Federal Bureau of Prisons
Health Services

National Formulary

Part I

Approved:

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Summary of Formulary Changes: Winter 2023 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 a non-formulary request.

The following is a summary of the major changes resulting from the Winter 2023 Bureau of Prisons (BOP) Formulary Meeting; please refer to the Winter 2023 National Pharmacy and Therapeutics (P&T) Meeting minutes for additional information. Revisions or changes from the previous year are highlighted in yellow throughout this document.

Topic	Final Actions
Amphetamine/dextroamphetamine (Adderall®)	**UPDATE** non-formulary use criteria **ADD** advisory
Anti-obesity agents	**UPDATE** non-formulary use criteria **REVIEW** at Winter 2024 P&T Meeting **DELETE** advisory
Atogepant (Qulipta®)	**ADD** non-formulary use criteria
Calcitonin gene-related peptide (CGRP) antagonists	**ADD** non-formulary use criteria
Cariprazine (Vraylar®)	**ADD** non-formulary use criteria
Dextroamphetamine (Dexedrine®)	**UPDATE** non-formulary use criteria **ADD** advisory
Dupilumab (Dupixent®)	**ADD** non-formulary use criteria
Eptinezumab-jjmr (Vyepti®)	**ADD** non-formulary use criteria
Erenumab-aooe (Aimovig®)	**UPDATE** non-formulary use criteria
Ergotamine/caffeine (Cafergot®)	**DELETE**
Ergotamine (all formulations)	**DELETE**
Fremanezumab (Ajovy®)	**ADD** non-formulary use criteria
Galcanezumab (Emgality®)	**ADD** non-formulary use criteria
Insulin glargine-yfgn (Semglee®)	**ADD** **DELETE** inclusionary criteria
Insulin glargine (Lantus®)	**ADD** non-formulary use criteria
Insulin detemir (Levemir®)	**ADD** non-formulary use criteria
Lasmiditan succinate (Reyvow®)	**ADD** non-formulary use criteria
Levonorgestrel (Plan B One-Step®)	**ADD** non-formulary use criteria **ADD** to National Permitted Night Stock List
Liraglutide (Saxenda®)	**UPDATE** non-formulary use criteria **REVIEW** at Winter 2024 P&T Meeting
Methylphenidate (Ritalin®)	**UPDATE** non-formulary use criteria **ADD a**dvisory
Naltrexone/bupropion (Contrave®)	**UPDATE** non-formulary use criteria **REVIEW** at Winter 2024 P&T Meeting
Omalizumab injection (Xolair®)	**ADD** non-formulary use criteria
Orlistat (Xenical®, Alli®)	**UPDATE** non-formulary use criteria **DELETE** advisory **REVIEW** at Winter 2024 P&T Meeting
Phentermine/topiramate (Qsymia®)	**ADD** non-formulary use criteria **DELETE** advisory **REVIEW** at Winter 2024 P&T Meeting
Rimegepant (Nurtec®)	**ADD** non-formulary use criteria
Rizatriptan oral tablets (Maxalt®)	**ADD** **ADD** advisory
Semaglutide (Wegovy®)	**UPDATE** non-formulary use criteria

	REVIEW at Winter 2024 P&T Meeting
Small-molecule calcitonin gene-related peptide antagonists (CGRPs)	**ADD** non-formulary use criteria
Sumatriptan oral tablets (Imitrex®)	**ADD** **ADD** advisory
Therapeutic substitution	**UPDATE**
Ubrogepant (Ubrelvy®)	**ADD** non-formulary use criteria

National BOP Formulary Mission and Procedural Statement

Purpose

A formulary system, as defined in ASHP Statement on the Formulary System, is the ongoing process through which a health care organization establishes practices "…on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a give population."

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 in, exclusion from, 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 and readily available.

The primary goals of BOP formulary management are to optimize therapeutic outcomes, optimize cost effectiveness of medications, and ensure medication use is conducive within the correctional environment.

Non-Formulary Request 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 for non-urgent requests, 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 / APPs / 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 use justifications/criteria are met.
5. Clinical Directors (CDs) 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 justifications 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 that 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 expected to provide pertinent information regarding patient compliance with formulary agents, drug cost information, and other comments as applicable to the request.
7. Institution administration (Health services administrator (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 used.
9. 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 request 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 elements of the Clinical Director's 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 non-formulary medication requests, 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

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

An allowance is given to dispense/administer a non-formulary medication for 4 days while awaiting non-formulary approval. This 4-day allowance is to only be utilized for urgent continuity of care purposes and not for the purpose of initiating routine/non-emergency non-formulary medications without appropriate approval.

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

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

Definitions/Rules

Formulary Rules

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

Compounding

Compounding 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" under the Federal Food, Drug, and Cosmetic Act (FDCA).

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

DEA Controlled Substances

** ALL CONTROLLED SUBSTANCES ARE RESTRICTED TO DIRECTLY OBSERVED THERAPY. **
** 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 (Formerly "Pill Line") Only

"Directly observed therapy only" is a restriction placed on controlled substances, some psychotropics, tuberculosis (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 in a Medication Administration Record (MAR) by the employee. A report of medications that are restricted to directly observed therapy only is available in the BOP electronic medical record (BEMR). Some medications are designated as directly observed therapy only for only certain indications (see National Formulary Part II for details).

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 directly observed therapy 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.

Icatibant Acetate Auto-Injector (Firazyr®)

1. Orders for icatibant acetate injection (Firazyr®) will be entered into BEMR as DOT.
2. The following statement will appear on the label after the directions:
   must present device and needle to pill line daily for integrity inspection
3. Compliance with daily integrity inspection will be monitored.
4. Inmate should be counseled regarding potential adverse actions if tampering is evident or product is lost or manipulated.
5. Staff education will be provided to facilitate these procedures.
6. Any needed local procedural changes will be made to facilitate these procedures.

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., HALFWAY HOUSE)**

FDA WEBSITE: http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm

Provision of FDA medication guides and display of the side effects statement **ARE NOT** required when the patient is:

1. Confined within a BOP institution.
2. Being transferred within the 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., halfway house).

Over the Counter Medications

Over the counter (OTC) medications may only be prescribed as a maintenance medication when treatment is medically necessary and associated with ongoing follow-up in a chronic care clinic. During institution triage / sick call, medical staff will refer inmates to the commissary in response to complaints related to cosmetic and general hygiene issues or symptoms of minor ailments.

Medical Center Only

Medical center only is a restriction placed on some medications requiring that the drug only be used within a Federal Medical Center.

Medication Restrictions

Medication restrictions are prescribing restrictions placed on certain medications. Variance from restrictions requires non-formulary authorization.

MLP Requires Cosign

MLP requires cosign is a restriction placed on some medications requiring that a physician sign the medical record each time the drug is prescribed. Subsequent medication orders for the 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, "Use of Placebo in Clinical Practice":
"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): " . . . 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 . . . ."

Look-Alike/Sound-Alike Medications

Both The Joint Commission (JC) and the Accreditation Association for Ambulatory Health 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 the Institute for Safe Medication Practices (ISMP).

BOP institutions must incorporate look-alike/sound-alike drugs into the agendas of local Pharmacy and Therapeutics Committee Meetings and review them on an annual basis. Discussions, decisions, and local policy must follow the requirements set forth by accrediting bodies (JC, AAAHC).

This responsibility is deferred to the local level owing to the varying functions of our institutions (e.g., medical referral centers, ambulatory institutions, detention centers, implementation of levels of care) and the fact that not all institutions carry exactly the same items from the BOP National Formulary.

RESOURCES:

1. The Joint Commission, http://www.jointcommission.org.
2. Institute for Safe Medication Practices (ISMP), https://www.ismp.org/.
3. ISMP, "List of Confused Drug Names," https://www.ismp.org/recommendations/confused-drug-names-list.
4. The Accreditation Association for Ambulatory Health Care, https://www.aaahc.org/.

Risk Evaluation and Mitigation Strategies

Risk Evaluation and Mitigation Strategies (REMS) are defined by the FDA as programs for managing a known or potential serious risk associated with a drug or biologic product. Medications with a REMS designation require increased levels of monitoring and control, with the most extreme requiring written contracts between the pharmacy/physician and the manufacturer.

Institution pharmacists and physicians should not sign any agreements without review by the BOP chief pharmacist or a 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/rems/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 certain 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 have instructed them to do so.

Keep On Person (KOP), Self-Carry Medications

Medications are generally excluded (i.e., not Keep On Person (KOP) / self-carry eligible) if:

- Potential for abuse or misuse (e.g., controlled substances)
- Injectable drugs
- Psychiatric medications (unless deemed to be very safe in excessive amounts)
- Most antipsychotics
- Close monitoring required (e.g., TB meds)
- Caustic or harmful agents (e.g., podofilox)
- Refrigeration required
- Potential for misuse of packaging (e.g., glass container, inhalers with piercing devices)
- Cost

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 dermatology consult in BEMR with a dermatologist.
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 Stimulant Medications: methylphenidate (Ritalin®), amphetamine/ dextroamphetamine (Adderall®/Dexedrine®)

1. Patient has documented diagnosis of ADHD.
2. Psychotherapy, with psychology referral to include individual therapy to learn coping, organizational, prioritization, and anger management skills for a minimum of 6 months. Psychotherapy should continue if medication is initiated. (Concurrent treatment recommended rather than sequential treatment.)
3. Failure of ALL non-stimulant agents after ADEQUATE trials for each step for a minimum of 6 weeks. Patient self-reported trials of medication regimens and doses will not be accepted. All medications trials must have occurred and been documented within the BOP.
    a. Atomoxetine
    b. Atomoxetine plus guanfacine
    c. Atomoxetine plus clonidine
    d. Desipramine +/- atomoxetine
    e. Clonidine
    f. Bupropion
4. 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. Assessment for history of drug misuse including type of drug (e.g., stimulant, opiate, benzodiazepine)
5. If stimulant use approved, recommend utilizing methylphenidate immediate-release formulation as opposed to mixed amphetamine salts immediate-release formulation due to methylphenidate's shorter half-life. Requests for long-acting stimulants will not be approved.
6. The use of stimulants in persons with a history of stimulant drug misuse will not be approved.

