Summary of Formulary Changes Winter 2022 Meeting

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

The following is a summary of the major changes as a result of the Winter 2022 BOP Formulary meeting; please refer to the Winter 2022 National P&T minutes for additional information and detailed discussion regarding all of the changes. Revisions or changes from the previous year are highlighted in yellow throughout the document.

Topic	Final Action
Amoxicillin/clavulanate (Augmentin®) oral	**ADD** inclusionary diagnostic criteria
Azithromycin	**UPDATE** inclusionary diagnostic criteria
Brexpiprazole (Rexulti®) oral	**ADD** Non-formulary Use Criteria
Budesonide, glycopyrrolate, and formoterol inhalation (Breztri® Aerosphere)	**DO NOT ADD** **ADD** Non-formulary Use Criteria
Clopidogrel (Plavix®) oral	**RETAIN**
Coal tar shampoo, gel, solution (OTC)	**ADD** Non-formulary Use Criteria
Desiccated Thyroid Extract Oral Tablets (Armour Thyroid®, NP Thyroid®, Nature-Thyroid®, etc.)	**DO NOT ADD** advisory
Diltiazem injection	**DO NOT ADD** to the Urgent Care Cart and Kit Content List
Docusate Sodium Oral	**ADD** inclusionary diagnostic criteria **DELETE** restriction
Emtricitabine/tenofovir alafenamide (Descovy®)	**ADD** inclusionary diagnostic criteria **ADD** Non-formulary Use Criteria
Emtricitabine/tenofovir disoproxil (Truvada®)	**DELETE** restriction
Fluticasone furoate, umeclidinium, and vilanterol inhalation (Trelegy®)	**DO NOT ADD** **ADD** Non-formulary Use Criteria
Glycopyrrolate/formoterol inhalation (Bevespi®)	**DO NOT ADD** **ADD** Non-formulary Use Criteria
Hydrocortisone cream, ointment (OTC)	**ADD** Non-formulary Use Criteria
Infliximab (Remicade®) injection	**ADD** Non-formulary Use Criteria
Insulin (Concentrated) Injection	**DELETE**
Latanoprost (Xalatan®) ophthalmic solution	**DELETE** restriction
Levofloxacin (Levaquin®) Oral/Injection	**ADD** exclusionary diagnostic criteria
Lumateperone (Caplyta®) oral	**ADD** Non-formulary Use Criteria
Magnesium sulfate injection	**ADD** to the Urgent Care Cart and Kit Content List
Naloxone Nasal Spray (Narcan® Nasal Spray)	**DELETE** restriction (with contingency) **UPDATE** to 365-day order duration
Norepinephrine injection	**DO NOT ADD** to the Urgent Care Cart and Kit Content List
Omeprazole/sodium bicarbonate (Zegerid®) oral	**DO NOT ADD**
Ondansetron injection	**RETAIN** **DO NOT ADD** to the Urgent Care Cart and Kit Content List
Prasugrel (Effient®) oral	**ADD** Non-formulary Use Criteria
Ramelteon (Rozerem®) oral	**ADD** Non-formulary Use Criteria
Ticagrelor (Brilinta®) oral	**ADD** Non-formulary Use Criteria
Tiotropium/olodaterol inhalation (Stiolto®)	**ADD** with inclusionary diagnostic criteria **ADD** Non-formulary Use Criteria
TNF-α inhibitors injection (class)	**UPDATE** Non-formulary Use Criteria
Umeclidinium/vilanterol inhalation (Anoro Ellipta®)	**DO NOT ADD** **ADD** Non-formulary Use Criteria

National BOP Formulary Mission / Procedural Statement

Purpose:

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

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

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

Expectations:

