

P&T Committee Meeting Minutes
Commercial/Marketplace/CHIP
June 25, 2021 e-vote

DRUG REVIEWS

ABECMA (idecabtagene vicleucel)

Review: Abecma is a T-cell immunotherapy product consisting of a patient's own T-cells, harvested and genetically modified with an anti-B-cell maturation antigen (BCMA)02 chimeric antigen receptor (CAR) lentiviral vector (LVV). It is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

The efficacy of Abecma was evaluated in the KarMMa trial, an open-label, single-arm study in adult patients with relapsed or refractory multiple myeloma who had received at least 3 prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody (88% of patients had received 4 or more prior lines of therapy and 85% percent of patients were triple class refractory).

Patients could receive bridging therapy during the manufacturing process and lymphodepleting chemotherapy was initiation 5 days prior to the target Abecma infusion date. Of the 135 patients who underwent leukapheresis, for 300 x 10⁶ and 450 x 10⁶ CAR-positive T cell dose cohorts, the efficacy evaluable population consisted of 100 patients (74%) who received Abecma in the recommended dosage range. The primary efficacy endpoint measuring overall response rate demonstrated a partial response or better in 72 patients. Duration of response was 11 months in patients with a partial response or better and 19 months in patients with a stringent complete response.

Similar to other CAR-T therapies, Abecma has a black box warning for cytokine release syndrome (CRS) and neurologic toxicities. The black box warnings also include Hemophagocytic Lymphohistiocytosis (HLH)/ Macrophage activation syndrome (MAS) and prolonged cytopenias. Because of the risk of CRS and neurologic toxicities, Abecma is only available through the ABECMA REMS program. During the KarMMa study, the most common adverse reactions (≥ 20%) included CRS, infections (unspecified pathogen), fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, and decreased appetite. Serious adverse reactions occurred in 67% of patients and fatal adverse reactions occurred in 6%. The most common Grade 3 or 4 laboratory adverse reactions (≥ 10 %) included neutropenia, leukopenia, lymphopenia, thrombocytopenia, anemia, hypophosphatemia, hyponatremia, and increased activated partial thromboplastin time (aPTT).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Abecma is a medical benefit and will not be added to the pharmacy formularies. Abecma will require prior authorization with the following criteria:

- Medical record documentation that Abecma is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of relapsed or refractory multiple myeloma **AND**
- Medical record documentation of at least four prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

AUTHORIZATION DURATION: One-time authorization for one administration of Abecma

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

AVSOLA (infliximab-axxq)

Review: Avsola is a biosimilar tumor necrosis factor alpha inhibitor (TNF α i, TNFi) that is highly similar to the US-licensed reference product, Remicade, indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, Crohn’s disease, and ulcerative colitis. Avsola is the third FDA approved (and marketed) infliximab biosimilar, the first being Inflectra (infliximab-dyyb) and the second being Renflexis (infliximab-abda). Ixifi (infliximab-qbtx) was FDA approved in December 2017; however, the anticipated availability is undetermined and is not expected to come to market. None of the infliximab biosimilar products are interchangeable with Remicade.

Study 20140108 was a randomized, single-blind, single-dose, three-arm, parallel-group study designed to demonstrate the pharmacokinetic (PK) similarity of Avsola to infliximab US or infliximab EU in healthy patients. The study demonstrated PK similarity between Avsola and EU and US infliximab. The safety, tolerability, and immunogenicity were similar across the three treatments.

Study 20140111 was a randomized, double-blind, active-controlled, comparative clinical study that evaluated the efficacy and safety of Avsola versus infliximab in adult patients with moderate to severe RA. The study demonstrated similarity in efficacy (ACR20 at week 22), safety, and immunogenicity between Avsola and Remicade. The single transition from Remicade to Avsola after week 22 did not impact efficacy. The incidence of binding and neutralizing antibodies was similar across groups and the single transition from Remicade to Avsola did not impact the rates of antibody development.

