

**P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
May 18, 2021**

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

Kimberly Clark called the meeting to order at 1:02 p.m., Tuesday, May 18, 2021.

Review and Approval of Minutes:

Kimberly Clark asked for a motion or approval to accept the March 16th, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

MARGENZA (margetuximab-cmkb)

Review: Margenza is a HER2/neu receptor agonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2 positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. Margenza was engineered to enhance efficacy in patients have lower affinity Cd16A genotypes (CD16A-158F carriers) who may not benefit maximally from Herceptin (or biosimilars), but clinical trials only showed a modest benefit in patients with certain genotypes.

Margenza offers a new alternative targeted treatment option for patients with metastatic HER2-positive breast cancer who have received prior treatment with two more anti-HER2 regimens.

The efficacy of Margenza was evaluated in the SOPHIA trial, an open-label, randomized clinical trial in 536 HER2-positive metastatic breast cancer who had received prior treatment with anti-HER2 therapies and had progression on or after the most recent line of therapy. Patients were randomized 1:1 to receive Margenza (15 mg/kg every 3 weeks) plus chemotherapy or trastuzumab (8 mg/kg loading dose, then 6 mg/kg every 3 weeks) plus chemotherapy. Patients were treated until disease progression or unacceptable toxicity. Progression free-survival was 5.8 months for patients treated with Margenza compared to 4.9 months for patients treated with Herceptin. Confirmed objective response rate was 22% with Margenza compared to 16% with Herceptin and duration of response was 6.1 months vs. 6.0 months. The PFS results were consistent across all subgroups defined by study stratification factors. At the prespecified second interim analysis of overall survival, the OS data was not mature with 50% of deaths in the overall population.

Margenza has two black box warnings for left ventricular cardiac dysfunction and embryo-fetal toxicity. There are also warnings for infusion-related reactions which occurring in 13% of patients in the SOPHIA trial. During the SOPHIA trial, serious adverse reactions occurred in 16% of patients treated with Margenza, most commonly febrile neutropenia, neutropenia, and infusion related reactions. The most common adverse reactions were fatigue, nausea, diarrhea, vomiting, constipation, headache, pyrexia, alopecia, abdominal pain, peripheral neuropathy, arthralgia/myalgia, cough, decreased appetite, dyspnea, infusion-related reactions, palmar-plantar erythrodysesthesia, and extremity pain.

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 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: Margenza is a medical benefit. When Margenza is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Margenza will require prior authorization with the following criteria:

- Medical record documentation that Margenza is prescribed by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of HER2-positive breast cancer **AND**
- Medical record documentation that Margenza will be used in combination with chemotherapy **AND**
- Medical record documentation of two or more prior anti-HER2 regimens, at least one of which was for metastatic disease

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

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

COSELA (trilaciclib)

Review: Cosela is a kinase inhibitor indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC). Trilaciclib is a transient inhibitor of CDK4 and 6. Hematopoietic stem and progenitor cells (HSPC) in the bone marrow give rise to circulating neutrophils, RBCs, and platelets. HSPC proliferation is dependent on CDK 4/6 activity. The current standard of care for management of myelosuppression with chemotherapy is G-CSF and ESAs. Theoretically, trilaciclib improves the tolerability of chemotherapy preventing delays and dose reductions to myelosuppressive adverse events. It can provide proactive protection for all lineages of cells. The recommended dose of Cosela is 240 mg/m² per dose. It should be administered as a 30-minute IV infusion completed within 4 hours prior to the start of chemotherapy on each day chemotherapy is administered.

Study 1 was a randomized, double-blind, placebo-controlled study. The trial included patients with newly diagnosed ES-SCLC not previously treated with chemotherapy. Patients were randomized to receive Cosela or placebo prior to treatment with etoposide, carboplatin, and atezolizumab. Dose reductions of carboplatin occurred in 2% of patients receiving Cosela and in 25% of patients receiving placebo; dose reductions of etoposide occurred in 6% of patients receiving Cosela and in 26% of patients receiving placebo. There was a statistically significantly shorter duration of severe neutropenia in Cycle 1 (0 vs. 4 days) and a lower proportion of patients with severe neutropenia (2% vs. 49%) in patients receiving Cosela compared to placebo. The rate of RBC transfusions over time was 1.7/100 weeks for patients receiving Cosela and 2.6/100 weeks for patients receiving placebo. Six percent of patients receiving Cosela received ESAs compared to 11% of patients receiving placebo. Of the patients on Cosela, 29.6% received G-CSF compared to 47.2% receiving placebo, which was also not statistically significant.

Study 2 was a randomized, double-blind, placebo-controlled study in patients with newly diagnosed ES-SCLC previously not treated with chemotherapy. The trial evaluated the use of Cosela or placebo administered prior to treatment with etoposide and carboplatin. Ten percent of patients receiving Cosela had Grade 3 or 4 decreased hemoglobin compared with 18% of patients receiving placebo. The rate of RBC transfusions over time was 0.5/100 weeks for patients receiving Cosela and 1.9/100 weeks for patients receiving placebo. Three percent of patients receiving Cosela received ESAs compared with 5% of patients receiving placebo. The duration of severe neutropenia was 0 in the Cosela arm, compared to 3 days with placebo. The percentage of patients with severe neutropenia was 5.1% in those receiving Cosela vs. 42.1% in the placebo arm. Less patients required G-CSF in the Cosela arm (10.3%) compared to placebo (63.2%).

Study 3 was a randomized, double-blind, placebo-controlled trial. The trial included patients with ES-SCLC previously treated with chemotherapy. The trial evaluated the use of Cosela or placebo administered prior to treatment with Topotecan. Thirty-eight percent of patients receiving Cosela had Grade 3 or 4 decreased hemoglobin compared with 59% of patients receiving placebo. The rate of RBC transfusions over time was 2.6/100 weeks for patients receiving Cosela and 6.3/100 weeks for patients receiving placebo. Three percent of patients receiving Cosela received ESAs compared with 21% of patients receiving placebo. The duration of severe neutropenia was less for those receiving Cosela (2 days) compared to placebo (7 days). The percentage of patients with severe neutropenia was less in those receiving Cosela (40.6%) compared to placebo (75.9%). 50% of patients receiving Cosela were also on G-CSF compared to 65.5% receiving placebo.

Cosela is contraindicated in patients with a history of serious hypersensitivity reactions to Trilaciclib. Reactions have included anaphylaxis. Cosela has warnings for injection-site reactions, acute drug hypersensitivity reactions, interstitial lung disease, and embryo-fetal toxicity. The most common adverse reactions ($\geq 10\%$ of patients with $\geq 2\%$ difference in incidence compared to placebo) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

Per National Comprehensive Cancer Network (NCCN), for management of neutropenia, Cosela may be used as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered

before (or granulocyte-colony stimulating factor may be administered after) platinum/etoposide +/- immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC) in the curative/adjuvant or palliative setting or as a secondary prophylaxis. For management of cancer and chemotherapy-induced anemia, Cosela may be used as a prophylactic option to decrease the incidence of chemotherapy-induced myelosuppression when administered before (or granulocyte-colony stimulating factor may be administered after) platinum/etoposide +/- immune checkpoint inhibitor-containing regimens or a topotecan-containing regimen for extensive-stage small cell lung cancer (ES- SCLC).

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

Clinical Discussion: It was discussed that the initial criteria should also be used as the reauthorization criteria. Bret asked if there was a reason when GCSF was added during the trials. Not specified in trials, only “when clinically indicated,” but not during cycle #1. Bret asked if we should limit GCSF during cycle #1 if receiving this medication. Committee was undecided and would look to clinical enterprise for guidance following their review. Bret suggested we try to obtain baseline data on members receiving this regimen and the number of transfusions or supplemental medication that were needed. 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: Cosela is a medical benefit. When Cosela is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Cosela will require prior authorization with the following criteria:

- Prescription written by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age \geq 18 years of age **AND**
- Medical record documentation of a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) **AND**
- Medical record documentation that the member is currently taking a platinum/etoposide-containing regimen or topotecan-containing regimen

AUTHORIZATION DURATION: Initial approval will be for 6 months and subsequent approvals will be for 6 months. Requests for reauthorization will be reviewed as follows:

- Prescription written by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of age \geq 18 years of age **AND**
- Medical record documentation of a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) **AND**
- Medical record documentation that the member is currently taking a platinum/etoposide-containing regimen or topotecan-containing regimen

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

PEPAXTO (melphalan flufenamide)

Review: Pepaxto, melphalan flufenamide or melflufen, is a peptide drug conjugate which includes a highly lipophilic formulation of the alkylating agent melphalan. In cellular assays, melphalan flufenamide inhibited proliferation and induced apoptosis of hematopoietic and solid tumor cells. It also showed synergistic cytotoxicity when used in combination with dexamethasone in melphalan resistant and non-resistant multiple myeloma patients. Pepaxto offers an alternative option with a new mechanism of action for patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal

antibody. It joins Blenrep and Xpovio as 5th line treatment options, although Xpovio may be used earlier in treatment as it is now approved in combination with bortezomib in patients who have received at least one prior therapy.

