

**P&T Committee Meeting Minutes  
Commercial/GHP Kids/Marketplace  
January 21, 2020**

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

Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, January 17, 2020.

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**Review and Approval of Minutes:**

Dr. Bret Yarczower asked for a motion or approval to accept the November 19, 2019 minutes as written. Kevin Szczecina accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

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## DRUG REVIEWS

### RINVOQ (upadacitinib)

**Review:** Rinvoq is the third orally administered JAK inhibitor available for the treatment of rheumatoid arthritis. All three available JAK inhibitors differ slightly in their specificity, with Rinvoq being the most selective. This high selectivity for the JAK 1 enzyme was intended to provide a safer drug profile, specifically lowering the risk of thrombosis that is commonly seen with this class of drugs. Rinvoq is approved for use in patients with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate. Rinvoq is available as 15mg extend release tablet and the FDA approved dose 15mg once daily. It should not be given in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants.

The safety and efficacy of Rinvoq was demonstrated in five phase 3 randomized double-blind, multicenter studies of patients 18 years and older with moderately to severely active RA. Patients treated with Rinvoq 15mg (alone or in combination with other cDMARDs) achieved a higher ACR response rate compared to methotrexate monotherapy or placebo. In two studies, a higher ACR20 response rate was seen at week one, compared to placebo. A higher proportion of patients treated with Rinvoq also achieved DAS28-CRP of less than 2.6. The DAS28-CRP is a disease activity score that looks at the patient's c-reactive protein levels as well as evaluating 28 different joints for swelling or tenderness. A DAS28-CRP score of less than 2.6 is considered remission. In the SELECT-COMPARE trial, Rinvoq was compared to adalimumab 40mg every other week, in combination with methotrexate. At week 12, Rinvoq was shown to be significantly better than placebo or adalimumab based on ACR50 and ACR 70 response rates. It also met the multiplicity-controlled superiority comparison to adalimumab for ACR 50, which was 45% in the upadacitinib group compared to 15% in placebo and 29% for adalimumab. A greater proportion of patients in the Rinvoq group reached low disease activity, based on the CDAI score at week 12, and achieved a DAS28-CRP score of less than 2.6 There was also a superiority to adalimumab seen in improvement of pain and physical function.

As with the other agents in the class, Rinvoq carries a boxed warning for serious infections, malignancy, and thrombosis. The most common adverse reactions seen in the study (incidence  $\geq 1\%$ ) were upper respiratory tract infections, nausea, cough and pyrexia. Rinvoq should not be used in patients with severe (Child Pugh C) hepatic impairment.

The American College of Rheumatology guidelines were last updated in 2015 and therefore do not include Rinvoq. The guidelines do not currently recommend use of one TNFi or nonTNFi biologic over another. At the time of the development of the AIM FARTHER 2 Carepath, Geisinger rheumatologists recommended having agents with various mechanisms of action as the preferred agents. Humira and Xeljanz were the agents initially recommended by the prescribers for preferred status. When asked about how Rinvoq would fit into their treatment protocols, the physicians stated that their experience was limited. Dr. Brian Opperman noted he felt it would be appropriate to position Xeljanz & Rinvoq on par with each other.

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. Keith Hunsicker made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Aubrielle Prater made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**Outcome:** Rinvoq is a pharmacy benefit that will be added to the pharmacy formularies at the Specialty tier or the Brand Non-Preferred tier for commercial members with a 3-tier benefit. The following prior authorization criteria will apply:

- Prescription is written by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate to severe rheumatoid arthritis made in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of RA **AND**
- Medical record documentation that Rinvoq is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to methotrexate

**QUANTITY LIMITS:** 1 tablet per day

**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 signs and symptoms of rheumatoid arthritis on six (6) months of Rinvoq 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 rheumatoid arthritis while on Rinvoq therapy.

**Other Policy Updates:**

As a result of this review, existing policies for treatment of RA will need to be updated to reflect the changes in preferred agents. The policies listed in the chart below should be updated to require the following for a diagnosis of Rheumatoid Arthritis:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a minimum 3 month trial of Humira, Rinvoq, OR Xeljanz

Commercial/Exchange	Medical Benefit
Actemra SC 321.0	Actemra IV MBP 76.0
Cimzia 197.0	Cimzia MBP 74.0
Enbrel 41.0	Inflectra MBP 5.0
Kevzara 472.0	Orencia IV MBP 40.0
Kineret 71.0	Simponi Aria MBP
Olumiant 530.0	112.0
Orencia SC 253.0	Rituxan MBP 48.0
Simponi 198.0	

As a result of this review, existing policies for Xeljanz/Xeljanz XR will need to be updated to reflect the move to a preferred status. The policies listed in the chart below should be updated to require the following for a diagnosis of Rheumatoid Arthritis:

Commercial/Exchange	
Xeljanz/Xeljanz XR 273.0	<b><u>Remove:</u></b>

	<p>Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira*</p> <p><b>Add:</b>  Medical record documentation of an inadequate response to a minimum 3 month trial of methotrexate or other disease modifying anti-rheumatic drug (DMARD) if methotrexate is not tolerated or contraindicated <b>OR</b> medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy</p>
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**Discussion:** No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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

**BAQSIMI (glucagon)**

**Review:** Baqsimi is an intranasal formulation of glucagon indicated for the treatment of severe hypoglycemia in patients with diabetes age 4 years and older. Unlike other available formulations of glucagon, it doesn't require reconstitution and has been shown to have higher rates of successful administration in usability studies. It does not need to be inhaled since the Baqsimi is passively absorbed through the nasal mucosa and can be administered to patients who are unresponsive.

The efficacy of Baqsimi was investigated in two randomized multicenter open-label crossover non-inferiority studies in adults and one randomized, quasi-blinded, quasi-crossover study in pediatric patients. In adult studies, patients were given an insulin infusion in a controlled environment to induce severe hypoglycemia (plasma glucose levels < 60 mg/dL) then randomized to receive Baqsimi 3 mg intranasally or GlucaGen HypoKit 1 mg intramuscularly. Baqsimi was found to be non-inferior to IM GlucaGen HypoKit for the primary efficacy endpoint of successful treatment, defined as an increase in plasma glucose to  $\geq 70$  mg/dL or an increase of  $\geq 20$  mg/dL from plasma glucose nadir within 30 minutes of glucagon administration. The mean time to treatment success in minutes was 11.6 for Baqsimi and 9.9 for GlucaGen in Study 1 and 15.9 for Baqsimi and 12.1 for GlucaGen in Study 2.

In the pediatric study, patients were assigned to one of 3 cohorts determined by age. The two cohorts that included patients between the ages of 4 and 12, randomized patients 1:1 to receive one of two crossover treatment sequences of Baqsimi 2 and 3 mg or one treatment with IM GlucaGen HypoKit (0.5 or 1 mg dose based on weight). For the third cohort of patients between the age of 12 and 17, patients were randomized to receive Baqsimi 3 mg or IM GlucaGen. For all cohorts, patients were given an IV infusion to reduce plasma glucose level to < 80 mg/dL in a controlled environment. The primary efficacy endpoint, successful reversal of lowered blood glucose levels by at least 25 mg/dL within 20 minutes following glucagon administration, was achieved in 100% of the Baqsimi 3 mg compared to 100% in patients treated with IM GlucaGen HypoKit. One patient in the Baqsimi 2 mg treatment group did not achieve the primary endpoint attributed to the patient blowing his nose immediately following the administration of the Baqsimi 2 mg. This patient later achieved the primary endpoint when dosed with the Baqsimi 3 mg treatment. Mean times to plasma glucose increase by  $\geq 25$  mg/dL were comparable between all treatment groups.

Overall the adverse events during clinical trials with Baqsimi were comparable to the known safety profile of intramuscular glucagon with similar incidences of non-nasal/ facial side effects reported between treatment groups. Patients treated with Baqsimi did have an increased incidence of headache, nasal congestion, and other nasal and

facial adverse events compared to intramuscular glucagon which is expected given the route of administration of Baqsimi.

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. Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Aubrielle Prater made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

**Outcome:** Baqsimi is a pharmacy benefit that will be added to the Brand Preferred tier. It will not require a prior authorization, but the following quantity limits will apply:

**QUANTITY LIMITS:**

**Commercial/CHIP:** 1 day supply per fill

**Exchange:** 1 unit per fill

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

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**GVOKE (glucagon)**

**Review:** Gvoke is a prefilled syringe or autoinjector containing glucagon indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. The easy administration of Gvoke reduces the steps required to prepare and administer glucagon in emergency situations arising from low blood sugar levels. Two multicenter, randomized, single-blind, two way crossover studies comparing Gvoke to Glucagon emergency kits in adult patients with Type 1 diabetes proved Gvoke to be non-inferior to Glucagon emergency kits. In both trials, patients received an IV infusion of insulin to a hypoglycemic state (plasma glucose < 50 mg/dL) then randomized 1:1 to receive Gvoke or Glucagon emergency kit. Gvoke achieved non-inferiority for the primary efficacy endpoint assessing patients for positive response, defined as an increase in plasma glucose to >70 mg/dL within 20 minutes of glucagon administration.

Clinical trials showed Gvoke had a similar safety profile to the known adverse event profile of glucagon. The most commonly reported adverse reactions reported during clinical trials in adult patients was nausea, vomiting, headache, and injection site edema (raised 1 mm or greater). Pediatric patients also reported abdominal pain, hypoglycemia, hyperglycemia, urticaria in addition to those reported in adult patients. These two studies, along with other pharmacokinetic studies, show that Gvoke is a safe and effective treatment option for hypoglycemia in adult and pediatric patients age 2 years and older with diabetes.

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. Tricia Heitzman made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

**Outcome:** Gvoke is a pharmacy benefit that will be added to the Brand Preferred tier of the formularies. It will not require a prior authorization, but the following quantity limits should apply:

**QUANTITY LIMITS:**

**Commercial/CHIP:** 1 day supply per fill

**Exchange:** 1 unit per fill

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

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**TRIKAFTA (elexacaftor, tezacaftor, and ivacaftor)**

**Review:** Trikafta (elexacaftor, tezacaftor, and ivacaftor) is indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. Trikafta is the first FDA-approved triple combination therapy available for CF and is the first indicated to treat patients who only have one *F508del* mutation (heterozygous mutations). It is anticipated that patients with at least one mutation in *F508del* make up approximately 90% of the 30,000 patients in the US with CF.

Previously approved therapies include Orkambi (lumacaftor/ivacaftor), which is only indicated for patients who are homozygous for the *F508del* mutation in the *CFTR* gene; Symdeko (tezacaftor/ivacaftor), which is indicated for patients who are homozygous for the *F508del* mutation or have at least one mutation in the *CFTR* gene; and Kalydeco (ivacaftor), which is not indicated for *F508del* mutations, but instead only for patients who have one mutation in the *CFTR* gene that is responsive to ivacaftor potentiation.

Trikafta is supplied as a fixed dose combination tablet containing elexacaftor 100 mg, tezacaftor 50 mg, and ivacaftor 75 mg, co-packaged with ivacaftor 150 mg tablets to be taken as two combination tablets in the morning and one ivacaftor tablet in the evening, approximately 12 hours apart. Efficacy was shown in two phase 3 trials, in which Trikafta improved FEV<sub>1</sub> and sweat chloride concentrations, amongst other efficacy measures, compared to placebo in heterozygous and homozygous patients and compared to Symdeko in homozygous patients at 4 weeks. Ongoing trials are investigating the efficacy of Trikafta in patients 6 to 11 years of age.

Warnings exist for elevated liver function tests, drug interactions with CYP3A inducers and inhibitors, and cataracts. Patients with severe hepatic impairment (Child-Pugh Class C) should not be treated with Trikafta. Use is not recommended in patients with moderate hepatic impairment (Child-Pugh Class B) unless the benefit exceeds the risk. If used in patients with moderate hepatic impairment, Trikafta should be used with caution and at a reduced dose.

