P&T Committee Meeting Minutes
Commercial, Marketplace, GHP Kids
Mach 16, 2021

Present (via skype):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Holly Bones, Pharm.D.
Megan Ammon, Pharm.D.	Dean Christian, MD
Kim Castelnovo	Alyssa Cilia, RPh
Kimberly Clark, Pharm.D.	Michael Evans, RPh
Kristen Bender, Pharm.D.	Rajneel Farley, Pharm.D.
Kelly Faust, Pharm.D.	Jonas Pearson, RPh
Tricia Heitzman, Pharm.D.	William Seavey, Pharm.D.
Nichole Hossler, MD	Michael Shepherd, MD
Jason Howay, Pharm.D.	Richard Silbert, MD
Keith Hunsicker, Pharm.D.	Robert Strony, MD MBA
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	

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:
Dr. Bret Yarczower asked for a motion or approval to accept the January 18, 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

ORGOVYX (relugolix)

Review: Orgovyx is a gonadotropin-releasing hormone (GnRH) receptor antagonist which binds GnRH receptors and reduces the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) in turn reducing testosterone which plays a role in prostate cancer cell growth. It offers the only oral treatment option for patients with advanced prostate cancer who require androgen deprivation therapy.

The efficacy of Orgovyx was evaluated in the HERO trial, a randomized, open-label trial in men with advanced prostate cancer requiring at least 1 year of androgen deprivation therapy. Patients were randomized 2:1 to received treatment with Orgovyx (360 mg loading dose, then 120 mg once daily) (n=622) or leuprolide acetate (22.5 mg injection every 3 months) (n=308).

The primary endpoint showed noninferiority of Orgovyx compared to leuprolide with sustained castration (cumulative probability of testosterone suppression [< 50 ng/dL] by day 29 through 48 weeks of treatment) achieved in 96.7% of patients receiving Orgovyx compared to 88.8% of patients treated with leuprolide. Key secondary endpoints measuring castration rates on Day 4 and 15 and castration rates with testosterone < 20 ng/dL at Day 15 showed superiority of Orgovyx over leuprolide. PSA levels were monitored throughout the clinical trials and were lowered on average by 92% after 3 months and remained suppressed throughout the 18 weeks of treatment. A substudy in 137 patients showed that patients who received no subsequent androgen deprivation therapy had testosterone levels which returned to above the lower limit of the normal range or baseline at 90 days after the discontinuation of Orgovyx.

There are no black box warnings for Orgovyx, but it does include warnings and precautions for QT/QTc interval prolongation and embryo-fetal toxicity. The most commonly reported adverse reactions (≥ 10 %) and laboratory abnormalities (≥ 15%) were hot flush, musculoskeletal pain, fatigue, constipation, diarrhea, decreased hemoglobin, and increased glucose, triglycerides, alanine aminotransferase (ALT) and aspartate aminotransferase (AST).

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

Clinical Discussion:
Is testosterone flair at initiation of treatment a clinically significant issue? It typically returns to baseline after approximately 4 weeks and is not clinically significant in most cases.

Should we add urologist to the approved prescribers? Will update to include urologist.

No additional comments or questions. The committee unanimously voted to accept the recommendations as amended. None were opposed.

Financial Discussion: Is there a reason we wouldn't want to put this behind other less expensive options given the clinical equivalence? Could consider, but this is equally as effective and provides the first oral option. May also see less savings due to paying for administration fees, etc. of alternatives. Consider evaluation for contracting opportunities.

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

Outcome: Orgovyx is a pharmacy benefit and will be added to the oral oncology brand non-preferred tier ($0 copay) of the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization will apply:

- Medical record documentation that Orgovyx is prescribed by a hematologist, oncologist or urologist **AND**
- Medical record documentation of a diagnosis of advanced prostate cancer

QUANTITY LIMIT: 64 tablets per 30 days

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

LAMPIT (nifurtimox)

Review: Lampit (nifurtimox) is a nitrofuran 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 ≥ 20% decrease in optical density measured by lysate and recombinant ELISA in pediatric patients ≥8 months to < 18 years or seroconversion to negative (negatived 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.

