Federal Bureau of Prisons

National Formulary Part 1

Approved:



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

Participants of the Pharmacy and Therapeutics (P&T) 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.

Non-Formulary Request Expectations

- 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.
- ALL comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
- 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.
- 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.
- Clinical Directors (CDs) are expected to support the BOP National Formulary and ensure compliance at their respective institutions. 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.
- 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.

- 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.
- 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.
- 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.
- It is expected that all institution inventory and ordering procedures will be conducive to acceptable inventory practices (e.g. two-week par levels on the shelf maintained with, at minimum, weekly medication ordering).

Compliance

- Completion and appropriateness of non-formulary medication requests are elements of the Clinical Director's peer review process.
- 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.
- The Medical Director may issue memos to the institution Warden regarding persistent problems or concerns with respect to the institution's compliance with this process.

Continuity of Care Provision

There are times when patients are processed into a facility after normal working hours, weekends, and holidays. In these cases, continuation of non-formulary medications prior to approval may be medically necessary because of the following reasons:

- There is no formulary substitute or changing to a formulary substitute will not allow for appropriate follow up monitoring until the next workday, **AND**
- Not providing the medication would pose a significant risk to the patient.

When continuation of a non-formulary medication prior to approval is medically necessary, an allowance is given to dispense/administer the medication for 4 days while awaiting 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, 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

1. Brand name products are for reference only
2. The least expensive generic and/or biosimilar product is to be utilized, when available. Otherwise, non-formulary approval is required.
3. Use against specific restrictions (i.e., directly observed therapy required, crush, etc.) requires non-formulary approval.
4. Use of a formulation not specifically included in the national formulary (e.g., extended release, nasal, topical, ophthalmic, rapid dissolve tablet, combination product) is not authorized and 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). Unless approved by National P&T, 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

1. All controlled substances are restricted to directly observed therapy.
2. Immediate release, non-enteric coated, oral controlled substances must be crushed (e.g. tablets) or pulled apart (e.g., capsules) and contents mixed with water at time of administration.
3. The above criteria apply to all drug items unless an item-specific exception is noted in the national formulary.

Directly Observed Therapy ("Pill Line") Only

"Directly observed therapy only" is a restriction placed on controlled substances and some other drugs requiring that a single dose of the drug be administered to a patient by a qualified employee at a designated time and place. 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).

FDA Medication Guides and Side Effects Statement

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:

- Confined within a BOP institution.
- 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 patient is:

- Being released to the community (including writs and furloughs)

- Sent to a Residential Reentry Center (RRC) (e.g., halfway house).

Formulary Diagnosis

Medications with a formulary diagnosis (i.e., "inclusionary") are formulary for specific diagnoses as approved by National P&T. Prescriptions written for patients without the approved diagnosis will require non-formulary review.

Immediate Use Pens

Epinephrine Auto-Injector (EpiPen®)

EpiPen® may be issued to patients with known anaphylaxis utilizing the procedure outlined below.

4. 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**"
5. The patient will present the Epipen® at pill line every day to ensure the seal is intact and that no manipulation has occurred.
6. Health services staff will document the encounter in the Medication Administration Record daily.
7. The patient 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. The patient should be counseled regarding the potential consequences and adverse actions that may occur if tampering is evident or the product is lost or manipulated.

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) with risk of negative outcomes
- Injectable drugs (except for those specifically permitted by the National Formulary)
- Close monitoring required (e.g., TB meds)
- Caustic or harmful agents (e.g., podofilox)
- Refrigeration required
- Potential for misuse of packaging (e.g., glass containers, inhalers with piercing devices)
- Cost

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 the same items from the BOP National Formulary.

Resources:

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

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 (e.g., days supply) 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.

Multi-Dose Single-Patient Pens (semaglutide, insulin, etc.)

Multidose, single-patient injection pens may be issued to patients utilizing the procedure outlined below.

4. The injection pen medication order is processed as Directly Observed Therapy with the BEMR directions: ***must present this device to pill-line [weekly, daily, etc.] for integrity inspection***
5. When a dose is due, patients will return to the health service department for a new pen needle, self-inject, and immediately dispose of the needle appropriately under staff supervision
6. Pen needles will not be dispensed to patients and will be controlled and inventoried according to policy.

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. Per Program Statement 6541.03 Over-the-Counter Medications, during institution triage / sick call, medical staff will refer patients to the commissary in response to complaints related to cosmetic and general hygiene issues or symptoms of minor ailments.

Placebos – Statement on Use

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

References:

7. **American Medical Association:** "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."
8. **American Society of Health-System Pharmacists:** " . . . 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 . . . ."

Risk Evaluation and Mitigation Strategies (REMS)

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.

All medications which require REMS program enrollment will include the non-formulary use criteria "Request must include confirmation of REMS enrollment."

Use Criteria

Select medications may require clinical review to ensure safe and effective utilization. Use Criteria are intended to prompt the exchange of information pertinent to patient-specific cases with the goal of improving care.

Use Criteria

Abrocitinib (Cibinqo®)

1. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE high potency/class 1 topical corticosteroids AND at least ONE topical calcineurin inhibitor AND
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
    e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

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® and biosimilars)

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. $\geq$ 10% BSA is affected (Severe CPP) OR
    d. At least $\geq$ 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.

Alemtuzumab (Lemtrada®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis – including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.
3. Failure (or use contraindicated) of formulary options or justification why formulary options cannot be used.

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.

Alogliptin (Nesina®)

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.

Alvimopan (Entereg®)

1. Request must include confirmation of REMS enrollment.

Amantadine (Symmetrel®)

Formulary Diagnoses:

- Parkinson's Disease
- Secondary Parkinsonism

Use Criteria:

1. Drug-induced extrapyramidal reactions not responsive to trihexyphenidyl or benztropine.

Amantadine ER (Gocovri®)

1. Failure of, or contraindication to, immediate release amantadine.

Ambrisentan (Letairis®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

Ammonium Lactate lotion/cream (Lac-hydrin®)

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.

Amoxicillin/Clavulanate XR (Augmentin XR)

1. Patient has acute bacterial rhinosinusitis AND one of the following risk factors for severe disease
    a. living in regions where resistant S. pneumoniae >10%;
    b. hospitalization in the last 3 months;
    c. multiple co-morbidities (i.e. chronic cardiac, liver, or kidney disease);
    d. severe infection (e.g. evidence of systemic toxicity or concern for suppurative complications).

Amphetamine/dextroamphetamine (Adderall®, Adzenys ®, Dexedrine®, Dyanavel®, Evekeo ®, Mydayis®, Zenzedi®)

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.
7. For narcolepsy: Documented verification of the patient's report, to include polysomnography obtained and provided.
8. For narcolepsy: Patient has failed non-pharmacologic management strategies.
9. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
10. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

Antihemophilic Agents (all brands and formulations)

1. Must be prescribed by an appropriate specialist (such as a hematologist) AND
2. Confirmed that the agent is being prescribed for appropriate hemophilia disorder (Hemophilia A vs. B) or other appropriate bleeding disorder, if applicable AND
3. Confirmed the agent and dosing is for appropriate indication (acute bleeding vs. prophylaxis dosing).

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.

Arformoterol nebulizer soln (Brovana®)

1. Use of LABA in asthma is contraindicated when not used in combination with an ICS. Must provide clinical justification for why formulary combination LABA/ICS cannot be used.
2. When treatment with a LABA is initiated in COPD, the preferred choice is a combination LAMA/LABA product. Must provide clinical justification for why formulary LAMA monotherapy cannot be used.

Aripiprazole lauroxil intramuscular injection (Aristada Initio®)

1. Patient is being initiated on long-acting aripiprazole and is unable to take lead-in oral aripiprazole.

Ascorbic Acid

1. 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®)

1. For migraine prevention: Documented failure of, contraindication to, or inability to utilize 8-week trials of at least 1 formulary option each from the beta-blockers and anticonvulsants classes, AND
2. Recommended by a neurologist.

Azithromycin (Zithromax®)

Formulary Diagnoses:

- Gonococcal infection
- Chlamydial infection

- Periapical or oral infection
- HIV/AIDs opportunistic infection treatment or prophylaxis
- Pneumonia
- Osteomyelitis
- Cellulitis
- Babesiosis
- Mycobacterial infection
- Conjunctivitis
- Legionnaires' disease

Use Criteria:

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Baclofen

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.

Baricitinib (Olumiant®):

1. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE high potency/class 1 topical corticosteroids AND at least ONE topical calcineurin inhibitor AND
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
    e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

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.

Beclomethasone AQ (Beconase®)

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.

Benzoyl Peroxide

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.

Bosentan (Tracleer®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

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.

Brivaracetam (Briviact®)

1. Prescribed for the treatment of partial-onset seizures AND
2. Recommended by a neurologist AND
3. Patient has failed an adequate trial of levetiracetam or has an allergy or intolerance to levetiracetam AND
4. Patient has failed an adequate trial of two or more formulary antiepileptics.

Budesonide/formoterol (Symbicort®, Breyna®)

Formulary Diagnoses:

- Asthma

Use Criteria:

1. COPD: Documented failure of, contraindication to, or inability to utilize LAMA-containing agents.
2. All inhaled corticosteroid/ long-acting beta-agonist (ICS/LABA) requests must be for the current BOP mandatory (NAT) contract item, unless clinically justified otherwise.

