

**P&T Committee Meeting Minutes
Medicaid
March 16, 2021**

Present (via Skype): Bret Yarczower, MD, MBA – Chair Megan Ammon, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Kristen Bender, 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. Derek Hunt, Pharm.D. Phillip Krebs, R.EEG T Perry Meadows, MD Jamie Miller, RPh Kimberly Reichard, Pharm.D. Melissa Renn, Pharm.D. Angela Scarantino Kristen Scheib, Pharm.D. Leslie Shumlas, Pharm.D. Aubrielle Smith, Pharm.D. Michael Spishock, RPh Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Kevin Szczecina, RPh Adam Root (non-voting participant) Sierra Strouse, Pharmacy Student	Absent: Holly Bones, Pharm.D. Dean Christian, MD Alyssa Cilia, RPh Michael Evans, RPh Rajneel Farley, Pharm.D. Jonas Pearson, RPh William Seavey, Pharm.D. Michael Shepherd, MD Richard Silbert, MD 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, March 16, 2021

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the January 19, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Lampit (nifurtimox)

Review: Lampit (nifurtimox) is a nitrofurant antiprotozoal, indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis), caused by *Trypanosoma cruzi*. Both nifurtimox and benznidazole have been available for treatment of Chagas disease caused by *T. cruzi* for several decades but have only recently been FDA approved for treatment in the U.S.

The efficacy and safety of Lampit were established in one prospective, randomized, double-blind trial in pediatric patients (birth to < 18 years) weighing at least 2.5 kg with a confirmed Chagas disease diagnosis. Patients with Chagas-disease related cardiac or gastrointestinal symptoms were excluded. Patients were randomized 2:1 to a 60-day (n=219) or 30-day (n=111) Lampit treatment regimen based on weight and followed for one year. Serological response was defined as $\geq 20\%$ decrease in optical density measured by lysate and recombinant ELISA in pediatric patients ≥ 8 months to < 18 years or seroconversion to negative (negative IgG concentration) in all patients at 10-year post treatment follow-up. Approximately one-third (70-76/219) of patients receiving the FDA approved 60-day treatment regimen of Lampit had a serological response at the one-year post-treatment follow up. Of the 70 patients showing serological response, 59-65 patients had at least a 20% decrease in optical density while 11 patients had a seroconversion to negative (negative IgG concentration).

There are no black box warnings for Lampit. There are warnings for genotoxicity and carcinogenicity, embryo-fetal toxicity, worsening neurological and psychiatric conditions, decreased appetite and weight loss, and porphyria. During clinical trials, the most frequently reported adverse reactions in patients treated with Lampit (60 days) were vomiting, abdominal pain, headache, decreased appetite, nausea, pyrexia, and rash.

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

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

Outcome: Lampit is a pharmacy benefit and should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Prescribed by or in consultation with an infectious disease specialist **AND**
- Medical record documentation of age less than or equal to 18 years **AND**
- Medical record documentation of weight greater than or equal to 2.5 kg **AND**
- Medical record documentation that Lampit is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
 - o Detection of circulating *T. cruzi* trypomastigotes on microscopy **OR**
 - o Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
 - o Two positive diagnostic serologic tests using different techniques (ex. enzyme-linked immunoassay (ELISA), indirect fluorescent antibody (IFA)) and antigens (ex. whole-parasite lysate, recombinant antigens) showing IgG antibodies to *T. cruzi*

Authorization Duration: 60 days, RX count 2

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

Xywav (Calcium/magnesium/potassium/sodium oxybates)

Review: Xywav is a central nervous system depressant indicated for the treatment of cataplexy and excessive daytime sleepiness in patients 7 year of age or older. Xywav is a combination of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate. Xywav joins Xyrem (sodium oxybate) as a derivative of gamma-hydroxybutyrate. Xywav offers a unique formulation of cations to provide an alternative that contains 92% less

sodium than Xyrem. Xywav is available as a 500 mg/mL oral solution. The recommended initial adult dosage is 4.5 grams per night, divided into two doses: 2.25 grams at bedtime and 2.25 grams taken 2.5 to 4 hours later. The dosage should be increased by up to 1.5 grams per night per week, to the recommended dosage range of 6 to 9 grams per night. The max dose is 9 grams per night. Pediatric dosing is based on the patient's weight per the packet insert.

Approval of Xywav is based on a double-blind, placebo-controlled, randomized-withdrawal study. The clinical study consisted of a 12-week open label optimized treatment and titration period, followed by a 2-week stable-dose period, and finally a 2-week week double-blind randomized withdrawal period. During the randomized withdrawal period, candidates were randomized 1:1 to continue treatment with Xywav or placebo. The primary efficacy outcome assessed was the change in the weekly number of cataplexy attacks from during the 2-week stable-dose period to the 2 weeks of the double-blind randomized withdrawal period. The key secondary efficacy outcome measured was the change in the Epworth Sleepiness Scale score measured by the reduction of excessive daytime sleepiness from the end of the stable-dose period to the end of the double-blind randomized-withdrawal period. There was statically significant worsening in the weekly number of cataplexy attacks in participants treated with the placebo (2.4) when compared to patients who were treated with Xywav. Patients treated with the placebo also had a statistically significant worsening of excessive daytime sleepiness (2.0) when compared to patients treated with Xywav.