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

Clinical Discussion: When you look at patient selection for trials, did they specify which phase of the disease they were in? There was no separation which may have contributed to the lower efficacy rates. Patients with advanced disease (CV or GI) were excluded, but there was no other differentiation between acute or chronic phase.

No additional 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: Lampit is a pharmacy benefit and will not be added to the Commercial, Marketplace, or GHP Kids formularies. The following prior authorization criteria will 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 of a diagnosis of Chagas disease confirmed by one (1) of the following diagnostic tests:
    - Detection of circulating *T. cruzi* trypomastigotes on microscopy **OR**
    - Detection of *T. cruzi* DNA by polymerase chain reaction assay **OR**
    - 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*

QUANTITY LIMIT:

- 30 mg tablets: 4.5 tablets per day, 30 day-supply per fill
- 120 mg tablets: 7.5 tablets per day, 30-day supply per fill

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 with narcolepsy. 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%).

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: Xywav is a pharmacy benefit and will be added to the specialty tier or the brand preferred tier for members with a three-tier benefit on the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization will apply:

- Medical record documentation of use for a Food and Drug Administration (FDA) approved indication **AND**
- Medical record documentation of therapeutic failure on modafinil **AND** methylphenidate immediate release or amphetamine/dextroamphetamine immediate release **AND**
- 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

QUANTITY LIMIT: 18 mL per day, 30 day supply per fill

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.

CABENUVA (cabotegravir/rilpivirine) & VOCABRIA (cabotegravir)

Review: Cabenuva, a 2-drug co-packaged product containing injectable suspensions of both cabotegravir and rilpivirine, is indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Cabenuva may be preferred by some patients due to the once monthly administration and it may offer an alternative for patients with trouble adhering to the once daily oral treatment options.

Vocabria, an oral formulation of cabotegravir, is intended for short-term use in combination with oral rilpivirine as an oral-lead in to assess the tolerability of cabotegravir prior to the administration of Cabenuva or for patients who will miss planned doses of Cabenuva (up to 2 consecutive months).

The efficacy of Cabenuva and oral lead-in with Vocabria have been evaluated in the FLAIR and ATLAS trials, two Phase 3, randomized, active-controlled, parallel-arm, open-label, non-inferiority trials. The FLAIR trial included HIV-1 infected patients who were initiated on HIV-1 treatment with 20 weeks of a dolutegravir INSTI-containing regimen while the ATLAS trial included HIV-1 infected patients who were virologically suppressed prior to study entry. In both trials, virologically suppressed patients were randomized 1:1 to receive a treatment regimen of cabotegravir + rilpivirine (oral-lead in for at least 4 weeks then monthly injections for an additional 44 weeks) or maintain their current regimen. Adjusted for study and randomization stratification factors, treatment difference of HIV-1 RNA greater than or equal to 50 copies/mL for the pooled data from both trials was 0.2% with 95% CI (-1.4%, 1.7%). Subjects in both trials were virologically suppressed from Day 1 (FLAIR) or study entry (ATLAS), and no clinically relevant change from baseline in CD4+ cell counts was observed. Assessments in the FLAIR trial, showed that a majority of patients treated with Cabenuva preferred the long-acting treatment over the previous oral therapy.

During clinical trials, the most frequent adverse reactions were injection site reactions which were mostly mild or moderate and lasted a median duration of 3 days following administration. The most commonly reported reactions were localized pain and discomfort, nodules, induration, swelling, erythema, pruritis, bruising, warmth, and hematoma. The most common adverse reactions during the oral lead-in period with Vocabria and Edurant were headache, nausea, abnormal dreams, anxiety, and insomnia (≤ 1% for all adverse reactions).