Budesonide/glycopyrrolate/formoterol (Breztri®)

1. New requests and renewals must contain documentation of counseling on inhaler technique and inhaler adherence.
2. 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)
3. COPD: Patient with a history of 0-1 exacerbations and blood eosinophil < 300 cells/µL, should have history of trial of LABA+LAMA used concomitantly.
4. 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
5. Triple agent is more cost-effective then formulary alternatives used in combination.

Buprenorphine transdermal patch and film (Butrans®, Belbuca®)

1. Patient has moderate-to-severe chronic unremitting pain not likely to abate in the short term that requires extended treatment with an around-the-clock opioid.
2. Documented failure of, contraindication to, or inability to utilize all non-pharmacologic and pharmacologic treatment options at maximum tolerated dose with documented compliance.
3. Documentation in EHR that OUD has been fully evaluated and ruled out.

Buprenorphine long-acting injection (Sublocade ®, Brixadi ®)

1. Institution has an active REMS enrollment, and documentation is clearly provided that demonstrates patient meets ANY of the following criteria:
    a. Failure to meet treatment goals on sublingual buprenorphine/naloxone despite an appropriate dosage (at least 16 mg daily), evidence of compliance, AND for a duration of at least 3 months. See OUD Modules for guidance on treatment goals.
    b. Confirmed diversion with documented clinical follow up to include counseling and assessment for reasons for diversion AND buprenorphine remains the best option.
    c. Patient has significant, documented neurological or psychiatric comorbidities which preclude successful administration of formulary options on directly observed therapy (pill line).
    d. Transferring custody within 30 days and use of a long-acting injection will more appropriately ensure continuity of care.

Bupropion (Wellbutrin® IR, SR, ER, 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 extended-release injection (Cabenuva®)

1. Documented failure of, contraindication to, or inability to utilize oral alternatives.
2. Requires consultation with a BOP HIV Clinical Pharmacist Consultant

Calcium carbonate

Formulary Diagnoses:

- Chronic kidney disease
- Hyperparathyroidism
- Dialysis

Use Criteria: Refer to OTC Use Criteria

Calcium polycarbophil

Formulary Diagnoses:

- Chronic idiopathic constipation
- Neurogenic bowel
- Irritable bowel syndrome, with constipation

Use Criteria: Refer to OTC Use Criteria

Canagliflozin (Invokana)

1. Patient has type 2 diabetes and either established atherosclerotic cardiovascular disease OR chronic kidney disease AND A1c goal not met on maximum tolerated therapeutic dose of metformin or documented contraindication to metformin.
2. If A1c is >9%, insulin is recommended
3. Consider in patients with difficulty controlling weight and blood glucose despite appropriate diet and exercise adherence; documentation required including; commissary purchases reviewed.
4. Empagliflozin is the preferred non-formulary agent in this class.
5. Avoid use in those with history of diabetic foot complications (ulcerations or other infections); peripheral vascular disease, genitourinary complications, in the elderly and others prone to effects of hypotension.

Candesartan (Atacand®)

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

Carbamazepine oral (Tegretol®, Tegretol XR ®)

Formulary Diagnoses:

- Trigeminal neuralgia
- Epilepsy/seizure disorders

Use Criteria:

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. Consider a directly-observed therapy restriction (pill-line only) for patients with a history of medication misuse.

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.

Carisoprodol (Soma®) – see baclofen

Certolizumab pegol (Cimzia®)

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.

Cetirizine (Zyrtec®)

Formulary diagnoses:

- Asthma
- Chronic sinusitis
- COPD

Use Criteria:

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.

Chlorzoxazone (Lorzone®) – see baclofen

Ciprofloxacin (Cipro®)

Formulary diagnoses:

- Prostatitis
- Neutropenia
- Rectal abscess
- Pseudomonas
- Salmonella
- Pyelonephritis
- Diverticulitis
- Malignant otitis externa

Use criteria:

1. UTI
    a. Complicated (e.g., obstruction, reflux, azotemia, transplant) or catheter associated OR

   b. For acute cystitis, first-line therapy with sulfamethoxazole/trimethoprim and nitrofurantoin have failed or are contraindicated.
2. Pneumonia
   a. Patient has risk factors for pseudomonas or MRSA. Comorbidities present (chronic heart, lung, liver, or renal disease; diabetes; alcohol use disorder; neoplastic disease, asplenia) OR
   b. Antibiotic use within the past 3 months.
3. COPD exacerbation
   a. Patient has risk factors for poor outcome (age greater than 65 years, FEV1 < 50%, recent hospitalization or antibiotic use, history of pseudomonas infection, more than 1 exacerbation in past 12 months).
   b. Patient has contraindications to azithromycin or cefdinir.
4. Acute sinusitis
   a. Patient has clinical failure after 3 days of empiric antibiotic treatment (persistent sinus pain, nasal congestion, purulent nasal discharge, and/or fever despite recommended therapy).
5. Otitis media
   a. Patient has had antibiotics in the previous month AND a has documented penicillin allergy OR
   b. Patient has clinical failure after 3 days of empiric antibiotic treatment (no change in ear pain, fever, bulging tympanic membrane, or otorrhea) AND has a documented penicillin allergy.
6. H. pylori
   a. Patient has failed both first-line treatment options (per current guidelines) OR
   b. Prescribed along with amoxicillin and omeprazole for 14 days at appropriate doses.
7. For biopsy/procedure: Please indicate if use for biopsy/procedure, if recommended by specialist, and date of procedure (if known).
8. For use based on available culture and sensitivity results: Susceptible to fluoroquinolone and intermediate or fully resistant to all other formulary options.

Clobazam (Sympazan®, Onfi®)

1. Prescribed for the treatment of Lennox-Gastaut syndrome AND
2. Recommended by a neurologist AND
3. Patient has failed an adequate trial of two or more formulary agents for Lennox-Gastaut syndrome.

Clobetasol Foam and Topical Solution

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

Clonazepam (Klonopin®)

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)

Clonidine transdermal patch(Catapres TTS®)

1. Dose taper over 2 to 4 days for arriving patients 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 oral tablet (Catapres®)

1. Refer to BOP Clinical Guidance for Medically Supervised Withdrawal for Inmates with Substance Use Disorders for use and dosing in appropriate conditions (e.g., opioid withdrawal, alcohol withdrawal).
2. Not to be used in hypertensive urgencies and emergencies. Refer to BOP Clinical Guidance for Hypertensive Crisis.
3. Clozapine induced hypersalivation (CIH): Documented failure of, contraindication to, or inability to utilize benztropine, amitriptyline, and alpha blocker, including combination therapy with benztropine and an alpha blocker, for 12 weeks.
4. Use in Tourette's syndrome.
5. ADHD: Documented failure of, contraindication to, or inability to utilize therapeutic doses and for a therapeutic duration of preferred agents (atomoxetine and guanfacine).

Clozapine

1. Is the order written by a psychiatrist?
2. Has the patient had failure of at least two other atypical agents?
3. Request must include confirmation of REMS enrollment.

Coal Tar Ointment, Gel, and Shampoo

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.).

Copper intrauterine device (Paragard®)

1. Request is for continuity of care for patient who entered BOP custody with this IUD already in place. (Patients entering the BOP with these devices in place must have the product name and expiration/replacement date documented in the health record. These devices may be removed upon expiration or sooner at the patient's request).
2. Unless this patient's case meets criteria #1, this request will be disapproved. The Patient Care program statement prohibits initiation of IUDs for birth control for inmates housed in BOP facilities.

Cyclobenzaprine (Flexeril®) – see baclofen

Cyclosporine ophthalmic emulsion (Restasis®)

Formulary Diagnoses:

- Rheumatoid arthritis
- Sjogren syndrome
- Lupus

Use Criteria:

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND,
2. For a pathological or structural abnormality (i.e., conditions that limit full blinking or eyelid closure) leading to chronic dry eye that is medically necessary AND,
3. Failed adequate trial of any artificial tear product.

Cyclosporine ophth solution (Vevye®, Cequa®)

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND
2. For a pathological or structural abnormality (i.e., conditions that limit full blinking or eyelid closure) leading to chronic dry eye that is medically necessary AND
3. Failed trial of any artificial tear product AND
4. Failed adequate trial of cyclosporine 0.05%.

Cyproheptadine (Periactin®)

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

Dabigatran (Pradaxa®)

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

Dantrolene (Dantrium®) – see baclofen

Dapagliflozin (Farxiga®), Dapagliflozin/Metformin (Xigduo®), Dapagliflozin/Saxagliptin (Qtern®)

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

Darbepoetin Alfa (Aranesp®)

Formulary Diagnoses:

- Hepatitis C
- Hepatitis

Use Criteria:

1. Hepatitis C:
    a. Patient receiving hepatitis C therapy AND patient is one of the following:
        i. Cirrhotic;
        ii. Pre or post-liver transplant
        iii. HIV/HCV co-infected;
        iv. Receiving HIV triple therapy; AND
    b. Patient underwent evaluation for other causes of anemia (e.g. bleeding, nutritional deficiency) and has been treated appropriately; AND
    c. 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
    d. Patient does not have exclusion criteria: Uncontrolled hypertension or risk for thrombosis.
2. Epoetin alfa-epbx (Retacrit®) is the preferred formulary alternative.

Darifenacin (Enablex®)

1. Documented failure of, contraindication to, or inability to utilize 12-week trials (with compliance) of at least two formulary anti-muscarinic agents (oxybutynin IR or ER, tolterodine, or solifenacin IR) to include an ER formulation.

Darunavir/cobicistat/tenofovir alafenamide/emtricitabine (Symtuza®)

1. Requires consultation with a BOP HIV Clinical Pharmacist Consultant

Denture Adhesive (Fixodent®, etc.)

