P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kidsa
October 22, 2020 e-vote

DRUG REVIEWS

BLENREP (belantamab mafodotin-blmf)

Review: Blenrep is a B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. Blenrep contains belantamab, an antibody directed against B-cell maturation antigen (BCMA), a protein with highly selective expression in multiple myeloma cells, and mafodotin, a microtubule inhibitor which disrupts the microtubule network which leads to cell cycle arrest and apoptosis. Through the binding of BCMA which plays a role in myeloma cell growth and survival, Blenrep also demonstrated extracellular antitumor activity by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

The efficacy of Blenrep was investigated in the ongoing DREAMM-2 trial, an open-label, two-arm phase 2 study in patients with relapsed or refractory multiple myeloma with disease progression after three or more lines of therapy. Patients were refractory to immunomodulatory drugs and proteasome inhibitors and refractory or intolerant to an anti-CD38 monoclonal antibody.

Patients were randomly assigned to receive Blenrep 2.5 mg/kg (n=97) or 3.4 mg/kg (n=99) every 3 weeks until disease progression or unacceptable toxicity. Randomization was stratified by the number of previous therapies (≥ 4 vs. <4) and the presence or absence of cytogenic features (high risk vs. non-high risk). Baseline characteristics were balanced between the two groups. A majority of patients in both treatment groups had been treated with at least 4 previous lines of therapy (84% in the 2.5 mg/kg group and 83% in the 3.4 mg/kg group).

The overall response rate in patients receiving the recommended dosage of 2.5 mg/kg was 31% with a majority of patients demonstrating a very good partial response or partial response. The median time to response was 1.4 months and 73% of responders had a response lasting at least 6 months. The median time to response was 1.4 months and 73% of responders had a response lasting at least 6 months. Median progression free survival was 2.9 months. At the time of data cutoff, overall survival was not mature, but the 6-month overall survival rate was 72%. Rates were comparable in the group receiving 3.4 mg/kg, but this group had a higher incidence of dose modifications and dose delays resulting in a dose intensity lower than the intended dose in this group (median 2.95 mg/kg).

Blenrep has a black box warning for ocular toxicity, including keratopathy, changes in visual acuity, blurred vision, and dry eye. Blenrep is only available through a REMS program due to risk of ocular toxicity. Most keratopathy events developed within the first 2 treatment cycles and were reported as Grade 3 reactions (45%), but left untreated, keratopathy can develop into extensive corneal defects. Due to the risk of ocular toxicity, Blenrep is only available through the Blenrep REMS program.

In clinical trials, 95 patients received the recommended dosage of 2.5 mg/kg intravenously every 3 weeks. Serious adverse reactions occurred in 40% of patients, including pneumonia, pyrexia, renal impairment, sepsis, hypercalcemia, and infusion-related reactions. Fatal reactions occurred in 3.2% of patients and included sepsis, cardiac arrest, and lung infection. The most frequent adverse reaction requiring discontinuation and dose interruptions and reductions was keratopathy. The most common adverse reactions were keratopathy, decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue.
A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, in DREAMM-2, 43% of patients were aged ≥ 65 years and 17% were aged 75 years and older. Clinical studies did not include sufficient number of patients 65 and older to determine if there is a difference in efficacy from younger patients. Keratopathy occurred in 80% of patients aged less than 65 years and 73% of patients 65 years and older. Among patients who received Blenrep at 2.5 mg/kg dose in DREAMM-2 (n=95), keratopathy occurred in 67% of patients less than 65 years and 73% of patients aged 65 years and older. Clinical studies did not include sufficient numbers of patients 75 years and older to determine whether they response differently compared with younger patients.

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: Blenrep is a medical benefit and will not be added to the Commercial, Marketplace, or GHP Kids pharmacy formulary. After 01/01/21, when Blenrep is processed at a specialty pharmacy, it should be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Blenrep 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 multiple myeloma **AND**
- Medical record documentation of treatment with at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent

AUTHORIZATION DURATION: 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 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 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.

INQOVI (decitabine and cedazuridine)

Review: Inqovi is indicated for the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

Inqovi is a combination of decitabine and cedazuridine, and is the first oral DNA hypomethylating agent approved by the Food & Drug Administration (FDA) for the treatment of myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML). Inqovi is a fixed-dose tablet, containing decitabine, a DNA hypomethylating agent (a nucleoside metabolic inhibitor), and cedazuridine, a cytidine deaminase (CDA) inhibitor. After phosphorylation, decitabine is incorporated into DNA and inhibits DNA methyltransferase, causing apoptosis. However, decitabine is not orally bioavailable since it can be rapidly cleared by CDA found in the gut and liver and is therefore combined with cedazuridine. Cedazuridine helps prevent decitabine from degrading in the digestive system and increases systemic exposure of decitabine, allowing for oral delivery of decitabine.

The only FDA-approved treatments for intermediate and high-risk MDS and CMML are the hypomethylating agents, Dacogen (decitabine) and Vidaza (azacitidine). These agents are administered primarily by intravenous (IV) infusion or by subcutaneous (SQ) injections.

The recommended dose of Inqovi is one tablet (35 mg decitabine/100 mg cedazuridine) orally once daily on Days 1 through 5 of each 28-day cycle taken while on an empty stomach for a minimum of 4 cycles until disease progression or unacceptable toxicity; a complete or partial response may take longer than 4 cycles. Inqovi should not be substituted for an intravenous decitabine product within a cycle.

The efficacy of Inqovi was evaluated in ASTX727-01-B, an open-label, randomized, 2-cycle, 2-sequence crossover study (NCT02103478) that included 80 adult patients with MDS (International Prognostic Scoring System [IPSS] Intermediate-1, Intermediate-2, or high-risk) or CMML. Patients were randomized 1:1 to receive Inqovi (35 mg decitabine and 100 mg cedazuridine) orally in Cycle 1 and decitabine 20 mg/m2 intravenously in Cycle 2 or the reverse sequence. Both Inqovi and intravenous decitabine were administered once daily on Days 1 through 5 of the 28-day cycle. Starting with Cycle 3, all patients received Inqovi orally once daily on Days 1 through 5 of each 28-day cycle until disease progression or unacceptable toxicity. Efficacy was established on the basis of complete response (CR) and the rate of conversion from transfusion dependence to transfusion independence. 18% of patients had a complete response. The median duration of complete response was 8.7 months

and the median time to complete response was 4.8 months. Among the dependent on transfusions at baseline, 49% became independent of RBC and platelet transfusions during any consecutive 56-day post-baseline period. Of the patients who were independent of transfusions at baseline, 64% remained transfusion-independent during any consecutive 56-day post-baseline period.

The efficacy of Inqovi was also evaluated in ASTX727-02, an open-label, randomized, 2-cycle, 2-sequence crossover study (NCT03306264) that included 133 adult patients with MDS or CMML, including all French-American-British (FAB) classification criteria and IPSS Intermediate-1, Intermediate-2, or high-risk prognostic scores. Patients were randomized in the same manner as the first study. Efficacy was established on the basis of CR and the rate of conversion from transfusion dependence to transfusion independence. 21% of patients had a complete response. The median duration of the complete response was 7.5 months. The median time to complete response was 4.3 months. Among the patients who were dependent on transfusions at baseline, 53% became independent of transfusions during any 56-day post-baseline period. Of the patients who were independent of transfusions at baseline, 63% remained transfusion-independent during any 56-day post-baseline period.

Inqovi has no boxed warnings or contraindications, but does have warnings and precautions for myelosuppression and embryo-fetal toxicity. The most common adverse reactions (≥ 20%) were fatigue, constipation, hemorrhage, myalgia, mucositis, arthralgia, nausea, dyspnea, diarrhea, rash, dizziness, febrile neutropenia, edema, headache, cough, decreased appetite, upper respiratory tract infection, pneumonia, and transaminase increased. The safety and effectiveness of Inqovi have not been established in pediatric patients.

The NCCN guidelines suggest that Inqovi could be considered as a substitution for IV decitabine for myelodysplastic syndromes.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, no overall differences in safety or effectiveness were observed between patients age 65 years and older, 75 years and older, and younger patients.

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: Inqovi will be a pharmacy benefit. Inqovi will be added to the Commercial, Marketplace, and GHP Kids formularies on the OralOncBrandNP tier. Inqovi will require a 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 myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups

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: 5 per 28 days; max qty supply: 5; min day supply: 28; max day supply: 28

Other Recommendations: The current Dacogen (decitabine) medical policy requires failure on Vidaza (azacitidine) for myelodysplastic syndrome. The initial reviewer added this criteria due to cost. Neither the FDA indication nor NCCN guidelines recommend the failure of Vidaza prior to Dacogen. It is recommended to update MBP 46.0 to remove the following criterion from the myelodysplastic syndrome section:
"….Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Vidaza (azacitidine)"

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

TECARTUS (brexucabtagene autoleucel)

Review: Tecartus is approved under accelerated approval for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL). It is a CD19-directed genetically modified autologous T cell immunotherapy, which is prepared by harvesting a patient's own T cells via a standard leukapheresis procedure and then genetically modifying them using retroviral transduction to produce chimeric antigen receptors (CARs). Following conditioning chemotherapy, the CAR T-cells are reinfused into the patient where they are directed to attach to and kill lymphoma cells expressing CD-19.

The efficacy of Tecartus was investigated in the ZUMA-2 trial, and open-label, single-arm trial in adult patients with histologically confirmed mantle-cell lymphoma with either cyclin D1 overexpression or presence of the translocation t and had disease that was relapsed or refractory to up to 5 prior therapies, which must have included anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody, and a Bruton tyrosine kinase inhibitor (BTKi; ibrutinib or acalabrutinib).

All eligible patients (74) underwent leukapheresis to obtain cells to manufacture Tecartus. Conditioning chemotherapy was administered on days -5, -4, and -3 before a single intravenous infusion of Tecartus was administered with a target dose of 2 x 10^6 CAR T cells per kilogram of body weight on day 0. The median time from leukapheresis to product delivery was 15 days and the median time from leukapheresis to product infusion was 27 days. All patients treated with Tecartus received the infusion on Day 0 and were hospitalized until at least Day 7.

Results of the primary efficacy endpoint evaluating objective response rate showed that 52/60 (87%) efficacy-evaluable patients had a response, with a majority of patients (62%) experiencing a complete response. The median time to response was 28 days with a median follow-up time for duration of response of 8.6 months. At 12 months, the estimated progression-free survival and overall survival were 61% and 83%, respectively. Subgroup analysis showed progression-free survival at 6 months was consistent among all patients, including those with poor prognostic features (i.e. Ki-67 proliferation index $\geq$ 50, blastoid or pleomorphic morphologic features or *TP53* mutation).

Tecartus carries a black box warning for Cytokine release syndrome (CRS) and neurologic toxicities, including life-threatening reactions, occurred following treatment with Tecartus. Because of the risk of CRS and neurologic toxicities, Tecartus is available only through a restricted REMS program called the YESCARTA and TECARTUS REMS program. Patients must be monitored for at least 7 days in the certified healthcare facility following the infusion of Tecartus. Tecartus also carries warnings and precautions for hypersensitivity reactions, severe infections, viral reactivation, febrile neutropenia, prolonged cytopenias, hypogammaglobulinemia, and secondary malignancies. In the ZUMA-2 clinical trial, the most common reactions were pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrythmia, infection, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia.

NCCN recommends use of Tecartus in certain circumstances without regard to response duration to prior chemoimmunotherapy or expected median progression free survival as subsequent therapy for patients with relapsed or refractory disease, only be given after chemoimmunotherapy and a Bruton tyrosine kinase inhibitor. This recommendation is consistent with the inclusion criteria for the Zuma-2 trial and is stricter than the FDA approved indication which does not specify a line of therapy.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, out of 82 patients treated with Tecartus, 42 patients were $\geq$ 65 years and 40 patients were < 65 years of age. No overall differences in safety and efficacy were observed between patients 65 years and older and younger patients.

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: Tecartus is a medical benefit and will not be added to the Commercial, Marketplace or GHP Kids pharmacy formularies. After 01/01/21, when Tecartus is processed at a specialty pharmacy, it should be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. The following prior authorization criteria should apply:

- Medical record documentation that Tecartus 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 relapsed or refractory mantle cell lymphoma (MCL)

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

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

FAST FACTS

DARZALEX (daratumumab)

Updated Indication: Darzalex is a CD38-directed cytolytic antibody now indicated for the treatment of adult patients with multiple myeloma in combination with carfilzomib (Kyprolis) and dexamethasone in patients who have received one to three prior lines of therapy.

Current formulary status: Medical Benefit requring a prior authorization

Recommendation: No changes are recommended to the formulary placement or authorization duration for Darzalex. The following criteria will be added to Medical Benefit Policy 139.0 to incorporate the new indication:

- 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 will be prescribed in combination with lenalidomide and dexamethasone **OR**
  - Medical record documentation that Darzalex will be prescribed in combination with bortezomib and dexamethasone **OR**
  - Medical record documentation that Darzalex will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

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.

