P&T Committee Changes
Effective 7/1/2023

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.

DAYBUE (trofinetide)

- A glycine-proline-glutamate analog.
- Indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.
- It is administered orally twice daily, morning and evening, according to patient weight. DAYBUE can be given with or without food.
- There are warnings for diarrhea and weight loss.

FILSPARI (sparsentan)

- An endothelin and angiotensin II receptor antagonist.
- 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 at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated.
- It is contraindicated in patients who are pregnant, or when coadministered with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren.
- There are black box warnings for hepatotoxicity and embryo-fetal toxicity.
- There are additional warnings for Filspari REMS, hypotension, acute kidney injury, hyperkalemia, and fluid retention.

JOENJA (leniolisib)

- A kinase inhibitor.
- Indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older and weighing at least 45kg.
- It is administered orally twice daily approximately 12 hours apart, with or without food.
- There are warnings for embryo- fetal toxicity and vaccinations.

LAMZEDE (velmanase alfa-tycv)

- A lysosomal alpha-mannosidase.

- Indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.
- It is administered through intravenous infusion. The recommended dosage of LAMZEDE is 1 mg/kg (actual body weight) administered once every week.
- There is a black box warning for severe hypersensitivity reactions.
- There are additional warnings for infusion-associated reactions and embryo-fetal toxicity.

LUMRYZ (sodium oxybate)

- A CNS depressant.
- Indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.
- It is taken once daily by mouth before bedtime, at least 2 hours after eating.
- It is contraindicated in combination with sedative hypnotics or alcohol, and in patients with succinic semialdehyde dehydrogenase deficiency.
- There are black box warnings for CNS depression and abuse and misuse.
- There are additional warnings for LUMRYZ REMS, respiratory depression and sleep-disordered breathing, depression and suicidality, behavioral adverse reactions, parasomnias, and use in patients sensitive to high sodium intake.

OMISIRGE (omidubicel-onlv)

- A nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood.
- Indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection
- It is administered via IV infusion under the supervision of a physician experienced in treatment of hematologic malignancies, in a center with expertise in hematopoietic stem cell transplants.
- There are black box warnings for infusion reactions, graft versus host disease, engraftment syndrome, and graft failure.
- There are additional warnings for malignancies of donor origin, transmission of serious infections, and transmission of rare genetic diseases.

QALSODY (tofersen)

- An antisense oligonucleotide.
- Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (*SOD1*) gene.
- It is administered intrathecally using a lumbar puncture.
- There are warnings for myelitis and/or radiculitis, papilledema and elevated intracranial pressure, and aseptic meningitis.

REZZAYO (rezafungin)

- A echinocandin antifungal.
- Indicated for patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis.
- It is administered by intravenous infusion with an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter.
- It is contraindicated in patients with known hypersensitivity to echinocandins.
- There are warnings for infusion- related reactions, photosensitivity, and hepatic adverse reactions.

SKYCLARYS (omaveloxolone)

- A nuclear factor erythroid 2-related factor 2 activator.
- Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.
- It is taken orally as 150 mg (3 capsules) once daily.
- There are warnings for elevation of aminotransferases, elevation of B-type natriuretic peptide, and lipid abnormalities.

SYFOVRE (pegcetacoplan)

- A complement inhibitor.
- Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
- It is given by intravitreal injection to each affected eye once every 25 to 60 days.
- It is contraindicated in patients with ocular or periocular infections or patients with active intraocular inflammation.
- There are warnings for endophthalmitis and retinal detachment, neovascular AMD, intraocular inflammation, and increased intraocular pressure.

VOWST (fecal microbiota spores, live-brpk)

- A bacterial spore suspension.
- Indicated to prevent the recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI).
- It is taken orally once daily for 3 consecutive days, 2 to 4 days following a course of antibacterial treatment for rCDI.
- There are warnings for transmissible infectious agents and potential presence of food allergens.

ZYNYZ (retifanlimab-dlwr)

- A programmed death receptor-1 (PD-1)–blocking antibody.
- Indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
- It is administered as an intravenous infusion every 4 weeks until disease progression, unacceptable toxicity, or up to 24 months.
- There are warnings for severe and fatal immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic HSCT, and embryo- fetal toxicity.