Albiglutide (Tanzeum®) – See Glucagon-like peptide 1 (GLP-1) receptor agonists

Alfuzosin (Uroxatral®)

1. Documentation of significant symptomatic hypotension, orthostatic hypotension, or syncope while receiving terazosin, doxazosin or tamsulosin.
2. Failure of doxazosin 8 mg, terazosin 20 mg, or tamsulosin 0.8 mg 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.

Ammonium lactate lotion/cream

1. Requests to improve appearance of skin will be disapproved.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Analgesics topical: capsaicin cream, salicylate / menthol (Bengay®)

1. Failed 30 day trial of oral NSAIDs or NSAIDs are contraindicated *AND*
2. Documented improvement in functional status (required for renewals) *OR*
3. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Anticoagulants: dabigatran (Pradaxa®), edoxaban (Savaysa®), rivaroxaban (Xarelto®)

1. Contraindication to or treatment failure on apixaban (Eliquis®) or warfarin.

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, **OR**
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, **OR**
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Antifungals (topical): clotrimazole, miconazole, terbinafine, tolnaftate

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives (ex: tolnaftate cream). Orders are limited to 60 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Antihistamines (oral: diphenhydramine (Benadryl®), hydroxyzine (Atarax®, Vistaril®), cyproheptadine (Periactin®)

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 DIRECTLY OBSERVED THERAPY ONLY for sedating antihistamines: diphenhydramine, hydroxyzine, & cyproheptadine.
7. **Urticaria:** Classified according to etiology or precipitating factor. 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 (e.g., prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**.

Antihistamines (oral, non-sedating): cetirizine (Zyrtec®), fexofenadine (Allegra®), loratadine (Claritin®)

1. Failure of two antihistamines obtained through the commissary within the last 90 days.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved based on indigent status alone. If renewed, indigent status will be reassessed
3. Ordered or recommended by an ENT specialist.

Anti-obesity agents: orlistat (Xenical®, Alli®), naltrexone/bupropion (Contrave®), liraglutide (Saxenda®), semaglutide (Wegovy®)

1. Body Mass Index (BMI) ≥ 30 kg/m^2 or BMI ≥ 27 kg/m^2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea, osteoarthritis, non-alcoholic fatty liver disease) AND
2. Verified lifestyle interventions (diet, physical activity, and counseling) for 6 months. Food and exercise logs, weight checks, commissary purchase records, and counseling with appropriate staff are verified in EHR. Inmate should be enrolled in at-risk program if available AND
3. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate.
4. Selection of medication will be dependent on patient comorbidities, contraindications, and potential adverse effects.
5. Semaglutide (Ozempic®) and liraglutide (Victoza®) are the preferred medications in patients with type 2 diabetes.

Antiplatelets (P2Y12 inhibitors) – See Prasugrel (Effient®), Ticagrelor (Brilinta®)

Apremilast (Otezla®)

Use for psoriasis must be in consultation with a dermatologist. Use for psoriatic arthritis:

1. Failure of methotrexate/prednisone, gold, or azathioprine.

2. Request must include a rheumatology consult report.

Artificial tears solution and ointment: various OTC formulations

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND
2. Failure of commissary alternatives OR patient is indigent AND treatment is medically necessary. Orders are limited to 30 days.

Ascorbic acid: vitamin C

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

Asenapine (Saphris®)

1. Request is in accordance with the Schizophrenia and/or Bipolar Clinical Guidance documents or justification as to why prescribing has diverged from recommendations is documented in request.
2. Patient has documented noncompliance per eMAR.
3. In noncompliant patients, justification for why a formulary Long Acting Injectable (LAI) antipsychotic cannot be used is documented in the request.
4. In noncompliant patients, documentation as to why more cost effective oral options for noncompliant patients cannot be used or why use of asenapine is preferred to each more cost effective agent is documented in the request. Cost comparison must be determined at time of submission for the following alternatives: aripiprazole ODT/solution, risperidone ODT/solution, olanzapine OTD, haloperidol elixir, and fluphenazine elixir/concentrate).

Atogepant (Qulipta™) – See Calcitonin gene-related peptide (CGRP) antagonists (small-molecule)

Baclofen – See Muscle relaxants

Benzoyl peroxide (wash/soap)

1. Chronic cystic scarring acne and/or causing secondary bacterial infections OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

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 and 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)

Beta-3 adrenergic agonists: mirabegron (Myrbetriq®) and vibegron (Gemtesa®)

1. Patient has a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge incontinence, urgency, and urinary frequency.
2. Treatment failure with behavioral interventions to include pelvic floor muscle training in women, bladder training, and fluid restriction.
3. Treatment failure of 12-week trial (with compliance) of an anti-muscarinic agent (or a contradiction to these agents).
4. Requested agent is used in combination with another anti-muscarinic agent (unless contraindicated).
5. CrCl > 15 ml/min and not be on hemodialysis

Betamethasone (Beconase® AQ) – See Steroid nasal sprays

Bismuth subsalicylate (Pepto Bismol®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives. Orders are limited to 30 days in duration.

Brexpiprazole (Rexulti®)

1. Medication is being used to treat schizophrenia OR to treat refractory depressive disorder as an augmentation medication to an existing antidepressant.
2. Schizophrenia: Patient had treatment failures with at least 3 other atypical antipsychotics (one of which MUST be aripiprazole unless contraindicated).
3. Refractory Depressive disorder: Patient had treatment failure with at least 3 other antidepressant augmentation strategies (one of which MUST be aripiprazole unless contraindicated)
4. Patient experienced an adverse event with aripiprazole that is not expected to occur with brexpiprazole (Rexulti®)
5. Details related to prior treatment failures (to include all antipsychotics and adjunct treatments for refractory depressive disorder) are documented in the below justification for use comments to include medications, doses, durations, compliance, and adverse drugs reactions (if applicable)
6. Patients who arrived to the BOP on this medication (post initial intake order): The provider has concerns related to potential destabilization if medication discontinued. Specific concerns must be detailed below.

Brimonidine 0.1% and 0.15% ophthalmic solution (Alphagan P®)

1. Documented allergy or sensitivity to brimonidine 0.2% ophthalmic solution.

Bupropion (Wellbutrin® IR, SR, and XL; Zyban®)

1. Restricted to bipolar depression or ADHD with coexisting mental health disorder.
2. Patient has NO history of diverting bupropion OR seizure disorders.
3. Bupropion is NOT being requested for smoking cessation or for use as a sleep agent.
4. Initiation requests: Only IR formulation will be approved.
5. BIPOLAR DEPRESSION: Maintained on a mood stabilizer and/or antipsychotic.
6. BIPOLAR DEPRESSION: Failed therapy with at least three (3) other formulary antidepressant agents UNLESS documented manic episode precipitated by the addition of an antidepressant.
7. ADHD: Documented failure of psychotherapy targeting coping, organizational, prioritization, and anger management skills for minimum of 6 months. Psychotherapy should continue if bupropion is approved.
8. ADHD: Failure of ADEQUATE trials (compliant > 6 weeks) of ALL medications listed below or justification of why they cannot be utilized (self-reported trials will not be accepted):
   a. Atomoxetine
   b. Atomoxetine plus guanfacine
   c. Atomoxetine plus clonidine
   d. Desipramine
9. ADHD with co-occurring anxiety disorder: failure with an ADEQUATE trial (compliant >6 weeks) of both an SSRI and SNRI.
10. The following are documented in detail within the comments section below or attached to the NFR request. Failure to provide all documentation may result is NFR deferral or denial:
    a. Psychiatric or psychological behavioral function evaluations with dates of BEMR/PDS notes
    b. Evidence (with specific examples) of inability to function in the correctional environment and the goals associated with bupropion initiation
    c. Medication information including initiation/discontinue dates, doses, DOT or KOP status, and compliance rates (as percentages), as well as any adverse reactions with their severity and date of occurrence.

Cabotegravir and rilpivirine intramuscular (IM) extended-release injectable suspension (Cabenuva®)

1. Patient is unable to use oral alternatives.

Calcitonin gene-related peptide (CGRP) antagonists: erenumab-aooe (Aimovig®), eptinezumab-jjmr (Vyepti®), fremanezumab-vfrm (Ajovy®), galcanezumab (Emgality®)

1. Failure of an 8-week trial (at a therapeutic dose) of one agent from each of the following agent/classes: calcium channel blockers, beta blockers (metoprolol and propranolol), SNRIs (venlafaxine), amitriptyline, ARBs/ACE inhibitors and anticonvulsants.

Calcitonin gene-related peptide (CGRP) antagonists (small-molecule): ubrogepant (Ubrelvy®), rimegepant (Nurtec® ODT), atogepant (Qulipta™)

1. Failure of or contraindication to formulary serotonin 5-HT1B/1D receptor agonists (“triptans”).

Calcium carbonate (Tums®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC indigent program alternatives. Orders are limited to 30 days in duration.

Canagliflozin (Invokana®) – See Sodium glucose co-transporter-2 (SGLT2) inhibitors

Carbamide peroxide 6.5% ear drops (Debrox®)

1. Patient is indigent AND treatment is medically necessary. Orders are limited to 10 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Carbamazepine oral (Tegretol®)

1. Bipolar disorder: Patient failed therapy (or use contraindicated) with lithium, lamotrigine, valproate, and/or second-generation antipsychotics.
2. Pain management: Patient failed therapy (or use contraindicated) with SNRIs and TCAs.
3. Pain management: Neuropathic pain confirmed by EMG (please attach).

