **three** other formulary agents.
8. BIPOLAR DEPRESSION USE: If patient had a manic episode precipitated by the addition of an antidepressant, failure of additional agents is not necessary.
9. ADHD USE: Failure of non-pharmacologic/education & Counseling/Psychology Referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for minimum of six months.
10. ADHD USE: Failure of ALL formulary noradrenergic re-uptake inhibitors after ADEQUATE trials for a minimum of six weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medication trials must have occurred and been documented within the BOP.
 - a. desipramine/imipramine
 - b. nortriptyline
 - c. venlafaxine
11. ADHD USE: Submitted documentation must include/show the following:
 - a. copy of full psychiatric and psychological behavioral function evaluations
 - b. evidence (with specific examples) of inability to function in the correctional environment (e.g., incident reports)
 - c. doses of formulary medications have been maximized or side effects documented
 - d. six week minimum trial of medication occurred at maximized dose
 - e. copy of Medication Administration Records (MARs) showing compliance at maximized dose for minimum six week trial
 - f. lab reports of plasma drug levels for desipramine/imipramine and nortriptyline
 - g. history of drug abuse including type of drug (e.g., stimulants, opiates, benzodiazepines, etc.)
12. Bupropion therapy will not be approved for smoking cessation therapy

Canagliflozin (Invokana™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Certolizumab (Cimzia™) - See [Immunomodulator TNF Inhibitors](#)

Cholinesterase Inhibitors for Alzheimer's disease (AD)

Donepezil (Aricept™) is the non-formulary drug of choice.

1. Request for its non-formulary use requires completion of the "Donepezil Non-formulary Use Criteria Algorithm" form.

Cilostazol (Pletal™)

1. Six months of documented unsuccessful lifestyle modifications (e.g. exercise, smoking cessation).
2. Treatment of cardiovascular disease risk factors.
3. Revascularization cannot be offered or is refused by the patient.

Clonazepam long-term use - See [Benzodiazepines](#)

Clonidine (Catapres™)

1. For use in opiate detoxification only. Oral test dose followed by clonidine patch is preferred protocol mechanism.
2. Dose taper over 2 to 4 days for arriving inmates taking greater than 1 mg per day. Refer to clonidine withdrawal guidance, particularly for patients on concomitant beta blocker therapy. Non-formulary request may be submitted after taper initiated.
3. Use in clozapine induced hypersalivation (CIH) after failure or contraindication to benztropine, amitriptyline, and alpha blocker. NOTE: Including combination therapy with benztropine and an alpha blocker for 12 weeks.
4. Use in Tourette's syndrome.
5. Not to be used in hypertensive urgencies/ emergencies. See Hypertensive clinical practice guidelines and 2006 National P&T Minutes, page 103.

Clonidine Discontinuation Guidance

Discontinuation of most any antihypertensive agent can lead to a corresponding withdrawal syndrome. However, this syndrome is most commonly seen with clonidine, beta-blockers, methyl dopa, and guanabenz. The withdrawal syndrome is thought to be caused by sympathetic over activity and includes nervousness, tachycardia, headache, agitation, and nausea. This is usually seen within 36 to 72 hours after cessation of therapy. In rare instances, a rapid increase in blood pressure to pre-treatment levels or above can be seen that could potentially lead to myocardial ischemia. Again, this is rare, especially when patients are not taking above the standard therapeutic doses of these agents. It also appears to occur more often when multiple medications are being withdrawn at the same time.

Abrupt discontinuation of clonidine, in particular those taking greater than 1 mg daily, may result in nervousness, agitation, restlessness, anxiety, insomnia, headache, sweating, palpitation, increased heart rate, tremor, hiccups, muscle pain, increased salivation, stomach pain, nausea and flushing. This may be due in part to the fact that clonidine has been shown to act upon opiate receptors. These effects generally appear within two to three hours after the first missed dose.

Blood pressure may increase in four to eight hours after the first missed dose of clonidine and is associated with a rise in catecholamine plasma concentrations. This potential may be exacerbated after administration of higher doses or continued concurrent therapy with a beta-blocker.

Severe blood pressure increases after clonidine discontinuation can be treated with the reinstatement of clonidine therapy followed by a short, gradual taper over two to four days; IV phentolamine +/- propranolol (propranolol should never be utilized alone as it may further elevate the BP); or utilization of a vasodilator such as hydralazine or diazoxide.

If a patient is taking clonidine concurrently with a beta-blocker, it is best to gradually withdraw the beta blocker, then withdraw the clonidine over two to four days. The beta-blocker can then be reinstated after clonidine has been successfully withdrawn. Concurrent beta-blocker therapy may exacerbate an increase in blood pressure upon clonidine withdrawal.

Appropriate follow-up to including adjustment of medication management of all patients is essential during this process.

Clopidogrel (Plavix™) - use > 30 days

Clopidogrel indications for use as single antiplatelet agent therapy (in lieu of aspirin):

1. Aspirin allergy (anaphylaxis, bronchospasm)
2. Recurrent non-cardioembolic cerebral ischemia while on aspirin

Clopidogrel indications for use as dual antiplatelet therapy with aspirin (by condition):

1. ACS (NSTEMI, STEMI, unstable angina (UA)) with no revascularization - 1 year
2. Post PCI - 1 year
3. Post CABG - 4 weeks
4. Non-coronary stenting
 - a. Carotid artery stent - similar to PCI

COX-2 Inhibitors: celecoxib (Celebrex™)

Documentation of:

1. Prior history of a serious GI event (hospitalization for perforation, ulcer, or bleed); **OR**;
2. Concurrent use of warfarin (for OA, these patients must ordinarily fail acetaminophen and salsalate prior to receiving a COX-2 inhibitor).

Non-formulary Requests for Cox-II inhibitors will ordinarily not be considered for approval for:

- Lack of response to traditional NSAIDs.
- Dyspepsia or GI intolerance to traditional NSAIDs.
- Patients receiving a proton pump inhibitor.
- Patients receiving low dose aspirin for cardiovascular prophylaxis.
- Patients with known cardiovascular disease.
- Dysmenorrhea.

Cyclobenzaprine (Flexeril™) - See [MUSCLE RELAXANTS](#)

Cyclosporine ophthalmic emulsion 0.05% (Restasis™)

1. Diagnosis of Sjogren's Syndrome
2. Diagnosis of Rheumatoid Arthritis
3. Failed appropriate duration of carboxymethylcellulose (Celluvisc™) containing ocular lubricants via approved non-formulary request.

Dabigatran (Pradaxa™) - See [Anticoagulants](#)

Dapagliflozin (Farxiga™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Darbopoetin Alfa (Aranesp™) - See [Erythropoiesis Stimulating Agents \(ESA's\)](#)

Delavirdine (Rescriptor™)

Patients who have previously tried efavirenz and nevirapine and were changed to delavirdine because of intolerance, adverse effects, or contraindications (e.g. rash or hepatotoxicity with nevirapine; pregnancy with efavirenz) citing specific reasons as to why efavirenz and nevirapine cannot be utilized.

Conversion Recommendations for those entering BOP institution on delavirdine, with undetectable viral load:

1st Alternative: Switch patient from **delavirdine to efavirenz** unless there is a contraindication (e.g. pregnancy). It is recommended that delavirdine therapy be stopped and efavirenz be started at full dose (600 mg HS) the next day.

2nd Alternative: Switch patient from **delavirdine to nevirapine**. Recommendation to stop delavirdine and start nevirapine utilizing dose escalation (e.g. 200 mg daily x 14 days, then 200 mg bid) as if beginning a treatment naive patient. Nevirapine has a higher incidence of rash than delavirdine. There is not 100% cross-reactivity in rash and the rash seems to be related to early blood levels, therefore dose escalation is still recommended. Viral resistance to nevirapine did not occur in clinical trials when patients were given escalating doses.

Delavirdine and nevirapine share resistant mutations so conversion will not lead to increased resistance. If resistance is a concern, on a case by case basis, it may be prudent to give a protease inhibitor (PI) plus nevirapine during the 2 week escalation period. For instance, the decision may depend on viral load; if < 50 for quite some time then no PI; if patient has detectable virus or blips, one may want to cover with a PI (e.g. nelfinavir) during nevirapine escalation. Nelfinavir will add pill burden and diarrhea but no drug interactions or overlapping toxicities exist between nelfinavir and nevirapine.

Inmates entering BOP on a delavirdine-containing regimen, whose viral load is not adequately suppressed, should have their entire HAART regimen re-evaluated in consultation with a specialist.

Dicyclomine (Bentyl™)

1. Clinical diagnosis of IBS AND
2. Three months of fiber (tablets) therapy without relief of symptoms AND
3. Three negative Fecal Occult Blood Tests documented in BEMR, AND
4. At least six months of chronic diarrhea symptoms AND
5. Absence of constipation and/or positive Fecal Occult Blood Test. Any new or renewal orders for dicyclomine must meet the criteria to be dispensed.

Dietary/Herbal Supplements

These agents are not FDA approved and will not be approved.