Trikafta was approved by the FDA using all available programs, including Priority Review, Fast Track, Breakthrough Therapy, and orphan drug designations, to approve this therapy 5 months ahead of its review goal date. Guidelines have not yet been updated to include Trikafta. However, it is anticipated that Trikafta will be a mainstay of therapy and that some existing users of previously approved therapies will transition therapy to Trikafta due to inadequate response. Additionally, those experiencing adverse events to lumacaftor specifically may benefit from a change in therapy to Trikafta.

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. Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

**Outcome:** Trikafta is a pharmacy benefit that will be added to the pharmacy formularies at the Specialty tier or the Brand Non-Preferred tier for commercial members with a 3-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that the patient is  $\geq 12$  years of age **AND**
- Medical record documentation of a diagnosis of cystic fibrosis **AND**
- Medical record documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene as determined by an FDA-cleared cystic fibrosis mutation test **AND**
- Medical record documentation that the medication is prescribed by, or in consultation with, a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

**QUANTITY LIMITS:** 3 tablets per day, 34 day supply per fill

**AUTHORIZATION DURATION:** Initial approval will be for four (4) months and subsequent approvals will be for twelve (12) months. Additional authorizations will require medical record documentation of improvement or stabilization in the signs and symptoms of cystic fibrosis. The medication will no longer be covered if the member experiences worsening of disease.

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

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## **OGIVRI (trastuzumab-dkst)**

**Review:** Ogivri was the first FDA approved biosimilar for Herceptin, and the second available in the US following Kanjinti, and shares the FDA approved indications of Herceptin in the treatment of adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer. Trastuzumab products, including Ogivri, combined with chemotherapy in patients with HER2 positive metastatic breast and gastric cancer has significantly improved response rates, progression free survival, and overall survival as well as improved survival in early HER2 positive breast cancer. NCCN recommends Ogivri as a substitution for trastuzumab in the treatment of breast cancer and gastric cancer (category 2A). NCCN does not currently recommend one biosimilar over another, stating that “an FDA-approved biosimilar is an appropriate substitution for trastuzumab”.

The approval of Ogivri was based on the results of pharmacokinetic studies comparing the pharmacokinetics and pharmacodynamics of Ogivri compared to Herceptin and a randomized, double-blind, parallel group study comparing the efficacy of Ogivri to Herceptin in patients with previously untreated HER2-positive metastatic breast cancer. In the clinical trial, 458 patients without previous exposure in the metastatic settings were randomized 1:1 to receive Ogivri or Herceptin every 3 weeks for a minimum 8 treatment cycles in combination with a taxane. After 8 cycles, chemotherapy could be discontinued and Ogivri or Herceptin treatments continued until disease progression or unacceptable toxicity. Ogivri was found to be statistically therapeutically equivalent to Herceptin for the primary efficacy endpoint of overall response rate at 24 weeks (69.6% vs. 64.0%, respectively). Secondary

endpoints measuring time to first progression, progression free survival, and overall survival also showed no statistically significant differences between the two groups.

During clinical trials, adverse events occurred were comparable between Ogivri and Herceptin in regard to type, severity, and incidence. The most frequently reported Grade 3 or higher adverse events were neutropenia and leukopenia, and the most frequently reported non-hematologic adverse events were peripheral neuropathy, diarrhea, asthenia, and nausea. The safety and immunogenicity profiles of Ogivri were generally consistent with the known profile of Herceptin and no new safety concerns were identified during clinical trials. Ogivri shares the same warnings, precautions, and black box warnings as Herceptin.

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. Keith Hunsicker made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

**Outcome:** Ogivri will be covered as a medical benefit and will not be added to the Commercial/Exchange/CHIP pharmacy formularies. It will not require a prior authorization

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

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## **XENLETA (lefamulin)**

**Review:** Xenleta (lefamulin) is an antibiotic that is first in its class. It comes as a tablet or single-use vial for IV infusion. The treatment duration is 5 days for the tablet and 5-7 days for the IV formulation. It is FDA approved to treat community acquired bacterial pneumonia that is susceptible to *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydomphila pneumoniae*. Of the most common bacterial causes for CABP, as described by the Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. lefamulin only does not cover *Moraxella catarrhalis*. Lefamulin is not recommended for empiric therapy. In two clinical trials, LEAP 1 and LEAP 2, lefamulin was shown to be noninferior to moxifloxacin. The main adverse event for the oral formulation is GI upset, mainly diarrhea, but nausea and vomiting were also noted. The most common adverse event with the injection was injection site reactions. Lefamulin can cause QT prolongation, embryo-fetal toxicity, *Clostridium difficile*-associate diarrhea (CDAD), and inappropriate use may lead to the development of drug resistant bacteria. Lefamulin has interactions within the CYP3A and P-gp systems. Currently, Xenleta is not recommended in guidelines but the 2019 Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America mentioned that further outpatient validation is needed.

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

**Clinical Discussion:** Steve commented that the IV product now has a unique J-code associated with it. 1 unit= 1 mg. Medical system should be configured with a RX count up to 2100 units. Tricia Heitzman made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.



**Financial Discussion:** No comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**Outcome:** Xenleta vials will be covered as a medical benefit and will not be added to the pharmacy formularies. Xenleta tablets are a pharmacy benefit that will be added to the pharmacy formularies at the Specialty tier or the Brand Non-Preferred tier for commercial members with a 3-tier benefit. The following prior authorization criteria will apply:

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation of a diagnosis of community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydomphila pneumoniae* **AND**
- Medical record documentation that patient is  $\geq 18$  years of age **AND**
- Medical record documentation of a 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 three (3) alternative antibiotics shown to be susceptible on the culture and sensitivity **OR**
- Medical record documentation that treatment with Xenleta was initiated within an inpatient setting

**QUANTITY LIMITS:**

- Medical – Facets RX Count: up to 2100 units
- Commercial/Exchange/CHIP – 10 tablets per 5 days

**AUTHORIZATION DURATION:**

- Medical – Up to 7 days of total treatment
- Commercial/Exchange/Medicaid – 5 days

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

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**BRUKINSA (zanubrutinib)**

**Review:** Brukinsa is a second generation Bruton Tyrosine Kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. It is the third BTK inhibitor to receive this indication, following Imbruvica and Calquence. Mantle cell lymphoma, a rare subtype of Non-Hodgkin lymphoma involving malignant B-cells, has an aggressive disease course where a majority of patients relapse after first-line treatments. BTK inhibitors are one of the NCCN preferred regimens for patients who achieve only a short duration of response to first line treatments.

The efficacy of Brukinsa was shown in two ongoing, open-label, single arm clinical trials in patients with relapsed or refractory mantle cell lymphoma. In the first trial, 86 adult patients who had failed to achieve at least a partial response to prior therapy received Brukinsa 160 mg twice daily until disease progression or unacceptable toxicity. The primary endpoint measuring overall response rate was 84% with 59% of patients achieving a completed response. Secondary outcomes showed a median duration of response of 19.5 months and progression free survival of 17 months. In the second trial, 32 adult patients who had failed at least one prior therapy received Brukinsa 160 mg twice daily or 320 mg daily until disease progression or unacceptable toxicity. The primary endpoint measuring overall response rate was 84%, with 22% of patients achieving a complete response. Secondary outcomes showed a median duration of response of 18.5 months and progression free survival of 15 months.

During clinical trials evaluating the safety and efficacy of Brukinsa in the treatment of mantle cell lymphoma, fatal events within 30 days of the last dose of Brukinsa occurred in 8/118 patients (7%), including cases of pneumonia and cerebral hemorrhage. Serious adverse reactions were reported in 36 patients (31%), most frequently pneumonia and hemorrhage and led to drug discontinuation in 7% of patients. During treatment with Brukinsa monotherapy, 50 % of patients experienced bleeding events with 2% of patients reporting Grade 3 or higher bleeding events. Serious and fatal infections have also occurred with Brukinsa, with 23% of patients reporting Grade 3 or high infections, most commonly pneumonia. Other reported serious adverse events included second primary malignancies, cytopenias, and cardiac arrhythmias.

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

**Clinical Discussion:** Bret asked if there were any clinical markers that predicted good/response? Nothing noted in studies. Aubrielle asked if everyone in the trial failed a prior therapy and if so, should the criteria be modified to state only failure (as opposed to intolerance and/or contraindication). Group in agreement to amend the criteria to remove “contraindication” from criteria. No other comments or questions. Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**Outcome:** Brukinsa is a pharmacy benefit that will be added to the Oral Oncology Brand Non Preferred Tier (\$0 copay) for the pharmacy formularies. The following prior authorization criteria should apply:

- Medical record documentation of age  $\geq$  18 years
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist
- Medical record documentation of a diagnosis of mantle cell lymphoma
- Medical record documentation of therapeutic failure on or intolerance to one prior therapy

**QUANTITY LIMITS:** 4 capsules per day

**AUTHORIZATION DURATION:** Approval will be for 12 months duration. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

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

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## **RYBELSUS (semaglutide)**

**Review:** Rybelsus is an oral GLP-1 receptor agonist indicated for the treatment of type 2 diabetes in adults. It is initially dosed as 3 mg daily for 30 days and then the dose is increased to 7 mg daily. The dose can further be increased to 14 mg daily if desired efficacy is not demonstrated with the 7 mg dose. Contraindications include a personal or family history of medullary thyroid carcinoma, patients with Multiple Endocrine Neoplasia syndrome type 2, or known hypersensitivity to semaglutide or to any of the components in Rybelsus. Warnings include thyroid C-cell tumors, pancreatitis, hypoglycemia, diabetic retinopathy, hypersensitivity, and acute kidney injury. Rybelsus was studied in a series of PIONEER trials that demonstrated efficacy alone or in combination with other diabetes therapies against placebo, DPP-4 inhibitors, SGLT2 inhibitors, another GLP-1 agonist. Rybelsus also showed weight loss benefit and efficacy in chronic kidney disease. Rybelsus was non-inferior to placebo regarding

cardiovascular outcomes. The GLP1 agonists Victoza and Ozempic, and the SGLT2 inhibitors Jardiance, Invokana, and Farxiga have demonstrated cardiovascular protection. Rybelsus falls into the same class (GLP-1 RA) as Victoza (liraglutide), Ozempic (semaglutide), Trulicity (dulaglutide), Bydureon and Byetta (exenatide), and Adlyxin (lixisenatide), however it is the only oral formulation. The American Diabetes Association has not yet updated its guidelines to include Rybelsus. However, it is anticipated that Rybelsus will be an alternative option in adults with type 2 diabetes who have not yet achieved glycemic control on first-line therapy, have renal disease, or may benefit from weight loss.

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

**Clinical Discussion:** Bret questioned if we should be concerned about this medication being mistakenly used with injectable medication with same mechanism. It was recommended to monitor this via DUR. No further comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Keith Hunsicker made a motion to accept the recommendations as written. Todd Spoenber seconded the motion. None were opposed.

**Outcome:** Rybelsus is a pharmacy benefit and will be added to the Brand Preferred tier of the pharmacy formularies.

**QUANTITY LIMITS:**

- 3 mg tablet – 30 tablets within a 180 day period
- 7 mg and 14 mg tablets – 1 tablet per day

**Other Recommendations:** The following criteria will be updated for Policy 131.0 Byetta, Policy 451.0 Adlyxin, Policy 350.0 Bydureon, and Policy 361.0 Trulicity.