Additions to the Standard Clinical Review List

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

NEO-SYNALAR (neomycin sulfate and fluocinolone acetonide)

- A corticosteroid.
- Indicated for the treatment of corticosteroid-responsive dermatoses with secondary infection. It has not been demonstrated that this steroid-antibiotic combination provides greater benefit than the steroid component alone after 7 days of treatment.
- It is applied topically to the affected area as a thin film from two to four times daily depending on the severity of the condition.
- It is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation. This product should not be used in the external auditory canal if the eardrum is perforated.

- There are warnings for nephrotoxicity and ototoxicity associated with neomycin.

Additions to the Specialty Medication List

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

ABILIFY ASIMTUFII (aripiprazole)

- An atypical antipsychotic.
- Indicated for the treatment of schizophrenia and as maintenance monotherapy treatment of bipolar I disorder in adults.
- It is administered as an intramuscular injection by a healthcare professional every 2 months.
- This is being added to the specialty drug list only because it is physician administered; it will not require clinical review.

UZEDY (risperidone)

- An atypical antipsychotic.
- Indicated for the treatment of schizophrenia in adults.
- It is administered as a subcutaneous injection by a healthcare professional every one to two months based on dosing.
- This is being added to the specialty drug list only because it is physician administered; it will not require clinical review.

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:

ABILIFY ASIMTUFII 720 (Aripiprazole IM ER Susp Prefilled Syringe 720 MG/2.4ML)

- 2.4 per 56 days

ABILIFY ASIMTUFII 960 (Aripiprazole IM ER Susp Prefilled Syringe 960 MG/3.2ML)

- 3.2 per 56 days

ABILIFY MYCITE STARTER KIT 2 MG (Aripiprazole Tab 2 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ABILIFY MYCITE STARTER KIT 5 MG (Aripiprazole Tab 5 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ABILIFY MYCITE STARTER KIT 10 MG (Aripiprazole Tab 10 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ABILIFY MYCITE STARTER KIT 15 MG (Aripiprazole Tab 15 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ABILIFY MYCITE STARTER KIT 20 MG (Aripiprazole Tab 20 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ABILIFY MYCITE STARTER KIT 30 MG (Aripiprazole Tab 30 MG with sensor, strips & pod Starter Pak)

- 30 per 180 days*

ELMIRON (Pentosan Polysulfate Sodium Caps 100 MG)

- 540 per 365 days*

LUMRYZ (Sodium Oxybate Susp)

- 30 per 30 days

NEO-SYNALAR (Neomycin Sulfate-Fluocinolone Acetonide Cream 0.5-0.025%)

- 60 per 90 days*

NEO-SYNALAR KIT (Neomycin-Fluocinolone Cream 0.5-0.025% & Emollient Cr Kit)

- 315 per 90 days*

RHOFADE (Oxymetazoline HCl Cream 1%)

- 30 per 30 days

TAKHZYRO 150 MG PFS (Lanadelumab-flyo Soln Pref Syringe 150 MG/ML)

- 2 per 28 days

TAKHZYRO 300 MG PFS (Lanadelumab-flyo Soln Pref Syringe 300 MG/2ML)

- 4 per 28 days

UZEDY 50 MG (Risperidone ER Susp Prefilled Syringe 50 MG/0.14 ML)

- 0.14 per 28 days

UZEDY 75 MG (Risperidone ER Susp Prefilled Syringe 75 MG/0.21 ML)

- 0.21 per 28 days

UZEDY 100 MG (Risperidone ER Susp Prefilled Syringe 100 MG/0.28 ML)

- 0.28 per 28 days

UZEDY 125 MG (Risperidone ER Susp Prefilled Syringe 125 MG/0.35 ML)

- 0.35 per 28 days

UZEDY 150 MG (Risperidone ER Susp Prefilled Syringe 150 MG/0.42 ML)

- 0.42 per 56 days

UZEDY 200 MG (Risperidone ER Susp Prefilled Syringe 200 MG/0.56 ML)

- 0.56 per 56 days

UZEDY 250 MG (Risperidone ER Susp Prefilled Syringe 250 MG/0.7 ML)