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: Cabenuva is limited in distribution. Recommend adding to the brand preferred tier in the event a member must receive from a specialty pharmacy. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

Outcome: Cabenuva is a medical benefit and should not be added to the Commercial, Marketplace, or GHP Kids pharmacy formularies. No prior authorization will be required.

Vocabria is a pharmacy benefit and will be added to the brand preferred tier of the Commercial, Marketplace, and GHP Kids pharmacy formularies. No prior authorization will be required.

The following quantity limits will apply to Cabenuva and Vocabria:

QUANTITY LIMIT:

- Cabenuva 600 mg/900 mg kit: 1 kit per 180 days
- Cabenuva 400 mg/600 mg kit: 1 kit per 28 days
- Vocabria: 1 tablet per day

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

FAST FACTS

ICLUSIG (ponatinib)

Updated Indication: Iclusig is now indicated for adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.

This change does not apply to accelerated phase (AP) or blast phase (BP) CML or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and these remain indicated only in patients for whom no other kinase inhibitors are indicated.

Current formulary status: OralOnc Brand Non-preferred tier, requiring prior authorization

Recommendations: No changes are needed to the authorization duration of Iclusig. The new strengths of Iclusig (10 mg and 30 mg) will be added to match the placement of the other strengths and the following quantity limits will apply. It is recommended that the following changes be made to Commercial Policy 278.0 to incorporate the new indication.

When Iclusig was initially approved in 2012, indications for accelerated phase, or blast phase chronic myeloid leukemia (CML) and for Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) included patients who were resistant and intolerant to prior tyrosine kinase inhibitor therapy. In 2013, because of Iclusig toxicity and black box warnings for arterial occlusive events, venous thromboembolic events, heart failure, and hepatoxicity and the implementation of a risk evaluation and mitigation strategy (REMS), this indication was updated to only include patients for whom no other kinase inhibitors are indicated. Benjamin Andrick, a clinical pharmacist with the Oncology Department at Geisinger Heath System, agreed that Iclusig would only be used in a patient with the T315I mutation or if they have resistance to all other TKIs. This is also reflected in the current NCCN guidelines. It is recommended that Commercial policy 278.0 be updated in accordance with these recommendations.

- Medical record documentation that Iclusig is prescribed by a hematologist or oncologist **AND**
- ~~Medical record documentation of adult patients with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML)~~ **~~OR~~** ~~Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)~~ **~~AND~~**
- ~~Medical record documentation of resistance or intolerance to one prior tyrosine kinase inhibitor therapy~~ **~~OR~~** ~~medical record documentation of T315I mutation~~
- 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 accelerated phase or blast phase chronic myeloid leukemia (CML) **OR** Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND**
    - Medical record documentation of therapeutic failure, contraindication, or intolerance to all other indicated tyrosine kinase inhibitors, including but not limited to bosutinib, dasatinib, imatinib, and nilotinib

  OR
    - Medical record documentation of T315I mutation positive chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)

  OR
    - Medical record documentation of chronic phase (CP) chronic myeloid leukemia (CML) **AND**
    - Medical record documentation of resistance or intolerance to at least two prior kinase inhibitors

QUANTITY LIMIT:

- 10 mg tablet, 15 mg tablet, 30 mg tablet, 45 mg tablet: 1 tablet 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.

TAGRISSO (osimertinib)

Updated Indication: Tagrisso is now indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Previously Tagrisso was indicated as first line treatment for metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations and as treatment for metastatic NSCLC with EGFR T790M positive mutations.