1. ALL BOP institutions, including Medical Centers, are expected to abide by the formulary as outlined in the BOP Pharmacy Services Program Statement. It is expected that persons in the review process will NOT be circumvented in the event of a short-term absence for non-urgent requests.
2. ALL comments made on the request are expected to be medically appropriate and of a nature conducive to being placed in the medical record.
3. It is expected that non-urgent non-formulary medications will not be initiated until AFTER authorization is received, even if the medication is on the shelf from a previous request. Doing so can be deemed an unauthorized procurement.
4. Prescribers (BOP Physician / MLP / Dentist/ Clinical Pharmacist) are expected to thoroughly justify the request including why the formulary agent cannot be used and provide pertinent laboratory information. It is expected that non- formulary use criteria will be thoroughly addressed point by point and that all non-formulary justifications/criteria are met.
5. Clinical Directors are expected to support the BOP National Formulary and ensure compliance at their respective institution. The CD is expected to review all requests ensuring that appropriate justification and corresponding non- formulary use criteria are met. It is expected that the CD will allow the pharmacist to appropriately comment and provide pertinent information on the request even if not supportive. It is expected that the CD will disapprove, at the local level, any request which does not meet the non- formulary use criteria.
6. Institution Chief Pharmacists are expected to review all medication orders for formulary compliance. This will include reviewing all non-formulary requests for completeness and appropriate justification, and, if applicable, commenting on information provided by the prescriber regarding non-formulary use criteria. The pharmacist is also expected to provide pertinent information regarding patient compliance for formulary agents, drug cost information, and other comments as they pertain to the request.
7. Institution Administration (HSA, Associate Warden, and Warden) are expected to support and ensure compliance with the BOP National Formulary. Administrative decisions regarding medical care are expected to be consistent with the BOP National Formulary and not conflict with the medically necessary provision of medications and restrictions set forth in the BOP National Formulary.
8. Consultant Physicians are expected to utilize and stay within the guidelines of the BOP National Formulary when making recommendations and to provide specific and adequate justification if formulary medications cannot be utilized.
9. Court Orders: Court orders recommending or ordering specific treatments should be referred to the appropriate BOP attorney(s). All such orders/recommendations are still subject to the non-formulary approval process.
10. It is expected that all institution inventories and ordering procedures will be conducive to acceptable inventory practices (e.g., two-week par levels on the shelf maintained with weekly medication ordering).

Compliance:

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

Continuity of Care Provision:

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

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

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

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

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

Definitions/Rules

Formulary Rules

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

Compounding:

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

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

DEA Controlled Substances:

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

Directly Observed Therapy (DOT):

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

Epinephrine Auto-injector (Epipen®):

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

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

Icatibant acetate Auto-injector (Firazyr®):

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

FDA Medication Guides and Side Effects Statement

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

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

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

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

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

Over The Counter Medications

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

Medical Center Only

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

Medication Restrictions

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

Directly Observed Therapy (Formerly "Pill Line") Only

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

MLP Requires Cosign

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

Placebos - Statement on Use

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

References:

AMA "Placebo Use in Clinical Practice" statement:

"In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient- physician relationship, and result in medical harm to the patient".

ASHP "Ethical Use of Placebos in Clinical Practice" (1116) "To affirm that the use of placebos in clinical practice is ethically acceptable only when patients have been informed of and agree to such use as a component of treatment; …"

Look Alike/Sound Alike Medications

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

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

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

RESOURCES:

1. The Joint Commission http://www.jointcommission.org
2. Institute of Safe Medicine Practices https://www.ismp.org/
3. ISMP's List of Confused drug names https://www.ismp.org/recommendations/confused-drug-names-list
4. The Accreditation Association for Ambulatory Care https://www.aaahc.org/

Risk Evaluation and Mitigation Strategies (REMS)

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

Institution pharmacists/physicians should not sign any agreements without first being reviewed by the BOP Chief Pharmacist or designee. The BOP Chief Pharmacist/designee will consult with the BOP Office of General Counsel as appropriate. A list of current REMS drugs can be found at: http://www.accessdata.fda.gov/scripts/cder/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 some complex REMs medications from a single BOP Pharmacy. Institutions and providers should not obtain REMS medications from a non-BOP pharmacy until all internal processes are exhausted and Central Office Pharmacy staff has instructed them to do so.

