P&T Committee Changes
Effective 4/1/2023

As your Prescription Benefit Facilitator, BeneCard PBF is committed to providing the highest quality service, innovative clinical solutions, and valuable trend management strategies.

BeneCard PBF controls trend through several factors, including our unique pass-through model, generic maximization, clinical programs, and formulary management. The BeneCard PBF Pharmacy and Therapeutics (P&T) Committee continually reviews the latest information available to keep our clinical rules and programs up to date to improve care and reduce costs.

As a result of detailed discussions regarding each medication, its indications, FDA guidelines, and potential member safety issues, the following changes have been approved.

Additions to the Specialty Medication and Standard Clinical Review List

For your reference, we have included the Therapeutic Category as well as the medication use.

ADSTILADRIN (nadofaragene firadenovec-vncg)

- A non-replicating adenoviral vector-based gene therapy.
- Indicated for the treatment of adult patients with high-risk Bacillus CalmetteGuérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- It is administered by intravesical instillation once every three months.
- There are warnings for risk of muscle invasive or metastatic bladder cancer with delayed cystectomy and risk of disseminated adenovirus infection.

BRIUMVI (ublituximab)

- A recombinant chimeric monoclonal IgG1 antibody.
- Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- It is administered by intravenous infusion. First Infusion: 150 mg intravenous infusion; Second Infusion: 450 mg intravenous infusion administered two weeks after the first infusion; Subsequent Infusions: 450 mg intravenous infusion administered 24 weeks after the first infusion and every 24 weeks thereafter.
- There are contraindications in patients with active HBV infection, and a history of life-threatening infusion reaction to Briumvi.
- There are warnings infusion reactions, infections, fetal risk, and reduction in immunoglobulins.

ELAHERE (mirvetuximab soravtansine)

- A folate receptor alpha (FRα) -directed antibody and microtubule inhibitor conjugate.
- Indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.
- It is administered by intravenous infusion. Administer the initial dose at the rate of 1 mg/min. If well tolerated after 30 minutes at 1 mg/min, the infusion rate can be increased to 3

mg/min. If well tolerated after 30 minutes at 3 mg/min, the infusion rate can be increased to 5 mg/min.
- There is a black box warning for ocular toxicity.
- There are additional warnings for ocular disorders, pneumonitis, peripheral neuropathy, and embryo-fetal toxicity.

IMJUDO (tremelimumab)
- A cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody.
- Indicated in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC), and in combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- It is administered as an intravenous infusion.
- There are warnings for severe and fatal immune-mediated adverse reactions, infusion-related reactions, and embryo-fetal toxicity.

JAYPIRCA (pirtobrutinib)
- A kinase inhibitor.
- Indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
- It is administered orally once daily with water, with or without food. The dose should be reduced in patients with severe renal impairment.
- There are warnings for infections, hemorrhage, cytopenias, atrial fibrillation and atrial flutter, second primary malignancies, and embryo-fetal toxicity.

JESDUVROQ (daprodustat)
- A hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor.
- Indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.
    - It has not been shown to improve quality of life, fatigue, or patient well-being.
    - It is not indicated for use as a substitute for transfusion in patients requiring immediate correction of anemia or in patients not on dialysis.
- It is administered orally once daily with or without food.
- It is contraindicated in patients taking concomitant strong CYP2C8 inhibitors such as gemfibrozil and in patients with uncontrolled hypertension.
- There is a black box warning for increased risk of death, myocardial infarction, stroke, venous thromboembolism, and thrombosis of vascular access.
- There are additional warnings for risk of hospitalization for heart failure, hypertension, gastrointestinal erosion, serious adverse events in patients not on dialysis, and malignancy.

KRAZATI (adagrasib)
- An irreversible inhibitor of KRAS G12C.
- Indicated for the treatment of adult patients with *KRAS* G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
- It is administered orally at 600mg twice daily until disease progression or unacceptable toxicity.
- There are warnings for gastrointestinal adverse reactions, QTc interval prolongation, hepatotoxicity, and interstitial lung disease/pneumonitis.

LEQEMBI (lecanemab)

- An amyloid beta-directed antibody.
- Indicated for the treatment of Alzheimer's disease.
    - Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.
- It is administered as an intravenous infusion once every two weeks.
- There are warnings for amyloid related imaging abnormalities and infusion-related reactions.