Cariprazine (Vraylar®)

1. Persistent negative symptoms after failing 2 or more antipsychotic agents.
2. Significant metabolic or movement disorders on 2 or more antipsychotic agents.

Casirivimab and imdevimab injection (REGEN-COV™)

1. Positive results for SARS-CoV-2 viral testing.
2. Mild-moderate COVID-19.
3. Patient is at high risk of progressing to severe COVID-19 and/or hospitalization according to the FDA emergency use authorization (EUA).
4. Patient requires oxygen or mechanical ventilation (not authorized).
5. Patient is hospitalized for COVID-19 (not authorized).
6. Patient is pregnant. Should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.
7. Patient is breastfeeding. Should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

Certolizumab pegol (Cimzia®) – See Immunomodulator TNF inhibitors

Cetirizine (Zyrtec®) – See Antihistamines (oral, non-sedating)

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.

Clobetasol topical solution and foam

1. Patient has failed clobetasol cream and ointment formulation AND
2. Patient has failed tacrolimus and/or calcipotriene topical agents.

Clonazepam (long-term use) – See Benzodiazepines

Clonidine (Catapres®)

1. 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.
2. 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.
3. Use in Tourette's syndrome.
4. Not to be used in hypertensive urgencies/ emergencies. See Hypertensive clinical practice guidelines and 2006 National P&T Minutes, page 103.
5. ADHD: Patient has documented diagnosis of ADHD.
6. ADHD: Patient has documented failure of (at a therapeutic dose and for a therapeutic duration) preferred agents (atomoxetine and guanfacine) or justification as to why alternatives cannot be utilized is explained in the comments below.
7. Patient does not have conditions that would predispose them to the negative cardiac outcomes that have been associated with clonidine (e.g., hypotension, heart block, bradycardia, etc.)
8. Patient's renal function is deemed acceptable for use.

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 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 reinstitution 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 reinstituted 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.

Coal tar shampoo/gel/solution

1. Documented failure of OTC commissary selenium or coal tar shampoo OR

2. Patient is indigent, treatment medically necessary, AND has failed OTC Indigent Program alternatives (ex: selenium 1% shampoo). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
3. For Psoriasis: lesions interfere with function.
4. For Psoriasis: Psoriasis affects >10% of BSA (refer patients to commissary for mild psoriasis) OR crucial body areas (hands, feet, face, etc.).

COX-2 inhibitors: celecoxib (Celebrex®)

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

2. Non-formulary Requests for COX-II inhibitors will ordinarily not be considered for approval for:
    a. Lack of response to traditional NSAIDs.
    b. Dyspepsia or GI intolerance to traditional NSAIDs.
    c. Patients receiving a proton pump inhibitor.
    d. Patients receiving low dose aspirin for cardiovascular prophylaxis.
    e. Patients with known cardiovascular disease.
    f. 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.

Cyproheptadine (Periactin®) – See Antihistamines

Dapagliflozin (Farxiga®) – See Sodium glucose co-transporter 2 (SGLT2) inhibitors

Darbopoetin alfa (Aranesp®) – See Erythropoesis-stimulating agents (ESAs)

Dibucaine ointment – See Hemorrhoidal cream/ointment

Dicyclomine (Bentyl®)

1. Clinical diagnosis of IBS AND
2. Three months of fiber (tablets) therapy without relief of symptoms AND
3. Age-appropriate screening for colorectal cancer with three negative Fecal Occult Blood Tests (or one negative Fecal Immunochemical Test) 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®)

1. 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 (oral, sedating)

Docusate sodium

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives . Orders are limited to 30 days in duration.

Dopaminergics for restless legs syndrome: pramipexole (Mirapex®), ropinirole (Requip®)

- Step 1. Sleep Hygiene
- Step 2. Evaluate Drug Therapy – consider medication change or dose reduction of SSRI, TCA, lithium, antihistamines, caffeine, dopamine agonists.
- Step 3. Evaluate for secondary causes – iron deficiency, chronic kidney disease, venous insufficiency, neurologic lesions, rheumatic disease, or diabetes – and manage disease states optimally.
- Step 4. Trial of oral iron therapy only for patients with iron deficiency or low ferritin levels (≤75mcg/L).
- Step 5. Treatment with pramipexole or ropinirole.

Dulaglutide (Trulicity®) – See Glucagon-like peptide 1 (GLP-1) receptor agonists

Dupilumab injection (Dupixent®)

1. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
2. The patient completed observed inhaler technique with correction as needed.
3. The patient has been tested for responsiveness to glucocorticoids AND **Injection of long-acting GC (e.g., IM triamcinolone 120 mg); post 2-week assessment achieving improvement in FEV1 and reduced rescue inhaler use**
4. The patient has a blood eosinophil level ≥ 150 cells/µl or FeNO ≥ 25 ppb.
5. The has patient failed omalizumab (Xolair®) (or has a contraindication).
6. Dupilumab been recommended by a specialist. (Please upload in Document Manager.)

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**

Emtricitabine / tenofovir alafenamide (Descovy®)

1. Does the patient have a CrCl < 60ml/min? (Yes/No)
2. Does the patient have osteoporosis or is at high risk for osteoporosis? (Yes/No)

Enfuvirtide (Fuzeon®) – See HIV medication/treatments

Eptinezumab-jjmr (Vyepti®) – See Calcitonin gene-related peptide (CGRP) antagonists

Erenumab-aooe (Amovig®) – See Calcitonin gene-related peptide (CGRP) antagonists

Ertugliflozen (Steglatro®) – See Sodium-glucose cotransporter-2 (SGLT2) inhibitors

Erythropoesis-stimulating agents (ESAs): epoetin alfa (Epogen®, Procrit®), epoetin alfa-epbx (Retacrit®), 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. Epoetin alfa-epbx (Retacrit®) is the preferred formulary alternative.
2. Patient receiving hepatitis C therapy; AND
3. 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
4. Patient underwent evaluation for other causes of anemia (e.g. bleeding, nutritional deficiency) and has been treated appropriately; AND
5. 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
6. Patient does not have exclusion criteria: Uncontrolled hypertension or risk for thrombosis.

Esketamine nasal solution (Spravato®)

1. Patient has documented diagnosis of treatment-resistant depression OR major depressive disorder (MDD) with acute suicidal ideation or behavior.
2. Provider, pharmacy, and patient are enrolled in Spravato risk evaluation mitigation strategy (REMS) program.
3. Provide appropriate patient monitoring according to manufacturer recommendations.
4. Patient does not have a history of aneurysmal vascular disease, arteriovenous malformation, or intracerebral hemorrhage.
5. Patient has documented failure (at a therapeutic dose and for a therapeutic duration) to several formulary agents from multiple classes to include augmentation strategies for depression or justification as to why alternatives cannot be utilized is explained in the comments above.
6. Appropriate monitoring related to blood pressure will be completed (before and after treatment) to reduce risk of increase in blood pressure or intracranial pressure.
7. Medication should be administered as Directly Observed Therapy ONLY due to potential of abuse and misuse.

Etanercept (Enbrel®) – See Immunomodulator TNF inhibitors

Etravirine (Intelence®) – See HIV medication/treatments

Exenatide (Byetta®), exenatide ER (Bydureon®) – See Glucagon-like peptide 1 (GLP-1) receptor agonists

Ezetimibe (Zetia®)

1. Ezetimibe 10 mg daily can be considered on a non-formulary basis for those high risk and very high risk patients not meeting their LDL-C goal and considered for PCSK9 inhibitor therapy on "intensive" statin therapy or highest tolerable statin dose.
2. Patient is "intolerant" to statins. Trials on multiple formulary statins to be considered before determining a patient is "intolerant" to all statins and/or when considering highest tolerable statin dose.

Febuxostat (Uloric®)

1. Inadequate response to allopurinol 600mg/day (300mg/day in patients with renal impairment).
2. Inadequate response to maximally tolerated allopurinol dose + maximally tolerated uricosuric agent: probenecid, fenofibrate, or losartan.
3. All non-essential pharmaceuticals that induce hyperuricemia have been discontinued (e.g., thiazides/loop diuretics, low-dose aspirin, beta-blocker, niacin).
4. Patient is intolerant to allopurinol.
5. Treatment with allopurinol is not advisable (HLA-B*5801-positive) or contraindicated.

Fexofenadine (Allergra®) See – Antihistamines (oral, non-sedating)

Filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym®) See – Granulocyte colony-stimulating factors (G-CSFs)

Fluticasone nasal spray (Flonase®) – See Steroid nasal sprays

Fluticasone oral inhaler (Flovent®)

1. Must fail two other inhaled corticosteroids with demonstrated compliance.

Fluticasone/salmeterol (Advair®, Advair Diskus®, AirDuo Respiclick®, Wixela Inhub®) See – Long-acting beta agonists (LABA) / inhaled corticosteroids (ICS)

Fluticasone/vilanterol (Breo Ellipta®) See – Long-acting beta agonists (LABA) / inhaled corticosteroids (ICS)

Fremanezumab-vfrm (Ajovy®) – See Calcitonin gene-related peptide (CGRP) antagonists

Gabapentin (Neurontin®)

1. Approved for neuropathic pain after failure of duloxetine, plus at least one other medication from the tricyclic antidepressant category.
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

Galcanezumab (Emgality®) – See Calcitonin gene-related peptide (CGRP) antagonists

Gemfibrozil (Lopid®)

1. Diagnosis of severe hypertriglyceridemia (triglycerides ≥500 mg/dL) AND failure of fenofibrate used for at least 6 months.