Xywav has black box warnings for central nervous system depression and abuse and misuse potential. It is contraindicated in patients with succinic semialdehyde dehydrogenase deficiency and in combination with sedative hypnotics or alcohol. The most common adverse reaction leading to discontinuation in the clinical study was nausea (1.5%). During the clinical study, the most common adverse reactions were headache, nausea, dizziness, decreased appetite, parasomnia, diarrhea, hyperhidrosis, anxiety, and vomiting (incidence $\geq 5\%$).

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

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

Outcome: Xywav is a pharmacy benefit and should not be added to the GHP Family formulary. The following prior authorization criteria should apply:

- Diagnosis of an FDA approved indication **AND**
- Medical record documentation that Xywav is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of one of the following:
 - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem **OR**
 - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment

AND

- For cataplexy with narcolepsy, medical record documentation of failure on, intolerance to, or contraindication to one of the following: venlafaxine XR or fluoxetine **OR**
- For excessive daytime sleepiness with narcolepsy:

- For patients 18 years and older, medical record documentation of failure on, intolerance to, or contraindication to one of the following: modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **OR**
- For patient 7-17 years, medical record documentation of failure on, intolerance to methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

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

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

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

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

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

FAST FACTS

Kalydeco (ivacaftor)

Updated Indication: Kalydeco is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.

Recommendation: Update the age requirement in the policy from 6 months to 4 months.

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.

Fetroja (cefiderocol)

Updated Indication: Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

Recommendation: Add the following criterion to the policy:

- Medical record documentation of a diagnosis of hospital-acquired bacterial pneumonia (HABP) **OR** Ventilator-associated bacterial pneumonia (VABP), caused by susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Serratia marcescens*, or *Enterobacter cloacae* complex

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.

Fetroja (cefiderocol)

Updated Indication: Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

Recommendation: Add the following criterion to the policy:

- Medical record documentation of a diagnosis of hospital-acquired bacterial pneumonia (HABP) **OR** Ventilator-associated bacterial pneumonia (VABP), caused by susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Serratia marcescens*, or *Enterobacter cloacae* complex

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: Keytruda is a highly selective anti-PD-1 humanized monoclonal antibody which is now indicated as a first-line treatment for patients with unresectable or metastatic MSI-H or dMMR colorectal cancer.

Recommendation: Add the following criterion to the policy:

- Medical record documentation Keytruda will be used as first-line treatment

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.

Enhertu (fam-trastuzumab deruxtecan-nxki)

Updated Indication: Enhertu is now indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.

Recommendation: Add the following criteria to the policy:

Locally Advanced or Metastatic Gastric Cancer

- Medical record documentation that Enhertu is written 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 locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**
- Medical record documentation of one or more prior trastuzumab-based therapies

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.

Eraxis (anidulafungin)

Updated Indication: Candidemia and other forms of Candida infections (intra-abdominal abscess and peritonitis) in adults *and pediatric patients (1 month of age and older)*

Recommendation: Update the age restriction in the policy to be at least 1 month of age.

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.

Opdivo (nivolumab)

Updated Indication: Opdivo is now indicated in combination with Cabometyx (cabozantinib) in patients with advanced renal cell carcinoma, as first line treatment. Opdivo has also been updated to remove the indication for treatment of patients with small cell lung cancer who have progressed after platinum-based chemotherapy and at least 1 other line of therapy.

Recommendation:

- Remove the criteria for SCLC from the policy
- Update the Renal Cell Carcinoma criteria as follows (addition in italics):

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age

AND

- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- Medical record documentation of a therapeutic failure on or intolerance to prior anti-angiogenic therapy, including, but not limited to, Sutent (sunitinib), Votrient (pazopanib), Inlyta (axitinib), Nexavar (sorafenib), Avastin (bevacizumab), Afinitor (everolimus), or Torisel (temsirolimus).

OR

- Medical record documentation of previously untreated advanced renal cell carcinoma **AND** one of the following:
 - *Medical record documentation that Opdivo will be given in combination with cabozantinib (Cabometyx)*

OR

- o Medical record documentation that the patient is at intermediate to poor risk (defined as having 1 or more 6 prognostic risk factors as per the IMDC criteria*) **AND** Medical record documentation that Opdivo will be given in combination with ipilimumab (Yervoy)

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.

February 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 February 23, 2021 to February 26, 2021. Responses were received from 20 members (out of 35) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
1537.0F Enspryng 1536.0F Evryssi 1056.0F Sylatron 1073.0F Sucraid 1267.0F Grastek 1269.0F Ragwitek 1268.0F Oralair 1239.0F Mirvaso 1360.0F Xuriden 1337.0F Keveyis 1433.0F Odactra 1416.0F Bevyexxa 1426.0F Benznidazole 1410.0F Norpace CR 1460.0F Jynarque 1499.0F Osphena 1497.0F Cablivi 1493.0F Aemcola 1488.0F Tegsedi 1489.0F Firdapse 1481.0F Qbrexza 1001.0F Linezolid 1522.0F Xenleta 1409.0F Benlysta 1171.0F Picato 1524.0F Pretomanid 1527.0F Oxervate 1528.0F Palforzia 1531.0F Isturisa 1532.0F Inqovi	“Medical record documentation that (drug) is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature” will be added to the noted policies during DHS’ annual policy review.

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Danyelza	<p>Danyelza is a medical benefit and should not be added to the GHP Family formulary. The following prior authorization criteria will apply:</p> <ul style="list-style-type: none"> • Medical record documentation of age greater than or equal to 1 year AND • Medical record documentation of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy AND • Medical record documentation that Danyelza will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)

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

Meeting adjourned at 3:14 pm

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on Tuesday, May 18, 2021 at 1:00 via Microsoft Teams.