The safety considerations of Avsola are consistent with those of the other infliximab reference and biosimilar products. Avsola, at doses greater than 5mg/kg, is contraindicated in patients with moderate to severe heart failure. Avsola is contraindicated in patients with a hypersensitivity to any infliximab product, inactive components of Avsola, or murine proteins. In clinical trials, there were no meaningful differences in safety between Avsola and Remicade. In Study 20140111, the most common adverse events included upper respiratory tract infection, nasopharyngitis, bronchitis, and pharyngitis.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Avsola is a medical benefit. Because all infliximab biosimilar products offer clinically similar safety and efficacy while also offering significant cost savings, with Avsola being the most cost effective, Avsola will be the preferred infliximab biosimilar. Grandfathering provisions will be removed from existing policies. When Avsola is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Avsola will require prior authorization with the following criteria:

~~GRANDFATHER PROVISION— Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature~~

Remicade (infliximab), Inflectra (infliximab-dyyb), ~~or~~ Renflexis (infliximab-abda), or Avsola (infliximab-axxq) will be considered medically necessary when all of the following criteria are met based on indication:

For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira*, Rinvoc*, OR Xeljanz* **AND**
- Continuation of effective dose of methotrexate during infliximab therapy

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) **AND** infliximab-abda (Renflexis), **AND** infliximab-dyyb (Inflectra).

Recommended guidelines for use in the treatment of rheumatoid arthritis

- 3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.
- For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.

For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:

- Must be 6 years of age or older; **AND**
- Prescription is written by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- One of the following:
 - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **OR**

- Physician documentation of Crohn's disease with actively draining fistulas.

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) AND infliximab-abda (Renflexis), AND infliximab-dyyb (Inflectra).

Recommended guidelines for use in the treatment of Crohn's disease or fistulizing Crohn's disease:

- 5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter
- For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.

For Treatment of Ulcerative Colitis:

- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (e.g., 6-mercaptopurine or azathioprine **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* OR medical record documentation of age < 18 years

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) AND infliximab-abda (Renflexis), AND infliximab-dyyb (Inflectra).

Recommended guidelines for the use in the treatment of ulcerative colitis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For Treatment of Ankylosing Spondylitis:

- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Cosentyx*

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) AND infliximab-abda (Renflexis), AND infliximab-dyyb (Inflectra).

Recommended guidelines for use in ankylosing spondylitis

- 5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter

For the treatment of Plaque Psoriasis:

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira* **AND** Cosentyx*

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) **AND** infliximab-abda (Renflexis), **AND** infliximab-dyyb (Inflectra).

Recommended guidelines for the use in the treatment of plaque psoriasis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For the treatment of Psoriatic Arthritis:

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
 - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of Humira* and Cosentyx*

AND

- For infliximab biosimilar requests other than Avsola (e.g. Renflexis, Inflectra), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola)
- For infliximab reference product requests (i.e. Remicade), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to infliximab-axxq (Avsola) **AND** infliximab-abda (Renflexis), **AND** infliximab-dyyb (Inflectra).

Recommended guidelines for the use in the treatment of psoriatic arthritis

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FOTIVDA (tivozanib)

Review: Fotivda is a tyrosine kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. It inhibits vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, and VEGFR-3. It also inhibits the proto-oncogene c-kit and platelet-derived growth factor receptor (PDGFR)-beta at clinically relevant concentrations. Tumor xenograft models in mice and rats showed that Fotivda inhibited angiogenesis, vascular permeability, and tumor growth in various tumor cell types. Fotivda offers another tyrosine kinase treatment option for patients with RCC who have failed previous therapies, but is unclear if it offers any advantage over the other available kinase inhibitor treatments available, some of which are NCCN preferred regimens and non-preferred regimen category 1 recommended treatment options.

The efficacy of Fotivda was evaluated in the TIVO-3 trial, an open-label, randomized, controlled trial comparing Fotivda to sorafenib in adult patients with relapsed or refractory advanced RCC who received two to three prior systemic treatments, including at least one VEGFR kinase inhibitor other than sorafenib or tivozanib. Patients were randomized 1:1 to receive Fotivda 1.34 mg orally once daily for 21 day of treatment followed by 7 days off for a 28-day cycle, or sorafenib 400 mg orally twice daily continuously. Treatment was continued until disease progression or unacceptable toxicity.

The primary efficacy endpoint of progression free survival showed a statistically significant improvement in median PFS for Fotivda compared to sorafenib (5.6 months vs. 3.9 months, respectively). Secondary endpoints showed that Fotivda did not demonstrate an improvement in overall survival compared to sorafenib (16.4 months vs. 19.2 months, respectively).