1. Patient is indigent. 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. Patient has no commissary access (confirmed through TRUFACTS).
3. Patient has a denture.

Deutetrabenazine (Austedo®, Austedo XR®)

1. TARDIVE DYSKINESIA
    a. Baseline Abnormal Involuntary Movement Scale (AIMS) score
    b. Documentation of specific involuntary movements (e.g., facial, oral extremity) and impact on functioning, quality of life, and social interactions

c. Documentation of attempts to reduce or discontinue the offending dopamine receptor blocking agent or evidence that such an adjustment is not clinically feasible.
d. Documented failure of, contraindication to, or inability to utilize tetrabenazine.

Desloratidine (Clarinex®)

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.

Dextroamphetamine – see Amphetamine/dextroamphetamine

Dibucaine ointment (Nupercainal®)

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.

Diclofenac 3% Gel and Solution (all strengths)

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.
4. Diclofenac gel 3% will not be approved without sufficient justification why 1% cannot be used.

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.

Difluprednate ophth (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.

Diphenhydramine oral (Benadryl®)

Formulary Diagnoses:

- Malignancy
- Dialysis
- ESRD

Use Criteria:

1. Patients taking antipsychotic medication with extrapyramidal symptoms not responsive to benztropine and trihexyphenidyl (diphenhydramine and hydroxyzine only).

2. Excessive salivation with clozapine (diphenhydramine and hydroxyzine only).
3. Chronic idiopathic urticaria (consider other formulary H2 blockers such as doxepin).
4. Chronic pruritus-associated dialysis (diphenhydramine and hydroxyzine only).
5. Non-formulary use approved via DIRECTLY OBSERVED THERAPY ONLY for cyproheptadine.
6. **Urticaria:** Classified according to etiology or precipitating factor. All potential precipitating factors have been considered and controlled.
7. **Urticaria:** IgE levels and/or absolute eosinophil count in conditions where this is typically seen.
8. **Urticaria:** Documented failure (ensuring compliance) of steroid pulse therapy (i.e. prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**.

Diroximel (Vumerity®) – see alemtuzumab

Docusate (Colace®)

Formulary Diagnoses:

- Opioid use disorder
- CKD
- Parkinson's
- Paralysis
- Anemia
- Neurogenic bowel
- Dialysis

Use Criteria:

1. Short-term orders should be obtained through the commissary.
2. Chronic management of hypo-motility disorders OR
3. Chronic use of iron or opioids OR
4. Patient is indigent, treatment is medically necessary, AND has failed OTC Indigent program alternatives (ex: Milk of Magnesia). Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Dulaglutide (Trulicity®)

1. May be approved for type 1 diabetes for comorbid conditions, not primarily for glycemic control.
2. Documented failure of, contraindication to, or inability to utilize preferred GLP-1 agonist or GIP/GLP 1 agonist.

Dupilumab (Dupixent®)

1. ASTHMA:
    a. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
    b. The patient completed observed inhaler technique with correction as needed.
    c. 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
    d. The patient has a blood eosinophil level 150 cells/ l or FeNO 25 ppb.
    e. The patient has failed omalizumab (Xolair®) (or has a contraindication).

   f. Dupilumab been recommended by a specialist. (Please upload in Document Manager.)
2. ATOPIC DERMATITIS
   a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
   b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
   c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories:
      i. High potency/class 1 topical corticosteroids
      ii. Topical calcineurin inhibitor
   d. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

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

Edoxaban (Savaysa®)

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

Empagliflozin (Jardiance®)

Formulary diagnoses:

- Diabetes Type II
- Heart failure
- CKD

Emtricitabine/Tenofovir alafenamide (Descovy®)

Formulary Diagnoses:

- HIV 1 or 2

Use Criteria:

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)
3. I no to 1 and 2, emtricitabine/tenofovir disoproxil (Truvada®) is the preferred PrEP medication.

Enfuviritide (Fuzeon®)

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

Epoetin alfa (Epogen®, Procrit®), epoetin alfa-epbx (Retacrit®) (if prescribed for HCV),

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

Epoprostenol (Veletri®, Flolan®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Eptinezumab-jjmr (Vyepti®) – see erenumab

Erenumab-aooe (Amovig®)

1. For migraine prevention: Documented failure of, contraindication to, or inability to utilize 8-week trials of at least 1 formulary option each from the beta-blockers and anticonvulsants classes, AND
2. Recommended by a neurologist.

Ertugliflozin (Steglatro®), ertugliflozin/metformin (Selguromet®), ertugliflozin/sitagliptin (Steglujan®)

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

Evolocumab (Repatha®)

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.

Esketamine (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®) and biosimilars

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. $\geq$ 10% BSA is affected (Severe CPP) OR
    d. At least $\geq$ 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.

Ethosuximide (Zarontin®)

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.
5. 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:
    a. To assess and follow the patient for potential adverse side-effects.
    b. Be aware of any potential drug-drug interactions.
    c. Adjust dose no more quickly than recommended by the manufacturer.
    d. Monitor compliance.

Etravirine (Intelence®)

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director.
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.
4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, and the complete HAART regimen being requested.

6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved. (same as other HIV medications)

Evolocumab (Repatha®)

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.

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.

Felbamate (Felbatol®)

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.
5. 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:
    a. To assess and follow the patient for potential adverse side-effects.
    b. Be aware of any potential drug-drug interactions.
    c. Adjust dose no more quickly than recommended by the manufacturer.
    d. Monitor compliance.

Fenofibrate micronized (Antara®, Lofibra®), non-micronized (Fenloglide®), choline (Trilipix®), and nanocrystal (Tricor®)

Formulary Diagnoses:

- Hyperlipidemia
- Hypertriglyceridemia

Use Criteria:

1. Failure of gemfibrozil used for at least 6 months.
2. Treatment of hyperglycemic patients. HbA1c should <8
3. Triglyceride level must be > 500 after compliance with criteria 1 and 2 above.

Fenofibrate non-micronized (Lipofen®)

1. Failure of gemfibrozil used for at least 6 months.
2. Treatment of hyperglycemic patients. HbA1c should <8
3. Triglyceride level must be > 500 after compliance with criteria 1 and 2 above.

Fesoterodine (Toviaz®)

1. Documented failure of, contraindication to, or inability to utilize 12-week trials (with compliance) of at least two formulary anti-muscarinic agents (oxybutynin IR or ER, tolterodine, or solifenacin IR) to include an ER formulation.

Fexofenadine (Allegra®)

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.

Fidaxomicin (Dificid®)

1. Use in patients > 65 years old who are immunocompromised
2. Use in severe *C. difficile* infection (WBC count > 15,000 cells/mcL; sCr >/= 1.5 mg/dL).

Filgastim (Neupogen®, Nivestym®, Zarxio®, and biosimilars)

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

Finerenone (Kerendia®)

1. Patient has type 2 diabetes mellitus with associated chronic kidney disease, AND
2. Persistently elevated urinary albumin excretion (urine albumin-to-creatinine ratio >=30mg/g), AND
3. Patient is on optimized preferred therapy (blood pressure control including ACEI-inhibitor or ARB, glycemic control, and kidney-protective therapy with SGLT-inhibitor)

Fluconazole (Diflucan®)

Formulary Diagnoses (oral only):

- HIV
- Cryptococcosis
- Candidal stomatitis
- Candidiasis
- Coccidioidomycosis
- Sporotrichosis
- Histoplasmosis
- Blastomycosis
- Osteomyelitis
- Meningitis

Use Criteria:

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.
5. Tinea/Superficial Mycosis: Failure of at least 4-weeks trial of topical antifungals. *[Oral only]*

Fluticasone oral inhaler (Flovent HFA®)

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

Fluticasone nasal spray (Flonase®)

Formulary Diagnoses:

- Asthma
- Chronic sinusitis
- COPD

Use Criteria – see Beclomethasone nasal spray

Fluticasone furoate/vilanterol (Breo Ellipta) – see budesonide/formoterol for use criteria

Fluticasone/salmeterol diskus (Advair®, Wixela®)

Formulary Diagnoses:

- Asthma

Use Criteria – see budesonide/formoterol

Fluticasone/salmeterol (AirDuo®, Advair HFA®, DuoAir RespiClick®) – see budesonide/formoterol for use criteria

Fluticasone/umeclidinium/vilanterol (Trelegy®) – see budesonide/glycopyrrolate/formoterol

Formoterol nebulizer soln (Perforomist®) – see arformoterol

Fremanezumab-vfrm (Ajovy®) – see erenumab

Gabapentin (Neurontin®)

Formulary diagnoses:

- Neuropathy

Use criteria:

1. Approved for neuropathic pain after failure of either a SNRI (ex: duloxetine) OR a tricyclic antidepressant (ex: amitriptyline).
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.

Galcanezumab (Emgality®) – see erenumab

Gemfibrozil (Lopid®)

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

Glycopyrrolate/formoterol (Bevespi Aerosphere®)

1. COPD: Patients must have failed monotherapy with anticholinergic agent tiotropium (Spiriva®) or meet criteria defined by GOLD guidelines: “Group B”: 0-1 moderate exacerbations not leading to hospital admission/year, modified Medical Research Council dyspnea questionnaire (mMRC) >/=2, and COPD Assessment Test (CAT) >/=10), or “Group E”: >/=2 moderate exacerbations not leading to hospital admission/year, or at least 1 exacerbation leading to hospitalization/year
2. ASTHMA: Only to be used as part of a combination product with inhaled corticosteroid. 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.
3. Non-formulary requests for LABA/LAMA that meet criteria will be approved for most cost-effective agent.