EMPLICITI (elotuzumab)

Updated Indication: Empliciti is a SLAMF7-directed immunostimulatory antibody is now indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Current formulary status: Medical benefit requiring prior authorization

Recommendations: There are no changes recommended to the formulary placement or authorization duration of Empliciti. The following criteria will be added to Medical Benefit Policy 140.0 to incorporate the new indication:

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of multiple myeloma **AND**
- Medical record documentation of one of the following:
  - Medical record documentation that the patient has previously been treated with at least one prior therapy for multiple myeloma AND medical record documentation of use in combination with lenalidomide (Revlimid) and dexamethasone

  OR
  - Medical record documentation that the patient has previously been treated with at least two prior therapies for multiple myeloma, including lenalidomide and a proteasome inhibitor AND medical record documentation of use in combination with pomalidomide (Pomalyst) and dexamethasone

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.

FARXIGA (dapagliflozin)

Updated Indication: Farxiga is now indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure and reduced ejection fraction (NYHA class II-IV).

Previously, Farxiga was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors.

Current formulary status: Farxiga is a pharmacy benefit and is non-formulary.

Recommendation: There are no changes recommended to formulary status at this time. However, it is recommended to update prior authorization criteria to reflect the new indication:

Diabetes:

- Medical record documentation of a diagnosis of type II diabetes mellitus **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Invokana **AND** Jardiance

Heart Failure:

- Medical record documentation of New York Heart Association (NYHA) class II-IV heart failure **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a reduced ejection fraction (left ventricular ejection fraction (LVEF) of less than or equal to 40%) **AND**
- Medical record documentation that the member is on optimized pharmacological therapy (e.g. combination of renin-angiotensin system inhibitor (ACEi/ARB/angiotensin receptor-nepreilysin inhibitor), evidence based beta-blocker (metoprolol succinate/carvedilol/bisoprolol), and a mineralocorticoid receptor antagonist, diuretic) unless contraindicated or not tolerated

There will be no changes to quantity limits.

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.

KYPROLIS (carfilzomib)

Updated Indication: Kyprolis is a proteasome inhibitor now indicated in combination with daratumumab (Darzalex) and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Previous combinations for this indication included Kyprolis in combination with dexamethasone OR lenalidomide and dexamethasone. Kyprolis is also indicated as a single agent for patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

Current formulary status: Medical Benefit requiring a prior authorization

Recommendation: No changes are recommended to the formulary placement or authorization duration for Kyprolis. It is recommended that the following criteria be added to the Medical Benefit Policy 97.0 to incorporate the new indication for Kyprolis:

- Medical record documentation that Kyprolis will be used:
  - As monotherapy OR
  - In combination with dexamethasone OR
  - In combination with dexamethasone and lenalidomide **OR**
  - In combination with daratumumab (Darzalex) and dexamethasone

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.

FREESTYLE LIBRE 2.0

Updated Product: The FreeStyle Libre 2.0 Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device with real time alarms capability indicated for the management of diabetes in persons age 4 and older. It is intended to replace blood glucose testing for diabetes treatment decisions, unless otherwise indicated. The System also detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is also intended to autonomously communicate with digitally connected devices. The System can be used alone or in conjunction with these digitally connected devices where the user manually controls actions for therapy decisions

It shares the features of the previous version of Freestyle libre with the addition of real time alarms which can be customized to notify the patient of high or low glucose readings and loss of signal between the sensor and the reader. Like FreeStyle Libre, sensors should be changed every 14 days. Battery life changed from 7 days to 4 days due to continuous transmission of data to generate alarms.

Current formulary status: Covered under DME or on the brand preferred tier requiring prior authorization

Recommendation: The following changes will be incorporated to Commercial Policy 594.0 FreeStyle Libre:

- Medical record documentation of type 1 or 2 diabetes mellitus **AND**
- If the request is for FreeStyle Libre: Medical record documentation of member age greater than or equal to 18 years **OR**
- If the request is for FreeStyle Libre 2.0: Medical record documentation of member age greater than or equal to 4 years

AND

- One of the following: o Medical record documentation of current insulin therapy use **OR**
  - Medical record documentation of functional barriers to finger stick blood glucose monitoring **OR**
  - Medical record documentation of history of recurrent hypoglycemia episodes **OR**
  - Medical record documentation of HgA1c greater than 9

QUANTITY LIMIT: Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization). Authorizations must be placed for both the reader and sensors.*

- Freestyle Libre 10 or 14 day reader or FreeStyle Libre 2.0 reader: 1 reader every 2 years
- Freestyle Libre 10 day sensors: 3 sensors per 30 days
- Freestyle Libre 14 day sensors or FreeStyle Libre 2.0 sensors: 2 sensors 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.

Voting responses were received from 21 of 35 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, November 17, 2020

Meeting will be via phone/Microsoft Teams

P&T Committee Meeting Minutes
Medicare
November 17, 2020

Present (via skype):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kenneth Bertka, MD
Megan Ammon, Pharm.D.	Holly Bones, Pharm.D.
Kristen Bender, Pharm.D.	Dean Christian, MD
Kim Castelnovo	Alyssa Cilia, RPh
Kimberly Clark, Pharm.D.	Michael Evans, RPh
Rajneel Farley, Pharm.D.	Jason Howay, Pharm.D.
Kelly Faust Pharm.D.	Steven Moscola, RPh
Tricia Heitzman, Pharm.D.	Jonas Pearson, RPh
Nichole Hossler, MD	William Seavey, Pharm.D.
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Phillip Krebs, R.EEG T	
Perry Meadows, MD	
Jamie Miller, RPh	
Aubrielle Prater Pharm.D.	
Kimberly Reichard Pharm.D.	
Melissa Renn, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Michael Shepherd, MD	
Richard Silbert, MD	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Kevin Szczecina, RPh	
Adam Root (non-voting participant)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, November 17, 2020.

Review and Approval of Minutes:
Dr. Bret Yarczower asked for a motion or approval to accept the September 15, 2020 and October 22, 2020 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

ONUREG (azacitidine)

Review: Onureg is a nucleoside metabolic inhibitor indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy. It inhibits DNA/RNA methyltransferases leading to reduced DNA and RNA methylation, which altered gene

expression, including genes regulating tumor suppression and cell differentiation, reduces RNA stability, and decreases protein synthesis. Antileukemic activity in vitro showed a reduction of cell viability and induction of apoptosis in AML cell lines. In vivo activity includes decreased tumor burden and increased survival. NCCN recommends Onureg for post-remission maintenance therapy as a single agent given orally in patients physiologic age < 60 years who decline or are not fit/eligible for allogeneic hematopoietic stem cell transplant and in patients physiologic age ≥ 60 years following complete response to previous intensive therapy.

The efficacy of Onureg was investigated in QUAZAR, a randomized, double-blind, placebo controlled study in patients ages 55 years or older with AML who were within 4 months of achieving first complete remission (CR) or complete remission with incomplete blood count recovery (Cri) with intensive induction chemotherapy with or without consolidation chemotherapy.

The trial randomized 472 patients 1:1 to receive Onureg 300 mg (n=238) or placebo (n=234) orally on Days 1 through 14 of each 28-day cycle. The trial showed a statistically significant improvement in overall survival for patients randomized to Onureg compared to placebo with a median overall survival of 24.7 months vs 14.8 months. A subgroup analysis showed a consistent benefit in overall survival for patients with either CR or CRi. The median relapse-free survival was significantly longer with Onureg compared to placebo (10.2 months vs. 7.8 months). Estimated RFS rates at 6 months were 67.4% for Onureg vs. 45.2% for placebo and at 12 months were 44.9% vs. 27.4% respectively.

There are no black box warnings for Onureg. Warnings and precautions include myelosuppression, increased risk of early mortality in patients with myelodysplastic syndromes and embryo-fetal toxicity (based on mechanism of action and animal study findings). In the QUAZAR trial, serious adverse reactions occurred in 15% of patients who received Onureg, including pneumonia (8%) and febrile neutropenia (7%). One fatal adverse reaction (sepsis) occurred in a patient who received Onureg. The most common adverse reactions reported were nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness, and pain in extremity.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, of 238 patients in QUAZAR who received Onureg, 72% were 65 years or older while 12% were 75 years of age or older. No overall differences in safety and effectiveness of Onureg were observed between older and younger patients.

Clinical Discussion: Bret asked about adverse reactions and the usual time it takes to present with them (as it pertains to suggested initial authorization duration). Not specified in studies but decreasing the authorization length would likely not provide any efficiencies. Kim stated that suggested authorization duration was based off median response to therapy. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Onureg is a pharmacy benefit and will be added to Oral Oncology Brand Non-Preferred Tier ($0 copay) for the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation that Onureg 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 acute myeloid leukemia **AND**
- Medical record documentation the member achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy **AND**
- Medical record documentation that member is not able to complete intensive curative therapy

QUANTITY LIMIT: 14 tablets per 28 days

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.

GAVRETO (pralsetinib)

Review: Gavreto is a tyrosine kinase inhibitor that targets rearranged during transfection (RET) fusions and mutations that play a role in tumor cell proliferation. It is indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC).

The efficacy of Gavreto was evaluated in the ARROW trial, a non-randomized, open-label, multi-cohort clinical trial which included two cohorts of adult patients with RET fusion-positive metastatic non-resectable NSCLC. One cohort included patients who had disease progression on platinum-based chemotherapy while a second cohort included treatment-naïve patients. Other cohorts investigated efficacy in patients with medullary thyroid cancer and other RET-altered solid tumors.

Patients were treated with Gavreto 400 mg once daily until disease progression or unacceptable toxicity. Efficacy results showed an overall response rate (ORR) of 57% in patients who had progression on prior platinum therapy with a duration of response that was not estimable (range 15.2 to NE) and 70% in treatment naïve patients with a duration of response of 9.0 months (range 6.3 months to NE). A majority of patients had a partial response and 80% of previously treated patients and 58% of treatment -naïve patients had a response lasting at least 6 months.

There are no black box warnings for Gavreto. Warnings and precautions are derived from the pooled safety population of Gavreto in 438 patients with RET altered solid tumors in the ARROW trial. Safety concerns include risk of interstitial lung disease/pneumonitis, hypertension, hepatotoxicity, hemorrhagic events, risk of impaired wound healing, and embryo-fetal toxicity. In the arrow trial, serious adverse reactions occurred in 45% of patients and included pneumonia, pneumonitis, sepsis, urinary tract infections, and pyrexia. Fatal adverse reactions were reported in 5% of patients and included pneumonia and sepsis. The most common adverse reactions (≥ 25%) were fatigue, constipation, musculoskeletal pain, and hypertension.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, of 438 patients, in the ARROW trial, 30% were age 65 years or older. No overall differences in pharmacokinetics (PK), safety, or efficacy were observed compared to younger patients.

Clinical Discussion: Bret asked if anyone knew if the RET test was available in liquid biopsy testing. Phil Krebs confirmed that RET gene sequence is included in FoundationOne CDx Liquid testing and in Guardant 360CDx. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

Outcome: Gavreto is a pharmacy benefit and will be added to Oral Oncology Brand Non-Preferred Tier ($0 copay) for the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation that Gavreto 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 metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a rearranged during transfection (RET) - fusion positive tumor as detected by a Food and Drug Administration (FDA) approved test*

***NOTE:** The FDA approved companion diagnostic test for Gavreto to determine the presence of a RET gene fusion is the Oncomine Dx Target Test.

QUANTITY LIMIT: 4 capsules 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.

DOJOLVI (triheptanoin)

Review: Dojolvi is a medium-chain triglyceride indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

LC-FAODs are a group of rare, life-threatening autosomal recessive genetic disorders in which the body is unable to convert long-chain fatty acids into energy, resulting in the accumulation of potentially toxic fatty-acid intermediates in cells. The inability to produce energy from fatty acids can also lead to the severe depletion of glucose in the body, causing serious complications (e.g. cardiomyopathy, rhabdomyolysis, arrhythmias, hypoglycemia, liver failure). Current treatment options for LC-FAODs are limited and include avoidance of fasting, low-fat/high-carbohydrate diets, and MCT supplementation. MCT oil is a medical food product – the over-the-counter supplement contains a mixture of even-carbon fatty acid chains (8, 10, or 12 carbon atoms), which works in the treatment of LC-FOADs by generating acetyl-CoA.

Dojolvi is the first agent to be FDA-approved for the treatment of LC-FAOD. Dojolvi contains odd-number carbon chains and provides substrates for both acetyl-CoA (to initiate the TCA cycle) and propionyl-CoA (which additionally replenishes TCA cycle intermediates in a process known as anaplerosis). Unlike even-chain fatty acids, odd-fatty acids can be converted to new glucose through the Krebs cycle, which can potentially be beneficial when glucose levels are too low.