Keep On Person (KOP), I.E. Self-Carry Medications

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

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

Non-Controlled Substances Restricted to Directly Observed Therapy

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

1. Tricyclic antidepressants
2. Muscle relaxants

****All items on this page are restricted to directly observed therapy administration.**
The pharmacy and therapeutics committee at each institution shall determine which additional medication(s) items are restricted to directly observed therapy. Health care professionals may also place specific patient orders on directly observed therapy.

****Any medications used to treat tuberculosis (including quinolones and other antibiotics not listed above) must be given by directly observed therapy.**

Non-Formulary Clinical Criteria/Justification Requirements, Algorithms, and Treatments

Acitretin (Soriatane®)

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

Adalimumab (Humira®) - See Immunomodulator TNF Inhibitors

Adult Attention Deficit Hyperactivity Disorder Medications: atomoxetine (Strattera®), guanfacine (Intuniv®), methylphenidate (Ritalin®), amphetamine/ dextroamphetamine (Adderall®/Dexedrine®)

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

Albiglutide (Tanzeum®) – See Glucagon-like Peptide 1 Receptor (GLP-1) Agonists

Alfuzosin (Uroxatral®)

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

Alirocumab (Praluent®) – See PCSK9 Inhibitors

Alogliptin (Nesina®) - See Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Amantadine (Symmetrel®)

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

Ammonium lactate lotion/cream

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

Analgesics Topical – capsaicin cream, diclofenac 1% (Voltaren®), salicylate/menthol (Bengay®)

1. Failed 30-day trial of oral NSAIDs or NSAIDs are contraindicated *AND*
2. Documented improvement in functional status (required for renewals) *OR*
3. Patient is indigent AND treatment is medically necessary. Orders are limited to 30 days in duration when approved on the basis of indigent status alone. If renewed, indigent status will be reassessed.
4. Diclofenac gel 3% will not be approved without sufficient justification why 1% cannot be used.

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

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

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

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

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

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

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

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

1. Diabetic or circulatory disorders evidenced by absence of pedal pulses and/or extremity hair loss due to poor circulation, or abnormal monofilament exam demonstrating loss of sensation, **OR**
2. Fungal nail infection (onychomycosis) with presence of secondary bacterial co-infection, **OR**
3. Patient is immunocompromised.
4. Onychomycosis requests meeting criteria will be approved for terbinafine (Lamisil®) 250 mg daily for 6 to 12 weeks for fingernails or toenails respectively.

Antifungals- Topical: clotrimazole, miconazole, terbinafine, tolnaftate

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

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

DIRECTLY OBSERVED THERAPY ONLY

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

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

Use must be approved by the BOP Chief Dietician

Apremilast (Otezla®, Celgene®)

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

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

Artificial tears - solution and ointment (various OTC formulations)

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

Ascorbic Acid (Vitamin C)

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

Asenapine (Saphris®)

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

Baclofen - See Muscle Relaxants

Benzoyl peroxide washes/soaps

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

Becaplermin (Regranex®)

1. Patients should have a recent glycosylated hemoglobin (hemoglobin A1C or HbA1C) less than 8. If not, aggressive control of their diabetes should be attempted.
2. Patients should be non-smoking or enrolled in a smoking cessation plan.
3. Stage III or IV (International Association of Enterostomal Therapy for staging chronic wounds) lower extremity diabetic ulcers that extend through the dermis into the subcutaneous tissue or beyond.
4. The wound must have an adequate blood supply measured by Oscillometry (at least 2 units), transcutaneous oxygen pressure (TcpO2 >30 mm Hg) or bleeding with debridement.
5. The wound must be free from infection.
6. If present, lower extremity edema should be treated.
7. The patient must have failed standard therapy for at least 2 months (careful/frequent debridement, moist dressing changes and non-weight bearing).
8. The provider must see the patient on a weekly to biweekly basis for debridement and assessment of ulcer response.
9. The provider must recalculate a new amount of becaplermin gel to be applied at every visit.

