P&T Committee Meeting Minutes
Commercial/Marketplace/CHIP
April 22, 2021 e-vote

DRUG REVIEWS

BREYANZI (lisocabtagene maraleucel)

Review: Breyanzi is a CD19-directed genetically modified autologous T cell immunotherapy comprised of CAR-positive viable T cells composed of CD8 and CD4 components. It is indicated for the treatment of 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 (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. The separation of CD4 and CD8 components results in less differentiated T-cell populations with a low variability in CD8-positive CAR T-cells, which has been associated with increased toxicity in previous studies.

The efficacy of Breyanzi was evaluated in the TRANSCEND trial, an open-label, single-arm trial in adult patients with relapsed or refractory large B-cell non-Hodgkin lymphoma after at least 2 lines of therapy. Patients received Breyanzi two to seven days following completion of lymphodepleting chemotherapy (fludarabine 30 mg/m^2/day and cyclophosphamide 300 mg/m^2/day concurrently for 3 days Of the 192 patients eligible for efficacy evaluation, the overall response rate was 73% with 104 (54%) patients having a complete response and 37 (19%) patients having a partial response. The median duration of response was 16.7 months with a longer duration of response in patients who achieved a complete response compared to partial response. Additional responses were seen in 27 patients who underwent leukapheresis and had radiographically evaluable disease which may have resulted from bridging therapy, responses after receipt of product outside of the intended dose range, and responses to product that did not meet release specifications. IRC-assessed overall response rate in the leukapheresed population (n=287) was 59% with 43% of patients achieving a complete response and 15% achieving a partial response.

Like other CAR-T therapies, Breyanzi has black box warnings for Cytokine Release Syndrome (CRS) and neurological toxicities which includes fatal or life threatening reactions. Due to risk of CRS and neurological toxicities, Breyanzi will only be available through the BREYANZI REMS program which restricts dispensing and administration to enrolled certified facilities with healthcare providers trained in the management of CRS and neurological toxicities.

Additional warnings and precautions include the risk of serious infection and viral reactivation, prolonged cytopenias, hypogammaglubulinemia (IgG < 500 mg/dL), risk of secondary malignancies, and risk of altered or decreased consciousness or impaired coordination. During clinical trials, serious adverse reactions occurred in 46% of patients, most commonly CRS, encephalopathy, sepsis, febrile neutropenia, aphasia, pneumonia, fever, hypotension, dizziness, and delirium. Fatal adverse reactions occurred in 4% of patients. The most common adverse reactions of any grade (≥ 20%) were fatigue, CRS, musculoskeletal pain, nausea, headache, encephalopathy, infections, decreased appetite, diarrhea, hypotension, tachycardia, dizziness, cough, constipation, abdominal pain, vomiting and edema.

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

- Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following diagnoses:
    - High-grade B-cell lymphoma **OR**
    - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) **OR**
    - Primary mediastinal large B-cell lymphoma **OR**
    - Follicular lymphoma grade 3B

AND

- Medical record documentation of two or more lines of prior systemic 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

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

Other Recommendations: The following changes will be made to Medical Benefit Policy 162.0 for Yescarta to incorporate all included FDA approved indications:

Large B-Cell 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 one of the following diagnoses:
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified **OR**
    - Relapsed or refractory primary mediastinal large B-cell lymphoma **OR**
    - Relapsed or refractory high-grade B-cell lymphoma **OR**
    - Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma

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

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

TEPMETKO (tepotinib)

Review: Tepmetko is a kinase inhibitor indicated for the treatment of adult patients with metastatic NSCLC harboring *MET* exon 14 skipping alterations. Prior to the approval of Tepmetko, Tabrecta was the only MET inhibitor approved by the FDA for patients with a *MET*ex14-skipping mutation. Tepmetko is administered once a day offering improved convenience related to Tabrecta which is administered twice daily. There have been no head to head trials comparing Tepmetko and Tabrecta.

Per NCCN, both Tabrecta and Tepmetko are recommended as preferred single-agents therapy for recurrent, advanced, or metastatic disease in patients with MET exon 14 skipping mutation positive tumors as first-line

therapy or subsequent therapy following progression on first-line systemic therapy with a non-MET exon 14 skipping mutation-targeted regimen.