Difluprednate (Durezol™)

Difluprednate has less ocular effect than prednisolone. Patient case must have potential or actual increase in intraocular pressure for non-formulary request approval.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: linagliptin (Tradjenta™), alogliptin (Nesina™), saxagliptin (Onglyza™), sitagliptin (Januvia™)

1. Patient has type 2 diabetes
2. Not to be used in combination with GLP-1 agonists.
3. Frequent hypoglycemia on sulfonylurea.
4. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
5. A1C goal not met on therapeutic doses of formulary agents.
6. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
7. Criteria 1 through 6 must be met for approval.

Diphenhydramine (Benadryl™) - See [Antihistamines](#)

Dulaglutide (Trulicity™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Dutasteride (Avodart™) -

1. Second line agent for BPH, after failure of alpha blocker.
2. American Urological Association criteria (including symptom score, digital rectal exam, PSA test, urine outflow record) are submitted.
3. Finasteride is the 5-alpha-reductase Inhibitor of choice**
4. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Edoxaban (Savaysa™) - See [Anticoagulants](#)

Empagliflozin (Jaridance™) - See [Sodium-glucose Cotransporter-2 \(SGLT2\) Inhibitors](#)

Enfuvirtide (Fuzeon™) - See [HIV Medication/Treatment](#)

Erythropoiesis Stimulating Agents (ESA's): epoetin Alfa (Epogen™, Procrit™) darbopoetin Alfa (Aranesp™)

All of the following must be true for patient to be eligible for ESA treatment of hepatitis C treatment-related anemia:

1. Patient receiving hepatitis C therapy; AND
2. Patient is one of the following:
 - a. Cirrhotic;
 - b. Pre or post-liver transplant
 - c. HIV/HCV co-infected;
 - d. Receiving HIV triple therapy;
- AND
3. Patient underwent evaluation for other causes of anemia (e.g. bleeding, nutritional deficiency) and has been treated appropriately; AND
4. Patient develops anemia defined as Hgb < 10 g/dL (or as clinically indicated for significant anemia-related signs and symptoms) and persists for at least two weeks after reducing the ribavirin dose to 600 mg/day; AND
5. Patient does not have exclusion criteria: Uncontrolled hypertension or risk for thrombosis.

Etanercept (Enbrel™) - See [Immunomodulator TNF Inhibitors](#)

Etravirine (Intelence™) - See [HIV Medication/Treatment](#)

Evolocumab (Repatha™) - See [PCSK9 Inhibitors](#)

Exenatide (Byetta™), exenatide ER (Bydureon™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Ezetimibe (Zetia™)

1. Must complete and submit Appendix 2, Steps 1-6, Management of Lipid Disorders, BOP Clinical Practice Guidelines.
2. Ezetimibe 10 mg daily can be considered on a non-formulary basis for those patients not meeting their LDL-C goal on simvastatin, lovastatin or atorvastatin 80 mg daily in combination with a bile acid sequestrant (BAS), or the maximally tolerated or recommended daily dose of a statin in combination with a bile acid sequestrant (BAS).
3. If simvastatin, lovastatin, or atorvastatin cannot be used (e.g., due to a drug interaction - CYP 3A4 metabolism) or not tolerated, the maximally tolerated or recommended dose of pravastatin or fluvastatin (e.g. 80 mg/d), in combination with BAS, should be reached prior to considering therapy with ezetimibe.
4. Since there is no evidence to show a benefit with regard to health outcomes with ezetimibe, monotherapy with ezetimibe should be limited to those patients unable to tolerate statins, bile acid sequestrants.

Fenofibrate (Tricor™)

1. Failure of gemfibrozil used for at least 6 months
2. Treatment of hyperglycemic patients. HbA1c should be < 8

3. Triglyceride level must be > 500 after compliance with criteria 1 and 2 above

Filgrastim/pegfilgrastim/tbo-filgrastim (Neupogen™/Neulasta™/Granix™)

1. Adjunctive therapy for cancer chemotherapy.
 - a. Chemotherapy primary prophylaxis for "dose dense" treatment regimen.
 - b. Chemotherapy primary prophylaxis for treatment regimen with 20% or higher risk of febrile neutropenia.
 - c. Chemotherapy primary prophylaxis for patient older than 65, poor performance status, combined chemoradiotherapy, poor nutritional status, advanced cancer, or other serious comorbidities.
 - d. Chemotherapy secondary prophylaxis for patient with history of prior neutropenic complications.
2. All of the following must be true for patient to be eligible for filgrastim treatment of hepatitis C treatment-related neutropenia:
 - a. Patient receiving hepatitis C therapy; AND
 - b. Patient develops neutropenia defined as either
 - i. ANC < 250/mm³; or
 - ii. ANC < 500mm³ with one of the following risk factors for developing infection;
 - a. Cirrhosis, biopsy proven or clinically evident;
 - b. Pre-or post-liver transplant;
 - c. HIV/HCV co-infection
 - d. Receiving HCV triple therapy;AND
 - c. Patient has failed to respond (i.e. neutropenia persists) despite at least two weeks of peginterferon dose reduction.

Fluticasone Oral inhaler (Flovent™)

Must fail two other inhaled corticosteroids with demonstrated compliance.

Fluticasone/Salmeterol (Advair™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Formoterol (Foradil™) - See [Long Acting Beta Agonists \(LABA\)](#) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Gabapentin (Neurontin™)

1. Approved for neuropathic pain after failure of duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
2. Functional status must be documented. If renewal request, the request must indicate that the inmate's functional status has improved with use of gabapentin.
3. Bipolar disorder: Approval will be considered only after documented failure of therapeutic trials of lithium, valproic acid, carbamazepine, and atypical antipsychotics, (alone and in combination), or documented prior response to gabapentin. Failure is defined as recurrence of mania or hypomania during active treatment with therapeutic doses/blood levels of approved medications, with documented compliance, or the presence of adverse side effects. Required documentation includes a mental health evaluation as outlined in the clinical guidelines for psychiatric evaluation, and blood levels (when appropriate) of formulary agents during episodes of recurrent illness.

Recommended Gabapentin Taper

Gabapentin should be tapered over a period of 2 - 4 weeks

Glucagon-like Peptide 1 Receptor (GLP-1) Agonists: albiglutide (Tanzeum™), dulaglutide (Trulicity™), exenatide (Byetta™), exenatide ER (Bydureon™), liraglutide (Victoza™; Saxenda™), lixisenatide (Adlyxin™)

1. Patient has type 2 diabetes.
2. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
3. A1C goal not met on therapeutic doses of formulary agents.
4. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
5. Consider in patients with difficulty controlling weight and blood glucose despite appropriate diet and exercise adherence, documentation required including commissary purchases reviewed.
6. Criteria 1 through 4 must be met for approval.

Golimumab (Simponi™) - See [Immunomodulator TNF Inhibitors](#)

Hepatitis C Treatment Algorithm:

"Medical HOLD" will be placed on inmate once Hepatitis C treatment therapy is initiated.

HIV Medications/Treatment: etravirine (Intelence™), maraviroc (Selzentry™), tipranavir (Aptivus™), enfuvirtide (Fuzeon™)

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director

Hormones to maintain secondary sexual characteristics: conjugated estrogens (Premarin™), esterified Estrogens (Menest™), estradiol (Alora™, Climara™, Delestrogen™, Depo-Estradiol™, Estrace™, Estraderm™, Vivelle™), finasteride (Proscar™), spironolactone (Aldactone™) testosterone (AndroGel™, Androderm™, Axiron™, Aveed™, Delatestryl™, Depo-Testosterone™, Fortesta™)

1. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Hydroxyzine (Atarax™, Vistaril™) oral - See [antihistamines](#)

Immunomodulator TNF Inhibitors: adalimumab (Humira™), certolizumab (Cimzia™), etanercept (Enbrel™), golimumab (Simponi™), infliximab (Remicade™),

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of methotrexate/prednisone, gold, or azathioprine.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. Request must include rheumatology consult report.
5. All new and renewal prescriptions for dermatologic use requires BOP Teledermatologist consultation.
6. Requests for patients with a TST \geq 5mm or a positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts).

Infliximab (Remicade™) - See [Immunomodulator TNF Inhibitors](#)

Insomnia medications: (Ambien™, Lunesta™, Sonata™)

Insomnia is typically a symptom, and not a disease state, and thus the clinical focus should be on identifying and treating the underlying cause (i.e. depression, anxiety, psychosis, poor sleep hygiene, and chronic medical conditions such as diabetes). The long term use of antidepressants or antihistamines for complaints of poor sleep in the absence of another Axis I diagnosis is not appropriate.

Insulin glargine/Insulin detemir, Long Acting Insulin (Lantus™/Levemir™)

1. Recurrent episodes of symptomatic hypoglycemia despite multiple attempts with various insulin dosing regimens. Non-formulary request must include documentation of blood glucose values in the hypoglycemic range (i.e. MARs), and the insulin regimens used. **OR;**
2. Failure to achieve target HbA1c goals despite compliance with an intensive insulin regimen (3 to 4 injections / day) using NPH and regular. Note: The evening dose of NPH should be administered as close to bedtime as staffing and institution procedures permit.) Non-formulary request must include the insulin regimens used, an assessment of compliance (i.e. MARs) and a recent HbA1c result with date.

Insulin Aspart/Insulin lispro, Rapid Acting Insulin (Novolog™/Humalog™)

NOTE: generally speaking insulin lispro and insulin aspart are too short acting to be used safely in most correctional environments.