Golimumab (Simponi®)

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 clinically-indicated 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. $\geq$ 10% BSA is affected (Severe CPP) OR
    d. At least $\geq$ 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.

Griseofulvin

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.

Hemorrhoidal rectal cream/ointment (Preparation H®)

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.

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.

Hydrocortisone cream, ointment 0.5%

1. For Psoriasis: lesions interfere with function

2. For Psoriasis: Psoriasis affects >10% of BSA (refer patients to commissary for mild psoriasis) OR crucial body areas (hands, feet, face etc.)

Hydrocortisone cream, ointment 1%

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.)

Hydrocortisone w/ or w/o pramoxine rectal cream/foam/lotion (, Anusol®, Proctosol HC®, Proctozone HC®, Pramosone®, Proctofoam HC®, Analpram HC®) – see Hemorrhoidal rectal cream/ointment

Hydroxyzine (Atarax®, Vistaril®)

Formulary Diagnoses (tablet only):

- Malignancy
- Dialysis
- ESRD

Use Criteria:

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

Iloprost (Ventavis®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Infliximab (Remicade®)

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

Infliximab biosimilars (Renflexis®, 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. $\geq$ 10% BSA is affected (Severe CPP) OR
    d. At least $\geq$ 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.

Insulin aspart and biosimilars (Fiasp®, Novolog®)

Formulary diagnoses:

- Presence of insulin pump

Use Criteria:

1. Unable to achieve glycemic control targets with the use of multiple insulin dosing regimens (including use of regular insulin, and use of highly intensive insulin such as QID administration). Provide the insulin regimens trialed and times of administration.
3. Patient is able to eat a meal immediately (within 15 minutes) after use of rapid-acting insulin.

Insulin aspart w/ protamine (Novolog 70/30®)

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.

Insulin degludec (Tresiba®)

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 detemir (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 glulisine (Apidra®)

1. Unable to achieve glycemic control targets with the use of multiple insulin dosing regimens (including use of regular insulin, and use of highly intensive insulin such as QID administration). Provide the insulin regimens trialed and times of administration.
2. Patient is able to eat a meal immediately (within 15 minutes) after use of rapid-acting insulin.
3. Insulin pump: insulin aspart or insulin lispro are preferred.

Insulin lispro and biosimilars (Humalog®) – see Insulin Aspart

Interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), pegylated interferon beta-1a (Plegridy®) – see alemtuzumab

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.

Itraconazole (Tolsura®, Sporanox®)

Formulary diagnoses (100mg capsule only)

- Blastomycosis
- Histoplasmosis
- Aspergillosis

Use Criteria

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.

Ketoconazole oral (Nizoral®)

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.

Ketoconazole shampoo (Nizoral®)

1. Documented failure of OTC commissary selenium sulfide, coal tar shampoo, clotrimazole, AND miconazole 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.

Lacosamide (Vimpat®)

1. Prescribed for the treatment of focal seizures or generalized seizures AND
2. Recommended by a neurologist AND
3. Patient has failed adequate trial of two or more formulary antiepileptics.

lebrikizumab-lbkz (Ebglyss®)

1. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE high potency/class 1 topical corticosteroids AND at least ONE topical calcineurin inhibitor AND
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
    e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Lecanemab (Leqembi®)

1. Failure of a cholinesterase inhibitor.

Levocetirizine (Xyxal®)

1. Chronic idiopathic urticaria (consider other formulary H2 blockers such as doxepin).
2. Non-formulary use approved via DIRECTLY OBSERVED THERAPY ONLY for cyproheptadine.

3. **Urticaria:** Classified according to etiology or precipitating factor. All potential precipitating factors have been considered and controlled.
4. **Urticaria:** IgE levels and/or absolute eosinophil count in conditions where this is typically seen.
5. **Urticaria:** Documented failure (ensuring compliance) of steroid pulse therapy (i.e. prednisone 30mg daily for 1 to 3 weeks). **Be aware of any contraindication to steroid use (i.e. bipolar disorder)**.

Levofloxacin

Formulary diagnoses:

- Prostatitis
- Neutropenia
- Rectal abscess
- Pseudomonas
- Salmonella
- Pyelonephritis
- Diverticulitis
- Epididymitis
- Orchitis

Use criteria:

1. UTI
    a. Complicated (e.g., obstruction, reflux, azotemia, transplant) or catheter associated OR
    b. For acute cystitis, first-line therapy with sulfamethoxazole/trimethoprim and nitrofurantoin have failed or are contraindicated.
2. Pneumonia
    a. Patient has risk factors for pseudomonas or MRSA. Comorbidities present (chronic heart, lung, liver, or renal disease; diabetes; alcohol use disorder; neoplastic disease, asplenia) OR
    b. Antibiotic use within the past 3 months.
3. COPD exacerbation
    a. Patient has risk factors for poor outcome (age greater than 65 years, FEV1 < 50%, recent hospitalization or antibiotic use, history of pseudomonas infection, more than 1 exacerbation in past 12 months).
    b. Patient has contraindications to azithromycin or cefdinir.
4. Acute sinusitis
    a. Patient has clinical failure after 3 days of empiric antibiotic treatment (persistent sinus pain, nasal congestion, purulent nasal discharge, and/or fever despite recommended therapy).
5. Otitis media
    a. Patient has had antibiotics in the previous month AND a has documented penicillin allergy OR
    b. Patient has clinical failure after 3 days of empiric antibiotic treatment (no change in ear pain, fever, bulging tympanic membrane, or otorrhea) AND has a documented penicillin allergy.
6. H. pylori
    a. Patient has failed both first-line treatment options (per current guidelines) OR
    b. Prescribed along with amoxicillin and omeprazole for 14 days at appropriate doses.
7. For biopsy/procedure: Please indicate if use for biopsy/procedure, if recommended by specialist, and date of procedure (if known).

8. For use based on available culture and sensitivity results: Susceptible to fluoroquinolone and intermediate or fully resistant to all other formulary options.

Levonorgestrel intrauterine device (Kyleena, Liletta®, Mirena®, Skyla®)

1. Request is for continuity of care for patient who entered BOP custody with this IUD already in place. (Patients entering the BOP with these devices in place must have the product name and expiration/replacement date documented in the health record. These devices may be removed upon expiration or sooner at the patient's request). OR
2. The primary indication for initiating this treatment is for the medically necessary management of the patient's medical condition (example: abnormal uterine bleeding) and not for the indication of contraception alone AND
3. Oral hormonal tablets and depot medroxyprogesterone have been tried and were not effective, were not tolerated, or are contraindicated for the patient AND
4. The patient's future reproductive plan aligns with the years-long contraception provided by the IUD
5. Levonorgestrel 19.5mg and 13.5mg IUD are indicated for contraception only and are not approved for initiation in the BOP.
6. If above criteria are met, request will be approved for the most cost-effective IUD at time of request.

Levonorgestrel oral (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.

Linaclotide (Linzess®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

Linagliptin (Tradjenta®) – see alogliptin

Linezolid (Zyvox®)

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

Liraglutide (Victoza®, Saxenda)

1. May be approved for type 1 diabetes for comorbid conditions, not primarily for glycemic control.

2. WEIGHT LOSS -- INITIAL REQUEST:
    a. Body Mass Index (BMI) > 35 kg/m2 or BMI > 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, chronic kidney disease, heart failure with preserved ejection fraction, previous myocardial infarction or stroke, symptomatic peripheral vascular disease, obstructive sleep apnea, osteoarthritis, metabolic dysfunction-associated steatotic liver disease (MASLD), AND
    b. 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
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
    d. Initial trial will be issued for 180 days with tirzepatide preferred.
3. WEIGHT LOSS -- POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.
4. MASH (non-cirrhotic metabolic dysfunction-associated steatohepatitis, with moderate to advanced liver fibrosis consistent with stages F2 to F3 fibrosis)

Lisdexamfetamine (Vyvanse®) – see amphetamine/dextroamphetamine

Loratadine (Claritin®)

Formulary diagnoses:

- Asthma
- Chronic sinusitis
- COPD

Use Criteria:

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.

Lorazepam (Ativan®)

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

Lubiprostone (Amitiza®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

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.)

Macitentan (Opsumit®), macitentan/tadalafil (Opsynvi®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is prescribed a phosphodiesterase-5 inhibitor, unless contraindicated or not tolerated.
3. Requests for endothelin receptor antagonists will be approved for ambrisentan, unless justification is provided for why this agent cannot be used.

Maraviroc (Selzentry®)

1. Regimen has been established in consultation with Regional HIV Consultant Pharmacist, expert consultation service or Regional Medical Director.
2. Patient must be highly treatment-experienced.
3. HAART selection must be directed by appropriate resistance testing.
4. The ability exists to construct a HAART regimen to include: 3 active and proper antiretroviral drugs or, at least 1 active drug plus an appropriate antiretroviral drug combination with some residual activity.
5. All supporting documents must be attached to include, at a minimum, copies of all available viral loads and CD4 counts, copies of all available resistance tests, description of all known previous HAART regimens, assessment of patient's adherence to HAART, and the complete HAART regimen being requested.