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

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

Bismuth Subsalicylate (Pepto Bismol®)

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

Brexpiprazole (Rexulti®)

1. Medication is being used to treat schizophrenia OR to treat refractory depressive disorder as an augmentation medication to an existing antidepressant
2. Schizophrenia: the patient had treatment failures with at least 3 other atypical antipsychotics (one of which MUST be aripiprazole unless contraindicated).
3. Refractory Depressive disorder: the patient had treatment failure with at least 3 other antidepressant augmentation strategies (one of which MUST be aripiprazole unless contraindicated)
4. The 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 (ADRs) (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% & 0.15% ophthalmic solution (Alphagan P®)

1. Documented allergy or sensitivity to brimonidine 0.2 ophthalmic Solution

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

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

Calcium carbonate (Tums®)

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

Canagliflozin (Invokana®)

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.
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.

Carbamide peroxide 6.5% ear drops (Debrox®)

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

Casirivimab-Imdevimab injection (REGEN-COV™)

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

Certolizumab (Cimzia®) - See Immunomodulator TNF Inhibitors

Cetirizine (Zyrtec®) – See Antihistamines

Cilostazol (Pletal®)

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

Clonazepam long-term use - See Benzodiazepines

Clonidine (Catapres®)

1. Dose taper over 2 to 4 days for arriving inmates taking greater than 1 mg per day. Refer to clonidine withdrawal guidance, particularly for patients on concomitant beta blocker therapy. Non-formulary request may be submitted after taper initiated.
2. Use in clozapine induced hypersalivation (CIH) after failure or contraindication to benztropine, amitriptyline, and alpha blocker. **NOTE:** Including combination therapy with benztropine and an alpha blocker for 12 weeks.

3. Use in Tourette's syndrome.
4. Not to be used in hypertensive urgencies/ emergencies. See Hypertensive clinical practice guidelines and 2006 National P&T Minutes, page 103.

Clonidine Discontinuation Guidance

Discontinuation of most any antihypertensive agent can lead to a corresponding withdrawal syndrome. However, this syndrome is most commonly seen with clonidine, beta-blockers, methyldopa, and guanabenz. The withdrawal syndrome is thought to be caused by sympathetic over activity and includes nervousness, tachycardia, headache, agitation, and nausea.

This is usually seen within 36 to 72 hours after cessation of therapy. In rare instances, a rapid increase in blood pressure to pre-treatment levels or above can be seen that could potentially lead to myocardial ischemia. Again, this is rare, especially when patients are not taking above the standard therapeutic doses of these agents. It also appears to occur more often when multiple medications are being withdrawn at the same time.
Abrupt discontinuation of clonidine, in particular those taking greater than 1 mg daily, may result in nervousness, agitation, restlessness, anxiety, insomnia, headache, sweating, palpitation, increased heart rate, tremor, hiccups, muscle pain, increased salivation, stomach pain, nausea and flushing. This may be due in part to the fact that clonidine has been shown to act upon opiate receptors. These effects generally appear within two to three hours after the first missed dose.

Blood pressure may increase in four to eight hours after the first missed dose of clonidine and is associated with a rise in catecholamine plasma concentrations. This potential may be exacerbated after administration of higher doses or continued concurrent therapy with a beta-blocker.
Severe blood pressure increases after clonidine discontinuation can be treated with the reinstitution of clonidine therapy followed by a short, gradual taper over two to four days; IV phentolamine +/- propranolol (propranolol should never be utilized alone as it may further elevate the BP); or utilization of a vasodilator such as hydralazine or diazoxide.

If a patient is taking clonidine concurrently with a beta-blocker, it is best to gradually withdraw the beta blocker, then withdraw the clonidine over two to four days. The beta-blocker can then be reinstituted after clonidine has been successfully withdrawn. Concurrent beta-blocker therapy may exacerbate an increase in blood pressure upon clonidine withdrawal.
Appropriate follow-up to including adjustment of medication management of all patients is essential during this process.