1. Unable to achieve glycemic control targets with the use of regular insulin, despite multiple attempts with various insulin dosing regimens.
2. Non-formulary request must include the insulin regimens that have been tried and found ineffective, including times of administration.
3. Self-monitoring of blood glucose or immediate access to blood glucose monitoring at all times.
4. Ability to eat a meal immediately (within 15 minutes) after injecting rapid-acting insulin.
5. Patients receiving highly intensive insulin therapy such as q.i.d. administration, including those who would otherwise be candidates for insulin pump therapy.
6. Will be used at Medical Centers only - is not an acceptable transfer medication.

Isotretinoin (Accutane™)

1. iPLEDGE enrollment and requirements located at <https://www.ipledgeprogram.com>
Proof of enrollment must be submitted with non-formulary request.
2. Central Office Physician or Regional Medical Director (RMD) have been consulted. This will occur prior to the enrollment of the physician and patient as well as enrollment and fee payment of the institution pharmacy into the iPLEDGE program.

Ketoconazole oral

Ketoconazole tablets are indicated only for the treatment of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, and paracoccidioidomycosis in patients in whom other treatments have failed or who are intolerant to other therapies.

Lidocaine Topical Patches (Lidoderm™)

1. Patient is being treated for post-herpetic neuralgia.
2. Patient utilized 4-6 week trial of formulary anticonvulsants and/or tricyclics.
3. Patient will be prescribed other concurrent analgesic therapies effective for neuropathic pain.

Linagliptin (Tradjenta™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Linezolid (Zyvox™)

1. IV vancomycin should be utilized when possible.
2. Case by case basis for transition of stable patients receiving IV vancomycin in hospital setting to institution which is unable to provide IV vancomycin.
3. Documentation of culture and sensitivity data must be submitted with non-formulary request.
4. Non-formulary approval will be for pill line administration only due to concerns of expense, compliance, and potential for resistance development.

Liraglutide (Victoza™; Saxenda™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Lixisenatide (Adlyxin™) - See [Glucagon-like Peptide 1 Receptor \(GLP-1\) Agonists](#)

Long Acting Beta Agonists (LABA) and Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS): salmeterol (Serevent™), formoterol (Foradil™), budesonide/Formoterol (Symbicort™) and fluticasone/salmeterol (Advair™)

1. COPD patients must have failed anticholinergic agent tiotropium (Spiriva™).
2. Continued nocturnal awakenings not managed by medium dose steroid inhaler OR low dose steroid inhaler plus a leukotriene receptor antagonist (i.e. - montelukast).
3. At least severe persistent asthma not controlled by medium dose inhaled corticosteroid alone.
4. Reversibility demonstrated with a short acting beta agonist. Reversibility is characterized by an increase in FEV₁ of greater than 200 mL and greater than 12% from baseline.
5. Not to be utilized as monotherapy.
6. Nebulizer solution will not be approved for use in asthma.
7. Non-formulary requests for long acting beta agonists that meet criteria will be approved for agent on mandatory contract.

Lorazepam long-term use - See [Benzodiazepines](#)

Lorcaserin (Belviq™) - See [Anti-Obesity Agents](#)

Loteprednol etabonate (Lotemax™, Alrex™)

After use of formulary ophthalmic steroid for greater than 28 days.

Maraviroc (Selzentry™) - See [HIV Medication/Treatment](#)

Metaxalone (Skelaxin™) - See [MUSCLE RELAXANTS](#)

Metoclopramide (Reglan™)

1. Restricted to 12 weeks of therapy for all formulations
2. If NFR approved, after 12 weeks, get periodic AIMS testing

Montelukast (Singulair™)

1. **Asthma:** Third line agent in the treatment of asthma. Compliance with other medications must be shown (e.g. oral steroid inhalers)
2. **Allergic Rhinitis:** Third line agent after documented compliance with OTC antihistamine and nasal steroid. Copies of progress notes detailing symptoms and exam findings will be required.
3. **Urticaria:** Montelukast will not be approved for this indication.

Muscle Relaxants: dantrolene (Dantrium™), baclofen (Lioresal™), cyclobenzaprine (Flexeril™), tizanidine (Zanaflex™), metaxalone (Skelaxin™), methocarbamol (Robaxin™), carisprodal (Soma™), chlorzoxazone (Parafon forte DSC™), orphenadrine (Norflex™)

PILL LINE ONLY

Approval for muscle relaxants will be considered for the following cases and all must be administered via PILL LINE:

1. Observable, documented muscle spasm due to:
 - a. Multiple sclerosis
 - b. Spinal cord injury or intrinsic cord lesions (not herniated spinal discs, not low back pain due to muscle spasm)
 - c. Stroke
 - d. Cerebral palsy
2. Approval for baclofen may be considered for intractable pain from neurological conditions, such as trigeminal neuralgia, that has been unresponsive to formulary agents.
3. Metaxalone is last resort skeletal muscle therapy after failure of all other muscle relaxants.

Compliance should be monitored at each visit. These medications are frequently diverted to other inmates due to their mood-altering effects. Abrupt discontinuation of baclofen can precipitate a drug withdrawal syndrome. There are generally no valid indications for long-term use of cyclobenzaprine or similar "muscle relaxants" such as methocarbamol. Lorazepam is recommended for short-term use in acute muscle spasm where sedation is desired.

Naloxone intranasal solution (Narcan™)

1. Prescribed on a case-by-case basis only for inmates with a high risk of opioid overdose who are releasing from BOP custody or transferring to a residential reentry center or home confinement.
2. Nasal dosage form is preferred first-line therapy prior to auto-injector use.
3. When naloxone nasal is prescribed, appropriate education on the risks and symptoms of opioid overdose and the use of naloxone must be provided to the inmate and documented in the medical record.

Narcolepsy Treatment - Stimulant medications: amphetamine, dextroamphetamine, modafinil, methylphenidate, selegiline

1. Documented verification of the inmate's report, to include polysomnography obtained and provided.
2. Patient has failed non-pharmacologic management strategies.
3. Functional impairment with work assignment, institution security, academic needs.
4. Failed treatment with modafinil and fluoxetine (for cataplexy).

Neuraminidase inhibitors: oseltamivir (TamiFlu™), zanamivir (Relenza™)

1. Therapy is only to be offered to patients within 48 hours of exposure. Antiviral therapy is not effective or recommended 48 hours post exposure.
2. Non-Formulary Drug requests for TamiFlu™ will be processed and expedited through Central Office.
3. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator. Region, Central Office and approved by the BOP Medical Director for treatment.
4. Note: Stockpile antivirals may only be approved for use by the BOP Medical Director under certain conditions as proclaimed by the World Health Organization.

Nutritional Supplements for oral consumption

1. Request for its non-formulary use requires completion of the ["Nutritional Supplements Worksheet"](#)
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietician for therapy > 60 days.

Ocuvite/AREDS/I-Caps

1. Item has been previously reviewed in regards to formulary status with ongoing consultation with a BOP ophthalmologist. Offenders wishing to purchase this item should be referred to, and allowed to purchase, from the commissary through a Special Purchase Order (SPO). This is a non-prescription item. The ophthalmic literature remains controversial on the effect on the course of macular degeneration (wet or dry).
2. Refer all renewals of previously approved non-formulary requests to the BOP National Ophthalmology Consultant.

Onychomycosis, oral treatment - See [Antifungals](#)

Orlistat (Xenical™) (Alli™ OTC) - See [Anti-Obesity Agents](#)

Oseltamivir (TamiFlu™) - See [Neuraminidase inhibitors](#)

Oxycodone Controlled Release (Oxycontin™)

1. Must have failed extended release morphine. Failure is defined as unable to titrate dose due to adverse effects unable to be resolved despite aggressive treatment.

PCSK9 Inhibitors: evolocumab (Repatha™), alirocumab (Praluent™)

1. Prescribed for an FDA approved indication only.
2. Failure to achieve cholesterol goals with maximum doses of at least two different HmgCoA reductase inhibitors, OR
3. Unable to tolerate HmgCoA reductase inhibitors.

Phenobarbital (Luminal™)

1. Diagnosis of seizure, **AND**
2. Used in combination with other anticonvulsant medications, **AND**
3. Used as 3rd line agent, **AND**
4. Compliance > 90% maintained

Phentermine/Topiramate (Qsymia™) - See [Anti-Obesity Agents](#)

Prasugrel (Effient™)

1. Does patient have aspirin allergy anaphylaxis, bronchospasm? (Indications for use as a single antiplatelet agent therapy)
2. Does patient have recurrent non-cardioembolic cerebral ischemia while on aspirin?
3. Did patient have ACS: (NSTEMI, STEMI, unstable angina (UA)) with no revascularization - 1 year therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
4. Is patient post PCI - 1 year therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
5. Is patient post CABG - 4 weeks therapy recommended (indication for use as dual antiplatelet therapy with aspirin)
6. Does patient have non-coronary stenting? (indication for use as dual antiplatelet therapy with aspirin)
7. Did patient fail clopidogrel therapy?
8. Is patient on pharmacotherapy that has a major interaction with clopidogrel but does not interact with prasugrel?
9. Patient under the age of 74?
10. Patient weighs 60 kg or more?

