

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

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

Dr. Bret Yarczower called the meeting to order at 1:04 p.m., Tuesday, July 21, 2020.

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**Review and Approval of Minutes:**

Dr. Bret Yarczower asked for a motion or approval to accept the May 19, 2020 and June 17, 2020 minutes as written. Jamie Miller accepted the motion and Kim Clark seconded the motion. None were opposed.

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## DRUG REVIEWS

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### TRODELVY (sacituzumab govitecan-hziy)

**Review:** Trodelvy, sacituzumab govitecan-hziy, is an antibody-drug conjugate indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease. It is comprised of the humanized monoclonal antibody sacituzumab coupled by a CL2A linker to govitecan (SN-38), a topoisomerase I inhibitor that is a more potent active metabolite of irinotecan. Sacituzumab binds trophoblast cell-surface antigen-2 (Trop-2)-expressing cancer cells where hydrolysis of the linker causes the subsequent release and internalization of the cytotoxic agent govitecan resulting in apoptosis and cell death. Trodelvy is the first antibody-drug conjugate (ADC) to target Trop-2 and is the first antibody-drug conjugate approved for patients with previously treated metastatic triple-negative breast cancer (mTNBC).

The efficacy of Trodelvy is supported by results of one cohort of the single arm, open-label IMMU-132-01 trial in 108 patients with metastatic triple-negative breast cancer (mTNBC) who had received at least two prior therapies for metastatic disease. Patients received Trodelvy 10 mg/kg intravenously on days 1 and 8 of each 21-day treatment cycle until disease progression or intolerance to treatment. The primary efficacy endpoint showed an objective response rate of 33.3% (36 out of 108 patients) with a majority of patients achieving a partial response. The median duration of response of 7.7 months. Median progression free survival was 5.5 months and median overall survival was 13.0 months. For the subgroup analysis of Trop-2 status, there were 23/57 (40.4%) responders among patients with moderate to strong staining, 0/5 (0%) responders among patients who had absent or weak staining, and 13/46 (28.3%) among patients with no Trop-2 immunohistochemistry results.

Trodelvy has warnings for severe or life-threatening neutropenia, including febrile neutropenia, gastrointestinal adverse reactions, including diarrhea, nausea, and vomiting, and embryo-fetal toxicity. Hypersensitivity reactions, including anaphylactic reactions have also been reported. The safety profile of Trodelvy in patients with mTNBC was generally consistent with that in the overall safety population who had a variety of tumor types. The most common adverse events during the IMMU-132-01 trial in patients with mTNBC were diarrhea, nausea, fatigue, neutropenia and anemia.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Trodelvy is a medical benefit that will not be added to the Commercial, Exchange, or CHIP pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation that Trodelvy is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of metastatic triple-negative breast cancer\* **AND**
- Medical record documentation of trial of two previous lines of therapy for metastatic disease

\***NOTE:** Triple negative breast cancer lack expression of estrogen receptor (ER-negative), progesterone receptor (PR-negative) and human epidermal growth factor receptor 2 (HER2-negative).

**AUTHORIZATION DURATION:** Initial approval will be for **6 months**. Subsequent approvals will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of

disease progression. The medication will no longer be covered if 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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## **TUKYSA (tucatinib)**

**Review:** Tukysa is a kinase inhibitor that targets human epidermal growth factor receptor 2-positive (HER2), inhibiting phosphorylation of HER2 which in turn inhibits downstream signaling and cell proliferation. It is indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. Tukysa offers a new second-line treatment option for patients needed a HER2-directed therapy and may be the preferred regimen in patients with brain metastases.

The efficacy of Tukysa was shown in the HER2CLIMB trial, a randomized, double blind placebo controlled trial in 612 adult patients with HER2-positive unresectable locally advanced or metastatic breast cancer, with or without brain metastases. Patients included in the trial were previously treated with trastuzumab, pertuzumab, and ado-trastuzumab emtansine, had measurable lesions defined by Response Evaluation Criteria in Solid Tumors (RECIST v 1.1), ECOG scores of 0 or 1, and life expectancy of at least 6 months. Patients were randomized 2:1 to receive Tukysa 300 mg twice daily (n=410) or matching placebo (n=202), in combination with trastuzumab (initial loading dose of 8 mg/kg based on body weight then 6 mg/kg every 21 days) and capecitabine (1000 mg/m<sup>2</sup> based on body-surface area twice daily on days 1 to 14 of each 21-day cycle). The primary efficacy endpoint evaluating progression free survival showed that at one year, the estimated progression free survival was 33.1% for the Tukysa treatment group compared to 12.3% in the placebo group, with a median duration of progression free survival of 7.8 months and 5.6 months, respectively. The confirmed objective response rate was significantly higher in the Tukysa treatment group with a majority of patients achieving a partial response. The Tukysa treatment group also had statistically significant improvements in overall survival and progression free survival in patients with brain metastases at baseline.

