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## 2011 Formulary Changes

\*\*\*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 an abbreviated summation of the major changes set forth in the 2011 BOP Formulary; please refer to the 2011 National P&T minutes for additional information and detailed discussion regarding all of this year's changes.

- **Aprepitant / Fosaprepitant (Emend™)** - ADDED with restrictions: "For use in highly emetic chemotherapy treatment regimens only"; "MRC Use Only"
- **Benzoin tincture** - ADDED restriction: "Clinic use only, not to be issued to inmate"
- **Bupropion** - ADDED suspension; ADDED advisory - a formulary suspension added to be used when abuse/diversion is suspected.
- **Colchicine** - ADDED 7 day order restriction; ADDED advisories: "For acute use...", "Use low dose regimen..."
- **Dabigatran (Pradaxa™)** - ADDED non-formulary use criteria
- **Divalproex sodium** - ADDED extended-release formulation
- **Epinephrine auto-injector** - APPROVED self-carry: recommendations provided
- **Ergotamine / caffeine (Cafergot™)** - ADDED restriction: "limit to 10 tablets per month"
- **Filgrastim** - ADDED with restrictions: "MRC use only"; "Oncologist use only"; ADD Inclusionary Dx Criteria
- **Insomnia meds** - ADDED exclusionary Dx criteria
- **Mupirocin** - DELETED
- **Nifedipine ER** - DELETED Adalat CC brand restriction
- **Nutritional Supplements** - EDITED restrictions; ADDED inclusionary Dx criteria
- **Oseltamivir (Tamiflu™)** - limit local stock to 30 tablets (3 courses) for Care Level 3 and 4 institutions only.
- **Pantoprazole IV (Protonix™)** - ADDED with restrictions: "MRC use only", "Inpatient use only"
- **Phenobarbital** - DELETED, ADDED non-formulary use criteria with provision for short term continuation in new intakes.
- **PharmaJet Needle-Free Injection System** - REVIEWED
- **Prasugrel (Effient™)** - ADDED non-formulary use criteria
- **Regadenoson (Lexiscan™)** - ADDED with restriction: "MRC use only"
- **Rifaximin (Xifaxan™)** - ADDED non-formulary use criteria
- **SSRIs (except paroxetine)** - DELETED 14-day self-carry restriction
- **Testosterone cypionate** - ADDED non-formulary use criteria
- **Vancomycin (oral formulation)** - DELETED, ADDED non-formulary use criteria

## 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. As participants of the Pharmacy, Therapeutics, and Formulary Meeting, defined healthcare staff 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 that optimal treatment options are uniformly consistent and readily available.

Optimization of therapeutic outcomes, costs related to the drug use process, and ensuring conduciveness within the correctional environment are the primary goals of BOP Formulary management.

### **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. It is expected that ALL comments made on the request are 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 medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.
4. Prescribers (BOP Physician / MLP / Dentist) 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 on the form and the 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 by basing administrative decisions regarding medical care consistent with the BOP

National Formulary, that do 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 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.

### 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 RELEASE CENTER (RRC) (E.G. HALF-WAY HOUSE) FDA WEBSITE:**

**<http://www.fda.gov/cder/Offices/ODS/labeling.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 with the inmate is:

1. being released to the community (including writs and furloughs)
2. sent to a Residential Release Center (RRC) (e.g. Half-Way House)

### HIV ANTIRETROVIRAL MEDICATION DISTRIBUTION RESTRICTION

A staged administration of antiretroviral medications is recommended for most inmates. Complete adherence to antiretroviral medications is critical for

treatment effectiveness. The following medication administration should be considered for inmates initiated on antiretroviral therapy:

Weeks 1 and 2:	Directly Observed Therapy (DOT), to monitor compliance and ability of inmate to tolerate medication.
Week 2 through 12:	If compliance is 100% with above with manageable side effects; issue one week supply.
Week 12 thru 6 mo:	If compliance is 100% with one week supply administration and side effects are manageable, inmate is not due to be transferred, and does not have history of going in/out of SHU; issue 2 week supply.
After 6 months:	If above criteria are met at 6 months and inmate's viral load and CD4 counts are indicative of successful therapy; issue 4 week supply. Ensuring successful therapy prior to increasing days' supply to inmate will avoid wasted medications from therapy changes.