Coal Tar shampoo/gel/solution

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

COX-2 Inhibitors: celecoxib (Celebrex®)

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

Non-formulary Requests for COX-II inhibitors will ordinarily not be considered for approval for:
- Lack of response to traditional NSAIDs.
- Dyspepsia or GI intolerance to traditional NSAIDs.

- Patients receiving a proton pump inhibitor.
- Patients receiving low dose aspirin for cardiovascular prophylaxis.
- Patients with known cardiovascular disease.
- Dysmenorrhea.

Cyclobenzaprine (Flexeril®) - See Muscle Relaxants

Cyclosporine ophthalmic emulsion 0.05% (Restasis®)

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

Cyproheptadine (Periactin®) – See Antihistamines

Dapagliflozin (Farxiga®)

1. A) Patient has type 2 diabetes and established atherosclerotic cardiovascular disease OR heart failure OR chronic kidney disease (GFR>45 or Micro/Cr>300 mcg/mg Cr) AND A1C goal not met on maximum tolerated therapeutic dose of metformin or documented contraindication to metformin.
   B) Patient has NYHA functional class II, III, or IV heart failure with reduced ejection fraction AND is currently taking maximally tolerated doses of a beta blocker and renin angiotensin system antagonist plus diuretic and mineralocorticoid receptor antagonist if indicated.
2. If A1C is >9%, insulin is recommended for treatment of diabetes.
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.
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.

Darbopoetin Alfa (Aranesp®) – See Erythropoiesis Stimulating Agents (ESA's)

Dibucaine ointment - See Hemorrhoidal cream/ointment- (Preparation H®, Anusol ®, others), dibucaine ointment

Dicyclomine (Bentyl®)

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

Dietary/Herbal Supplements

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

Difluprednate (Durezol®)

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

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

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

Diphenhydramine (Benadryl®) - See Antihistamines

Docusate sodium

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

Dopaminergics for Restless Leg Syndrome: pramipexole (Mirapex®), ropinirole (Requip®)

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

Dulaglutide (Trulicity®) – See Glucagon-like Peptide 1 Receptor (GLP-1) Agonists

Dutasteride (Avodart®)

1. Second line agent for BPH, after failure of alpha blocker.
2. American Urological Association criteria (including symptom score, digital rectal exam, PSA test, urine outflow record) are submitted.
3. Finasteride is the 5-alpha-reductase Inhibitor of choice**

Empagliflozin (Jaridance®) - See Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors

Emtricitabine/tenofovir alafenamide (Descovy®)

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

Enfuvirtide (Fuzeon®) – See HIV Medication/Treatment

Erenumab-aooe (Amovig®)

1. Failure of migraine prophylaxis with TWO formulary agents. (ex. Amitriptyline, propranolol, verapamil etc.)

Ertugliflozen (Steglatro®) - See Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors

Erythropoiesis Stimulating Agents (ESA's): epoetin Alfa (Epogen®, Procrit®), epoetin alfa-epbx (Retacrit®), darbopoetin Alfa (Aranesp®)

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

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

Esketamine nasal solution (Spravato®)

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

Etanercept (Enbrel®) - See Immunomodulator TNF Inhibitors

Etravirine (Intelence®) – See HIV Medication/Treatment Evolocumab (Repatha®)

Exenatide (Byetta®), exenatide ER (Bydureon®) – See Glucagon-like Peptide 1 Receptor (GLP- 1) Agonists

Ezetimibe (Zetia®)

1. Ezetimibe 10mg 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 "intolerant" to all statins and/or when considering highest tolerable statin dose.

Febuxostat (Uloric®)

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

Fexofenadine (Allergra®) See – Antihistamines

Filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym®) See - Granulocyte Colony-Stimulating Factors (G-CSF's)

Fluticasone Oral inhaler (Flovent®)

Must fail two other inhaled corticosteroids with demonstrated compliance.