Glucagon-like peptide 1 (GLP-1) receptor agonists: albiglutide (Tanzeum®), dulaglutide (Trulicity®), exenatide (Byetta®), exenatide ER (Bydureon®), liraglutide (Victoza®, Saxenda®), lixisenatide (Adlyxin®), semaglutide oral (Rybelsus®)

1. Preferred agent: semaglutide (Ozempic®) injection.
2. Not approved for Type 1 DM.

Golimumab (Simponi®) – See Immunomodulator TNF inhibitors

Granulocyte colony-stimulating factors (G-CSFs): filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym®), pegfilgrastim (Neulasta®), pegfilgrastim-jmdb (Fulphila®), pegfilgrastim-cbqv (Udenyca®), tbo-filgrastim (Granix®), pegfilgrastim-bmez (Ziextenzo®)

1. Pegfilgrastim-bmez (Ziextenzo®) is the preferred formulary agent.
2. 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 chemo- radiotherapy, poor nutritional status, advanced cancer, or other serious comorbidities.
   d. Chemotherapy secondary prophylaxis for patient with history of prior neutropenic complications.
3. 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

Hemorrhoidal cream/ointment: phenylephrine (Preparation H®), hydrocortisone (Anusol®), dibucaine

1. Pending hemorrhoid surgery or 30 days (or less) post-hemorrhoid surgery OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Hepatitis C treatment algorithm

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

HIV medications/treatments: 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.

Hydrocortisone cream, ointment (OTC)

1. Patient is indigent and has failed OTC Indigent Program alternatives (ex: Hydrocortisone 0.5% cream) and treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
2. For Psoriasis: lesions interfere with function
3. For Psoriasis: Psoriasis affects >10% of BSA (refer patients to commissary for mild psoriasis) OR crucial body areas (hands, feet, face etc.)

Hydroxyzine (Atarax®, Vistaril®) – See Antihistamines (oral, sedating)

Icosapent ethyl (Vascepa®)

1. Failure to achieve therapeutic triglyceride level (<150 mg/dL) with maximally tolerated statin AND diabetes, ASCVD, or high risk for CV events (ASCVD risk >7.5%) OR
2. Severe hypertriglyceridemia (≥ 500 mg/dL)

Immunomodulator tumor necrosis factor (TNF) inhibitors: adalimumab (Humira®), certolizumab (Cimzia®), etanercept (Enbrel®), golimumab (Simponi®), infliximab-abda (Renflexis®), infliximab-dyyb (Inflectra®)

1. Adalimumab is recommended agent before etanercept and golimumab due to better side effect profile and cost effectiveness.
2. Failure of an adequate trial of maximally dosed/tolerated methotrexate/prednisone or other formulary non-biologic DMARDs.
3. Intolerable side effects of methotrexate where a TNF agent may allow a decrease in methotrexate dose.
4. All new and renewal prescriptions require consultation with an appropriate specialist based on the disease state being treated (for example, dermatologist, gastroenterologist, or rheumatologist). Consult must be uploaded in BEMR.
5. Requests for patients with a TST > or = 5mm or positive IGRA (interferon gamma release assay) test must be accompanied by evidence of LTBI treatment completion (medication used with ingested dose counts). TST or IGRA must be repeated yearly.
6. Initial requests must include HBV/HCV serology for prior evidence of hepatitis infection.
7. For chronic plaque psoriasis:
    a. Request includes documented percent of affected BSA % AND
    b. Patient has failed of an adequate trial of a clinically indicated formulary non-biologic agent AND
    c. ≥ 10% BSA is affected (Severe CPP) OR
    d. At least ≥ 5% of BSA (Moderate CPP) AND crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    e. NFR renewals must include documentation of improved symptoms (% BSA impacted)
    f. Patients with mild CPP may be managed with formulary topical treatments.

Infliximab (Remicade®)

1. Infliximab abda (Renflexis®) is the preferred infliximab agent over both infliximab (Remicade®) and infliximab dyyb (Inflectra®).

Infliximab-abda (Renflexis®), infliximab-dyyb (Inflectra®) – 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 (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. Failure of or contraindication to insulin glargine-yfgn (Semglee®).

Insulin detemir, long-acting insulin (Levemir®)

1. Failure or contraindication to insulin glargine-yfgn (Semglee®).
2. 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;**
3. 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.

Ipratropium bromide HFA (Atrovent® HFA)

1. Patient is unable to tolerate a short-acting beta agonist (e.g., albuterol).

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

1. 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.

Lasmiditan succinate (Reyvow®)

1. Failure of formulary serotonin 5-HT1B/1D receptor agonists ("triptans").

Levonorgestrel (Plan B One-Step®)

1. Administered as soon as possible, within 72 hours of having unprotected sex.
2. Contact the regional chief pharmacist or regional medical director to ensure timely review. Non-Formulary Drug Requests for emergency contraception will be processed and expedited through Central Office.

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.

Liraglutide (Victoza®) – Glucagon-like peptide 1 (GLP-1) receptor agonists

Liraglutide (Saxenda®) – See Anti-obesity agents

Lixisenatide (Adlyxin®) – See Glucagon-like peptide 1 (GLP-1) receptor agonists

Long-acting beta agonists (LABAs): salmeterol (Serevent Diskus®)

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.

Long-acting beta agonists (LABAs) / inhaled corticosteroids (ICS): budesonide/formoterol (Symbicort®), fluticasone/salmeterol (Advair®, Advair Diskus®, AirDuo Respiclick®, Wixela Inhub®), mometasone/formoterol (Dulera®), fluticasone/vilanterol (Breo Ellipta®)

1. COPD patients must have failed anticholinergic agent tiotropium (Spiriva®).
2. All inhaled corticosteroid/ long-acting beta-agonist (ICS/LABA) requests must be for fluticasone/salmeterol (Wixela Inhub®) per mandatory contract, unless clinically justified otherwise.

Long-acting beta agonists (LABAs) / inhaled long-acting muscarinic antagonists (LAMAs): glycopyrrolate/formoterol (Bevespi®), tiotropium/olodaterol (Stiolto®), umeclidinium/vilanterol (Anoro Ellipta®)

1. COPD patients must have failed monotherapy with anticholinergic agent tiotropium (Spiriva®)
2. Non-formulary requests for LABA/LAMA that meet criteria will be approved for most cost-effective agent.
3. Asthma: Long-acting beta-agonist (LABA) not to be used as single-agent product or as combination product with long-acting muscarinic-antagonist (LAMA) in asthma. Only to be used as part of a combination product with inhaled corticosteroid.

Long-acting beta agonists (LABAs) / long-acting muscarinic antagonists (LAMAs) / inhaled corticosteroid (ICS): budesonide/glycopyrrolate/formoterol (Breztri® Aerosphere), fluticasone furoate/umeclidinium/vilanterol (Trelegy®)

1. COPD patient with a history of exacerbations requiring hospitalization or ≥ 2 moderate exacerbations/year and a blood eosinophil count of > 300 cells/µL. (Attach labs)
2. Asthma: patient failed high dose ICS/LABA combination. *Evidence to the benefits of triple therapy is limited in asthma – if asthma control not improved in 90-day trial, add-on should be discontinued
3. Non-formulary requests for LABA/LAMA/LABA that meet criteria will be approved for most cost-effective agent or combination of agents.

Loperamide (Immodium®)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives . Orders are limited to 30 days in duration.

Loratadine (Claritin®) – See Antihistamines (oral, non-sedating)

Lorazepam, long-term use – See Benzodiazepines

Loteprednol etabonate (Lotemax®, Alrex®)

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

Lumateperone (Caplyta®)

1. Medication is being utilized to treat patients who carry diagnosis in BEMR for a schizophrenia spectrum disorder
2. Failure of three or more formulary oral antipsychotic treatment trials due to significant adverse reactions that are unable to be managed by dose reductions of the causative agent
3. Details related to prior antipsychotic treatment failures are documented in the above comments to include medications, doses, durations, compliance, and (as applicable) adverse drug reactions (ADRs).

Lurasidone (Latuda®)

1. Request is in accordance with the Schizophrenia and/or Bipolar Clinical Guidance documents or has justification as to why prescribing is different from recommendations in clinical guidance.

2. If weight gain is a concern, patient must have documented failure with or contraindications to formulary weight neutral options (aripiprazole and ziprasidone). Dose and duration of failed treatments as validated via eMAR. Must specify why weight gain is concerning in this patient (e.g., comorbid medical conditions, notably elevated BMI, etc.)

Magnesium/aluminum/simethicone-containing products (Maalox®/Mylanta®/Gaviscon®, Milk of Magnesia®, etc.)

1. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives . Orders are limited to 30 days in duration.

Maraviroc (Selzentry®) – See HIV medication/treatments

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

Mirabegron (Myrbetriq®) – See Beta-3 adrenergic agonists

Moisturizers (topical): all formulations except Vitamins A and D

1. Failed a 30-day trial of two commissary moisturizers OR
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Mometasone nasal spray (Nasonex®) – See Steroid nasal sprays

Mometasone/formoterol (Dulera®) – See Long-acting beta agonists (LABAs) / inhaled corticosteroid (ICS)

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®)

Approval for muscle relaxants will be considered for the following cases and all must be administered via DIRECTLY OBSERVED THERAPY:

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.

Naltrexone/bupropion (Contrave®) – See Anti-obesity agents

Naphazoline/pheniramine ophthalmic drops (Visine-A®, Opcon-A®)

1. Initiated by an optometrist or ophthalmologist, with ongoing evaluation AND
2. Failure of commissary alternatives OR patient is indigent AND treatment is medically necessary. Orders are limited to 3 days.

Narcolepsy treatment with 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 clinical justification from a BOP registered dietitian or 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 dietitian for therapy > 30 days.

Ocuvite (ICaps AREDS)

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.