Current formulary status: OralOnc Brand Non-preferred tier, requiring prior authorization

Recommendations: No changes are recommended to the formulary placement of Tagrisso at this time. No changes to the existing quantity limit of 1 tablet per day are recommended. It is recommended that the following changes are made to Policy 405.0 – Tagrisso to account for the updated indication:

Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of an epidermal growth factor receptor (EGFR) exon 19 deletion, EGFR exon 21L858R mutation, or EGFR T790 mutation **AND**
- Medical record documentation of one of the following:
    - If member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation: Medical record documentation that Tagrisso is being used as first-line treatment **OR**
    - If member has epidermal growth factor receptor (EGFR) T790 mutation positive disease: Medical record documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib)

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.

Adjuvant Treatment of Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Tagrisso is being used as adjuvant treatment following complete tumor resection **AND**

- Medical record documentation that tumors have an epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation

AUTHORIZATION DURATION: Initial approval will be for **12 months**. **Up to two (2)** subsequent approvals will each be for an additional 12 months or less if the reviewing provider feels it is medically appropriate to equal **a total treatment duration of 3 years** 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.

Authorization of Tagrisso for adjuvant treatment of Non-Small Cell Lung Cancer (NSCLC) will not exceed the FDA-approved treatment duration of 3 years (36 months). For requests exceeding the above limit, documentation will be required of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

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.

XPOVIO (selinexor)

Updated Indication: Xpovio is now indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Previously, Xpovio was indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who had received at least four prior therapies. Xpovio is also indicated for the treatment of relapse or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified.

Current formulary status: OralOnc Brand Non-preferred tier, requiring prior authorization

Recommendations: There are no changes recommended to the current formulary placement, quantity limits or authorization duration. The following changes are recommended to Commercial Policy 584.0 to incorporate the new indication:

Multiple Myeloma

- Medical record documentation that Xpovio 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 that Xpovio will be used in combination with dexamethasone **AND** Medical record documentation of a diagnosis of relapsed or refractory multiple myeloma and the member has received at least four prior complete regimens which include at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody

    OR

    - Medical record documentation that Xpovio will be used in combination with bortezomib **AND** dexamethasone **AND** Medical record documentation of a diagnosis of multiple myeloma and the member has received at least one prior therapy

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.

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.

If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

Previously Kalydeco was indicated for patients 6 months and older.

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

Recommendations: There are no changes to the current formulary placement or quantity limits. It is recommended to make the following changes to Commercial Policy 251.0 to incorporate the updated indication:

- Medical record documentation of age greater than or equal to ~~6 months~~ 4 months **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.

FETROJA (cefiderocol)

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

Current formulary status: Medical benefit - specialty tier or Brand non-preferred for members with a three tier benefit when processed at a specialty pharmacy, prior authorization required, QL: 8 vials per day,
AUTHORIZATION DURATION: Approval will be given for a duration of 14 days

Recommendations: No changes are recommended to the formulary placement, authorization duration, or quantity limits. The following prior authorization criteria should be added to Medical Benefit Policy 219.0 to incorporate the new indication:

- Prescription is written by or in consultation with Infectious Disease AND

- Medical record documentation that the member is greater than or equal to 18 years of age AND
- Medical record documentation of one of the following:
    - Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, or Enterobacter cloacae complex* ~~AND~~ **OR**
    - **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***

AND

- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments OR a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity.

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.

NUCALA (mepolizumab)

Updated Indication: Nucala is now indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.

Current formulary status: Nucala Vial: Medical Benefit requring a prior authorization
Nucala prefilled syringe or autoinjector: Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit, requiring a prior authorization

Recommendations: No changes are recommended to the formulary placement for Nucala. It is recommended that the following prior authorization criteria and quantity limits be added to Medical Benefit Policy 141. and Commercial Policy 592.0 to incorporate the new indication:

Hypereosinophilic syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy.

*Note: Non-hematologic secondary causes can include but are not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy

Medical Benefit Policy 141.0 Nucala vials
Quantity Limit: 1 vial (100mg) per 28 days (for eosinophilic asthma), 3 vials (300mg) per 28 days (for EGPA or HES)

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.