The efficacy of Pepaxto in combination with dexamethasone was evaluated in the HORIZON trial, a single-arm trial in 157 patients with relapsed or refractory multiple myeloma. Efficacy was measured in 97 patients had at least 4 prior lines of therapy and were triple-class-refractory (refractory to at least one proteasome inhibitor, at least one immunomodulatory agent, and at least one CD38-directed monoclonal antibody). Patients received Pepaxto 40 mg intravenously on Day 1 and dexamethasone 40 mg on Days 1, 8, 15, and 22 of each 28-day cycle until disease progression or unacceptable toxicity. The median duration of treatment was 3.8 months. Efficacy endpoints demonstrated an overall response rate of 23.7% with 9 patients having a very good partial response and 14 patients having a partial response. The duration of response was 4.2 months.

There are no black box warnings for Pepaxto. Warnings and precautions include thrombocytopenia, neutropenia, anemia, risk of infections, secondary malignancy, embryo-fetal toxicity, and risk of mortality when giving at dosages higher than the recommended dosage. The most common adverse reactions were fatigue, nausea, diarrhea, pyrexia, and respiratory tract infection. The most common laboratory abnormalities were decreased leukocytes, platelets, lymphocytes, neutrophils, and hemoglobin, and increased creatinine.

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 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: Pepaxto is a medical benefit. When Pepaxto is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Pepaxto will require prior authorization with the following criteria:

- Medical record documentation that Pepaxto 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 **AND**
- Medical record documentation that member is refractory to at least one anti-CD38 monoclonal antibody, one proteasome inhibitor, and one 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.

OXLUMO (lumasiran)

Review: Oxlumo is the first medication in the class hydroxyacid oxidase 1 (HAO-1)-directed small interfering ribonucleic acid (siRNA) and first drug to be approved specifically for the treatment of primary hyperoxaluria type 1 (PH1). PH1 is caused by genetic mutations in the AGXT gene, resulting in the overproduction of oxalate, which combines with calcium to cause crystal aggregation, urolithiasis, and/or nephrocalcinosis. PH1 accounts for 70-80% of all PH cases, affecting approximately 1 to 3 Americans per million with a median age of onset of about 5-6 years old. Oxlumo reduces levels of glycolate oxidase (GO) enzyme through HAO-1 messenger ribonucleic acid (mRNA) inhibition in hepatocytes. Decreased levels of GO cause decrease concentrations of glyoxylate, which is needed for oxalate production. In addition to Oxlumo, the treatment of PH1 includes increased fluid intake, pyridoxine, oral potassium citrate and thiazide-type diuretics. Dialysis and liver or kidney transplant may also be considered on an as needed basis.

Illuminate-A and Illuminate-B trials were conducted to investigate the safety and efficacy of Oxlumo. Illuminate-A found a statistically significant difference in the LS mean percent change from baseline in 24-hour urinary oxalate between the Oxlumo and placebo group. Illuminate-B, a single-arm study, found patients treated with Oxlumo had a percent reduction in the oxalate:creatinine ratio of 71%.

Illuminate-A determined the most common adverse reactions were injection site reactions, including erythema, pain, pruritus and swelling. The symptoms were generally mild, resolved within one day of receiving the injection, and did not lead to discontinuation of the treatment. Illuminate-B observed a similar safety profile to the one seen in Illuminate-A.

Oxlumo is supplied as a 0.5 mL single-dose vial containing 94.5 mg of drug per 0.5 mL solution. Oxlumo is a subcutaneous injection that follows weight-based dosing.

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

Clinical Discussion: Bret asked if the oxalate excretion was measured by a 24 hour collection or spot specimen collection. Spot specimen collection was used in the trials. Aubrielle suggested looking at kidney function and liver transplant status upon reauthorization. No comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Financial Discussion: Bret asked if actual or ideal body weight is used for dosing. Actual weight was used in the trials. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Oxlumo is a medical benefit. When Oxlumo is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Oxlumo will require prior authorization with the following criteria:

- Prescription written by or in consultation with an appropriate specialist (including but not limited to a nephrologist, urologist, geneticist, or hepatologist) **AND**
- Medical Record documentation of primary hyperoxaluria type 1 (PH1) as confirmed by ONE of the following:
 - Molecular genetic testing that confirms a mutation of alanin:glyoxylate aminotransferase (AGXT) gene* **OR**
 - A liver biopsy to confirm absent or significantly reduced alanin:glyoxylate aminotransferase (AGT) **AND**
- Medical record documentation of metabolic screening that demonstrates ONE of the following:
 - Markedly increased urinary oxalate excretion (i.e. generally greater than 0.7 mmol/1.73 m² per day or greater than the upper limit of normal) **OR**

- Increased urinary oxalate to creatinine ratio (i.e. greater than the age-specific upper limit of normal) **AND**
- Medical record documentation of sufficient kidney function as defined by ONE of the following:
 - Medical record documentation patient has an eGFR ≥ 30 mL/min/1.73m² **OR**
 - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range **AND**
- Medical record documentation that the patient does not have a history of liver transplant.

***NOTE:** AGXT genotypes include but are not limited to: PR/RR, PR/M, PR/N, M/M, M/N, N/N

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Sufficient kidney function as defined by ONE of the following:
 - Medical record documentation patient has an eGFR ≥ 30 mL/min/1.73m² **OR**
 - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range **AND**
- Medical record documentation that the patient does not have a history of liver transplant

Ongoing subsequent approvals will be for a **duration of twelve (12) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- Sufficient kidney function as defined by ONE of the following:
 - Medical record documentation patient has an eGFR ≥ 30 mL/min/1.73m² **OR**
 - If eGFR is not calculated due to age limitations, a serum creatine within the normal age-specific reference range **AND**
- Medical record documentation that the patient does not have a history of liver transplant

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

ORLADEYO (berotralstat)

Review: Orladeyo is the first oral, non-steroidal treatment option for long-term prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. It works by binding plasma kallikrein and inhibits its proteolytic activity and controls excess bradykinin generation in patients with HAE.

The efficacy of Orladeyo for prevention of angioedema attacks was evaluated in a randomized, double-blind, placebo-controlled, parallel-group study in 120 patients 12 years and older with Type I or II HAE (HAE-C1INH). Diagnosis was confirmed by C1-INH function level (< 50% by chromogenic assay) and complement 4 (C4) level less than the lower limit of normal. The study included patients who had at least two investigator-confirmed attacks within the first 8 weeks of the run-in period and took at least one dose of study treatment.

Patients were randomized 1:1:1 to receive once daily oral treatment with Orladeyo 110 mg, Orladeyo 150 mg, or placebo for the 24-week treatment period. The primary endpoint evaluating reduction of HAE Attack Rate in the Intent-to-Treat (ITT) population demonstrated a statistically significant reduction in the rate of HAE attack compared to placebo for both Orladeyo 110 mg and 150 mg, without regard to baseline attack rate. Attack rate reductions were observed in the first month of treatment and maintained throughout the 24 weeks for Orladeyo. There were no statistically significant differences between Orladeyo and placebo for Angioedema Quality of Life Questionnaire (AE-QoL) scores. Exploratory endpoints showed that 58% and 51% of patients receiving Orladeyo 150 mg and 110 mg, respectively, had at least a 50% reduction in HAE attack rates compared to baseline versus 25% of patients receiving placebo.

There are no black box warnings for Orladeyo. Warnings and Precautions include risk of QT prolongation when Orladeyo was administered at dosages higher than the recommended 150 mg once daily dosage. The most commonly reported adverse reactions were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease

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

Clinical Discussion: Bret asked if we removed Danazol from the other policies for HAE. More information is available in the financial section, but to summarize, it was not removed at this time as it's still suggested by guidelines as being possibly effective, although side effects may be more likely. Will reach out to experts for additional feedback. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Financial Discussion: It was asked if we are in line with other organizations by requiring failure of Danazol. It's a mixed bag with some also requiring failure of tranexamic acid. It was also asked if we should require failure of Orladeyo prior to other HAE agents, but other agents are potentially more effective. There are also no contracting opportunities available in this space. No other comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation that Orladeyo is prescribed by an allergist, immunologist, hematologist, or dermatologist **AND**
- Medical record documentation of a diagnosis of hereditary angioedema (HAE) established and supported by documentation of:
 - Recurrent, self-limiting, non-inflammatory subcutaneous angioedema without urticaria which lasts more than 12 hours **OR**
 - Laryngeal edema **OR**
 - Recurrent, self-remitting abdominal pain which lasts more than 6 hours, without clear organic etiology **AND**
- Medical record documentation of specific abnormalities in complement proteins, in the setting of a suggestive clinical history or episodic angioedema without urticaria; supported by:
 - Medical record documentation of two (2) or more sets of complement studies, separated by one month or more, showing consistent results of:
 - Low C4 levels **AND**
 - Less than 50% of the lower limit of normal C1-INH antigenic protein levels **OR**
 - Less than 50% of the lower limit of normal C1-INH functions levels **AND**
- Medical record documentation of history of more than one (1) severe event per month **OR** a history of laryngeal attacks **AND**
- Medical record documentation that Orladeyo is being used as prophylactic therapy for hereditary angioedema (HAE) attacks **AND**
- Medical record documentation that Orladeyo is not being used in combination with another prophylactic human C1 esterase inhibitor (Cinryze or Haegarda) or lanadelumab (Takhzyro) therapy for hereditary angioedema **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to danazol

QUANTITY LIMIT: 1 capsule per day, 28 day supply per fill

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 12 months or less if the

reviewing provider feels it is medically appropriate and will required medical record documentation of continued disease improvement or lack of disease progression. Orladeyo 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.