Olanzapine pamoate intramuscular injection (Zyprexa®, Relprevv™)

1. Non-compliance to oral antipsychotic therapy documented on eMAR.
2. Provider, pharmacy, and patient are enrolled in Relprevv® risk evaluation mitigation (REMS) program.
3. Institution has proper staffing to monitor for post-injection delirium/sedation syndrome (PDSS) for 3 hours after each injection.
4. Patients with a history of cardiovascular disease have been educated on signs and symptoms of postural hypotension and bradycardia.
5. Patient has documented failure to alternative long acting injectable (LAI) second generation antipsychotics or justification as to why alternatives cannot be utilized is explained in the comments above.
6. If patient currently stable on oral olanzapine and compliance concerns are the basis for this non-formulary submission, utilization of olanzapine orally disintegrating tablets (ODT) has been considered and justification for why they cannot be utilized is given in the comments section.
7. Appropriate monitoring related to diabetes, dyslipidemia, and weight gain has been ordered and patient will be educated on ways to mitigate these associated adverse reactions to the medication.

Omalizumab (Xolair®)

1. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
2. The patient completed observed inhaler technique with correction as needed.
3. The patient has severe uncontrolled asthma with an allergic component.
4. Pre-treatment serum IgE is 30 to 700 IU/mL
5. The patient has positive skin tests or in vitro reactivity to a perennial allergen.
6. Omalizumab been recommended by a specialist. (Please upload in Document Manager.)

Omega-3 fatty acid ethyl esters (Lovaza®)

1. Icosapent ethyl (Vascepa®) is the preferred omega 3 fatty acid agent.
2. Prior failure of or contraindication to icosapent omega-3 fatty acid (Vascepa®) AND
3. Failure to achieve therapeutic triglyceride level (<150 mg/dL) with maximally tolerated statin AND established cardiovascular disease (ASCVD) or diagnosis of diabetes, or high risk for CV events (ASCVD risk >7.5%) OR
4. Severe hypertriglyceridemia (≥ 500 mg/dL) or unable to take fenofibrate.

Onychomycosis, oral treatment – See Antifungals

Orlistat (Xenical®, Alli® OTC) – See Anti-obesity agents

Omeprazole (Prilosec®)

1. Can be approved up to 60 days one time for GERD. Recommend further evaluation for alarm symptoms for further approvals.
2. Consider step-down to H2 therapy and/or antacids.

Oseltamivir (Tamiflu®) – See Neuraminidase inhibitors

Oxycarbamazepine oral (Trileptal®)

1. Bipolar disorder: Patient failed therapy (or use contraindicated) with lithium, lamotrigine, valproate, and/or second-generation antipsychotics
2. Pain management: Patient failed therapy (or use contraindicated) with SNRIs and TCAs
3. Pain management: Neuropathic pain confirmed by EMG (please attach)

Oxycodone controlled release (CR) (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.

Paliperidone palmitate ER (Invega Trinza®)

1. Non-compliance to oral antipsychotic therapy documented on eMAR.
2. Patient has been stable for at least 4 months on paliperidone palmitate (Invega Sustenna®).
3. Details in non-formulary comments illustrate that when patient is not on a medication to treat their mental health condition(s), they pose a threat to themselves, others, or property.
4. Patient is currently on involuntary medication status. Note, this is not required for approval, but will aid the likelihood of approval.

Pantoprazole (Protonix®)

1. Patient is currently taking clopidogrel.

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.

Pegfilgrastim (Neulasta®), pegfilgrastim-jmdb (Fulphila®), pegfilgrastim-cbqv (Udenyca®), pegfilgrastim-bmez (Ziextenzo®) – See Granulocyte colony-stimulating factors (G-CSFs)

Phenobarbital (Luminal®)

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

Phentermine/topiramate (Qsymia®)

1. Failure of all non–controlled substance alternatives.

Potassium-lowering agents: sodium zirconium cyclosilicate (Lokelma®), patiromer (Veltassa®)

1. Persistent or recurrent serum potassium ≥ 5.5 mEq/L despite the following measures to manage hyperkalemia:
   a. Adjustment or discontinuation of medications that may contribute to hyperkalemia (i.e. potassium supplements, ACE inhibitors, ARBs, ARN inhibitors, MRAs, NSAIDs), if appropriate. Consider clinical practice guidelines and risk vs. benefit of continued use.
   b. Initiation or adjustment of diuretic therapy (loop or thiazide), if appropriate
   c. Patient education regarding a low potassium diet and avoidance of potassium salt substitutes
2. If inmate has Chronic Kidney Disease (CKD), consultation with nephrology

Pramipexole (Mirapex®) – See Dopaminergics for restless legs syndrome

Prasugrel (Effient®)

1. Patient has clopidogrel allergy**.**
2. Patient failed clopidogrel therapy.
3. Is patient on pharmacotherapy that has major interaction with clopidogrel but does not interact with prasugrel?
4. Patient has an active pathologic bleed or has a history of transient ischemic attack (TIA) or stroke? (Contraindicated**)**
5. Patient over the age of 74? (Not recommended, increases bleeding risk)
6. Patient weighs less than 60kg, is prone to bleeding and/or concomitant use of medications that increase the risk of bleeding (eg, warfarin, heparin, fibrinolytic therapy, long-term use of NSAIDs? (Risk factors for bleeding)

Pregabalin (Lyrica®)

1. Approved for neuropathic pain after failure of duloxetine, plus at least one other medication from the tricyclic antidepressant category.
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/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 directly observed therapy and crushed prior to administration unless otherwise restricted by package insert.

Quinine

Non-formulary requests will not be approved for leg cramps.

Ramelteon (Rozerem®)

1. Patient has documented diagnosis of insomnia
2. Insomnia relates specifically to time to sleep onset and NOT sleep maintenance
3. Clear documentation of how insomnia is negatively affecting a secondary diagnosis or functional status is explained above in the comments AND in a BEMR encounter
4. Medication is recommended by a sleep specialist or a psychiatrist
5. Patient has received sleep hygiene counseling, it is documented in Patent Education, AND the date(s) it was provided is listed above.
6. Patient has documented failure to a adequate trials of at least three (3) formulary agents to include a TCA (e.g., amitriptyline, doxepin, etc.), mirtazapine, and trazodone or justification as to why these medications cannot be utilized is explained in the comments above.

7. Patient does NOT have a history of severe sleep apnea or severe hepatic impairment.
8. Patient is NOT currently prescribed any strong CYP1A2 inhibitors (e.g., fluvoxamine).

Ranolazine (Ranexa®)

1. First line agent (beta-blockers, calcium channel blockers, nitrates) use is contraindicated.
2. Treatment failure with isosorbide (mononitrate or dinitrate).
3. Documented Cardiology consult in BEMR.

Rifaximin (Xifaxan®)

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

Rimegepant (Nurtec® ODT) – See Calcitonin gene-related peptide (CGRP) antagonists (small-molecule)

Ropinirole (Requip®) – See Dopaminergics for restless legs syndrome

Salicylic acid: external patch 40%, solution/gel 17%

1. Patient is indigent AND treatment medically necessary. Orders are limited to 60 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Salmeterol (Serevent®) – See Long-acting beta agonists (LABAs)

Saxagliptin (Onglyza®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Selenium shampoo/lotion

1. Documented failure of OTC commissary selenium or coal tar shampoo OR
2. Patient is indigent, treatment medically necessary AND has failed OTC Indigent Program alternatives (ex: Selenium Shampoo 1%Shampoo). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Semaglutide oral (Rybelsus®) – See Glucagon-like peptide 1 (GLP-1) receptor agonists

Semaglutide (Wegovy®) – See Anti-obesity agents

Simethicone tablets/capsules (Gas-X®)

1. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Sitagliptin (Januvia®) – See Dipeptidyl peptidase-4 (DPP-4) inhibitors

Sodium-glucose cotransporter-2 (SGLT2) inhibitors: canagliflozin (Invokana®), dapagliflozin (Farxiga®), ertugliflozin (Steglatro®)

1. Preferred agent is empagliflozin (Jardiance®).
2. Not approved for Type 1 DM.

Steroid nasal sprays: beclomethasone AQ (Beconase®), fluticasone (Flonase®), mometasone (Nasonex®), triamcinolone (Nasacort®)

1. Failure of commissary steroid nasal spray and saline nasal spray (or cromolyn nasal spray) within the last 90 days.
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved based on indigent status alone. If renewed, indigent status will be reassessed.

Sunscreen (various formulations)

1. Prescribed an essential medication causing documented photosensitivity *OR*
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
3. Requests due to unavailability of protective clothing will be disapproved.
4. Approvals will be for SPF 30 products only.

Hyaluronic acids: hylan G-F 20 (Synvisc®), sodium hyaluronate (Hyalgan®)

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.

Tacrolimus topical (Protopic®)

1. Patient has failed topical emollients/moisturizers.
2. Patient has failed topical corticosteroids.
3. Patient requires application to sensitive areas such as face or skin folds.

Tbo-filgrastim (Granix®) – See Granulocyte colony-stimulating factors (G-CSFs)

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

1. Evidence of 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.

Ticagrelor (Brilinta®)

1. Patient has clopidogrel allergy.
2. Patient failed clopidogrel therapy.
3. Patient has an active pathological bleeding or a history of intracranial hemorrhage. (Contraindicated)
4. Patient is on concurrent aspirin (>100mg per day) and ticagrelor therapy. (Reduces ticagrelor effectiveness)
5. Patient has severe hepatic impairment. (Increases ticagrelor exposure)

Tipranavir (Aptivus®) – See HIV medication/treatments

Topiramate (Topamax®)

1. Medication is being used for the treatment of Refractory Bipolar Disorder or Refractory Borderline Personality Disorder.
2. Bipolar Disorder: Patient has failed treatment with or has contraindication to formulary options: valproic acid/divalproex, lithium, aripiprazole, olanzapine, risperidone, and carbamazepine.
3. Borderline Personality Disorder: Provider is targeting symptoms of affective dysregulation, impulsivity, and/or aggression.
4. Borderline Personality Disorder: Patient has failed treatment with or has contraindications to multiple formulary agents (E.G., valproic acid/divalproex, aripiprazole, ziprasidone, olanzapine, and haloperidol).