XELJANZ/XELJANZ ORAL SOLUTION (tofacitinib)

Updated Indication: Xeljanz/ Xeljanz oral solution is now indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.

Limitations of Use: The use of Xeljanz/ Xeljanz Oral solution in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Note: Xeljanz/Xeljanz XR is indicated for adult patients with Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC).

Current formulary status: Xeljanz/Xeljanz XR is a pharmacy benefit available at the Specialty tier or the Brand Non-Preferred tier for mememberswith a three tier benefit. Xeljanz oral solution is not on formulary.

Recommendations: There are no changes recommended to the formulary status for Xeljanz/Xeljanz XR. However, it is recommended to add Xeljanz oral solution to the pharmacy benefit at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit. It will be reviewed under policy 273.0. It is also recommended to add a section to the current policy to reflect the new indication:
Polyarticular Course Juvenile Idiopathic Arthritis

- Medical record documentation of a diagnosis of active polyarticular course juvenile idiopathic arthritis AND
- Medical record documentation of age greater than or equal to 2 years AND
- Prescription written by a rheumatologist AND
- Medical record documentation of an inadequate response to a minimum 3 month trial of Humira* AND
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent AND
- Medical record documentation that Xeljanz or Xeljanz oral solution is being dosed consistent with Food and Drug Administration (FDA)-approved labeling

NOTE: Xeljanz XR is not indicated for the treatment of pcJIA. The maximum dose for pcJIA is 5 mg (tablet or solution) twice daily. Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment.

QUANTITY LIMIT: There will be no changes to the current quantity limits. However, it is recommended to add the following quantity limit: **Xeljanz oral solution: 10 mL per day, 30 day supply per fill.**

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of polyarticular course juvenile idiopathic arthritis is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of polyarticular course juvenile idiopathic arthritis while on Xeljanz or Xeljanz oral solution.

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.

SIMPONI ARIA (golimumba)

Updated Indication: Simponi Aria is now indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older and for active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older.

Previously, Simponi Aria was indicated for the treatment of adult patients with moderately to severely active Rheumatoid Arthritis (RA), active Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS).

Current formulary status: Medical benefit requiring a prior authorization

Recommendations: There are no changes recommended for the formulary placement or authorization duration of Simponi Aria. The following changes are recommended to incorporate the new indications:

Rheumatoid Arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation that Simponi Aria will be given in combination with methotrexate **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of Humira*, Rinvoq*, **OR** Xeljanz* therapy

Psoriatic Arthritis

- Requesting provider must be a rheumatologist or dermatologist **AND**
- Medical record documentation of age ≥~~18 years~~ 2 years **AND**

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis, which must include the following:
    - Documentation of active psoriatic lesions **OR** documentation of a history of psoriasis

AND

- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- For patients 18 years of age and older, medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** adalimumab (Humira*) therapy

Ankylosing Spondylitis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age ≥18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation that Simponi Aria is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of secukinumab (Cosentyx*) **AND** adalimumab (Humira*) therapy.

Polyarticular juvenile idiopathic arthritis

- Requesting provider must be a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a diagnosis of active polyarticular juvenile idiopathic arthritis **AND**
- Medical record documentation that Actemra is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, contraindication to or intolerance to a minimum 4 month trial of Humira*

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of disease at six (6) months of Simponi Aria therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of disease while on Simponi Aria therapy.

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.

WAKIX (pitolisant)

Updated Indication: Wakix is now indicated for the treatment of cataplexy in adult patients with narcolepsy.

Previously it was indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

Current formulary status: Non-formulary

Recommendations: There are no changes to the formulary status, authorization duration, or current quantity limits. It is recommended that the following changes be made to Commercial Policy 612.0 to incorporate the new indication:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of narcolepsy with cataplexy **OR**
- Medical record documentation of a diagnosis of excessive daytime sleepiness associated with narcolepsy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil* or armodafinil **AND** 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 symptoms of excessive daytime sleepiness **OR**
- Medical record documentation of reduction in frequency of cataplexy attacks

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

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

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: 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.