Tukysa has warnings for severe diarrhea, severe hepatotoxicity, and embryo-fetal harm. In the HER2CLIMB trial, 26% of patients treated with Tukysa experienced serious adverse reactions including diarrhea, vomiting, nausea, abdominal pain, and seizure. Fatal adverse reactions occurred in 2% of patients and included sudden death, sepsis, dehydration, and cardiogenic shock. The most common adverse reactions in patients treated with Tukysa ( $\geq 20\%$ ) were diarrhea, palmar-plantar erythrodysesthesia, nausea, fatigue, hepatotoxicity, vomiting, stomatitis, decreased appetite, abdominal pain, headache, anemia, and rash.

NCCN recommends Tukysa for use in combination with capecitabine and trastuzumab for recurrent or advanced unresectable or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive disease, including patients with brain metastasis, who have received one or more lines of prior HER2-targeted therapy in the metastatic setting that is hormone receptor negative or hormone receptor positive with or without endocrine therapy (category 1). The recommendation for patients with limited or extensive brain metastases says Tukysa may be considered as initial treatment in select patients (e.g., patients with small asymptomatic brain metastases), treatment for recurrent brain, and as treatment of relapsed disease with stable systemic disease or reasonable systemic treatment options (category 2A).

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 was any specific benefit to brain metastases. Kim called out the PFS results (7.6 months v 5.4 months) in those with brain metastases. No further comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Tukysa is a pharmacy benefit and will be added to the Oral Oncology Brand Non-Preferred tier (\$0 copay) of the Commercial, Exchange, and CHIP pharmacy formularies. The following prior authorization criteria will apply:

- Medical record documentation that prescription is written by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases **AND**
- Medical record documentation that Tukysa will be given in combination with trastuzumab and capecitabine **AND**
- Medical record documentation of prior treatment with at least one anti-HER2 based regimens in the metastatic setting

**QUANTITY LIMIT:**

- **50 mg tablet:** 4 tablets per day
- **150 mg tablet:** 4 tablets per day
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**AUTHORIZATION DURATION:** Initial approval will be for **12 months**. Subsequent approvals will be for an additional 12 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

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

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**TEPEZZA (teprotumumab-trbw)**

**Review:** Tepezza is an insulin-like growth factor-1 receptor indicated for the treatment of Thyroid Eye Disease. Tepezza is the first FDA-approved treatment for thyroid eye disease, also known as Graves' ophthalmopathy/orbitopathy. Prior to the approval of Tepezza, patients had limited treatment options; high-dose glucocorticoids and/or surgery are often used to treat thyroid eye disease.

Tepezza is available as a 500 mg single-dose vial. The recommended dose of Tepezza is an IV infusion of 10 mg/kg for the initial dose followed by 20mg/kg as an IV infusions every 3 weeks for 7 additional infusions. The infusion is administered over 90 minutes for the first two doses. If tolerated, infusion time can be reduced to a minimum of 60 minutes. If the infusion is not well-tolerated, the minimum infusion time should remain at 90 minutes.

