

**P&T Committee Meeting Minutes
Medicaid
September 15, 2020**

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

Dr. Bret Yarczower called the meeting to order at 1:03 p.m., Tuesday, September 15, 2020

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the July 21, 2020 minutes as written. Minutes approved unanimously. None were opposed.

QUANTITY LIMITS

The following quantity limits were presented and approved:

Drug	Dosage Form and Strength	Formulary Therapeutic Recommendation
Fintepla	Oral solution	Add QL: 12 mL per day

Rukobia	Tablet	Add QL: 2 tablets per day
Dayvigo	Tablet	Add QL: 1 tablet per day
Tivicay	10 mg Tablet	Update QL: 8 tablets daily
Tivicay PD	5 mg Tablet for Suspension	Update QL: 12 tablets daily

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

DRUG REVIEWS

Monjuvi (tafasitamab-cxix)

Review: Monjuvi is a CD19-directed cytolytic antibody indicated in combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). It is a humanized monoclonal antibody that binds the CD19 antigen expressed on both normal and malignant B-cells and causes B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). In vitro studies in DLBCL tumor cells showed that the combination of Monjuvi and lenalidomide produced and increase in ADCC activity compared to either agent alone.

The efficacy of Monjuvi in combination with lenalidomide followed by Monjuvi as monotherapy was evaluated in L-MIND, and open-label, single arm trial in 71 adult patients with relapsed or refractory DLBCL after 1 to 3 prior therapies, including a CD20-directed cytolytic antibody, who were not candidates for high-dose chemotherapy followed by autologous stem cell transplantation (ASCT). Patients received Monjuvi 12 mg/kg intravenously (dosed according to recommended schedule) in combination with lenalidomide (25 mg orally on Days 1 to 21 of each 28 day cycle) for a maximum of 12 cycles, followed by Monjuvi as monotherapy until disease progression or unacceptable toxicity.

The primary efficacy endpoint evaluating overall response rate showed 39 out of 71 patients (55%) achieved a response with 37% achieving a complete response and 18% achieving a partial response. The median duration of response was 21.7 months. At a median follow-up of 17.3 months for progression-free survival, the median progression-free survival was 12.1 months. At a median follow-up of 19.6 months for overall survival, 36% of patients had died and the median overall survival was not reached.

Monjuvi has no black box warnings, but contains warnings for infusion related reactions, myelosuppression, including neutropenia, thrombocytopenia, and anemia, serious and potentially fatal infections, and embryo-fetal toxicity. In the L-MIND clinical trial, serious adverse reactions occurred in 52% of patients. The most common adverse reactions were neutropenia, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, respiratory tract infection, and decreased appetite.

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: Monjuvi 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 of age greater than or equal to 18 years **AND**
- Medical record documentation that Monjuvi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma **AND**
- Medical record documentation that the member is not eligible for autologous stem cell transplant (ASCT) **AND**
- Medical record documentation that Monjuvi will be used in combination with Revlimid (lenalidomide)

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

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

Isturisa (osilodrostat)

Review: Isturisa is indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Isturisa is the first oral cortisol synthesis inhibitor to be approved by the Food & Drug Administration (FDA) and joins Signifor (pasireotide diaspertate) and Signifor LAR (pasireotide pamoate) for the subpopulation of Cushing's Disease (CD) for whom pituitary surgery is not an option or has not been curative. Prior to Isturisa's approval, ketoconazole, mitotane, metyrapone, and etomidate have been used off-label, though each has its own limitations. All of these agents work by acting as adrenal enzyme inhibitors at various enzyme targets that would otherwise lead to cortisol production.

Isturisa is available as 1 mg, 5 mg, and 10 mg tablets. The recommended initial dose of Isturisa is 2 mg orally twice daily, without regard to food. The maintenance dose requires patient individualization based upon cortisol levels, tolerability, and signs/symptoms of CD. The maximum recommended dose is 30 mg twice daily.

The efficacy of Isturisa was assessed in a 48-week, multicenter study (called the Core Period) that consisted of four study periods. The trial enrolled CD patients with persistent or recurrent disease despite pituitary surgery or de novo patients for whom surgery was not indicated or who had refused surgery. Overall, 96% of patients had received previous treatments for CD prior to entering the study, of which 88% had undergone surgery. Persistence or recurrence of CD was evidenced by the mean of three 24-hour UFC (mUFC) > 1.5x upper limit of normal (ULN). Period 1 (Week 1 to 12) 137 patients received a starting dose of 2 mg Isturisa orally twice daily that could be titrated up to a maximum of 30 mg twice daily at no greater than 2-week intervals to achieve a mUFC within the normal range. Period 2 (Week 13 to 24) 130 patients entered Period 2. The daily dose for patients that achieved a mUFC within the normal range in Period 1 was maintained during Period 2. Patients who did not require further dose increase, tolerated the drug, and had a mUFC ≤ ULN at Week 24 (end of Period 2) were to be considered responders and eligible to enter the Randomization Withdrawal phase (Period 3). Patients whose mUFC became elevated during Period 2 could have their dose increased further, if tolerated, up to 30 mg twice daily. These patients were considered non-responders and did not enter Period 3, but they continued open-label treatment. Period 3 (Week 26 to 34) At Week 26, 71 patients were considered responders and were randomized 1:1 to continue receiving Isturisa (n = 36) or to switch to placebo (n = 35) for 8 weeks. Period 4 (Week 26 or 34 to 48) This period included patients who were not eligible for randomization (n = 47) at Week 26, patients who were considered non-responders during Period 3 (n = 29), and patients who were considered responders during Period 3 (n = 41). Open-