Tepmetko is available as 225 mg tablets. The recommended dose is 450 mg orally once daily with food until disease progression or unacceptable toxicity. The recommended dose for the management of adverse reactions is 225 mg orally once daily. In those who cannot tolerate 225 mg orally once daily, Tepmetko should be discontinued.

Tepmetko was studied in a phase 2, single-arm, open-label, multicenter, non-randomized, multicohort study. Patients were required to have advanced or metastatic NSCLC harboring METex14 skipping alterations. The population included 69 treatment naïve patients and 83 previously treated patients. The median age was 73 years, 43% never smoked, 86% had adenocarcinoma, and 98% had metastatic disease. Among those previously treated, 89% received prior platinum-based chemotherapy. Patients received Tepmetko 450 mg once daily until disease progression or unacceptable toxicity. The overall response rate was 43% in treatment-naïve patients and 43% in previously treated patients. The median duration of response was 10.8 months in treatment naïve patients and 11.1 months in previously treated patients.

There are no contraindications or black boxed warnings. Tepmetko has warnings and precautions for interstitial lung disease/pneumonitis, hepatotoxicity, and embryo-fetal toxicity. The most common adverse reactions (≥ 20%) were edema, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea. The safety and efficacy in pediatric patients have not been established.

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: Tepmetko is a pharmacy benefit that will be added to the formulary at the OralOncBrandNP tier. Tepmetko will require prior authorization with the following criteria:

- Prescription written by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations

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 the member experiences unacceptable toxicity or worsening of disease.

QUANTITY LIMIT: 60 tablets per 30 days

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

OLINVYK (oliceridine)

Review: Olinvyk (oliceridine) is a schedule II opioid agonist that is relatively selective to the mu-opioid receptor and selectively activates G-protein signaling. It is indicated for adult patients for the management of acute pain severe enough to require an intravenous opioid analgesic in whom other treatment options are inadequate. It is only indicated for short-term IV use and has only been studied up to a duration of 48 hours. It offers an additional intravenous opioid treatment option for acute pain in patients who cannot use other available IV opioids, all of which are available as generics (e.g. morphine, hydromorphone, fentanyl).

The efficacy of Olinvyk was evaluated in the APOLLO-1 and the APOLLO-2 trials in patients with moderate to severe acute pain following orthopedic surgery (bunionectomy) or plastic surgery (abdominoplasty). In each study, patients were randomized to blinded treatment with one of three Olinvyk treatment regimens, a placebo-control regimen, or a morphine-control regimen. Each treatment consisted of a loading dose, incremental doses on-demand via PCA device, and supplemental doses beginning one hour after the initial dose, and hourly thereafter as needed.

The APOLLO-1 trial was a randomized double-blind, placebo- and active-controlled study in 389 adult patients who underwent bunionectomy and reported at least moderate pain on a categorical scale and a score ≥4 on an 11-point numeric rating scale within 9 hours after discontinuation of regional perineural anesthesia. Patients could continue treatment for up to 48 hours. There was a statistically significant increase over placebo in analgesic effect observed in both the 0.35 mg and 0.5 mg Olinvyk treatment groups. The Olinvyk group also showed a decrease in pain intensity over time compared to placebo, but not as great as the decrease in the morphine treatment group.

The APOLLO-2 trial was a randomized double-blind, placebo- and active-controlled study in 401 adult patients following abdominoplasty surgery if they reported at least moderate pain on a categorical scale and a score ≥5 on an 11-point numeric rating scale within 4 hours after end of surgery. Patients could continue treatment for up to 24 hours. Results were consistent with the first trial showing a statistically significant increase in analgesic effect observed in both the 0.35 mg and 0.5 mg Olinvyk treatment groups. As with the first trial, the Olinvyk group also showed a decrease in pain intensity over time compared to placebo, but not as great as the decrease in the morphine treatment group.