The efficacy of Tepezza was assessed in two randomized, placebo-controlled studies of 171 patients with Thyroid Eye Disease. Inclusion criteria for Study 2 included a diagnosis of Graves' disease and moderate-to-severe thyroid eye disease (i.e., lid retraction of  $\geq 2$  mm, moderate or severe soft-tissue involvement, proptosis of  $\geq 3$ mm above the normal values for race and sex, and periodic or constant diplopia) with a Clinical Activity Score of at least 4 in the most symptomatic eye, and symptoms that started within 9 months before the baseline assessment. Patients were

randomized to Tepezza (10mg/kg once then 20mg/kg for remaining infusions) or placebo infusion once every 3 weeks for a total of 8 infusions. The responder rate at 24 weeks was defined as the percentage of patients with  $\geq 2$  mm reduction in proptosis in the study eye from baseline, without worsening of the non-study eye ( $\geq 2$  mm increase) in proptosis. Patients were also evaluated for signs and symptoms of Thyroid Eye Disease including pain, gaze evoked orbital pain, swelling, eyelid erythema, redness, chemosis, inflammation, clinical activity score and assessments of functional vision and patient appearance. In both studies, patients on Tepezza had a significant improvement compared to placebo in the primary outcome of proptosis response at week 24, as well as in all secondary outcomes. In Study 2, the median time to response was 6.4 weeks. Following the discontinuation of treatment in Study 1, 53% of patients who were proptosis responders at week 24 maintained proptosis response 51 weeks after the last Tepezza infusion. Out of the diplopia responders at week 24, 67% of patients maintained response 51 weeks after the last Tepezza infusion.

Tepezza does not carry any black box warnings or contraindications. Warnings and precautions for Tepezza include infusion reactions, exacerbation of pre-existing inflammatory bowel disease, and hyperglycemia. The most common adverse reactions that occurred in 5% or more of patients treated with Tepezza (incidence greater than placebo) included muscle spasms, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache and dry skin. Tepezza should not be used in pregnancy and appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose. If the patient becomes pregnant during treatment, Tepezza should be discontinued. The safety and effectiveness have not been established in pediatric patients.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Outcome:** Tepezza will be a medical benefit for commercial/exchange/CHIP members. Tepezza will require a prior authorization with the following criteria:

- Prescription written by an ophthalmologist **AND**
- Medical record documentation of the member being  $\geq 18$  years of age **AND**
- Medical record documentation of a diagnosis of Grave's disease **AND**
- Medical record documentation of moderate to severe Thyroid Eye Disease with documentation of one or more of the following: lid retraction of  $\geq 2$ mm, moderate or severe soft-tissue involvement, proptosis  $\geq 3$  mm above normal values for race and sex; and periodic or constant diplopia **AND**
- Medical record documentation that the member is euthyroid or has mild hypo- or hyperthyroidism (free T4 and free T3 levels  $<50\%$  above or below normal limits) prior to starting Tepezza therapy **AND**
- Medical record documentation that the member is being prescribed an appropriate dose and duration of Tepezza (10 mg/kg as a single dose, followed by 20 mg/kg IV every 3 weeks for 7 additional doses) **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to systemic steroids

**AUTHORIZATION DURATION:** Approval will be for one (1) 6 month authorization for the FDA-approved maximum of 8 doses of Tepezza. Requests for authorizations exceeding these limits will require the following medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration.

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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### **PALFORZIA (Peanut (*Arachis hypogaea*) Allergen Powder-dnfp)**

**Review:** Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with confirmed diagnosis of peanut allergy. Palforzia is indicated for initial dose escalation in patients 4 to 17 years and for up-dosing and maintenance in patients 4 years and older. It is a peanut-derived oral biologic drug with a design similar to non-standardized oral immunotherapy (OIT) but offers more precise dosing that gradually exposes the immune system to increasing amounts of peanut protein over time. It does not provide a complete tolerance to peanuts and patients will still need to be managed with a peanut-avoidant diet and epinephrine for severe reactions due to accidental exposure.

The efficacy of Palforzia was shown in the PALISADES trial, a randomized double-blind placebo controlled trial in patients with a clinical history of peanut allergy confirmed by peanut-specific IgE or skin prick test results. Patients underwent a screening double-blind, placebo controlled food challenge and were eligible for randomization if they had an allergic reaction with dose-limiting symptoms to < 100 gm of peanut protein. Patients were randomized 3:1 to receive Palforzia (initial dose escalation, up-dosing, and maintenance dose) or matching placebo for approximately 12 months. At the end of the trial, patients underwent a second double-blind, placebo controlled food challenge designed similar to the first, but included higher doses of peanut protein (300 mg, 600 mg, 1000 mg). The primary efficacy endpoint investigating treatment response rate in patients 4 to 17 years showed that 67.2% of patients treated with Palforzia were able to ingest a single dose of at least 600 mg of peanut protein during the exit food challenge, with no dose-limiting symptoms compared to 4.0% for placebo. Secondary endpoints showed a significant decrease in allergic reactions to 300 mg and 1000mg as well as a decrease in the severity of reactions, a decrease in epinephrine use from baseline, and a decrease in wheal size on skin prick test results.