LUNSUMIO (mosunetuzumab)

- A bispecific CD20-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
- It is administered as an intravenous infusion for 8 cycles, unless patients experience unacceptable toxicity or disease progression.
- There is a black box warning for cytokine release syndrome.
- There are additional warnings for neurologic toxicity, infections, cytopenias, tumor flare, and embryo-fetal toxicity.

NEXOBRID (anacaulase-bcdb)

- A mixture of proteolytic enzymes.
- Indicated for eschar removal in adults with deep partial thickness and/or full thickness thermal burns.
    - Safety and effectiveness have not been stablished for treatment of: chemical or electrical burns, burns on the face, perineum, or genitalia, burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease, circumferential burns, or burns in patients with significant cardiopulmonary disease, including inhalation injury.
    - NEXOBRID is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance.
- It is applied topically in up to two applications of 4 hours each, with the second application occurring 24 hours after the first application. Total body surface area (BSA) treated must not exceed 20%.
- It is contraindicated in patients with known hypersensitivity to pineapples or any other drug components.
- There are warnings for hypersensitivity reactions, pain management, proteolytic injury to non-target tissues, and coagulopathy.

ORSERDU (elacestrant)

- An estrogen receptor antagonist.
- Indicated for treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.
- It is administered orally once daily with food.
- There are warnings for dyslipidemia and embryo-fetal toxicity.

REBYOTA (donor human stool suspension)

- A fecal microbiota suspension.

- Indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI.
    - It is not indicated for treatment of CDI.
- It is administered rectally by a healthcare provider as a single dose 24 to 72 hours after the last dose of antibiotics for CDI.
- There are warnings for transmissible infectious agents, management of acute allergic reactions, and potential presence of food allergens.

REZLIDHIA (olutasidenib)

- An isocitrate dehydrogenase-1 (IDH1) inhibitor.
- Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
- It is administered orally twice daily on an empty stomach at least 1 hour before or 2 hours after a meal.
- There is a black box warning for differentiation syndrome.
- There is an additional warning for hepatotoxicity.

TECVAYLI (teclistamab)

- A bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
- It is administered by subcutaneous injection only. The recommended dosage of TECVAYLI is step-up doses of 0.06 mg/kg and 0.3 mg/kg followed by 1.5 mg/kg once weekly until disease progression or unacceptable toxicity.
- There is a black box warning for cytokine release syndrome and neurologic toxicity including immune effector cell-associated neurotoxicity syndrome.
- There are additional warnings for TECVAYLI REMS, hepatotoxicity, infections, neutropenia, hypersensitivity and other administration reactions, and embryo-fetal toxicity.

TZIELD (teplizumab-mzwv)

- A CD3-directed monoclonal antibody (humanized IgG1 kappa).
- Indicated to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with Stage 2 type 1 diabetes.
- It is administered by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing, once daily for 14 consecutive days.
- There are warnings for cytokine release syndrome, serious infections, lymphopenia, hypersensitivity reactions, and vaccinations.

Additions to the Standard Clinical Review List

For your reference, we have included the Therapeutic Category as well as the medication use.

FUROSCIX (furosemide)

- A loop diuretic.
- Indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure.
- Not indicated for emergency situations or in patients with acute pulmonary edema.

- It is administered as a single-use, on-body infusor for subcutaneous administration.
- It is not for chronic use and should be replaced with oral diuretics as soon as practical.
- It is contraindicated in patients with anuria, hypersensitivity to furosemide or medical adhesives, hepatic cirrhosis, or ascites.
- There are warnings for fluid, electrolyte, and metabolic abnormalities, worsening renal function, ototoxicity, and acute urinary retention.

LACRISERT (hydroxypropyl cellulose)

- A sterile, translucent, rod-shaped, water soluble, ophthalmic insert.
- Indicated in patients with moderate to severe dry eye syndromes, including keratoconjunctivitis sicca, especially in patients who remain symptomatic after an adequate trial of therapy with artificial tear solutions.
- It is inserted into each eye once or twice daily. One LACRISERT ophthalmic insert in each eye once daily is usually sufficient to relieve the symptoms associated with moderate to severe dry eye syndromes; some patients may require twice daily use for optimal results.
- There is a warning regarding closely following instructions for inserting and removing LACRISERT, due to risk for corneal abrasion.