**NOTE:** Physicians and nurses incorrectly predicted adherence to antiretrovirals 30-40% of the time in one study. Adherence should be assessed using objective measures.

**Prescribers and pharmacists should have low threshold for resuming DOT if non-adherence is suspected clinically or virologically.**

#### **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 is supported by an appropriate and commensurate indication. Refer to the Formulary OTC Prescribing Criteria Matrix, Pages 34-36.

#### **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 BEMR. There are some medications that are designated as pill line only for certain indications (see page 12).

#### **PHYSICIAN INITIATION ONLY**

A restriction placed on some medications requiring that a physician be the originator of that drug therapy. This restriction implies that a Mid-Level Provider may continue this medication for the inmate at a later date without obtaining the physician's written or oral approval.

## **PHYSICIAN USE ONLY**

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:**

<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8083.shtml>

"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 statement"**

<http://www.ashp.org/DocLibrary/BestPractices/policypositions2009.aspx>

Page 52 0517 Ethical use of Placebos "To affirm that the use of placebos in clinical practice is acceptable ethically only when patients grant informed consent for the use of placebos as a component of treatment..."



## LOOK ALIKE / SOUND ALIKE MEDICATIONS

The Joint Commission on Accreditation of Health Care Organizations continues to revise and publish National Patient Safety Goals regarding Look Alike / Sound Alike medications. Look Alike / Sound Alike medication lists are available, including a list compiled by The Joint Commission utilizing FDA, ISMP (Institute of Safe Medicine Practices), and USP (United States Pharmacopeia) lists.

Each BOP institution needs to incorporate look-alike / sound-alike drugs into the agenda of the local Pharmacy & Therapeutics Committee Meetings. The discussions, decisions, and respective local policy must follow the requirements set forth in the current Joint Commission National Patient Safety Goal. Recommendations and options are also provided for identified medications.

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. However, a list will be maintained and provided on SallyPort for all institutions to utilize.

### **RESOURCES** The Joint Commission

[www.jointcommission.org](http://www.jointcommission.org)

Institute of Safe Medicine Practices

[www.ismp.org](http://www.ismp.org)

The Joint Commission National Patient Safety Standard Goal, Improve the Safety of Using Medications, Look-Alike / sound-Alike element

<http://www.jointcommission.org/NR/rdonlyres/C92AAB3F-A9BD-431C-8628-11DD2D1D53CC/0/LASA.pdf>

USP Quality Review Publication:

<http://www.usp.org/pdf/EN/patientSafety/qr792004-04-01.pdf>

## NON-SUBSTITUTABLE PRODUCTS

<u>GENERIC DRUG NAME</u>	<u>REQUIRED BRAND PRODUCT</u>
ESTROGENS, CONJUGATED	Premarin™ (Wyeth-Ayerst)
PHENYTOIN SODIUM, EXTENDED RELEASE CAPSULE	Dilantin™ (Parke-Davis)
QUINIDINE GLUCONATE, SUSTAINED-RELEASE TABLETS	Quinaglute™ (Berlex)
WARFARIN SODIUM	Coumadin™ (DuPont Pharmaceuticals)
PURIFIED PROTEIN DERIVATIVE	Tubersol™
LEVOTHYROXINE SODIUM	Levothroid™
NIACIN	Niaspan™

**NON-CONTROLLED SUBSTANCES  
RESTRICTED TO PILL LINE**

\*REFER TO BEMR RX PILL LINE REPORT FOR AN ALL INCLUSIVE LISTING\*

ANTIEPILEPTIC DRUGS used for treatment of psychiatric disorders

- CARBAMAZEPINE
- LAMOTRIGINE
- LEVETIRACETAM
- OXCARBAZEPINE
- VALPROIC ACID

GABAPENTIN all uses

HIV MEDICATIONS according to HIV Antiretroviral Medication  
Distribution Restrictions (refer to page 7)

METHICILLIN RESISTANT STAPH AUREUS (MRSA) TREATMENT

- CLINDAMYCIN
- DOXYCYCLINE
- LINEZOLID (NF)
- MINOCYCLINE (NF)
- RIFAMPIN
- TRIMETHOPRIM-SULFAMETHOXAZOLE

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.\*\***

**Clinical Criteria/Justification to be Met for Commonly Requested Non-formulary Medications:**

**Adalimumab (Humira™) - See Immunomodulator TNF Inhibitors**

**Adult Attention Deficit Hyperactivity Disorder Medications/**

**Treatment:** bupropion (Wellbutrin™), 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 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
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.