Palforzia is peanut-derived and may cause similar severe allergic reactions, including anaphylaxis, which has been reported during all phases of Palforzia dosing. Due to this risk, Palforzia must be slowly titrated in a healthcare setting while the patient is monitored for reactions. Patients must also be enrolled in a REMS program which requires them to be informed about the need to have injectable epinephrine available for immediate use at all times, the need for monitoring after each dose increase, and the need for continued dietary peanut avoidance. Other warnings include increased risk of serious outcomes in patients with uncontrolled or severe asthma and gastrointestinal adverse reactions, which may be severe. In clinical trials, the most common adverse reactions in subjects treated with Palforzia were gastrointestinal, respiratory, and skin symptoms commonly associated with allergic reactions. Adverse reactions from Palforzia led to discontinuation in 9.3% of patients during the initial dose escalation and up-dosing phases combined and no subjects in the maintenance phase. The most common causes of discontinuation were gastrointestinal reactions and respiratory disorders.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Palforzia is a pharmacy benefit and will not be added to the Commercial, Exchange, or CHIP pharmacy formularies. The following prior authorization criteria should apply:

- Medical record documentation that Palforzia is prescribed by an allergist, immunologist, or a physician qualified to prescribe allergy immunotherapy **AND**
- If the request is for initial dose escalation: Medical record documentation that member is greater than or equal to 4 years of age to less than 18 years of age **OR**
- If the request is for up-dosing or maintenance dose: Medical record documentation that member is greater than or equal to 4 years of age

**AND**

- Medical record documentation of confirmed diagnosis of peanut-allergy with history of allergic reaction from peanuts **AND** one of the following:
  - positive skin test **OR**
  - *in vitro* testing for peanut-specific IgE antibodies

**AND**

- Medical record documentation that Palforzia will be used in conjunction with peanut-avoidant diet **AND**
- Medical record documentation that the member has (or will receive) a prescription for an epinephrine auto-injector **AND**
- Medical record documentation that the member does not have severe, unstable, or uncontrolled asthma **AND**
- Medical record documentation that the member has no experienced severe or life-threatening anaphylaxis within 60 days of Palforzia initiation

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

Packaging Presentation	Quantity Limits
<b>Initial Dose Escalation</b>	
0.5 mg to 6 mg capsules	13 capsules / 1 days, RX Count: 2
<b>Up-Dosing</b>	
3 mg (Level 1)	3 capsules / day, 30 day supply per fill
6 mg (Level 2)	6 capsules / day, 30 day supply per fill
12 mg (Level 3)	3 capsules / day, 30 day supply per fill
20 mg (Level 4)	1 capsule / day, 30 day supply per fill
40 mg (Level 5)	2 capsules / day, 30 day supply per fill
80 mg (Level 6)	4 capsules / day, 30 day supply per fill
120 mg (Level 7)	2 capsules / day, 30 day supply per fill
160 mg (Level 8)	4 capsules / day, 30 day supply per fill
200 mg (Level 9)	2 capsules / day, 30 day supply per fill
240 mg (Level 10)	4 capsules / day, 30 day supply per fill
300 mg (Level 11)	1 packet / day, 30 day supply per fill
<b>Maintenance</b>	
300 mg (Level 11)	1 packet / day, 30 day supply per fill

**AUTHORIZATION DURATION:** Initial authorizations for Palforzia will be approved for a period of 12 months. Subsequent authorizations will be for a period of 12 months and will require the following criteria:

- Medical record documentation that patient is not experiencing unacceptable toxicity **AND**
- Medical record documentation that patient does not have recurrent asthma exacerbations or persistent loss of asthma control **AND**
- Medical record documentation that patient does not have suspected eosinophilic esophagitis

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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## **REYVOW (lasmiditan)**

**Review:** Reyvow is indicated for the acute treatment of migraine with or without aura in adults. Reyvow is the first and only serotonin (5-HT)<sub>1F</sub> receptor agonist approved by the FDA for the treatment of acute migraine. Traditionally for acute migraine treatment, the American Headache Society (AHS) recommends triptan products as the current gold standard, in addition to NSAIDs and ergotamine derivatives. Reyvow, ergots, and the triptans all target serotonin receptors, though the specific receptor target and affinity differs among these agents. Reyvow has not demonstrated in trials to have significant cardiovascular effects such as those seen with triptans.