There are no black box warnings for Fotivda. Warnings and precautions include hypertension, cardiac failure, cardiac ischemia, arterial thromboembolic events, and venous thromboembolic events. Other warnings include hemorrhagic events, proteinuria, thyroid dysfunction, risk of impaired wound healing, reversible posterior leukoencephalopathy syndrome, and embryo-fetal toxicity. The most common ($\geq 20\%$) adverse reactions were fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis. The most common Grade 3 or 4 laboratory abnormalities ($\geq 5\%$) were decreased sodium and phosphate and increased lipase.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Fotivda is a pharmacy benefit that will be added to the formulary at the OralOncBrandNP tier (\$0 copay). Fotivda will require prior authorization with the following criteria:

- Medical record documentation that Fotivda is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of relapsed or refractory advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation of treatment with two or more prior systemic therapies

QUANTITY LIMITS: 21 tablets/28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

GEMTESA (vibegron)

Review: Gemtesa is a selective beta-3 adrenergic receptor agonist which increased bladder capacity by relaxing the detrusor smooth muscle during bladder filling. It is the second beta-3 adrenergic receptor agonist approved for the treatment of OAB following Myrbetriq. It is unclear if Gemtesa offers a clinical advantage in efficacy or safety over Myrbetriq. Myrbetriq has warnings for increased blood pressure although cardiovascular safety was found to be comparable to antimuscarinic agents. Gemtesa is more selective and does not appear to have the same cardiovascular concerns.

The efficacy of Gemtesa was evaluated in the EMPOWUR trial, a 12-week, double-blind, placebo-controlled, and active controlled trial in 1515 adult patients with OAB (urge urinary incontinence, urgency, and urinary frequency). Patients were randomized 5:5:4 to Gemtesa 75 mg, placebo, or tolterodine 4 mg extended release once daily for 12 weeks. The co-primary endpoints were change from baseline in average daily number of micturitions and average daily number of UUI episode at week 12. Additional endpoints included change from baseline in average daily number of “need to urinate immediately” (urgency) episodes and average volume voided per micturition. Gemtesa demonstrated a statistically significant improvement over placebo for all endpoints at week 12.

There are no black box warnings for Gemtesa. There is a warning for urinary retention with Gemtesa and this may be increased in patients with bladder outlet obstruction or in patients taking muscarinic antagonist medications for the treatment of OAB. The most common adverse events ($\geq 2\%$ of patients) treated with Gemtesa included headache, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Gemtesa is a pharmacy benefit and will not be added to the formulary. Gemtesa will be added to Commercial Policy 49.0 and will require prior authorization with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to use of oxybutynin, oxybutynin XL or tolterodine **AND** solifenacin

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

IMCIVREE (setmelanotide)

Review: Imcivree is the first obesity medication that targets an underlying genetic cause of obesity. It is a melanocortin 4 receptor (MC4R) agonist and works to restore MC4R activation resulting in reduced hunger and weight loss through decreased caloric intake and increased energy expenditure. Imcivree is only indicated for treatment in patients who have a POMC-, PCSK1-, or LEPR-deficiency confirmed through genetic testing and is not indicated when these variants are classified as benign or in other types of obesity not associated with these genetic variants.

The safety and efficacy of Imcivree for chronic weight management in patients with obesity due to POMC, PCSK1, and LEPR deficiency were assessed in 2 identical, 1-year, open-label studies, each with an 8-week, double-blind withdrawal period. The POMC trial included patients aged 6 years or older with obesity and a genetically confirmed POMC or PCSK1 deficiency. The LEPR trial included patients aged 6 years and older with obesity and a genetically confirmed LEPR deficiency.

After enrollment, patients had an open-label dose titration period of 2 to 12 weeks, followed by a 10 week open-label treatment period. Patients who achieved at least a 5 kg weight loss (or 5% weight loss if baseline body weight was less than 100 kg) at the end of the open-label treatment period continued on to a double-blind withdrawal period lasting 8 weeks (blinded sequence of 4 weeks of Imcivree and 4 weeks of placebo). Following the withdrawal treatment, patients resumed active treatment with Imcivree at the therapeutic dose for up to 32 weeks.