Olinvyk has a side effect profile consistent with other opioids. Olinvyk contains black box warnings for addiction, abuse and misuse, respiratory depression, neonatal opioid withdrawal syndrome, and risk from concomitant use with benzodiazepines or other CNS depressants. Olinvyk has also shown mild QTc interval prolongation with the maximum daily cumulative dose of 27 mg in a multiple-dose study. The effect of total cumulative daily doses exceeding 27 mg per day has not been studied and may increase the risk of QTc interval prolongation. During clinical trials, the most common adverse reactions were nausea, vomiting, dizziness, headache, constipation, pruritis, and hypoxia.

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

- Medical record documentation of age greater than or equal to 18 **AND**
- Medical record documentation of moderate to severe acute pain **AND**
- Medical record documentation that patient requires an intravenous opioid analgesic **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three generic intravenous opioid analgesics

AUTHORIZATION DURATION: 2 days

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

UKONIQ (umbralisib)

Review: Ukoniq is a kinase inhibitor which inhibits phosphoinositide-3-kinase-delta (PI3Kδ) which is expressed in normal and malignant B-cells. It also inhibits Casein Kinase 1 epsilon (CK1ε) which regulates a pathway involved in lymphoid malignancy pathogenesis (cell survival, proliferation, and migration). It is indicated for the treatment of relapsed/refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and for the treatment of relapsed/refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

The efficacy of Ukoniq was evaluated for MZL and FL in two arms of an open-label, multicohort study, UNITY-NHL.

The efficacy of Ukoniq for the treatment of marginal zone lymphoma was evaluated in a single-arm cohort which included patients with relapsed or refractory MZL who had received at least one prior therapy, including an anti-CD20 based regimen. The cohort included a total of 69 patients with MZL (extranodal, nodal, and splenic) who received Ukoniq 800 mg once daily until disease progression or unacceptable toxicity. Efficacy was evaluated as overall response rate assessed by Independent Review Committee (IRC) using International Working Group criteria for malignant lymphoma. The overall response rate was 49% with 11 patients (16%) achieving a complete response and 23 patients (33%) achieving a partial response. The median time to response was 2.8 months and median duration of response was not reached (range: 0.0 months to 21.8 months). Overall response rates were 44.7%, 60.0%, and 45.5% for the MZL sub-type (extranodal, nodal, and splenic, respectively).

The efficacy of Ukoniq for the treatment of follicular lymphoma was evaluated in another single-arm cohort which included patients with relapsed or refractory FL who had received at least two prior systemic therapies, including an anti-CD20 monoclonal antibody and an alkylating agent. The cohort included a total of 117 patients with FL with ECOG performance status of 0 to 1 and who had received a median of 3 prior lines of therapy. Patients received Ukoniq 800 mg once daily until disease progression or unacceptable toxicity. Efficacy was evaluated as overall response rate assessed by Independent Review Committee (IRC) using International Working Group criteria for malignant lymphoma. The median follow-up time was 20.1 months. The overall response rate was 43% with 4 patients (3.5%) achieving a complete response and 46 (39%) achieving a partial response. The median time to response was 4.4 months and median duration of response was 11.1 months.

In clinical trials, the most common adverse reactions were increased creatine, diarrhea-colitis, fatigue, nausea, neutropenia, transaminase elevation, musculoskeletal pain, anemia, thrombocytopenia, upper respiratory tract infection, vomiting, abdominal pain, decreased appetite, and rash.

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: Ukoniq is a pharmacy benefit that will be added to the formulary at the OralOncBrandNP tier. Ukoniq will require prior authorization with the following criteria:

Marginal Zone Lymphoma

- Medical record documentation that Ukoniq is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of marginal zone lymphoma **AND**
- Medical record documentation of relapsed or refractory disease after at least one prior anti-CD20-based regimen

Follicular Lymphoma

- Medical record documentation that Ukoniq is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of follicular lymphoma **AND**
- Medical record documentation of relapsed or refractory disease after at least three prior lines of systemic therapy

QUANTITY LIMITS: 4 tablets per day

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable 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.