Triamcinolone nasal spray (Nasacort®) – See Steroid nasal sprays

Ubrogepant (Ubrelvy®) – See Calcitonin gene-related peptide (CGRP) antagonists (small-molecule)

Vancomycin oral (Vancocin HCI 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.

Vibegron (Gemtesa®) – See Beta-3 adrenergic agonists

Vitamin A and D ointment

1. Diabetes with Neuropathy OR
2. Circulatory disorder evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation OR
3. Patient is indigent AND treatment medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Witch hazel and glycerin pads topical (Tucks® Pads)

1. Pending hemorrhoid surgery or 30 days (or less) post-hemorrhoid surgery *OR*
2. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Zanamivir (Relenza®) – See Neuraminidase inhibitors

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: _____

BMI = 703 x [weight(lb) / height^2(in)]

Ideal Weight Range (lb):_____to _____

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

Percent Weight Loss(%), unintentional:

Over past month_____, past 3 months_____, past 6 months_____

Percent weight loss = (UBW – current weight / UBW) x 100

Medical Diagnoses – check all that apply (must have at least one):

- ☐ Dysphagia
- ☐ Crohn's Disease
- ☐ Alzheimer's Disease
- ☐ Swallowing Problems
- ☐ Mastication Problems
- ☐ Ulcerative Colitis
- ☐ Malabsorptive Disorder – Specify_____
- ☐ Failure to Thrive
- ☐ Burns - % Body Surface Area_____
- ☐ Hunger Strike
- ☐ Cancer
- ☐ End Stage Renal Disease on Dialysis
- ☐ Multiple Dental Extractions or Extensive Dental Surgery (short term use)
- ☐ Chronic Wounds (describe in notes below)
- ☐ Other(s): _____

BOP Food Service Diet(s)Tried – check all that apply:

- ☐ Regular
- ☐ Soft
- ☐ Mechanical Soft/Edentulous
- ☐ Low Residue / Low Fiber
- ☐ Clear Liquid
- ☐ Full Liquid
- ☐ Pureed
- ☐ Gluten Free
- ☐ Diabetic Snack
- ☐ 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:

- Scan into BEMR Document Manager as .pdf file
- Attach to BEMR non-formulary request for selected nutritional supplement and/or protein powder/liquid when the patient has not been evaluated a BOP dietitian.
- For nutritional supplement use > 30 days and ALL 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

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:
_____
_____
_____

[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.

BOP Pharmacy

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

NO

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

YES

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

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	
Amiodarone50 mg/ml	A	
Aspirin 81 mg tabs	A	B
Atropine1 mg/10ml	A	
Benztropine1mg/ml injection	A	B
D5W	A	B
Dextrose 50% injection	A	B
Digoxin 0.5 mg injection	A	
Dopamine 400 mg/5ml	A	
Epinephrine1:10000 syringe	A	
Epinephrine1:1000amps	A	
epinephrineauto-injector0.3	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 OR Midazolam injection	A	B
Magnesium sulfate injection	A	
Morphine Sulfate injection	A	B
Naloxone 0.4 mg/ml injection	A	B
Nitroglycerin S.L. 0.4 mg tabs	A	B
Normal Saline	A	B
Procainamide100 mg	A	
Propranolol1 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 injection	A	B
Nitroglycerin 50mg/10ml	A	

Hypertensive Emergency and 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 ≤ 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

1. Diabetes Mellitus (high blood sugar)
2. Hypertension (high blood pressure)
3. Cardiac problems - history of heart attacks, abnormal heart rhythms, congestive heart failure, or currently having chest pain.
4. Anyone taking warfarin/Coumadin® or other blood thinners*****
5. HIV infection
6. Cirrhosis of the liver
7. Uncontrolled asthma/COPD (emphysema) or have run out of medications*****
8. Uncontrolled seizures or have run out of seizure medicine*****
9. Any cases of active pulmonary tuberculosis*****
10. Mental health conditions such as bipolar disorder, psychotic disorders (e.g. schizophrenia); any psychiatric condition requiring antipsychotics, mood stabilizers or benzodiazepines are high risk*****
11. Hepatitis C infection - currently being treated with interferon/ribavirin, with or without protease inhibitors*****
12. Medications with withdrawal potential - chronic benzodiazepines, barbiturates, chronic narcotics, etc.*****
13. Dialysis
14. Cancer receiving active treatment
15. 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.

Therapeutic Substitution on Intake

Introduction

This document authorizes the process of therapeutic substitution by pharmacists for intake orders within the confines of the following tables. This authorization is limited to intake orders only. Any institution implementing additional agents for therapeutic substitution must obtain approval 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

As noted below, each institution utilizing therapeutic substitution on intake must develop a process to notify both the original prescriber and the patient that therapeutic substitution has taken place. A description of this notification process should be placed in the local institution's P&T minutes. Copies of the institution's substitution program must be available to all providers in Health Services. Institutional Chief Pharmacists should educate applicable health care providers of this process prior to its implementation. Participation in a collaborative practice agreement (CPA) is not required for therapeutic substitution as authorized here.

NOTE: The listed equivalencies below have been approved via the National P&T Meeting and are the only ones eligible for therapeutic substitution on intake. Requests for additions to the approved list may be submitted for consideration to the National P&T Meeting via the P&T mailbox. 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.

<table>
<tr><th>Written Order</th><th>Formulary Equivalent
(Adult dosing only, formulary agents in bold)</th></tr>
<tr><td>ACE Inhibitors</td><td>The following chart will be used to substitute a non-formulary ACE inhibitor for lisinopril:

<table>
<tr><th>Generic Name</th><th colspan="4">Dose Equivalents (mg/day)</th></tr>
<tr><td colspan="5">Short-acting</td></tr>
<tr><td>Captopril</td><td>No sub.</td><td>No sub.</td><td>No sub.</td><td>No sub.</td></tr>
<tr><td colspan="5">Intermediate-acting</td></tr>
<tr><td>Benazepril</td><td>5</td><td>10</td><td>20</td><td>40</td></tr>
<tr><td>Enalapril</td><td>5</td><td>10</td><td>20</td><td>40</td></tr>
<tr><td>Moexipril</td><td>-</td><td>7.5</td><td>15</td><td>30</td></tr>
<tr><td>Quinapril</td><td>5</td><td>10</td><td>20</td><td>40</td></tr>
<tr><td>Ramipril</td><td>2.5</td><td>5</td><td>10</td><td>20</td></tr>
<tr><td colspan="5">Long-acting</td></tr>
<tr><td>Lisinopril</td><td>5</td><td>10</td><td>20</td><td>40</td></tr>
<tr><td>Fosinopril</td><td>5</td><td>10</td><td>20</td><td>40</td></tr>
<tr><td>Perindopril</td><td>2</td><td>4</td><td>4–8</td><td>8–16</td></tr>
<tr><td>Trandolapril</td><td>–</td><td>1</td><td>2</td><td>4–8</td></tr>
</table>
</td></tr>
</table>

Antipsychotic LAIs (long-acting injectables)

The chart below will be used to substitute a non-formulary antipsychotic long acting injectable:

Generic Name	Approximate dose equivalents				
Paliperidone ER tablet	3 mg/day		6 mg/day	9 mg/day	12 mg/day
Paliperidone monthly IM injection	39 mg (25 mg as base)	78 mg (50 mg as base)	117 mg (75 mg as base)	156 mg (100 mg as base)	234 mg (150 mg as base)
Paliperidone 3-month IM injection*	x	273 mg (175 mg as base)	410 mg (263 mg as base)	546 mg (350 mg as base)	819 mg (525 mg as base)
Paliperidone 6-month IM injection ǂ	x	X	X	1,092 mg	1,560 mg
Risperidone ER IM injection	X	25 mg every 2 weeks	37.5 mg every 2 weeks	50 mg every 2 weeks	X
Risperidone tablet	1 mg/day	2 mg/day	3 mg/day	4 mg/day	5 mg/ day

*Initiation of paliperidone 12-week LAI may occur only after a patient has been established on monthly paliperidone LAI for a period of at least four months, with the last two months at the same dose.

ǂ Initiation of paliperidone six-month LAI may occur after the individual has been established on paliperidone (monthly) LAI for a minimum of four months or paliperidone 12-week LAI for at least one cycle (three months).

<table>
<tr><td>ARBs (angiotensin receptor blockers)</td><td>The chart below will be used to substitute a non-formulary ARB:

<table>
<tr><th>Generic Name</th><th colspan="2">Dose Equivalents (mg/day)</th></tr>
<tr><td>Candesartan</td><td>8</td><td>16</td></tr>
<tr><td>Eprosartan</td><td>400</td><td>600</td></tr>
<tr><td>Irbesartan</td><td>75</td><td>150</td></tr>
<tr><td>Losartan</td><td>25</td><td>50</td></tr>
<tr><td>Olmesartan</td><td>10</td><td>20</td></tr>
<tr><td>Telmisartan</td><td>20</td><td>40</td></tr>
<tr><td>Valsartan</td><td>40</td><td>80</td></tr>
</table></td></tr>
<tr><td>Benzodiazepines</td><td>The following chart will be used to substitute a non-formulary benzodiazepine:

<table>
<tr><th>Generic Name</th><th>Potency/Dose equivalency</th></tr>
<tr><td>Alprazolam</td><td>0.25mg</td></tr>
<tr><td>Chlordiazepoxide</td><td>10mg</td></tr>
<tr><td>Clonazepam</td><td>0.25mg-0.5mg</td></tr>
<tr><td>Diazepam</td><td>5mg</td></tr>
<tr><td>Lorazepam</td><td>1mg</td></tr>
<tr><td>Oxazepam</td><td>15-30mg</td></tr>
<tr><td>triazolam</td><td>0.25mg</td></tr>
<tr><td>temazepam</td><td>10mg</td></tr>
</table></td></tr>
<tr><td>Biologic Agents (Parent Compound)</td><td>Any VA Contract FDA-approved biosimilar corresponding to the originated parent biologic as found in the FDA Purple Book (https://purplebooksearch.fda.gov).</td></tr>
</table>

Bupropion

The following chart will be used to substitute a long-acting (XL or SR) bupropion with the immediate release (IR) formulation:

Two Pill Line (DOT) Institution		
Bupropion XL Once Daily Dose	150mg	300mg
Bupropion IR Dose BID*	**75mg**	**150mg**
Bupropion SR Dose BID	100mg	150mg
Bupropion IR Dose BID*	**100mg**	**150mg**

*Exact dosing equivalency may require TID dosing (see next chart).