Efficacy analysis was conducted in 21 patients (10 in POMC study, 11 in LEPR study) who completed at least 1 year of treatment at the prespecified data cutoff. The primary endpoint evaluating patients achieving $\geq 10\%$ weight loss after 1 year of treatment with Imcivree was reached by 80% of patients in the POMC study and 46% of patients in the LEPR study. This was supported by results of secondary endpoints evaluating weight gain during the withdrawal period and changes from baseline in Hunger scores.

There are no black box warnings for Imcivree. Warnings and precautions include disturbances in sexual arousal, depression and suicide ideation, skin pigmentation and darkening of pre-existing nevi, and risk of serious adverse reactions in neonates and low birth weight infants (due to benzoyl alcohol preservative). The most common adverse reactions were injection site reactions, skin hyperpigmentation, nausea, headache, diarrhea, abdominal pain, back pain, fatigue, vomiting, depression, upper respiratory tract infection, and spontaneous penile erection.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Imcivree is a pharmacy benefit and will be excluded from the Commercial, Exchange, and GHP Kids pharmacy formularies. For certain TPA clients that request this benefit (weight loss), Imcivree will be added to the Specialty tier or Brand Non-preferred tier for members with a three tier benefit. Imcivree will require prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation of one of the following:
 - For patients 18 years and older: Medical record documentation of body mass index (BMI) of ≥ 30 kg/m²
 - For patients age 6 years to less than 18 years: Medical record documentation of weight $\geq 95^{\text{th}}$ percentile using growth chart assessments

AND

- Medical record documentation of a proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency **AND**
- Medical record confirmation of genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)*

NOTE*: Imcivree is not indicated for treatment of:

- Obesity due to suspected POMC-, PCSK1-, or LEPR-deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity

QUANTITY LIMIT: 0.3 mL per day

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

KLISYRI (tirbanibulin)

Review: Klisyri is a microtubule inhibitor that is thought to treated actinic keratosis through disruption of the intracellular microtubular network, resulting in cell cycle arrest and apoptosis of keratinocytes. It also inhibits Src protein tyrosine kinase (PTK) which has been implicated in hyperproliferative skin diseases. Klisyri provides a novel mechanism of action for a self-administered topical field treatment option for AK which has the advantage of a short, once-daily treatment course and milder side effect profile, but is only indicated in for use on the face and scalp and may have a higher recurrence rate compared to other first-line treatment options.

The efficacy of Klisyri was evaluated in two double-blind, vehicle-controlled clinical trials in 702 adult patients with 4 to 8 actinic keratosis lesions on the face or scalp in a contiguous area of 25 cm². Patients were randomized 1:1 to received Klisyri 1% ointment or vehicle ointment which was applied to the affected area for 5 consecutive days. The primary endpoint assessment at day 57 for complete (100%) clearance of AK lesions demonstrated a 40% and 42% improvement in clearance rate for Klisyri over placebo for Study 1 and 2. The secondary endpoint assessment showed a 52% and 57% improvement in partial (75%) clearance rate at Day 57 for Klisyri over placebo for Study 1 and 2. Efficacy was consistent across sex and age (< 65 and ≥ 65 years) subgroups. At 12 months post-day 57, the recurrence rate (proportion of patients with new or recurrent lesion in previously treated area) was 73%.

There are no black box warnings for Klisyri. Local skin reactions were the most commonly reported adverse reactions and can include erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosion/ulceration. A majority of local skin reactions were mild to moderate in severity and no patients discontinued from clinical trials due to adverse reactions.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Klisyri is a pharmacy benefit and will be added to the brand non-preferred tier of the formulary. Klisyri will require prior authorization with the following criteria:

- Medical record documentation that Klisyri is prescribed by a dermatologist **AND**
- Medical record documentation of actinic keratosis of the face or scalp **AND**
- Medical record documentation of greater than or equal to 4 lesions within a contiguous 25 cm² area **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

QUANTITY LIMIT: 1 package (5 packets) per dispensing

Other Recommendations: Diclofenac 3% gel is only indicated for the treatment of actinic keratosis and has limited efficacy compared to fluorouracil and imiquimod which are recommended as first line treatment options according to current treatment guidelines. It is recommended that a policy be created for diclofenac 3% gel as follows:

- Medical record documentation of actinic keratosis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND** imiquimod

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

VERQUVO (vericiguat)

Review: Verquvo is a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%. Verquvo is the second drug in the novel class of sGC stimulators and the first indicated in heart failure. The heart failure treatment guidelines have not been updated since the approval of Verquvo, but based on the FDA approved indication for higher risk patients, it will likely be recommended as a second-line or later treatment option for patients with severe heart failure who have failed other first and/or second-line agents.