DARZALEX FASPRO (daratumumab/hyaluronidase)

Review: Darzalex Faspro is a combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase. The multiple myeloma indications for Darzalex Faspro are similar to the indications of Darzalex for intravenous use, with one additional indication for Darzalex Faspro being for the treatment of adult patients with light-chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. A limitation for use was also added. Darzalex Faspro is not indicated and is not recommended for the treatment of patients with light chain amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

Darzalex Faspro (daratumumab and hyaluronidase) is the subcutaneous injection of Darzalex, the intravenous injection used to treat multiple myeloma. Hyaluronidase works locally to depolymerize hyaluronan, thereby

increasing permeability into subcutaneous tissue. In addition to receiving most multiple myeloma indications included with the intravenous formulation, Darzalex Faspro also received accelerated approval to be used in newly diagnosed light-chain amyloidosis.

Light-chain (AL) amyloidosis is a rare plasma disorder resulting in organ damage, specifically to the heart, kidney and liver. Results of the ANDROMEDA study showed improved hematologic responses in patients with AL amyloidosis, which is strongly associated with organ response and improved survival.

The safety and efficacy of Darzalex Faspro in newly diagnosed multiple myeloma and relapsed/refractory multiple myeloma in combination with other medications was evaluated in a single-arm cohort of the phase 2 PLEIADES trial. The safety and efficacy of Darzalex Faspro used as monotherapy for refractory multiple myeloma was evaluated in the phase 3 COLUMBA trial.

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: Darzalex Faspro is a medical benefit. When Darzalex Faspro 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. Darzalex Faspro will require prior authorization with the following criteria:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation a diagnosis of multiple myeloma **AND**

<u>If newly diagnosed multiple myeloma (transplant ineligible):</u>

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) **AND**
- Medical record documentation that Darzalex Faspro will be given in combination with one of the following:
    - bortezomib (Velcade), melphalan, AND prednisone [VMP] **OR**
    - Lenalidomide (Revlimid) AND dexamethasone

<u>If newly diagnosed multiple myeloma (transplant eligible):</u>

- Medical record documentation that the member is eligible for stem-cell transplantation **AND**
- Medical record documentation that Darzalex Faspro will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

<u>If relapsed/refractory multiple myeloma:</u>

- One of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**

- Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) **AND** one of the following:
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with lenalidomide and dexamethasone OR
  - Medical record documentation that Darzalex Faspro will be prescribed in combination with bortezomib and dexamethasone OR

<u>If light-chain (AL) amyloidosis:</u>

- Prescription written by or in consultation with and hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis **AND**
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* **AND**
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

*Mayo Cardiac Stage IIIB defined as NT-proBNP > 8500 ng/L

QUANTITY LIMIT: 2.15 mL/day (15 mL per week)

AUTHORIZATION DURATION: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable 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.

CONJUPRI (levamlodipine)

Review: Conjupri is calcium channel blocker and may be used alone or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Conjupri (levamlodipine) is the pharmacologically active isomer of amlodipine, a dihydropyridine calcium slow-channel blocker which inhibits the entry of calcium ions into the cardiac muscle and vascular smooth muscle. Relaxation of this muscle results in a reduction in peripheral vascular resistance and reduction in blood pressure.

No new clinical efficacy studies were conducted and support for approval comes from previous findings of safety and efficacy of amlodipine tablets as well as one randomized, three-way crossover study comparing the pharmacokinetics of levamlodipine to amlodipine. Results demonstrated bioequivalence for levamlodipine compared to amlodipine for both peak concentration (C_{max}) and the area under the curve (AUC). A cursory review of post-approval studies conducted in China showed that the antihypertensive effect of levamlodipine was

generally comparable to amlodipine. Safety findings in these studies demonstrated consistent adverse reactions and adverse event rates between the two drugs.