6. Maraviroc requests must include results of the CCR5 co-receptor tropism assay.
7. None of the antiretroviral drugs of the new / proposed HAART regimen should be started until the non-formulary requests are approved.(same as other HIV medications)

Memantine XR (Namenda® XR)

1. Failure of, or contraindication to, immediate release memantine.

Metaxalone (Skelaxin®) – see baclofen

Methadone (Dolophine®)

In the treatment of Opioid Use Disorder, the following use criteria apply:

1. Intake:
    a. Receipt of methadone for treatment of opioid use disorder has been confirmed by the prior OTP through outside medical records or contact with the prior OTP.
    b. Ordering provider must have ordering rights for methadone or a TO/VO has been obtained from a provider with methadone ordering rights.
    c. For continuation upon intake, request will be approved by Regional Chief Pharmacist for 30 days pending initial evaluation if appropriate.
2. Initiation:
    a. Patient has documented diagnosis of opioid use disorder and/or opioid dependence.
    b. Ordering provider must have ordering rights for methadone.
    c. Documentation in BEMR of plans for continuity of care after release.
    d. Must also meet at least one of following:
        i. Patient is pregnant and prefers use of methadone over buprenorphine.
        ii. Patient has clearly documented serious allergy and/or side effect to buprenorphine in the FBOP.
        iii. Patient has clearly documented failure (e.g., severe opioid cravings, objective signs of opioid withdrawal, and/or continued use of illicit opioids to supplement treatment, etc.) in the FBOP with consistent compliance with the following:
            1. Buprenorphine sublingual up to 24 mg daily > 2 months.
            2. Appropriate dosing of long-acting buprenorphine injection > 4 months.

Methocarbamol (Robaxin®) – see baclofen

Methotrexate auto-injector (Rasuvo ®, Otrexup®)

1. Oral methotrexate dose is at least 15 mg/week and is not effective OR not tolerated
2. Recommended by a rheumatologist
3. Institution does not have access to proper controls to prepare and administer more cost-effective methotrexate injection from a vial.
4. Requests shall be approved for the least expensive autoinjector product (ex. Rasuvo, Otrexup).

Methotrexate sodium injection

1. Hazardous antineoplastic drug. Does your institution have appropriate ventilated controls for preparation? If no, recommend using prefilled-autoinjector product instead for non-oncology uses.

Methyl salicylate / menthol external cream (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.
4. Diclofenac gel 3% will not be approved without sufficient justification why 1% cannot be used.

Methylphenidate (Ritalin®, Concerta®, Daytrana®) – see amphetamine/dextroamphetamine

Metoclopramide (Reglan®)

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

Minocycline, oral

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Mirabegron (Myrbetriq®)

1. Documented failure of, contraindication to, or inability to utilize 12-week trials (with compliance) of all formulary anti-muscarinic agents – oxybutynin IR or ER, tolterodine, AND solifenacin IR.

Mitoxantrone (Novantrone®) – see alemtuzumab

Moisturizers, topical (Aquaphor®, Eucerin®, Lubriderm®, Vanicream®, Cerave®, etc.)

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.

Modafanil (Provigil®)

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

Mometasone nasal spray (Nasonex®)

Formulary Diagnoses:

- Asthma
- Chronic sinusitis
- COPD

Use Criteria – see beclomethasone nasal spray

Mometasone/formoterol INH (Dulera®) – see budesonide/formoterol for use criteria

Monomethyl fumarate (Bafiertam®) – see alemtuzumab

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.

Multivitamins, general

Formulary Diagnoses:

- Bariatric surgery

Use Criteria:

1. Dialysis patient (BC Plex, Dialyvite, Nephrovite)
2. Pregnant patient (prenatal vitamins)
3. Patient undergoing active detoxification for substance abuse
4. Patient has a malnutrition/ malabsorption disorder

Multivitamin, eye (AREDS®, AREDS2®, Ocuvite®, I-Caps®, I-Vite®)

Formulary Diagnoses (AREDS and AREDS2 only):

- Macular degeneration

Use Criteria:

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.

Naltrexone/bupropion (Contrave®)

1. Failure of all non-controlled substance alternatives for weight loss.

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

Formulary Diagnoses:

- Keratoconus

Use Criteria:

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

Natalizumab (Tysabri®) – see alemtuzumab

Nemoluzimab (Nucala®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Netarsudil (Rhopressa®) ophthalmic solution

1. Diagnosis of open-angle glaucoma or ocular hypertension AND
2. Initiated by optometrist or ophthalmologist with ongoing evaluation AND
3. Inadequate response/failure of three formulary agents (e.g., latanaprost, dorzolamide/timolol (or individual agents), brimonidine).

Nutritional Supplements

Formulary Diagnoses (standard only):

- Gastrostomy
- Palliative care
- Facial fractures
- Surgical extraction

Use Criteria:

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.

Ocrelizumab (Ocrevus®) – see alemtuzumab

Ocrelizumab/hyaluronidase (Ocrevus Zunovo®)

1. Prescribed by, or in consultation with, a neurologist or other appropriate specialist for the treated disease state.
2. Confirmed diagnosis of relapsing forms of multiple sclerosis including clinically isolated syndrome, relapsing-remitting disease, and active secondar progressive disease.

Ofatumumab (Kesimpta®) – see alemtuzumab

Olanzapine IM (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.

Olmesartan (Benicar®), olmesartan/HCTZ (Benicar HCT®)

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

Olodaterol (Striverdi®) – see arformoterol

Omalizumab (Xolair®)

1. ASTHMA
    a. The patient has persistently uncontrolled asthma after a reasonable trial of high-dose ICS/LABA and antileukotriene (e.g., montelukast).
    b. The patient completed observed inhaler technique with correction as needed.
    c. The patient has severe uncontrolled asthma with an allergic component confirmed via positive skin tests or in vitro reactivity to a perennial allergen.
    d. Pre-treatment serum IgE is 30 to 700 IU/mL
2. ATOPIC DERMATITIS
    a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
    b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
    c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
        i. High potency/class 1 topical corticosteroids
        ii. Topical calcineurin inhibitor
    d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.

   e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.
3. URTICARIA
   a. Documented chronic or spontaneous idiopathic urticaria for 6 weeks or longer.
   b. Insufficient symptom relief after adequate trials of each of the below agents, documented in BEMR or via commissary sales within the last 90 days.
      i. TWO second generation antihistamines titrated up to the maximum daily dose as tolerated,
      ii. AND an H_2 antagonist,
      iii. AND a first-generation antihistamine or doxepin at bedtime.
4. SINUSITIS:
   a. Documented chronic rhinosinusitis with nasal polyps and failure of adequate trial of intranasal corticosteroids.
   b. Pre-treatment serum IgE level 30 to 1,500 IU/mL.
5. FOOD ALLERGIES:
   a. Documentation of IgE mediated severe food allergies that cannot be mitigated through avoidance.
   b. Pre-treatment serum IgE level 30 to 1,850 IU/mL
   c. Omalizumab is NOT indicated for emergency treatment of allergic reactions, including anaphylaxis. Patient must have a concomitant order for an epinephrine auto-injector.
6. ALL indications: Omalizumab recommended by a specialist. (Please upload in Document Manager.)

Omega-3 Fatty Acid Esthers (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.

Orforglipron (Foundayo®)

1. WEIGHT LOSS -- INITIAL REQUEST:
   a. Body Mass Index (BMI) > 35 kg/m2 or BMI > 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, chronic kidney disease, heart failure with preserved ejection fraction, previous myocardial infarction or stroke, symptomatic peripheral vascular disease, obstructive sleep apnea, osteoarthritis, metabolic dysfunction-associated steatotic liver disease (MASLD), AND
   b. 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
   c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
   d. Initial trial will be issued for 180 days with tirzepatide or orflorglipron preferred.

2. WEIGHT LOSS -- POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.

Orlistat (Xenical®, Alli®)

1. INITIAL REQUEST:
    a. Body Mass Index (BMI) ≥ 30 kg/m2 or BMI ≥ 27 kg/m2 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
    b. 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
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate
2. POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved.
    b. Has patient lost = or > than 5% of body weight from baseline? If not, requests for renewal will not be approved.

Orphenadrine (Norflex®) – see baclofen

Oseltamivir Phosphate (Tamiflu®)

1. Use within 48 hours of symptom onset.
2. May be initiated more than 48 hours after symptom onset but no more than five days after symptom onset for patients that may progress to requiring hospitalization and for pregnant patients (of any trimester)
3. Non-Formulary Drug requests will be processed and expedited through Central Office and should not delay initiation within 48 hours of symptom onset when all other criteria are met.
4. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator, Region and Central Office and approved by the BOP Medical Director for treatment.

Over-the-Counter-Medications (OTC) *unless otherwise specified*

1. Patient is indigent, treatment is medically necessary, AND has failed OTC indigent program alternatives. Orders are limited to [60 days or 30 days *dependent on drug*] in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.

Oxcarbazepine (Trileptal®)

Formulary diagnoses:

- Epilepsy and recurrent seizures
- Trigeminal nerve disorder
- Postherpetic trigeminal neuralgia

Use Criteria:

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, TCAs and gabapentin.
3. Consider a directly-observed therapy restriction (pill-line only) for patients with a history of medication misuse.

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.

Ozanimod – see alemtuzumab

Paliperidone Palmitate ER (Invega Halfyera®)

1. Patient has been stable for at least 4 months on paliperidone palmitate ER (Invega Sustenna®) OR at least 1 month on paliperidone palmitate ER (Invega Trinza®) AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care

Paliperidone Palmitate ER (Invega Sustenna®, Erzofri®)

1. Patient is stable on oral paliperidone, oral risperidone, or long-acting risperidone AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care.