PHESGO (pertuzumab, trastuzumab, and hyaluronidase)

Review: Phesgo is a combination of two monoclonal antibodies with hyaluronidase for use in combination with chemotherapy as neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer, as part of a complete treatment regimen for early breast cancer and as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. It is also recommended to be used in combination with docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Phesgo is a subcutaneous injection comprised of a fixed dose of pertuzumab, trastuzumab and hyaluronidase. Pertuzumab is a recombinant humanized monoclonal antibody that blocks ligand-dependent heterodimerization of HER2, thereby inhibiting mitogen-activated protein (MAP) kinase and phosphoinositide 3-kinase (PI3K) pathways. Trastuzumab is a monoclonal antibody that blocks ligand-independent, HER2 mediated cell proliferation and PI3K signaling. The combination of pertuzumab and trastuzumab has increased anti-tumor activity in HER2 overexpressing xenograft models.

Intravenous formulations of pertuzumab and trastuzumab are currently available, as separate products. In addition, a subcutaneous form of trastuzumab (Herceptin Hylecta) was approved in 2019. Phesgo is the first combination product containing pertuzumab and trastuzumab approved for use in breast cancer.

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 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: Phesgo is a medical benefit. When Phesgo is processed at a specialty pharmacy, it will be processed on the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. Phesgo will not require prior authorization.

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

WINLEVI (clascoterone)

Review: Winlevi is a first-in-class topical androgen receptor inhibitor that is approved for the topical treatment of acne vulgaris in patients 12 years of age and older (for both men and women). Although the exact mechanism of action for the treatment of acne vulgaris is unknown, it is thought that clascoterone competes with androgens, particularly dihydrotestosterone (DHT) for binding to androgen receptors within the sebaceous gland and hair follicles

The safety and efficacy of Winlevi 1% cream were evaluated in two identical, randomized, double-blind, vehicle controlled studies in 1421 patients aged 12 years and older with facial acne vulgaris with Investigator's Global Assessment (IGA) of moderate or severe facial acne vulgaris (score of 3 or 4), 30 to 75 inflammatory lesions (papules, pustules, and nodules) and 30 to 100 non-inflammatory lesions (open and closed comedones). Eligible patients were randomized 1:1 to receive Winlevi 1% or vehicle cream both of which were to be applied to the entire face (approximately 1 gram) twice daily for 12 weeks.

The major efficacy outcome at 12 weeks was the proportion of patients with ≥ 2 points IGA reduction from baseline and IGA score 0 (clear) or 1 (almost clear), and absolute change and percentage change from baseline in non-inflammatory and inflammatory lesions. IGA success showed a 10.1% and 14.3% difference over vehicle in Trial 1 and Trial 2, respectively. There was also a mean absolute difference of Winlevi over vehicle of 7.3% in non-inflammatory lesions and 3.9% in inflammatory lesions in Trial 1 and 8.7% in non-inflammatory lesions and 7.5% in inflammatory lesions in Trial 2. Although the trial did include patients 9 to <12 years of age, subgroup analysis did not show a beneficial treatment effect and the incidence of treatment-emergent adverse events in this age group were higher than in older adolescents and adult patients.

There are no black box warnings for Winlevi, and warnings include risk of local irritation and Hypothalamic-pituitary-adrenal (HPA) axis suppression. The most commonly reported reactions during clinical trials were local irritation, including erythema/redness, pruritis, and scaling/dryness.

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 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: Winlevi is a pharmacy benefit and will not be added to the formulary. Winlevi will be added to Commercial Policy 476.0 for Non-Preferred Acne Medications and will require prior authorization with the following criteria:

- Medical record documentation a diagnosis of acne, acne vulgaris, or adult onset acne **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives

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

FAST FACTS

XOLAIR (omalizumab)

Updated Indication: Xolair is now indicated for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.

Xolair prefilled syringes (75 mg/0.5 mL, 150 mg/mL) which were previously only approved for administration by a healthcare professional are now approved for self-administration by the patient or caregiver for all indications for adults and pediatric patients 6 years of age and older.

Current formulary status: Xolair Vial and prefilled syringes: medical benefit, requiring PA; Specialty tier/Brand NP tier for three-tier benefit when processed at a specialty pharmacy

Recommendation: There are no changes recommended to the formulary placement of Xolair 150 mg vial for reconstitution. The following criteria should be added to the Medical benefit policy 22.0 to incorporate the new indication for Xolair.

Nasal Polyps

- Medical record documentation that Xolair is prescribed by or in consultation with an otolaryngologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

With the approval of self-administration for Xolair 75 mg and 150 mg prefilled syringes, they can now be processed as a pharmacy benefit and should be added to the Commercial, Marketplace, and GHP Kids pharmacy formularies to the Specialty tier or Brand Non-preferred tier for members with a three tier benefit. The following prior authorization criteria should apply:

Asthma:

- Medical record documentation that Xolair is prescribed by an allergist or pulmonologist **AND**
- Medical record documentation that member is compliant with current therapeutic regimen **AND**
- Medical record documentation of age greater than or equal to 6 years of age **AND**
- Medical record documentation of diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
- Medical record documentation of inadequate control or intolerance, despite a 3 month trial of: medium – high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
- Medical record documentation of the following:
 - For members age 12 and older, an IgE level of > 30 IU/ml and < 700 IU/ml **OR**
 - For members age 6 through 11, an IgE level of > 30 IU/ml and < 1300 IU/ml **AND**
- Medical record documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
- Medical record documentation that known environmental triggers within the member's control have been eliminated. **AND**
- Medical record documentation that Xolair is not being used in combination with Dupixent (dupilumab), Fasentra (benralizumab), Nucala (mepolizumab), or Cinqair (reslizumab)

QUANTITY LIMIT: 75mg/0.5mL prefilled syringe: 5 mL per 28 days
150 mg/1mL prefilled syringe: 4 mL per 28 days

*Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:

1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

*Severe persistent asthma is defined by the NHLBI as:

1. Continual symptoms
2. Limited physical activity
3. Frequent exacerbations
4. Frequent nighttime symptoms
5. Lung function of FEV1 less than or equal to 60% predicted

**The 12% improvement target value is calculated using the following methodology: The target value = baseline FEV1 x 1.12 The actual clinical calculation is: $\frac{\text{post-treatment FEV1} - \text{baseline FEV1}}{\text{baseline FEV1}} = \% \text{ improvement}$

For Chronic Idiopathic Urticaria:

- Medical record documentation that Xolair is prescribed by an allergist, immunologist, or dermatologist **AND**
- Medical record documentation of age greater than or equal to 12 years of age **AND**
- Medical record documentation of a diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
- Medical record documentation of at least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
- Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of ALL of the following treatment alternatives:
 - At least two different high dose antihistamines
 - Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g., montelukast)
 - High dose antihistamine used in combination with H2 receptor antagonist (e.g., ranitidine)
 - Dose advancement of potent antihistamine (e.g., hydroxyzine or doxepin)

QUANTITY LIMIT: 75mg/0.5mL prefilled syringe and 150 mg/1mL prefilled syringe: 2 mL per 28 days

Nasal Polyps

- Medical record documentation that Xolair is prescribed by or in consultation with an otolaryngologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids

QUANTITY LIMIT: 75mg/0.5mL prefilled syringe and 150 mg/1mL prefilled syringe: 8 mL per 28 days

AUTHORIZATION DURATION: Initial approval will be for 12 months. Reauthorization will require documentation of improvement in the signs and symptoms of disease and will be for a duration of 12 months.

Discussion: Bret asked if the clinical trial differentiated patients with nasal polyps in isolation, and those with polyps/asthma/aspirin sensitivity. Trial did not specify.

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.

IMFINZI (durvalumab)

Updated Indication: AstraZeneca has voluntarily withdrawn the Imfinzi indication for previously treated adult patients with locally advanced or metastatic bladder cancer. Previously this indication was granted accelerated approval, with continued approval contingent on results from the DANUBE Phase III trial in the first line metastatic bladder cancer setting. The withdrawal comes after this trial failed to meet its primary endpoints in 2020. It does not impact the other indications for Imfinzi. NCCN recommendations for Imfinzi currently align with the remaining indications in Non-small Cell Lung Cancer and Small Cell Lung Cancer.

Current formulary status: medical benefit or pharmacy benefit on the Specialty tier, requiring a PA

Recommendation: The following criteria and authorization duration will be removed from Medical Benefit Policy 156.0 to reflect the withdrawal of the urothelial carcinoma indications for Imfinzi. No changes are recommended for the indications in NSCLC and SCLC:

1. Urothelial Carcinoma

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥ 18 years of age AND
- Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND one of the following:
 - Disease progression during or following platinum-containing chemotherapy OR
 - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

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

Discussion: No comments or questions.

Outcome: The committee 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.

HETLIOZ/ HETLIOZ LQ (tasimelteon)

Updated Indication: HetlioZ LQ oral suspension is indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 years to 15 years of age. HetlioZ capsules are also now indicated for nighttime sleep disturbances in SMS in patients 16 years of age and older.

Previously HetlioZ capsules were only indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults.