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: Conjupri is a pharmacy benefit and will not be added to the formulary. Conjupri will require prior authorization with the following criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

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

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KATERZIA (amlodipine)

Review: Katerzia is indicated alone or in combination with other antihypertensive and antianginal agents for the treatment of:

- Hypertension
    - Katerzia is indicated for adults and pediatric patients 6 years and older, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction.
- Coronary Artery Disease
    - Chronic Stable Angina
    - Vasospastic Angina (Prinzmetal's or Variant Angina)
    - Angiographically documented Coronary Artery Disease in patients without heart failure or an ejection fraction < 40%

Katerzia is a ready-to-use oral suspension of amlodipine designed to replace extemporaneous compounding of tablets for treatment in patients with difficulty swallowing tablets. The efficacy of Katerzia is supported by a randomized, three-way crossover study assessing the pharmacokinetics which showed Katerzia suspension is bioequivalent to Norvasc for the peak concentration (C_{max}) and area under the curve (AUC). The approval of Katerzia relies on previous safety data from Norvasc and new issues regarding the safety of Katerzia were raised during bioequivalence studies.

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: Katerzia is a pharmacy benefit and will not be added to the formulary. Katerzia will require prior authorization with the following criteria:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary calcium channel blockers, one of which must be amlodipine

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

FAST FACTS

LIBTAYO (cemiplimab-rwlc)

Updated Indication: Libtayo is now indicated for the treatment of:
Basal Cell Carcinoma

- for the treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- for the treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

The mBCC indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for mBCC may be contingent upon verification and description of clinical benefit.

Non-Small Cell Lung Cancer (NSCLC)

- for the first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:
    - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
    - metastatic.

Previously Libtayo was approved for the treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

Current formulary status: Medical Benefit or pharmacy benefit on the specialty tier or brand non-preferred tier for members with a three tier benefit when processed at a specialty pharmacy

Recommendation: No changes are recommended to the formulary placement or authorization duration for Libtayo. The following prior authorization criteria will be added to Medical Benefit Policy 186.0 to incorporate the new indications:

Basal Cell Carcinoma

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of one of the following:
    - Documentation of a diagnosis of locally advanced BCC (laBCC) **OR**
    - Documentation of a diagnosis of metastatic BCC (mBCC)

AND

- Medical record documentation of previous treatment with a hedgehog pathway inhibitor or documentation that a hedgehog pathway inhibitor is not appropriate

Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record docuemntation of non-small cell lung cancer (NSCLC) **AND** medical record documentation of one of the following:
    - Documentation of locally advanced disease AND the patient is not a candidate for surgical resection or definitive chemoradiation **OR**

- Documentation of metastatic disease

AND

- Medical record documentation of high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test **AND**
- Medical record documentation of no EGFR, ALK, or ROS1 genomic tumor aberrations **AND**
- Medical record documentation that Libtayo is being used as first-line treatment

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.

PRALUENT (alirocumb)

Updated indication: Praluent is a PCSK9 inhibitor indicated:

- To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C.
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Previously, Praluent was only indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease and as an adjunct to diet, alone, or in combination with other lipid lowering therapies (e.g. statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C.

Current formulary status: Praluent is a pharmacy benefit and is available at the brand preferred tier. Praluent requires a prior authorization.

Recommendations: There are no changes to formulary status. The following updates will be made to prior authorization criteria:

- Medical record documentation of a diagnosis of:
  - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
  - Primary hyperlipidemia **OR**
  - Heterozygous familial hypercholesterolemia **AND** either:
    - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
    - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization **OR**

    - Homozygous familial hypercholesterolemia (HoFH) **AND** either:
        - Genetic testing to confirm diagnosis showing at least one low-density lipoprotein (LDL) receptor-defective mutation **OR**
        - Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL AND either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation that Praluent is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy showing:
    - Low-density lipoprotein (LDL) greater than 100 for primary prevention **OR**
    - Low-density lipoprotein (LDL) greater than 70 for secondary prevention **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation that Praluent is not being used in combination with another PCSK9 inhibitor or Juxtapid

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: 2 mL per 28 days

AUTHORIZATION DURATION: Initial authorizations for Praluent will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Praluent continues to not be used in combination with another PCSK9 inhibitor or Juxtapid

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.

DRUG UPDATES

REPATHA (evolocumab)

In patients with HoFH, setting a specific LDL-C target may not always be feasible, it is usually determined by patient preference, cost, and availability of therapies. Those with HoFH often have an untreated LDL-C of > 500 mg/dL. Experts have not agreed on a specific LDL-C goal for these patients, however values < 50 mg/dL and 135 mg/dL have been expressed. Values at the low end of the range may difficult to achieve.