Fluticasone/Salmeterol (Advair®, Advair Diskus®, AirDuo Respiclick®, Wixela Inhub®) See - Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Fluticasone/vilanterol (Breo Ellipta®) See - Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Gabapentin (Neurontin®)

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

Recommended Gabapentin Taper

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

Gemfibrozil (Lopid®)

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

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

1. Patient has type 2 diabetes and established atherosclerotic cardiovascular 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. Semaglutide or dulaglutide are the preferred non-formulary agents.
5. Avoid in history of GI disorder (pancreatitis, gastroparesis, etc.); history or family history of thyroid cancer or neuroendocrine tumors, caution in diabetes retinopathy (semaglutide).
6. For patients with established heart failure or kidney disease a SGLT2 is preferred unless otherwise contraindicated or not tolerated.

Golimumab (Simponi®) - See Immunomodulator TNF Inhibitors

Granulocyte Colony-Stimulating Factors (G-CSF's): Filgrastim (Neupogen®), filgrastim-sndz (Zarxio®), filgrastim-aafi (Nivestym®) pegfilgrastim (Neulasta®), pegfilgrastim-jmdb (Fulphila®), pegfilgrastim- cbqv (Udenyca®), tbo-filgrastim (Granix®), pegfilgrastim-bmez (Ziextenzo®),

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

Hemorrhoidal cream/ointment- (Preparation H®, Anusol ®, others), dibucaine ointment

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

Hepatitis C Treatment Algorithm:

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

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

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

Hydrocortisone cream, ointment (OTC)

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

Hydroxyzine (Atarax®, Vistaril®) oral - See Antihistamines

Icosapent ethyl (Vascepa®)

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

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

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

Infliximab (Remicade®)

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

Infliximab abda (Renflexis®), infliximab dyyb (Inflectra®)– See Immunomodulator TNF Inhibitors

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

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

Insulin glargine, (Lantus®, Semglee®)

1. Recurrent episodes of symptomatic hypoglycemia despite multiple attempts with various insulin dosing regimens. Non-formulary request must include documentation of blood glucose values in the hypoglycemic range (i.e., MARs), and the insulin regimens used. **OR;**
2. Failure to achieve target HbA1C goals despite compliance with an intensive insulin regimen (3 to 4 injections / day) using NPH and regular. **NOTE:** The evening dose of NPH should be administered as close to bedtime as staffing and institution procedures permit.) Non-formulary request must include the insulin regimens used, an assessment of compliance (i.e., MARs) and a recent HbA1C result with date.

Insulin detemir, Long Acting Insulin (Levemir®)

1. Failure or contraindication to insulin glargine (Semglee®).
2. Recurrent episodes of symptomatic hypoglycemia despite multiple attempts with various insulin dosing regimens. Non-formulary request must include documentation of blood glucose values in the hypoglycemic range (i.e., MARs), and the insulin regimens used. **OR;**
3. Failure to achieve target HbA1C goals despite compliance with an intensive insulin regimen (3 to 4 injections / day) using NPH and regular. **NOTE:** The evening dose of NPH should be administered as close to bedtime as staffing and institution procedures permit.) Non-formulary request must include the insulin regimens used, an assessment of compliance (i.e., MARs) and a recent HbA1C result with date.

Insulin aspart/Insulin lispro, Rapid Acting Insulin (Novolog®/Humalog®)

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

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

Ipratropium bromide HFA (Atrovent HFA®)

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

Isotretinoin (Accutane®)

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

Ketoconazole oral

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

Lidocaine Topical Patches (Lidoderm®)

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

Linagliptin (Tradjenta®) – See Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Linezolid (Zyvox®)

1. IV vancomycin should be utilized when possible.
2. Case by case basis for transition of stable patients receiving IV vancomycin in hospital setting to institution which is unable to provide IV vancomycin.
3. Documentation of culture and sensitivity data must be submitted with non- formulary request.

