

P&T Committee Meeting Minutes
Medicaid
May 18, 2021

Present (via Teams): Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D. Jeremy Bennett, MD Dean Christian, MD Alyssa Cilia, RPh Kimberly Clark, Pharm.D. Kristen Bender, 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 Austin Paisley, PharmD. Kimberly Reichard, Pharm.D. Melissa Renn, Pharm.D. 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 Amanda Taylor, MD Adam Root (non-voting participant)	Absent: Holly Bones, Pharm.D. Kim Castelnovo, RPh Michael Evans, RPh Rajneel Farley, Pharm.D. Jason Howay, Pharm.D. Perry Meadows, MD Jonas Pearson, RPh Angela Scarantino William Seavey, Pharm.D. Robert Strony, MD MBA
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Call to Order:

Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, May 18, 2021

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the March 16, 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.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Margenza is a medical benefit that will be managed by GHP and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply

- 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.

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).

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Cosela will be a medical benefit for GHP Family members. Cosela will require a 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.

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.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Pepaxto is a medical benefit that will be managed by Geisinger and should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria should apply:

- 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 Injection)

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 Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Oxlumo is a medical benefit that will be GHP managed. Oxlumo should not be added to the GHP Family pharmacy formulary. The following prior authorization criteria will apply:

- 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

Phesgo (pertuzumab, trastuzumab, and hyaluronidase)

Review: NCCN recommends that Phesgo may be substituted anywhere that the combination of intravenous pertuzumab and intravenous trastuzumab are given as part of systemic therapy. Phesgo is indicated for use in combination as either 1) neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer or 2) adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. Phesgo is also recommended to use in combination with docetaxel for treatment of HER2 metastatic breast cancer who have not received anti-HER2 therapy (Category 2A).

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Phesgo is a medical benefit that will be GHP managed. Phesgo should not be added to the GHP Family pharmacy formulary. No prior authorization criteria will apply.

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

FAST FACTS

Imfinzi

Updated Indication: AstraZeneca has voluntarily withdrawn the Imfinzi indication for previously treated adult patients with locally advanced or metastatic bladder cancer.

Recommendation: urothelial carcinoma criteria should be removed from the policy.

Outcome: The committee unanimously voted to accept the recommendations.

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

Vyxeos

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.

Recommendation: update age in policy to ≥ 1 year

Outcome: The committee unanimously voted to accept the recommendations.

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

Blincyto

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).

Recommendation: Make the following update to the policy:

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)

Outcome: The committee unanimously voted to accept the recommendations.

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.

Recommendation: Remove criteria for Small Cell Lung Cancer from policy

Outcome: The committee unanimously voted to accept the recommendations.

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

Sarclisa

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.

Recommendation: Update the policy to:

- 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

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

Orilissa

Recommendation: 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. It is recommended to update the authorization to:

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

Outcome: The committee unanimously voted to accept the recommendations.

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

Mirvaso

Recommendation: 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 it is recommended to update prior authorization to:

- Medical record documentation that Mirvaso is being use for the treatment of persistent (nontransient) facial erythema of rosacea **AND**
- Medical record documentation of age ≥ 18

Outcome: The committee unanimously voted to accept the recommendations.

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

05.2021 DUR Report

The May 2021 GHP Family DUR/Adherence Report was presented to the Committee for review.

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

April Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from April 22, 2021 to April 29, 2021. Responses were received from 21 members (out of 37) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Breyanzi and Yescarta	<p><u>Breyanzi</u> – Medical drug requiring prior authorization:</p> <ul style="list-style-type: none">• Medical record documentation that Breyanzi is prescribed by a hematologist/oncologist AND• Medical record documentation of age greater than or equal to 18 years AND• Medical record documentation of one of the following diagnoses:<ul style="list-style-type: none">○ High-grade B-cell lymphoma OR○ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma) OR○ Primary mediastinal large B-cell lymphoma OR○ Follicular lymphoma grade 3B <p>AND</p>