TARPEYO (budesonide)

- A synthetic corticosteroid.
- Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.
- It is administered orally once daily, in the morning at least 1 hour before a meal for 9 months.
- There are warnings for hypercorticism and adrenal axis suppression, risks of immunosuppression, and other corticosteroid effects.

Additions to the Quantity Limit List

For your reference, we have included the generic name and dosage along with the appropriate quantity.

New Quantity Limits:

AIRSUPRA (Albuterol and budesonide Inh)

- 10.7 per 30 days

ALVESCO (Ciclesonide Inhal Aerosol)

- 6.1 per 30 days

AMJEVITA 20MG PEN (Adalimumab-atto Soln Auto-injector 20 MG/0.4ML)

- 0.8 per 28 days

AMJEVITA 20MG PFS (Adalimumab-atto Soln Prefilled Syringe 20 MG/0.4ML)

- 0.8 per 28 days

AMJEVITA 40MG PEN (Adalimumab-atto Soln Auto-injector 40 MG/0.8ML)

- 1.6 per 28 days

AMJEVITA 40MG PFS (Adalimumab-atto Soln Prefilled Syringe 40 MG/0.8ML)

- 1.6 per 28 days

AZELASTINE NASAL (Azelastine HCl Nasal Spray)
- 30 per 25 days

BEOVU PFS (Brolucizumab-dbll Intravitreal Soln Pref Syringe)
- 0.05 per 56 days

BEOVU SOLN (Brolucizumab-dbll Intravitreal Soln)
- 0.05 per 56 days

BRIUMVI (Ublituximab-xiiy Soln For IV Infusion)
- 18 per 168 days

BYOOVIZ (Ranibizumab-nuna Intravitreal Inj)
- 0.05 per 28 days

CLENPIQ (Sod Picosulfate-Mg Ox-Citric Ac Sol)
- 320 per 30 days

FUROSCIX (Furosemide Subcutaneous Cartridge Kit)
- 8 per 30 days

IMBRUVICA SUSP (Ibrutinib Oral Susp)
- 216 per 36 days

JAYPIRCA 50MG (Pirtobrutinib Tab 50 MG)
- 30 per 30 days

JAYPIRCA 100MG (Pirtobrutinib Tab 100 MG)
- 60 per 30 days

JESDUVROQ 1MG (Daprodustat Tab 1 MG)
- 30 per 30 days

JESDUVROQ 2MG (Daprodustat Tab 2 MG)
- 30 per 30 days

JESDUVROQ 4MG (Daprodustat Tab 4 MG)
- 30 per 30 days

JESDUVROQ 6MG (Daprodustat Tab 6 MG)
- 60 per 30 days

JESDUVROQ 8MG (Daprodustat Tab 8 MG)
- 90 per 30 days

LACRISERT (Artificial Tear Ophth Insert)
- 60 per 30 days

NEXOBRID (Anacaulase-bcdb Gel)
- 55 per 30 days

OLOPATADINE NASAL (Olopatadine HCl Nasal Soln)
- 30.5 per 30 days

OMLONTI (Omidenepag Isopropyl Ophth Soln)
- 2.5 per 30 days

ORKAMBI 75-94MG PACKET (Lumacaftor-Ivacaftor Granules Packet 75-94 MG)
- 56 per 28 days

ORKAMBI 100-125MG PACKET (Lumacaftor-Ivacaftor Granules Packet 100-125 MG)
- 56 per 28 days

ORKAMBI 100-125MG TABLET (Lumacaftor-Ivacaftor Tab 100-125 MG)
- 112 per 28 days

ORKAMBI 150-188MG PACKET (Lumacaftor-Ivacaftor Granules Packet 150-188 MG)
- 56 per 28 days

ORKAMBI 200-125MG TABLET (Lumacaftor-Ivacaftor Tab 200-125 MG)
- 112 per 28 days

ORSERDU 86MG (Elacestrant Hydrochloride Tab 86 MG)
- 90 per 30 days

ORSERDU 345MG (Elacestrant Hydrochloride Tab 345 MG)
- 30 per 30 days

OXYBUTYNIN SOLN (Oxybutynin Chloride Solution)
- 600 per 30 days

PEG-3350/ELECTROLYTES (PEG 3350-KCl-Na Bicarb-NaCl-Na Sulfate For Soln)
- 4000 per 30 days