The recommended target daily dosage of Dojolvi is up to 35% of the patient's total prescribed DCI divided into at least four doses, to be administered with meals or snacks. Dojolvi provides 8.3 kcal/mL. The total daily dosage is converted to a volume of Dojolvi to be given in mL using the following calculation: Total daily dose (mL) = [patient's DCI (kcal) x target % dose of DCI] / 8.3 (kcal/mL of Dojolvi).

The NDA submission included an open open-label Phase 2 study in 29 patients; a long-term safety and efficacy extension study in 75 patients (including 20 patients who were previously naïve to Dojolvi); a retrospective medical

record review of 20 original compassionate-use patients; data from 70 patients treated through expanded access; and a randomized controlled, investigator-sponsored study of 32 patients with LC-FAOD.

The Phase 2 single-arm, open-label study evaluated 29 pediatric and adult patients (age range: 10 months to 58 years) with LC-FAOD. The frequency of major clinical events (MCEs) (hospitalizations, ER visits, and emergency home interventions) due to rhabdomyolysis, hypoglycemia, and cardiomyopathy occurring during the 78 weeks of triheptanoin treatment was compared to events collected retrospectively from medical records for 78 weeks before triheptanoin initiation. At week 78, 48.1% reduction (P=0.021) in mean annualized rate of MCEs and 50.3% reduction (P=0.028) in mean annualized duration rate of all MCEs after 78 weeks of treatment, compared with mean annualized number and duration of events in the 18-24 months prior to treatment with triheptanoin. Hospitalizations due to rhabdomyolysis comprised the majority of events.

Data from the ongoing long-term safety and efficacy study have been reported and included a total of 75 patients, including 24 patients who were previously enrolled in the Phase 2 study, 20 naïve patients who had not been previously treated, and 31 patients from expanded access or investigator-sponsored trials. Patients who previously completed the Phase 2 company-sponsored study and rolled over to the extension study (n=24) have received treatment for an additional 78 weeks (minimum of 3 years of total treatment). Over the entire treatment period, patients had a 67% reduction in median annualized event rate and 66% reduction in the median annualized duration rate. Patient who were naïve to triheptanoin (n=20) at study entry have received up to 78 weeks of treatment. These patients have demonstrated a 70% reduction in the median annualized event rate and an 80% reduction in the median annualized duration rate.

The efficacy of Dojolvi as a source of calories and fatty acids was evaluated in Study 3 (NCT01379625), a phase 2, 4-month, double-blind, randomized controlled study that compared Dojolvi (which contains 7-carbon chain fatty acids) to trioctanoin (which consists of 8-carbon chain fatty acids). The study enrolled 32 adult and pediatric patients with a confirmed diagnosis of LC-FAOD, as evidenced by at least one significant episode of rhabdomyolysis and at least two of the following diagnostic criteria: 1) disease-specific elevations of acylcarnitines on a newborn blood spot or in plasma, 2) low enzyme activity in cultured fibroblasts, or 3) one or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB. After 4 months, patients in both groups had similar mean changes from baseline in left ventricular ejection fraction and wall mass on resting echocardiogram, as well as similar maximal heart rates on treadmill ergometry. Rates of rhabdomyolysis were similar between groups: five patients experienced 7 events of rhabdomyolysis in the Dojolvi group, and four patients experienced 7 events of rhabdomyolysis in the trioctanoin group. No differences were observed between the Dojolvi and trioctanoin groups in blood markers of metabolism including glucose, insulin, lactate, total serum, ketones, acylcarnitines, and serum-free fatty acid concentrations.

Dojolvi bears no black box warnings or contraindications. It carries warnings and precautions for feeding tube dysfunction and intestinal malabsorption in patients with pancreatic insufficiency. The most common adverse reactions to Dojolvi (≥ 10%) were abdominal pain, diarrhea, vomiting, and nausea. The safety and effectiveness of Dojolvi have been established in pediatric patients.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical studies did not include sufficient number of patients aged 65 and older to determine whether they respond differently from younger patients

Clinical Discussion: A question was asked if MCT oils are covered under any circumstances under the medical benefit, such as an inborn error of metabolism (knowing that commercially available products today are excluded under pharmacy due to being considered medical foods). Yes, may be covered under medical benefit. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

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

Outcome: Dojolvi is a pharmacy benefit and will be added d that Dojolvi be added to the Commercial, Marketplace, and GHP Kids formularies at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

- Prescription written by or in consultation with a metabolic disease specialist or a physician who specializes in the management of long-chain fatty acid oxidation disorders **AND**
- Medical record documentation of a diagnosis of long-chain fatty acid oxidation disorders (LC-FAOD) confirmed by at least two of the following:
    - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma
    - Low enzyme activity in cultured fibroblasts
    - One or more known pathogenic mutations in a gene associated with a long-chain fatty acid oxidation disorder (e.g. *CPT2, ACADVL, HADHA*, or *HADHB)* **AND**
- Medical record documentation that the member is currently managed on a treatment regimen, which may include a low-fat, high carbohydrate; avoidance of fasting; and/or medium-chain triglyceride (MCT) oil.

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.

*Signs of improvement for a patient with LC-FAOD can include but not limited to the following: gross motor development/motor function for infants and young children, exercise tolerance and endurance for older children and adults, and a decrease in the frequency of major medical episodes of hypoglycemia, rhabdomyolysis, and exacerbation of cardiomyopathy.

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

ZEPOSIA (ozanimod)

Review: Zeposia is a sphingosine 1-phosphate (S1P) receptor modulator which binds S1P receptors 1 and 5 with high affinity. It blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The exact mechanism that leads to the therapeutic effect of Zeposia in multiple sclerosis is unknown but may involve the reduction of auto-aggressive lymphocyte circulation into the central nervous system. Previously approved S1P receptor modulators for treatment of multiple sclerosis are Gilenya and Mayzent. Zeposia and Mayzent are both indicated for the treatment of adult patients, while Gilenya can be used for treatment in patients 10 years and older.

The efficacy of Zeposia was investigated in the SUNBEAM and RADIANCE trials, 2 randomized, double-blind, double-dummy, parallel group, active comparator-controlled trials in adult patients with relapsing forms of MS. In SUNBEAM, patients were randomized 1:1:1 to receive Zeposia 0.92 mg or Zeposia 0.46 mg orally once daily, or weekly intramuscular interferon beta-1a 30 µg for 12 months. In the RADIANCE trial, patients were randomized 1:1:1 to receive Zeposia 0.92 mg or Zeposia 0.46 mg orally once daily, or weekly intramuscular interferon beta-1a 30 µg for 24 months. Both clinical trials showed significantly lower annualized relapse rates in patients treated with Zeposia compared to those who received interferon beta-1a. The number of new or enlarging T2 lesions and the number of Gadolinium-enhancing (Gd+) lesions were also significantly lower in patients treated with Zeposia compared to those treated with interferon beta-1a.

There are no black box warnings for Zeposia. Warnings and precautions include the risk of infection, bradyarrhythmia and atrioventricular conduction delays, liver injury, increased blood pressure, reductions in forced expiratory volume over 1 second (FEV_1), macular edema, risk of fetal harm, posterior reversible encephalopathy syndrome, disease rebound, and immune system effects. During clinical trials, the most common adverse reactions that occurred in at least 4% of Zeposia treated patients were upper respiratory infection (26%), hepatic transaminase elevation (10%), orthostatic hypotension (4%), urinary tract infection (4%), back pain (4%), and hypertension (4%).

Zeposia was generally well tolerated and has a similar safety profile compared to Gilenya and Mayzent. Dose titration when initiating Zeposia may limit some of the first-dose bradycardia and hypotension effects that are associated with Gilenya and has less-stringent first-dose monitoring requirements more consistent with Mayzent. Unlike Mayzent, Zeposia does not require genetic testing prior to initiation to determine CYP2C9 genotype and guide dosing strategy.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical studies of Zeposia did not include sufficient numbers of subjects aged 65 and older to determine if they respond differently than younger patients.

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

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

Outcome: Zeposia is a pharmacy benefit and will be added to the should be added to the Specialty tier of the Marketplace pharmacy formulary and the Brand Preferred tier of the Commercial/GHP Kids pharmacy formularies. The following quantity limits will apply:

QUANTITY LIMITS:

- 7 Day Starter Pack: 7 capsules per 180 days
- Starter Kit (7 Day Starter Pack and 0.92 mg 30 count bottle): 37 capsules per 180 days
- 0.92 mg capsules: 1 capsule per day

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

UPLIZNA (inebilizumab-cdon)

Review: Uplizna is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. Neuromyelitis optica spectrum disorder (NMOSD) is a very rare autoimmune disease, resulting from inflammation of the central nervous system leads to demyelination and axonal damage, mostly targeting the spinal cord and optic nerve.

Treatment is broken down into two sections: acute attacks and prevention of attacks. Patients are initially treated with high-dose IV methylprednisolone (1 gram for three to five consecutive days) for acute attacks. Experts believe that long-term therapy should be given to all NMSOD patients to prevent attacks. These therapies include rituximab, azathioprine, and mycophenolate. Soliris is FDA approved for the treatment of NMOSD in anti-AQP4 antibody

positive patients. Uplizna and Enspryng (approval in August 2020, subQ monthly injection) are now available to treat the same population.

Uplizna is initially administered as an IV infusion of at 300 mg followed by a second dose of 300 mg 2 weeks later. Uplizna is then administered as a single 300 mg IV infusion every 6 months (starting 6 months from the first infusion).

The efficacy of Uplizna was established in a randomized, double-blind, placebo-controlled trial that enrolled a total of 230 patients with NMOSD; 213 patients who are anti-AQP4 antibody positive and 17 who are anti-AQP4 antibody negative. Patients included in the trial had a history of one or more relapses that required rescue therapy within the year prior to screening, or 2 or more relapses that required rescue therapy in 2 years prior to screening. Patients also were included if they had an Expanded Disability Status Scale (EDSS) score of 7.5 or less (patients with an EDSS score of 8.0 were eligible if they were deemed capable of participating). The EDSS scale ranges from 1 to 10 units of 0.5. The higher the number the worse the disability. Of the 213 patients enrolled anti-AQP4 antibody positive patients, 161 were randomized to receive treatment with Uplizna and 52 were randomized to receive placebo. Uplizna was administered according to the recommended dosage regimen. The primary efficacy endpoint was the time to onset of the first adjudicated relapse on or before Day 197. The time to first adjudicated relapse was significantly longer in patients treated with Uplizna compared to patients who received placebo. In the anti-AQP4 antibody positive population, Uplizna reduced the risk of NMOSD relapse by 77%. There was no evidence of benefit in patients who were anti-AQP4 antibody negative.

Uplizna is contraindicated in patients with a history of a life-threatening infusion reaction to Uplizna, active hepatitis B infection, and active or untreated latent tuberculosis. Uplizna has warning for infusion reactions, infections, reduction in immunoglobulins, and fetal risk. The most common adverse reactions (at least 10% of patients treated with Uplizna and greater than placebo) were urinary tract infection and arthralgia. The safety and effectiveness in pediatric patients have not been established.

Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical studies of Uplizna did not include a sufficient number of patients aged 65 years and over to determine whether they respond different from younger patients.

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

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

Outcome: Uplizna will be a medical benefit for Commercial, Marketplace, and GHP Kids members. After 1/1/21, when Uplizna is processed at a specialty pharmacy, it should be added to the Specialty tier or Brand Non-preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Prescribed by or in consultation with a neurologist **AND**
- Medical record documentation that member is 18 years or older **AND**
- Medical record documentation of diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) **AND**
- Medical record documentation that member is anti-aquaporin-4 (AQP4) antibody positive **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to rituximab or rituximab biosimilar product

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.

QUANTITY LIMIT:
Initial 12-month Authorization: Rx count of 3
Subsequent 12 month authorizations: 30 mL per 180 days; max qty supply: 30; min day supply: 168; max day supply: 180

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

Phexxi (lactic acid/citric acid/potassium bitartrate)

Review: Phexxi is the first FDA approved, on-demand non-hormonal gel contraceptive. Other contraceptives available for "on-demand" use include over the counter barrier products such as spermicide (nonoxynol-9). Phexxi works by lowering the pH and sperm motility in the vagina. Although Phexxi has a unique mechanism of action, it appears to be comparable to spermicide in efficacy (Pearl Index of 27.5-28 failures per 100 person-years [Table 1]) and safety (similar adverse reaction profile). Phexxi has an advantage over spermicide when vaginal yeast infection medications are required as these may lower the efficacy of spermicides but can be used in combination with Phexxi.

The efficacy of Phexxi for the prevention of pregnancy was evaluated in an open-label, single-arm clinical trial in 1183 female patients of reproductive potential 18 to 35 years of age with regular menstrual cycles (21 to 35 days). The primary efficacy endpoint evaluating the 7-cycle typical use cumulative pregnancy rate was 13.7, excluding cycles with back-up contraception, cycles <21 days or >35 days, and cycles in which no intercourse was reported. The estimated Pearl Index (based on the data from the 7-cycle study) was 27.5.