**Policy 131.0 Byetta and Policy 451.0 Adlyxin:**

- Medical record documentation of a diagnosis of Type 2 diabetes **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza **AND either Ozempic or Rybelsus**

**Policy 350.0 Bydureon, and Policy 361.0 Trulicity:**

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of Victoza **AND Ozempic or Rybelsus**, within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Victoza **AND either Ozempic or Rybelsus**

**Discussion:** No comments or questions. Keith Hunsicker made a motion to accept the recommendations as presented. Todd Spoenberg seconded the motion. None were opposed

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

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**TRUXIMA (rituximab-abbs)**

**Review:** Truxima is a biosimilar CD20-directed cytolytic antibody that is highly similar to the US-licensed reference product, Rituxan, indicated for the treatment of adults with chronic lymphocytic leukemia (CLL) and various instances of Non-Hodgkin's Lymphomas (NHL). Truxima targets the CD20 antigen on the surface of pre-B and mature B-lymphocytes to mediate B-cell lysis through complement dependent cytotoxicity and/or antibody dependent cell mediated cytotoxicity. Truxima is not accompanied with a hyaluronidase product to allow for subcutaneous administration at this time.

No new clinical trials were included in the Truxima prescribing information. The clinical trials in the prescribing information are consistent with those presented in the Rituxan prescribing information (for comparable indications). The Truxima 3.3 trial demonstrated non-inferiority of pharmacokinetic (PK) parameters of Truxima and reference rituximab as well as no significant differences between the two products in progression free survival and overall survival. The Truxima 3.4 trial demonstrated a statistically similar overall response between Truxima and reference rituximab. The secondary endpoints also showed no statistically significant differences. A study of real-world clinical effectiveness in DLBCL showed a 70% complete response and 23% partial response in patients treated with Truxima. A Phase III study in patients with rheumatoid arthritis indicated similar efficacy results between Truxima, US reference rituximab, and EU reference rituximab. A phase I study in patients with rheumatoid arthritis indicated equivalent PKs and highly similar efficacy endpoints when comparing Truxima to reference rituximab. An extension of the Phase I study indicated that patient can be effectively switched from reference rituximab to Truxima without changes in efficacy or safety (however, note that this trial does not meet necessary requirements as an interchangeability study for the associated designations).

The safety profile of Truxima was consistent with the known safety profile of reference rituximab, and no significant differences were seen between Truxima and reference rituximab in terms of safety endpoints. The most common reported adverse events included neutropenia, infusion related reactions, fatigue, anemia, peripheral neuropathy, nausea, constipation, and diarrhea. In the switching study, similar instances of anti-drug antibodies were detected between Truxima treated patients and reference rituximab treated patients. Patients were able to switch from reference rituximab to Truxima without changes in adverse events. Rapid infusion clinical trials indicated that Truxima can be administered via rapid infusion with effects similar to that of reference rituximab.

The NCCN guidelines indicate that Truxima may be a substitute for rituximab in the treatment of B-cell lymphomas and chronic lymphocytic leukemias/small lymphocytic lymphomas.

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. Tricia Heitzman made a motion to accept the recommendations as written. Todd Spenberg seconded the motion. None were opposed.

**Financial Discussion:** No comments or questions. Tricia Heitzman made a motion to accept the recommendations as written. Todd Spenberg seconded the motion. None were opposed.

**Outcome:** Truxima will be a medical benefit requiring prior authorization as outlined by MBP 48.0. Truxima should not be added to the respective pharmacy formularies at this time. It is recommended that the prior authorization criteria of its reference product, Rituxan, outlined by Policy MBP 48.0 apply. Note: MBP 48.0 does not require medical PA for diagnoses of CLL, NHL, or MS.

MBP 48.0

**For Rheumatoid Arthritis:**

**All of the following criteria must be met:**

- Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
- At least 18 years of age or older; **AND**
- Prescription written by a rheumatologist; **AND**
- Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
- Medical record documentation that Rituxan is not being used concurrently with a TNF blocker; **AND**
- Physician documentation of an inadequate response to 12 weeks of therapy with adalimumab (Humira); **AND**

**LIMITATIONS:**

If criteria are met, approval will be limited to one course of therapy defined as two infusions, one given on day 1 and another on day 15.

Additional courses may be considered medically necessary if the following criteria are met:

- At least 6 months has elapsed since the previous treatment course; **AND**
- Physician documentation of improvement or lack of progression in the signs and symptoms of rheumatoid arthritis; **AND**
- Physician documentation showing previous treatment course did not result in active infection.

**For Chronic Immunothrombocytopenia (ITP):**

**All of the following criteria must be met:**

- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm<sup>3</sup> with active bleeding or < 20,000/mm<sup>3</sup> with increased risk of bleeding **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND** IVIg\* **AND** splenectomy (\*prior authorization required)

**Authorization Duration\*:** If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.

**For Chronic Lymphoid Leukemia:**

*Note: Prior authorization is not required for diagnosis codes C91.10, C91.11 and C91.12. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL)

**For Microscopic Polyarteritis Nodosa**

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

**For Wegner's Granulomatosis**

- Medical record documentation of a diagnosis of Wegner's granulomatosis used in combination with glucocorticoids

**For Non-Hodgkin Lymphoma**

*Note: Prior authorization is not required for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Non-Hodgkin Lymphoma

**For Multiple Sclerosis (MS)**

*Note: Prior authorization is not required for diagnosis code G35. In the event a requestor would like a medical necessity review completed the following criteria would apply:*

- Medical record documentation of a diagnosis of Multiple Sclerosis

**For Refractory Chronic Debilitating Myasthenia Gravis**

- Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

*Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone  
Cholinesterase inhibitors: pyridostigmine, neostigmine  
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan*

#### **For Pemphigus Vulgaris (PV)**

- Prescription written by a dermatologist **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids **AND** a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

#### **AUTHORIZATION DURATION:**

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

For all other indications: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate (\*except for the diagnosis for ITP). Subsequent approvals will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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

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## **FAST FACTS**

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### **MYOBLOC (rimabotulinumtoxinB)**

**Updated Indication:** Myobloc is now indicated for the treatment of chronic sialorrhea in adults.

Previously, Myobloc was only indicated for the treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.

**Current formulary status:** Medical benefit requiring prior authorization

**Recommendation:** No changes will be made to the formulary placement of Myobloc at this time. The criteria outlined in MBP 11.0 will be updated to account for Myobloc's new indication.

#### MBP 11.0 – Botulinum Toxin

Geisinger Health Plan approved FDA labeled indications for Botulinum Toxin Type B (**Myobloc**):

1. Cervical Dystonia in adults
2. Chronic Sialorrhea in adults

**Discussion:** Tricia questioned if adults were called out for cervical dystonia in our current policy. Current policy does not. No further comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

**Other Recommendations:** The ages outlined in the criteria of MBP 11.0 will be updated/corrected as follows:

### **32.Upper Limb Spasticity**

Botulinum toxin A for the treatment of upper limb spasticity is considered medically necessary when the following criteria are met:

- Medical record documentation that Botox or Xeomin is being used for the treatment of upper limb spasticity **AND**
- For Botox, documentation that the patient is at least 2 years of age **OR**
- For Xeomin, documentation that the patient is at least 18 years of age

### **2.Lower Limb Spasticity**

- Medical record documentation that Botox is being used for the treatment of lower limb spasticity to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus) **AND**
- Documentation that patient is at least 2 years of age **AND**
- Medical record documentation of failure to control spasticity with conventional therapies, e.g., physical therapy, splinting/bracing, or systemic antispasticity medication

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed

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

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### **CLENPIQ (sodium picosulfate/magnesium oxide/anhydrous citric acid)**

**Updated Indication:** Clenpiq is combination of sodium picosulfate, a stimulant laxative, and magnesium oxide and anhydrous citric acid, which form magnesium citrate, an osmotic laxative, indicated for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients ages 9 years and older.

Previously Clenpiq was indicated for cleansing the colon as preparation for colonoscopy in adults.

**Current formulary status:** Brand Non-Preferred tier

**Recommendation:** Because there are currently no age restrictions on Clenpiq and it is available without a prior authorization, no changes will be made to Clenpiq at this time.

**Discussion:** No comments or questions.

**Outcome:** Megan Ammon made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

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## **HARVONI (ledipasvir/sofosbuvir)**

**Updated Indication:** Harvoni is now approved in age 3 and up, Genotype 1,4,5 or 6 Chronic Hepatitis C infection.

Previously it was approved in age 12 and up or weighing at least 35kg.

**Current formulary status:** Non-formulary for Commercial/Chip; Specialty tier requiring a prior authorization for Exchange

**Recommendation:** There are no changes recommended to formulary placement, quantity limits, and authorization duration at this time. However, it is recommended to revise the criteria in Commercial Policy 358.0 for Harvoni to reflect the updated age, ribavirin dosing in pediatrics, and treatment duration as below. Harvoni's warning in severe renal impairment and ESRD was also removed. Reauthorization criteria is not necessary, as we follow the duration based on the current AASLD/IDSA guidelines.

### **Commercial Policy 358.0 Harvoni For Treatment of Hepatitis C:**

An exception for coverage of Harvoni may be made for members who meet the following criteria:

- **Medical record documentation of age 3 years or older using weight-based dosing AND**
- ~~Medical record documentation of age greater than or equal to 12 years OR weight greater than 35 kg AND~~
- Medical record documentation of a diagnosis of hepatitis C infection **AND**
- Medical record documentation of the member's hepatitis C genotype **AND**
- Medical record documentation of a diagnosis of hepatitis C virus (HCV) genotype 1, 4, 5 or 6 infection **AND**
- Medical record documentation of METAVIR liver scoring **AND**
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) **AND**
- Medical record documentation of:
  - Genotype 1
    - As monotherapy **OR**
    - Concurrent therapy with ribavirin if treatment experienced with cirrhosis **OR**
    - Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis **OR**
    - Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **OR**
  - Genotype 4
    - As monotherapy **OR**
    - Concurrent therapy with ribavirin if treatment naïve or experienced with decompensated cirrhosis **OR**
    - Concurrent therapy with ribavirin if treatment naïve or experienced with or without compensated cirrhosis in liver transplant recipients **OR**
    - Concurrent therapy with ribavirin if treatment experienced with compensated cirrhosis **OR**
  - Genotype 5



- As monotherapy **OR**
  - Genotype 6
    - As monotherapy **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if greater than or equal to 75 kg, or 1000 mg per day if less than 75 kg, or 15mg/kg in pediatric patients < 47kg), if indicated **AND**
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following with the past 3 months:
  - Hepatic function panel
  - Complete blood count including differential
  - Basic metabolic panel
  - Baseline hepatitis C virus (HCV) RNA viral load **AND**
- Medical record documentation that member does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m<sup>2</sup>) or end stage renal disease requiring hemodialysis **AND**
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver related co-morbid conditions **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**TREATMENT DURATION:**

**Consistent with AASLD/ IDSA Guidelines** (8 weeks, 12 weeks, 24 weeks)

\*\*8 weeks duration is only for treatment-naïve, Genotype 1 patients who are HIV-uninfected and whose HCV RNA level is < 6million IU/ml

- ~~Genotype 1:~~
  - ~~Harvoni will be approved for a time period of 8 weeks if member is treatment naïve without cirrhosis and has pre-treatment hepatitis C virus (HCV) RNA less than 6 million IU/mL **OR**~~
  - ~~Harvoni will be approved for a time period of 12 weeks **OR**~~
  - ~~Reauthorization is required for a treatment duration of 24 weeks if treatment experienced with cirrhosis and ribavirin ineligible **OR**~~
  - ~~Reauthorization is required for a treatment duration of 24 weeks if treatment experienced with sofosbuvir and with advanced fibrosis **OR**~~
- ~~Genotype 4, 5, or 6:~~
  - ~~Harvoni will be approved for a time period of 12 weeks~~

**CONTINUATION OF THERAPY CRITERIA:**

- ~~Medical record documentation that the member is compliant with hepatitis C medications as evidenced by Hepatitis C Virus (HCV) RNA viral load and medication claims **AND**~~
- ~~Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen and duration that is inside the parameters of use approved by the FDA or supported in the widely used compendia available~~

**QUANTITY LIMIT:** One (1) tablet per day, 28 day supply per fill

**Discussion:** Bret asked if Mavyret was approved for 3 years of age and older. Currently no, but is being studied. No further comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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## SOVALDI (sofosbuvir)

**Updated Indication:** Sovaldi is now approved to treat chronic Hepatitis C in pediatrics age 3 and up, Genotype 2 and 3, using weight-based dosing.