Paliperidone Palmitate ER (Invega Trinza®)

1. Patient has been stable for at least 4 months on paliperidone palmitate ER (Invega Sustenna®) AND
2. Inadequate response to risperidone long-acting injection (Risperdal Consta®)
3. Requests for patients stabilized on paliperidone palmitate ER will be approved for continuity of care

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

Pegfilgastim (Neulasta®) and biosimilars

Formulary diagnoses (pegfilgastim-bmez, Ziextenzo® only):

- Lymphoma
- Melanoma
- Neoplasm
- Carcinoma

Use Criteria:

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

Perfluorohexyloctane ophth solution (Miebo®)

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND,
2. For a pathological or structural abnormality (i.e., conditions that limit full blinking or eyelid closure) leading to chronic dry eye that is medically necessary AND,
3. A documented tear film break-up time (TBUT) of ≤ 5 seconds, AND
4. Failed trial of any artificial tear product AND,
5. Failed lipid-based artificial tear product (example: Carboxymethylcellulose/glycerin 0.5-0.9% or mineral oil/light mineral oil 1-4.5%), AND
6. Failed adequate trial of cyclosporine 0.05%.

Petrolatum, White (Gel, Jelly, Ointment)

Formulary diagnoses:

- Diabetes mellitus
- Dialysis

Use Criteria:

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.

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, Phentermine/Topiramate ER (Qsymia®)

1. Failure of all non-controlled substance alternatives for weight loss.

Plecanatide (Trulance®)

1. Treatment is for chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS C).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (e.g. polyethylene glycol, lactulose).
3. If appropriate, will be approved for most cost-effective agent between lubiprostone, linaclotide, and plecanatide.
4. Approval for lubiprostone in IBS-C will be limited to female patients.

Ponesimod (Ponvory®) – see alemtuzumab

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).

Prucalopride (Motegrity®)

1. Treatment is for chronic idiopathic constipation (CIC).
2. Failure of or intolerance to adequate trials of fiber supplement AND osmotic laxative (i.e., polyethylene glycol, lactulose).
3. Failure of or intolerance to adequate trials of lubiprostone, linaclotide, AND plecanatide.

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 Sulfate

1. Non-formulary 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 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)

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)

1. For migraine prevention: Documented failure of, contraindication to, or inability to utilize 8-week trials of at least 1 formulary option each from the beta-blockers and anticonvulsants classes
2. For migraine treatment: Documented failure of, contraindication to, or inability to utilize all formulary options (e.g., triptans)
3. For both migraine prevention and treatment, recommended by a neurologist.

Riociguat (Adempas®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension AND
2. May be considered as an alternative to PDE-5 inhibitor in intermediate-low risk patients not reaching goal on endothelin receptor antagonist plus phosphodiesterase-5 inhibitor.

Rivaroxaban (Xarelto®)

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

Salmeterol (Serevent®) – see arformoterol

Saxagliptin (Onglyza®) – see alogliptin

Scopalamine (Transderm Scop®)

Formulary diagnoses:

- Palliative care

Use Criteria:

1. Motion sickness refractory to oral formulation meclizine or dimenhydrinate OR
2. Surgery with anesthesia within 24 hours of first dose, approved up to 24 hours after surgery OR
3. Terminal secretions not otherwise managed with sublingual atropine

Selegeiline (Zelapar®, Emsam®)

1. For narcolepsy: Documented verification of the inmate's report, to include polysomnography obtained and provided.

2. For narcolepsy: Patient has failed non-pharmacologic management strategies.
3. For narcolepsy: Functional impairment with work assignment, institution security, academic needs.
4. For narcolepsy: Failed treatment with modafinil and fluoxetine (for cataplexy).

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.

Selexipag (Uptravi®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Semaglutide (Ozempic®, Wegovy)

Formulary diagnoses (Ozempic only):

- Diabetes, type II

Use Criteria:

1. May be approved for type 1 diabetes for comorbid conditions, not primarily for glycemic control.
2. WEIGHT LOSS -- INITIAL REQUEST:
    a. Body Mass Index (BMI) > 35 kg/m2 or BMI > 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, chronic kidney disease, heart failure with preserved ejection fraction, previous myocardial infarction or stroke, symptomatic peripheral vascular disease, obstructive sleep apnea, osteoarthritis, metabolic dysfunction-associated steatotic liver disease (MASLD), AND
    b. 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
    c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
    d. Initial trial will be issued for 180 days with tirzepatide preferred.
3. WEIGHT LOSS -- POST TRIAL REQUEST:
    a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved
    b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.
4. MASH (non-cirrhotic metabolic dysfunction-associated steatohepatitis, with moderate to advanced liver fibrosis consistent with stages F2 to F3 fibrosis)

Sildenafil (Revatio®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Simponimod (Mayzent®) – see alemtuzumab

Sitagliptin (Januvia®) – see alogliptin

Sodium zirconium cyclosilicate (Lokelma®)

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 patient has Chronic Kidney Disease (CKD), consultation with nephrology

Sotatercept (Winrevair®)

1. Patient under the care of a specialist for the treatment of pulmonary hypertension AND
2. Patient is stabilized on dual or triple therapy for pulmonary arterial hypertension for at least 30 days AND
3. Risk factors for bleeding have been considered and addressed, including evaluating the continued need for drugs that increase bleeding risk.

Sunscreen (various formulations)

Formulary diagnoses:

- Basal cell carcinoma of skin
- Actinic keratosis

Use Criteria:

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.

Suzetrigine (Jounavx®)

1. Patients undergoing surgical procedure expected to result in moderate to severe pain AND
2. Failure of, contraindication to, or inability to utilize systemic NSAIDS, acetaminophen, opioids AND
1. Pregnancy must be excluded prior to receiving suzetrigine

Tacrolimus topical (Protopic®)

Formulary diagnoses:

- Psoriasis NOS
- Atopic Dermatitis

Use Criteria:

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.

Tadalafil (Adcirca®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Tears, artificial (gels, solutions, ointment)

Formulary diagnoses:

- Graft-versus-host disease
- Lagophthalmos
- Parkinson’s disease

- Presence of artificial eye
- Recurrent erosion of cornea
- Rheumatoid arthritis, unspecified
- Sjogren syndrome, UNS
- Systemic lupus erythematosus, unspecified
- Thyrotoxicosis w/o thyrotoxic crisis or storm (Grave's disease)

Use Criteria:

1. Initiated by an optometrist or ophthalmologist with ongoing evaluation AND
2. For a pathological or structural abnormality (i.e., conditions that limit full blinking or eyelid closure) leading to chronic dry eye that is medically necessary.

Telmisartan (Micardis®)

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

Terbinafine oral (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.

Teriflunomide (Aubagio®)

Formulary diagnoses:

- Multiple Sclerosis

Use Criteria – see alemtuzumab

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

Use Criteria:

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. Laboratory AND clinical evidence of testosterone deficiency (e.g., fatigue, depression, mood swings; decrease in pubic hair, hematocrit etc.) is confirmed after the 6-month washout period.
5. Two baseline serum total testosterone levels of < 300 ng/dL within the last 12 months, at least 1 week apart, drawn fasting, between 8:00 a.m. and 10:00 a.m.

Tetracycline (Sumycin®, Achromycin V®)

(non-formulary for indications of acne)

1. Acne: Treatment of moderate or severe acne.
2. Acne: Failure of at least 2 topical agents.

Thickening Agents (Thick-It®, Thick-It #2®, Resource ThickenUp®, Simply Thick®)

1. Requires swallow study for approval.

Tiagabine (Gabitril®)

1. Prescribed as adjunctive treatment for focal seizures AND
2. Recommended by a neurologist AND
3. Patient has failed adequate trial of two or more formulary antiepileptics AND
4. Patient is currently/will be maintained on one or more additional first-line antiepileptics.

Ticagrelor (Brilinta®)

1. Documented failure of, contraindication to, or inability to utilize clopidogrel and prasugrel
2. Recommended by a cardiologist.

Tiotropium/olodaterol (Stiolto Respimat®)

Formulary Diagnoses:

- COPD

Use Criteria: – see glycopyrrolate/formoterol

Tipranavir (Aptivus®)

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

Tirzepatide (Mounjaro®, Zepbound®)

Formulary Diagnoses:

- Diabetes, type II

Use Criteria:

1. May be approved for type 1 diabetes for comorbid conditions, not primarily for glycemic control.
2. WEIGHT LOSS -- INITIAL REQUEST:
    a. Body Mass Index (BMI) > 35 kg/m2 or BMI > 27 kg/m2 with at least 1 weight-related comorbidity (e.g., hypertension, type 2 diabetes, dyslipidemia, chronic kidney disease, heart failure with preserved ejection fraction, previous myocardial infarction or stroke, symptomatic peripheral

vascular disease, obstructive sleep apnea, osteoarthritis, metabolic dysfunction-associated steatotic liver disease (MASLD), AND
   b. 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
   c. Completion of medication review to identify medications that can cause weight gain and change to alternatives when clinically appropriate AND
   d. Initial trial will be issued for 180 days with tirzepatide preferred.
3. WEIGHT LOSS -- POST TRIAL REQUEST:
   a. Has the patient been compliant with lifestyle interventions (i.e. participation in at-risk programs if available, commissary purchase review)? If not, requests for renewal will not be approved
   b. Has patient lost = or > than 5% body weight from baseline? If not, requests for renewal will not be approved.
4. MASH (non-cirrhotic metabolic dysfunction-associated steatohepatitis, with moderate to advanced liver fibrosis consistent with stages F2 to F3 fibrosis)

Tizanidine (Zanaflex®) – see baclofen

Topiramate (Topamax®)

Formulary Diagnoses:

- Migraine disorder

Use Criteria:

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).
5. Seizures: Prescribed for the treatment of generalized focal seizures or tonic-clonic seizures.