The most common adverse reactions were vulvovaginal burning sensation (18.0%) and vulvovaginal pruritis (14.5%). The majority were mild, and few led to discontinuation (0.7% and 0.1%, respectively). Among male partners of subjects who used Phexxi for contraception in Study 2, 9.8% of patients reported symptoms of local discomfort (burning, itching, pain, and "other").

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: Phexxi is a contraceptive that must be covered according to the Affordable Care Act and will be covered for $0 copay. It will not require a prior authorization.

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

FAST FACTS

ILARIS (canakinumab)

Updated Indication: Ilaris is now indicated for the treatment of Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

Previously Ilaris was indicated in Systemic Juvenile Idiopathic Arthritis (SJIA) in patients 2 years and older in addition to other indications for Crypopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Familial Mediterranean Fever (FMF).

Current formulary Medical Benefit requiring a prior authorization, Specialty/Brand Non-Preferred tier when processed at a specialty pharmacy

Recommendation: No changes are recommended for the formulary placement, authorization duration, or quantity limit for Ilaris. The following changes are recommended for Medical Benefit Policy 77.0 to incorporate the new indication:

2. Active Still's Disease

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 2 years of age and older with Systemic Juvenile Idiopathic Arthritis when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- **Must not be used in conjunction with tumor necrosis factor inhibitors AND**
- Medical record documentation of active Systemic Juvenile Idiopathic Arthritis (SJIA) diagnosed prior to age 16 years **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on Actemra

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 16 years of age and older with Adult Onset Still's Disease when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- **Must not be used in conjunction with tumor necrosis factor inhibitors AND**
- Medical record documentation of Adult Onset Still's Disease diagnosed after age 16 years with active disease characterized by:
    - Disease activity based on Disease Activity Score 28 (DAS28) ≥ 3.2 **AND**
    - At least 4 painful and 4 swollen joints at screening and baseline

Discussion: No comments or questions

Outcome: The committee unanimously 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 in combination with Yervoy for first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

Current formulary status: Medical benefit, requiring a prior authorization

Recommendation: No changes are recommended to the formulary placement of Opdivo. It is recommended to add the following criteria to Medical Benefit Policy 126.0 to incorporate the new indications for Opdivo:

11. Unresectable Malignant Pleural Mesothelioma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of unresectable malignant pleural mesothelioma **AND**
- Medical record documentation of use in combination with ipilimumab (Yervoy)

****For first line-treatment of metastatic NSCLC expressing PD-L1 (≥ 1%) , for first-line treatment of metastatic or recurrent NSCLC, and first line treatment of unresectable malignant pleural mesothelioma:** 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 (≥ 1%), for first-line treatment of metastatic or recurrent NSCLC, and first line treatment of unresectable malignant pleural mesothelioma: 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

Note: The FDA-approved treatment duration for use of Opdivo for first-line treatment in NSCLC and first-line treatment of unresectable malignant pleural mesothelioma is for up to 2 years in patients without disease progression.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

YERVOY (ipilimumab)

Updated Indication: Yervoy is now indicated in combination with Opdivo for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma.

Current formulary status: Medical benefit, requiring a prior authorization

Recommendation: No changes are recommended to the formulary placement of Yervoy. It is recommended to add the following criteria to Medical Benefit Policy 91.0 to incorporate the new indications for Yervoy:

6. *Unresectable Malignant Pleural Mesothelioma*
- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 18 years of age or older **AND**
- Medical record documentation of unresectable malignant pleural mesothelioma **AND**
- Medical record documentation of use in combination with nivolumab (Opdivo)

For first line-treatment of metastatic NSCLC expressing PD-L1 (≥ 1%), first-line treatment of metastatic or recurrent NSCLC, and first line treatment of unresectable malignant pleural mesothelioma:

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 Yervoy for the first line-treatment of metastatic NSCLC expressing PD-L1 (≥ 1%), first-line treatment of metastatic or recurrent NSCLC, and first-line treatment of unresectable malignant pleural mesothelioma 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

Note: *The FDA-approved treatment duration for use of Yervoy for first-line treatment in NSCLC and first-line treatment of unresectable malignant pleural mesothelioma is for up to 2 years in patients without disease progression.*

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

BOTOX (onabotulinumtoxin A) and DYSPORT (abobotulinumtoxin A)

Updated Indication: Botox is now indicated for the treatment of spasticity in patients 2 years of age and older.

Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

Previously, Botox's pediatric lower limb spasticity indication excluded patients with spasticity caused by cerebral palsy

Dysport is now indicated for the treatment of spasticity in patients 2 years of age and older.

Previously, Dysport's pediatric upper limb spasticity indication excluded patients with spasticity caused by cerebral palsy.

Current formulary status: Medical benefit requiring prior authorizaiton

Recommendation: No changes are recommended at this time for Commercial, Marketplace, or GHP Kids members. Applicable policies do not exclude use in patients with spasticity caused by cerebral palsy and current criteria appropriately address the FDA approved indications of Dysport and Botox.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

RECARBRIO (imipenem/cilastatin/relebactam)

Updated Indication: Recarbrio is now indicated for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens.*

Previously Recarbrio was approved for treatment of complicated urinary tract infections and complicated intra-abdominal infections in patients with limited or no alternative treatment options.

Current formulary status: Medical Benefit, requring a prior authorization

Recommendation: No changes are recommended to the formulary placement, quantity limit, or authorization duration of Recarbrio. It is recommended to add the following criteria to Medical Benefit Policy 215.0:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of one of the following:
  - Diagnosis of Complicated Urinary Tract Infection (including Pyelonephritis) (cUTI) caused by the following susceptible gram-negative microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa **OR**
  - Diagnosis of Complicated Intra-abdominal Infection (cIAI) caused by the following susceptible gram-negative microorganisms: Bacteroides caccae, Bacteroides fragilis, Bacteroides ovatus, Bacteroides stercoris, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Fusobacterium nucleatum, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Parabacteroides distasonis, and Pseudomonas aeruginosa **OR**
  - Diagnosis of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia, caused by the following susceptible gram-negative microorganisms: *Acinetobacter calcoaceticus-baumannii* complex, *Enterobacter cloacae*, *Escherichia coli, Haemophilus influenzae*, *Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens*

AND

- Medical record documentation of a culture and sensitivity showing the patient's infection is not susceptible to preferred alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to three (3) preferred alternative antibiotics shown to be susceptible on the culture and sensitivity **AND**
- Medical record documentation of a therapeutic failure on imipenem/cilastatin OR medical rationale of why imipenem/cilastatin cannot be used

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

TREMFYA (guselkumab)

Updated Indication: Tremfya is now indicated for the treatment of adult patients with active psoriatic arthritis. Tremfya is also indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Previously, Tremfya was only indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis.

Current formulary status: Non-formulary

Recommendation: There are no changes to formulary status at this time. However, it is recommended to update the policy to include a section for PsA:

- Medical record documentation that Tremfya is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of active psoriatic arthritis which must include the following:
  - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 3 months of therapy with Cosentyx* **AND** Humira*

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriatic arthritis on six (6) months of Tremfya is required. After the initial six (6) month approval, subsequent approval will be for a duration of one (1) year. Reevaluation will be every one (1) year requiring medical record documentation of continued or sustained improvement in signs and symptoms of psoriatic arthritis while on Tremfya therapy.

QUANTITY LIMIT: (update for **both** indications):

Initial-one-time, two-week authoriaztion: Quantity limit: 1 mL per 28 days; Max quantity supply: 1; Min day supply: 28; Max day supply: 28

Remainder/subsequent:
Quantity limit: 1 mL per 56 days; Max quantity supply:1; Min day supply: 56; Max day supply: 56

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

SIRTURO (bedaquiline)

Updated Indication: Sirturo is a diarylquinolone antimycobacterial drug indicated as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided.

This indication is approved under accelerated approval based on time to sputum culture conversion. Previously Sirturo was indicated in adult and pediatric patients 12 years and older weighing at least 30 kg.

Current formulary status: Pharmacy benefit on the Specialty tier or Brand Non-Preferred for patients with a three-tier benefit, requiring a prior authorization

Recommendation: No changes are recommended to the formulary placement or authorization duration of Sirturo. The following changes are recommended to the criteria and quantity limit of Commercial Policy 297.0 to incorporate the new indication.:

- Age greater than or equal to ~~12 years, weighing at least 30 kg~~ 5 years and weighing at least 15 kg **AND**

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

BRILINTA (ticagrelor)

Updated Indication: Brilinta is now indicated:

- to reduce the risk of a first MI or stroke in patients with coronary artery disease (CAD) at high risk for such events. While use is not limited to this setting, the efficacy of Brilinta was established in a population with type 2 diabetes mellitus (T2DM)
- to reduce the risk of stroke in patients with acute ischemic stroke (NIH Stroke Scale Score ≤ 5) or high-risk transient ischemic attack (TIA)

Current formulary status: Brand Non-Preferred tier

Recommendation: Currently, Brilinta is available without a prior authorization and no changes are recommended to formulary placement for the two new indications.

Discussion: No comments or questions.

Outcome: The committee unanimously 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

TRULICITY (dulaglutide)

Current Formulary Status/Prior Authorization Criteria: Trulicity is a pharmacy benefit available at the Brand Non-Preferred tier. Trulicity requires a step therapy with the following criteria.

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Victoza **AND** Ozempic or Rybelsus, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND** either Ozempic or Rybelsus

QUANTITY LIMIT: Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Step Therapy box (no QLs need to be entered within the authorization).

- 0.072 mL per day

Recommendation: Based on the similar efficacy between Victoza, Ozempic, Rybelsus, and Trulicity and the rebate opportunities available for Trulicity, it is recommended to add Trulicity to the Brand Preferred tier and remove the step therapy for Commercial, Marketplace, and GHP Kids members.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

COPAY PER 100 DIABETIC TESTING STRIPS

Recommendation: Many Commercial and self-insured plans currently utilize a copay per box of 100 blood glucose test strips in an attempt to control utilization. In order to allow for additional visibility to members regarding these limitations it is recommended that the copay per box of 100 is removed effective 1/1/2021 and replaced with a traditional quantity limit. The proposed quantity limit is 200 blood glucose test strips per 30 days. Members currently utilizing more than 200 strips in 30 days will receive a grandfather authorization.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

XYREM (Sodium Oxybate)

Current Formulary Status/Prior Authorization Criteria: Xyrem is a pharmacy benefit available at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit. Xyrem requires a prior authorization with the following criteria:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**

- Medical record documentation of therapeutic failure on modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

QUANTITY LIMIT: 18ml/day, max 30 days supply per fill

Recommendation: There are no changes recommended to formulary status or criteria, however it is recommended to add an authorization duration to reassess efficacy:

AUTHORIZATION DURATION:
Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required:

- Medical record documentation of reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in frequency of cataplexy attacks **OR**
- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

Discussion: Keith suggested adding some modification to the reauthorization criteria to consider a reduction in symptoms compared to baseline. No other comments or questions.

Outcome: The committee unanimously 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.

WAKIX (pitolisant)
Current Formulary Status/Prior Authorization Criteria: Wakix is a pharmacy benefit and is non-formulary. Wakix requires a prior authorization with the following criteria:

- Medical record documentation of diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of the member being ≥ 18 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to: modafinil* or armodafinil* **AND** methylphenidate IR or amphetamine/dextroamphetamine IR

QUANTITY LIMIT: 2 tablets per day

Recommendation: There are no changes recommended to formulary status or criteria, however it is recommended to add an authorization duration to reassess efficacy:

AUTHORIZATION DURATION:
Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. For continued coverage, the following is required.

- Medical record documentation of reduction in symptoms of excessive daytime sleepiness

After the initial 12 month approval, subsequent approvals will be for a duration of 12 months. Reevaluation will be every 12 months requiring the following:

- Medical record documentation of continued or sustained reduction in symptoms of excessive daytime sleepiness

Discussion: Keith suggested adding some modification to the reauthorization criteria to consider a reduction in symptoms compared to baseline. No other comments or questions.

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

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

MEDICAL BENEFIT SPECIALTY MEDICATION DAY SUPPLY LIMIT

Recommendation: The drug products included in the below table were added to a pharmacy benefit tier at the September P&T meeting to allow for processing at a specialty vendor. It is recommended that a 34 day supply limit is added to these products to prevent inappropriate utilization. This is consistent with the limit on other specialty medications.