	<ul style="list-style-type: none"> • Medical record documentation of two or more lines of prior systemic therapy AND • Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy <p><u>Yescarta</u> – update criteria for Large B-Cell Lymphoma:</p> <ul style="list-style-type: none"> • Prescription written by a hematologist/oncologist AND • Medical record documentation that patient is 18 years of age or older AND • Medical record documentation of one of the following diagnoses: <ul style="list-style-type: none"> ○ Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified OR ○ Relapsed or refractory primary mediastinal large B-cell lymphoma OR ○ Relapsed or refractory high-grade B-cell lymphoma OR ○ Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma <p>AND</p> <ul style="list-style-type: none"> • Medical record documentation of a therapeutic failure on two or more previous lines of therapy AND • Medical record documentation that the member has not received prior treatment with CAR-T cell therapy or other genetically modified T cell therapy
Olinvyk	<p>Medical drug requiring prior authorization:</p> <ul style="list-style-type: none"> • Medical record documentation of age greater than or equal to 18 AND • Medical record documentation of moderate to severe acute pain AND • Medical record documentation that patient requires an intravenous opioid analgesic AND • Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three generic intravenous opioid analgesics. <p>Authorization Duration: 2 days</p>
Darzalex Faspro	<p>Medical drug requiring prior authorization:</p> <ul style="list-style-type: none"> • Prescription written by a hematologist/oncologist AND • Medical record documentation a diagnosis of multiple myeloma AND <p><u>If newly diagnosed multiple myeloma (transplant ineligible):</u></p> <ul style="list-style-type: none"> • Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) AND • Medical record documentation that Darzalex Faspro will be given in combination with one of the following: <ul style="list-style-type: none"> ○ bortezomib (Velcade), melphalan, AND prednisone [VMP] OR ○ Lenalidomide (Revlimid) AND dexamethasone <p><u>If newly diagnosed multiple myeloma (transplant eligible):</u></p> <ul style="list-style-type: none"> • Medical record documentation that the member is eligible for stem-cell transplantation AND • Medical record documentation that Darzalex Faspro will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

	<p><u>If relapsed/refractory multiple myeloma:</u></p> <ul style="list-style-type: none"> • One of the following: <ul style="list-style-type: none"> ○ Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR ○ Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR ○ Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) AND one of the following: <ul style="list-style-type: none"> ▪ Medical record documentation that Darzalex Faspro will be prescribed in combination with lenalidomide and dexamethasone OR ▪ Medical record documentation that Darzalex Faspro will be prescribed in combination with bortezomib and dexamethasone OR <p><u>If light-chain (AL) amyloidosis:</u></p> <ul style="list-style-type: none"> • Prescription written by or in consultation with and hematologist/oncologist AND • Medical record documentation of a diagnosis of light-chain (AL) amyloidosis AND • Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* AND • Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone <p>*Mayo Cardiac Stage IIIB defined as NT-proBNP > 8500 ng/L</p> <p>Quantity Limit: 2.15 mL/day (15 mL per week)</p> <p>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.</p>
Libtayo	<p>Additional prior authorization criteria:</p> <p>Basal Cell Carcinoma</p> <ul style="list-style-type: none"> • Prescription written by a hematologist or oncologist AND • Medical record documentation that the patient is 18 years of age or older AND