Our current PCSK9 inhibitor policies for commercial, do not address the indication to reduce LDL-C in patients with primary hyperlipidemia without heterozygous familial hypercholesterolemia. In the absence of clinical cardiovascular outcomes in this patient population, PCSK9 inhibitors are not recommended for patients without familial hypercholesterolemia. In the primary hyperlipidemia clinical trials, the primary outcomes were changes in LDL-C, Non-HDL-C, Apo B, and total cholesterol. Statins have demonstrated reductions in myocardial infarction and cardiovascular mortality. Our prior authorization criteria still requires a step through statins, so we will add the primary hyperlipidemia indication to our policies to match Gold. Also, Kynamro has been discontinued.

Current formulary status: Repatha is a pharmacy benefit and is available at the brand preferred tier. Praluent requires a prior authorization.

Recommendations: There are no changes to formulary status. The following updates will be made to prior authorization criteria:

- Medical record documentation of a diagnosis of:
    - Clinical atherosclerotic cardiovascular disease (ASCVD), including acute coronary syndromes (a history of myocardial infarction or unstable angina), coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin **OR**
    - Primary hyperlipidemia **OR**
    - Heterozygous familial hypercholesterolemia (HeFH) **AND** either:
        - Genetic testing to confirm a mutation in the low-density lipoprotein (LDL) receptor, PCSK9, or ApoB gene **OR**
        - Medical record documentation of definite heterozygous familial hypercholesterolemia (HeFH) (score greater than 8) on the diagnostic criteria scoring system (Table 1) as defined by the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS) guidelines and the World Health Organization **OR**
    - Homozygous familial hypercholesterolemia (HoFH) **AND** either:
        - Genetic testing to confirm diagnosis showing at least one low-density lipoprotein (LDL) receptor-defective mutation **OR**
        - Diagnosis made based on a history of an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL **AND** either xanthoma before 10 years of age **OR** evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents **AND**
- Medical record documentation that Repatha is prescribed by a cardiologist or lipidologist **AND**
- Medical record documentation of a baseline low-density lipoprotein (LDL) drawn within 3 months of the start of PCSK9 therapy
    - Low-density lipoprotein (LDL) greater than 100 for primary prevention **OR**
    - Low-density lipoprotein (LDL) greater than 70 for secondary prevention **AND**
- 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 medical record documentation of age greater than or equal to 13 years if the diagnosis is homozygous familial hypercholesterolemia (HoFH) **AND**

- Medical record documentation that patient is currently on and is adherent to (taking at least 90% of prescribed doses over the past three months) maximally tolerated dose of atorvastatin or rosuvastatin or has documented therapeutic failure on, intolerance to, or contraindication to atorvastatin and rosuvastatin **AND**
- Medical record documentation that non-pharmacologic therapies are in place including cholesterol lowering diet, exercise, and weight management strategies **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to ezetimibe **AND**
- Medical record documentation that Repatha is not being used in combination with another PCSK9 inhibitor or Juxtapid **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **AND**
- If requesting 420 mg every 2 weeks:
    - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
    - One of the following:
        - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**
        - Medical record documentation that the member is on lipid apheresis every 2 weeks

AUTHORIZATION DURATION: Initial authorizations for Repatha will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Medical record documentation of an up to date low density lipoprotein (LDL) cholesterol level since the date of the previous review showing the patient has had a clinically significant response to treatment with a PCSK9 inhibitor **AND**
- Medical record documentation that the patient is not experiencing any significant adverse events related to therapy **AND**
- Claims history and attestation from the provider showing the patient is adherent to PCSK9 therapy **AND**
- Claims history or attestation from the provider that the patient is staying adherent to (filling at least 90% of doses) statin therapy (if statin tolerant) **AND**
- Medical record documentation that Repatha continues to not be used in combination with another PCSK9 inhibitor or Juxtapid **AND**
- If requesting Repatha Syringe or Repatha Sureclick 420 mg dose (3 mL), medical record documentation of therapeutic failure on, intolerance to, or contraindication to Repatha Pushtronex **AND**
- If requesting 420 mg every 2 weeks:
    - Medical record documentation of a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
    - One of the following:
        - Medical record documentation that the member has been on 420 mg once monthly for 12 weeks and a clinically meaningful response has not been achieved **OR**
        - Medical record documentation that the member is on lipid apheresis every 2 weeks

QUANTITY LIMIT:

- Pen/Syringe: 2 mL per 28 days
- Pushtronex: 3.5 mL per 28 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.

