P&T Committee Changes
Effective 10/1/2023

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.

BEYFORTUS (nirsevimab)

- A respiratory syncytial virus (RSV) F protein-directed fusion inhibitor.
- Indicated for the prevention of RSV lower respiratory tract disease in:
    - Neonates and infants born during or entering their first RSV season.
    - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

BRIXADI (buprenorphine)

- A partial opioid agonist.
- Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.
- There is a black box warning for risk of serious harm or death with intravenous administration; Brixadi risk evaluation, and mitigation strategy.

COLUMVI (glofitamab)

- A bispecific CD20-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.
- There is a black box for cytokine release syndrome.

ELEVIDYS (delandistrogene moxeparvovec-rokl)

- An adeno-associated virus vector-based gene therapy.
- Indicated for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene.
- There are warnings for acute serious liver injury, immune-mediated myositis, myocarditis, and pre-existing immunity against AAVrh74.

ELFABRIO (pegunigalsidase alfa)

- A hydrolytic lysosomal neutral glycosphingolipid-specific enzyme.
- Indicated for the treatment of adults with confirmed Fabry disease.
- There is a black box warning for hypersensitivity reactions including anaphylaxis.

EPKINLY (epcoritamab-bysp)

- A bispecific CD20-directed CD3 T-cell engager.
- Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.
- There is a black box warning for cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome.

IZERVAY (avacincaptad pegol)

- A complement inhibitor.
- Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

LANTIDRA (donislecel-jujn)

- An allogeneic pancreatic islet.
- Indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use in conjunction with concomitant immunosuppression.
- There are warnings for procedural complications, increased risk of islet graft rejection, transmission of donor-derived infections, and panel reactive Antibodies (PRA).

LITFULO (ritlecitinib)

- A kinase inhibitor.
- Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
- It is taken 50 mg orally once daily with or without food.
- There is a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.

NGENLA (somatrogon-ghla)

- A human growth hormone analog.
- Indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.
- There are warnings for severe hypersensitivity, increased risk of neoplasms, glucose intolerance and diabetes mellitus, intracranial hypertension, fluid retention, hypoadrenalism, hypothyroidism, slipped capital femoral epiphysis, progression of preexisting scoliosis, pancreatitis, lipoatrophy, and laboratory tests.

ROCTAVIAN (valoctocogene roxaparvovec-rvox)

- An adeno-associated virus (AAV) vector-based gene therapy product.
- Indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test.

- There are warnings for infusion-related reactions, hepatotoxicity, thromboembolic events, monitoring laboratory tests, and malignancy.

RYSTIGGO (rozanolixizumab-noli)
- A neonatal Fc receptor blocker.
- Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive.
- There are warnings for infections, aseptic meningitis, and hypersensitivity reactions.

VANFLYTA (quizartinib)
- A kinase inhibitor.
- Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.
- There are black box warnings for QT prolongation, Torsades de Points, and cardiac arrest.

VYJUVEK (beremagene geperpavec-svdt)
- A suspension of a HSV-1 vector-based gene therapy.
- Indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the *collagen type VII alpha 1 chain* (*COL7A1*) gene.
- There is a warning for accidental exposure to VYJUVEK.
- Women who are pregnant should not prepare, administer, or receive VYJUVEK. Women of childbearing potential should use an effective method of contraception during treatment.

VYVGART HYTRULO (efgartigimod alfa and hyaluronidase)
- A combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase.
- Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- There are warnings for infections and hypersensitivity reactions.

XACDURO (sulbactam and durlobactam)
- A co-packaged product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, a beta lactamase inhibitor.
- Indicated in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
    - It is not indicated for the treatment of HABP/VABP caused by pathogens other than susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex.
- There are warnings for hypersensitivity reactions, *Clostridioides difficile*-associated diarrhea (CDAD), and development of drug-resistant bacteria.

YCANTH (cantharidin)

- A topical solution containing 7 mg of active ingredient cantharidin (0.7%), a lipophilic compound.
- Indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.
- There are warnings for infections and hypersensitivity reactions.

Additions to the Standard Clinical Review List

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

LODOCO (colchicine)

- An alkaloid.
- Indicated to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease.
- There are warnings for blood dyscrasias and neuromuscular toxicity.

MIEBO (perfluorohexyloctane)

- A semifluorinated alkane.
- Indicated for treatment of the signs and symptoms of dry eye disease.
- There is a warning for use with contact lenses.

SKINVIVE (hyaluronic acid with lidocaine)

- A sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colorless, homogeneous gel implant consisting of hyaluronic acid (HA) produced by *Streptococcus* species of bacteria crosslinked with 1,4-butanediol diglycidyl ether (BDDE) formulated to a concentration of 12 mg/mL with 0.3% w/w lidocaine in a physiologic buffer.
- Indicated for intradermal injection to improve skin smoothness of the cheeks in adults over the age of 21.
- There are warnings for injecting into the vasculature, injecting into sites with an active inflammatory process, and use only by health care professionals who have appropriate training and experience.

VEOZAH (fezolinetant)

- A neurokinin 3 (NK3) receptor antagonist.
- Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.
- There is a warning for hepatic transaminase elevation.

VEVYE (cyclosporine)

- A calcineurin inhibitor immunosuppressant.
- Indicated for the treatment of the signs and symptoms of dry eye disease.
- It is instilled by one drop of VEVYE twice a day in each eye approximately 12 hours apart. If used with other eye drops, a 15-minute interval between products should occur.
- There are warnings for potential eye injury and contamination and use with contact lenses.