Liraglutide (Victoza®; Saxenda®) - See Glucagon-like Peptide 1 Receptor(GLP-1) Agonists

Lixisenatide (Adlyxin®) - See Glucagon-like Peptide 1 Receptor (GLP-1)Agonists

Long Acting Beta Agonists (LABA): salmeterol (Serevent Diskus®)

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

Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS): budesonide/formoterol (Symbicort®), fluticasone/salmeterol (Advair®, Advair Diskus®, AirDuo Respiclick®, Wixela®), mometasone/formoterol (Dulera®), and fluticasone/vilanterol (Breo Ellipta®)

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

Long-Acting Beta-Agonist/ Inhaled Long-Acting Muscarinic-Antagonist (LABA/LAMA): glycopyrrolate/formoterol (Bevespi®), tiotropium/olodaterol (Stiolto®), umeclidinium/vilanterol (Anoro Ellipta®)

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

Long-Acting Beta-Agonist/Long-Acting Muscarinic-Antagonist/Inhaled Corticosteroid (LABA/LAMA/ICS): budesonide, glycopyrrolate, and formoterol (Breztri® Aerosphere), fluticasone furoate, umeclidinium, and vilanterol (Trelegy®)

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

Loperamide (Immodium®)

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

Loratadine (Claritin®) – See Antihistamines

Lorazepam long-term use - See Benzodiazepines

Loteprednol etabonate (Lotemax®, Alrex®)

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

Lumateperone (Caplyta®)

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

Lurasidone (Latuda®)

1. Request is in accordance with the Schizophrenia and/or Bipolar Clinical Guidance documents or has justification as to why prescribing is different from recommendations in clinical guidance.
2. If weight gain is a concern, patient must have documented failure with or contraindications to formulary weight neutral options (aripiprazole and ziprasidone). Dose and duration of failed treatments as validated via eMAR. Must specify why weight gain is concerning in this patient (e.g., comorbid medical conditions, notably elevated BMI, etc.)

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

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

Maraviroc (Selzentry®) – See HIV Medication/Treatment

Metaxalone (Skelaxin®) - See Muscle Relaxants

Metoclopramide (Reglan®)

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

Moisturizers topical (all formulations except Vitamin A&D)

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

Mometasone/formoterol (Dulera®) – See Long Acting Beta Agonists/Inhaled Corticosteroid (LABA/ICS)

Montelukast (Singulair®)

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

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

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

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

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

Naphazoline-pheniramine Ophthalmic drops (Visine-A®, Opcon A®)

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

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

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

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

1. Therapy is only to be offered to patients within 48 hours of exposure. Antiviral therapy is not effective or recommended 48 hours post exposure.
2. Non-Formulary Drug requests for TamiFlu® will be processed and expedited through Central Office.

3. Treatment requests for outbreaks, prophylaxis, and exposures will be conducted through the Infectious Disease Coordinator. Region, Central Office and approved by the BOP Medical Director for treatment.
4. **NOTE:** Stockpile antivirals may only be approved for use by the BOP Medical Director under certain conditions as proclaimed by the World Health Organization.

Nutritional Supplements for oral consumption

1. Request for its non-formulary use requires clinical justification from a BOP registered dietitian or completion of the "Nutritional Supplements Worksheet".
2. Failure of medical diets, special diets, and supplemental feeding options available through Food Service, **AND**
3. A documented medical diagnosis affecting nutritional status, **AND**
4. Nutritional Assessment Consult by BOP registered dietitian for therapy > 30 days.