Three Pill Line (DOT) Institution		
Bupropion XL Once Daily Dose	150mg	300mg
Bupropion IR Dose TID	**50mg (1/2 tab of 100mg)**	**100mg**
Bupropion SR Dose BID	100mg	150mg
Bupropion IR Dose TID	**75mg (or 100mg BID)**	**100mg**

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	**110–220 mcg**	**330–440 mcg**	**> 440 mcg**
Beclomethasone HFA	80–240 mcg	280–480 mcg	> 480 mcg
Ciclesonide HFA	160–320 mcg	> 320–640 mcg	> 640 mcg
Budesonide DPI	180–600 mcg	630–1200 mcg	> 1200 mcg
Flunisolide HFA	320 mcg	> 320–640 mcg	> 640 mcg
Fluticasone HFA	88–264 mcg	> 264–440 mcg	> 440 mcg
Fluticasone DPI	100–300 mcg	> 300–500 mcg	> 500 mcg

DPI: dry powder inhaler; HFA: hydrofluoroalkane.

ICS/LABA (inhaled corticosteroid/long-acting beta-agonist)

The chart below will be used to substitute a non-formulary ICS/LABA:

Generic Name	Low Dose	Medium Dose	High Dose
Fluticasone propionate/ Salmeterol HFA	45/21	115/21	230/21
Fluticasone propionate/ Salmeterol Respiclick®	55/14	113/14	232/14
Fluticasone propionate/ Salmeterol Diskus/inhub	100/50	250/50	500/50
Budesonide/ formoterol HFA	80/4.5	160/4.5	x
Mometasone furoate/ formoterol	x	100/5	200/5
Fluticasone furoate/ vilanterol	x	100/25	200/25

Corticosteroids (Nasal)

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

Generic Name	Dose
Fluticasone propionate	**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

EN: each nostril.

Corticosteroids (Topical)

The chart below will be used to substitute a non-formulary topical corticosteroid:

Potency	Generic Name	Dosage form	Strength (%)
Super-high potency (group 1)	Betamethasone dipropionate augmented	Lotion, gel	0.05
		Ointment, lotion, gel	
	Clobetasol propionate	Cream, Cream (emollient base), Gel (scalp), ointment, shampoo, spray aerosol, foam aerosol, solution (scalp)	0.05
	Fluocinonide	Cream	0.1
	Flurandrenolide	Tape (roll)	4 mcg/ cm2

			Halobetasol propionate	Lotion, Cream, Ointment, Foam	0.05
		High potency (group 2)	Amcinonide	Ointment	0.1
			Betamethasone dipropionate	Ointment: cream augmented form	0.05
			Clobetasol propionate	Cream	0.025
			Desoximetasone	Cream, Ointment, Spray	0.25
				Gel	0.05
			Diflorasone diacetate	Ointment, Cream (emollient)	0.05
			Fluocinonide	Gel, solution	0.05
				Cream, ointment	
			Halcinonide	Cream, Ointment, Solution	0.1
			Halobetasol propionate	Lotion	0.01
		High potency (group 3)	Amcinonide	Cream, lotion	0.1
			Betamethasone dipropionate	Cream (hydrophilic emollient)	0.05
			Betamethasone valerate	Ointment	0.1
				Foam	0.12
			Desoximetasone	Cream, ointment	0.05
			Diflorasone diacetate	Cream	0.05
			Fluocinonide	Cream (aqueous emollient)	0.05
			Fluticasone propionate	Ointment	0.005
			Mometasone furoate	Ointment	0.1
			Triamcinolone acetonide	Cream, ointment	0.5
		Medium potency (group 4)	Betamethasone dipropionate	Spray	0.05
			Clocortolone pivalate	Cream	0.1
			Fluocinonide acetonide	Ointment	0.025
			Flurandrenolide	Ointment	0.05
			Fluticasone propionate	Cream	0.02
			Hydrocortisone valerate	Ointment	0.2
			Mometasone furoate	Cream, lotion, solution	0.1
			Triamcinolone acetonide	Cream, ointment, dental paste	0.1
				Ointment	0.05

		Lower-mid potency (group 5)	Betamethasone dipropionate	Lotion	0.05
			Betamethasone valerate	Cream	0.1
			Desonide	Gel	0.05
				Ointment	
			Fluocinolone acetonide	Cream	0.025
			Flurandrenolide	Cream, lotion	0.05
			Fluticasone propionate	Lotion	0.05
			Hydrocortisone butyrate	Cream, lotion, ointment, solution	0.1
			Hydrocortisone probutate	Cream	0.1
			Hydrocortisone valerate	Cream	0.2
			Prednicarbate	Cream (emollient), ointment	0.1
			Triamcinolone acetonide	Lotion	0.1
				Ointment	0.025
		Low potency (group 6)	Aloclometasone dipropionate	Cream, ointment	0.05
			Betamethasone valerate	Lotion	0.1
			Desonide	Cream, lotion, foam	0.05
			Fluocinolone acetonide	Cream, solution, shampoo, oil	0.01
			Triamcinolone acetonide	Lotion	0.025
				Cream, lotion	0.025
		Lowest potency	Hydrocortisone (base, ≥ 2%)	Cream, ointment, solution	2.5
				Lotion	2
			Hydrocortisone (base <2%)	Cream	1
				Ointment, gel, lotion, spray, solution,	
				Cream, ointment	0.5
			Hydrocortisone acetate	Cream	2.5
				Cream	1
				Lotion	2

GLP-1 (glucagon-like peptide-1) agonists

The chart below will be used to substitute a non-formulary GLP-1:

Generic Name	Frequency	Approximate Dose Equivalents				
Semaglutide	QW (weekly)		0.25 mg	0.5 mg	1 mg	2 mg
Dulaglutide	QW		0.75 mg	1.5 mg	3 mg	4.5 mg
Exenatide	QW			2 mg		
Liraglutide	QD (daily)	0.6 mg	1.2 mg	1.8 mg		
Lixisenatide	QD	10 mcg	20 mcg			
Oral Semaglutide	QD	3 mg	7 mg	14 mg		
Exenatide	BID (twice daily)	5 mcg	10 mcg			

HMG-CoA Reductase Inhibitors ("Statins")

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

Generic Name	Dose Equivalents (mg/day) *Intensity:*	*Low*	*Medium*		Avg. Cost/Month
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

SNRIs (serotonin and norepinephrine reuptake inhibitors)

The chart below will be used to substitute a non-formulary SNRI:

Generic Name	Usual starting Dose (mg/day)	Usual total dose (mg/day)
Desvenlafaxine	25 – 50	50 – 100
Duloxetine	30 – 60	60
Levomilnacipran	20	20 – 40
Milnacipran	12.5	100 –200
Venlafaxine	37.5 - 75	75 – 375
Venlafaxine XR	37.5 - 75	75 – 225

<table>
<tr>
<td>SGLT2 (sodium-glucose cotransporter-2) inhibitors</td>
<td>The chart below will be used to substitute a non-formulary SGLT2:
<table>
<tr><th>Generic</th><th>Initial Dose (mg/day)</th><th>Maintenance Dose (mg/day)</th></tr>
<tr><td>Canagliflozin</td><td>100</td><td>300</td></tr>
<tr><td>Dapagliflozin</td><td>5</td><td>10</td></tr>
<tr><td>Empagliflozin</td><td>10</td><td>25</td></tr>
<tr><td>Ertugliflozin</td><td>5</td><td>15</td></tr>
</table>
</td>
</tr>
</table>

Naloxone Protocol and Standing Order

Indication: Naloxone is indicated for the emergency treatment of known or suspected opioid overdose presenting with symptoms of respiratory or central nervous system depression. Symptoms of central nervous system depression may include: unresponsive or unconscious, stuporous or dulled/slowed responsiveness, constricted or pinpoint pupils.

Symptoms of respiratory depression may include: slow or shallow breathing, absence of breathing, choking or snoring sounds, blue lips. These symptoms may be caused by other conditions, including cardiac arrest. If there is no pulse, initiate CPR/AED protocol. If there is a pulse but no breathing, initiate rescue breathing protocol. Administer naloxone prior to initiating CPR or rescue breathing if immediately available.

The surrounding environment may have evidence that supports the suspicion of drug overdose; e.g., pill bottles and drug paraphernalia such as needles, tourniquets, balloons, etc.

Formulation: Naloxone nasal spray 4mg/0.1ml, or equivalent is the product that will be purchased, stocked, and used by BOP staff for treatment of known or suspected opioid overdose with symptoms of respiratory or central nervous system depression.

Other formulations may be stocked in Health Services for use by medical staff as determined by the BOP National Formulary.

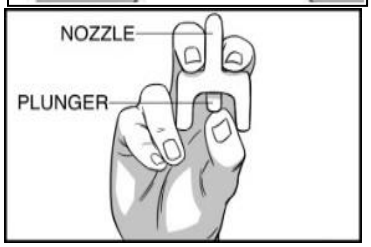
Administration: BOP staff who have successfully completed the required training should administer naloxone for the treatment of known or suspected overdose.