Previously, Sovaldi was indicated in patients age 12 and up or weight greater than 35kg.

**Current formulary status:** Non-formulary

**Recommendation:** There are no changes recommended to formulary placement or quantity limits at this time. However, it is recommended to update the prior authorization criteria in Commercial Policy 326.0 for Sovaldi to reflect the pediatric indication. Many of the old criteria are no longer applicable due to Sovaldi falling out of favor to many of the new direct acting antivirals. Reauthorization criteria is not necessary, as we follow the duration based on the current AASLD/IDSA guidelines.

### For Treatment of Hepatitis C:

An exception for coverage of Sovaldi may be made for members who meet the following criteria:

- **Medical record documentation of age greater than or equal to 3 using weight-based dosing AND**
- ~~Medical record documentation of age greater than or equal to 18 years OR~~
- ~~Medical record documentation of age greater than or equal to 12 years OR weight greater than 35 kg in genotype 2 or 3 AND~~
- Medical record documentation of a diagnosis of hepatitis C infection AND
- Medical record documentation of the member's hepatitis C genotype AND
- **Medical record documentation of a diagnosis of Hepatitis C Virus (HCV) genotype 1, 2, 3, or 4 infection in adults OR HCV genotype 2 or 3 in pediatric patients  $\geq$  3 years of age in combination with ribavirin AND**
- ~~Medical record documentation of a diagnosis of Hepatitis C Virus (HCV) genotype 1, 2, 3, or 4 infection AND~~
- Medical record documentation of METAVIR liver scoring AND
- Medical record documentation of a hepatocellular carcinoma screening in those with cirrhosis (METAVIR score F4) AND
- ~~Medical record documentation of:~~
  - ~~Genotype 1~~
    - ~~Concurrent therapy with ribavirin and having a history of previous failed therapy with a HCV protease inhibitor OR~~
    - ~~Concurrent therapy with peginterferon and ribavirin OR~~
  - ~~Genotype 2~~
    - ~~Concurrent therapy with ribavirin OR~~
  - ~~Genotype 3~~
    - ~~Concurrent therapy with peginterferon and ribavirin if cirrhotic OR~~
    - ~~Concurrent therapy with Daklinza\* if noncirrhotic or post liver transplant OR~~
    - ~~Concurrent therapy with ribavirin OR~~
  - ~~Genotype 4~~
    - ~~Concurrent therapy with peginterferon and ribavirin OR~~
  - ~~Hepatocellular carcinoma awaiting liver transplantation~~
    - ~~Concurrent therapy with ribavirin AND~~

- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**
- Medical record documentation of appropriate duration of treatment **AND**
- Medical record documentation of previous treatment and treatment response **AND**
- Medical record documentation of concurrent therapy with appropriate dose and duration of ribavirin (weight-based dosing of ribavirin 1200 mg per day if greater than or equal to 75 kg, or 1000 mg per day if less than 75 kg, **or 15mg/kg in pediatric patients < 47kg**), if indicated **AND**
- ~~Medical record documentation of concurrent therapy with appropriate dose and duration of peginterferon alfa 2a 180 mcg by subcutaneous injection weekly, if indicated **AND**~~
- Medical record documentation of any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact) **AND**
- Medical record documentation of receiving the following with the past 3 months:
  - Hepatic function panel
  - Complete blood count including differential
  - Basic metabolic panel
  - Baseline Hepatitis C Virus (HCV) RNA viral load **AND**
- ~~Medical record documentation that member does not have severe renal impairment (estimated glomerular filtration rate less than 30 mL/min/1.73 m<sup>2</sup>) or end stage renal disease requiring hemodialysis **AND**~~
- Medical record documentation of a negative pregnancy test if member is female of childbearing potential and receiving ribavirin **AND**
- When concurrent ribavirin therapy is indicated and prescribed, medical record documentation for male members that female partner is not pregnant **AND**
- If the member or their partner are of childbearing potential, medical record documentation that the member was instructed to practice effective contraception during therapy with ribavirin and for 6 months following discontinuation of ribavirin therapy **AND**
- ~~When concurrent peginterferon alfa therapy is indicated and prescribed, medical record documentation of a psychiatric evaluation and treatment clearance within the past 6 months if there is a history of prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance dependency disorders (within the past 3 years), anxiety disorders, borderline personality disorder and/or antisocial personality disorder **OR** for all others a mental health evaluation performed by the prescriber **AND**~~
- If actively abusing alcohol or intravenous (IV) drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse, and an offer of a referral for substance use disorder treatment **AND**
- Medical record documentation that member received pre-treatment readiness education about hepatitis C treatment expectations by a health care provider **AND**
- Medical record documentation that the member commits to the documented planned course of treatment including anticipated blood tests and visits, during and after treatment **AND**
- Medical record documentation that member does not have a limited life expectancy of less than 12 months due to non-liver-related co-morbid conditions **AND**
- ~~\*When concurrent peginterferon is indicated, but not prescribed, medical record documentation of peginterferon ineligibility, as defined by GHP as one or more of the following:
 
  - Hypersensitivity to peginterferon or any of its components **OR**
  - Prior reaction to peginterferon requiring discontinuation **OR**
  - History of depression with suicidality or resulting in hospital admission and the member is currently receiving antidepressant therapy **OR**
  - Autoimmune hepatitis and other immune disorders **OR**~~

- ~~A baseline neutrophil count below 1500/ $\mu$ L, a baseline platelet count below 90,000/ $\mu$ L, or baseline hemoglobin below 10 g/dL~~ **OR**
- ~~Decompensated hepatic disease with a MELD (Model for End Stage Liver Disease) score greater than or equal to 15~~ **AND**
- Medical record documentation of completed:
  - Hepatitis B immunization series **OR**
  - Hepatitis B screening (sAb/sAg and cAb/cAg) **AND** Quantitative hepatitis B virus (HBV) DNA if positive for hepatitis B sAg or cAb or cAg **AND**
    - If there is detectable hepatitis B virus (HBV) DNA, will be treated for Hepatitis B **OR**
    - If negative for hepatitis B sAb, is being vaccinated against Hepatitis B **AND**
- Medical record documentation of human immunodeficiency virus (HIV) screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay:
  - Is being treated for human immunodeficiency virus (HIV) **OR**
  - If not being treated for human immunodeficiency virus (HIV), the medical record documents the rationale for the beneficiary not being treated **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate **AND**
- Medical record documentation that member has been evaluated and treated by a contracted Center of Excellence in hepatitis C management

**OR**

- Medical record documentation of a hepatitis C negative recipient receiving a transplant from a hepatitis C positive donor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Mavyret, if clinically appropriate

**NOTE:** Center of Excellence (COE) requirements do not apply to strategic partner TPA plans (i.e. St Luke's, AtlantiCare, Northern Light Health).

#### **TREATMENT DURATION:**

**Consistent with AASLD/ISDA Guidelines**

- Genotype 1:
  - ~~Sovaldi will be approved for a time period of 12 weeks~~ **OR**
  - ~~Reauthorization is required for a treatment duration of 24 weeks if peginterferon ineligible\*~~
- Genotype 2:
  - Sovaldi will be approved for a time period of 12 weeks
- Genotype 3:
  - ~~Sovaldi will be approved for a time period of 12 weeks~~ **OR**
  - ~~Reauthorization is required for treatment duration of 24 weeks if peginterferon ineligible\*~~
- Genotype 4:
  - Sovaldi will be approved for a time period of 12 weeks
- Hepatocellular carcinoma awaiting liver transplantation:
  - ~~Sovaldi will be approved for a time period of 12 weeks~~ **AND**
  - ~~Reauthorization is required for a treatment duration of up to 48 weeks if approved (12-week authorization at a time and requires pharmacist consult with a medical director)~~

#### **INITIAL AUTHORIZATION:**

- If used with peginterferon alfa and ribavirin or with ribavirin: Sovaldi will be approved for 12 weeks

A pharmacist consult with a medical director is required for patients with hepatocellular carcinoma awaiting liver transplantation to target treatment for 12 weeks as close as possible to planned liver transplantation.

**SECOND AUTHORIZATION:**

If used ribavirin: Following the initial authorization approval of 12 weeks, continued authorization for the remaining treatment duration must meet the following criteria:

- Medical record documentation that the member is compliant with hepatitis C medications as evidenced by Hepatitis C Virus (HCV) RNA viral load and medication claims **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen and duration that is inside the parameters of use approved by the FDA or supported in the widely used compendia available

**THIRD AUTHORIZATION:**

If used with ribavirin: Following the initial authorization approval of 12 weeks and the first reauthorization of 12 weeks, continued authorization for the remaining treatment duration will be in 12 week increments and must meet the following criteria:

- Medical record documentation that the member is compliant with hepatitis C medications as evidenced by Hepatitis C Virus (HCV) RNA viral load and medication claims **AND**
- Medical record documentation of the member receiving a Food and Drug Administration (FDA) approved medication regimen and duration that is inside the parameters of use approved by the FDA or supported in the widely used compendia available

~~For members being treated for hepatocellular carcinoma awaiting liver transplantation, medical record documentation that the patient is still awaiting liver transplantation is required. Reauthorization period will be in 12 week increments (maximum total duration is 48 weeks or whichever comes first). A pharmacist consult with a medical director is required.~~

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary box (no QLS need to be entered within the authorization).*

- 1 tablet per day, 28 day supply per fill

**Discussion:** No comments or questions.

**Outcome:** Tricia Heitzman made a motion to accept the recommendations as presented. Kim Reichard seconded the motion. None were opposed.

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

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**ACZONE 7.5% gel (dapsone)**

**Updated Indication:** Aczone 7.5 % (only 7.5%, not 5%) gel is a sulfone indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Previously, Aczone 7.5 % gel was indicated for patients at least 12 years of age. Aczone 5% gel has not been studied in pediatric patients less than 12 years of age and is not recommended for use in this age group.

**Current formulary status:** Non-formulary

**Recommendation:** There are no changes recommended to the formulary placement of Aczone or Dapsone at this time. There are no age restrictions in the Commercial Policy 476.0 for Non-Preferred Acne medications and there are no changes recommended to the current policy.

**Discussion:** Aubrielle recommend that formulary alternatives in policy should be stratified by age if needed. Group in agreement. No further comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

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**TEFLARO (ceftaroline fosamil monoacetate)**

**Updated Indication:** Teflaro is now indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adult and pediatric patients (at least 34 weeks gestational age and 12 days postnatal age).

Previously, Teflaro was indicated in for ABSSSI and community-acquired bacterial pneumonia (CABP) in patients 2 months of age and older. The CABP indication remains unchanged.

**Current formulary status:** Medical benefit NOT requiring PA

**Recommendation:** Teflaro is available unrestricted as a medical benefit for all lines of business and unrestricted as a pharmacy benefit on the brand non-preferred tier for Gold. As such, there are no current age restrictions. No changes are recommended to the coverage of Teflaro at this time.

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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**OFEV (nintedanib esylate)**

**Updated Indication:** Ofev is now indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Previously, Ofev was only indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

**Current formulary status:** Non-formulary for Commercial/Chip; Specialty tier requiring a prior authorization for Exchange

**Recommendation:** There are no changes recommended to formulary placement at this time. However, it is recommended to update Policy 365.0 for Ofev to include the new indication. The policy will be broken into two sections: IPF and SSc-ILD. There will be no changes to IPF criteria and no changes to the quantity limits. The following criteria will apply for SSc-ILD.