Ocuvite/AREDS/I-Caps

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

Olanzapine pamoate intramuscular injection (Zyprexa® Relprevv™)

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

Omega-3 fatty acid (Lovaza®)

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

Onychomycosis, oral treatment - See Antifungals

Orlistat (Xenical®) (Alli® OTC) - See Anti-Obesity Agents

Oseltamivir (TamiFlu®) – See Neuraminidase inhibitors

Oxycodone Controlled Release (Oxycontin®)

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

Paliperidone palmitate ER (Invega Trinza®)

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

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

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

Pegfilgrastim (Neulasta®), pegfilgrastim-jmdb (Fulphila®), pegfilgrastim-cbqv (Udenyca®), pegfilgrastim-bmez (Ziextenzo®) – See Granulocyte Colony-Stimulating Factors (G-CSF's)

Phenobarbital (Luminal®)

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

Phentermine/Topiramate (Qsymia®) - See Anti-Obesity Agents

Potassium Lowering Agents: sodium zirconium cyclosilicate (Lokelma®), patiromer (Veltassa®)

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

Pramipexole (Mirapex®) – See Dopaminergics for Restless Leg Syndrome

Prasugrel (Effient®)

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

Pregabalin (Lyrica®)

1. Diabetic neuropathy - well documented as insufficient functional response to duloxetine plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
2. Postherpetic Neuralgia - well documented intolerance or insufficient functional response at maximally tolerated doses of tricyclic antidepressants and topical analgesics such as capsaicin cream

3. Fibromyalgia - documented diagnosis of fibromyalgia by rheumatologist. Documented insufficient functional response to duloxetine, plus at least one other medication from the tricyclic antidepressant or antiepileptic categories.
4. Partial onset seizures - well documented intolerance or insufficient response to at least two other agents (i.e., Carbamazepine, lamotrigine, levetiracetam, phenytoin, topiramate).

Protein Powder/Protein Liquid

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

Quetiapine (Seroquel®)

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

Quinine

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)

Ranolazine (Ranexa®)

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

Rifaximin (Xifaxan®)

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

Ropinirole (Requip®) – See Dopaminergics for Restless Leg Syndrome

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

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

Salmeterol (Serevent®) - See Long Acting Beta Agonists (LABA)

Saxagliptin (Onglyza®) – See Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Selenium shampoo/lotion

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

Semaglutide (Ozempic®) - See Glucagon-like Peptide 1 Receptor(GLP-1) Agonists

Simethicone tablets/capsules (Gas-X®)

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

Sitagliptin (Januvia®) – See Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors: empagliflozin (Jardiance®) and ertugliflozen (Steglatro®) – NOTE: See individual Use Criteria for Canagliflozin (Invokana®) and Dapagliflozin (Farxiga®)

1. Patient has type 2 diabetes and established atherosclerotic cardiovascular disease OR heart failure OR chronic kidney disease (GFR >45 or Micro/Cr> 300mcg/mg Cr) 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.
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.

Sunscreens (various formulations)

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

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

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

surgery. These agents may also be considered as a bridging option before resorting to surgery.

Tbo-Filgrastim (Granix®) – See Granulocyte Colony-Stimulating Factors (G-CSF's)

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

1. Evidence of bilateral orchiectomy, Klinefelter's syndrome, pituitary adenoma, hypothalamic adenoma, or other confirmed disease of the testes, pituitary or hypothalamus.
2. Testosterone supplementation is not approved or continued for unlabeled uses, e.g., strength training, increased libido.
3. A six-month washout period is required for patients with no confirmed disease of the testes, pituitary or hypothalamus.
4. Patient is experiencing significant withdrawal symptoms, e.g., anxiety, depression, mood swings during six-month washout period (60-day taper schedule).
5. Laboratory **AND** clinical evidence (decrease in energy, mood; decrease in sexual hair, hematocrit, muscle mass and strength, and bone mineral density) of testosterone deficiency is confirmed after the six-month washout period.

Ticagrelor (Brilinta®)

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

Tipranavir (Aptivus®) – See HIV Medication/Treatment

Topiramate (Topamax®)

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

Vancomycin, Oral (Vancocin HCI Pulvules®)

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

Vitamin A&D Ointment

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

Witch hazel & glycerin pads topical (Tucks® Pads)

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

Zanamivir (Relenza®) – See Neuraminidase Inhibitors