**Alfuzosin (Uroxatral™) - See Tamsulosin (Flomax™)**

**Amantadine (Symmetrel™)**

1. Parkinson's Disease / syndrome
2. Drug induced extrapyramidal reactions not responsive to trihexyphenidyl or bztropine.
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.

**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, griseofulvin, fluconazole, 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 - (Benadryl™), hydroxyzine (Atarax™, Vistaril™) loratadine (Claritin™), cetirizine (Zyrtec™), cyproheptadine (Periactin™), and fexofenadine (Allegra™) oral**

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 for.
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)\*\*

**ARB (Angiotensin Receptor Blocker): losartan (Cozaar™), valsartan (Diovan™), irbesartan (Avapro™), candesartan (Atacand™), telmisartan (Micardis™), eprosartan Tevetan™, olmesartan (Benicar™)**

1. Documentation that patient was unable to tolerate ACE Inhibitor due to cough even after trial of fosinopril via non-formulary request, or angioedema.
2. Combination therapy with an ACE inhibitor after failure to control or treat proteinuria (remains greater than 1 gm/day) with an ACE inhibitor alone at the maximum recommended dose and compliance documented.
3. Check "yes" if noted. The ARB of choice for non-formulary approval will be the most cost effective at the time the original non-formulary request is submitted. Institutions should attempt to select the most cost effective ARB when renewing previously approved non-formulary requests.

### **Ascorbic Acid (Vitamin C)**

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

### **Atorvastatin (Lipitor™)**

1. Documented failure of simvastatin at maximum dose.
2. Failure of niacin utilization via the brand name Niaspan™ Formulation.
3. Must complete and submit Appendix 2, Steps 1-6, Management of Lipid Disorders, BOP Clinical Practice Guidelines.

### **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 nonsmoking 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 (T<sub>cp</sub>O<sub>2</sub> >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 which 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)

### **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.

### **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, non-formulary request may be submitted after opiate detox protocol initiated. 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, methyldopa, 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 which 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 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 (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:**

1. Lack of response to traditional NSAIDs.
2. Dyspepsia or GI intolerance to traditional NSAIDs.
3. Patients receiving a proton pump inhibitor.
4. Patients receiving low dose aspirin for cardiovascular prophylaxis.
5. Patients with known cardiovascular disease.
6. Dysmenorrhea.

## **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™)**

1. Patients being treated for atrial fibrillation with an INR that is unable to be stabilized on warfarin therapy
2. Patients previously stabilized on dabigatran 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.

## **Delavirdine (Rescriptor™)**

1. 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 & 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.

### **Dietary/Herbal Supplements**

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

### **Diphenhydramine - see antihistamines**

### **Dutasteride (Avodart™) - see finasteride**

### **Enfuvirtide (Fuzeon™)**

1. Inmate is candidate for antiretroviral therapy (ART) per USPHS Guidelines <http://www.aidsinfo.nih.gov/>
2. Infectious disease consultant recommends enfuvirtide. Consult must include complete proposed HAART regimen and must be submitted with non-formulary request.
3. Inmate has failed, is resistant to or is intolerant of at least two PI-based regimens and one NNRTI-based regimen.
4. Resistance testing must be submitted.
5. At least two other medications are also potentially effective based on resistance testing, and these two medications can be safely co-administered. (Examples of combinations which are contraindicated include TDF+ABC+3TC, TDF+ddI+3TC, AZT+d4T, d4T+ddC, d4T+ddI, and ddI+ddC.)
6. Inmate motivated to try new injectable regimen.

Additional Comments:

1. Inmate understands that medication will be discontinued if ineffective.
2. Inmate understands that if compliance falls below 95%, for any and all HAART medications, therapy will be discontinued.
3. All HAART medications will be administered as **pill line only**.

### **Etanercept (Enbrel™) - See Immunomodulator TNF Inhibitors**

### **Etravirine (Intelence™)**

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.