**SSc-ILD:**

- Prescription written by or in consultation with a pulmonologist and/or rheumatologist AND
- Medical record documentation of patient age 18 years or older AND
- Medical record documentation of a diagnosis of systemic sclerosis according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) AND
- Medical record documentation of systemic sclerosis related to interstitial lung disease confirmed by all of the following:
  - $\geq 10\%$  fibrosis on a chest high resolution computer tomography AND
  - FVC  $\geq 40\%$  of predicted normal AND
  - DLCO (diffusion capacity of the lung for carbon monoxide) 30-89% of predicted normal

Note: ACR/ELAR Diagnostic Criteria for Systemic Sclerosis

Item	Sub-item(s)	Weight/score†
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints ( <i>sufficient criterion</i> )	–	9
Skin thickening of the fingers ( <i>only count the higher score</i> )	Puffy fingers	2
	Sclerodactyly of the fingers (distal to the metacarpophalangeal joints but proximal to the proximal interphalangeal joints)	4
Fingertip lesions ( <i>only count the higher score</i> )	Digital tip ulcers	2
	Fingertip pitting scars	3
Telangiectasia	–	2
Abnormal nailfold capillaries	–	2
Pulmonary arterial hypertension and/or interstitial lung disease ( <i>maximum score is 2</i> )	Pulmonary arterial hypertension	2
	Interstitial lung disease	2
Raynaud's phenomenon	–	3
SSc-related autoantibodies (anticentromere, anti-topoisomerase I [anti-Scl-70], anti-RNA polymerase III) ( <i>maximum score is 3</i> )	Anticentromere	3
	Anti-topoisomerase I	
	Anti-RNA polymerase III	

\* These criteria are applicable to any patient considered for inclusion in an SSc study. The criteria are not applicable to patients with skin thickening sparing the fingers or to patients who have a scleroderma-like disorder that better explains their manifestations (e.g., nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft-versus-host disease, diabetic cheiroarthropathy).

† The total score is determined by adding the maximum weight (score) in each category. Patients with a total score of  $\geq 9$  are classified as having definite SSc.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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**TALTZ (ixekizumab)**

**Updated Indication:** Taltz is a humanized interleukin-17A antagonist now indicated for the treatment of adults with active ankylosing spondylitis.



Previously Taltz was indicated in the treatment of adults with moderate to severe plaque psoriasis or active psoriatic arthritis.

**Current formulary status:** Specialty tier/Brand Non-Preferred for members with three tier benefit; requiring prior authorization

**Recommendation:** There are no changes to the current formulary placement of Taltz. It is recommended to add the following prior authorization criteria for the new indication to Commercial Policy 431.0 for Taltz

**For the treatment of ankylosing spondylitis**

- Medical record documentation that Taltz is written by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of ankylosing spondylitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Humira\* **AND** Cosentyx\*
- Medical record documentation that Taltz is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent.

**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 ankylosing spondylitis on six (6) months of Taltz therapy is required.

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

**QUANTITY LIMIT:**

- At time of initial authorization (loading dose):
  - One-time, one-week authorization of 3 mL per 28 days
  - Remainder of six (6) month authorization duration: 1 mL per 28 days
- For ongoing or reauthorization: 1 mL per 28 days

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

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**ENSTILAR (calcipotriene and betamethasone)**

**Updated Indication:** Enstilar is indicated for the topical treatment of plaque psoriasis in patients 12 years and older.

Previously, Enstilar was only indicated in patients 18 years and older.

**Current formulary status:** Non-formulary

**Recommendation:** There is no change to formulary placement recommended at this time. However, it is recommended to add a policy with the following criteria.

- Medical record documentation of a diagnosis of plaque psoriasis AND
- Medical record documentation of patient age 12 years or older AND
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to a combination of a topical vitamin D analog and a topical corticosteroid.

**Discussion:** No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as presented. Keith Hunsicker seconded the motion. None were opposed.

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

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## **ZEJULA (niraparib)**

**Updated Indication:** Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:

- a deleterious or suspected deleterious *BRCA* mutation, or
- genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

Previously, Zejula was only indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy

**Current formulary status:** ORALONCBRANDNP tier, requiring a prior authorization

**Recommendation:** No changes are recommended to the current formulary placement, quantity limits, or authorization duration. It is recommended to update the criteria for Commercial Drug Policy 455.0 for the new indications as follows:

### **Commercial Drug Policy 455.0**

- Medical record documentation that Zejula is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years

**AND**

- Medical record documentation of a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with both of the following:
  - Medical record documentation that Zejula is being used as maintenance treatment **AND**
  - Medical record documentation of a complete or partial response to platinum based chemotherapy

**OR**

- Medical record documentation of diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer with both of the following:
  - Medical record documentation of treatment with three or more prior chemotherapy regimens AND
  - Medical record documentation of homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious *BRCA* mutation OR genomic instability with progression more than six months after response to last platinum-based chemotherapy

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 3 tablets per day, 30 day supply per fill

**Discussion:** Bret questioned genomic studies and any possible mention of Microsatellite stability or instability. Kim wasn't positive, but thought something might have been mentioned in the study. Will do further research. No further comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

## **SIRTURO (bedaquiline)**

**Updated Indication:** Sirturo is indicated as part of combination therapy in adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided.

Limitations of Use: Do not use Sirturo for the treatment of latent, extrapulmonary or drug-sensitive tuberculosis or for the treatment of infections caused by non-tuberculous mycobacteria. Safety and efficacy of Sirturo in HIV-infected patients with MDR-TB have not been established, as clinical data are limited.

Previously, Sirturo was indicated for adult patients ( $\geq 18$  years).

**Current formulary status:** Sirturo is a pharmacy benefit available at the Specialty tier or Brand Non-Preferred tier for members with a three tier benefit, requiring a prior authorization.

**Recommendation:** There will be no updates to formulary placement at this time. However, it is recommended to update the prior authorization criteria to the following.

- Medical record documentation Sirturo is prescribed by a physician specializing in infectious disease AND
- Medical record documentation of one of the following:
  - Age greater than or equal to 18 years OR
  - Age greater than or equal to 12 years, weighing at least 30 kg AND
- Medical record documentation of resistance to isoniazid AND rifampin AND
- Medical record documentation that an effective treatment regimen cannot be attained with other available treatment options AND
- Medical record documentation of one of the following:
  - Sirturo is being prescribed in combination with at least 3 other drugs to which the patient's multi-drug resistant tuberculosis (MDR-TB) isolate has been shown to be susceptible to in vitro OR

- If in vitro testing results are unavailable, Sirturo is being prescribed in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible

**QUANTITY LIMIT:**

First Fill – 56 tablets

Subsequent Fills – 24 tablets

**AUTHORIZATION DURATION:** 24 weeks

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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**ORKAMBI (ivacaftor/lumacaftor)**

**Updated Indication:** Orkambi is indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the *F508del* mutation in the *CFTR* gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the *F508del* mutation on both alleles of the *CFTR* gene.

Previously, Orkambi was only indicated in patients age 6 years and older.

**Current formulary status:** Orkambi is a specialty benefit available at the Brand Non-Preferred tier or Specialty tier for members with a three tier benefit, requiring a prior authorization.

**Recommendation:** There is no change to formulary placement at this time. However, it is recommended to update the age restriction to the following:

- Medical record documentation that Orkambi is prescribed by a pulmonologist or cystic fibrosis specialist AND
- Medical record documentation of patient age greater than or equal to 2 years AND
- ~~Medical record documentation of patient age greater than or equal to 6 years AND~~
- Medical record documentation of a diagnosis of cystic fibrosis (CF) AND
- Medical record documentation that the member is homozygous for the F508del CFTR (cystic fibrosis transmembrane conductance regulator) mutation as documentation by an Food and Drug Administration (FDA)-cleared cystic fibrosis (CF) mutation test

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

4 tablets per day, 30 day supply per fill

2 packets per day, 28 day supply per fill

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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## **CALQUENCE (acalabrutinib)**

**Updated Indication:** Calquence is now indicated for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Previously, Calquence was indicated in patients with mantle cell lymphoma who had received at least one prior therapy.

**Current formulary status:** ORALONCBRANDNP tier requiring prior authorization

**Recommendation:** No changes are recommended to the current formulary placement, quantity limits or authorization duration. The following changes are recommended to the prior authorization criteria in Commercial Policy 480.0 to incorporate the new indication.

### **Commercial Policy 480.0**

- Medical record documentation that Calquence is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- ~~Medical record documentation a diagnosis of mantle cell lymphoma (MCL) **AND**~~
- ~~Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one prior therapy **AND**~~
- Medical record documentation one of the following:
  - Medical record documentation of a diagnosis of mantle cell lymphoma (MCL) **AND** therapeutic failure on, intolerance to, or contraindication to one prior therapy **OR**
  - Medical record documentation of diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

**AND**

- If the requested dose is 400 mg daily: Medical record documentation that the patient is using Calquence in combination with a strong CYP3A inducer, including but not limited to carbamazepine, enzalutamide, fosphenytoin, lumacaftor, mitotane, phenytoin, rifampin, St. John's Wort

**QUANTITY LIMIT:** 2 capsules per day, 30 day supply per fill

**AUTHORIZATION DURATION:** Each treatment period will be defined as 12 months. Subsequent approval after 12 months will require documentation of continued disease improvement or lack of disease progression.

**NOTE:** Acalabrutinib has not been shown to be effective for ibrutinib refractory CLL/SLL in patients with BTK C481S mutations

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Todd Sponenberg seconded the motion. None were opposed.

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

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## **TECENTRIQ (atezolizumab)**

**Updated Indication:** Tecentriq is now indicated in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.

Previously it was indicated in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations and for adult patients with metastatic NSCLC who have disease progression during and following platinum-containing chemotherapy. Tecentriq is also indicated for urothelial carcinoma, triple-negative breast cancer, and small cell lung cancer.

**Current formulary status:** Medical Benefit requiring prior authorization

**Recommendation:** There are no changes recommended to the current formulary placement or authorization duration of Tecentriq. The following changes are recommended to the prior authorization criteria for the Medical Benefit Policy 144.0 to incorporate the new indication.

### **Medical Benefit Policy 144.0**

#### **2. Non-Small Cell Lung Cancer:**

- Prescription written by an oncologist **AND**
  - Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations:
    - Medical record documentation of disease progression during or following platinum-containing chemotherapy
- OR**
- Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.)
- OR**
- Medical record documentation of a non-squamous histologic subtype **AND**
  - Medical record documentation that Tecentriq will be given as first-line treatment **AND**
  - Medical record documentation that Tecentriq will be given in combination with one of the following:
    - bevacizumab, paclitaxel, **AND** carboplatin **OR**
    - **paclitaxel protein-bound and carboplatin **AND****
  - Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## VASCEPA (icosapent ethyl)

**Updated Indication:** Vascepa is now indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and

- established cardiovascular disease or
- diabetes mellitus and 2 or more additional risk factors for cardiovascular disease

Previously, Vascepa was indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia.