The efficacy of Verquvo was evaluated in the Victoria trial, a randomized, parallel-group, placebo-controlled, double-blind, event-driven, multi-center trial comparing Verquvo and placebo in 5,050 adult patients with symptomatic chronic heart failure (New York Heart Association [NYHA] class II-IV) and left ventricular ejection

fraction (LVEF) less than 45% following a worsening heart failure event (heart failure hospitalization within past 6 months or use of outpatient IV diuretics for heart failure within past 3 months). Patients were randomized 1:1 to receive Verquvo 10 mg (titrated from 2.5mg according to recommended schedule) or matching placebo. The primary endpoint, a composite of time to first event of CV death or hospitalization for heart failure, showed that Verquvo was superior to placebo in reducing the risk of CV death or heart failure hospitalization based on a time-to-event analysis. This was driven mostly by the reduction of heart failure hospitalization.

There are no black box warnings for Verquvo. There is a warning for embryo-fetal toxicity based on animal reproduction studies. During clinical trials, the adverse drug reactions that occurred more commonly with Verquvo than placebo and occurred in more than 5% of patients treated with Verquvo were hypotension and anemia.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Verquvo is a pharmacy benefit and will be added to the brand non-preferred tier of the formulary. Verquvo will require prior authorization with the following criteria:

- Medical record documentation that Verquvo is written by a cardiologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of symptomatic chronic New York Heart Association Class II-IV heart failure **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of hospital admission due to heart failure within the previous 6 months **OR**
 - Medical record documentation of outpatient intravenous (IV) diuretic treatment for heart failure within the previous 3 months

AND

- Medical record documentation of a left ventricular ejection fraction (LVEF) less than or equal to 45% **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary angiotensin converting enzyme inhibitor (ACEi), angiotensin receptor blocker (ARB) or angiotensin receptor and neprilysin inhibitor (ARNI) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one formulary beta-blocker

QUANTITY LIMIT: 1 tablet per day

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

ZOKINVY (brolucizumab)

Review: Zokinvy is a farnesyltransferase inhibitor indicated in patients 12 months of age and older with a body surface area of 0.39 m² and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS) and for the treatment of processing-deficient Progeroid Laminopathies (PL) with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Zokinvy is an oral farnesyltransferase inhibitor designed to prevent the accumulation of progerin and progerin-like proteins in the inner nuclear membrane, which are implicated in the pathogenesis of HGPS. Inhibition of farnesylation also has implications in processing-deficient PLs.

The starting dose of Zokinvy for patients with a BSA of 0.39m² and above is 115 mg/m² twice daily with morning and evening meals to reduce the risk of gastrointestinal adverse reactions. After 4 months of treatment, increase the dose to 150 mg/m² twice daily with morning and evenings meals. All total daily dosages should be rounded to the nearest 25 mg increment.

The efficacy of Zokinvy is based on results from Observational Cohort Survival Study, which retrospectively compared survival data from two Phase 2 studies in patients with HGPS to those from a natural history cohort. Study 1 was a Phase 2 open-label, single-arm trial that evaluated the efficacy of Zokinvy in 28 patients. Patients received Zokinvy for 24 to 30 months. Patients initiated treatment with Zokinvy 115 mg/m² twice daily. After 4 months, patients who tolerated treatment had an increase in dose to 150 mg/m² twice daily. Among the 28 patients treated, 27 patients with HGPS (16 females, 11 males) were included in the survival assessment. Following completion of Study 1, 26 patients enrolled in a second Phase 2 open label, single arm trial which consisted of two study phases. In the first phase of Study 2, patients received Zokinvy with additional therapies for about 5 years. In the second phase of Study 2, patients received Zokinvy 150 mg/m² twice daily for a period of up to 3 years. There were 35 treatment naïve patients with HGPS enrolled into the second phase of Study 2. The retrospective survival analysis was based on the mortality data from 62 treated patients (27 patients in Study 1 and 35 treatment naïve patients in Study 2) and data from matched, untreated patients in a separate natural history cohort. This included only HGPS patients. Patients were matched by mutation status, sex, and continent of residence using a fixed 50th percentile matching algorithm. The mean lifespan of HGPS patients treated with Zokinvy increased by an average of 3 months through the first 3 years of follow-up and 2.5 years through the last follow-up time (11 years) compared to untreated patients.