Pregabalin (Lyrica™)

1. Diabetic neuropathy - well documented as insufficient functional response to duloxetine plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
2. Postherpetic Neuralgia - well documented intolerance or insufficient functional response at maximally tolerated doses of tricyclic antidepressants and topical analgesics such as capsaicin cream
3. Fibromyalgia - documented diagnosis of fibromyalgia by rheumatologist. Documented insufficient functional response to duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
4. Partial onset seizures - well documented intolerance or insufficient response to at least two other agents (i.e. Carbamazepine, lamotrigine, levetiracetam, phenytoin, topiramate).

Protein Powder/Protein Liquid

1. Request for its non-formulary use requires completion of the ["Nutritional Supplements Worksheet"](#)
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietician required for every request.

Quetiapine (Seroquel™)

1. Use in psychotic disorder, bipolar disorder, or borderline personality disorders only.
2. Requests must include justification and treatment history in accordance with the Antipsychotic Treatment Algorithm, BOP Clinical Practice Guidelines, Pharmacological Management of Schizophrenia.
3. Non-formulary approvals for oral formulation will be restricted to the IR formulation only. Quetiapine IR must be administered via pill line and crushed prior to administration unless otherwise restricted by package insert.

Quinine

Non-formulary will not be approved for leg cramps.

Restless Leg Syndrome Algorithm

Step 1. Sleep Hygiene - Refer to Sallyport Guidelines

Step 2. Evaluate Drug Therapy - consider medication change or dose reduction of SSRI, TCA, lithium, antihistamines, caffeine, dopamine agonists.

Step 3. Trial of oral iron therapy.

Step 4. Evaluate for secondary causes - iron deficiency, chronic kidney disease, venous insufficiency, neurologic lesions, rheumatic disease, or diabetes - and manage disease states optimally.

Step 5. Treatment with pramipexole, ropinirole, or levodopa/carbidopa.

Rifaximin (Xifaxan™)

1. Treatment of hepatic encephalopathy
2. Patient refractory to lactulose (patient obtained 3 loose stool per day)
3. Patient intolerant to lactulose

Rivaroxaban (Xarelto™) - See [Anticoagulants](#)

Salmeterol (Serevent™) - See [Long Acting Beta Agonists \(LABA\)](#)

Saxagliptin (Onglyza™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Sitagliptin (Januvia™) - See [Dipeptidyl Peptidase-4 \(DPP-4\) Inhibitors](#)

Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors: canagliflozin (Ivokana™), dapagliflozin (Farxiga™), empagliflozin (Jardiance™)

1. Patient has type 2 diabetes and established cardiovascular disease.
2. Failed maximum tolerated dose of metformin or documented contraindication to metformin.
3. A1C goal not met on therapeutic doses of formulary agents.
4. A1C <9% (if A1C is ≥9%, then insulin therapy is indicated instead of this agent).
5. Consider in patients with difficulty controlling weight and blood glucose despite appropriate diet and exercise adherence, documentation required including commissary purchases reviewed.
6. Criteria 1 through 4 must be met for approval.

Synvisc™ (Hylan G-F 20), Hyalgan™ (Sodium Hyaluronate)

1. Osteoarthritis of the knee(s) (American College of Rheumatology criteria) confirmed by history, exam, and x-ray.
2. Documented inadequate control of pain or intolerance to adequate trial of acetaminophen (4 grams/day), NSAIDs, and other non-narcotic or narcotic analgesics.
3. Inadequate response to intra articular corticosteroid injections.
4. Inadequate response to bracing and use of canes or crutches.
5. Inadequate response to measures such as weight loss and physical therapy.
6. Surgery is not an option due to concurrent medical conditions that preclude the patient as candidate for surgery. These agents may also be considered as a bridging option before resorting to surgery.

Tbo-Filgrastim (Granix™) - See [Filgrastim](#)

Testosterone (Androgel™, Androderm™, Axiron™, Aveed™, Delatestryl™, Depo-Testosterone™, Fortesta™)

1. Evidence of bilateral orchiectomy, Klinefelter's syndrome, pituitary adenoma, hypothalamic adenoma, or other confirmed disease of the testes, pituitary or hypothalamus.
2. Testosterone supplementation is not approved or continued for unlabeled uses, e.g. strength training, increased libido.
3. A six-month washout period is required for patients with no confirmed disease of the testes, pituitary or hypothalamus.
4. Patient is experiencing significant withdrawal symptoms, e.g. anxiety, depression, mood swings during six-month washout period (60-day taper schedule).
5. Laboratory AND clinical evidence (decrease in energy, mood; decrease in sexual hair, hematocrit, muscle mass and strength, and bone mineral density) of testosterone deficiency is confirmed after the six-month washout period.
6. Use in Gender Dysphoria / Transgender cases will be referred to Central Office Transgender Clinical Management Team for review.
7. Consultation with BOP Chief Psychiatrist and/or Central Office Transgender Clinical Management Team when providing transgender care.

Tipranavir (Aptivus™) - See [HIV Medication/Treatment](#)

Vancomycin, Oral (Vancocin HCl Pulvules™)

1. Use in severe and severe-complicated clostridium difficile infection (CDI) only.
2. Second line agent therapy for non-severe CDI after compliant trial of metronidazole.

Zanamivir (Relenza™) - See [Neuraminidase Inhibitors](#)

Non-Formulary Algorithm for Donepezil (Aricept™) Approval
(# 1,3,5,9,10 only for renewal)

1. Initial treatment: _____ Follow-up: 3 mo 6 mo 12 mo other _____
Dose of donepezil: _____
2. Inmate has dementia, Alzheimer's type: (Circle one)
a. mild b. moderate
c. Severe - does not qualify for trial. Consider Reduction in Sentence
3. Mini-Mental State Score: _____
(Other objective measures may be utilized, such as Dementia Rating Scale, however, the same test should be used at each interval to document response to treatment).
Test _____ Score _____
4. Physical findings: **Please attach copy of most recent exam, must include weight, vital signs, neurologic screening.**
5. Laboratory results: Date: _____
Hgb _____ WBC _____ Plts _____ MCV _____
RDW _____ AST _____ ALT _____ Alk Phos _____
Tot Prot _____ Alb _____ SCR _____ FBG _____
RPR _____ B-12 _____ Folate _____ TSH _____
U/A: RBC _____ Leukocytes _____ Prot _____ Gluc _____
6. CT head or MRI head results (**attach copy of report**).
7. Major Depression has been effectively treated or ruled out?
Yes No Current Treatment: _____
8. Delirium has been ruled out by: _____ (Physician) on: _____ (Date):
Yes No If no, describe: _____

9. List all current medications and their doses and blood levels if appropriate, e.g. lanolin, anti-seizure meds: _____

10. No contraindications to cholinesterase inhibitor (e.g. PUD, asthma, COPD, bradycardia, liver disease, anticholinergic drugs, parkinsonism):
11. Prior treatment with cholinesterase inhibitor?
Drug(s): _____ Dates: _____
Outcome: _____
12. Comments: _____