Brand Name	Generic Name	Strength	Dosage Form	Route
ACTEMRA	TOCILIZUMAB	200MG/10ML, 400MG/20ML, 80 MG/4 ML	VIAL	INTRAVEN.
AVASTIN	BEVACIZUMAB	25 MG/ML	VIAL	INTRAVEN.
BIVIGAM	IMMUN GLOB G(IGG)/GLY/IGA OV50	10 %	VIAL	INTRAVEN.
BLENREP	BELANTAMAB MAFODOTIN-BLMF	100 MG	VIAL	INTRAVEN.
CINRYZE	C1 ESTERASE INHIBITOR	500 (5 ML)	VIAL	INTRAVEN.
CYTOGAM	CYTOMEGALOVIRUS IMMUNE GLOBULN	50 MG/ML	VIAL	INTRAVEN.
ELELYSO	TALIGLUCERASE ALFA	200 UNIT	VIAL	INTRAVEN.
ELZONRIS	TAGRAXOFUSP-ERZS	1000MCG/ML	VIAL	INTRAVEN.
GLASSIA	ALPHA-1-PROTEINASE INHIBITOR	1 G/50 ML	VIAL	INTRAVEN.
ILUVIEN	FLUOCINOLONE ACETONIDE	0.19 MG	IMPLANT	INTRAOCULR
INJECTAFER	FERRIC CARBOXYMALTOSE	750MG/15ML	VIAL	INTRAVEN.
KHAPZORY	LEVOLEUCOVORIN	175 MG, 300 MG	VIAL	INTRAVEN.
LIBTAYO	CEMIPLIMAB-RWLC	350 MG/7ML	VIAL	INTRAVEN.
LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK	1 MG	VIAL	INTRAVEN.
LUXTURNA	VORETIGENE NEPARVOVEC-RZYL	1.5X10EX11	VIAL	INTRAOCULR
MIRCERA	METHOXY PEG-EPOETIN BETA	100MCG/0.3, 150MCG/0.3, 200MCG/0.3, 30 MCG/0.3, 50 MCG/0.3, 75 MCG/0.3	SYRINGE	INJECTION
MITOMYCIN	MITOMYCIN	20 MG, 40 MG, 5 MG	VIAL	INTRAVEN.
NULOJIX	BELATACEPT	250 MG	VIAL	INTRAVEN.

ORTHOVISC	HYALURONATE SODIUM	30 MG/2 ML	SYRINGE	INTRAARTIC
PERJETA	PERTUZUMAB	420MG/14ML	VIAL	INTRAVEN.
POLIVY	POLATUZUMAB VEDOTIN-PIIQ	140 MG, 30 MG	VIAL	INTRAVEN.
POTELIGEO	MOGAMULIZUMAB-KPKC	20 MG/5 ML	VIAL	INTRAVEN.
REBLOZYL	LUSPATERCEPT-AAMT	25 MG, 75 MG	VIAL	SUBCUTANE.
RHOGAM ULTRA-FILTERED PLUS	RHO(D) IMMUNE GLOBULIN	1500 UNIT	SYRINGE	INTRAMUSC.
RHOPHYLAC	RHO(D) IMMUNE GLOBULIN	1500 UNIT	SYRINGE	INTRAMUSC.
RITUXAN	RITUXIMAB	10 MG/ML	VIAL	INTRAVEN.
RITUXAN HYCELA	RITUXIMAB/HYALURONIDASE,HUMAN	1400/11.7, 1600/13.4	VIAL	SUBCUTANE.
SUSTOL	GRANISETRON	10MG/0.4ML	LIQ ER SYR	SUBCUTANE.
SYNVISC	HYLAN G-F 20	16MG/2ML	SYRINGE	INTRAARTIC
SYNVISC-ONE	HYLAN G-F 20	48 MG/6 ML	SYRINGE	INTRAARTIC
THYROGEN	THYROTROPIN ALFA	1.1 MG	VIAL	INTRAMUSC.
ULTOMIRIS	RAVULIZUMAB-CWVZ	300MG/30ML	VIAL	INTRAVEN.
VELETRI	EPOPROSTENOL SODIUM (ARGININE)	0.5 MG. 1.5 MG	VIAL	INTRAVEN.
VPRIV	VELAGLUCERASE ALFA	400 UNIT	VIAL	INTRAVEN.
WINRHO SDF	RHO(D) IMMUNE GLOBULIN/MALTOSE	1500/1.3ML, 15000/13ML , 2500/2.2ML, 5000/4.4ML	VIAL	INJECTION
XIALFEX	COLLAGENASE CLOSTRIDIUM HIST.	0.9 MG	VIAL	INJECTIOn
YERVOY	IPILIMUMAB	200MG/40ML, 50 MG/10ML	VIAL	INTRAVEN.
YESCARTA	AXICABTAGENE CILOLEUCEL		PLAST. BAG	INTRAVEN.
ZINPLAVA	BEZLOTOXUMAB	1000 MG/40	VIAL	INTRAVEN.
ZOLGENSMA	ONASEMNOGENE ABEPARVOVEC-XIOI	2X10E13/ML	KIT	INTRAVEN.
ZULRESSO	BREXANOLONE	100MG/20ML	VIAL	INTRAVEN.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

TIER ASSIGNMENT FOR MEDICAL BENEFIT COST SHARE MEDICATIONS

Recommendation: The Geisinger Health Plan Benefit Review Team (BRT) has approved the removal of the medical benefit cost share copayment when the below listed medications are processed at a specialty pharmacy. In order for members to continue to receive these therapies at an in-network specialty pharmacy it is necessary to assign an appropriate pharmacy benefit cost sharing tier. All clinical utilization management criteria (prior authorization, step therapy, quantity limits, authorization durations, etc.) will continue to apply without change. The estimated cost and proposed tier assignment is presented in the below chart:

Brand Name	AWP OR Average Cost per Medical Claim	Proposed Triple Tier Formulary Placement	Proposed 4 Tier Formulary Placement	Proposed Marketplace Formulary Placement
Elzonris	$146,850 - $293,160 per 21 day cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Fasenra	$37,168.28 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Iluvien	$10,560.00 every 36 months	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Imfinzi	$40,076.16 per 12 week supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Injectafer	$1,367.60 per dose	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Kanjinti	$79,900 - $83,900 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Khapzory	$840.00 – $1440.00 per vial	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Kymriah	$570,000.00 (one-course treatment)	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Libtayo	$10,920.00 per 21 day cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Lumoxiti	$30,000 per 28 day cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Lutathera	$228,000.00 per treatment course	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Luxturna	$1,020,000 per lifetime	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Mepsevii	$529,354.29 – $1,852,740.00 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Micrhogam		Medical (No longer on specialty list)	Medical (No longer on specialty list)	Medical (No longer on specialty list)
Mircera	$1,056.00 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Mitomycin	$799.99 per 40 mg vial	Generic (Tier 1)	Generic (Tier 1)	Generic Non-Preferred (Tier 2)
Monjuvi	Cycle 1: $36,000 Cycles 2 and 3: 28,800 Cycles 4 and beyond: $14,400	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Mvasi	$53,650.08 per 6 cycles	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Mylotarg	Newly-diagnosed AML (combination): $49,200 Newly-diagnosed AML (single-agent): $127,920 R/R AML (single-agent): $29,520 (one cycle)	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Nucala	$3,000.00 per 28 days	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Ocrevus	$6,500.00 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Ogivri	$79,900 - $83,900 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Onpattro	$592,800 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Ontruzant	$84,000 - $89,000 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Padcev	$30,384 - $34,180 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Parsabiv	$7,063.20 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)

Perseris	$2,052.00 – $2,736.00 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Polivy	$18,000 – $36,000 per cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Poteligeo	Induction: $72,768 Maintenance: $36,384	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Prevymis		Medical (No longer on specialty list)	Medical (No longer on specialty list)	Medical (No longer on specialty list)
Radicava	$13,032.00 per 28 day cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Reblozyl	$210,600 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Reclast		Excluded (generic available)	Excluded (generic available)	Excluded (generic available)
Remodulin		Excluded (generic available)	Excluded (generic available)	Excluded (generic available)
Renflexis	$3,616.28 per 56 days	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Revcovi	$47,308.80 – $567,705.60 per 28 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Rhophylac	$174.96 per dose	Brand Preferred (Tier 2)	Brand Preferred (Tier 2)	Brand Preferred (Tier 3)
Sarclisa	Initial: $21,840* Subsequent: $10,920*	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Scenesse	$324,738 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Signifor LAR	$15,670.08 per 28 days	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Spravato	Induction: $5,664 to $8,142 Maintenance: $1,416 to $4,248	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Sublocade	$1,896.00 per syringe	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Sustol	$1,485.00 - $2,970.00 per cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Temsirolimus	$1,910.95 per dose	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Tepadina	$23,040.00 per course of therapy	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Tepezza	$411,240 (8 infusions over 24 weeks)	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Thiotepa	$27,840.00 per course of therapy	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Trazimera	$69,100 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Triptodur	$3,280.00 per 30 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Trisenox	Induction: $64,152.00 Consolidation: $85,536.00	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Trodelvy	$19,320 per 21 day cycle	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Ultomiris	$ 537,936 - $645,523 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Vyondys 53	20kg patient: $599,040.00 per year 80kg patient: $2,396,160.00 per year	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Vyxeos	Induction: $55,800.00 Consolidation: $18,600.00	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Xialfex	$6,044.92 per vial	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)

Yescarta	$447,600.00 (one-course treatment)	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Zepzelca	$15,919.20 per 21 day supply	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Zinplava	$3,648.00 per treatment	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Zolgensma	$2,550,000.00 one time	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)
Zulresso	$30,038.40 per treatment	Brand Non-Preferred (Tier 3)	Brand Non-Preferred Tier (Tier 4)	Specialty (Tier 5)

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

MULTI-SOURCED BRAND MEDICATION TIERING FORMULARY UPDATE

Recommendation: Several years ago, a prior authorization for new starts only was added to multi-source brand medications currently on the Commercial formulary. Those medications are currently listed in the BrandMS bucket of the Commercial formulary and they do not print in member materials. It is recommended that those medications are moved to a non-formulary status effective 1/1/2021. Members who are currently utilizing one of these medications will be allowed to continue with no change.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

SANTYL (collagenase)

Current Formulary Status: Santyl ointment is a pharmacy benefit available at the Brand Preferred tier. Santyl ointment does not require a prior authorization.

Recommendation: There are no changes to formulary status at this time. However, it is recommended to add a prior authorization with the following criteria.

- Medical record documentation that the member has been evaluated by a burn, a wound care specialist, or other specialist with experience in the management of severe wounds **AND**
- Medical record documentation of the wound length and width **AND**
- Medical record documentation of anticipated duration of therapy **AND**
- Medical record documentation that the prescribed dose is medically necessary based on the size and intended duration of therapy*

***NOTE:** Please calculate the dose on the manufacturer's website to confirm it is within a medically appropriate range- https://santyl.com/hcp/dosing

AUTHORIZATION DURATION: Initial approval will be for 3 months. Subsequent approval will be for 3 months. Reauthorization will require medication record documentation that continued use of Santyl ointment is medically necessary because debridement of necrotic tissue is incomplete and granulation of tissue is not well established.

Discussion: Nichole asked if we had specifics on the high cost claims or if we reached out to any specialists on our recommendations. Aubrielle stated the highest cost claim came from plastic surgery. We did not reach out for any specialist input. No other comments or questions.

Outcome: the committee unanimously voted to accept the recommendations as amended. None were opposed.

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

ATTR AMYLOIDOSIS CENTER OF EXCELLENCE

Background: Amyloidosis is a general term for a condition in which proteins within the body misfold and deposit within the body's organs and tissues. Clinical manifestations can vary but may include renal disease, cardiomyopathy, gastrointestinal disease, neurologic abnormalities, etc. There are more than 30 precursor proteins known to cause amyloidosis.

Three newly FDA approved medications focus on the cardiac and polyneuropathy manifestations when amyloidosis is caused by the protein transthyretin. Transthyretin amyloidosis (ATTR) can be broken down into hereditary (hATTR) or wild-type (ATTRwt).

hATTR vs. ATTRwt
ATTRwt is caused as a result of aging where symptoms begin typically in the sixth to eighth decade of life and primarily affects the heart. Misfolded TTR protein is deposited but is not of mutant genetic origin. ATTRwt was previously known as senile amyloidosis.

hATTR is caused by a genetic mutation present at birth. hATTR amyloidosis affects multiple organs and body systems (e.g. heart, nervous system, GI tract, and kidney). Patients who carry a TTR mutation do not experience symptoms secondary to amyloid deposits until they have reached adulthood, but age of onset is highly variable and thought to be related to the exact genetic mutation involved.

- As a hereditary condition it will be necessary to screen the siblings and children of patients with confirmed hATTR. There is a 50% chance that the sibling or child will also carry the ATTR mutation.
- In addition to patients identified because they have clinically treatable disease, Geisinger has begun screening patients for this genetic mutation through MyCode.