Tralokinumab (Adbry®)

1. ATOPIC DERMATITIS
   a. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
   b. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
   c. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE high potency/class 1 topical corticosteroids AND at least ONE topical calcineurin inhibitor AND
   d. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
   e. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Tramadol (Ultram®)

1. Approvals will be restricted to the IR formulation only. Tramadol IR must be administered crushed via pill line.

Treprostinil (Remodulin®, Tyvaso DPI®)

1. Patient is under the care of a specialist for the treatment of pulmonary hypertension.

Triamcinolone nasal spray (Nasacort®) – see beclomethasone nasal spray

Trospium (Sanctura®, Sanctura XR®) – see mirabegron

Ublituximab-xiiy (Briumvi®) – see alemtuzumab

Ubrogepant (Ubrelvy®) – see rimegepant

Umeclidinium-Vilanterol (Anoro Ellipta®) – see glycopyrrolate/formoterol

Upadacitinib (Rinvoq®)

1. Patient has been diagnosed with moderate to severe atopic dermatitis by a dermatologist AND
2. Self-management with fragrance-free moisturizers has been tried for at least 6 continuous weeks without symptom improvement AND
3. Patient has a contraindication to, intolerability to, or have failed at least 12 weeks of treatment with at least ONE medication in EACH of the following categories: AND
    a. High potency/class 1 topical corticosteroids
    b. Topical calcineurin inhibitor
4. Patients has an allergy, documented intolerance, or failure with an adequate trial of dupilumab or tralokinumab.
5. If all other criteria are met, the least costly biologic for the requested indication at the time of request will be approved.

Valbenazine (Ingrezza®)

1. TARDIVE DYSKINESIA
    a. Baseline Abnormal Involuntary Movement Scale (AIMS) score
    b. Documentation of specific involuntary movements (e.g., facial, oral extremity) and impact on functioning, quality of life, and social interactions
    c. Documentation of attempts to reduce or discontinue the offending dopamine receptor blocking agent or evidence that such an adjustment is not clinically feasible.
    d. Documented failure of, contraindication to, or inability to utilize tetrabenazine.

Vancomycin oral (Vancocin®)

Formulary Diagnoses:

- *C. difficile* infection

Vibegron (Gemtesa®) – see mirabegron

Vigabatrin (Sabril®)

1. Prescribed for the treatment of refractory complex partial seizures AND
2. Prescribed/recommended by a neurologist AND
3. Patient has failed adequate trial of three or more antiepileptics AND
4. Patient is properly enrolled in required REMS program AND
5. Initial request will be approved for 60 days pending initial evaluation.

Viloxazine ER (Qelbree®)

1. Preferred formulary agents for ADHD are atomoxetine, guanfacine, and desipramine.
2. Preferred non-formulary agents for ADHD are clonidine and bupropion.
3. Reserved for failure of adequate trials (confirmed compliance > 6 weeks) of ALL of the following medications: atomoxetine, atomoxetine plus guanfacine, atomoxetine plus clonidine, desipramine, and bupropion.

Vitamin A and D Ointment

Formulary Diagnoses:

- Kidney disease
- Type 2 diabetes mellitus with diabetic neuropathy
- Peripheral vascular disease
- Dialysis
- Type 1 diabetes mellitus with diabetic neuropathy

Use Criteria:

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®)

1. Use within 48 hours of symptom onset,
2. May be initiated more than 48 hours after symptom onset but no more than five days after symptom onset for patients that may progress to requiring hospitalization and for pregnant patients (of any trimester).
3. Per CDC, inhaled zanamivir is not recommended for people with underlying respiratory disease (e.g., asthma, COPD).
4. Non-formulary requests will be processed and expedited through Central Office and should not delay initiation within 48 hours of symptom onset when all other criteria are met.
5. 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.

Zonisamide (Zonegran®)

1. Prescribed for the treatment of partial-onset seizures AND
2. Prescribed/recommended by a neurologist AND
3. Patient has failed an adequate trial of two or more other antiepileptics.

Worksheet for Use of Nutritional Supplements

Patient Name:	**Register Number:**	**Institution:**
Date of Birth:	**Usual Body Weight (lb):**	
Weight(lb):	**Height(in):**	**Gender: M / F**

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 by 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 worksheet, along 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** include the following in the request:

- Pharmacy Name
- Pharmacy Phone Number
- Pharmacy Address
- RX # (if available)
- Any directions and/or ingredients if available.

Label Product per 2011 National P&T Minutes:

- Must enter order into BEMR with the BOP label referencing the medication name, filling pharmacy name, and statement that "patient 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 the compound in BEMR already?

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

Complete the **MASTER FORMULATION RECORD WORKSHEET** on the next page and submit to the BEMR Informatics team for addition to the National Drug File.

Complete the **COMPOUNDING RECORD WORKSHEET** on the following pages and store in Document Manager

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
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 Adverse Drug Reactions: _____

Urgent Care Cart and Kit Content

Non-MRCs are not authorized to stock medications in “column A” (Advanced Cardiac Life Support (ACLS) medications) unless approved through a policy waiver routed through the Regional Medical Director and approved by the BOP Medical Director. Medical Referral Centers (MRC) that want to utilize ACLS protocols as part of their emergency response may elect to stock their Urgent Care Cart with “A” list medications. MRCs stocking medications in Column A must have an appropriate written plan in their Institution Supplement. The plan should include verification of ACLS certification training requirements, equipment maintenance, and appropriately provisioned crash carts. All other institutions not approved to provide ACLS 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 (CD) in accordance with established protocols approved by the CD. Refer to the Program Statement **Patient Care** for additional guidance on emergency and urgent care.

Medication	MRCs and approved	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	
Epinephrine auto-injector 0.3	A	B
Furosemide injection	A	
Glucagon injection	A	B
Glucose paste/tabs	A	B
Haloperidol lactate inj 5mg/ml	A	B
Hydrocortisone OR methylprednisolone injection	A	B
Lactated Ringers	A	B
Lorazepam 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	
List continues on next page		

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		
Medication	**MRCs and approved Care 3**	**All others**
Albuterol Inhaler	A	B
Albuterol Solution	A	B
Charcoal	A	B
Diphenhydramine 50 mg injection	A	B
Nitroglycerin 50mg/10ml	A	

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.

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.

   e. 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**
   f. 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.

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.**")
The institution should develop a mechanism to inform the patient of the therapeutic change.
Local P&T meetings should periodically review substitution procedures for quality assurance.

Medication Dose Equivalency Guide by Drug Class

ACE Inhibitors	Generic Name	Dose Equivalents (mg/day)			
	Short-acting				
	Captopril	No sub	No sub	No sub	No sub
	Intermediate-acting				
	Benazepril	5	10	20	40
	Enalapril	5	10	20	40
	Moexipril	-	7.5	15	30
	Quinapril	5	10	20	40
	Ramipril	2.5	5	10	20
	Long-acting				
	Lisinopril	5	10	20	40
	Fosinopril	5	10	20	40
	Perindopril	2	4	4–8	8–16
	Trandolapril	–	1	2	4–8

Antipsychotic Long-Acting Injectables	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).					

Angiotensin Receptor Blockers	Generic name	Dose Equivalents (mg/day)	
	Candesartan	8	16
	Eprosartan	400	600
	Irbesartan	75	150
	Losartan	25	50
	Olmesartan	10	20
	Telmisartan	20	40
	Valsartan	40	80

Benzodiazepines	Generic name	Approximate Dose Equivalents
	Alprazolam	0.25
	Chlordiazepoxide	10
	Clonazepam	0.25 - 0.5
	Diazepam	5
	Lorazepam	1
	Oxazepam	15 - 30
	triazolam	0.25
	temazepam	10

Biologic Agents (Parent Compound)	Any VA Contract FDA-approved biosimilar corresponding to the originated parent biologic as found in the FDA Purple Book (https://purplebooksearch.fda.gov).

Bupropion	Formulation	Dose Equivalent & Frequency		
	Two Pill Lines			
	Bupropion XL	N/A	150mg QD	300mg QD
	Bupropion SR	100mg BID	N/A	150mg BID
	Bupropion IR	100mg BID	75mg BID	150mg BID
	Three Pill Lines			
	Bupropion XL		150mg QD	300mg QD
	Bupropion SR	100mg BID	150mg BID	
	Bupropion IR			

Corticosteroids (inhaled)	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

Corticosteroids (nasal)	Generic Name	Dose (*each nostril)*
	Fluticasone propionate	2 sprays daily
	Fluticasone furoate	2 sprays daily
	Beclomethasone	1–2 sprays BID
	Budesonide	1–4 sprays daily
	Ciclesonide	2 sprays daily
	Flunisolide	2 sprays BID/TID
	Mometasone	2 sprays daily
	Triamcinolone	1–2 sprays daily

Corticosteroids (topical)	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	01
		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

Corticosteroids (topical) ***Continued***	Potency	Generic Name	Dosage Form	Strength (%)
	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)	Alclometasone 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

ICS/LABA (inhaled corticosteroid /long-acting beta-agonist)	Generic Name	Low Daily Dose	Medium Daily Dose	High Daily 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

GLP-1 (glucagon-like peptide-1) agonists	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			
	Semaglutide (oral)	QD	3 mg	7 mg	14 mg		
	Exenatide	BID (twice daily)	5 mcg	10 mcg			

1. HMG-CoA Reductase Inhibitors (“Statins”)	Generic name	Dose Equivalents (mg/day)			
		Intensity	Low	Moderate	High
	Atorvastatin		--	10-20	40-80
	Fluvastatin		20-40	80	--
	Lovastatin		20	40-80	--
	Pitavastatin		--	1-4	--
	Pravastatin		10-20	40-80	--
	Rosuvastatin		--	5-10	20-40
	Simvastatin		10	20-40	--

SNRIs (serotonin and norepinephrine reuptake inhibitors)	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

SGLT2 (sodium-glucose cotransporter-2) inhibitors	Generic name	Initial dose (mg/day)	Maintenance dose (mg/day)
	Canagliflozin	100	300
	Dapagliflozin	5	10
	Empagliflozin	10	25
	Ertugliflozin	5	15

Naloxone Protocol & 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. Upon first encountering the situation, activate emergency response right away and if drug overdose cannot be ruled out:

- **Non-medical professionals** should immediately administer naloxone and if unconscious and unresponsive without a pulse, begin CPR.
- **Licensed medical professionals** should assess the individual, if in cardiac arrest, focus on providing high quality CPR and ask a second staff member, when one becomes present, to administer naloxone.