Recommendations by Institution Chief Psychiatrist or Clinical Director: _____

Approved: _____ Medical Director Date: _____

Disapproved: _____ Medical Director Date: _____

Inmate Name: _____ Reg. No: _____

Institution: _____

Worksheet for Use of Nutritional Supplement

| | | | | | | | | | | | | | | | | | | |
|---|--|----------------------|------------------------------------|--|--|--|---|--------------------------------------|--|--|---|--|---|---|---|--|--|--|
| Inmate Name: | Register Number: | Institution: | | | | | | | | | | | | | | | | |
| Date of Birth: | Usual Body Weight – UBW(lb): | | | | | | | | | | | | | | | | | |
| Weight(lb): | Height(in): | Gender: M / F | | | | | | | | | | | | | | | | |
| BMI: _____ <i>BMI = 703 x [weight(lb) / height²(in)]</i> | | | | | | | | | | | | | | | | | | |
| Ideal Weight Range(lb): _____ to _____ <i>Hamwi method: men = 106 lb + 6 lb for each inch >5 ft, women = 100 lb + 5 lb for each inch > 5 ft, then +/- 10% for range</i> | | | | | | | | | | | | | | | | | | |
| Percent Weight Loss(%), unintentional: Over past month _____, past 3 months _____, past 6 months _____ <i>Percent weight loss = (UBW – current weight / UBW) x 100</i> | | | | | | | | | | | | | | | | | | |
| Medical Diagnoses – check all that apply (must have at least one): <table style="width:100%; border:none;"> <tr> <td style="width:50%; border:none;"><input type="checkbox"/> Dysphagia</td> <td style="width:50%; border:none;"><input type="checkbox"/> Burns - % Body Surface Area _____</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Crohn’s Disease</td> <td style="border:none;"><input type="checkbox"/> Hunger Strike</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Alzheimer’s Disease</td> <td style="border:none;"><input type="checkbox"/> Cancer</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Swallowing Problems</td> <td style="border:none;"><input type="checkbox"/> End Stage Renal Disease on Dialysis</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Mastication Problems</td> <td style="border:none;"><input type="checkbox"/> Multiple Dental Extractions or Extensive Dental Surgery (short term use)</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Ulcerative Colitis</td> <td style="border:none;"><input type="checkbox"/> Chronic Wounds (describe in notes below)</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Malabsorptive Disorder – Specify _____</td> <td style="border:none;"><input type="checkbox"/> Other(s): _____</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Failure to Thrive</td> <td style="border:none;"></td> </tr> </table> | | | <input type="checkbox"/> Dysphagia | <input type="checkbox"/> Burns - % Body Surface Area _____ | <input type="checkbox"/> Crohn’s Disease | <input type="checkbox"/> Hunger Strike | <input type="checkbox"/> Alzheimer’s Disease | <input type="checkbox"/> Cancer | <input type="checkbox"/> Swallowing Problems | <input type="checkbox"/> End Stage Renal Disease on Dialysis | <input type="checkbox"/> Mastication Problems | <input type="checkbox"/> Multiple Dental Extractions or Extensive Dental Surgery (short term use) | <input type="checkbox"/> Ulcerative Colitis | <input type="checkbox"/> Chronic Wounds (describe in notes below) | <input type="checkbox"/> Malabsorptive Disorder – Specify _____ | <input type="checkbox"/> Other(s): _____ | <input type="checkbox"/> Failure to Thrive | |
| <input type="checkbox"/> Dysphagia | <input type="checkbox"/> Burns - % Body Surface Area _____ | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Crohn’s Disease | <input type="checkbox"/> Hunger Strike | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Alzheimer’s Disease | <input type="checkbox"/> Cancer | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Swallowing Problems | <input type="checkbox"/> End Stage Renal Disease on Dialysis | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Mastication Problems | <input type="checkbox"/> Multiple Dental Extractions or Extensive Dental Surgery (short term use) | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Ulcerative Colitis | <input type="checkbox"/> Chronic Wounds (describe in notes below) | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Malabsorptive Disorder – Specify _____ | <input type="checkbox"/> Other(s): _____ | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Failure to Thrive | | | | | | | | | | | | | | | | | | |
| BOP Food Service Diet(s)Tried – check all that apply: <table style="width:100%; border:none;"> <tr> <td style="width:50%; border:none;"><input type="checkbox"/> Regular</td> <td style="width:50%; border:none;"><input type="checkbox"/> Full Liquid</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Soft</td> <td style="border:none;"><input type="checkbox"/> Pureed</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Mechanical Soft/Edentulous</td> <td style="border:none;"><input type="checkbox"/> Gluten Free</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Low Residue / Low Fiber</td> <td style="border:none;"><input type="checkbox"/> Diabetic Snack</td> </tr> <tr> <td style="border:none;"><input type="checkbox"/> Clear Liquid</td> <td style="border:none;"><input type="checkbox"/> Snack for Increased Calories</td> </tr> </table> | | | <input type="checkbox"/> Regular | <input type="checkbox"/> Full Liquid | <input type="checkbox"/> Soft | <input type="checkbox"/> Pureed | <input type="checkbox"/> Mechanical Soft/Edentulous | <input type="checkbox"/> Gluten Free | <input type="checkbox"/> Low Residue / Low Fiber | <input type="checkbox"/> Diabetic Snack | <input type="checkbox"/> Clear Liquid | <input type="checkbox"/> Snack for Increased Calories | | | | | | |
| <input type="checkbox"/> Regular | <input type="checkbox"/> Full Liquid | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Soft | <input type="checkbox"/> Pureed | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Mechanical Soft/Edentulous | <input type="checkbox"/> Gluten Free | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Low Residue / Low Fiber | <input type="checkbox"/> Diabetic Snack | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Clear Liquid | <input type="checkbox"/> Snack for Increased Calories | | | | | | | | | | | | | | | | | |
| Reason(s) Nutritional Needs Could Not be Met Through Food Service Offerings: _____ _____ | | | | | | | | | | | | | | | | | | |
| Additional notes: _____ _____ | | | | | | | | | | | | | | | | | | |
| Name / Title / Signature of Requestor: | | Date: | | | | | | | | | | | | | | | | |
| Procedure for Submitting Nutritional Supplement Algorithm: <ul style="list-style-type: none"> - Scan into BEMR Document Manager as .pdf file - Attach to BEMR non-formulary request for selected nutritional supplement and/or protein powder/liquid - For nutritional supplement use > 30 days and <u>ALL</u> protein-only supplement requests: a BOP registered dietitian nutritional assessment consult must be attached (completed locally at MRCs or via tele-nutrition at all others) | | | | | | | | | | | | | | | | | | |

Non-Sterile Compounding Worksheet

Attach this, with any other required documentation with your NFR request.

Requesting Institution: _____ **Date:** _____

Who is making the compound?

Outside Pharmacy

BOP Pharmacy

**Attach copy of medication label
+/- recipe (if will give)**

OR,

Pharmacy Name: _____

Pharmacy Phone Number: _____

Pharmacy Address: _____

Rx # (if have): _____

Any Directions/Ingredients they will give:

Is Compound in BEMR
Already?

1. Go to: Reports -> Drug File
2. Make "Formulary" = ALL
3. Select the box next to "Compound" towards the bottom
4. Click "View"
5. Review report and see if desired compound is listed

Complete the MASTER FORMULATION RECORD WORKSHEET on Page 2 and submit to the BEMR Workgroup for addition to the National Drug File.

Complete the COMPOUNDING RECORD WORKSHEET on Page 3 and store in Document Manager OR complete any documentation dictated by local law, policy, and procedures.

- [Label Product per 2011 National P&T Minutes:](#)
- Must enter order into BEMR with our label referencing the medication name, filling pharmacy name, and statement that "inmate is authorized to carry this medication"
 - Cannot repackage, instead place non-BOP medication items into a clear plastic bag with the BEMR label affixed to the plastic bag to authorize self-carry.

MASTER FORMULATION RECORD WORKSHEET

Name and Strength of Product: _____ Quantity: _____
 (# of units, volume, weights, etc.)

Intended Use: _____ Intended Route of Administration: _____

Formula:

| Ingredient | Quantity | Physical Description | Solubility | Function |
|------------|----------|----------------------|------------|----------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Compatibility/Stability Information (Literature Search):

Special Equipment, if any: _____

Calculations:

Method/Directions for Preparation:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

Description of Finished Product: _____

Quality Control Tests:

Beyond-Use Dating/Recommended Storage (Check one):

- Solid and Non-Aqueous Formulations** - No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6 months, whichever is earlier
- Aqueous Formulations** - No later than 14 days for liquid preparations when refrigerated (36°F to 46°F)
- All other Formulations** - No later than 30 days OR duration of therapy, whichever is earlier

Packaging: _____

Labeling: _____
 (Product content and auxiliary labels)

COMPOUNDING RECORD WORKSHEET

Name of Master Formulation Record: _____ Rx#: _____

Date Compounded: _____

Preparer Name: _____

| Ingredient | Amount | Manufacturer/Source | Lot # | Expiration Date |
|------------|--------|---------------------|-------|-----------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Total quantity compounded: _____

Assigned Beyond-Use Date: _____

| | |
|---|---|
| Solid and Non-Aqueous Formulations | No later than 25% of the time remaining until the earliest ingredient's expiration date OR 6 months, whichever is earlier |
| Aqueous Formulations | No later than 14 days for liquid preparations when refrigerated (36°F to 46°F) |
| All other Formulations | No later than 30 days OR duration of therapy, whichever is earlier |

Copy of Label:

Description of final preparation: _____

Pharmacist Verification: _____

QC Completed by: _____

Results of QC:

Any QC issues that arose:

Any Reported ADRs:

Urgent Care Cart and Kit Content

MRCs with 24 hour coverage that have a sufficient number of trained staff to perform ACLS 24 hours per day, 7 days per week may elect to stock their Urgent Care Cart with "A" list medications. Care Level III institutions with 24 hour coverage that have sufficient numbers of trained staff to perform ACLS 24 hours per day, 7 days per week wanting to stock "A" list medications must submit a request for a waiver to the Medical Director, BOP - routed through the Regional Medical Director - for approval. All other institutions will stock only medications on the "B" list. Staff using "Urgent Care Cart" supplies for resuscitation should be trained and privileged by the Clinical Director in accordance with established protocols approved by the CD.

| Medication | MRCs and approved Care IIIs | All others |
|--|------------------------------------|-------------------|
| Adenosine 6 mg | A | |
| Amiodarone 50 mg/ml | A | |
| Aspirin 81 mg | A | B |
| Atropine 1 mg/10ml | A | |
| Benztropine inj 1mg/ml | A | B |
| D5W | A | B |
| Dextrose 50% injection | A | B |
| Digoxin 0.5 mg injection | A | |
| Dopamine 400 mg/5ml | A | |
| Epinephrine 1:10000 syringe | A | |
| Epinephrine 1:1000 amps | A | |
| epinephrine auto-injector 0.3 | A | B |
| Furosemide injection | A | |
| Glucagon injection | A | B |
| Glucose Paste/Tabs | A | B |
| Haloperidol lactate inj 5mg/ml | A | B |
| Hydrocortisone OR Methylprednisolone injection | A | B |
| Lactated Ringers | A | B |
| Lorazepam injection | A | B |
| Morphine Sulfate injection | A | B |
| Naloxone 0.4 mg/ml | A | B |
| Nitroglycerin S.L. 0.4 mg tabs | A | B |
| Normal Saline | A | B |
| Procainamide 100 mg | A | |
| Propranolol 1 mg/ml | A | |
| Sodium Bicarbonate 50 meq | A | |
| Sodium Chloride 0.9% injection | A | B |
| Other items to consider having quick access to in the Urgent Care Room, but not necessarily stored in the cart | | |
| Albuterol Inhaler | A | B |
| Albuterol Solution | A | B |
| Charcoal | A | B |
| Diphenhydramine 50 mg inj | A | B |
| Nitroglycerin 50 mg/10ml | A | |