Zokinvy is contraindicated in patients taking strong/moderate CYP3A4 inhibitors or inducers, midazolam, and lovastatin, simvastatin, or atorvastatin. The most common adverse reactions were: vomiting (90%), diarrhea (81%), infection (78%), nausea (56%), decreased appetite (53%), fatigue (51%), upper respiratory tract infection (51%), abdominal pain (48%), musculoskeletal pain (48%), electrolyte abnormalities (43%), decreased weight (37%), headache (37%), myelosuppression (35%), increased aspartate aminotransferase (35%), decreased blood bicarbonate (33%), cough (33%), hypertension (29%), and increased alanine aminotransferase (27%).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented.

Clinical Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Financial Discussion: No comments or questions. The committee voted to accept the recommendations as presented. None were opposed.

Outcome: Zokinvy is a pharmacy benefit and will be added to the specialty tier or the brand non-preferred tie for members with a three tier benefit. Zokinvy will require prior authorization with the following criteria:

- Medical record documentation of a confirmed diagnosis through genetic testing of one of the following:

- Hutchinson-Gilford Progeria Syndrome
- Processing-deficient progeroid laminopathy with either:
 - Heterozygous *LMNA* mutation with progerin-like protein accumulation
 - Homozygous or compound heterozygous *ZMPSTE24* mutations **AND**
- Medical record documentation of age greater than or equal to 12 months **AND**
- Medical record documentation of body surface area of at least 0.39m² **AND**
- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation that the requested dose is appropriate based on the patient's body surface area **AND**
- Medical record documentation that all potential drug interactions have been addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact)

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

FAST FACTS

CARBAGLU (cemiplimab-rwlc)

Updated Indication: Carbaglu is a carbamoyl phosphate synthetase 1 (CPS 1) activator now indicated in pediatric and adult patients for adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

Previously it was indicated for adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency and maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency.

Current formulary status: Commercial/CHIP: NF; Marketplace: Brand NP tier, requiring a prior authorization

Recommendation: There are no changes recommended to the formulary placement of Carbaglu. It is recommended that a policy be created as outlined below to ensure appropriate utilization, dosage, and duration of therapy:

N-acetylglutamate synthase (NAGS) deficiency

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of hyperammonemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: 6 months

Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)

- Medical record documentation that Carbaglu is prescribed by a metabolic disorder specialist **AND**
- Medical record documentation of a diagnosis of propionic acidemia (PA) or methylmalonic acidemia (MMA) **AND**
- Medical record documentation of plasma ammonia level greater than or equal to 50 micromol/L **AND**
- Medical record documentation that Carbaglu is being prescribed as adjunctive treatment to standard of care (including but not limited to intravenous glucose, insulin, L-carnitine, protein restriction, and dialysis) **AND**
- Medical record documentation that Carbaglu is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: 7 days

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

OPDIVO (nivolumab)

Updated indication: Opdivo is now indicated:

- for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy
- in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Current formulary status: Medical benefit requiring a prior authorization

Recommendations: There are no changes recommended to the formulary placement of Opdivo. It is recommended that the following prior authorization criteria and changes to the authorization durations be added to Medical Benefit Policy 126.0 to incorporate the new indications:

Adjuvant Treatment of Resected Esophageal or Gastroesophageal Junction Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease **AND**
- Medical record documentation that patient has received neoadjuvant chemoradiotherapy
- Medical record documentation Opdivo is being used in the adjuvant setting **AND**
- Medical record documentation Opdivo is being used as a single agent

***(Note: The FDA-approved treatment duration for use of Opdivo in the adjuvant setting for resected esophageal or gastroesophageal junction cancer is for up to 1 year, see specific reauthorization criteria below.)*

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma **AND**
- Medical record documentation that Opdivo will be used in combination with fluoropyrimidine- and platinum-based chemotherapy.