PLENVU (PEG 3350-KCl-NaCl-Na Sulfate-Na Ascorbate-C For Soln)
- 3 per 30 days

REBYOTA (Fecal Microbiota, Live-jslm Rectal Susp)
- 150 per 365 days

RELEXXII 45MG (Methylphenidate HCl Tab ER Osmotic Release (OSM) 45 MG)
- 30 per 30 days

RELEXXII 63MG (Methylphenidate HCl Tab ER Osmotic Release (OSM) 63 MG)
- 30 per 30 days

SUPREP (Sod Sulfate-Pot Sulf-Mg Sulf Oral Sol 17.5-3.13-1.6 GM/177ML)

- 354 per 30 days

TADLIQ (Tadalafil Oral Susp 20 MG/5ML (PAH))

- 300 per 30 days

TASCENSO ODT 0.5MG (Fingolimod Lauryl Sulfate Tablet Disintegrating 0.5 MG)

- 30 per 30 days

TEZSPIRE (Tezepelumab-ekko Subcutaneous Soln Pref Syr)

- 1.91 per 28 days

TURALIO (Pexidartinib HCl Cap 125 MG)

- 120 per 30 days

TZIELD (Teplizumab-mzwv IV Soln 2 MG/2ML (1 MG/ML))

- 28 per 365 days

VERKAZIA (Cyclosporine (Ophth) Emulsion 0.1%)

- 120 per 30 days

XACIATO (Clindamycin Phosphate Vaginal Gel 2%)

- 5 per 30 days

ZORYVE (Roflumilast Cream 0.3%)

- 60 per 30 days

Changes to the Step Therapy List

Primary and Performance Formularies

New Standard Algorithms:

TOPICAL PLAQUE PSORIASIS (Plaque Psoriasis)

- Calcipotriene cream, solution, and ointment, and generic topical corticosteroids: i.e., triamcinolone, halobetasol, fluocinonide, betamethasone, etc. are 1st line medications.
- Vtama and Zoryve are 2nd line medications.
- A 2nd line medication is approved if the patient has tried at least 2 different first line medications, each for a 30-day trial, within the past 180 days.

ENTADFI (BPH)

- Generic BPH meds e.g., tamsulosin, doxazosin, dutasteride, and finasteride PLUS tadalafil 5mg are 1st line medications.
- Entadfi is a 2nd line medication.
- A 2nd line medication is approved if the patient has tried at least 2 different first line medications, one of which is tadalafil 5mg, each for a 30-day trial, within the past 180 days.

RYALTRIS (Allergic Rhinitis)

- Olopatadine nasal, azelastine nasal, flunisolide, fluticasone propionate nasal spray, triamcinolone, and mometasone are 1st line medications.
- Ryaltris is a 2nd line medication.
- A 2nd line medication is approved if the patient has tried at least 2 different first line medications, each for a 30-day trial, within the past 180 days.

VERKAZIA (Vernal Keratoconjunctivitis)

- Olopatadine, azelastine, epinastine, and ketotifen are 1st line medications.
- Verkazia is a 2nd line medication.

NAUSEA AND VOMITING OF PREGNANCY (Nausea and Vomiting of Pregnancy)

- Doxylamine/pyridoxine is a 1st line medication.
- Diclegis and Bonjesta are 2nd line medications.

LOOP DIURETICS (Edema)

- Bumetanide, furosemide, and torsemide are 1st line medications.
- Bumex, Edecrin, Furoscix, Lasix, and Soaanz are 2nd line medications.

VIVJOA (Recurrent Vulvovaginal Candidiasis (RVVC))

- Fluconazole, itraconazole, and ketoconazole are 1st line medications.
- Vivjoa is a 2nd line medication.

Updates to Current Standard Algorithms:

TOPICAL PLAQUE PSORIASIS (Plaque Psoriasis)

- Renamed algorithm to Topical Plaque Psoriasis -- Vitamin D analog/corticosteroids.
- Vtama removed as a 2nd line medication.
- Calcipotriene/betamethasone added as a 2nd line medication.

CONDYLOMA (Condyloma)

- Zyclara 2.5% moved from a 1st to a 2nd line medication.