XDEMVY (lotilaner)

- An ectoparasiticide (anti-parasitic).
- Indicated for the treatment of Demodex blepharitis.
- There are warnings for the risk of contamination and use with contact lenses.

ZURZUVAE (zuranolone)

- A neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator.
- Indicated for the treatment of postpartum depression (PPD) in adults.
- There are warnings for CNS depressant effects, suicidal thoughts and behavior, and embryo fetal toxicity.

Additions to the Quantity Limit List

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

ATORVALIQ (Atorvastatin Calcium Susp)

- 600 per 30 days

FILSPARI (Sparsentan Tab)

- 30 per 30 days

INPEFA (Sotagliflozin Tab)

- 30 per 30 days

LODOCO (Colchicine Tab)

- 30 per 30 days

MIEBO (Perfluorohexyloctane Ophth Soln)

- 3 per 30 days

OPVEE (Nalmefene Nasal Spray)

- 4 per 30 days

TEZSPIRE AUTO-INJECTOR (Tezepelumab-ekko Subcutaneous Soln Auto-Inj)

- 1.91 per 28 days

VEOZAH (Fezolinetant Tab)

- 30 per 30 days

VEVYE (Cyclosporine Ophth Soln)

- 60 per 30 days

ZURZUVAE (Zuranolone Cap)

- 14 per 365 days

Responsible Rx Additions

- Keyfolic*
- Profola*
- Zolpidem 7.5mg capsule

* = also added to medical supplies drug category due to not FDA approved

Changes to the Step Therapy List

Primary and Performance Formularies

New Standard Algorithms:

PEPCID (GERD)
- Cimetidine, famotidine, and nizatidine are 1st line medications.
- Pepcid (Rx only) is a 2nd line medication.

ACCRUFER (Iron Deficiency)
- Ferrous sulfate, ferrous gluconate, and ferrous fumarate are 1st line medications.
- Accrufer is a 2nd line medication.

AURYXIA (Phosphate-Removing Agent)
- For diagnosis of iron deficiency anemia, ferrous sulfate, ferrous gluconate, and ferrous fumarate are 1st line medications.
- For diagnosis of hyperphosphatemia, calcium acetate, sevelamer, and lanthanum carbonate are 1st line medications.
- Auryxia is a 2nd line medication.

Updates to Current Standard Algorithms:

SGLT2 INHIBITORS (Diabetes)
- Inpefa and Brenzavvy added as 2nd line medications.

VAGINAL ANTIBIOTICS (Vaginal Infection)
- Xaciato added as a 2nd line medication.

TOPICAL ESTROGEN (Vaginal Infection)
- Divigel moved from a 1st to a 2nd line medication.
- Estradiol patches and cream added as 1st line medications.

ZONISAMIDE [Focal (Partial) Onset Seizures]
- Zonisade added as a 2nd line medication.

SLEEP AIDS (Insomnia)
- Zolpidem 7.5mg capsule moved from a 1st to a 2nd line medication.

STATINS (Cholesterol)
- Ezetimibe/atorvastatin added as a 2nd line medication.

ANTICONVULSANT - TOPAMAX (Seizures, Migraine)
- Eprontia added as a 2nd line medication.

INSULINS, RAPID-ACTING (Diabetes)
- Humalog Tempo added as a 2nd line medication.

COLCHICINE (Gout)

- Colchicine capsules moved from a 1st to a 2nd line medication.

ANTI-INFLAMMATORY (Inflammation)

- Meloxicam suspension moved from a 1st to a 2nd line medication.

FIBRATES (Cholesterol)

- Fenofibrate 120mg tablet moved from a 1st to a 2nd line medication.

TETRACYCLINE - ORAL (Tetracycline - Oral)

- Doxycycline hyclate DR tablet and doxycycline monohydrate capsules (Chartwell Rx manufacturer) moved from 1st to 2nd line medications.

CALCIUM CHANNEL BLOCKERS - DIHYDROPYRIDINES (Hypertension)

- Amlodipine (Greenstone manufacturer) moved from a 1st to a 2nd line medication.

Updates to Current Specialty Algorithms:

HIV (HIV)

- Sunlenca added as a 3rd line medication. It requires a 30 day trial of TWO first line medications within 180 days.

PULMONARY ARTERIAL HYPERTENSION - PDE-5 INHIBITORS (PAH)

- Sildenafil (Greenstone manufacturer) moved from a 1st to a 2nd line medication.

IMMUNOSUPPRESSANTS - SIROLIMUS (Transplant)

- Sirolimus suspension (Greenstone manufacturer) moved from a 1st to a 2nd line medication.

INFERTILITY - CHORIONIC GONADATROPIN (Infertility)

- Novarel and chorionic gonadotropin moved from 1st to 2nd line medications.
- Ovidrel moved from a 2nd to a 1st line medication.

AUTOIMMUNE INFLAMMATION (Inflammatory Conditions)

- All Humira biosimilars other than Cyltezo and Amjevita added as 4th line medications. They require trial and failure of Humira, Amjevita, and Cyltezo.
- Added the following statement to the step 2 column of the algorithm:
    - **Humira Biosimilars (directed to three step 1 agents: Humira, Amjevita, and Cyltezo):** For all FDA approved indications, Humira and the two biosimilars Amjevita and Cyltezo are the preferred agents. All other Humira biosimilars are non-preferred and require trial and failure of the three preferred agents.