- 0.7 per 56 days

UZEDY 250 MG (Risperidone ER Susp Prefilled Syringe 250 MG/0.7 ML)

- 0.7 per 56 days

VITAMIN D 1.25 MG (50000 UT) (Ergocalciferol Cap 1.25 MG)

- 36 per 84 days

XARELTO STARTER PACK 15 & 20 MG (Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG)

- 51 per 30 days

ZAVZPRET (Zavegepant Nasal Spray)
- 6 per 28 days*

* = This symbol indicates a quantity over time limit. The quantity per day supply on each individual claim will not be limited, but the member will only be able to fill the specified quantity (total over any number of fills) within the specified time period.

Changes to the Quantity Limit List:

PROZAC 20 (Fluoxetine HCl Cap 20 MG)
- Increased from 60 per 30 days to 90 per 30 days

Starter Dose Additions

- Revlimid

Removed from the Starter Dose List:

- Xeloda (capecitabine)

Responsible Rx Additions

- Acanya
- Amirx
- Dayavite*
- Folamax*
- Qsymia
- Solodyn

* = 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:

NITROGLYCERIN (Angina)
- Nitroglycerin patch and sublingual tablets are 1st line medications.
- Nitrostat, Nitrolingual, Nitro-DUR, Gonitro, and nitroglycerin translingual spray are 2nd line medications.

CALCITRIOL (Hyperparathyroidism)
- Calcitriol capsules is a 1st line medication.
- Rocaltrol capsules and solution, Zemplar capsules, calcitriol 1 mcg/mL solution, doxercalciferol capsules, and paricalcitol capsules are 2nd line medications.

ZONISAMIDE (Focal (Partial) Onset Seizures)

- Zonisamide is a 1st line medication.
- Zonegran is a 2nd line medication.

Updates to Current Standard Algorithms:

TOPICAL ACNE/ ANTIBIOTIC COMBINATIONS (Acne/ Antibiotics)

- Neuac added as a 2nd line medication.

ANTI-INFLAMMATORY (Inflammation)

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

CENTRAL MUSCLE RELAXANTS (Muscle Pain)

- Chlorzoxazone 250mg strength moved from a 1st to a 2nd line medication.

TOPICAL CORTICOSTEROIDS (Topical Inflammation)

- Halcinonide 0.1% cream moved from a 1st to a 2nd line medication.

CALCIUM CHANNEL BLOCKERS - DIHYDROPYRIDINES (Hypertension)

- Nicardipine, isradipine, and nisoldipine ER 20, 30, and 40mg moved from 1st to 2nd line medications.

ACE/CCB COMBO (Hypertension)

- Trandolapril/verapamil moved from a 1st to a 2nd line medication.

ANTIDEPRESSANTS OTHER (Mental Health)

- Auvelity added as a 2nd line medication.

Updates to Current Specialty Algorithms:

AUTOIMMUNE INFLAMMATION (Inflammatory Conditions)

- Amjevita added as a 4th line agent for the disease states listed below. It is directed to three step 1 agents, one of which must be Humira.
  - Ankylosing Spondylitis
  - Crohn's Disease
  - Polyarticular Juvenile Idiopathic Arthritis
  - Psoriasis
  - Psoriatic Arthritis
  - Rheumatoid Arthritis
  - Ulcerative Colitis
- Amjevita added as a 2nd line agent for the disease states listed below. It is directed to Humira.
  - Uveitis
  - Hidradenitis Suppurativa

KUVAN (Phenylketonuria)

- Javygtor added as a 2nd line medication.

AMMONIA DETOXICANT (Urea Cycle Metabolism)

- Pheburane added as a 3rd line medication.

Performance Formulary

Updates to Current Standard Algorithms:

GLP-1 AGONISTS (Diabetes)

- Mounjaro added as a 1st line medication.

Primary Formulary

Updates to Current Standard Algorithms:

ADAPALENE (Acne)

- Adapalene pads and solution moved from 1st to 2nd line medications.

GLP-1 AGONISTS (Diabetes)

- Mounjaro moved from a 3rd to a 2nd line medication.