TRIPTANS (Migraines)

- Sumatriptan/naproxen moved from a 1st to a 2nd line medication.

LONG-ACTING ANALGESICS (Pain)

- Oxymorphone ER moved from a 1st to a 2nd line medication.

ARBS (Hypertension)

- Valsartan oral solution moved from a 1st to a 2nd line medication.

BOWEL PREP (Colonoscopy)

- PEG-3350/electrolytes/ASC (MoviPrep generic) moved from a 1st to a 2nd line medication.

PANCREATIC ENZYMES (Pancreatic Insufficency)

- Viokace added as a 2nd line medication.

ULCER THERAPY COMBINATIONS (Ulcer/GERD)

- Omeclamox-pak and Helidac therapy pack added as 2nd line medications.

ANTINAUSEA (Nausea)

- Akynzeo added as a 2nd line medication.

ANTICONVULSANT - MISCELLANEOUS (Seizures)

- Elepsia XR added as a 2nd line medication.

BENZODIAZEPINES (Anxiety)

- Alprazolam intensol moved from a 1st to a 2nd line medication.

New Specialty Algorithms:

CAMZYOS (Cardiomyopathy)

- Generic beta blockers: i.e., acebutolol, atenolol, betaxolol, bisoprolol, carvedilol, esmolol, labetaol, metoprolol, nadolol, pindolol, propranolol, sotalol are 1st line medications.
- Camzyos is a 2nd line medication.

RECORLEV (Cushing's Syndrome)

- Ketoconazole is a 1st line medication.
- Recorlev is a 2nd line medication.

MYELOFIBROSIS (Myelofibrosis)

- Jakafi is a 1st line medication.
- Inrebic and Vonjo are 2nd line medications.

ZTALMY (Seizures)

- Clobazam, valproate, topiramate, and levetiracetam are 1st line medications.
- Ztalmy is a 2nd line medication.

Updates to Current Specialty Algorithms:

HIV (HIV)

- Apretude added as a 2nd line medication.

PULMONARY ARTERIAL HYPERTENSION - PDE-5 INHIBITORS (PAH)

- Tadalafil (PAH) added as a 1st line medication.
- Alyq and Tadliq added as 2nd line medications.

INFERTILITY - GNRH ANTAGONISTS (Fertility)

- Cetrorelix added as a 2nd line medication.

AUTOIMMUNE INFLAMMATION (Inflammatory Conditions)

- Rinvoq added as a step 1b medication for non-radiographic axial spondyloarthritis. It is directed to one step 1a TNF inhibitor: Cimzia.

COLONY STIMULATING FACTOR (Hematopoietic Agents)

- Stimufend added as a 2nd line medication.

ZEPOSIA (MS/UC)

- Fingolimod added as a 1st line medication for multiple sclerosis.

MULTIPLE SCLEROSIS (Multiple Sclerosis)

- Fingolimod moved from a 3rd to a 1st line medication.

Primary Formulary

New Standard Algorithms:

BIJUVA (Menopausal Symptoms)

- Amabelz, estradiol/norethindrone actetate, Fyavolv, Jinteli, Mimvey, and norethindrone/ethinyl estradiol are 1st line medications.
- Bijuva is a 2nd line medication.

LEVONOGESTREL/ETHINYL ESTRADIOL (Contraception)

- Generics: i.e., levonorgestrel/ethinyl estradiol, Amethia, Fayosim, Rivelsa, Simpesse, etc. are 1st line medications.
- Twirla and Balcoltra are 2nd line medications.

Updates to Current Standard Algorithms:

LONG-ACTING INSULIN (Diabetes)

- Tresiba added as a 1st line medication.
- Insulin glargine (Winthrop) and insulin glargine solostar (Winthrop) moved from 1st to 2nd line medications.
- Insulin degludec added as a 2nd line medication.

DRY EYE (Dry Eye Disease)

- Lacrisert added as a 2nd line medication.

NUVARING (Vaginal Contraceptive)

- Annovera added as a 2nd line medication.

New Specialty Algorithms:

ACTHAR (Adrenocorticotropin Stimulating Hormone)

- Cortrophin is a 1st line medication.
- Acthar is a 2nd line medication.

TYVASO (Pulmonary Arterial Hypertension (PAH))

- Tyvaso solution is a 1st line medication.
- Tyvaso DPI is a 2nd line medication.