FORMULARY OTC PRESCRIBING CRITERIA MATRIX 2018

(Please note, although the OTC medication doses recommended by the manufacturer are typically less than prescription doses, the labeling does allow for higher doses if recommended by a clinician.)

| Class / Indication | Formulary Agent | Dispense from Pharmacy (if Medically Necessary) | Refer to Commissary | Available Commissary Items |
|--|---|--|---------------------|---|
| Pain**10 (See OTC Matrix Nomogram – Pain, below as note 10) | - NSAIDS - salsalate-acetaminophen-aspirin **NOTE see comments at end of matrix | Ortho/Rheum diagnosis and followed in a related chronic care clinic**1,2,3 - Acute injury or dental procedure [limit 7 days therapy (no refills) per month]**4 - Inmates being followed in a neurology or pain CCC with migraine diagnosis may receive a short burst of NSAIDS or acetaminophen limited to 7 days (eg 21 tablets) per month for the acute treatment of migraines. Consideration of prophylactic treatment must be documented. - Inmates with a diagnosis/indication of Gout may receive a short burst of NSAIDS limited to 7 days (eg 21 tablets) per fill for the acute treatment of gout flare ups. - Inmates on interferon therapy should be able to receive short burst of acetaminophen to relieve post interferon injection discomfort (for example 3 day supply weekly) while on treatment. NSAIDS should NOT be used in patients with liver disease. or OTC Med Qualified* and medically appropriate | all others | - ibuprofen - naproxen - acetaminophen - aspirin - Midol™ max strength |
| Eye | - naphazoline-pheniramine eye drops (Visine-A™) - artificial tears | OTC Med Qualified* and medically appropriate | all others | Allergy eye drops: - naphazoline-pheniramine eye drops (Visine™ A or Opcon™ A) - ketotifen - Artificial tears |
| Multi-vitamin | - iron - B-6 - calcium - calcium with Vit D - vitamin B-12 tablets - thiamine - folic acid - vitamin D | - anemia, osteoporosis, renal disease, alcohol detox or GI malabsorption diagnosis; or on INH therapy and followed in a related chronic care clinic - Vitamin D – documented deficiency or dermatologist approved sun-restricted conditions (including Lupus, solar urticarial, history of non-melanoma and melanoma skin cancers) | all others | - multivitamin - Vit E - Vit C - calcium - calcium with Vit D - Vit B Complex - Vit D - folic acid |
| Hemorrhoid | - dibucaine - glycerin-witch hazel topical (Tucks™) - fiber tablets - docusate | pending hemorrhoid surgery or OTC Med Qualified* and medically appropriate | all others | - dibucaine ointment - hemorrhoidal cream - Tucks™ pads - fiber tablets - docusate |
| Stomach | - Maalox™/ | OTC Med Qualified* and medically appropriate**5 | all others | - Maalox™/Mylanta™ |

| | | | | |
|---|---|---|------------|---|
| | <p>Mylanta™ - calcium carbonate (Tums™) - Gaviscon™ - MOM - bismuth subsalicylate - simethicone - loperamide - fiber tablets - docusate</p> | | | <p>antacid tablets - calcium carbonate (Tums™, Roloids™) - Gaviscon™ - MOM - bismuth subsalicylate - simethicone - loperamide - fiber tablets - docusate - methylcellulose (Citrucel™)</p> |
| <p>H2/PPI**11 (See OTC Matrix Nomogram – H2/PPI Use, below as note 11)</p> | <p>- ranitidine - omeprazole</p> | <p>OTC Med Qualified* and medically appropriate with gastrointestinal diagnosis and followed in a related chronic care clinic**6</p> | all others | <p>- ranitidine - famotidine - omeprazole</p> |
| Dental | none | acute dental | all others | - anesthetic gel, dental |
| Anti-histamine, Nasal Steroid Cough and Cold Allergy | - fluticasone nasal spray | <p>OTC Med Qualified* and medically appropriate**9 Non-Formulary - Refer to Use Criteria and OTC Policy</p> | all others | <p>- CTM - loratadine - cough drops - throat lozenges - saline nasal spray - Vicks Vapor Rub™ - guaifenesin syrup - Cromolyn Nasal Spray - triamcinolone nasal spray</p> |
| Ear | - carbamide peroxide ear drops (Debrox™) | OTC Med Qualified* and medically appropriate | all others | - carbamide peroxide ear drops |
| Topical | <p>- coal tar - antibiotic ointment - calamine - hydrocortisone - vit A & D - selenium - salicylic acid pads - zinc oxide</p> | OTC Med Qualified* and medically appropriate**8 | all others | <p>- coal tar shampoo - sunscreen - antibiotic ointment - calamine - analgesic balm - hydrocortisone - vit A & D - selenium - salicylic acid pads - chapstick - zinc oxide - Lac-Hydrin™</p> |
| Antifungal | <p>- clotrimazole - miconazole - nystatin</p> | <p>OTC Med Qualified* and medically appropriate skin diagnosis and followed in a related chronic care clinic; x 30 days only per formulary restriction Nystatin – can prescribe for appropriate treatment of yeast infection – max 30 days only per formulary restriction</p> | all others | <p>- clotrimazole - tolnaftate - miconazole - terbinafine (Lamisil™)</p> |

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

* If inmate is identified as ‘OTC Med Qualified’ (i.e. indigent) in TruFacs and meets guidance in ‘Dispense from Pharmacy’ column, item may only be prescribed up to a 15 day supply (no refills) per month. Refer to PS6541.02 for items available to indigent inmates without an HSU visit.

Note: Refer to current OTC Program Statement for list of medications that can be provided to indigent inmates without signing up for sick call. If a similar medication is not on the indigent OTC list, the inmate may have a short-term prescription.

** 1. Chronic pain conditions with objective abnormalities, e.g. rheumatoid arthritis, osteoarthritis with abnormal x-ray or abnormal findings, - Inmate should be enrolled in Ortho/Rheum chronic care clinic and prescriptions should be written by a clinician and dispensed by the pharmacy for prescription strength medication. For institutions without a pharmacist: inmates who are receiving chronic NSAID or acetaminophen therapy for pain and also receiving an NSAID or acetaminophen for breakthrough pain will be limited to 7 day supply per month of the secondary medication.

2. Chronic pain symptoms without any objective findings (in these cases it is assumed that significant pathology has been ruled out and symptoms are relatively minor) - these patients should be referred to commissary to purchase OTC medications.

3. Acute pain that is relatively minor should be referred to purchase OTC medication from the commissary. This would include minor injuries and headaches.

4. Acute pain that is severe, and short-term post - operative pain management in general should be managed with prescription strength medication written by a clinician and dispensed by the pharmacy ‘acute injury or dental procedure [limit up to 7 days of therapy (no refills) per month]’. Patients with severe pain must receive an appropriate evaluation to rule out causes that require urgent intervention rather than just pain management.

5. Stomach: Short-term laxative and antacid therapy for self-limiting conditions should be referred to the commissary. Non-stimulant laxatives and stool softener therapy may be provided for chronic GI hypo-motility disorders or in conjunction with iron and opioid analgesic orders.