**Current formulary status:** Brand Non-Preferred; prior authorization required for Exchange

**Recommendation:** No changes are recommended for commercial or CHIP formularies. It is recommended that the following prior authorization criteria be put in place for Exchange:

- Medical record documentation of a diagnosis of severe hypertriglyceridemia (triglycerides  $\geq 500$  mg/dL)  
**AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to omega-3 acid ethyl esters (generic Lovaza)

**OR**

- Medical record documentation of established cardiovascular disease (documented history of coronary heart disease, cerebrovascular or carotid disease, or peripheral arterial disease) **OR** documentation of a diagnosis of diabetes mellitus and at least **TWO** cardiovascular additional risk factors\* **AND**
- Medical record documentation of use in combination with, or an intolerance to, or contraindication to moderate- or high-intensity statin therapy **AND**
- Medical record documentation of a baseline (pre-initiation of Vascepa) triglyceride level  $\geq 150$  mg/dL

### QUANTITY LIMITS:

Vascepa 0.5 grams: 8 capsules per day

Vascepa 1 gram: 4 capsules per day

\*Note to reviewer:

- Age (men  $\geq 55$ ; women  $\geq 65$  years of age);
- Cigarette smoker or stopped smoking within 3 months;
- Hypertension (BP  $\geq 140$  mmHg systolic OR  $\geq 90$  mmHg diastolic) or on antihypertensive medication
- HDL-C  $\leq 40$  mg/dL for men or  $\leq 50$  mg/dL for women;
- High sensitivity C-Reactive Protein  $> 3.00$  mg/L (0.3 mg/dL);
- CrCL  $> 30$  and  $< 60$  mL/min;
- Retinopathy
- Micro- or macroalbuminuria
- ABI  $< 0.9$  without symptoms of intermittent claudication

**Discussion:** No comments or questions.

**Outcome:** Tricia Heitzman made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## **BENLYSTA (belimumab)**

**Updated Indication:** Benlysta (for IV infusion) is a B-lymphocyte stimulator (BLyS)-specific inhibitor now indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.

Previously, Benlysta was only indicated in adult patients. The subcutaneous formulation is still only indicated for patients 18 years and older.

**Current formulary status:** Benlysta vials: Medical benefit requiring prior authorization; Benlysta Subcutaneous (autoinjector or prefilled syringe): Specialty tier or Brand Non-Preferred for members with 3 tier benefit, requiring prior authorization

**Recommendation:** There are no changes recommended to the current formulary placement of Benlysta. It is recommended to update the age in the Medical Benefit Policy 90.0 as follows.

### **Medical Benefit Policy 90.0**

Benlysta (belimumab) will be considered medically necessary for the treatment of ~~adults~~ insured individuals with active, autoantibody positive, systemic lupus erythematosus (SLE) when ALL of the following criteria are met:

- **Medical record documentation of age  $\geq 5$  years**
- Physician provided documentation of a diagnosis of active lupus; and
- Positive ANA/anti-dsDNA antibody; and
- Stable treatment regimen with prednisone, NSAID, anti-malarial or immunosuppressant; and
- No active severe nephritis or CNS involvement; and
- Must be prescribed by a Rheumatologist

### **Re-authorization Criteria:**

Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as Prednisone

### **LIMITATIONS**

Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.

**Other Recommendations:** Benlysta administered subcutaneously is only indicated in adult patients and has not been updated to include pediatric patients. Since age is not currently addressed in the Benlysta subcutaneous policies, it is recommended to update Commercial Policy 475.0 with the following criteria:

### **Commercial Policy 475.0 and GHP Family Policy 1409.0F Benlysta Subcutaneous**

- **Medical record documentation of age  $\geq 18$  years**
- Medical record documentation a diagnosis of active systemic lupus erythematosus **AND**
- Medical record documentation that Benlysta SC is prescribed by a rheumatologist **AND**
- Medical record documentation of a positive ANA/anti-dsDNA antibody **AND**



- Medical record documentation that member is concurrently receiving a stable treatment regimen with prednisone, an NSAID, anti-malarial or immunosuppressant **AND**
- Medical record documentation of no active severe nephritis or central nervous system (CNS) involvement

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).*

- 4 mL per 28 days

**AUTHORIZATION DURATION:** Each authorization will be for a period of 12 months. Re-review is required with medical record documentation showing a clinical benefit of one of the following:

- Improvement in functional impairment
- Decrease in the number of exacerbations since the start of Benlysta
- Decrease in the daily required dose of oral corticosteroids such as prednisone

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Melissa Renn seconded the motion. None were opposed.

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

## **XTANDI (enzalutamide)**

**Updated Indication:** Xtandi is now indicated for the treatment of patients with:

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

Previously, Xtandi was indicated for the treatment of patients with castration-resistant prostate cancer.

**Current formulary status:** Xtandi is pharmacy benefit available at the OralOncBrandNP requiring prior authorization.

**Recommendation:** There is no change recommended to formulary placement at this time. However, it is recommended to update the prior authorization criteria to the following:

- Medical record documentation that Xtandi is prescribed by a hematologist, oncologist, or urologist **AND**
- Medical record documentation of diagnosis of prostate cancer **AND**
- ~~Medical record documentation that the member is no longer responding to castration or is hormone resistant~~ **AND**
- Medical record documentation of one of the following:
  - That the member is no longer responding to castration or is hormone resistant **OR**
  - That the member has metastatic castration-sensitive prostate cancer

**AND**

- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**Quantity Limit:** 4 tablets per day, 30 day supply per fill

**Authorization Duration:** Treatment period will be defined as 12 months. Re-review will occur every 12 months. Xtandi will no longer be covered if there is medical record documentation of disease progression.

There are no updates to quantity limits or authorization duration at this time.

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## UPDATES

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### INFLECTRA/RENFLEXIS – POLICY UPDATE

**Updated Indication:** Inflectra and Renflexis are now indicated for reducing signs and symptoms and inducing and maintaining clinical remission of moderate to severe active ulcerative colitis in pediatric patients 6 years of age and older who have had an inadequate response to conventional therapy following the loss of Remicade's orphan drug exclusivity for the treatment of pediatric ulcerative colitis.

There are no changes recommended to the current formulary placement, authorization duration, or quantity limits for Inflectra and Renflexis. It is recommended to update the Medical Benefit Policy 5.0 (Remicade, Inflectra, Renflexis

#### Medical Benefit Policy 5.0 Remicade, Inflectra, Renflexis

##### For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater **AND**
- Requesting provider must be a rheumatologist **AND**
- 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 the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira\* **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra\*

##### *Recommended guidelines for use in the treatment of rheumatoid arthritis*

- 3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.

- For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.

##### For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:

- Must be 6 years of age or older; **AND**

- Prescription is written by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- One of the following:
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira\* **OR**
  - Physician documentation of Crohn's disease with actively draining fistulas.

**AND**

- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra\*

***Recommended guidelines for use in the treatment of crohn's disease or fistulizing crohn's disease:***

- 5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter

- For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.

**For Treatment of Ulcerative Colitis:**

- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis; **AND**
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (eg, 6-mercaptopurine or azathioprine **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira\* **OR** medical record documentation of age < 18 years **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra\* **OR** medical record documentation of age < 18 years **OR**
- For new start Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of Inflectra\*

***Recommended guidelines for the use in the treatment of ulcerative colitis***

- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

**For Treatment of Ankylosing Spondylitis:**

- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira\* **AND** Cosentyx\* **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra\*

***Recommended guidelines for use in ankylosing spondylitis***

*- 5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter*

**For the treatment of Plaque Psoriasis:**

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation that the infliximab product 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 at least 3 months of Humira\* **AND** Cosentyx\* **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra\*

***Recommended guidelines for the use in the treatment of plaque psoriasis***

*- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

**For the treatment of Psoriatic Arthritis:**

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
  - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation that the infliximab product 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\* and Cosentyx\* **AND**
- For new start Remicade or Renflexis requests, medical record documentation of an intolerance to contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra\*

***Recommended guidelines for the use in the treatment of psoriatic arthritis***

*- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

**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 the treated indication at six (6) months of infliximab 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 the treated indication while on infliximab therapy.

**LIMITATIONS:** Inflectra and Renflexis are not approved for the use in pediatric ulcerative colitis due to orphan drug exclusivity for Remicade.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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### **MAVYRET (glecaprevir/pibrentasvir)**

**Recommendation:** There are no changes to the indication or dosing of Mavyret, however the treatment duration in treatment naïve, compensated cirrhosis was reduced to 8 weeks instead of 12 weeks.

No adjustments needed to current policies as we follow the duration based on the current AASLD/IDSA guidelines.

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Aubrielle Prater seconded the motion. None were opposed.

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

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### **RETIRED POLICIES- UPDATE**

**Recommendation:** Currently, we have medication-specific policies for the PCSK9 inhibitors and Hepatitis C agents, therefore the following commercial/exchange class policies will be retired:

- Policy 377.0- PCSK9 Inhibitors
- Policy 320.0- Hepatitis C Direct Acting Antivirals

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Tricia Heitzman seconded the motion. None were opposed.

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

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### **PRASUGREL UPDATE**

**Recommendation:** Prasugrel is available on the generic tier requiring a prior authorization. Based on the results of the ISAR-REACT 5 trial that show treatment with prasugrel had a significantly lower incidence of death, MI, or stroke compared to Brilinta, no significant differences between the two groups for the incidence of major bleeding (numerically lower for prasugrel), and the availability of prasugrel as a generic, it is recommended to remove the prior authorization for prasugrel.

**Discussion:** No comments or questions.

**Outcome:** Keith Hunsicker made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## **MENOPUR UPDATE**

**Specialist Feedback:** Dr. Jennifer Gell from the Reproductive Endocrinology and Infertility clinic at Geisinger Wyoming Valley shared that for IVF, Menopur is used regardless of LH levels and that it is standard protocol when GnRH antagonist is used. Menopur can be used alone or in combination with other gonadotropin products, including Gonal-f or Follistim.

**Additional background:** For the other situations listed in the criteria above (poor/diminished ovarian reserve, tubal factor infertility, Menopur being used with donor eggs), other types of assisted reproductive technology (ART) may be used that are very similar to IVF.<sup>1</sup> Menopur can also be used alone or in combination for these situations.

**Recommendation:** No changes are recommended to the formulary placement of Menopur, but it is recommended to not require failure on Gonal-f when Menopur is used for the indications presented here. Other criteria not listed below should not be adjusted, but the related criteria for Menopur should be updated as follows:

- Medical record documentation that Menopur is prescribed by or in consultation with a reproductive specialist or infertility specialist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of one of the following:
  - Poor/diminished ovarian reserve **OR**
  - Tubal factor infertility **OR**
  - Menopur is being used with donor eggs **OR**
  - In Vitro Fertilization **AND**
- ~~Medical record documentation of therapeutic failure, contraindication, or intolerance to Gonal-f~~

**Discussion:** No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as presented. Kevin Szczecina seconded the motion. None were opposed.

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

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## **January 2020 DUR/Adherence Update**

### **Commercial/Exchange and TPAs**

#### **Drug Use Evaluations (DUEs)**

- Statin Use in Persons with Diabetes DUE
  - This is the 2019 4th quarter MedImpact DUE for Commercial/Exchange and GHP Family
  - From this report, we identified members whose medication history was suggestive of the presence of diabetes and who were not receiving a statin drug during the previous three-month period.
  - Brandy P. completed the mail merge and sent out the letters to the member's providers on 12/5/2019.