Note: there is minimal to no harm in administering naloxone to an individual who is not having an opioid overdose.

Formulation

Naloxone nasal spray 4mg/0.1ml, or equivalent is the product that will be purchased, stocked, and used by all FBOP employees 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 employees as determined by the FBOP National Formulary.

Administration

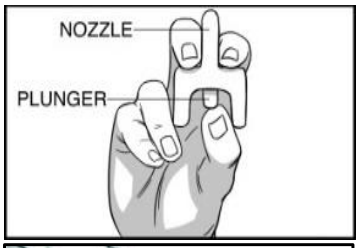
All FBOP employees who have successfully completed the required training are expected to administer naloxone for the treatment of known or suspected overdose.

Cautions and Contraindications

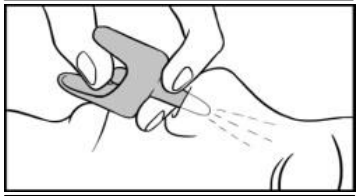
Pregnancy – Administration is permitted in pregnant females if overdose is suspected by the responder. Since administration of naloxone to the mother may cause opioid withdrawal in the fetus, medical personnel responding to the emergency must be notified of the pregnancy and administration of naloxone.

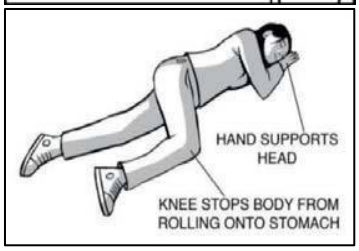
Breast feeding – It is unknown whether naloxone is excreted into human milk or the effects on a breast fed infant.

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











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. If pulseless, start or resume CPR. If there is a pulse and breathing, 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. Health Services employees document administration in BEMR.

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.

_____ _____

Dr. Elizabete Stahl, DO — Date

Medical Director

National Permitted Night Stock Items

For night stock items authorized at sites covered by Central Pharmacy Services (CPS), please refer to CPS procedures.

Pyxis Name
NS Acetaminophen 325 MG tablet 3 days (24)
NS Acyclovir 800 MG tablet 3 days (15)
NS Albuterol 8.5 GM Inhaler
NS Amlodipine 5 MG tablet 3 days (3)
NS Amoxicillin 500 MG capsule 3 days (9)
NS Amoxicillin dental 2 GM (4x500mg capsule)
NS Apixaban 5 MG tablet 3 days (6)
NS Aspirin 325 MG tablet 1 day (1)
NS Augmentin 875/125 MG tablet 3 days (6)
NS Augmentin 500 MG tablet 3 days (6)
NS Azithromycin 250 MG tablet (Z-Pak) (6)
NS Bisacodyl 5 MG tablet prep (4)
NS Carvedilol 6.25 MG tablet 3 days (6)
NS Carvedilol 25 MG tablet 3 days (6)
NS Cefuroxime 500 MG tablet 3 day (6)
NS Cephalexin 500 MG capsule 3 days (12)
NS Ciprofloxacin 500 MG tablet 3 days (6)
NS Clindamycin 300 MG capsule 3 days (12)
NS Clindamycin 150 MG capsule 3 days (24)
NS Clonidine 0.1 MG tablet 3 days (9)
NS Clonidine 0.1 MG weekly patch (1)
NS Clonidine 0.2 MG weekly patch (1)
NS Clopidogrel 75 MG tablet 3 days (3)
NS Cortisporin otic susp (10 mL)
NS Diclofenac 0.1% ophth soln (2.5 mL)
NS Doxycycline 100 MG tablet 3 days (6)
NS Erythromycin opth oint 3.5 GM
NS Furosemide 20 MG tablet 3 days (3)
NS Golytely oral powder for solution (4000 ML)
NS HIV PEP (bictegravir/TAF/FTC) 3 days (3)
NS Hydralazine 50 MG tablet 3 days (6)
NS Hydrochlorothiazide 25 MG tablet 3 days (3)
NS Ibuprofen 600 MG tablet 3 days (12)
NS Ibuprofen 800 MG tablet 3 days (12)
NS Levetiracetam 500 MG tablet 3 days (12)
NS Levofloxacin 500 MG tablet 3 days (3)

NS Levofloxacin 750 MG tablet 3 days (3)
NS Levonorgestrel 1.5 MG tablet (1)
NS Lisinopril 10 MG tablet 3 days (3)
NS Lisinopril 20 MG tablet 3 days (3)
NS Loperamide 2 MG capsule 3 days (6)
NS Methylprednisolone 4 MG tablet DosePak (21)
NS Metoprolol tartrate 25 MG tablet 3 days (6)
NS Metoprolol tartrate 50 MG tablet 3 days (6)
NS Metronidazole 500 MG tablet 3 days (9)
NS Naloxone nasal spray (2 pack)
NS Naproxen 500 MG tablet 3 days (6)
NS Nirmatrelvir/ritonavir 300/100 MG tablet 1 course (30)
NS Nitrostat 0.4 MG tablet sublingual bottle
NS Nitrofurantoin 100 MG capsule 3 days (6)
NS Ofloxacin 0.3% ophth soln (5 mL)
NS Ondansetron 8 MG tablet 3 days (6)
NS Oseltamivir 75 MG capsule 5 days (10)
NS Penicillin 500 MG tablet 3 days (12)
NS Permethrin 5% cream (60 GM)
NS Phenazopyridine 95 MG tablet 2 days (12)
NS Phenytoin 100 MG capsule 3 days (9)
NS Phytonadione 5 MG tablet (1)
NS PREA kit azithromycin/metronidazole combo 1 day
NS Prednisolone acetate 1% ophth soln 5 ML
NS Prednisone 10 MG tablet (48 dose pack)
NS Prednisone 20MG tablet 3 days (6)
NS Sulfamethoxazole/trimethoprim 800/160 MG tablet 3 days (6)
NS Thiamine 100 MG tablet 3 days (3)
NS Tobramycin 0.3% ophth soln (5 ML)
NS Triamcinolone 0.1% dental paste (5 GM)
Items expected to be stocked as unit dose due to variance in dosing
Warfarin
Ivermectin

Approved Over-the-Counter Medications for Inmates Without Funds

The following over-the-counter (OTC) medications may be supplied through pharmacy for inmates without funds (indigent). Per Program Statement **Over-the-Counter Medications**, local institutions may choose to utilize a list that is more, but not less, restrictive than this list. A list of all OTCs approved for sale in the commissary can be found under Page Resources on the BOP intranet – Trust Fund site. Institutions must follow the procedures outlined in this Program Statement when providing OTC medications to indigent inmates.

Over-the-Counter Item	Common Brand name	28-day Limit	Common Reason(s) for Use
Acetaminophen 325mg tablets	Tylenol	100 tablets	Pain, headache
Artificial tears		1 (15ml) bottle	Dry eyes
Calcium carbonate 500mg chewable tablets	Tums	150 tablets	Heartburn
Calcium polycarbophil 625mg tablets	Fiber-lax	60 tablets	Constipation
Clotrimazole 1% cream	Lotrimin	1 tube	Fungal skin infections
Coal tar shampoo 0.5%	T/Gel, MG217	1 bottle	Dandruff, seborrhea
Docusate 100mg capsules	Colace	100 capsules	Constipation
Famotidine 20mg	Pepcid	25 tablets	Heartburn
Hemorrhoidal cream	Preparation H	1 tube	Hemorrhoids
Hydrocortisone 1% cream		1 tube	Skin irritation, itching
Ibuprofen 200mg tablets	Motrin	100 tablets	Pain, headache
Loratadine 10mg tablets	Claritin	30 tablets	Allergies, itching
Miconazole 2% vaginal cream	Monistat7	1 tube	Vaginal yeast infection
Milk of Magnesia liquid		12 ounces	Constipation
Calcium Carbonate/Magnesium or aluminum hydroxide/simethicone liquid	Mylanta	12 ounces	Heartburn, gas, upset stomach
Omeprazole 20mg tablets/capsules	Prilosec	14 tablets/capsules	Heartburn
Selenium 1% shampoo	Selsun	1 bottle	Dandruff, seborrhea

BOP National Formulary Part II

For a complete list of medications, including, but not limited to, advisories, administration requirements, etc.:

Refer to BEMR RX Formulary Drug File Report