4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, **and the complete HAART regimen being requested.**
6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved. (same as other HIV medications)

### **Ezetimibe (Zetia™)**

1. Failure of niacin utilization via the brand name Niaspan™ formulation.
2. Must complete and submit Appendix 2, Steps 1-6, Management of Lipid Disorders, BOP Clinical Practice Guidelines.
3. 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) or niacin.
4. 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 or niacin, should be reached prior to considering therapy with ezetimibe.
5. 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, and niacin.

### **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 (Neupogen™/Neulasta™)**

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. Treatment for hepatitis-treatment-induced neutropenia must be done in consultation with Central Office staff in accordance with the BOP Hepatitis C Clinical Practice Guidelines.

### **Finasteride (Proscar™) and 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 Non-Formulary 5 $\alpha$ -Reductase Inhibitor of Choice\*\*

### **Formoterol (Foradil™) - See Long Acting Beta Agonists (LABA)**

### **Hormones to maintain secondary sexual characteristics**

1. Institution Clinical Director concurrence that hormonal therapy is medically indicated and safe.
2. Confirmation of legitimate prescribing prior to incarceration.
3. Psychiatric diagnostic evaluation and treatment plan.

### **Hydroxyzine (Atarax™, Vistaril™) oral - see antihistamines**

### **Immunomodulator TNF Inhibitors Etanercept (Enbrel™) and adalimumab (Humira™)**

1. Adalimumab is recommended agent due to better side effect profile.
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.

### **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, Long Acting Insulin (Lantus™)**

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.
- 3.

### **Insulin lispro, Rapid Acting Insulin (Novolog™, Humalog™)**

NOTE: generally speaking lispro is 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 & 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 [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and [www.ncpdp.org](http://www.ncpdp.org) must be followed. 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.

### **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.

### **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.

### **Long Acting Beta Agonists (LABA) Salmeterol and Formoterol**

1. COPD patients must have failed anticholinergic agent tiotropium (Spiriva™).
2. Continued nocturnal awakenings not managed by maximum dose of steroid inhaler and/or low dose night time theophylline.
3. At least moderately severe asthma not controlled by maximum dose of inhaled corticosteroid alone.

### **Lorazepam long-term use - see Benzodiazepines**

### **Loteprednol etabonate (Lotemax™, Alrex™)**

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

### **Maraviroc (Selzentry™)**

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.
4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, **and the complete HAART regimen being requested.**
6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved. (same as other HIV medications)

### **Methicillin Resistant Staff aureus (MRSA) treatment (minocycline, linezolid)**

1. Restricted to pill line when utilized for MRSA.

### **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™)**

PILL LINE ONLY

Approval for baclofen or dantrolene will be considered for the following cases and must be administered via

PILL LINE:

**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

Approval for baclofen may be considered for intractable pain from neurological conditions, such as trigeminal neuralgia, that has been unresponsive to formulary agents.

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.

### **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).

### **Onychomycosis, oral treatment - See Antifungals**

### **Oseltamivir (TamiFlu™)**

1. TamiFlu™ institutional stock can be utilized via the non-formulary process.
2. Institutional Clinical Directors diagnosing H1N1 cases at their local institutions can order TamiFlu™ therapy from their local TamiFlu™ stock. This should be done on a case by case basis and patients should
3. meet CDC criteria for H1N1 which are fever, lethargy, lack of appetite, coughing, runny nose, sore throat, nausea, vomiting and diarrhea.
4. Therapy is only to be offered to patients within 48 hours of exposure. Antiviral therapy is not effective or recommended 48 hours post exposure.
5. Non Formulary Drug requests for TamiFlu™ will be processed and expedited through Central Office.
6. Pharmacists will utilize TamiFlu™ purchased from McKesson to fill acute and isolated H1N1 cases.
7. 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.

### **Phenobarbital (Luminal™)**

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

### **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. Painful diabetic neuropathy - well documented as insufficient response to gabapentin at the maximum dose and at least one tricyclic agent, venlafaxine, AED's used alone or in combination.
2. Postherpetic Neuralgia - well documented intolerance to gabapentin or insufficient response at maximally tolerated doses of gabapentin tricyclics and topical agents such as lidocaine patch 0.5%
3. Fibromyalgia - documented diagnosis of fibromyalgia by Rheumatologist. Trial of gabapentin and other agent such as TCA, SSRIs, or venlafaxine.
4. Partial onset seizures - well documented intolerance or insufficient response to at least two other agents (i.e. Carbamazepine, gabapentin, lamotrigine, levetiracetam, phenytoin, topiramate).