Current formulary status: non-formulary

Recommendation: There are no changes recommended to the formulary placement or authorization duration for HetlioZ/HetlioZ LQ. It is recommended to make the following changes to Commercial Policy 329.0 to incorporate the new indication:

- Medical record documentation of a diagnosis of Non-24-Hour Sleep-Wake Disorder (Free-Running Disorder) AND
- Medical record documentation that the member is totally blind with no perception of light AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least 6 months of melatonin therapy
- **OR**
- **Medical record documentation of a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) AND**
- **Medical record documentation of age greater than or equal to 3 years**

QL FOR LETTER ONLY: **Capsules:** 1 capsule per day, 30 day supply per fill; **Oral Suspension: 5 mL per day**

Discussion: A discussion was had regarding sleep quality and sleep time results, and if there were any results on behavioral issues. HetlioZ failed to show a significant difference in sleep time but showing a significant difference in sleep quality. Sleep quality was rated on a scale by parents so it was a very subjective measure. There were no improvements in behavioral problems related to SMS reported.

Outcome: The committee voted 20-3 in favor of accepting the recommendations as presented.

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

LORBRENA (lorlatinib)

Updated Indication: Lorbrena is now indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Previously the indication was for ALK-positive NSCLC whose disease had progressed on crizotinib and at least one other ALK inhibitor or on alectinib or ceritinib, as the first ALK inhibitor therapy for metastatic disease.

Current formulary status: Brand NP Oral Oncology tier (\$0 Copay), requiring a prior authorization

Recommendation: There are no changes recommended to the formulary placement, authorization duration, or quantity limits for Lorbreña. It is recommended to make the following changes to Commercial Policy 539.0 to incorporate the new indication:

- Medical record documentation that Lorbreña is prescribed by or in consultation with a hematologist or oncologist AND
- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) AND
- Medical record documentation of disease progression on one of the following:
 - Crizotinib (Xalkori) and at least one other anaplastic lymphoma kinase (ALK) inhibitor for metastatic disease; OR
 - Alectinib (Alecensa) as the first anaplastic lymphoma kinase (ALK) inhibitor therapy for metastatic disease; OR
 - Ceritinib (Zykadia) as the first anaplastic lymphoma kinase (ALK) inhibitor therapy for metastatic disease

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.

VYXEOS (daunorubicin/cytarabine liposomal)

Updated Indication: Vyxeos is now indicated for the treatment of newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year of age and older.

Previously, Vyxeos was only indicated in adults (18 years of age and older).

Current formulary status: Medical benefit requiring prior authorization

Recommendation: No changes are recommended to the formulary placement, quantity limits, or authorization durations for any lines of business. It is recommended that the age requirements for each line of business be updated as follows.

- Medical record documentation of age of ≥ 18 years 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.

BLINCYTO (blinatumomab)

Updated Indication: The indications for Blincyto, a bispecific CD19-directed CD3 T-cell engager, were revised to specify use in CD19-positive patients. Blincyto is now indicated for the treatment of adults and children with:

- CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.
- Relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL).

No new studies or safety findings were submitted to the FDA with this revision.

Current formulary status: Medical benefit requiring a prior authorization; When processed at Specialty pharmacy, it processes at the Specialty tier/Brand NP tier for three-tier members.

Recommendation: No changes are recommended for the formulary placement. The following changes are recommended to Medical Benefit Policy 128.0 to match the FDA approved indications:

Relapsed or Refractory B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of relapsed or refractory **CD19-positive** B-cell precursor acute lymphoblastic leukemia (ALL)

AUTHORIZATION DURATION: Approval will be limited to one lifetime 9 cycle (20 month) course. Subsequent approval for treatment past the initial 9 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

MRD-positive B-cell Precursor ALL

- Prescription written by an oncologist/hematologist **AND**
- Medical record documentation of a diagnosis of **CD19-positive** B-cell precursor acute lymphoblastic leukemia (ALL) in first or second remission **AND**
- Medical record documentation of a minimal residual disease (MRD) greater than or equal to 0.1%

AUTHORIZATION DURATION: Approval will be limited to one lifetime 4 cycle (6 month) course. Subsequent approval for treatment past the initial 4 cycle course will require documentation of well-controlled, peer-reviewed literature with evidence to support this request.

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.

KEYTRUDA (pembrolizumab)

Updated Indication: The indication for patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy has been withdrawn.

Keytruda is a highly selective anti-PD-1 humanized monoclonal antibody which is now indicated as first-line therapy for locally advanced or metastatic esophageal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above the GEJ) carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with platinum- and fluoropyrimidine-based chemotherapy.

Previously Keytruda was only approved for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by an FDA approved test, with disease progression after one or more prior lines of systemic therapy.

Current formulary status: Keytruda is a medical benefit and requires a prior authorization

Recommendation: There will be no changes to the formulary status or authorization duration at this time. It is recommended to update the policy to include the new indication. It is recommended to remove the criteria pertaining Small Cell Lung Cancer due to withdrawal of the indication from FDA approved labeling.

Small Cell Lung Cancer (SCLC)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of a diagnosis of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation that tumors express PD-L1 (CPS ≥ 10) as determined by an FDA approved test **AND**
- Medical record documentation of disease progression on or after two lines of therapy, one of which must be platinum-based chemotherapy

Esophageal Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- **One of the following:**
 - Medical record documentation of a diagnosis of locally advanced or metastatic squamous cell carcinoma of the esophagus **AND**
 - Medical record documentation that tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-approved test **AND**
 - Medical record documentation of disease progression after one or more prior lines of systemic therapy for advanced disease
- **OR**
 - Medical record documentation of a diagnosis of locally advanced or metastatic esophageal or gastroesophageal junction (GEJ) carcinoma not amenable to surgical resection or definitive chemoradiation **AND**
 - Medical record documentation of use in combination with platinum (oxaliplatin or cisplatin) and fluoropyrimidine-based (fluorouracil or capecitabine) chemotherapy

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.

SARCLISA (isatuximab-irfc)

Updated Indication: Sarclisa is now approved in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.

Previously Sarclisa was indicated in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 2 therapies including lenalidomide and a proteasome inhibitor.

Current formulary status: Medical benefit, requiring a prior authorization; Specialty tier or Brand NP tier (for members with three-tier benefit) when processed at a specialty pharmacy

Recommendation: There are no changes recommended to the formulary placement of Sarclisa. It is recommended that the following prior authorization criteria be added to the Medical Benefit Policy 213.0:

- Medical record documentation that Sarclisa 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 one of the following:
 - Medical record documentation of diagnosis of multiple myeloma **AND** both of the following:
 - Medical record documentation that Sarclisa will be used in combination with pomalidomide (Pomalyst)* and dexamethasone **AND**
 - Medical record documentation of prior treatment with at least two lines of therapy, which included lenalidomide (Revlimid)* **AND** a proteasome inhibitor (including but not limited to Velcade (bortezomib)*, Kyprolis (carfilzomib)*, or Ninlaro (ixazomib)*)

OR

- Medical record documentation of diagnosis of relapsed or refractory multiple myeloma **AND** both of the following:
 - Medical record documentation that Sarclisa will be used in combination with carfilzomib and dexamethasone **AND**
 - Medical record documentation of prior treatment with one to three lines of therapy

*Prior authorization required

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.

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

XTANDI (enzalutamide)

Background: Xtandi received approval for a new dosage formulation (film-coated tablets) and a new strength (80 mg). Previously Xtandi was approved as 40 mg capsules. There are no changes for the indications of Xtandi and both tablets and capsules are approved for:

- Castration-resistant prostate cancer AND
- Metastatic castration-sensitive prostate cancer

The recommended dosage remains unchanged at 160mg orally once daily. This dosage can be taken as two 80 mg tablets, four 40 mg tablets, or four 40 mg capsules.

Approval for the new products comes from results of a bioequivalence study between Xtandi capsules and tablets which demonstrated bioequivalence for single-dose AUCs under fasted and fed conditions. The tablets and capsules can be used interchangeably without affecting efficacy. The tablets are smaller than the previous capsules to address potential issues with swallowing. The new strength decreases the daily required pill intake and is anticipated to improve treatment adherence.

Current formulary status: Capsules: Brand NP Oral Oncology tier (\$0 Copay), requiring a prior authorization, QL: 4 capsules per day, 30 day supply per fill

Recommendations: No changes are recommended to the auth duration or prior authorization criteria for Xtandi. It is recommended that Xtandi 40 mg tablets and Xtandi 80 mg tablets be added to the formulary to match the placement of the 40 mg capsules with the following quantity limits:

Brand NP Oral Oncology tier (\$0 Copay), requiring a prior authorization

QUANTITY LIMITS: 40 mg tablets: 4 tablets per day, 30 day supply per fill, 80 mg tablets: 2 tablets per day, 30 day supply per fill

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.

MIRVASO (brimonidine tartrate)

Background: Based on comments from DHS that treatment guidelines no longer support metronidazole as a first line treatment for rosacea unless the disease manifest with papules and pustules

Current formulary status: brand non-preferred tier requiring prior authorization

Recommendation: Recommended to update prior authorization criteria to the following:

- Medical record documentation that Mirvaso is being use for the treatment of persistent (non-transient) facial erythema of rosacea AND
- Medical record documentation of age greater than or equal to 18 years

Discussion: It was asked if a similar updated was necessary for the Finacea policy. It was determined that the indication for Finacea is similar to that of metronidazole for both pustules and papules. No additional 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.