VIIBRYD (vilazodone)

It was brought to our attention that some behavioral health providers are questioning the specific requirement to fail bupropion in our current Viibryd policies. Their main concern was the requirement to try bupropion for members with anxiety disorders.

Current formulary status: Viibryd is a pharmacy benefit and is available at the brand non-preferred tier. Viibryd requires a prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, at least three antidepressant classes, one of which is bupropion

Recommendations: There are no changes to formulary status. The following updates will be made to prior authorization criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of major depressive disorder **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to, at least three antidepressant classes

QUANTITY LIMIT: 1 tablet per day

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.

MINIMUM AND MAXIMUM DAY SUPPLY UPDATE

The medications listed in the chart below will only pay when processed within the appropriate minimum and maximum day supply. The minimum and maximum day supply limitations are based on FDA approved dosing. Claims processing outside of these limits will deny and we be reviewed with the quantity limit exception policy, 487.0, unless it is addressed in the drug policy.

Drug Name	Min Day Supply	Max Day Supply
Abilify Maintena	28	30
Actemra	21	30
Aristada 1064 mg	56	60
Aristada 441 mg	28	30
Aristada 662 mg	28	30
Aristada 882 mg	28	42
Avsola	28	60
Benlysta subQ	28	30
Bethkis	56	60
Boniva/Ibandronate IV	84	90
Botox	N/A	90
Cimzia syringe	28	30
Cinqair	28	30
Cosentyx Prefilled Syringe	28	60
Cosentyx Auto-injector	28	60
Cotellic	28	30
Dysport	N/A	90
Eligard 22.5 mg	84	90
Eligard 30 mg	112	120
Eligard 45 mg	168	180
Eligard 7.5 mg	28	30
Enbrel	28	30
Entyvio	56	60
Eylea	28	90
Farydak	21	21
Fasenra	56	60
Firmagon	28	30
Forteo	28	30
Teriparatide	28	31
Galafold	28	30
Humira	28	30
Ibrance	28	30
Ibrandronate	28	30
Ilaris	28	60
Ilumya	84	90
Iluvien	1080	1095
Inflectra	28	60
Invega Sustenna	28	30
Invega Trinza	84	90

Inqovi	28	30
Kevzara	28	30
Kisqali	28	30
Kisqali Femara Co-Pack	28	30
Lemtrada	365	365
Lonsurf	28	30
Lucentis	28	90
Lupaneta Pack 1 month	28	30
Lupaneta Pack 3 month	84	90
Lupron 22.5 mg	84	90
Lupron 3.75 mg	28	30
Lupron 30 mg	112	120
Lupron 45 mg	168	180
Lupron 7.5 mg	28	30
Lupron Deport-Ped 15 mg (1-month)	28	30
Lupron Depot-Ped 11.25 mg (1-month)	28	30
Lupron Depot-Ped 11.25 mg (3-month)	84	90
Lupron Depot-Ped 30 mg (3-month)	84	90
Lupron Depot-Ped 7.5 mg	28	30
Lupron 11.25 mg	84	90
Mavyret	28	30
Medroxyprogesterone 104 mg/mL IM syringe	84	98
Medroxyprogesterone 150 mg/mL IM syringe	84	91
Myobloc	Hard to define	90
Ninlaro	28	30
Nucala	28	30
Nucala prefilled syringe/auto-injector	28	30
Ocrevus	180	180
Onpattro	21	21
Orencia	28	30
Orencia	28	30
Onureg	28	30
Pemazyre	21	21
Perseris	28	30
Probuphine	168	180
Prolia	180	180
Reclast	365	365
Renflexis	28	60
Remicade	28	60
Retisert	900	900