Previously Keytruda was only approved for the treatment of adult or pediatric patients with unresectable or metastatic MSI-H or dMMR colorectal cancer that had progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.

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

Recommendations: 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:

Microsatellite Instability-High Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors **OR** colorectal cancer **AND**
- For solid tumors:
    - Medical record documentation of progression following prior treatment(s) AND
    - Medical record documentation of no satisfactory alternative treatment options
- For colorectal cancer:
    - Medical record documentation Keytruda will be used as first-line treatment **OR**
    - Medical record documentation of progression following treatment with fluoropyrimidine, oxaliplatin, and irinotecan

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 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: Do we need to specify that Keytruda is being used as monotherapy within the criteria? Decision was made to leave prior authorization criteria to match FDA approved language. Recommendation to evaluate entire policy to ensure consistency with the way language is applied.

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.

XALKORI (crizotinib)

Updated Indication: Xalkori is now indicated in pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK)-positive. The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.

Previously Xalkori was indicated in patients with metastatic NSCLC whose tumors were ALK or ROS-1 positive.

Current formulary status: OralOnc Brand Non-preferred tier, requiring prior authorization

Recommendations: There are no changes recommended for the formulary placement and authorization duration of Xalkori. It is recommended to add the following criteria and update the quantity limits as follows to incorporate the new indication:

Anaplastic Large Cell Lymphoma (ALCL)

- Medical record documentation that Xalkori is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 1 year of age **AND**
- Medical record documentation of a diagnosis of relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is anaplastic lymphoma kinase (ALK) positive **AND**
- Medical record documentation of at least one prior systemic treatment

QUANTITY LIMIT: 4 capsules 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.

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.

Previously it was indicated for unresectable or metastatic HER2-positive breast cancer.

Current formulary status: Medical benefit or Specialty tier/Brand Non-Preferred tier for members with a three tier benefit when processed at a specialty pharmacy; requiring a prior authorization
Recommendations: There are no changes recommended to the current formulary placement or the authorization duration of Enhertu. It is recommended that the following prior authorization criteria be added to Medical Benefit Policy 280.0 to incorporate the new indication:

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

QUANTITY LIMIT: 4 capsules 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.

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)***

Current formulary status: Medical benefit requiring prior authorization

Recommendations: No changes are recommended to the formulary placement, authorization duration, or quantity limits. The following prior authorization criteria should be added to Medical Benefit Policy 53.0 to incorporate the new patient population:

- The insured individual is at least ~~17 years of age~~ ***1 month of age*** and non-neutropenic: **AND**
- There is physician provided documentation of a diagnosis of candidemia or other *Candida* infection as determined by an infectious disease specialist; **OR**
- There is physician provided documentation of a diagnosis of esophageal candidiasis with failure on, intolerance to, or contraindication to fluconazole therapy as determined by an infectious disease specialist.

Discussion: No comments or questions.

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

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

OPDIVO (nivolumab)

Updated Indication: Opdivo is now indicated in combination with Cabometyx (cabozantinib) in patients with advanced renal cell carcinoma, as first line treatment.

Previously, Opdivo had indications in patients with advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy and in patients with intermediate or poor risk advanced renal cell carcinoma, as first-line treatment in combination with ipilimumab (Yervoy).

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. It was initially approved under an accelerated approval based on response rates and duration of response. This indication was voluntarily withdrawn after confirmatory trial, CHECKMATE-451 and CHECKMATE-331, failed to meet primary endpoints of overall survival.

Current formulary status: Medical benefit requiring prior authorization

Recommendations: There are no changes recommended to the formulary placement or auth duration for Opdivo. The following prior authorization criteria should be added to Medical Benefit Policy 126.0 to incorporate the new indication for treatment of renal cell carcinoma. It is recommended to remove the criteria from the medical benefit policy for treatment of small cell lung cancer since this indication has been voluntarily withdrawn:

3. *Renal Cell Carcinoma*

- 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 <u>single agent</u> 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
    - 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)

~~*9. 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 of disease progression after two different lines of therapy, one of which must be a platinum-based 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.