ORILISSA (elagolix sodium)

Background: Orilissa is available as 150mg and 200mg tablets for the management of moderate to severe pain associated with endometriosis. Duration of therapy is dependent on the dose of Orilissa being prescribed.

Current formulary status: brand non-preferred tier requiring prior authorization

Recommendation: Modify the authorization duration to the following:

AUTHORIZATION DURATION:

Orilissa 150mg tablets: Initial approval will be for 24 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 150 mg tablets).

Orilissa 200mg tablets: Initial approval will be for 6 months (or less if there is medical record documentation of a previous incomplete course of therapy with Orilissa 200 mg tablets).

REAUTHORIZATION:

Medical record documentation that the patient has not been treated for more than a total of 24 months with Orilissa 150 mg once daily OR more than a total of 6 months with Orilissa 200 mg twice daily OR documentation of medical or scientific literature to support the use of this agent beyond the FDA-approved treatment duration

MEDISPAN AUTHORIZATION LEVEL: GPI-14

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.

SITE OF CARE POLICY UPDATES

Background: On October 1st, 2019 Geisinger Health Plan (GHP) implemented a new site of care program for infliximab products and intravenous/subcutaneous immune globulin products, which direct members to the most cost-effective, yet clinically appropriate location to receive drug infusions under the medical benefit. The site of care program is administered as part of the existing prior authorization program which requires clinical approval of the medication as well as approval at hospital based outpatient facilities via the following prior authorization criteria. Since that time, additional drugs have been added to the site of care program in phases.

On July 15, 2021 GHP will implement Phase 6 drugs (Fabrazyme, Lumizyme, Naglazyme, Cerezyme, and Aldurazyme) to the site of program, and on August 15, 2021 GHP will implement Phase 7 drugs (Ilaris, Cimzia, Vyepi, Ilumya, and Stelara) to the site of care program. The current Site of Care Policy (MBP 181.0) will apply in addition to the drugs' respective existing clinical prior authorization program.

Recommendation: It is recommended that the following changes (highlighted in green) be made to MBP 181.0 so that this policy may apply to the Phase 6 and Phase 7 drugs (Fabrazyme, Lumizyme, Naglazyme, Cerezyme, Aldurazyme, Ilaris, Cimzia, Vyepiti, Ilumya, and Stelara). In addition to the drugs outlined above, it is recommended that the criteria are updated to account for additional self-injected drugs.

MBP 181.0 Site of Care

I. Policy:

Site of Care Review Guidelines for Infusion Drugs and Specialty Medications

II. Purpose/Objective:

To provide a policy of coverage regarding the use of hospital based outpatient facilities as a site of care for drugs that require administration via intravenous infusion or injection. This policy applies to these medications:

1. Abatacept (Orencia IV)
2. Agalsidase Beta (Fabrazyme) [effective 7/15/21]
3. Alglucosidase Alfa (Lumizyme) [effective 7/15/21]
4. Belimumab (Benlysta IV)
5. Benralizumab (Fasenra)
6. C1 esterase Inhibitor [Human] (Cinryze)
7. Canakinumab (Ilaris) [effective 8/15/21]
8. Certolizumab (Cimzia) [effective 8/15/21]
9. Denosumab (Prolia, Xgeva)
10. Eptinezumab (Vyepiti) [effective 8/15/21]
11. Galsulfase (Naglazyme) [effective 7/15/21]
12. Golimumab (Simponi Aria)
13. Immune Globulin (IVIG)
14. Imiglucerase (Cerezyme) [effective 7/15/21]
15. Infliximab & infliximab biosimilar products
16. Laronidase (Aldurazyme) [effective 7/15/21]
17. Mepolizumab (Nucala)
18. Omalizumab (Xolair)
19. Tildrakizumab (Ilumya) [effective 8/15/21]
20. Tocilizumab (Actemra IV)
21. Ustekinumab (Stelara) [effective 8/15/21]
22. Vedolizumab (Entyvio)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.
7. Site of Care – choice of physical location for administration of intravenous infusions or injections. Site of care locations include hospital inpatient, hospital based outpatient facilities, physician's office, ambulatory infusion centers, or home infusion services.
8. Alternative less intensive site of care facilities include non-hospital affiliated outpatient infusion centers such as ambulatory infusion centers or physician's offices and home infusion
9. Hospital based outpatient facilities include ER services, intravenous drug infusions or injections, observation services, outpatient surgery, lab tests, or x-rays, or any other hospital services where the patient is not admitted as an inpatient.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:

Specific intravenous and injectable drugs must meet applicable medical necessity criteria for coverage. If these criteria are met, this coverage policy will be used to determine the medical necessity of administration in the hospital based outpatient setting. If medical necessity criteria for administration in the hospital based outpatient setting are not met, an alternative less intensive site of care facility should be utilized.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Administration in the hospital based outpatient setting will be considered medically necessary and LIMITED to a duration of 60 days when one of the following criteria are met:

- This is the initial medication infusion **OR**
- Member is reinitiating treatment after not receiving any treatments for at least 6 months.

AUTHORIZATION DURATION: Initial approval will be for a duration of 60 days. Administration in the hospital based outpatient setting for longer than 60 days will be required to meet the authorization criteria in the section below.

Administration in the hospital based outpatient setting will be considered medically necessary for a duration of greater than 60 days when one of the following criteria are met:

- The medication has a site of care restriction for administration per the FDA approved label **OR**
- Documented previous history of severe or potentially life-threatening adverse event during or following administration and the adverse event cannot be managed using pre-medication(s) or adjusting the rate of infusion **OR**
- All of the following:
 - All alternate non-hospital outpatient settings are not within a reasonable distance from the member's home (within 50 miles) **AND**
 - Home healthcare or infusion provider has determined that the patient, home caregiver, or home environment is not appropriate for home infusion or home infusion services are not available due to limited network access **AND**
 - For request of a provider administered drug, for which a self-administered formulation is available, including but not limited to abatacept, belimumab, benralizumab, certolizumab, golimumab, mepolizumab, omalizumab, and tocilizumab, and ustekinumab: medical record documentation of a therapeutic failure of or intolerance to a 3 month trial of the self-administered formulation of the respective product.

OR

- For IVIG any of the above criteria **OR**
 - Change of immune globulin products (one infusion will be permitted in the hospital outpatient setting) **OR**
 - Laboratory confirmed immunoglobulin A (IgA) deficiency with anti-IgA antibodies

OR

- For Xgeva (denosumab) any of the above criteria **OR**
 - Patient is receiving Xgeva concomitantly with intravenous chemotherapy as part of the same encounter

AUTHORIZATION DURATION: Initial approval will be for the same length of time as the authorization of the specific drug being administered. Subsequent approvals will be required if the specific drug requires subsequent authorizations.

NOTE: To prevent a delay in care and allow adequate transition time for members to an alternate infusion site, members already established on therapy who do not meet any of the above criteria will be given a 60-day transition auth to allow them to continue receiving therapy at their current hospital based outpatient facility while they transition to a different infusion site.

LIMITATIONS: If none of the above criteria are met and the proposed hospital based outpatient facility is considered a least costly site of care, the hospital outpatient infusion would be approved.

Discussion: The question was raised if we have an estimate of the cost impact from the site of care program. This is reported monthly. No additional 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.

ZUBSOLV AND BUNAVAIL POLICY UPDATES

Background: A review of the Bunavail policy conducted as part of an NQTL analysis for mental health parity identified that the counseling attestation for Bunavail may represent more stringent application than the analogous specialist requirements included in many medical/surgical medication policies. In order to remedy this potential compliance concern, it is recommended that the counseling requirement be updated to remove the attestation.

It is also recommended that the participating physician requirement is removed from both the Bunavail and Zubsolv policies as this criterion is not currently enforceable.

Lastly, it is recommended that the criterion requiring failure of a sublingual buprenorphine product is updated in both policies to require rationale that the member cannot use either buprenorphine/naloxone SL tablets or films.

Recommendation:

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

- Medical record documentation of rationale for why the member cannot use buprenorphine/naloxone SL tablets **AND** buprenorphine/naloxone SL films

Discussion: No comments or questions.

Outcome: The committee 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.