Revlimid	21	30
Risperdal Consta	28	30
Sandostatin LAR	28	30
Scenesse	56	60
Signifor LAR	28	30
Simponi	28	30
Simponi Aria	56	60
Somatuline Depot	28	60
Spinraza	120	120
Stelara 45 mg	84	90
Stelara 90 mg	56	90
Stivarga	28	30
Sublocade	26	30
Supprelin LA	365	365
Sutent	28	42
Synagis	28	30
Takhzyro	28	30
Taltz	28	30
Tobi	56	60
tobramycin	56	60
Trelstar 11.25 mg	84	90
Trelstar 22.5 mg	168	180
Trelstar 3.75 mg	28	30
Tremfya	56	60
Triptodur	168	180
Tymlos	30	30
Tysabri	28	60
Tyvaso	28	30
Uplizna	168	180
Vivitrol	28	30
Vyepti	84	90
Xeomin	Hard to define	90
Xgeva	28	30
Yutiq	1080	1095
Zyprexa Relprevv	28	30

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.

MINIMUM AND MAXIMUM DAY SUPPLY WITH LOADING DOSE UPDATE

The minimum and maximum day supply will apply to all fills. In order, to account for loading doses, we will need to enter overrides for the initial authorizations. Majority of the exceptions to the minimum and maximum day supply edits (e.g. loading doses) were brought to previous P&T meetings. However, this is a finalized list.

Drug	Min Day Supply	Max Day Supply	Dosing	Recommendations For initial auths for day supply override only
Entyvio	56	60	300 mg IV infusion at 0, 2, and 6 weeks, and then every 8 weeks thereafter.	Initial 6 month auth: enter one-time, two week auth with reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 2. Enter max day supply of 42 (in the initial and maintenance override fields). Enter a min day supply of 42 (in the initial override field).
Fasenra	56	60	30 mg every 4 weeks for the first 3 doses, then once every 8 weeks.	Initial 3 month auth: enter reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 1. Enter max day supply of 28 (in the initial and maintenance override fields). Enter a min day supply of 28 (in the initial override field).

Ilumya	84	90	100 mg at weeks 0 and 4 and then every 12 weeks.	Initial 6 month: enter one-time, two week auth with reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 1. Enter max day supply of 28 (in the initial and maintenance override fields). Enter a min day supply of 28 (in the initial override field).
Simponi Aria	56	60	2 mg/kg at weeks 0,4, and then every 8 weeks.	Initial 6 month: enter one-time, two week auth with reason code DS and OUP. Enter max day supply of 28 (in the initial and maintenance override fields). Enter a min day supply of 28 (in the initial override field).
Spinraza	120	120	12 mg intrathecally once every 14 days for 3 doses then 12 mg once 30 days after the third dose; then 12 mg once every 4 months.	Initial 42 day auth: enter reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 5. Enter max day supply of 14 (in the initial and maintenance override fields). Enter a min day supply of 14 (in the initial override field). Enter an Rx count of 3.

Stelara 45 mg	84	90	For PP (≤ 100 kg) & PsA: 45 mg initially and 4 weeks later, then 45 mg every 12 weeks.	Initial 6 month: enter one-time, two week auth with reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 0.5. Enter max day supply of 28 (in the initial and maintenance override fields). Enter a min day supply of 28 (in the initial override field).
Stelara 90 mg	56	90	For PP (>100 kg) & PsA with severe PP: 90 mg initially and 4 weeks later, then 90 mg every 12 weeks.	Initial 6 month for PsA and PP: enter one-time, two week auth with reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 1. Enter max day supply of 28 (in the initial and maintenance override fields). Enter a min day supply of 28 (in the initial override field).
Tremfya	56	60	100 mg at weeks 0, 4, and then every 8 weeks.	Initial 6 month: enter one-time, two week auth with reason code DS and OUP. Enter max quantity dispensed (in initial and maintenance override fields) of 1. Enter max day supply of 28 (in the initial and maintenance

				override fields). Enter a min day supply of 28 (in the initial override field).

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 21 of 37 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, May 18, 2021.

Meeting will be via phone/Microsoft Teams.