### **Protein Powder**

1. Diagnosed with acute/ chronic health conditions (excluding liver disease) resulting in possible depressed protein concentration with one of the following lab results:
  - a. Albumin: < 3.5 mg/dl
  - b. Prealbumin < 15 mg/dl
  - c. Transferrin: < 215 mg/dl (male), < 250 mg/dl (female)
  - d. Retinol - Binding Protein: < 2.6 mg/dl
  - e. GFR: < 20 ml/min
  - f. Daily dose < 0.8-1gm/kg
2. Weight loss or other calorie related issues should first attempt to increase intake via ordering snacks and then potentially advancing to a formulary liquid nutritional supplement.
3. Dosing: Start with serving size of 15-20 grams once or twice daily. Adjust according to patient need and/ or response.



### **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 only be approved for Seroquel™ XR. Seroquel™ XR formulation should not be crushed.

### **Quinine**

1. NON-FORMULARY. WILL NOT BE APPROVED FOR LEG CRAMPS

### **Raltegravir (Isentress™)**

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.
4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, **and the complete HAART regimen being requested.**
6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved. (same as other HIV medications)

### **Rifaximin (Xifaxan™)**

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

### **Salmeterol (Serevent™) - see Long Acting Beta Agonists (LABA)**

### **Synvisc™ (Hylan G-F 20) or 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.

### **Tamsulosin (Flomax™) & alfuzosin (Uroxatral™)**

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

### **Testosterone Cypionate Injection (Depo-Testosterone™)**

1. Has the patient had an orchiectomy
2. Status post transphenoidal surgery for pituitary adenoma or hypothalamus adenoma
3. Use in Gender Identity Disorder (GID) cases will be referred to Central Office Psychiatrist for review
4. Use for low testosterone levels for reasons not listed above must have the following information documented.
  - a. Two serum total (<300 mg/dL) and free testosterone (<5 mg/dL) levels. Must be at least two weeks apart and obtained between 0700 and 1100, AND
  - b. Prostate-specific antigen (PSA) level, AND
  - c. Luteinizing hormone (LH) level, AND
  - d. Follicle stimulating hormone (FSH) level, AND
  - e. Evidence of increased LDL, OR
  - f. Evidence of Osteoporosis, OR
  - g. Evidence of Refractory depression

### **Thiazolidinediones (i.e. "glitazones") [e.g. Pioglitazone (Actos™) or Rosiglitazone (Avandia™)]**

1. Failure to achieve target HbA1c goals in type 2 diabetes despite compliance with and adequate duration of a treatment regimen of sulfonylurea plus metformin, insulin plus metformin, insulin plus a sulfonylurea (when metformin is contraindicated), or insulin plus
2. metformin plus sulfonylurea. Current total insulin dose must be > 1 unit / kg / day of body weight. **OR**
3. A type 2 diabetic inmate newly-incarcerated in the BOP who arrives on a glitazone with good glycemic control and a past history of failed therapy with or contraindication to metformin. (NOTE: If the inmate
4. has never received treatment with metformin and has no contraindication, metformin should be added to the regimen and the glitazone approved by non-formulary request for 6 months to allow for an adequate trial and titration of metformin.)
5. Pioglitazone is the preferred glitazone when non-formulary use criteria are met. Exception: Inmates arriving on rosiglitazone who meet the criteria in #2 and who have no known coronary artery disease or other contraindication to glitazone therapy, may be continued on rosiglitazone.
6. Documentation to be included in non-formulary request: type of diabetes (1 or 2), current treatment regimen and duration at current doses, and most recent HbA1c value with date.

### **Tipranavir (Aptivus™)**

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.
4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, **and the complete HAART regimen being requested.**
6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved. (same as other HIV medications)

### **Oral Vancomycin (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

### **Zalcitabine (Hivid™, DDC)**

1. Patient is taking zalcitabine upon arrival to a BOP institution.
2. Documentation of undetectable viral load provided with the request.
3. Patient tolerance to therapy is addressed in the request.
4. Other patients should be converted to another NRTI or HIV regimen based upon USPHS HIV Guidelines, National HIV Telephone Consultation Services (Warmline) 1-800-933-3413, or a HIV Specialist Consultant.