Cardiac Amyloidosis Caused by ATTR
Complications of cardiac amyloidosis include congestive heart failure and eventual death. Current treatments arrest the progression of disease but do not reverse damage which is already present. All patients with symptomatic disease should begin treatment as soon as possible. Much is still unknown about when to begin treatment in patients who have been identified as having the hATTR mutation but do not have symptomatic disease.

hATTR Polyneuropathy or Autonomic Dysfunction
Symptoms of hATTR polyneuropathy begin to develop between ages 20 to 70 years. Most commonly the peripheral nervous system is affected. However, most patients can, and often do, display symptoms of both cardiac

and nerve involvement simultaneously with overlapping clinical presentations. There are 2 scores to assess the functional disability of patients with polyneuropathies: the FAP stage and polyneuropathy disability score. FAP stage is numbered 1 through 3; 1-unimpaired ambulation, 2- assistance with ambulation, 3- wheelchair-bound or bedridden. Polyneuropathy disability score includes: I- preserved walking, sensory disturbances, II- impaired walking without need for stick/crutches, IIIa- walking with 1 stick/crutch, IIIb- walking with 2 sticks/crutches, and IV-wheelchair or bedridden.

Polyneuropathy clinical presentation varies from patient to patient and may or may not include a variety of other symptoms, including gastrointestinal involvement (diarrhea, constipation, nausea, vomiting), orthostatic hypotension, neurogenic bladder, and cardiac involvement (conduction system issues, thickening of ventricle walls, and rapidly progressive heart failure).

Current FDA Approved Treatments

Tafamidis (Vyndamax) **Pfizer**

- The only FDA approved treatment for ATTR-CM
- List price is $225,000 per year

Inotersen (Tegsedi) **Akcea Therapeutics**

- FDA approved for hATTR polyneuropathy or autonomic dysfunction
- List price is $450,000 per year

Patisiran (Onpattro) **Alnylam Pharmaceuticals**

- FDA approved for hATTR polyneuropathy or autonomic dysfunction
- List price is $450,000 per year

Patients could potentially be eligible for Vyndamax in combination with Tegsedi or Onpattro

Recommendation: It is recommended that a Center of Excellence if created for the treatment of ATTR Amyloidosis. The following credentialing criteria will apply:

Criteria	Benchmark	COE Evaluation	Chairperson Signature Once Criteria is Met
Demonstrates best practices by using clinically proven health care management techniques	Follows evidence-based literature and guidelines		
Has evidence of measured, favorable outcomes	<u>Efficacy:</u> **Cardiac** -NT-proBNP -hsTrop -Pre-albumin **Neurologic** -MRC scale **Possible patient reported scales:**		

	KCCQ (cardiac) Norfolk QOL (neurologic)		
Encompasses a multidisciplinary team including, but not limited to, a board certified specialist, nurse educator, clinical pharmacist, psychiatrist, case management professional and social worker			
Has licensed, professional staff dedicated to educating patients about their ailment and its optimal management	Nurse Case Manager and/or Clinical Pharmacist		
Has a board-certified specialist who is actively involved in his/her discipline as evidenced through research and clinical enterprises			
Has the capabilities to, and has historically, managed high volumes of patients			
Has the ability to complete testing/diagnostics on location	**Cardiac** -ECHO -Cardiac MRI -PYP Scan -Labs **Neurologic** -EMG -Muscle Biopsy		
Actively enrolls patients in	Documentation in the medical record		

appropriate clinical trials	of evaluation and/or enrollment in clinical trials		
Is authorized as a Center of Excellence by the Geisinger Health Plan Credentialing Committee			

Discussion: No comments or questions.

Outcome: The committee unanimously voted to accept the recommendations as amended. 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

Background: PerformRx is able to code minimum and maximum day supplies for medications without GHP having to manually enter them into the authorizations. If a claim is billed less than the minimum day supply or over the maximum day supply, the claim will block. The following minimum and maximum day supplies will apply to all fills, unless an authorization is entered to override this.

Recommendation:

Drug Name	Benefit	Min Day Supply	Max Day Supply
Abilify Maintena	Medical	28	30
Actemra	Pharmacy	28	28
Aristada 1064 mg	Medical	56	60
Aristada 441 mg	Medical	28	30
Aristada 662 mg	Medical	28	30
Aristada 882 mg	Medical	28	42
Benlysta subQ	Pharmacy	28	28
Boniva/Ibandronate	Medical	84	90
Botox	Medical	-	90
Cimzia syringe	Pharmacy	28	28
Cinqair	Medical	28	28
Cotellic	Pharmacy	28	28
Dysport	Medical	-	90
Eligard 22.5 mg	Medical	84	90
Eligard 30 mg	Medical	112	120
Eligard 45 mg	Medical	168	180
Eligard 7.5 mg	Medical	28	30

Enbrel	Pharmacy	28	28
Entyvio	Medical	56	56
Eylea	Medical	28	84
Farydak	Pharmacy	21	21
Fasenra	Medical	56	56
Firmagon	Medical	28	28
Forteo	Pharmacy	28	28
Teriparatide	Pharmacy	28	31
Galafold	Pharmacy	28	28
Humira	Pharmacy	28	28
Ibrance	Pharmacy	28	28
Ibrandronate	Pharmacy	28	30
Ilaris	Medical	28	28
Ilumya	Medical	84	84
Iluvien	Medical	1080	1095
Inflectra	Medical	28	56
Invega Sustenna	Medical	28	30
Invega Trinza	Medical	84	84
Inqovi	Pharmacy	28	28
Kevzara	Pharmacy	28	28
Kisqali	Pharmacy	28	28
Kisqali Femara Co-Pack	Pharmacy	28	28
Kynamro	Pharmacy	28	28
Lemtrada	Medical	365	365
Lonsurf	Pharmacy	28	28
Lucentis	Medical	28	84
Lupaneta Pack 1 month	Medical	28	30
Lupaneta Pack 3 month	Medical	84	90
Lupron 22.5 mg	Medical	84	90
Lupron 3.75 mg	Medical	28	30
Lupron 30 mg	Medical	112	120
Lupron 45 mg	Medical	168	180
Lupron 7.5 mg	Medical	28	30
Lupron Deport-Ped 15 mg (1-month)	Medical	28	30
Lupron Depot-Ped 11.25 mg (1-month)	Medical	28	30
Lupron Depot-Ped 11.25 mg (3-month)	Medical	84	90
Lupron Depot-Ped 30 mg (3-month)	Medical	84	90
Lupron Depot-Ped 7.5 mg	Medical	28	30
Lupron 11.25 mg	Medical	84	90
Macugen	Medical	42	42
Mavyret	Pharmacy	28	28

Medroxyprogesterone 104 mg/mL IM syringe	Pharmacy	84	98
Medroxyprogesterone 150 mg/mL IM syringe	Pharmacy	84	91
Myobloc	Medical	-	90
Ninlaro	Pharmacy	28	28
Nucala	Medical	28	28
Nucala prefilled syringe/auto-injector	Pharmacy	28	28
Nuvaring	Pharmacy	28	28
Ocrevus	Medical	180	180
Onpattro	Medical	21	21
Orencia	Pharmacy	28	28
Orencia	Medical	28	28
Onureg	Pharmacy	28	28
Pemazyre	Pharmacy	21	21
Perseris	Medical	28	30
Praluent	Pharmacy	28	28
Probuphine	Medical	168	180
Prolia	Medical	180	180
Reclast	Medical	365	365
Reflexis	Medical	28	56
Remicade	Medical	28	56
Repatha	Pharmacy	28	28
Retisert	Medical	900	900
Revlimid	Pharmacy	28	28
Risperdal Consta	Medical	28	28
Rydapt	Pharmacy	28	28
Sandostatin LAR	Medical	28	28
Scenesse	Medical	56	60
Signifor LAR	Medical	28	28
Simponi	Pharmacy	28	28
Simponi Aria	Medical	56	56
Somatuline Depot	Medical	28	56
Spinraza	Medical	120	120
Stelara 45 mg	Pharmacy	84	84
Stelara 90 mg	Pharmacy	56	84
Stivarga	Pharmacy	28	28
Sublocade	Medical	28	30
Supprelin LA	Medical	365	365
Sutent	Pharmacy	28	42
Synagis	Medical	28	30
Takhzyro	Pharmacy	28	28
Taltz	Pharmacy	28	28

Trelstar 11.25 mg	Medical	84	84
Trelstar 22.5 mg	Medical	168	168
Trelstar 3.75 mg	Medical	28	28
Tremfya	Pharmacy	56	56
Triptodur	Medical	168	180
Tymlos	Pharmacy	30	30
Tysabri	Medical	28	56
Tyvaso	Pharmacy	28	28
Uplizna	Medical	168	180
Vivitrol	Medical	28	28
Vyepti	Medical	84	90
Xeomin	Medical	-	90
Xgeva	Medical	28	28
Yutiq	Medical	1080	1095
Zyprexa Relprevv	Medical	28	28

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

GENERIC SPECIALTY MEDICATION UPDATE

Background: It was discovered that a few generic specialty medications were on the Specialty tier with the same copay as the brand medication. With the availability of coupon assistance for certain brand medications, patients were paying higher copays for the generic medications. This results in resistance from members to change to generic products. I analyzed the generic/brand medications currently on the Specialty tier for Commercial/Exchange formularies. The following formulary changes are recommended:

Recommendation:
Marketplace:

Drug	Current Tier	Recommended Tier	Rationale
Arixtra	Specialty	It is recommended to make Arixtra non-formulary.	Available as a generic and there are no recent claims for brand.
Clovique	Specialty	It is recommended to make Clovique non-formulary.	Available as a generic and there are no recent claims for brand or generic.
Daraprim	Specialty	It is recommended to make Daraprim non-formulary.	Available as a generic and there are no recent claims for brand.

Deferasirox	Specialty	It is recommended to add deferasirox to the generic non-preferred tier.	There is a coupon available for generic for up to $0 (max amount is $100 for 30 day supply). Since this is at a Specialty tier, certain members will have a $50 copay (full copay is $150) which is more than the brand copay, due to the patient assistance provided for the brand.
Enoxaparin	Specialty	It is recommended to add enoxaparin to the generic non-preferred tier.	Due to the cost. Lovenox is $99.22 per mL. Enoxaparin is $10.05 per mL.
Firazyr	Specialty	It is recommended to make Firazyr non-formulary.	Available as a generic and there are no recent claims for brand.
Forteo	Specialty	It is recommended to make Forteo non-formulary.	Available as a generic and there is copay assistance available for generic ($0 copay up to $12,000 per year).
Harvoni	Specialty	It is recommended to make Harvoni non-formulary.	Available as a generic and there are no recent claims for brand.
Hepsera	Specialty	It is recommended to make Hepsera non-formulary.	Available as a generic and there are no claims for generic or brand.
Jadenu/ Jadenu Sprinkle	Specialty	It is recommended to make Jadenu non-formulary.	Available as generic. Only one member was using brand and switched to generic.
Letairis	Specialty	It is recommended to make Letairis non-formulary.	Available as a generic. Only 1 member is utilizing brand.
Lovenox	Specialty	It is recommended to make Lovenox non-formulary.	Available as generic and there are no recent claims for brand.
Noxafil	Specialty	It is recommended to make Noxafil non-formulary.	Available as a generic and there are no recent claims for brand .

Octreotide	Specialty	It is recommended to add octreotide to the generic non-preferred tier.	Due to cost. For the 100 mg/mL syringe its $7.40 per mL vs. $32.21 per mL for brand.
Revatio suspension	Specialty	It is recommended to make Revatio suspension non-formulary.	Available as a generic and no recent claims.
Sildenafil 20 mg tablets	Specialty	It is recommended to add sildenafil 20 mg tablets to the generic non-preferred tier.	Due to cost. Sildenafil 20 mg tablets are $0.12 per tablet.
Tecfidera	Specialty	It is recommended to make Tecfidera non-formulary.	Available as a generic and the generic has a coupon available for $0 copay ($9000 for the year).
Tracleer tablet	Specialty	It is recommended to make Tracleer tablet non-formulary.	Available as a generic and there are no recent claims for brand.
Valcyte (tablets and solution)	Specialty	It is recommended to make Valcyte non-formulary.	Available as a generic and there are no recent claims for brand.
Valganciclovir tablets	Specialty	It is recommended to add valganciclovir tablets to the generic non-preferred tier.	Due to cost. Valcyte is $106 per tablet vs. generic is $3.99 per tablet.
Zavesca	Specialty	It is recommended to make Zavesca non-formulary.	Available as a generic and there are no recent claims for brand or generic.

Commercial/GHP Kids:

Drug	Current Tier	Recommended Tier	Rationale
Daraprim	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Daraprim non-formulary.	Available as a generic and there are no recent claims for brand.
Enoxaparin	Specialty or generic tier for members with a 3-tier benefit.	It is recommended to add enoxaparin to the generic tier.	Due to the cost. Lovenox is $99.22 per mL. Enoxaparin is $10.05 per mL.
Firazyr	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Firazyr non-formulary.	Available as a generic and only one member is using brand.
Forteo	Specialty or Brand Non-preferred tier for members with a 3-tier benefit	It is recommended to make Forteo non-formulary.	Available as a generic and there is copay assistance available for generic ($0 copay up to $12,000 per year).