MARKETPLACE FORMULARY UPDATES

Recommendation:

It is recommended that the following multi-source brand drugs are removed from the Marketplace formulary effective 1/1/2022:

Brand Name	CUI	Generic on Formulary	Other Comments
Afinitor Oral Tablet 2.5 MG	998191	Yes, \$0 Oncology Tier	
Afinitor Oral Tablet 5 MG	845518	Yes, \$0 Oncology Tier	
Afinitor Oral Tablet 7.5 MG	1119402	Yes, \$0 Oncology Tier	
Alcaine Ophthalmic Solution 0.5 %	1191026		Used for ophthalmic anesthesia, no utilization in 2020
Proparacaine HCl Ophthalmic Solution 0.5%	1191013		Used for ophthalmic anesthesia, no utilization in 2020
Bleph-10 Ophthalmic Solution 10%	1006122	Yes, Tier 2	
Carafate Oral Suspension 1 GM/10ML	208094	Yes, Tier 2	
Coumadin Oral Tablet 1 MG	855290	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 10 MG	855298	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 2 MG	855304	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 2.5 MG	855314	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 3 MG	855320	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 4 MG	855326	Yes, Tier 1	Discontinued by manufacturer

Coumadin Oral Tablet 5 MG	855334	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 6 MG	855340	Yes, Tier 1	Discontinued by manufacturer
Coumadin Oral Tablet 7.5 MG	855346	Yes, Tier 1	Discontinued by manufacturer
Cuprimine Oral Capsule 250 MG	207369	Yes, Tier 2	
Delestrogen Intramuscular Oil 20 MG/ML	206715	Yes, Tier 2	
Delestrogen Intramuscular Oil 40 MG/ML	206813	Yes, Tier 2	
E.E.S. Granules Oral Suspension Reconstituted 200 MG/5ML	863603	Yes, Tier 2	
EryPed 400 Oral Suspension Reconstituted 400 MG/5ML	686420	Yes, Tier 2	
Eurax External Lotion 10 %	207864		Discontinued by manufacturer.
Fareston Oral Tablet 60 MG	152880	Yes, \$0 Oncology Tier	
Felbatol Oral Suspension 600 MG/5ML	209028	Yes, Tier 2	
Felbatol Oral Tablet 400 MG	209026	Yes, Tier 2	
Felbatol Oral Tablet 600 MG	209027	Yes, Tier 2	
Ferriprox Oral Tablet 500 MG	1190357	Yes, Tier 5	
Icar-C Plus Oral Tablet 100-250-0.025-1 MG	1087418		Excluded, iron preparation.
Isordil Titrados Oral Tablet 40 MG	793872	Yes, Tier 2	
Kaletra Oral Solution 400-100 MG/5ML	847749	Yes, Tier 2	
Kuvan Oral Packet 100 MG	1111020	Yes, Tier 5	
Kuvan Oral Packet 500 MG	1653221	Yes, Tier 5	
Kuvan Oral Tablet 100 MG	1486691	Yes, Tier 5	
Lidoderm External Patch 5 %	1011705	Yes, Tier 2	

Makena Intramuscular Oil 250 MG/ML	1087968	Yes, Tier 5	
Makena Intramuscular Oil 250 MG/ML	1796692	Yes, Tier 5	
Mar-Cof CG Expectorant Oral Liquid 225-7.5 MG/5ML	995443	No	Multiple other generic strengths of guaifenesin/codeine on formulary.
MoviPrep Oral Solution Reconstituted 100 GM	800918	Yes, Tier 2	
Naftin External Gel 1 %	896108	Yes, Tier 2	
Neutrogena On- The-Spot External Cream 2.5 %	308688	No	Excluded, OTC product.
Nitrostat Sublingual Tablet Sublingual 0.3 MG	207331	Yes, Tier 2	
Nitrostat Sublingual Tablet Sublingual 0.4 MG	207346	Yes, Tier 2	
Nitrostat Sublingual Tablet Sublingual 0.6 MG	207361	Yes, Tier 2	
Oxsoralen Ultra Oral Capsule 10 MG	207074	No	Recommend addition of methoxsalen to formulary.
Plaquenil Oral Tablet 200 MG	979094	Yes, Tier 2	
ProAir HFA Inhalation Aerosol Solution 108 (90 Base) MCG/ACT	745752	Yes, Tier 2	
Proglycem Oral Suspension 50 MG/ML	207634	Yes, Tier 2	
Protonix Oral Packet 40 MG	763308	Yes, Tier 2	
Proventil HFA Inhalation Aerosol Solution 108 (90 Base) MCG/ACT	746763	Yes, Tier 2	
Rapamune Oral Solution 1 MG/ML	351901	No	Recommend addition of sirolimus solution to formulary.

Reclast Intravenous Solution 5 MG/100ML	705875	Yes, Tier 2	
Remodulin Injection Solution 100 MG/20ML	352213	Yes, Tier 5	
Remodulin Injection Solution 20 MG/20ML	352211	Yes, Tier 5	
Remodulin Injection Solution 200 MG/20ML	352214	Yes, Tier 5	
Remodulin Injection Solution 50 MG/20ML	352212	Yes, Tier 5	
Ritalin LA Oral Capsule Extended Release 24 Hour 10 MG	1091143	Yes, Tier 2	
Salvax External Foam 6 %	824983	Yes, Tier 2	
Samsca Oral Tablet 30 MG	849835	Yes, Tier 2	
SandoSTATIN Injection Solution 100 MCG/ML	207198	Yes, Tier 2	
SandoSTATIN Injection Solution 50 MCG/ML	207194	Yes, Tier 2	
SandoSTATIN Injection Solution 500 MCG/ML	207200	Yes, Tier 2	
Saphris Sublingual Tablet Sublingual 10 MG	859979		
Saphris Sublingual Tablet Sublingual 2.5 MG	1606490		
Saphris Sublingual Tablet Sublingual 5 MG	859983		
Sarafem Oral Tablet 10 MG	647555	Yes, Tier 1	
Sarafem Oral Tablet 20 MG	—	Yes, Tier 1	
Sklice External Lotion 0.5 %	1298427	Yes, Tier 2	
Soriatane Oral Capsule 10 MG	213069	Yes, Tier 2	
Soriatane Oral Capsule 25 MG	213070	Yes, Tier 2	

Suboxone Sublingual Film 12-3 MG	1307063	Yes, Tier 2	
Suboxone Sublingual Film 2-0.5 MG	1010603	Yes, Tier 2	
Suboxone Sublingual Film 4-1 MG	1307058	Yes, Tier 2	
Suboxone Sublingual Film 8-2 MG	1010606	Yes, Tier 2	
Tamiflu Oral Capsule 30 MG	728111	Yes, Tier 2	
Tamiflu Oral Capsule 45 MG	728115	Yes, Tier 2	
Tamiflu Oral Capsule 75 MG	261315	Yes, Tier 2	
Tamiflu Oral Suspension Reconstituted 6 MG/ML	1115700	Yes, Tier 2	
Tarceva Oral Tablet 100 MG	1088251	Yes, \$0 Oncology Tier	
Tarceva Oral Tablet 150 MG	1088253	Yes, \$0 Oncology Tier	
Tarceva Oral Tablet 25 MG	1088255	Yes, \$0 Oncology Tier	
Tepadina Injection Solution Reconstituted 100 MG	1919209	Yes, Tier 5	
Tepadina Injection Solution Reconstituted 15 MG	1919211	Yes, Tier 5	
Topamax Oral Tablet 100 MG	151228	Yes, Tier 2	
Topamax Oral Tablet 200 MG	151229	Yes, Tier 2	
Topamax Oral Tablet 25 MG	152855	Yes, Tier 2	
Topamax Oral Tablet 50 MG	151227	Yes, Tier 2	
Topamax Sprinkle Oral Capsule Sprinkle 15 MG	845478	Yes, Tier 2	
Topamax Sprinkle Oral Capsule Sprinkle 25 MG	845479	Yes, Tier 2	

Transderm Scop (1.5 MG) Transdermal Patch 72 Hour 1 MG/3DAYS	351875	Yes, Tier 2	
Tridesilon External Cream 0.05 %	103439	Yes, Tier 2	
Tykerb Oral Tablet 250 MG	672152	Yes, \$0 Oncology Tier	
Urogesic-Blue Oral Tablet 81.6 MG	1251290	Yes, Tier 2	
Veletri Intravenous Solution Reconstituted 0.5 MG	1302755	Yes, Tier 5	
Veletri Intravenous Solution Reconstituted 1.5 MG	1009216	Yes, Tier 5	
Vfend Oral Suspension Reconstituted 40 MG/ML	546624	Yes, Tier 2	
Vfend Oral Tablet 200 MG	352219	Yes, Tier 2	
Vfend Oral Tablet 50 MG	352218	Yes, Tier 2	
Xeloda Oral Tablet 150 MG	213292	Yes, \$0 Oncology Tier	
Xeloda Oral Tablet 500 MG	213293	Yes, \$0 Oncology Tier	
Zarontin Oral Capsule 250 MG	201737	Yes, Tier 2	
Zarontin Oral Solution 250 MG/5ML	755357	Yes, Tier 2	
Zonegran Oral Capsule 100 MG	284408	Yes, Tier 2	
Zonegran Oral Capsule 25 MG	404725	Yes, Tier 2	
Adapalene- Benzoyl Peroxide External Pad 0.1- 2.5 %	2471107		Non-FDA approved product.

AgonEaze External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine cream and occlusive dressings.
Anodyne LPT External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine cream and occlusive dressings.
Aprizio Pak External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine cream, dressings, and medical scissors.
Aprizio Pak II External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine cream, dressings, and medical scissors.
BenzePrO Creamy Wash External Liquid 7 %	1605437		Non-FDA approved product.
BenzePrO Foaming Cloths External Miscellaneous 6 %	1605441		Non-FDA approved product. Available as OTC.
BP 10-1 External Emulsion 10-1 %	1000720		Non-FDA approved product.
BP Cleansing Wash External Emulsion 10-4 %	1000861		Non-FDA approved product.
BPO External Gel 4 %	308691		Non-FDA approved product. Available as OTC.
BPO External Gel 8 %	308697		Non-FDA approved product. Available as OTC.
CadiraMD External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine cream and supplies necessary for venipuncture.
CEM-Urea External Solution 45 %	1242631		Non-FDA approved product. Urea in a vehicle containing menthol, camphor, and eucalyptus oil.
Debacterol Mouth/Throat Solution 30-50 %	1369589/1547711		Non-FDA approved product. Used as part of dental treatment for canker sores.
DermacinRx Empricaine External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
DermacinRx Prizopak External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Econasil External Kit 1 %	857366		Non-FDA approved product. Repackaged kit to include econazole cream, gauze pads, and silicone tape
Empricaine-II External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.