Non-Formulary Algorithm for Donepezil (Aricept™) Approval

1. Initial treatment \_\_\_\_\_ Follow-up: 3 mo 6 mo 12 mo other \_\_\_\_\_  
Dose of donepezil \_\_\_\_\_ (# 1,3,5,9,10 only for renewal)
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 \_\_\_\_\_  
Creatinine \_\_\_\_\_ Fasting Glucose \_\_\_\_\_ RPR \_\_\_\_\_  
B-12 \_\_\_\_\_ Folate \_\_\_\_\_ TSH \_\_\_\_\_  
U/A: RBC \_\_\_\_\_ Leukocytes \_\_\_\_\_ Protein \_\_\_\_\_ Glucose \_\_\_\_\_
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 name) on \_\_\_\_\_  
(Date): Yes No If no, describe: \_\_\_\_\_
9. List all current medications and their doses and blood levels if appropriate, e.g. lanolin, antiseizure 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: \_\_\_\_\_

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Approved \_\_\_\_\_ Medical Director Date \_\_\_\_\_

Disapproved \_\_\_\_\_ Medical Director Date \_\_\_\_\_

Inmate Name: \_\_\_\_\_

Reg. No: \_\_\_\_\_

Institution: \_\_\_\_\_

**Emergency Cart Content**

MRCs with 24 hour coverage who have a sufficient number of trained staff to perform ACLS 24 hours per day, 7 days per week may elect to stock their crash 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 "crash cart" supplies for resuscitation should be trained and privileged by the Clinical Director in accordance with established protocols approved by the CD.

<b>Medication</b>	<b>MRCs and approved Care IIIs</b>	<b>All others</b>
Adenosine 6 mg	A	
Amiodarone 50 mg/ml	A	
Aspirin 81 mg	A	B
Atropine 1 mg/10ml	A	
Calcium Chloride	A	
D5W	A	B
Dextrose 50% injection	A	B
Digoxin 0.5 mg injection	A	
Dopamine 400 mg/5ml	A	
Epinephrine 1:10000 syringe	A	B
Epinephrine 1:10000 amps	A	
Furosemide injection	A	
Glucagon injection	A	B
Glucose Paste/Tabs	A	B
Hydrocortisone OR Methylprednisolone injection	A	B
Lactated Ringers	A	B
Lorazepam injection	A	B
Morphine Sulfate	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%	A	B

injection		
Vasopressin 20 U/ml	A	
Verapamil 5 mg	A	
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**