CABOMETYX (cabozantinib)

Updated Indication: Cabometyx is now indicated for patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab (Opdivo).

Previous indications include advanced renal cell carcinoma and hepatocellular carcinoma in patients who have been previously treated with sorafenib.

Current formulary status: OralOncBrandNP tier, requiring prior authorization

Recommendations: No changes are recommended to the current formulary status, authorization duration, or quantity limits. It is recommended to add the following prior authorization criteria to incorporate the new indication:

Renal Cell Carcinoma

- Medical record documentation that Cabometyx is prescribed by an oncologist **AND**
- Medical record documentation of use in combination with nivolumab (Opdivo) for previously untreated advanced renal cell carcinoma **OR**
- Medical record documentation of use as a single agent for relapse or for surgically unresectable advanced or metastatic renal cell carcinoma **AND**
- If the requested dose is 80 mg daily: Medical record documentation that the patient is using Cabometyx in combination with a strong CYP3A4 inducer, including but not limited to, rifampin, phenytoin, carbamazepine, phenobarbital, rifabutin, rifapentine, and St. John's Wort

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

PALYNZIQ (pegvaliase injection)

Background: Palzyniq received FDA approval for updated dosing guidelines which allow for a maximum dosage of 60 mg once daily in patients who have been on 40 mg once daily continuously for at least 16 weeks without achieving blood phenylalanine control. Previously, the maximum recommended dose was 40 mg once daily.

Approval comes from prior studies of Palzyniq (study 301 and 302) which allowed patients to increase up to a dose of 60 mg once daily based on investigator discretion to achieve blood phenylalanine lowering during the continuous treatment period. Twelve patients achieved their first response at a dose of 60 mg once daily, with 8 (67%) achieving it by 16 weeks of treatment.

The rates and types of adverse reactions reported during the maintenance phase were similar in patients receiving Palynziq 20 mg, 40 mg, and 60 mg.

Recommendation: The following quantity limits changes are recommended:

QUANTITY LIMIT:

- o 2.5mg/0.5 mL syringe: 4 mL per 28 days
- o 10 mg/0.5 mL syringe: 14 mL per 28 days
- o 20 mg/mL syringe: ~~56 mL~~ 84 mL per 28 days

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.

KESIMPTA (ofatumumab)

Background: Kesimpta is packaged as 20 mg/0.4 mL single-dose prefilled Sensoready pen or a 20 mg/0.4 mL single-dose prefilled syringe. Proposed quantity limits for Kesimpta were incorrectly recommended in 1 mL increments and the quantity limits will be corrected to increments of 0.4 mL.

Recommendation: The following quantity limits changes are recommended:

Initial – One-time, one-week authorization	**Remainder/Subsequent**
Quantity limit: 1.2 mL per 28 days Max quantity supply: 1.2 Min day supply: 28 Max day supply: 28	Quantity limit: 0.4 mL per 28 days Max quantity supply: 0.4 Min day supply: 28 Max day supply: 28

Discussion: No comments or questions.

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

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

QUARTERLY CASE AUDIT

Discussion: The Quarterly Case Audit for 4th quarter 2020 was reviewed at 2 meetings. The reports were reviewed at the medical director/pharmacist meeting on March 8, 2021. The cases were reviewed at the pharmacist meeting on March 11, 2021. An update to the Orilissa 150mg authorization duration will be brought to the May P&T meeting. Will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings. No other comments or questions.

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

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

Meeting adjourned at 3:14 pm.

Voting responses were received from 23 of 35 members. The vote was unanimously approved.

Future Scheduled Meetings

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

All of these meetings are scheduled to be held virtually.