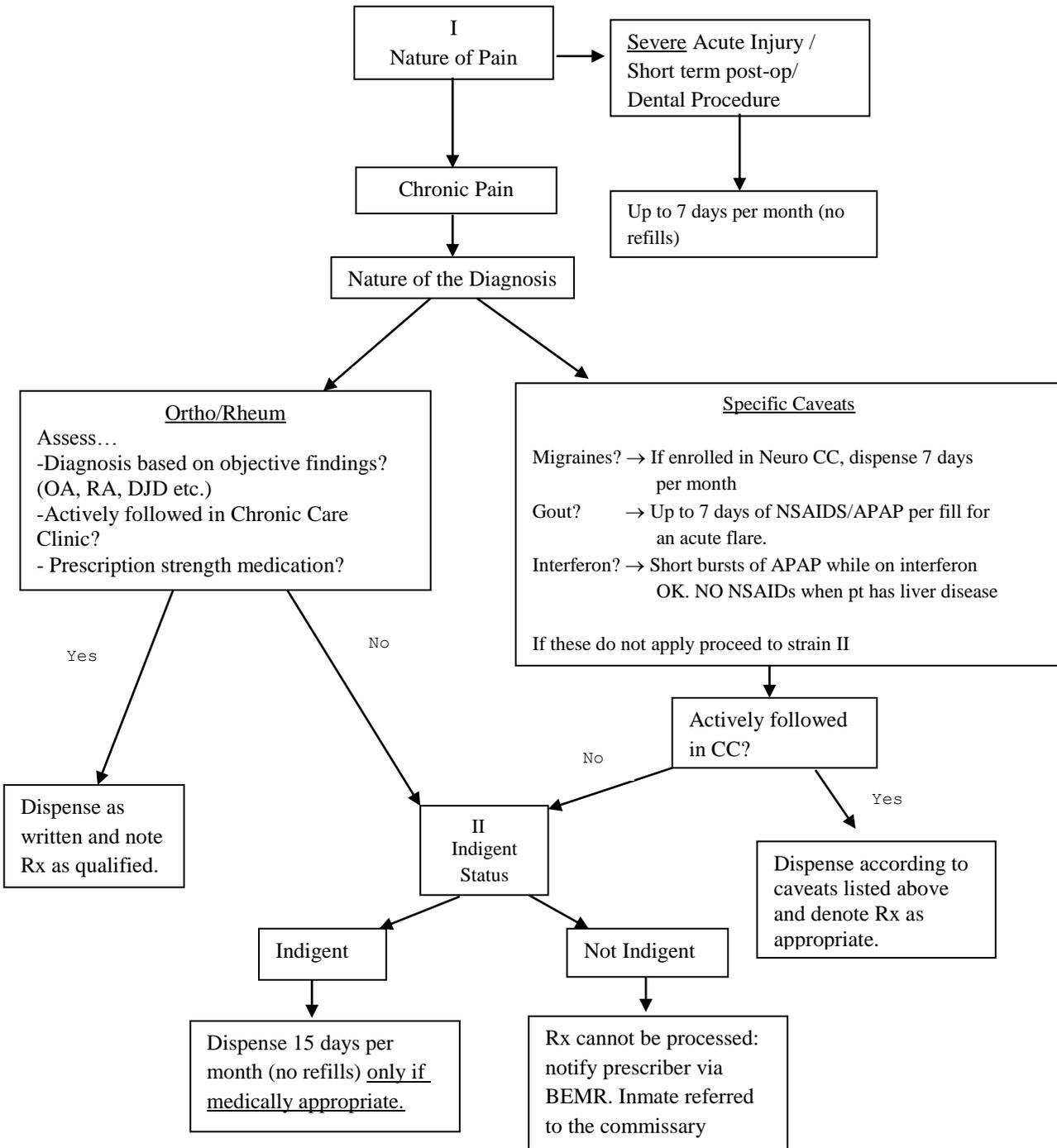
6. H2/PPI’s: **Non-indigent inmates must purchase all OTC strength “Ranitidine or Omeprazole” from the commissary (for: Relief of heartburn, acid indigestion, sour stomach, prn use, QD use for Ranitidine and GERD) unless they are being actively followed in a GI Chronic Care Clinic with documented findings to justify use of these medications for the following: Severe GERD, Zollinger-Ellison Syndrome, Schatzki’s Ring, Barrett’s Esophagitis, Esophageal Stricture, Hiatal Hernia, Previous GI Bypass or Ulcer Surgery, chronic oral steroid use in transplants, Documentation of Chronic need for NSAIDS with Prior History of GI Bleed and Short-Term Treatment of H. Pylori.

7. Non-indigent inmates should be referred to the commissary to purchase OTC eye drops (artificial tears and allergy eye drops) for minor eye conditions (dry eye, red eye, and Pterygium – unless surgical intervention is required). Eye conditions with objective abnormalities, e.g. short-term post-surgical eye procedures, Sjorgren’s syndrome, and prosthetic eye implants – inmates should be enrolled in a general chronic care clinic and followed by an optometrist or ophthalmologist.

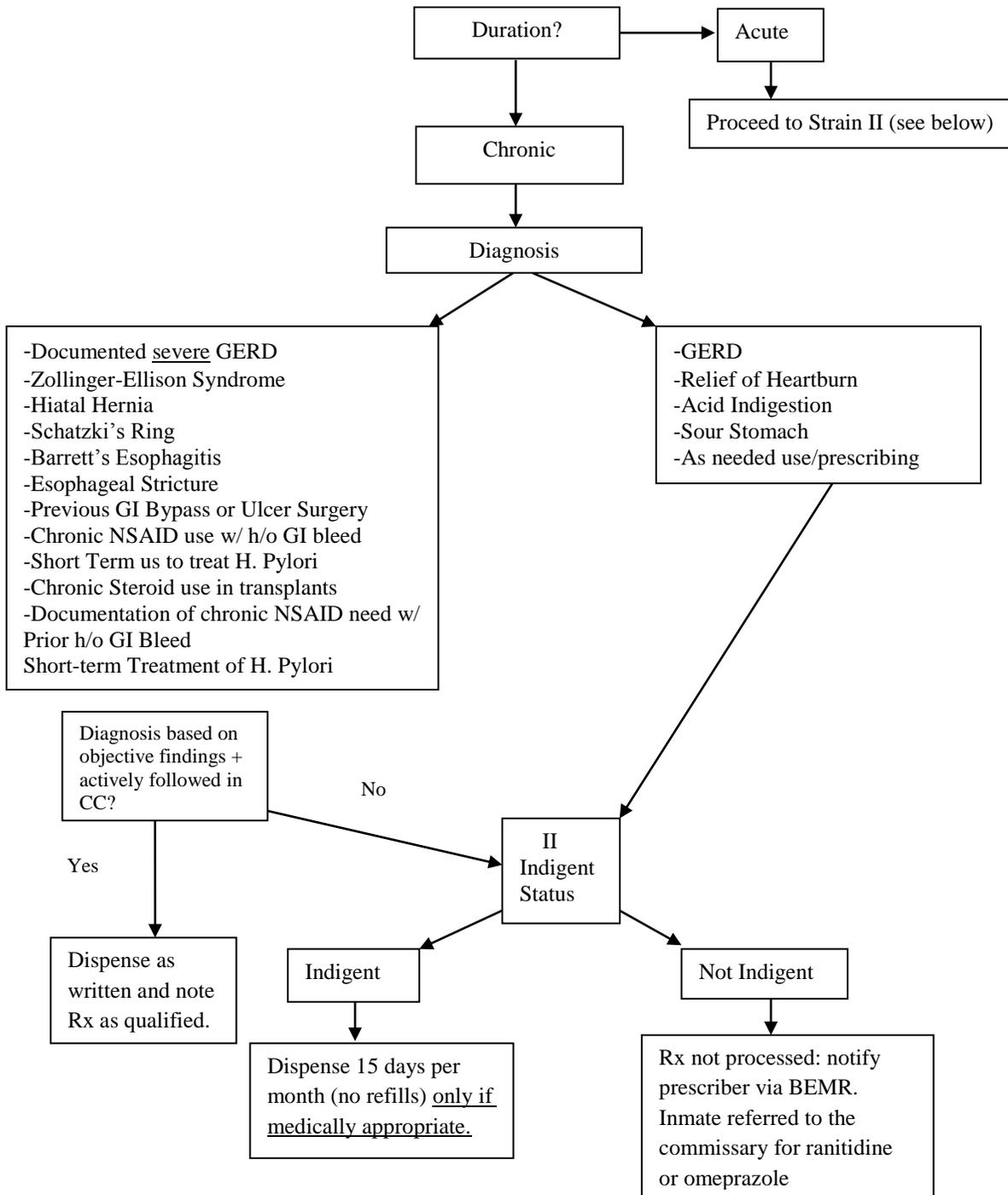
8. Topicals: Non-indigent inmates should be referred to the commissary to purchase OTC topical medications for minor conditions and in accordance with formulary restrictions. Short-term use of topical OTC medications should be purchased from the commissary.

9. Nasal: Non-indigent inmates should be referred to the commissary to purchase OTC nasal sprays for minor symptoms of allergic rhinitis symptoms (rhinorrhea, congestion, and itching). Seasonal use of nasal OTC medications should be purchased from the commissary. Nasal corticosteroid may be provided for chronic allergic rhinitis symptoms with significant adverse effects (significant nasal irritation, persistent epistaxis, pharyngitis), allergic rhinitis with comorbid asthma/serious respiratory disease, or for post-operative use following ENT surgery. Inmates must be enrolled in a general chronic care clinic.

10. OTC Matrix Nomogram – NSAIDs



11. OTC Matrix Nomogram – H2/PPI Use



Hypertensive Emergency & Urgency Guidance

The following is guidance regarding the appropriate management of hypertensive emergencies and urgencies for BOP health care providers. It should be noted that an excessive hypotensive response via unnecessarily aggressive treatment may result in more risk than benefit leading to potential ischemic events such as stroke, myocardial infarction, and blindness. All institutions should provide a local in-service for their providers regarding the appropriate management for these situations. Providers should review the BOP Hypertension Clinical Practice Guideline. Nurses should also reference the BOP nursing protocols when available.

Hypertensive Emergency

Definition: severe hypertension, greater than 180 mmHg systolic or 120 mmHg diastolic, associated with end-organ damage.

Examples: malignant hypertension and hypertensive encephalopathy, ischemic stroke, subarachnoid or intracerebral hemorrhage, acute pulmonary edema, angina pectoris, acute myocardial infarction, aortic dissection, withdrawal of antihypertensive medications, acute increase in sympathetic therapy, pregnancy (preeclampsia or exacerbation of preexistent hypertension).

Goal: immediate, careful reduction in blood pressure utilizing intravenous antihypertensive medications.

Comments: contact emergency responders (911) in cases of hypertensive emergencies. Medical referral center (MRC) providers familiar with management of hypertensive emergencies may choose to initiate intravenous antihypertensive medications depending on availability within institution.

Hypertensive Urgency

Definition: severe asymptomatic hypertension, greater than 180 mmHg systolic or 110-120 mmHg diastolic, with no end-organ damage. Goal: reduce blood pressure to \leq 160/100 over several hours to days.