Escavite D Oral Tablet Chewable 0.25-6 MG	—		Non-FDA approved product.
Escavite LQ Oral Liquid 0.25-6 MG/ML	—		Non-FDA approved product.
Escavite Oral Tablet Chewable 0.25-7.5 MG	—		Non-FDA approved product.
Flucaine Ophthalmic Solution 0.25-0.5 %	1247445/1247576		Non-FDA approved product. Used as part of ophthalmic procedures.
Homatropaire Ophthalmic Solution 5 %	992759		Non-FDA approved product. Used as part of ophthalmic procedures.
Homatropine HBr Ophthalmic Solution 5 %	992757		Non-FDA approved product. Used as part of ophthalmic procedures.
Hydrocortisone-Iodoquinol External Cream 1-1 %	310870		Non-FDA approved product.
Ketoconazole-Hydrocortisone External Cream 2-2.5 %	—		Non-FDA approved product.
Lido BDK External Kit 2.5-2.5 %	—		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine cream and supplies necessary for venipuncture.
Lidocaine HCl External Cream 3 %	1010835		Non-FDA approved product. Available as OTC.
Lidocaine HCl External Cream 3.88 %	—		Non-FDA approved product.
Lidocaine HCl External Lotion 3 %	1010836		Non-FDA approved product.
Lidocaine-Prilocaine External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
Lido-K External Lotion 3 %	1010836		Non-FDA approved product.
Lidopin External Cream 3 %	1010835		Non-FDA approved product.
Lidopril External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
Lidopril XR External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.

LiProZonePak External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and Tegaderm dressings.
LidoPure Patch External Kit 5 %	1745091		Non-FDA approved product. Repackaged kit to include lidocaine patches, Xrylix sheets, and medical scissors.
Lido-Prilo Caine Pack External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
Lido-Sorb External Lotion 3 %	1010836		Non-FDA approved product.
Lidozion External Lotion 3 %	1010836		Non-FDA approved product.
Livixil Pak External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include Non-FDA approved product. lidocaine/prilocaine and dressings.
MagneBind 400 Oral Tablet 400- 200-1 MG	794747		Non-FDA approved product. Vitamin excluded from coverage.
Medolor Pak External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and Tegaderm dressings.
Nuvakaan External Kit 2.5- 2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Nuvakaan-II External Kit 2.5- 2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
Phenazopyridine HCl Oral Tablet 100 MG	1094107		Non-FDA approved product. Available as OTC.
Phenazopyridine HCl Oral Tablet 200 MG	1094104		Non-FDA approved product. Available as OTC.
Phenylephrine HCl Ophthalmic Solution 10 %	1234571		Used as part of ophthalmic procedures.
Phenylephrine HCl Ophthalmic Solution 2.5 %	1234579		Non-FDA approved product. Used as part of ophthalmic procedures.
PR Benzoyl Peroxide Wash External Liquid 7 %	845988		Non-FDA approved product.
Prilolid External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovix External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.

Prilovix Lite External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovix Lite Plus External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovix Plus External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovix Ultralite External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovix Ultralite Plus External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prilovixil External Kit 2.5-2.5 %	197877		Non-FDA approved product. Repackaged kit to include lidocaine/prilocaine and dressings.
Prizopak II External Kit 2.5-2.5 %	197877		Repackaged kit to include lidocaine/prilocaine and dressings.
PureFe Plus Oral Capsule 106-1 MG	1314654		Non-FDA approved product, inactive.
Quflora FE Oral Tablet Chewable 0.25 MG	—		Dietary supplement.
Quflora FE Pediatric Oral Liquid 0.25-9.5 MG/ML	—		Non-FDA approved product.
Quflora Pediatric Oral Solution 0.25 MG/ML	—		Non-FDA approved product.
Quflora Pediatric Oral Solution 0.5 MG/ML	—		Non-FDA approved product.
Quflora Pediatric Oral Tablet Chewable 0.25 MG	—		Non-FDA approved product.
Quflora Pediatric Oral Tablet Chewable 0.5 MG	—		Non-FDA approved product.
Quflora Pediatric Oral Tablet Chewable 1 MG	—		Non-FDA approved product.
Salvax External Foam 6 %	824983		Non-FDA approved product.
Sila III External Therapy Pack 0.1 %	1085636		Non-FDA approved product. Repackaged kit to include triamcinolone ointment, silicone tape, and gauze pads.

Zilacaine Patch External Therapy Pack 5 %	1745091		Non-FDA approved product. Repackaged kit including lidocaine patches, Nuvazil dressing, and medical scissors.
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Marketplace Formulary Additions/Changes

It is recommended that the following medication are added to the Marketplace formulary immediately:

Brand Name	CUI	Recommendations								
Methoxsalen Rapid Oral Capsule 10 MG	1812434	Add to Tier 2, PA required								
Sirolimus Oral Solution 1 MG/ML	314230	Add to Tier 2, PA required								
Fluoxetine HCl (PMDD) Oral Tablet 10 MG & 20 MG	310384 & 2532159	<p>Treatment of premenstrual syndrome and premenstrual dysphoric disorder (PMDD): Per UpToDate: Because of their proven efficacy and safety profile, we recommend SSRIs for women with premenstrual symptoms that include socioeconomic dysfunction that have been documented prospectively and who do not desire hormonal contraception</p> <p>Clinical trials and systematic reviews of SSRIs for PMS and PMDD conclude that these medications are effective. We typically start sertraline, citalopram, escitalopram, or fluoxetine, as these are extensively studied. Paroxetine is also effective but is more likely to be associated with weight gain.¹</p> <p>Note: Only paroxetine CR, sertraline, and fluoxetine are indicated for PMDD.</p> <table border="1"> <thead> <tr> <th>Drug Name</th> <th>Cost per Tablet</th> </tr> </thead> <tbody> <tr> <td>Fluoxetine</td> <td>\$16.25 - \$17.41</td> </tr> <tr> <td>Paroxetine CR</td> <td>\$0.78 - \$0.92</td> </tr> <tr> <td>Sertraline</td> <td>\$0.02 - \$0.04</td> </tr> </tbody> </table> <p>Recommendation: Currently on Tier 1. Recommend moving to Tier 2 and adding the following prior authorization criteria:</p> <ul style="list-style-type: none"> • Medical record documentation of use for premenstrual dysphoric disorder AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to sertraline 	Drug Name	Cost per Tablet	Fluoxetine	\$16.25 - \$17.41	Paroxetine CR	\$0.78 - \$0.92	Sertraline	\$0.02 - \$0.04
Drug Name	Cost per Tablet									
Fluoxetine	\$16.25 - \$17.41									
Paroxetine CR	\$0.78 - \$0.92									
Sertraline	\$0.02 - \$0.04									

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.

Commercial/Exchange/TPAs

Drug Use Evaluations (DUEs)

- Statin Use in Persons with Diabetes DUE
 - This is the 2020 4th quarter MedImpact DUE for Commercial/Exchange and GHP Family
 - From this report, we identified members whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 12/3/2020.
 - Adam K. re-ran this data on 4/6/2021 to analyze the effectiveness of the letter. Of the original 618 members that we sent letters; 419 are still active. Of those 419 members, 88 now have a claim for a statin medication. This equates to about 21% of the targeted members.
 - See below for letters sent:

▪ For GHS01: 98	▪ For GHS05: 87
▪ For GHS25: 9	▪ For GHS90: 95
▪ For GT045: 33	▪ For GT046: 26
▪ For GT062: 26	▪ For GT095: 87
▪ For GT400: 99	▪ For GT900: 60
- Asthma DUE
 - This is the 2020 3rd quarter MedImpact DUE for all LOBs
 - From this report, we identified members who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/26/2020.
 - Adam K. re-ran this data on 12/11/2020 to analyze the effectiveness of the letter. Of the original 412 members that we sent letters, 372 are still active. Of those 372 members, 30 now have a claim for a controller medication. This equates to about 8.1% of the targeted members.
 - See below for letters sent:

▪ For GHS01: 98	▪ For GHS05: 62
▪ For GHS25: 4	▪ For GHS90: 99
▪ For GT023: 2	▪ For GT036: 1
▪ For GT045: 5	▪ For GT046: 6
▪ For GT056: 3	▪ For GT062: 1
▪ For GT070: 1	▪ For GT089: 2
▪ For GT095: 22	▪ For GT106: 1
▪ For GT140: 2	▪ For GT210: 1
▪ For GT291: 1	▪ For GT310: 3
▪ For GT400: 96	▪ For GT902: 2
- Congestive Heart Failure DUE
 - This is the 2020 2nd quarter MedImpact DUE for Commercial/Exchange and GHP Family
 - From this report, we identified members who have a presumed diagnosis of heart failure taking metoprolol succinate, carvedilol, or bisoprolol, and who were not taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) drug therapy in a 3-month timeframe