AUTHORIZATION DURATION:

****For adjuvant treatment of metastatic melanoma (completely resected melanoma) and adjuvant treatment of resected esophageal or gastroesophageal junction cancer:**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo for the adjuvant treatment of metastatic melanoma and adjuvant treatment of resected esophageal or gastroesophageal junction cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

****For first line-treatment of metastatic NSCLC expressing PD-L1 ($\geq 1\%$), for first-line treatment of metastatic or recurrent NSCLC, first line treatment of unresectable malignant pleural mesothelioma, and treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma:**

Initial approval:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **18 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Opdivo for the first line-treatment of metastatic NSCLC expressing PD-L1 ($\geq 1\%$), for first-line treatment of metastatic or recurrent NSCLC, first line treatment of unresectable malignant pleural mesothelioma and treatment of gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma: should not exceed the FDA-approved treatment duration of 2 years (24 months) in patients without disease progression. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For all other indications:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

TRODELVY (sacituzumab govitecan-hziy)

Updated Indication: Trodelvy is indicated under the accelerated approval process for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor.

The indication is approved under accelerated approval based on both tumor response rate and duration of response. Continued approval for the indication may be contingent on verification and description of clinical benefit in a confirmatory trial.

Previously, Trodelvy was only approved for adult patients with unresectable locally advanced or metastatic triplenegative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

Current formulary status: Medical benefit requiring a prior authorization

Recommendation: There are no changes recommended to the formulary placement or authorization duration for Trodelvy. It is recommended to make the following changes to Medical Benefit Policy 216 to incorporate the new indication:

Breast Cancer

- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of metastatic triple-negative breast cancer* **AND**
- Medical record documentation of trial of two previous lines of therapy for metastatic disease

***Note:** Triple negative breast cancer lack expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

Urothelial Cancer

- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of locally advanced or metastatic urothelial cancer **AND**
- Medical record documentation of progression on platinum-containing chemotherapy **AND**
- Medical record documentation of progression on a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor

AUTHORIZATION DURATION: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

YESCARTA (axicabtagene ciloleucel)

Updated Indication: Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy now indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Previously Yescarta was indicated for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Current formulary status: Medical benefit requiring prior authorization

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Yescarta. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy 162.0 to incorporate the new indication:

Follicular Lymphoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of relapsed or refractory follicular lymphoma (FL) **AND**
- Medical record documentation of a therapeutic failure on two or more previous lines of therapy **AND**
- Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

UPDATES

BUNAVAIL AND ZUBSOLV POLICY UPDATES

Background: The Department of Health and Human Services recently released new guidance waiving the federal certification requirements related to training, counseling, and other ancillary services when prescribing buprenorphine. Under this new guidance, eligible physicians may treat up to 30 patients without meeting the certification requirements. At the May P&T meeting it was determined that the following policy requirement would be removed from the Zubsolv and Bunavail policies:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**

After further review of the guidance it was determined that while the certification requirements are waived, eligible physicians still must apply for an X-DEA number in order to prescribe buprenorphine. Because of this, it is recommended that the previously removed criteria be reinstated.

Additionally, it is recommended that the following originally proposed criteria is removed as it is not relevant:

- Buprenorphine/naloxone must be used unless there is medical record documentation of intolerance to, contraindication to, or therapeutic failure on buprenorphine/naloxone (ex. use in pregnancy/breast feeding) **AND**

Recommendations: In order to prevent disruption and ensure appropriate prescribing, these changes were already enacted into policy. The following are the finalized criteria:

- Must be prescribed for the treatment of opioid dependence and the prescriber must have a unique identification number issued by the Drug Enforcement Agency (DEA) certifying prescribing authority for buprenorphine agents **AND**
- Member must be initially referred to and actively involved in formal counseling with a licensed behavioral health provider. Must provide the name of counselor and/or facility or rationale for non-participation **AND**
- For re-authorization, the member must be adherent to Bunavail therapy and must not be using opiates. Must be verified by lab screen (dated within 28 days of request date) for opiates and buprenorphine. The presence of controlled substances other than buprenorphine must be addressed **AND**
- Behavioral health vendor and/or plan case managers may contact prescriber, member, or counselor/facility to ensure compliance with these requirements. Continued approval for the drug is dependent on cooperation with this effort **AND**
- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

QVAR AND ASMANEX

Background: In terms of the inhaled corticosteroids, we currently have Arnuity Ellipta, Asmanex HFA, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler, and Qvar Redihaler on formulary at a Tier 2. We were presented with a rebate opportunity if we were to move Asmanex and Qvar to a Tier 3 requiring a step through the preferred brands.