	<ul style="list-style-type: none"> • Medical record documentation of a diagnosis of one of the following: <ul style="list-style-type: none"> ○ Documentation of a diagnosis of locally advanced BCC (laBCC) OR ○ Documentation of a diagnosis of metastatic BCC (mBCC) <p>AND</p> <ul style="list-style-type: none"> • Medical record documentation of previous treatment with a hedgehog pathway inhibitor or documentation that a hedgehog pathway inhibitor is not appropriate <p>Non-Small Cell Lung Cancer (NSCLC)</p> <ul style="list-style-type: none"> • Prescription written by a hematologist or oncologist AND • Medical record documentation that the patient is 18 years of age or older AND • Medical record documentation of non-small cell lung cancer (NSCLC) AND medical record documentation of one of the following: <ul style="list-style-type: none"> ○ Documentation of locally advanced disease AND the patient is not a candidate for surgical resection or definitive chemoradiation OR ○ Documentation of metastatic disease <p>AND</p> <ul style="list-style-type: none"> • Medical record documentation of high PD-L1 expression [Tumor Proportion Score (TPS) \geq 50%] as determined by an FDA-approved test AND • Medical record documentation of no EGFR, ALK, or ROS1 genomic tumor aberrations AND • Medical record documentation that Libtayo is being used as first-line treatment 																																
Maximum Day Supply Update	<p>Specialty medications are limited to a month supply. The medications listed in the chart below will pay up to the appropriate maximum day supply. The maximum day supply limitations are based on FDA approved dosing.</p> <table border="1" data-bbox="516 1228 1318 1911"> <thead> <tr> <th data-bbox="516 1228 1104 1297">Drug Name</th> <th data-bbox="1104 1228 1318 1297">Max Day Supply</th> </tr> </thead> <tbody> <tr> <td data-bbox="516 1297 1104 1339">Aristada 1064 mg</td> <td data-bbox="1104 1297 1318 1339">60</td> </tr> <tr> <td data-bbox="516 1339 1104 1381">Aristada 882 mg</td> <td data-bbox="1104 1339 1318 1381">42</td> </tr> <tr> <td data-bbox="516 1381 1104 1423">Avsola</td> <td data-bbox="1104 1381 1318 1423">60</td> </tr> <tr> <td data-bbox="516 1423 1104 1465">Bethkis</td> <td data-bbox="1104 1423 1318 1465">60</td> </tr> <tr> <td data-bbox="516 1465 1104 1507">Botox</td> <td data-bbox="1104 1465 1318 1507">90</td> </tr> <tr> <td data-bbox="516 1507 1104 1549">Cosentyx Prefilled Syringe</td> <td data-bbox="1104 1507 1318 1549">60</td> </tr> <tr> <td data-bbox="516 1549 1104 1591">Cosentyx Auto-injector</td> <td data-bbox="1104 1549 1318 1591">60</td> </tr> <tr> <td data-bbox="516 1591 1104 1633">Dysport</td> <td data-bbox="1104 1591 1318 1633">90</td> </tr> <tr> <td data-bbox="516 1633 1104 1675">Eligard 22.5 mg</td> <td data-bbox="1104 1633 1318 1675">90</td> </tr> <tr> <td data-bbox="516 1675 1104 1717">Eligard 30 mg</td> <td data-bbox="1104 1675 1318 1717">120</td> </tr> <tr> <td data-bbox="516 1717 1104 1759">Eligard 45 mg</td> <td data-bbox="1104 1717 1318 1759">180</td> </tr> <tr> <td data-bbox="516 1759 1104 1801">Entyvio</td> <td data-bbox="1104 1759 1318 1801">60</td> </tr> <tr> <td data-bbox="516 1801 1104 1843">Eylea</td> <td data-bbox="1104 1801 1318 1843">90</td> </tr> <tr> <td data-bbox="516 1843 1104 1885">Fasenra</td> <td data-bbox="1104 1843 1318 1885">60</td> </tr> <tr> <td data-bbox="516 1885 1104 1911">Ilaris</td> <td data-bbox="1104 1885 1318 1911">60</td> </tr> </tbody> </table>	Drug Name	Max Day Supply	Aristada 1064 mg	60	Aristada 882 mg	42	Avsola	60	Bethkis	60	Botox	90	Cosentyx Prefilled Syringe	60	Cosentyx Auto-injector	60	Dysport	90	Eligard 22.5 mg	90	Eligard 30 mg	120	Eligard 45 mg	180	Entyvio	60	Eylea	90	Fasenra	60	Ilaris	60
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	Ilumya	90	
	Iluvien	1095	
	Inflectra	60	
	Invega Trinza	90	
	Lemtrada	365	
	Lucentis	90	
	Lupaneta Pack 3 month	90	
	Lupron 22.5 mg	90	
	Lupron 30 mg	120	
	Lupron 45 mg	180	
	Lupron Depot-Ped 11.25 mg (3-month)	90	
	Lupron Depot-Ped 30 mg (3-month)	90	
	Lupron 11.25 mg	90	
	Myobloc	90	
	Ocrevus	180	
	Probuphine	180	
	Prolia	180	
	Reclast	365	
	Renflexis	60	
	Remicade	60	
	Retisert	900	
	Scenesse	60	
	Simponi Aria	60	
	Somatuline Depot	60	
	Spinraza	120	
	Stelara 45 mg	90	
	Stelara 90 mg	90	
	Supprelin LA	365	
	Sutent	42	
	Tobi	60	
	Tobramycin	60	
	Trelstar 11.25 mg	90	
	Trelstar 22.5 mg	180	
	Tremfya	60	
	Triptodur	180	
	Tysabri	60	
	Uplizna	180	
	Vyepti	90	
	Xeomin	90	
	Yutiq	1095	

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 Tuesday, July 20, 2021 at 1:00 via Microsoft Teams.