Class / Indication	Formulary Agent	Dispense from Pharmacy (if Medically Necessary)	Refer to Commissary	Available Commissary Items
Pain	<ul style="list-style-type: none"> <li>- NSAIDS</li> <li>- salsalate</li> <li>- acetaminophen</li> <li>- aspirin</li> <li>**NOTE see comments at end of matrix</li> </ul>	<p>Ortho/rheum diagnosis and followed in a related chronic care clinic *acute injury or dental procedure [limit 7 days therapy (no refills) per month]</p> <p>- 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.</p> <p>- 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.</p> <p>- 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 <b>NOT</b> be used in patients with liver disease.</p> <p>or OTC Med Qualified* and medically appropriate</p>	all others	<ul style="list-style-type: none"> <li>- ibuprofen</li> <li>- naproxen</li> <li>- acetaminophen</li> <li>- aspirin</li> </ul>
Eye	<ul style="list-style-type: none"> <li>- naphazoline-pheniramine eye drops (Visine™ or Visine-A™)</li> <li>- artificial tears</li> </ul>	<p>general clinic with eye problems and regular optometrist or ophthalmologist visits</p> <p>or OTC Med Qualified* and medically appropriate</p>	all others	<ul style="list-style-type: none"> <li>- allergy eye drops</li> <li>- artificial tears</li> </ul>
Multi-vitamin	<ul style="list-style-type: none"> <li>- iron</li> <li>- B-6</li> <li>- calcium</li> <li>- vitamin B-12 tablets</li> <li>- thiamine</li> <li>- folic acid</li> </ul>	<p>anemia, osteoporosis, renal disease, alcohol detox or GI malabsorption diagnosis; or on INH therapy and followed in a related chronic care clinic</p>	all others	<ul style="list-style-type: none"> <li>- multivitamin</li> <li>- Vit E</li> <li>- Vit C</li> <li>- calcium</li> <li>- Vit B Complex</li> </ul>
Hemorrhoid	<ul style="list-style-type: none"> <li>- dibucaine</li> <li>- glycerin-witch hazel topical (Tucks™)</li> <li>- Fiber Tablets/Powder</li> </ul>	<p>pending hemorrhoid surgery</p> <p>or OTC Med Qualified* and medically appropriate</p>	all others	<ul style="list-style-type: none"> <li>- dibucaine ointment</li> <li>- hemorrhoidal cream</li> <li>- Tucks™ pads</li> <li>- Fiber Tablets/Powder</li> </ul>
Stomach	<ul style="list-style-type: none"> <li>- ranitidine</li> <li>- Maalox™/Mylanta™</li> <li>- calcium carbonate (Tums™)</li> <li>- Gaviscon™</li> <li>- MOM</li> <li>- simethicone</li> <li>- kapectate</li> <li>- loperamide</li> <li>- Fiberlax™</li> </ul>	<p>gastrointestinal diagnosis** and followed in a related chronic care clinic</p> <p>or OTC Med Qualified* and medically appropriate</p> <p>**Non-indigent inmates must purchase OTC stomach medications "Ranitidine or Omeprazole" from the commissary (for: Relief of heartburn, acid indigestion, sour stomach, prn use and GERD) unless they are being actively followed in a GI Chronic Care Clinic for the following: Documented Severe GERD,</p>	all others	<ul style="list-style-type: none"> <li>- ranitidine</li> <li>- famotidine</li> <li>- Maalox™/Mylanta™</li> <li>- antacid tablets</li> <li>- Gaviscon™</li> <li>- MOM</li> <li>- simethicone</li> <li>- kaolin/pectin</li> <li>- loperamide</li> <li>- Metamucil™</li> <li>- docusate</li> </ul>

	- Colace™ - omeprazole	Zollinger-Ellison Syndrome, Schatzki's Ring, Barrett's Esophagitis, Esophageal Stricture, 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.		- omeprazole
Dental	Orabase™	acute dental	all others	- anesthetic gel, dental
Anti-histamine Cough and Cold Allergy	none	Non-Formulary - Refer to Use Criteria and OTC Policy	all others	- CTM - loratadine - cough drops - throat lozenges - saline nasal spray - Vicks Vapor Rub™ - guaifenesin syrup - Cromolyn Nasal Spray
Ear	- carbamide peroxide ear drops (Debrox™) - antipyrine-benzocaine (Auralgan™)	OTC Med Qualified* and medically appropriate	all others	- carbamide peroxide ear drops
Topical	- coal tar - double antibiotic - calamine - hydrocortisone - vit A & D - selenium - salicylic acid pads - moisturizing lotion	OTC Med Qualified* and medically appropriate  or  in accordance with formulary restrictions, appropriate skin diagnosis, and followed in a related chronic care clinic	all others	- coal tar shampoo - sunscreen - antibiotic ointment - calamine - analgesic balm - hydrocortisone cream - vit A & D ointment - selenium - salicylic acid pads - Lac-Hydrin™
Antifungal	- clotrimazole - miconazole - nystatin	OTC Med Qualified* and medically appropriate or appropriate skin diagnosis and followed in a related chronic care clinic; x 30 days only per formulary restriction	all others	- clotrimazole - tolnaftate - miconazole - terbinafine (Lamisil™)

\* 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 for a 7 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 which can be provided to indigent inmates without signing up for sick call. If a medication is not on the indigent OTC list, the inmate must have a prescription.

\*\* 1. Chronic pain conditions with objective abnormalities, e.g. rheumatoid arthritis, osteoarthritis with abnormal x-ray, - 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.



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

## 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™ (blood thinner)\*

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\*

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.

**PART II**

**NATIONAL**  
**BOP FORMULARY**

**REFER TO BEMR RX**  
**FORMULARY DRUG**  
**FILE REPORT**