label treatment with Isturisa continued in these patients until Week 48. The primary efficacy endpoint of the study was to compare the percentage of complete responders at the end of the 8-week randomized withdrawal period (Period 3) between patients randomized to continue Isturisa versus the patients switched to placebo. A complete responder for the primary endpoint was defined as a patient who had $mUFC \leq ULN$ based on central laboratory result at the end of Period 3 (Week 34), and who neither discontinued randomized treatment or the study nor had any dose increase above their Week 26 dose. At the end of Period 3, the percentage of complete responders for the primary endpoint was 86% and 29% in the Isturisa and placebo group.

The most common adverse reactions (> 20%) are adrenal insufficiency, fatigue, nausea, headache, and edema. There are no black box warnings or contraindications for Isturisa. However, there are warnings for hypocortisolism (including the potential for life-threatening adrenal insufficiency), QTc prolongation (dose-dependent) leading to cardiac arrhythmias, and elevations in adrenal hormone precursors and androgens (leading to hypokalemia, worsening hypertension, and edema). As such, patients should have hypokalemia and hypomagnesemia corrected prior to starting Isturisa along with a baseline electrocardiogram (ECG). ECG should be repeated within one week after initiation, and as clinically indicated thereafter. Temporary discontinuation of Isturisa should be considered in the case of an increase in QTc interval > 480 ms. The safety and effectiveness in pediatric patients have not been established.

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: Isturisa will be a pharmacy benefit. It is recommended that Isturisa not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Medical record documentation of age 18 years or older AND
- Prescription written by an endocrinologist AND
- Medical record documentation of a diagnosis of Cushing's disease AND
- Medical record documentation that pituitary surgery is not an option or has not been curative AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) of the following: ketoconazole, metopirone, Signifor, Signifor LAR

Authorization Duration: Initial approval will be for 12 months. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Reauthorization requires medical record documentation of improvement in urinary free cortisol levels compared to baseline.

Quantity Limit:

1 mg tablets: 8 tablets per day, 30 day supply per fill
5 mg tablets: 2 tablets per day, 30 day supply per fill
10 mg tablets: 6 tablets per day, 30 day supply per fill

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

Review: Zepzelca is an alkylating agent that offers a second-line treatment option for patients with metastatic SCLC. It binds guanine residues in the minor groove of DNA, resulting in adduct formation and bending the DNA resulting in double strand breaks that lead to cell death. It has been shown to have antiproliferative and cytotoxic activity in multiple tumor cell lines.

The efficacy of Zepzelca was investigated in one cohort of a single arm, open-label, multi-cohort trial (Study B-005) in 105 adult patients with small cell lung cancer (SCLC) who had disease progression on or after platinum-based chemotherapy. Patients in the trial received Zepzelca 3.2 mg/m² by intravenous infusion every 21 days (one cycle) and received a median of 4 cycles of Zepzelca. All patients also received antiemetic prophylaxis. The major efficacy outcome, confirmed investigator-assessed overall response rate (ORR), showed 37 (35.2%) patients had an overall response and all were partial responses. The median duration of response was 5.3 months and investigator assessed median progression-free survival was 3.5 months in the overall population. At data cutoff, median overall survival was 9.3 months in the overall population. Post-hoc analysis of the 37 patients who had an initial objective response showed that median overall survival exceeded 1 year in the overall population.

There are no black box warnings for Zepzelca. Warnings and precautions for Zepzelca include myelosuppression, hepatotoxicity and embryo-fetal toxicity. The most common adverse reactions during clinical trials were leukopenia, lymphopenia, fatigue, anemia, neutropenia, thrombocytopenia, increased ALT and AST, nausea, decreased appetite, musculoskeletal pain, constipation, diarrhea, vomiting, cough, and dyspnea.

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: Zepzelca 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 of age greater than or equal to 18 years **AND**
- Medical record documentation that Zepzelca is written by a hematologist or oncologist **AND**
- Medical record documentation of metastatic small cell lung cancer (SCLC) **AND**
- Medical record documentation of disease progression on or after platinum-based chemotherapy

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

FAST FACTS

Reblozyl (luspatercept-aamt)

Updated Indication: Reblozyl is indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with

myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)..