Recommendations: The following changes are recommended for 1/1/2022:

Asmanex:

For Commercial/Exchange/CHIP, it is recommended to move Asmanex to a Tier 3 and it will require a Step Therapy with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Arnuity Ellipta or Flovent Diskus/Flovent HFA AND Pulmicort Flexhaler.

Qvar:

For Commercial/Exchange/CHIP, it is recommended to move Qvar to a Tier 3 and it will require a Step Therapy with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Arnuity Ellipta or Flovent Diskus/Flovent HFA AND Pulmicort Flexhaler.

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

REPATHA

Background: The current Repatha policies do not have an age requirement for the diagnosis of primary hyperlipidemia. Repatha is indicated as an adjunct to diet, alone or in combination with other LDL-C lowering therapies, in **adults** with primary hyperlipidemia, including heterozygous familial hypercholesterolemia to reduce LDL-C.

Recommendations: There are no changes to the formulary status at this time, however it is recommended to update the age requirement in the policy to the following:

- “Medical record documentation of age greater than or equal to 18 years if the diagnosis is clinical atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) **or primary hyperlipidemia** OR medical record documentation of age greater than or equal to 13 years if the diagnosis is homozygous familial hypercholesterolemia (HoFH) AND...”

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SKYRIZI

Background: Previously, Skyrizi was only available as a carton with two, 75 mg prefilled syringes and it was billed as 1 kit. The recommended dose is 150 mg at Week 0, Week 4, and every 12 weeks thereafter. Now, Skyrizi is available as 150 mg/mL in both a prefilled syringe and a single-dose pen. The Skyrizi 2 x 75 mg kit will be discontinued in 2021 and patients must transition to the 150 mg/mL single-dose prefilled syringe or single-dose pen.

Recommendations: At this time, the kit is still available so it is recommended to update the QLs to the following:

For the Prefilled Syringe Kit 75 mg/0.83 mL:

- **Initial Approval** – *Two authorizations must be entered.*
 - Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter
 - In PA Hub: Add ST, PA, and PE. *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.* Start date of this authorization is one-day after loading dose ends.
 - In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and 1 kit per 28 days (max quantity 1, min/max day supply 28) with a duration of one-week.
 - QL FOR LETTER: Loading dose: 1 kit per 28 days; Maintenance dose: 1 kit per 84 days
- **Renewal** – No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.
 - QL FOR LETTER: 1 kit per 84 days

For the Prefilled 150 mg/mL Syringe or Auto-Injector:

- **Initial Approval** – *Two authorizations must be entered.*
 - Skyrizi 150 mg at weeks 0, 4, and then every 12 weeks thereafter
 - In PA Hub: Add ST, PA, and PE. *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.* Start date of this authorization is one-day after loading dose ends.
 - In Darwin: Add ST, PA, PE, OQL, enter 1 in max number of claims authorized, and 1 mL per 28 days (max quantity 1, min/max day supply 28) with a duration of one-week.
 - QL FOR LETTER: Loading dose: 1 mL per 28 days; Maintenance dose: 1 mL per 84 days
- **Renewal** – No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.
 - QL FOR LETTER: 1 mL per 84 days

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

SPECIALTY DRUG LIST UPDATES

Recommendations: The following specialty medications were removed from the specialty drug list, so they will not process through the pharmacy benefit at a specialty pharmacy. They will process through the medical benefit.

CAR-T Immunotherapy:

- CAR-T immunotherapy uses a patient's immune cells to treat cancer and it is available through certified treatment centers. CAR-T immunotherapy is not available through specialty pharmacies.
 - Kymriah
 - Yescarta
 - Tecartus
 - Breyanzi
 - Abecma

Other medications:

- The following medications are used during procedures/diagnostic scans and would not be dispensed by specialty pharmacies.
 - Byfavo
 - Cerianna
 - Xaracoll

Discussion: No comments or questions.

Outcome: The committee voted to accept the recommendations as presented. None were opposed.

Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Voting responses were received from 24 of 39 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, July 20, 2021.

Meeting will be via phone/Microsoft Teams.