Jadenu/ Jadenu Sprinkle	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Jadenu non-formulary.	Available as a generic and there are no recent claims for brand.
Letairis	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Letairis non-formulary.	Available as a generic. Only 1 member is utilizing brand.
Noxafil	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Noxafil non-formulary.	Available as a generic and only 1 member is utilizing brand.
Revatio	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Revatio non-formulary.	Available as a generic and there are no recent claims for brand.
Tecfidera	Specialty or Brand Preferred tier for members with a 3-tier benefit	It is recommended to make Tecfidera non-formulary.	Available as a generic and the generic has a coupon available for $0 copay ($9000 for the year).
Tracleer tablet	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Tracleer non-formulary.	Available as a generic and only 1 member is utilizing brand.
Valcyte solution	Specialty or Brand Non-preferred tier for members with a 3-tier benefit	It is recommended to make Valcyte solution non-formulary.	Available as a generic and there are no recent claims for brand.
Zavesca	Specialty or Brand Non-preferred tier for members with a 3-tier benefit.	It is recommended to make Zavesca non-formulary.	Available as a generic and there are no recent claims for brand or generic.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

2021 MARKETPLACE FORMULARY

Recommendation: The current Marketplace 2021 formulary is submitted for approval by the committee. Ongoing maintenance and updates will continue to be made as approved at the November P&T committee meeting.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

Meeting adjourned at 3:45 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, January 19, 2021 at 1:00 HCN3A & 3B Conference room

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821 or will be held virtually.

P&T Committee Meeting Minutes
Commercial, Marketplace, GHP Kids
December 22, 2020 e-vote

DRUG REVIEWS

Evrysdi (risdiplam)

Review: Evrysdi is a survival of motor neuron 2 (SMN2) splicing modifier which allows for the inclusion of exon 7 into SMN2 mRNA transcripts and allows for the formation of full-length functional and stable SMN protein. It is indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older. Evrysdi is the third disease-modifying treatment approved for patients with SMA (e.g. Spinraza, Zolgensma) and is the first oral treatment option.

There are four ongoing clinical trials for Evrysdi in patients with spinal muscular atrophy, FIREFISH, SUNFISH, JEWELFISH, and RAINBOWFISH. The approval of Evrysdi was based on results of the FIREFISH and SUNFISH trials.

The FIREFISH trial, an ongoing, open-label, 2 part study, investigated the safety and efficacy of Evrysdi in patients with Type 1 SMA (symptom onset between 28 days and 3 months of age). Patients included in the trial had a confirmed diagnosis of 5q-autosomal recessive SMA and 2 SMA2 gene copies.
Part 1 of the study was designed to evaluated safety, tolerability, pharmacokinetics, and pharmacodynamics of Evrysdi as well as to determine the dose for part 2 of the study while Part 2 was intended to evaluate the efficacy of Evrysdi on motor development milestones. After initial positive interim results, Part 1 was submitted as the pivotal efficacy study while Part 2 continued enrollment and provided safety data for the submission
The key primary endpoint for was the proportion of infants sitting without support for ≥ 5 seconds is assessed in the Bayley Scales of Infant and Toddler Development (BSID-III) gross motor scale after 12 months of treatment. Seven out of 21 patients were able to sit independently for ≥ 5 seconds after 12 months of treatment. All 7 patients achieving this endpoint received the recommended dosage of Evrysdi 0.2 mg/kg/day. Key secondary endpoints included changes in motor function and developmental milestones (HINE-2, CHOP-INTEND), and time to death or permanent ventilation, defined as requiring a tracheostomy or more than 21 consecutive days of either non-invasive ventilation (≥ 16 hours per day) or intubation in the absence of an acute reversible event. After 12 months of treatment with Evrysdi, 90% (19/21) of patients were alive without permanent ventilation. After a minimum of 23 months of treatment, 28% (17/21) were alive without permanent ventilation. Give the natural course of untreated infantile-onset SMA, patients would not be expected to attain the ability to sit independently and no more than 25% of patients would be expected to survive without permanent ventilation beyond 14 months of age.

In patients receiving the higher dosage of Evrysdi, a ≥ 4 point increase in the CHOP-INTEND score was achieved by 82% (14/17) of patients and the median change from baseline was 19 points. Thirteen (76.5%) patients receiving the recommended dose of Evrysdi and 1 patient (25%) receiving the low dose of Evrysdi were motor milestone responders as assessed by HINE-2 at month 12. Additionally, in part 1 no infant lost the ability to swallow, 78.9% were able to feed exclusively by mouth and 94.7% were able to feed orally or in combination with a feeding tube.

The SUNFISH trial, a 2-part, randomized, placebo controlled, double-blind study, evaluated Evrysdi in patients age 2 to 25 years with a confirmed genetic diagnosis of 5q-autosomal recessive Type 2 or Type 2 SMA. Part 1, a dose finding and exploratory phase, evaluated safety, tolerability, pharmacokinetics and pharmacodynamics in both ambulatory and non-ambulatory patients while Part 2 evaluated the safety and efficacy of Evrysdi in non-ambulatory patients (unable to walk unassisted for 10 meters or more).

The Evrysdi treated group in Part 2 of the study showed a statistically significant improvement in the key primary endpoint assessing motor function ability related to daily function (MFM-32 score) at month 12 compared to the placebo group (Table 2). The key secondary endpoint assessing Revised Upper Limb Module (RULM) score also show a significant improvement in patients treated with Evrysdi, with the greatest improvement seen in patients 2 to 5 years old (3.41 points [95% CI: 1.55, 5.26]). Improvement was also shown in the secondary endpoint assessing Hammersmith Functional Motor Score – Expanded (HFMSE), but this was not found to be a statistically significant change and subsequent secondary endpoints in the rest of the statistical hierarchy were considered exploratory. There was also an improvement seen in caregiver assessed SMAIS scores which measures the level of independence when completely activities of daily living, but statistical significance cannot be inferred.

There are no black box warnings, contraindications, or warnings or precautions associated with Evrysdi. The safety of Evrysdi in patients with both infantile-onset and later-onset SMA were evaluated in the FIREFISH and SUNFISH trials. During the SUNFISH trial, 180 patients with SMA Type 2 or 3 who ranged in age from 2 to 25 years at the time of treatment. The most common adverse reactions were fever, diarrhea, and rash. The FIREFISH trial showed adverse reactions similar to the SUNFISH trial, as well as upper respiratory tract infection (including nasopharyngitis, rhinitis, respiratory tract infection), pneumonia, constipation, and vomiting. Animals studies showed some functional and structural retinal abnormalities were induced by Evrysdi treatment, but a no-effect dose for the retinal findings was associated with plasma exposures (AUC) similar to exposures in humans at the recommended dose (5 mg).

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, clinical studies have not included a sufficient number of patients aged 65 years and older to determine if they respond differently from younger patients.

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: Evrysdi is a pharmacy benefit and will be added to the Specialty tier or the Brand Non-Preferred tier for patients with a three-tier benefit of the Commercial, Exchange, and GHP Kids formularies. The following prior authorization criteria will apply:

- Medical record documentation that Evrysdi is prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of age of 2 months or older **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion OR
    - Homozygous exon 7 conversion mutation OR
    - Compound heterozygous exon 7 mutation

  OR
- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

  AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza)

***NOTE:** Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

QUANTITY LIMIT: 240 mL per 36 days

AUTHORIZATION DURATION: Evrysdi will be approved for an initial authorization duration of 12 months. Subsequent authorizations will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with the prescribed risdiplam regimen **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza)

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

Other Recommendations

Although safety of treatment with Evrysdi in patients with previously treated SMA was evaluated in the JEWELFISH, efficacy in previously treated SMA was not evaluated. The safety and efficacy of concomitant use of Evrysdi in combination with Spinraza was not evaluated. It is recommended to make the following changes to the prior authorization criteria in the Zolgensma and Spinraza policies.

Zolgensma Medical Benefit Policy 199.0

- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion **OR**
    - Homozygous exon 7 conversion mutation **OR**
    - Compound heterozygous exon 7 mutation

  OR
    - Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

AND

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation that the patient will be less than 2 years of age at the time of dosing **AND**
- Medical record documentation that patient does not have anti-AAV9 antibody titers >1:50 as determined by ELISA (within two weeks of the anticipated infusion date) **AND**
- Medical record documentation that patient is not permanent ventilator-dependent **AND**
- Medical record documentation that patient has not received a prior dose of Zolgensma **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Spinraza, Evrysdi) with Zolgensma (Note: Any current authorizations for SMN modifying therapy will be terminated upon Zolgensma approval)

Spinraza Medical Benefit Policy 151.0

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion **OR**
    - Homozygous exon 7 conversion mutation **OR**

- Compound heterozygous exon 7 mutation

OR

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies.

AND

- Medical record documentation that the patient has not received prior treatment with gene therapy (e.g. Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Evrysdi)

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

AUTHORIZATION DURATION: If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of 12 months. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of 12 months when the following criteria are met:

- Medical record documentation that member is compliant with prescribed nusinersen regimen. **AND**
- Medical record documentation that the patient has not received prior treatment with gene therapy (Zolgensma)* **AND**
- Medical record documentation that patient will not receive routine concomitant SMN modifying therapy (e.g. Evrysdi)

*Note: Requests for members that show decline in clinical status following treatment with Zolgensma will be reviewed on a case by case basis.

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

VEKLURY (remdesivir)

Review: Veklury is indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

Veklury is the first official FDA approved treatment for COVID-19 and it was initially given EUA on May 1, 2020. The EUA permitted the use of Veklury for treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.

Veklury is available as 100 mg vial. The recommended dosage for adults and pediatric patients 12 years of age and older and weighing at least 40 kg is a single loading dose of Veklury 200 mg on Day 1 via IV infusion followed by once-daily maintenance doses of Veklury 100 mg from Day 2 via intravenous infusion. Veklury must be prepared and administered under the supervision of a healthcare provider. The recommended treatment duration is anywhere from 5 to 10 days, depending on the clinical situation.

Veklury was studied in a randomized, double-blind, placebo-controlled clinical trial of hospitalized adult subjects with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19. The trial compared 10 day treatment with Veklury (n=541) to placebo (n=521). Patients treated with Veklury received 200 mg on Day 1 and 100 mg on subsequent days for 10 days of treatment via IV infusion. Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to the completion of 10 days of treatment. 10% of patients in

both treatment groups had mild/moderate disease and 90% of subjects had severe disease in both treatment groups. The primary clinical endpoint was time to recovery within 29 days after randomization. The median time to recovery was 10 days in the Veklury group compared to 15 days in the placebo group ($p<0.01$). In terms of secondary outcomes, the odds of improvement in the ordinal scale (see Summary of Clinical trials above) were higher in the Veklury group at Day 15 compared to placebo (odds ratio 1.54 [95% CI 1.25 to 1.91]). Overall, 29-day mortality was 11% for the Veklury group vs 15% for the placebo group (hazard ratio 0.73 [95% CI 0.52 to 1.03]).

A randomized, open-label multi-center clinical trial in adult subjects with confirmed SARS-CoV-2 infection, an SpO2 of ≤ 94% on room air, and radiological evidence of pneumonia compared Veklury treatment for 5 days (n=200) vs. 10 days (n=197). Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to completion of their protocol-defined duration of treatment. The primary endpoint was clinical status on Day 14 assessed on a 7-point ordinal scale (see Summary of Clinical trials above). Subjects receiving a 5-day course of Veklury had similar clinical status on Day 14 as those receiving a 10-day course. There were no statistically significant differences in recovery rates or mortality rates in the 5-day and 10-day groups once adjusted for between-group differences at baseline.

A randomized, open-label multi-center clinical trial of hospitalized adult subjects with confirmed SARS-CoV-2 infection, SpO2 > 94% and radiological evidence of pneumonia compared treatment with Veklury for 5 days (n=191) and treatment with Veklury for 10 days (n=193) with standard of care (n=200). Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to completion of their protocol-defined treatment duration. The primary endpoint was clinical status on Day 11 assessed on a 7-point ordinal scale (see Summary of Clinical trials above). Overall, the odds of improvement in the ordinal scale were higher in the 5-day Veklury group at Day 11 when compared to those receiving only standard of care ($p=0.017$). The odds of improvement in clinical status with the 10-day treatment group when compared to those receiving only standard of care were not statistically significant. All-cause mortality at Day 28 was ≤2% in all treatment groups.

Veklury is contraindicated in patients with a history of clinically significant hypersensitivity reactions to Veklury or any components of the product. Hypersensitivity reactions, including infusion-related and anaphylactic reactions have been observed during and following administration of Veklury. The most common adverse reactions in clinical trials (incidence greater than or equal to 5%, all grades) were nausea, ALT increased, and AST increased. The safety and effectiveness of Veklury have not been established in pediatric patients younger than 12 years of age or weighing less than 40 kg. Because the excipient betadex sulfobutyl ether sodium is renally cleared and accumulates in patients with decreased renal function, it is not recommended to give to patients with an eGFR less than 30 mL per minute.