Recommendation: No changes are recommended to the formulary placement or authorization duration of Reblozyl. It is recommended to add the following criteria to incorporate the new indication.

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with one of the following:
 - Documentation of greater than or equal to 15% ring sideroblasts **OR**
 - Documentation of greater than or equal to 5% ring sideroblasts **AND** an SF3B1 mutation
- AND**
- Medical record documentation of very low to intermediate risk **AND**
- Medical record documentation that patient requires 2 or more red blood cell units over 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to an erythropoiesis stimulating agent **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

Notes:

*In clinical trials for β -thalassemia, regular red blood cell transfusions was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: For β -thalassemia: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks

For MDS-RS and MDS/MPN-RS-T: 1mg/kg every 3 weeks increasing to a dose of 1.33 mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen, then increasing up to a maximum of 1.75mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.75mg/kg every 3 weeks

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months**. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months**, requiring medical record documentation of:

- a decrease in red blood cell (RBC) transfusion burden **AND**
- Reblozyl is being dosed consistent with FDA-approved labeling**

Ongoing subsequent approvals will be for a **duration of six (6) months**, requiring medical record documentation of:

- A sustained reduction of red blood cell (RBC) transfusion burden **AND**
- Reblozyl is being dosed consistent with FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

Outcome: No comments or questions. 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.

Corlanor (ivabradine)

Updated Indication: Corlanor is now indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate

Recommendations: No changes are recommended to the formulary placement of Corlanor. The following changes are recommended:

- Must be prescribed by a cardiologist **AND**
 - Medical record documentation of being in sinus rhythm with resting heart rate greater than or equal to the lower limit of the normal range based on age* **AND**
 - Medical record documentation of one of the following:
 - Medical record documentation of age greater than or equal to 18 years **AND**
 - Medical record documentation of stable, symptomatic heart failure with a left ventricular ejection fraction less than or equal to 35% **AND**
 - Medical record documentation of hospitalization for worsening heart failure within the previous 12 months.
 - OR**
 - Medical record documentation of age greater than or equal to 6 months and less than 18 years **AND**
 - Medical record documentation of stable, symptomatic heart failure due to dilated cardiomyopathy **AND**
 - Medical record documentation of class II to IV heart failure according to New York Heart Association [NYHA] functional class or Ross classification **AND**
 - Medical record documentation of a left ventricular ejection fraction less than or equal to 45%.
- AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to the maximum tolerated dose of 2 formulary beta-blockers one of which must be carvedilol **AND**
 - If the request is for Corlanor Solution: Medical record documentation of one of the following:
 - Medical record documentation of patient weight less than 40 kg **OR**
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Corlanor tablets **OR**
 - Medical record documentation that patient has dysphagia or is unable to swallow tablets

QUANTITY LIMIT: Corlanor tablets: 2 tablets per day
Corlanor solution: 10 mL per day

Outcome: No comments or questions. 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.

Sivextro (tedizolid)

Updated Indication: Sivextro is now indicated for the treatment of adults and pediatric patients ≥ 12 years of age with acute bacterial skin and skin structure infections caused by susceptible isolates of the following gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant and methicillin-susceptible isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.

Recommendations: No changes are recommended to the current formulary placement of Sivextro. It is recommended to update the age in the policy to greater than or equal to 12 years.

Outcome: No comments or questions. 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.

UPDATE

The Geisinger Drug Utilization Review MCO Survey and a DUR Update were presented to the Committee. There were no comments or questions.

August Electronic Vote

Due to the volume of full drug reviews and fast facts that must reviewed by the P&T Committee an additional electronic vote was held from August 19, 2020 to August 27, 2020. Responses were received from 21 members (out of 35) and all voted to approve.

The following was approved for GHP Family:

Drug	Dosage Form and Strength	Formulary Therapeutic Recommendation
Nexletol	Tablet	Add QL: 1 tablet daily
Nexlizet	Tablet	Add QL: 1 tablet daily
Dupixent (for atopic dermatitis)	200 mg Injection every other week	Add QL: <u>Initial (one-time authorization):</u> 4.56 mL per 42 days, Max quantity supply: 4.56 mL Min day supply: 42, Max day supply: 42 <u>Ongoing:</u> 2.28 mL per 28 days, Max quantity supply: 2.28 mL, Min day supply: 28, Max day supply: 28
Dupixent (for atopic dermatitis)	300 mg Injection every four weeks	Add QL: <u>Initial (one-time authorization):</u> 8 mL per 42 days, Max quantity supply: 8 mL Min day supply: 42, Max day supply: 42 <u>Ongoing:</u> 4 mL per 28 days, Max quantity supply: 4 mL, Min day supply: 28, Max day supply: 28
Tivicay	10 mg Tablet	Add QL: 4 tablets daily

Tivicay PD	5 mg Tablet for Suspension	Add QL: 6 tablets daily
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Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Meeting adjourned at 4:47 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, November 17, 2020 at 1:00 HCN3A & 3B Conference room

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