- See below for letters sent:
 

<ul style="list-style-type: none"> <li>▪ For GHS01: <b>93</b></li> <li>▪ For GHS25: <b>14</b></li> <li>▪ For GT023: <b>8</b></li> <li>▪ For GT038: <b>3</b></li> <li>▪ For GT045: <b>34</b></li> <li>▪ For GT056: <b>6</b></li> <li>▪ For GT064: <b>2</b></li> <li>▪ For GT072: <b>7</b></li> <li>▪ For GT075: <b>1</b></li> <li>▪ For GT089: <b>14</b></li> <li>▪ For GT095: <b>99</b></li> <li>▪ For GT017: <b>3</b></li> <li>▪ For GT180: <b>3</b></li> <li>▪ For GT230: <b>18</b></li> <li>▪ For GT260: <b>2</b></li> <li>▪ For GT310: <b>6</b></li> <li>▪ For GT900: <b>13</b></li> </ul>	<ul style="list-style-type: none"> <li>▪ For GHS05: <b>91</b></li> <li>▪ For GHS90: <b>98</b></li> <li>▪ For GT036: <b>1</b></li> <li>▪ For GT039: <b>1</b></li> <li>▪ For GT046: <b>31</b></li> <li>▪ For GT062: <b>98</b></li> <li>▪ For GT065: <b>90</b></li> <li>▪ For GT074: <b>1</b></li> <li>▪ For GT088: <b>4</b></li> <li>▪ For GT093: <b>4</b></li> <li>▪ For GT106: <b>3</b></li> <li>▪ For GT140: <b>10</b></li> <li>▪ For GT210: <b>4</b></li> <li>▪ For GT231: <b>1</b></li> <li>▪ For GT280: <b>6</b></li> <li>▪ For GT400: <b>100</b></li> </ul>
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- We will have Adam K. re-run this data in March 2020 to show us the effectiveness of the letter.
- Asthma DUE
  - This is the 2019 3<sup>rd</sup> quarter MedImpact DUE for all LOBs
  - From this report, we identified members who received 4 or more prescriptions for an asthma medication over a 12-month period but did not receive an asthma controller medication in that same 12-month period.
  - Brandy P. completed the mail merge and sent out the letters to the member's providers on 8/26/2019.
  - See below for letters sent:
 

<ul style="list-style-type: none"> <li>▪ For GHS01: <b>93</b></li> <li>▪ For GHS05: <b>68</b></li> <li>▪ For GHS25: <b>5</b></li> <li>▪ For GHS90: <b>95</b></li> <li>▪ For GT023: <b>3</b></li> <li>▪ For GT036: <b>2</b></li> <li>▪ For GT038: <b>1</b></li> <li>▪ For GT045: <b>6</b></li> <li>▪ For GT046: <b>4</b></li> <li>▪ For GT056: <b>1</b></li> <li>▪ For GT062: <b>9</b></li> <li>▪ For GT065: <b>59</b></li> <li>▪ For GT072: <b>4</b></li> <li>▪ For GT086: <b>3</b></li> <li>▪ For GT089: <b>5</b></li> <li>▪ For GT095: <b>18</b></li> <li>▪ For GT140: <b>2</b></li> <li>▪ For GT230: <b>4</b></li> <li>▪ For GT280: <b>2</b></li> <li>▪ For GT400: <b>95</b></li> <li>▪ For GT900: <b>1</b></li> </ul>	
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- Adam K. was able to re-run the data on this population on 12/13/2019 and of the original 480 members that we sent letters to 424 members are still active. Of those 424 members 34 members now have a claim for an asthma controller medication. This equates to 8% of the members.
- Congestive Heart Failure DUE
  - This is the 2019 2<sup>nd</sup> quarter MedImpact DUE for Commercial/Exchange and GHP Family
  - From this report, we identified members who have a presumed diagnosis of heart failure taking metoprolol succinate, carvedilol, or bisoprolol, and who were not taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) drug therapy in a 3-month timeframe.
  - See below for letters sent:
    - For GHS01: **85**
    - For GHS05: **85**
    - For GHS90: **86**
    - For GT038: **30**
    - For GT065: **71**
    - For GT095: **82**
    - For GT400: **92**
  - Adam K. was able to re-run the data on this population on 9/25/2019 and of the original 531 members that we sent letters to 479 members are still active. Of those 479 members 44 members now have a claim for an ACEI or ARB medication. This equates to 9.2% of the members.
- Coronary Artery Disease DUE
  - This is the 2019 1<sup>st</sup> quarter MedImpact DUE for all LOBs
  - From this report, we identified members age 40-75 years who are not on a statin drug therapy in a 3-month timeframe and who have at least one of the following cardiovascular disease (CVD) risk factors: diabetes, hypertension, or smoking.
  - Brandy P. completed the mail merge and sent out the letters to the member's providers on 2/19/2019
  - See below for letters sent:
    - For GHS01: **98**
    - For GHS05: **98**
    - For GHS90: **98**
    - For GT038: **12**
    - For GT065: **94**
    - For GT095: **100**
    - For GT400: **99**
  - Adam K. was able to re-run the data on this population and below indicates the percentage of the active members who now have a claim for a statin medication.
    - For GHS01: **5.7%** (5/87)
    - For GHS05: **12.8%** (12/94)
    - For GHS90: **6.8%** (6/88)
    - For GT038: **36.4%** (4/11)
    - For GT065: **6.9%** (6/87)
    - For GT095: **11.1%** (11/99)
    - For GT400: **12.5%** (12/96)

## **In Progress**

- STENT Adherence Report
  - Currently in the process of functionalizing an adherence report to replace the current STENT program
  - We will identify members on an antiplatelet medication and then flag for betablocker and statin medication claims



- We will assess adherence to all 3 medications and outreach to members with PDC <80% via letter and/or telephonic outreach
- HEDIS Reports
  - Statin Therapy for Patients with Diabetes (SPD)
    - In the process of functionalizing a report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
      - We will reach out to providers to initiate therapy and members to encourage adherence via letter
  - Statin Therapy for Patients with Cardiovascular Disease (SPC)
    - In the process of functionalizing a report to identify members with cardiovascular disease and who have not received a statin medication or who are non-adherent to statin therapy
      - We will reach out to providers to initiate therapy and members to encourage adherence via letter
  - Adherence to Antipsychotics for Individuals with Schizophrenia (SAA)
    - Currently, Kayla Stanishefski runs this report monthly, and we send letters to the flagged members who appear non-adherent to their antipsychotic medications for GHP Family
    - As of 1/1/2020, this measure now applies for all LOBs so we will do the same for Commercial/Exchange
- DUR Duplicate Anticoagulant Report
  - We get this report weekly for **all LOBs** flagging members filling duplicate anticoagulant medications. We personally reach out to the providers/pharmacy of the flagged members to confirm proper medication therapy.
  - For 2019:
    - For GHS01: **5 members** reviewed and **0 interventions** made
    - For GHS02: **8 members** reviewed and **0 interventions** made
    - For GHS05: **8 members** reviewed and **0 interventions** made
    - For GHS90: **20 members** reviewed and **2 interventions** made
    - For GT038: **3 members** reviewed and **0 interventions** made
    - For GT056: **1 member** reviewed and **0 interventions** made
    - For GT062: **2 members** reviewed and **0 interventions** made
    - For GT065: **18 members** reviewed and **2 interventions** made
    - For GT074: **2 members** reviewed and **0 interventions** made
    - For GT095: **2 members** reviewed and **1 intervention** made
    - For GT400: **22 members** reviewed and **0 interventions** made
- Duplicate Specialty Therapy
  - We run an in-house retrospective report quarterly for **all LOBs** with help from Adam Kelchner and Aubrielle Prater. These members are identified and written up and sent to a medical director if follow up is needed.
    - For Commercial/Exchange 2019- we have reviewed reports through Q3, and have made the following interventions:
      - GHS05: **1**
      - GT056: **1**
      - GT400: **1**
- Suboxone with an Opioid Report
  - We are getting this report weekly for **all LOBs** from Adam Kelchner. These members are being forwarded to Dr. Meadows, and he is looking into whether it is appropriate to end the opioid authorizations still in place
  - For Commercial/Exchange and TPAs in 2019, see below for the new members reviewed and those referred to Dr. Meadows

- For GHS01: we have reviewed **7 new members** and **1 members** were referred to Dr. Meadows
  - For GHS05: we have reviewed **4 new members** and **1 members** were referred to Dr. Meadows
  - For GHS90: we have reviewed **9 new members** and **6 members** were referred to Dr. Meadows
  - For GT045: we have reviewed **1 new member** and **0 members** were referred to Dr. Meadows
  - For GT062: we have reviewed **1 new member** and **0 members** were referred to Dr. Meadows
  - For GT065: we have reviewed **1 new member** and **0 members** were referred to Dr. Meadows
  - For GT070: we have reviewed **1 new member** and **0 members** were referred to Dr. Meadows
  - For GT095: we have reviewed **2 new member** and **0 members** were referred to Dr. Meadows
  - For GT400: we have reviewed **8 new members** and **4 member** were referred to Dr. Meadows
- Ending Opioid Authorizations
  - We are working on identifying members who have active opioid authorizations in place but have since started Buprenorphine therapy. The letter is sent to the members notifying them the opioid authorization has been ended due to the start of buprenorphine therapy.
  - For Commercial/Exchange and TPAs in 2019, see below for the number of letters we have sent to members notifying them that we are ending their opioid authorization(s):
    - For GHS01: **1**
    - For GHS90: **4**
    - For GT095: **1**
    - For GT400: **4**
- Opioid Overutilization Report
  - We are getting this report **monthly** from MedImpact and we are writing up each member that flags on the report. We have been monitoring the members that are continuously showing up on the report by any change in their MED. For those members we deem appropriate we will send a letter to their PCP.
  - For Commercial/Exchange and TPAs in 2019, see below for the number of reviewed cases.
    - For GHS01: **4**
    - For GHS05: **3**
    - For GHS90: **11 (4 referred to Dr. Meadows)**
    - For GT062: **1**
    - For GT095: **3**
    - For GT400: **3**
- FWA Reports
  - We are getting this report **weekly** for **all LOBs** from Marie Strausser. We prepare this report by determining which claims need to be verified, and the Wilkes pharmacy students/GHP technicians have been making the calls to pharmacies.
  - We review claims for anti-hypertensives, statins, 1-day supply, and inhalers
    - For GHS01 in 2019, we have reviewed **39 cases** so far and **corrected 38 claims**, resulting in a **cost savings of \$1,623.76**
    - For GHS05 in 2019, we have reviewed **45 cases** so far and **corrected 26 claims**, resulting in a **cost savings of \$1,621.27**

- For GHS90 in 2019, we have reviewed **104 cases** so far and **corrected 42 claims**, resulting in a **cost savings of \$959.55**
  - For GT038 in 2019, we have reviewed **27 cases** so far and **corrected 12 claims**, resulting in a **cost savings of \$783.22**
  - For GT045 in 2019, we have reviewed **5 cases** so far and **corrected 5 claims**, resulting in a **cost savings of \$47.46**
  - For GT046 in 2019, we have reviewed **4 cases** so far and **corrected 3 claims**, resulting in a **cost savings of \$2.00**
  - For GT065 in 2019, we have reviewed **44 cases** so far and **corrected 26 claims**, resulting in a **cost savings of \$1,338.27**
  - For GT089 in 2019, we have reviewed **2 cases** so far and **corrected 2 claims**, resulting in a **cost savings of \$2.20**
  - For GT095 in 2019, we have reviewed **24 cases** so far and **corrected 24 claims**, resulting in a **cost savings of \$1,638.45**
  - For GT400 in 2019, we have reviewed **40 cases** so far and **corrected 24 claims**, resulting in a **cost savings of \$1,419.67**
- Stent Antiplatelet Adherence Program
  - We continue to identify new stent patients for **all LOBs** at GMC/GWV/CMC/Susq and follow these members for 1 year after discharge to ensure adherence to their aspirin, beta blocker, antiplatelet, and statin therapy regimens.
  - For Commercial/Exchange in 2019:
    - For GHS01: we identified and outreached to **26 new stent patients**
    - For GHS02: we identified and outreached to **28 new stent patients**
    - For GHS03: we identified and outreached to **2 new stent patients**
    - For GHS05: we identified and outreached to **15 new stent patients**
    - For GHS25: we identified and outreached to **1 new stent patient**
    - For GHS90: we identified and outreached to **32 new stent patients**
    - For GT034: we identified and outreached to **1 new stent patient**
    - For GT038: we identified and outreached to **2 new stent patients**
    - For GT045: we identified and outreached to **2 new stent patients**
    - For GT070: we identified and outreached to **1 new stent patient**
    - For GT089: we identified and outreached to **4 new stent patients**
    - For GT092: we identified and outreached to **1 new stent patient**
    - For GT095: we identified and outreached to **1 new stent patient**
    - For GT105: we identified and outreached to **10 new stent patients**
    - For GT106: we identified and outreached to **1 new stent patient**
    - For GT230: we identified and outreached to **1 new stent patient**
    - For GT400: we identified and outreached to **22 new stent patients**
  - As of November 2019, this program was terminated and the STENT adherence report that is currently in progress will take its place
- Severity Report
  - This is a monthly report for **all LOBs** on members who have filled a medication that has a level one interaction with another medication they have a claim for
  - For Commercial/Exchange in 2019, we have sent letters to providers on the below members:
    - For GHS01: **32**
    - For GHS05: **24**
    - For GHS90: **56**
    - For GT038: **3**
    - For GT045: **1**
    - For GT046: **3**