Comments: there is no proven benefit of rapidly reducing blood pressure in patients with severe asymptomatic hypertension and could actually induce cerebral or myocardial ischemia / infarction. All patients should be scheduled for follow up with their primary care provider within several days following an episode of severe asymptomatic hypertension.

Treatment:

1. Allow patient to rest in a quiet room for 15 minutes and repeat blood pressure.
2. If blood pressure is still above 180/110-120, initiate oral treatment.
3. In patients previously **untreated** for hypertension, administer 20 mg furosemide (if normovolemic) or 12.5 mg captopril. May increase dose of furosemide to 40 mg if patient has documented renal insufficiency. Do **NOT** use captopril in pregnant patients.
4. In patients previously **treated** for hypertension, resume medications in noncompliant patients, increase dosage of medications for compliant patients or give 20 mg furosemide.
5. Observe the patient over several hours to ensure blood pressure reduction. Contact the on-call provider if there is no change.

High priority Medical Conditions/Diagnoses

Diabetes Mellitus (high blood sugar)

Hypertension (high blood pressure)

Cardiac problems - history of heart attacks, abnormal heart rhythms, congestive heart failure, or currently having chest pain.

Anyone taking warfarin/Coumadin™ or other blood thinners*

HIV infection

Cirrhosis of the liver

Uncontrolled asthma/COPD (emphysema) or have run out of medications*

Uncontrolled seizures or have run out of seizure medicine*

Any cases of active pulmonary tuberculosis*

Mental health conditions such as bipolar disorder, psychotic disorders (e.g. schizophrenia); any psychiatric condition requiring antipsychotics, mood stabilizers or benzodiazepines are high risk*

Hepatitis C infection - currently being treated with interferon/ribavirin, with or without protease inhibitors*

Medications with withdrawal potential - chronic benzodiazepines, barbiturates, chronic narcotics, etc.*

Dialysis

Cancer receiving active treatment

Antirheumatic DMARDs, non-biologic or biologic (non-urgent)*

* Starred conditions will be less of a priority for transfer consideration if the inmates are being appropriately treated and are able to receive their medications consistently.

Guidance on Therapeutic Substitution on Intake

Introduction

This document provides guidance to local Pharmacy and Therapeutics (P&T) meetings that choose to adopt a process of therapeutic substitution by pharmacists for intake orders. Discussion of therapeutic substitution in this document is limited to intake orders only. Any institution implementing therapeutic substitution must approve of the process through their local P&T.

Therapeutic substitution is defined as the dispensing of a drug that is therapeutically equivalent to, but chemically different from, the drug originally prescribed by a physician or other authorized prescriber. When properly established, a therapeutic substitution program may reduce costs, prevent unnecessary non-formulary requests, increase workplace efficiency, enhance medication access, and improve inventory management.

Requirements

Before initiating a substitution program, each institution's P&T must approve the substitutions included in this document. Documentation of this approval must be included in the institutional P&T minutes which are sent to Central Office. Copies of the institution's substitution program must be available to all providers in Health Services.

NOTE: The listed equivalency tables (see below) have been approved by the National P&T meeting and are the only ones eligible for automatic therapeutic substitution. Requests for additions to the approved list may be submitted for consideration to the National P&T Meeting via the P&T mailbox. As previously noted, these substitutions must be approved by the local P&T before they are used. Any other parameters desired for substitution must be discussed with the prescriber first, on a patient-by-patient basis.

Process

The following process will be adhered to by the pharmacist when performing therapeutic substitution of an intake medication order:

1. After receipt of an intake order for a non-formulary medication that is eligible for automatic therapeutic substitution, the pharmacist will write a BEMR Admin Note using the 'Pharmacy Note' and 'Pharmacy Therapeutic Interchange' designations.
2. All notes will discontinue the non-formulary drug order and add a drug order for the equivalent drug and strength found in the below equivalency tables.
 - a. For pharmacists without a CPA covering the new drug in question, a TO/VO order is required. A co-signature from the prescriber selected on the original intake order is required. OR

- b. For pharmacists with a CPA covering the new drug in question, a regular admin note will suffice with a review by the prescriber selected on the original intake order.
3. For each prescription interchanged, pharmacy staff will manually add the short sig code 'PTI' in the sig field of the new order. (PTI expands to "***Pharmacy Therapeutic Interchange.**")
4. The institution should develop a mechanism to inform the patient of the therapeutic change.
5. Local P&T meetings should periodically review substitution procedures for quality assurance.

| Written Order | Formulary Equivalent (Adult dosing only) | | | | |
|-----------------------|--|---------------------------|----------------|----------------|----------------|
| ACE Inhibitors | The following chart will be used to substitute a non-formulary ACE inhibitor for lisinopril. | | | | |
| | Generic Name | Dose Equivalents (mg/day) | | | |
| | <i>Short-acting</i> | | | | |
| | Captopril | No sub. | No sub. | No sub. | No sub. |
| | <i>Intermediate-acting</i> | | | | |
| | Benazepril | 5 | 10 | 20 | 40 |
| | Enalapril | 5 | 10 | 20 | 40 |
| | Moexipril | - | 7.5 | 15 | 30 |
| | Quinapril | 5 | 10 | 20 | 40 |
| | Ramipril | 2.5 | 5 | 10 | 20 |
| | <i>Long-acting</i> | | | | |
| | Lisinopril | 5 | 10 | 20 | 40 |
| | Fosinopril | 5 | 10 | 20 | 40 |
| | Perindopril | 2 | 4 | 4-8 | 8-16 |
| | Trandolapril | - | 1 | 2 | 4-8 |
| | *Formulary agents in bold. | | | | |

Corticosteroids (Inhaled)

The following chart will be used to substitute a non-formulary inhaled corticosteroid for mometasone DPI.

| Generic Name | Low Daily Dose | Medium Daily Dose | High Daily Dose |
|-----------------------|-------------------|-------------------|-------------------|
| Mometasone DPI | 110-220mcg | 330-440mcg | >440mcg |
| Beclomethasone HFA | 80-240mcg | 280-480mcg | >480mcg |
| Ciclesonide HFA | 160-320mcg | >320-640mcg | >640mcg |
| Budesonide DPI | 180-600mcg | 630-1200mcg | >1200mcg |
| Flunisolide HFA | 320mcg | >320-640mcg | >640mcg |
| Fluticasone HFA | 88-264mcg | >264-440mcg | >440mcg |
| Fluticasone DPI | 100-300mcg | >300-500mcg | >500mcg |

*Formulary agent in bold.

DPI = dry powder inhaler
HFA = hydrofluoroalkane

Corticosteroids (Nasal)

The following chart will be used to substitute a non-formulary nasal corticosteroid for fluticasone propionate.

| Generic Name | Dose |
|--------------------------|--------------------------|
| Fluticasone Prop. | 2 sprays EN daily |
| Fluticasone Furoate | 2 sprays EN daily |
| Beclomethasone | 1-2 sprays EN BID |
| Budesonide | 1-4 sprays EN daily |
| Ciclesonide | 2 sprays EN daily |
| Flunisolide | 2 sprays EN BID/TID |
| Mometasone | 2 sprays EN daily |
| Triamcinolone | 1-2 sprays EN daily |

*Formulary agent in bold.

EN= each nostril

HMG CoA Reductase Inhibitors (“Statins”)

The following chart will be used to substitute a non-formulary statin:

| Generic Name | Dose Equivalents (mg/day) | | | | Ave. Cost/Month |
|---------------------|---------------------------|-----------|-----------|--------------|-----------------|
| | Intensity: | Low | Medium | High | |
| Atorvastatin | | 10 | 20 | 40-80 | \$1.20 |
| Fluvastatin | 20-40 | 80 | - | - | \$75.00 |
| Lovastatin | 10-20 | 40 | 80 | - | \$0.90 |
| Pitavastatin | 1 | 2 | 4 | - | \$109.20 |
| Pravastatin | 10-20 | 40 | 80 | | \$2.40 |
| Rosuvastatin | | 5 | 10 | 20-40 | \$1.80 |
| Simvastatin | 5-10 | 20 | 40 | 80 | \$0.90 |

*Formulary agents in bold

Resources:

1. Professional Resource, Statin Dose Comparison. Pharmacist’s Letter/Prescriber’s Letter. July 2016.
2. Clinical Resource, ACE Inhibitor Antihypertensive Dose Comparison. Pharmacist’s Letter/Prescriber’s Letter. November 2016.
3. Clinical Resource, Inhaled Corticosteroid Dose Comparison in Asthma. Pharmacist’s Letter/Prescriber’s Letter. April 2017.
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14. Wang JS, Fogerty RL, Horwitz LI (2017). Effect of therapeutic interchange on medication reconciliation during hospitalization and upon discharge in a geriatric population. PLoS ONE 12(10): e0186075. Available from: <https://doi.org/10.1371/journal.pone.0186075>.
15. University of North Carolina School of Medicine. [Internet]. Antihypertensive Initiation and Titration; [cited 2018 May 6]. Available from: https://www.med.unc.edu/im/files/enhanced-care-files/HTN_Protocol_6.05.pdf

PART II

NATIONAL
BOP FORMULARY

REFER TO BEMR RX
FORMULARY DRUG
FILE REPORT