- The Print Shop completed the mail merge and sent out letters to the member's providers on 6/30/2020.
- Adam K. re-ran this data on 10/21/2020 to analyze the effectiveness of the letter. Of the original 559 members that we sent letters, 503 are still active. Of those 503 members, 28 now have a claim for an ACEI or ARB. This equates to about 5.6% of the targeted members.
- See below for letters sent:

▪ For GHS01: 89	▪ For GHS05: 84
▪ For GHS25: 6	▪ For GHS90: 81
▪ For GT038: 51 -Life Geisinger	▪ For GT046: 23
▪ For GT062: 13	▪ For GT095: 87
▪ For GT400: 92	▪ For GT900: 33
- Coronary Artery Disease DUE
 - This is the 2020 1st quarter MedImpact DUE for all LOBs
 - From this report, we identified members age 40-75 years who are not on a statin drug therapy in a 3-month timeframe and who have at least one of the following cardiovascular disease (CVD) risk factors: diabetes, hypertension, or smoking.
 - Brandy P. is completed the mail merge and sent out letters to the member's providers on 2/21/2020.
 - See below for letters sent:

▪ For GHS01: 91	▪ For GHS05: 87
▪ For GHS25: 36	▪ For GHS90: 100
▪ For GT023: 54	▪ For GT033: 32
▪ For GT036: 12	▪ For GT038: 14
▪ For GT041: 15	▪ For GT045: 100
▪ For GT046: 100	▪ For GT056: 43
▪ For GT062: 100	▪ For GT064: 14
▪ For GT065: 100	▪ For GT070: 27
▪ For GT088: 18	▪ For GT089: 74
▪ For GT095: 100	▪ For GT106: 23
▪ For GT107: 14	▪ For GT108: 14
▪ For GT140: 31	▪ For GT180: 13
▪ For GT210: 22	▪ For GT230: 65
▪ For GT260: 30	▪ For GT310: 28
▪ For GT400: 100	▪ For GT900: 100
 - Adam K. was able to re-run the data on this population on 8/5/2020 and of the original 1,296 members that we sent letters to 1,195 are still active. Of those 1,195 members, 128 now have a claim for a statin. This equates to 11% of the members.

In Progress

- Working internally to create new quarterly DUEs

Ongoing

- DUR Duplicate Anticoagulant Report
 - We get this report **weekly** for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy/patient of the flagged members to confirm proper medication therapy.
 - For 2021:
 - For COMM (Commercial): **1 member** reviewed and **0 interventions** made

- For D6 (Exchange): **0 members** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
 - We run an in-house retrospective report **quarterly** for **all LOBs** with help from Adam Kelchner and Aubrielle Smith. These members are identified and written up and sent to a medical director if follow up is needed.
 - For Commercial/Exchange/TPA in 2021, we are in the process of reviewing the Q1 report
- Suboxone with an Opioid Report
 - We are getting this report **weekly** for **all LOBs** from Adam Kelchner. These members are being forwarded to Dr. Meadows, and he is looking into whether it is appropriate to end the opioid authorizations still in place
 - For Commercial/Exchange/TPA in 2021, see below for the new members reviewed and those referred to Dr. Meadows:
 - For COMM: we have reviewed **3 new members** and **1 member** was referred to Dr. Meadows
 - For D6: we have reviewed **3 new members** and **1 member** was referred to Dr. Meadows
 - For EMYD: we have reviewed **2 new members** and **1 member** was referred to Dr. Meadows
 - For TG48: we have reviewed **2 new members** and **0 members** were referred to Dr. Meadows
- Ending Opioid Authorizations
 - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
 - For Commercial/Exchange/TPA in 2021, see below for the number of letters we have sent to members notifying them that we are ending their opioid authorization(s):
 - For D6: **1**
- Opioid Overutilization Report
 - We are getting this report **monthly** from PerformRx and we are writing up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
 - For Commercial/Exchange/TPA in 2021, see below for the number of reviewed cases.
 - For COMM: we have reviewed **1 patient** and sent **1 case** to Dr. Meadows for review
 - For EMYD: we have reviewed **2 patients** and sent **0 cases** to Dr. Meadows for review
 - For TG48: we have reviewed **1 patient** and sent **1 case** to Dr. Meadows for review
- FWA Reports
 - We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
 - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
 - For COMM in 2021, we have reviewed cases and corrected claims, resulting in a **cost savings of \$831.88**
 - For D6 in 2021, we have reviewed cases and corrected claims, resulting in a **cost savings of \$89.95**
 - For TG48, TG51 in 2021, we reviewed cases and corrected claims, resulting in a **cost savings of \$16.87**

- **Members for Statin:**
 - COMM: **34**
 - D6: **17**
 - EMYD: **6**
 - SASN: **1**
 - TG48, TG51: **7**
 - TP23: **1**
 - TP45: **2**
 - TP46: **1**
 - TP56: **0**
 - TP88: **1**
 - TPA6: **1**
 - WF89: **0**
 - *member may flag for more than one measure and are included in the count for each measure
 - We are also attempting telephonic outreach to members who are non-adherent in all 3 measures to encourage adherence.
- **HEDIS Initiatives: *We are awaiting first round of proactive data for 2021***
- **Asthma Medication Ratio (AMR)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
 - For Commercial/Exchange in 2021, see below for letters sent to members:
 - COMM:
 - D6:
- **Antidepressant Medication Management (AMM)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
 - For Commercial/Exchange in 2021, see below for letters sent to members:
 - Effective Acute Phase:
 - COMM:
 - D6:
 - Effective Continuation Phase:
 - COMM:
 - D6:
- **Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)**
 - Jesse Barsh runs this report **monthly**, and we send letters to the flagged members who appear non-adherent to their antipsychotic medications.
 - HEDIS Specifications: The percentage of members 19-64 years of age during the measurement year with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80% of their treatment period.
 - For Commercial/Exchange in 2021, see below for letters sent to members:
 - COMM:
 - D6:
- **Statin Therapy for Patients with Cardiovascular Disease (SPC)**
 - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy

- For Commercial/Exchange in 2021, see below for letters sent to **providers** to encourage statin therapy initiation:
 - COMM:
 - D6:
 - For Commercial/Exchange in 2021, see below for letters sent to **members** to promote statin adherence:
 - COMM:
 - D6:
 - Statin Therapy for Patients with Diabetes (SPD)
 - This is a **monthly** report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
 - For Commercial/Exchange in 2021, see below for letters sent to **providers** to encourage statin therapy initiation:
 - COMM:
 - D6:
 - For Commercial/Exchange in 2021, see below for letters sent to **members** to promote statin adherence:
 - COMM:
 - D6:
 - Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
 - This is a **monthly** report to identify members with a diagnosis of AMI who received beta-blocker treatment for 6 months after discharge and who are non-adherent to beta-blocker therapy
 - For Commercial/Exchange in 2021, **letters** have been sent to members.

Completed

- Commercial/Exchange DUR/FWA Program Fliers
 - Last updated 02/2021 next update 08/2021
- Current Provider Letters
 - Congestive Heart Failure DUE
 - Coronary Artery Disease DUE
 - Statin Use in Persons with Diabetes DUE
 - Asthma Med Ratio DUE
 - Opioid Overutilization
 - Severity Report
 - Duplicate Anticoagulant Report
 - Statin Therapy for Patients with Cardiovascular Disease (SPC)
 - Statin Therapy for Patients with Diabetes (SPD)
- Current Member Letters
 - Ending Opioid Authorizations
 - Adherence to Antipsychotics (SAA)
 - Antidepressant Medication Management (AMM)
 - Asthma Medication Ratio (AMR)
 - Statin Therapy for Patients with Cardiovascular Disease (SPC)
 - Statin Therapy for Patients with Diabetes (SPD)
 - Persistence of Beta-Blocker Treatment After a Heart Attack (PBH)
 - STENT Adherence Report

CHIP (GHS32 = CHBQ)

- All of our Medicaid adherence/DUR reports include logic to identify the CHIP population
- Only reports in which CHIP members have flagged to date are included here

Drug Use Evaluations (DUEs)

- Asthma DUE
 - This is the 2020 3rd quarter MedImpact DUE for all LOBs
 - From this report, we identified **28 members** who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
 - The Print Shop completed the mail merge and sent out letters to the member's providers on 8/26/2020.
 - Adam K. re-ran this data on 12/11/2020 to analyze the effectiveness of the letter. Of the original 28 members that we sent letters, 26 are still active and 2 now have a claim for a controller medication. This equates to about 7.7% of the targeted members.

Ongoing

- FWA Reports
 - We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
 - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
 - For CHBQ in 2021, we have not reviewed any cases or corrected any claims yet
- Duplicate Antipsychotics
 - Adam Kelchner runs this report **quarterly**, and we send letters to the PCPs to address potential duplicate therapy issues.
 - For CHBQ in 2021, we have sent letters to **0 providers**
- HEDIS Initiatives: *We are awaiting first round of proactive data for 2021*
- Asthma Medication Ratio (AMR)
 - Jesse Barsh runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
 - For CHBQ in 2021, we have sent **_ letters** to members
- Antidepressant Medication Management (AMM)
 - Jesse Barsh runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
For CHBQ in 2021, we sent **_ letters** to members in the **Effective Acute Phase**, and **0 letters** to members in the **Effective Continuation Phase**

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

Meeting adjourned at 3:38 pm

Future Scheduled Meetings: The next bi-monthly scheduled meeting will be held on July 20th, 2021 at 1:00 p.m.

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.