Activate emergency medical response and basic life support (rescue breathing/CPR) as soon as possible in accordance with established local protocols and procedures.

Step 1. Don nitrile gloves, then lay the person on his/her back to receive a dose of naloxone nasal spray.

Step 2. Remove naloxone nasal spray from the box. Peel back the tab with the circle to open the naloxone nasal spray.

Step 3. Hold the naloxone nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.



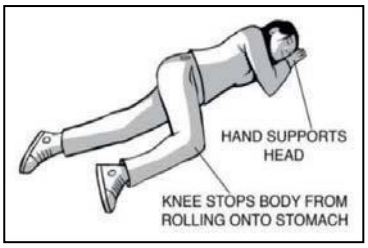
Step 4. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril until your fingers on either side of the nozzle are against the bottom of the person's nose.

Step 5. Press the plunger firmly to give the dose of naloxone nasal spray.

Step 6. Remove the naloxone nasal spray from the nostril after giving the dose.

Step 7. **GET EMERGENCY MEDICAL HELP RIGHT AWAY.** Activate/initiate additional emergency response measures as appropriate/in accordance with established procedures, e.g., basic life support, rescue breathing, cardiopulmonary resuscitation, calling for emergency medical assistance.

Move the person on their side (recovery position) after giving naloxone nasal spray.



Watch the person closely.

If the person does not respond by waking up, to voice or touch, or breathing normally, another dose may be given. Naloxone nasal spray may be given every 2 to 3 minutes in alternating nostrils.

Repeat steps 2 through 6 using a new naloxone nasal spray to give another dose in the other nostril. Steps 2 through 6 may be repeated every 2 to 3 minutes until the person responds or emergency medical help is received.

Step 8. Place the used naloxone nasal spray(s) back into its box and return to Health Services for disposal and replacement.

Cautions and Contraindications:

Pregnancy – Administration is permitted in pregnant females if overdose is suspected by the responder. Since administration of naloxone to the mother may cause opioid withdrawal in the fetus, medical personnel responding to the emergency must be notified of the pregnancy and administration of naloxone.

Breast feeding – It is unknown whether naloxone is excreted into human milk or the effects on a breast fed infant.

Contraindications – Allergy (hypersensitivity) to naloxone or any other ingredients.

Standing Order: Health Services staff may dispense/distribute to appropriate staff in sufficient quantities to meet local procedures for administration to persons who are suspected of experiencing an opioid overdose.

ELIZABETE STAHL Digitally signed by ELIZABETE STAHL
Date: 2023.06.20 13:28:36 -04'00'

Dr. Elizabete Stahl, DO Date

Medical Director

National Permitted Night Stock Items

Nightstock Item
NS Acetaminophen 325 MG Tablet 3 day Pack (24)
NS Acetaminophen Tablet 3 day Pack (12)
NS Acyclovir 200 mg Caps 3 day (15) Bottle
NS Acyclovir 400 MG Tablet 3 day pack (9)
NS Acyclovir 800 MG Tablet 3 day pack (15)
NS Albuterol 8.5 GM Inhaler
NS Amlodipine Tablet 3 day pack (3) 5 MG Each
NS Amoxicillin Capsule 3 day pack (9) 250 MG Bottle
NS Amoxicillin 500 MG Capsule 3 day pack (9)
NS Amoxicillin Dental pack 2GM (4 x500mg caps)
NS Apixaban 2.5mg tablet 3 day pack (6)
NS Apixaban 5mg tablet 3 day pack (6)
NS Aspirin 325 MG Tablet 1 Day pack (1)
NS Aspirin E.C. 325 MG Tablet 3 Day Pack (24)
NS Atenolol 25 MG Tablet 3 Day Pack (3)
NS Atenolol 50 MG tablet 3 day pack (3)
NS Augmentin 875/125MG Tablet 3 day Pack (6)
NS Augmentin 500mg Tablet 3 day pack (6)
NS Azithromycin 250 MGz-Pack
NS Sulfamethoxazole/Trimeth 800mg /160mg Tablet 3 day pak (6)
NS Bisacodyl 5 MG Tablet prep (4)
NS Captopril 12.5 MG Tablet 1 dose
NS Carvedilol 6.25 MG Tablet 3 Day Pack (6)
NS Carvedilol 25 MG tablet 3 day pack (6)
NS Cephalexin Capsule 3 day 250 MG Bottle
NS Cephalexin 500 MG Capsule 3 day Pack (9)
NS Cephalexin 500 MG Capsule (12) Pack
NS Ciprofloxacin 500 MG Tablet 3 Day Pack (6)
NS Clarithromycin 500 MG Tablet 3 Day Pack (6)
NS Clindamycin 300 MG Capsule 3 Day Pack (12)
NS Clindamycin 150 MG Capsule 3 Day Pack (24)
NS Clonidine 0.1 mg weekly Patch (1)
NS Clonidine 0.2 MG weekly Patch (1)
NS Clopidogrel Tablet 3 day (3) 75 MG Bottle
NS Clopidogrel 300 MG One Time Dose
NS Cortisporin otic susp 10 ml
NS Diclofenac 0.1% ophth soln (2.5 mL) Bottle
NS Dolutegravir 50mg Tablet 3 day pack (3)
NS Doxycycline 100 MG Capsule 3 Day Pack (6)
NS Erythromycin opth oint 3.5 GM
NS Furosemide 20 MG Tablet 3 Day Pack (3)
NS Furosemide 40 MG Tablet 3 day Pack (3)
NS Gentamycin Ophth Soln 5 ML
NS Gentamycin Opth Ointment (3.5 GM) Tube
NS Glipizide 5 MG Tablet 3 day pack (6)
NS Glucose pack (10)

NS Golytely orals soln reconstit 4000 ml
NS Hydralazine 50mg Tab 3 day(6) Pack
NS Hydrochlorothiazide 25 MG Tablet 3 Day Pack (3)
NS Ibuprofen 400 MG Tablet 3 day pack (9)
NS Ibuprofen 400 MG Tablet 3 day pack (12)
NS Ibuprofen 600 MG Tablet 3 day pack (9)
NS Ibuprofen 600 MG Tablet 3 day pack (12)
NS Ibuprofen 800 MG Tablet 3 day pack (9)
NS Ibuprofen 800 MG Tablet 3 day pack (12)
NS Levetiracetam 500mg 3 days supply (12) Bottle
NS Levofloxacin 500mg Tablet 3 day Pack (3)
NS levofloxacin 750MG tablet 3 day pack (3)
NS Levonorgestrel 1.5mg tablet (1)
NS Levothyroxine 50 MCG Tablet 3 day pack (3)
NS Lisinopril 10 MG Tablet 3 Day Pack (3)
NS Lisinopril 5 MG Tablet 3 Day Pack (3)
NS Lisinopril 20 MG Tablet 3 Day Pack (3)
NS Loperamide 2 MG Capsule 3 Day Pack (6)
NS Metformin 500 MG Tablet 3 Day Pack
NS Metformin Tablet 3 day pack 1000 MG
NS Methylprednisolone 4 MG 21 Dose Pack
NS Metoprolol Tablet 50 MG 3 Day Pack (6)
NS Metoprolol 25 MG Tablet 3 Day Pack (6)
NS Metronidazole 250 MG Tablet 3 day Pack (24)
NS Metronidazole 250 MG tablet 3 day Pack (18)
NS Metronidazole 500 MG tablet 3 day pack (12)
NS metronidazole 500mg 3 day (6) pack Bottle
NS Molnupiravir 200mg Caps 1 course (2) *** Mail Order sites ONLY*
NS Milk of MMagnesia Oral susp 30 ML
NS Naproxen 500 MG Tablet 3 Day Pack (6)
NS Nirmatrelvir/ritonavir oral 1 course (2)
NS Nitrostat bottle 0.4 MG Tablet Sublingual
NS Nitrofurantoin Caps 100mg 3 day pack (6)
NS Ofloxacin 0.3% ophth soln 5 mL
NS Ondansetron 8 MG Tablets (6) Bottle
NS Oseltamivir 75 MG 5 Day Pack (10)*** Mail Order sites ONLY*
NS Penicillin 500 MG Tablet 3 day pack (12)
NS Exposure Kit (combo pack-ralt/truv) 3 day Bottle
NS Exposure Kit (combo pack-dolu/truvada 3 day) Bottle
NS Permethrin 5% cream 60 GM
NS Permethrin 1% Lotion 60 ML
NS phenazopyridine 95MG tab 2 day (12) pack
NS Phenytoin 100 MG Capsule 3 Day pack (9)
NS Phytonadione 5 MG 1 Dose
NS PREA Kit (azith/metronid Combo -1 day)
NS Prednisone 10 MG 21 Dose Pack
NS Prednisone 10 MG 48 Dose Pack
NS Prednisone 20 MG Tablet (3) 3 day pack
NS Prednisone 20MG Tablet (6) 3 day pack

NS Prednisone 5 MG 21 Dose Pack
NS Prednisone 5 MG 48 Dose Pack
NS Prednisolone Acetate 1% ophth soln 5 ml
NS Raltegravir 400 MG Tablet 3 Day Pack
NS Sulfamethoxazole/Trimeth 800mg /160mg Tablet 3 day pack (6)
NS Tenofovir/Emtricitabine 300/200MG Tablet 3 Day Pack
NS Thiamine 100 mg Tablet 3 Day Pack (3)
NS Tobramycin 0.3% ophth soln 5 ml
NS Triamcinolone dental paste 0.1% 5 gm
Items expected to be stocked as UNIT Dose due to variance in Dosing
Warfarin Tablets
Ivermectin

Part II

NATIONAL BOP FORMULARY

REFER TO BEMR RX FORMULARY DRUG FILE REPORT