A Clinical Review including Clinical Information, Efficacy Evidence, Safety Evidence, Other Considerations and a Financial Review Based on Cost Analysis were presented. For geriatric members, reported clinical experience has not identified differences in responses between the elderly and younger patients.

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: Veklury will be a medical benefit for Commercial, Marketplace, and GHP Kids members. Veklury will not require a prior authorization.

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

FAST FACTS

KEYTRUDA (pembrolizumab)

Updated Indication: Keytruda now has traditional approval for the treatment of Classical Hodgkin lymphoma (cHL) in :

- Adult patients with relapsed or refractory cHL and
- Pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy

The new indication is based on results of KEYNOTE-204, a confirmatory clinical trial. Previously this indication was based on results from the Keynote-087 and Keytruda was granted accelerated approval for treatment of adult and pediatric patients with refractory cHL, or who relapsed after 3 or more prior lines of therapy.

Keytruda is also now indicated in combination with chemotherapy, for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA approved test. This indication is approved under accelerated approval based on progression-free survival.

Current formulary status: Medical benefit requiring a prior authorization, Specialty/Brand Non-Preferred tier when processed at a specialty pharmacy

Recommendation: There are no updates recommended to the authorization duration or the formulary placement for Keytruda. It is recommended to make the following changes to Medical Benefit Policy 199.0 to incorporate the change in the indication for Classical Hodgkin Lymphoma and to add the new indication in Triple Negative Breast Cancer:

4. Classical Hodgkin Lymphoma

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of Classical Hodgkin Lymphoma **AND**
- One of the following:

  a. Medical record documentation of a diagnosis of refractory Classical Hodgkin Lymphoma **OR**
  b. Medical record documentation of age greater than or equal to 18 years AND relapse following one (1) or more prior lines of therapy **OR**
  c. Medical record documentation of age less than 18 years AND relapse following two (2) or more prior lines of therapy

Triple Negative Breast Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) **AND**
- Medical record documentation that tumors express PD-L1 [Combined Positive Score (CPS) greater than or equal to 10] as determined by an FDA approved test **AND**
- Medical record documentation that Keytruda will be given in combination with chemotherapy (paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin)

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.

CRYSVITA (burosumab)

Update: In clinical trials of Crysvita for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia, elevated FGF23 levels were determined by Kainos assay. At this time, the Kainos assay is not commercially available in the United States and there is no standardized testing for FGF23 testing.

Current formulary status: Pharmacy benefit on the Specialty tier or brand non-preferred tier for members with a three tier benefit, requiring prior authorization and quantity limit

Recommendations: Based on the availability of the Kainos assay as well as feedback from Dr. Evan Norfolk and the nephrology department at Geisinger Medical Center, the following changes are recommended to Medical Benefit Policy 182.0 to allow for other testing for FGF23 levels:

FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)

- Medical record documentation that the patient is at least 2 years of age or older **AND**
- Medical record documentation that Crysvita is being prescribed by, or in consultation with, an endocrinologist, nephrologist, geneticist, or oncologist **AND**
- Medical record documentation of a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors **AND**
- Medical record documentation of ~~a serum level of FGF23 greater than or equal to 100 pg/mL determined by Kainos assay~~ an elevated serum level of FGF23 **AND**
- Medical record documentation that tumors cannot be curatively resected or localized AND
- Medical record documentation that the patient is not concurrently using vitamin D analogs or phosphate supplements.

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.

2021 AON, COMMERCIAL, GHP KIDS AND NORTHERN LIGHT FORMULARIES

Recommendation: The current Commercial, AON, GHP Kids, and Northern Light 2021 formularies are submitted for approval by the committee.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

GLUCAGON PRODUCT QUANTITY LIMIT UPDATES

Recommendation: Gvoke hypopen, Gvoke prefilled syringe, and Baqsimi intranasal device are all available in two-dose packs as well as single packs. The current quantity limit of 1 unit per fill is not allowing the two-dose packs to be processed. It is recommended that the quantity limits for the Gvoke hypopen, Gvoke prefilled syringe, and Baqsimi intranasal device be updated to 2 units per fill to allow for the two-dose packs.

Discussion: No comments or questions.

Outcome: The committee unanimously 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.

PREVENTIVE VACCINE UPDATE

Recommendation: The U.S. Department of Health and Human Services recently released an update granting state-licensed pharmacists the authority to administer vaccinations to patients ages 3 through 18 years. The vaccination must be ordered and adminsitered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules. In order to facilitate the adminsitration of these vaccinations, it is recommended that the following formulary changes are approved to expand access at in-network pharmacies:

Brand Name	Generic Name	Current Formulary Status	Current Age Restriction	FDA Approved Age Range	Recommendations
ACTHIB	HAEMOPH B POLY CONJ-TET TOX/PF	Excluded	–	2 months through 5 years	Add to $0 tier with upper age limit of 5 years
ADACEL TDAP	DIPH,PERTUSS(ACELL),TET VAC/PF	$0	DENY IF OUTSIDE 18-64 YEAR AGE RANGE	10 through 64 years	Remove lower age limit
BEXSERO	MENINGOCOCCAL B VACCINE,4-COMP	$0	DENY IF OUTSIDE 18-25 YEAR AGE RANGE	10 through 25 years	Remove lower age limit
BOOSTRIX TDAP	DIPHTH,PERTUSS(ACELL),TET VAC	$0	DENY FOR AGE 17 YEARS AND YOUNGER	10 years and older	Remove age limit
DAPTACEL DTAP	DIPH,PERTUSS(ACELL),TET PED/PF	Excluded	–	6 weeks through 6 years	Add to $0 tier with upper age limit of 6 years
DIPHTHERIA-TETANUS TOXOIDS-PED	TETANUS,DIPHTHERIA TOXD PED/PF	Excluded	–	6 weeks through 6 years	Add to $0 tier with upper age limit of 6 years
ENGERIX-B ADULT	HEPATITIS B VIRUS VACCINE/PF	$0	DENY FOR AGE	20 years and older	No change necessary

			19 YEARS AND YOUNGER		
ENGERIX-B PEDIATRIC-ADOLESCENT	HEPATITIS B VIRUS VACCINE/PF	$0	DENY IF OUTSIDE 18-19 YEAR AGE RANGE	Birth through 19 years	Remove lower age limit
GARDASIL 9	HPV VACCINE 9-VALENT/PF	$0	DENY IF OUTSIDE 18-45 YEAR AGE RANGE	9 through 45 years	Remove lower age limit
HAVRIX 1440/ML	HEPATITIS A VIRUS VACCINE/PF	$0	DENY FOR AGE 18 YEARS AND YOUNGER	19 years and older	No change necessary
HAVRIX 720/0.5ML	HEPATITIS A VIRUS VACCINE/PF	$0	DENY IF NOT 18 YEARS OF AGE	12 months through 18 years	Remove lower age limit
HEPLISAV-B	HEPATITIS B VACCINE/CPG1018/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	18 years and older	No change necessary
HIBERIX	HAEMOPH B POLY CONJ-TET TOX/PF	Excluded	–	6 weeks through 4 years	Add to $0 tier with upper age limit of 4 years
INFANRIX DTAP	DIPH,PERTUSS(ACELL),TET PED/PF	Excluded	–	6 weeks through 6 years	Add to $0 tier with upper age limit of 6 years
IPOL	POLIOMYELITIS VACCINE, KILLED	Excluded	–	6 weeks through 18 years	Add to $0 tier with upper age limit of 18 years
KINRIX	DIPH,PERTUS(ACEL),TET,POLIO/PF	Excluded	–	4 through 6 years	Add to $0 tier with upper age limit of 6 years
MENACTRA	MENING VAC A,C,Y,W-135 DIP/PF	$0	DENY IF OUTSIDE 18-55 YEAR AGE RANGE	9 months through 55 years	Remove lower age limit
MENVEO A-C-Y-W-135-DIP	MENING VAC A,C,Y,W-135 DIP/PF	$0	DENY IF OUTSIDE 18-55 YEAR AGE RANGE	2 months through 55 years	Remove lower age limit
MENVEO MENA COMPONENT	MENING A CONJ VACC, 1 OF 2/PF	Excluded	–	2 months through 55 years	Add to $0 tier with upper age limit of 55 years

MENVEO MENCYW-135 COMPONENT	MENING C,Y,W-135 VAC 2 OF 2/PF	Excluded	–	2 months through 55 years	Add to $0 tier with upper age limit of 55 years
M-M-R II VACCINE	MEASLES,MUMPS,RUBELLA VACC/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	12 months and older	Remove age limit
PEDIARIX	HEP B VACCINE/DP(A)T-POLIO/PF	Excluded	–	6 weeks through 6 years	Add to $0 tier with upper age limit of 6 years
PEDVAXHIB	HAEMPH B POLYSAC CONJ-MENIN/PF	Excluded	–	2 to 71 months	Add to $0 tier with upper age limit of 6 years
PENTACEL	DIPHT,PERT(A),TET-POLIO/HIB/PF	Excluded	–	6 weeks through 4 years	Add to $0 tier with upper age limit of 4 years
PENTACEL DTAP-IPV COMPONENT	DTAP-IPV COMPONENT 1 OF 2/PF	Excluded	–	6 weeks through 4 years	Add to $0 tier with upper age limit of 4 years
PENTACEL DTAP-IPV COMPONENT	DTAP-IPV COMPONENT 1 OF 2/PF	Excluded	–	6 weeks through 4 years	Add to $0 tier with upper age limit of 4 years
PNEUMOVAX 23	PNEUMOCOCCAL 23-VAL P-SAC VAC	$0	DENY FOR AGE 17 YEARS AND YOUNGER	50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease	Remove age limit
PREVNAR 13	PNEUMOC 13-VAL CONJ-DIP CRM/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	6 weeks and older	Remove age limit
PROQUAD	MEASLES,MUMPS,RUB,VARICELLA/PF	$0	–	12 months through 12 years	Add upper age limit of 12 years
QUADRACEL DTAP-IPV	DIPH,PERTUS(ACEL),TET,POLIO/PF	Excluded	–	4 through 6 years	Add to $0 tier with upper age limit of 6 years
RECOMBIVAX HB 10 MCG/ML	HEPATITIS B VIRUS VACCINE/PF	$0	DENY FOR AGE 19 YEARS AND YOUNGER	All ages (dose approved for 11 and older)	Add lower age limit of 11 years
RECOMBIVAX HB 40 MCG/ML	HEPATITIS B VIRUS VACCINE/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	18 years and older	No change necessary
RECOMBIVAX HB 5MCG/0.5ML	HEPATITIS B VIRUS VACCINE/PF	$0	DENY IF OUTSIDE	All ages (dose	Remove lower age limit

			18-19 YEAR AGE RANGE	approved for up to and including 19 years)	
ROTARIX	ROTAVIRUS VAC,LIVE ATT, 89-12	Excluded	–	6 weeks to 24 weeks	Remain excluded
ROTATEQ	ROTAVIRUS VACCINE,LIVE ORAL PV	Excluded	–	6 weeks to 32 weeks	Remain excluded
SHINGRIX	VARICELLA-ZOSTER GE/AS01B/PF	$0	ZOSTER VACCINE LIVE/PF	50 years and older	No change necessary
TDVAX	TETANUS, DIPHTHERIA TOX,ADULT	$0	DENY FOR AGE 17 YEARS AND YOUNGER	7 years and older	Remove lower age limit
TENIVAC	TETANUS-DIPHTHERIA TOXOIDS/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	7 years and older	Remove lower age limit
TRUMENBA	N.MENINGITIDIS B,LIPID FHBP RC	$0	DENY IF OUTSIDE 18-25 YEAR AGE RANGE	10 through 25 years	Remove lower age limit
TWINRIX	HEPATITIS A AND B VACCINE/PF	$0	DENY FOR AGE 17 YEARS AND YOUNGER	18 years and older	No change necessary
VAQTA 25 UNIT/0.5ML	HEPATITIS A VIRUS VACCINE/PF	$0	DENY IF NOT 18 YEARS OF AGE	12 months or age and older	Remove lower age limit
VAQTA 50 UNIT/ML	HEPATITIS A VIRUS VACCINE/PF	$0	DENY FOR AGE 18 YEARS AND YOUNGER	12 months or age and older	Remove age limit
VARIVAX VACCINE	VARICELLA VACCINE LIVE/PF	Excluded	–	12 months and older	Remove age limit
ZOSTAVAX	ZOSTER VACCINE LIVE/PF	$0	ZOSTER VACCINE LIVE/PF	50 years and older	No change necessary

Discussion: No comments or questions.

Outcome: The committee unanimously 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 19 of 35 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, January 19, 2021

Meeting will be via phone/Microsoft Teams