- For GT062: **7**
  - For GT065: **9**
  - For GT093: **1**
  - For GT095: **7**
  - For GT400: **21**
- Enbrel Overutilization for Treating Plaque Psoriasis
  - A **monthly** report was created to determine members who have been overutilizing Enbrel twice weekly dosing as outlined by the FDA approved dose.
    - We put in place QLs for Enbrel, so we should not be seeing these cases moving forward for new starts and at re-authorization periods for members currently on therapy
    - Working on follow up to ensure members are on proper therapy.
- Tobacco Cessation Program
  - Quarterly meeting with Wellness/MTDM RPhs to create a program that identifies GHP members who may benefit from tobacco cessation interventions/medications.
  - We gathered drug utilization data to determine which medications are being commonly prescribed and assessed proper utilization. We also informed the group of the Chantix updates approved at the March 2018 P&T meeting: Chantix was added to the Brand Tier for GHP Family without prior authorization.
  - We send a letter and resource pamphlet to members on prolonged tobacco cessation treatment to provide additional behavioral health support through Geisinger Health and Wellness.
  - For Commercial/Exchange in 2019, we have sent letters to the below members:
    - For GHS01: **18**
    - For GHS05: **18**
    - For GHS90: **27**
    - For GT033: **4**
    - For GT038: **1**
    - For GT045: **2**
    - For GT062: **5**
    - For GT065: **23**
    - For GT089: **1**
    - For GT095: **2**
    - For GT400: **25**
- Antidepressant Medication Management
  - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who appear non-adherent to their antidepressant medications.
  - For Commercial/Exchange in 2019, we have sent letters to below members:
    - For GHS01: **4**
    - For GHS90: **11**
- Asthma Medication Ratio
  - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who have a ratio of controller to total asthma medications of < 0.5.
  - For Commercial/Exchange in 2019, we have sent letters to below members:
    - For GHS01: **17**
    - For GHS90: **3**
- Medication Management for People with Asthma
  - Kayla Stanishefski runs this proactive HEDIS report **monthly**, and we send letters to the flagged members who appear non-adherent to their asthma controller medications.
  - For Commercial/Exchange in 2019, we have sent letters to below members:
    - For GHS01: **29**
    - For GHS90: **19**

## Completed

- Commercial/Exchange DUR/FWA Program Fliers
  - Last updated 10/2019 next update January 2020
- Current Provider Letters
  - Congestive Heart Failure DUE
  - Coronary Artery Disease DUE
  - Polypharmacy DUE
  - Statin Use in Persons with Diabetes DUE
  - Adherence to Antidepressants DUE
  - Asthma Med Ratio DUE
  - Opioid Overutilization
  - Severity Report
  - Duplicate Anticoagulant Report
- Current Member Letters
  - Ending opioid Authorizations
  - Stent Antiplatelet Adherence Program
  - Antidepressant Medication Management-AMM
  - Asthma Medication Ratio-AMR
  - Medication Management for People with Asthma-MMA

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## QUARTERLY CASE AUDIT RESULTS

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The Quarterly Case Audit was held on December 5th. The audit resulted in an update for Vascepa based on the results of the Reduce-It trial, but Vascepa received FDA approval in the meantime for that indication so a Fast Facts was done instead. Will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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## RESULTS OF ELECTRONIC VOTE

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**The following products were presented to the committee as an electronic vote in December of 2019. The below recommendations were approved by the P&T Committee on December 31, 2019 with 18 votes of approval.**

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### ADHANSIA XR (methylphenidate)

**Recommendation:** Adhansia XR is a pharmacy benefit that will not be added to the pharmacy formularies. It will require a prior authorization and will be added to the existing Commercial/Exchange Policy 94.0.

### **Policy 94.0 Adhansia XR, Aptensio XR, Daytrana, Quillichew ER, Dexmethylphenidate, and Quillivant XR**

An exception for coverage of Adhansia XR, Aptensio XR, Daytrana, dexmethylphenidate HCl ER, QuilliChew ER, or Quillivant XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD **AND** amphetamine/dextroamphetamine SR combination.

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLS need to be entered within the authorization).*

- Adhansia XR: 1 capsule per day

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

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### **BIJUVA (estradiol/progesterone)**

**Recommendation:** Bijuva is a pharmacy benefit that will not be added to the pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of use for treatment of moderate to severe vasomotor symptoms due to menopause AND
- Medical record documentation of an intact uterus AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to estradiol used in combination with progesterone.

**QUANTITY LIMIT:** 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.

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### **CEQUA (cyclosporine)**

**Recommendation:** Cequa will be a pharmacy benefit and will not be added to the pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of keratoconjunctivitis sicca (dry eye).
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Xiidra (lifitegrast) AND Restasis (cyclosporine).

**QUANTITY LIMIT:** 2 vials per day

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

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### **DRIZALMA (duloxetine)**

**Recommendation:** Drizalma Sprinkle is a pharmacy benefit that will not be added to the pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of one of the following:
  - Medical record documentation major depressive disorder, diabetic peripheral neuropathic pain, or chronic musculoskeletal pain in member age  $\geq 18$  years **OR**
  - Medical record documentation of generalized anxiety disorder in members age  $\geq 7$  years

**AND**

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be duloxetine capsules.

**QUANTITY LIMIT:** 2 capsules per day

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

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**EZALLOR (rosuvastatin)**

**Recommendation:** Ezallor Sprinkle is a pharmacy benefit that will not be added to the pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of administration through a nasogastric tube **OR**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternatives, one of which must be rosuvastatin.

**QUANTITY LIMIT:** 1 capsule per day

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

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**JORNAY PM (methylphenidate)**

Jornay PM will be a pharmacy benefit that will not be added to the pharmacy formularies at this time. Jornay PM will require prior authorization and will be added to the existing Commercial/Exchange Policy 94.0.

**Policy 94.0 Adhansia XR, Aptensio XR, Daytrana, Dexmethylphenidate, Jornay PM, Quillichew ER, and Quillivant XR**

An exception for coverage of Adhansia XR, Aptensio XR, Daytrana, dexmethylphenidate HCl ER, QuilliChew ER, Quillivant XR, or Jornay PM may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of attention deficit disorder (ADD) or attention deficit hyperactivity disorder (ADHD) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Metadate CD **AND** amphetamine/dextroamphetamine SR combination

**QUANTITY LIMIT:** Pharmacist note to CSR: *Authorization should be entered by HICL and only checking the Formulary PA required box (no QLS need to be entered within the authorization).*

- Jornay PM: 1 capsule per day

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

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**KAPSPARGO (metoprolol succinate ER)**

**Recommendation:** Kapspargo is a pharmacy benefit that will not be added to the pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation of difficulty swallowing **OR**

- Medical record documentation of use through nasogastric tube **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) generic formulary beta-blocking agents, one of which must be metoprolol succinate.

**QUANTITY LIMIT:** 25 mg, 50 mg, 100 mg capsule: 1 capsule/day  
200 mg capsule: 2 capsules/day

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

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### **KHAPZORY (levoleucovorin)**

**Recommendation:** Khapzory is a medical benefit and will not be added to the pharmacy formularies. The following prior authorization criteria should apply.

- Medical record documentation of intolerance to or contraindication to preferred levoleucovorin calcium products.

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

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### **QMIIZ ODT (meloxicam ODT)**

**Recommendation:** Qmiiz ODT is a pharmacy benefit that will not be added to the Commercial and Exchange. The following prior authorization criteria will apply:

- Medical record documentation of one of the following:
  - Medical record documentation of a diagnosis of osteoarthritis or rheumatoid arthritis **OR**
  - Medical record documentation of diagnosis juvenile rheumatoid arthritis in member age  $\geq 2$  years and weighing at least 60 kg

**AND**

- Medical record documentation of difficulty swallowing **OR**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) formulary medications, one of which must be meloxicam.

**QUANTITY LIMIT:** 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.

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### **SIKLOS (hydroxyurea)**

**Recommendation:** Siklos is be a pharmacy benefit that will added to the pharmacy formularies at the Specialty tier of Brand Non-Preferred tier for members with a three tier benefit. The following prior authorization criteria will apply:

- Prescription written by or in consultation with a hematologist **AND**
- Medical record documentation of the member being  $\geq 2$  years of age **AND**



- Medical record documentation of a diagnosis of sickle cell anemia AND
- Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea.

Note:

Siklos can be dispersed in a small quantity of water in a teaspoon and administered immediately.

Hydroxyurea is available as 500 mg capsules.

Droxia (hydroxyurea) is available as 200 mg, 300 mg, 400 mg capsules.

Siklos is available in 100 mg and 1,000 mg tablets. The 100 mg tablets can be split into 2 parts (50 mg each). The 1,000 mg tablets can be split into 4 parts (250 mg each).

**Other Recommendations:** Endari requires “medical record documentation of therapeutic failure on, intolerance to, or contraindication to hydroxyurea”, with a note to the reviewer explaining per the NHLBI guidelines, a clinical response to treatment with hydroxyurea may take 3-6 months. To match the language for Siklos, it is recommended to replace that specific criterion with the following for all lines of business.

“Medical record documentation of intolerance to, or contraindication to, or therapeutic failure on a minimum 3 month trial of generic hydroxyurea.”

The following note can be removed from the Endari policies for all lines of business:

“Per the NHLBI guidelines, a clinical response to treatment with hydroxyurea may take 3-6 months”

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

### **SYMPAZAN (clobazam)**

**Recommendation:** Sympazan is a pharmacy benefit that will be added to the brand non-preferred tier of the pharmacy formularies at this time. The following prior authorization criteria will apply:

- Medical record documentation of a diagnosis of Lennox-Gastaut syndrome **AND**
- Medical record documentation that Sympazan is being prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two formulary alternatives, one of which must be generically available clobazam tablets or oral suspension

**QUANTITY LIMIT:** Pharmacist note to CSR: Authorization should be entered by HICL and only checking the Formulary PA required box (no QLs need to be entered within the authorization).

- 2 films per day

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

### **XELPROS (latanoprost)**

**Recommendation:** Xelpros is a pharmacy benefit and will be added to the Brand Preferred tier of the pharmacy formularies. The following step therapy criteria will apply:

**Step therapy for all LOB:**

1. Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
2. If the electronic step therapy criteria are not met, prescribing provider should request an exception for coverage indicating therapeutic failure on, intolerance to, or contraindication to latanoprost.

**Other recommendations:** Zioptan is currently on the brand preferred tier without a prior authorization for Commercial/Exchange and Gold. A prior authorization will be added for new starts. The following criteria will apply:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to latanoprost or Xelpros **AND** Travatan Z

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

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**YUTIQ (fluocinolone acetonide)**

**Recommendation:** Yutiq will be covered as a pharmacy benefit and should not be added to the pharmacy formularies. It will not require a prior authorization.

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

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Meeting adjourned at 3:47 pm.

**Future Scheduled Meetings**

The next bi-monthly scheduled meeting will be held on Tuesday, March 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.