Reyvow is available as 50 mg and 100 mg tablets in a blister pack of 8 tablets. The recommended dose of Reyvow is 50 mg, 100 mg, or 200 mg taken orally, as needed, with or without food. No more than one dose should be taken in 24 hours, and Reyvow should not be taken unless the patient can wait at least 8 hours between dosing and driving or operating machinery. A second dose of Reyvow has not been shown to be effective for the same migraine attack. The safety of treating an average of more than four migraine attacks in a 30-day period has not been established.

The efficacy of Reyvow in the acute treatment of migraine was demonstrated in two randomized, double-blind, placebo-controlled trials. In both trials, patients were randomized to Reyvow or placebo. In both studies, the percentage of patients achieving pain freedom and MBS freedom 2 hours after treatment was significantly greater among patients receiving Reyvow at all doses compared to those receiving placebo. For the Reyvow 200 mg cohort, the number needed to treat compared to placebo at two hours for pain freedom, MBS freedom, and pain relief was 6, 7-9, and 7, respectively.

The most common adverse reactions (at least 5%) were dizziness, fatigue, paresthesia, and sedation. Although Reyvow is not expected to have significant cardiovascular effects like the triptans, it is suggested that heart rate and blood pressure be monitored, especially if the patient is taking other medications that influence heart rate and blood pressure. There are no black box warnings or contraindications for Reyvow, but there are warnings and precautions to include driving impairment, central nervous system depression, serotonin syndrome, and medication overuse headaches. Additionally, Reyvow is a schedule V controlled substance due to its abuse potential related to desirable effects of relaxation, euphoria and hallucinations seen to a greater extent with Reyvow when compared to placebo; euphoric effects of Reyvow were similar to alprazolam, but relaxation was noted in more of the alprazolam cohort than with any dose of Reyvow. However, Reyvow was not shown to exhibit physical withdrawal following abrupt cessation after 7 daily doses. The safety and effectiveness in pediatric patients have not been established.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** If packs come in quantities of 8, may they be split, since we are implementing a QL of 4 for the 50 mg tablets; Yes, packs can be split, so should be able to provide a quantity of 4. Keith asked, if QL for the 100 mg is 8/day (to make a 200 mg dose), if there was a way to assure patients were not treating more than 1 headache daily (100 mg now, then 100 mg later). Should a dosing criteria be added to the authorization criteria? Even if they were using a second dose, they would still be below the max dose of 200 mg. committee decided to not add additional dosing criteria at this time. If quantity limit exceeded, would review a quantity limit exception

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

**Outcome:** Reyvow is a pharmacy benefit and will not be added to the formulary. Reyvow will require a prior authorization with the following criteria.

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Reyvow will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to nonsteroidal anti-inflammatory drug (NSAID) therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary triptans

**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).

- **50 mg: 4 tablets per 30 days**
- **100 mg: 8 tablets per 30 days**

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

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### **NURTEC ODT (rimegepant)**

**Review:** Nurtec ODT is indicated for the acute treatment of migraine with or without aura in adults. The American Headache Society recommends triptans and ergots as the traditional standards for treatment of acute migraine of moderate to severe intensity, or refractory to simpler analgesics (e.g. non-steroidal anti-inflammatory drugs). Nurtec ODT is the first orally disintegrating tablet formulation of the small molecule calcitonin gene-related peptide (CGRP) receptor antagonist drug class to be approved by the FDA, joining Ubrelvy (ubrogepant) in the space of oral CGRP receptor inhibitors for the treatment of acute migraine.

Nurtec ODT is available as a 75 mg orally disintegrating tablet. The recommended dose of Nurtec ODT is 75 mg taken orally; the maximum dose in a 24-hour period is 75 mg, and the safety of treating more than 15 migraines in a 30-day period has not been established. Unlike Ubrelvy, Nurtec does not allow for repeat dosing.

The efficacy of Nurtec ODT for the acute treatment of migraine with and without aura in adults was demonstrated in a randomized, double-blind, placebo-controlled trial that randomized patients to 75 mg of Nurtec ODT or placebo. The percentage of patients achieving headache pain freedom and most bothersome symptom (MBS) freedom two hours after a single dose was statistically significantly greater in patients who received Nurtec ODT compared to those who received placebo. Additionally, statistically significant effects of Nurtec ODT compared to placebo were demonstrated for the secondary efficacy endpoints of pain relief at 2 hours, sustained pain freedom at 2-48 hours, use of rescue medication within 24 hours, and the percentage of patients reporting normal function at two hours after dosing. Also, the incidence of photophobia and phonophobia was reduced following administration of Nurtec ODT as compared to placebo.

The most common adverse reaction in Study 1 was nausea (2% in patients who received Nurtec ODT compared to 0.4% of patients who received placebo). There are no black box warnings for Nurtec ODT and the only contraindication is for avoidance in patients with a history of hypersensitivity reaction to rimegepant, Nurtec ODT, or any components. Nurtec ODT's label indicates a recommendation to avoid use with strong CYP3A4 inhibitors and avoid another dose of Nurtec ODT within 48 hours for moderate CYP3A4 inhibitors. Nurtec should be avoided

with strong or moderate inducers, as well as P-gp or BCRP inhibitors. Additionally, Nurtec ODT's label recommends avoiding its use in severe hepatic or end-stage renal disease. The safety and effectiveness in pediatric patients have not been established.

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

**Clinical Discussion:** No comments or questions. The committee voted to accept the recommendations as presented. None were opposed. Todd Sponenberg abstained from voting on this product.

**Financial Discussion:** No comments or questions. The committee voted to accept the recommendations as presented. None were opposed. Todd Sponenberg abstained from voting on this product

**Outcome:** Nurtec ODT is a pharmacy benefit and will not be added to formulary. Nurtec ODT will require a prior authorization with the following criteria:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Nurtec ODT will be used for the acute treatment of migraine with or without aura **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to nonsteroidal anti-inflammatory drug (NSAID) therapy **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary triptans **AND**
- Medical record documentation that Nurtec ODT will not be used concomitantly with another calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine (e.g. Ubrelvy)

**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).

- **15 tablets per 30 days**

**Additional recommendations:** It is recommended to add the following language to the Ubrelvy policy (Policy 626.0):

- Medical record documentation that Ubrelvy will not be used concomitantly with another CGRP antagonist indicated for the acute treatment of migraine (e.g. Nurtec ODT)

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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## **VYEPTI (eptinezumab-jjmr)**

**Review:** Vyepti is Indicated for the preventive treatment of migraine in adults. Vyepti joins Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), and Emgality (galcanezumab-gnlm) as the fourth calcitonin gene-related peptide (CGRP) antagonist approved for the preventive treatment of migraine in adults. Vyepti is the first intravenous CGRP antagonist. Vyepti represents a new option for patients that do not want to self-administer medications and has a less frequent dosing schedule for the prevention of migraines in both the episodic and chronic populations.

Vyepti is available as 100 mg/mL solution in a single-dose vial for intravenous infusion given over 30 minutes by a healthcare provider. The recommended dosage is 100 mg every 3 months; some patients may benefit from a dosage of 300 mg every 3 months.

The safety and efficacy of Vyepti for the preventive treatment of episodic or chronic migraine was evaluated in two multicenter, placebo-controlled studies, both with 6-month double-blind periods: one study included patients with episodic migraine (Study 1) and one study included patients with chronic migraine (Study 2). In both studies, Vyepti was administered as an intravenous infusion every 3 months; however, the primary endpoint was measured at 12 weeks.

Study 1 included adults with a history of episodic migraine (4 to 14 headache days per month, of which at least were 4 migraine days). A total of 665 patients were randomized to placebo, Vyepti 100 mg, or Vyepti 300 mg every 3 months for 12 months. Vyepti demonstrated statistically significant improvement in change from baseline in mean monthly migraine days over months 1-3 compared to placebo. Secondary endpoints included the percentage of patients with 50% or greater and 75% or greater reductions from baseline in monthly migraine days over months 1-3. Vyepti 100 mg and 300 mg had a statistically significant greater percentage of patients with at least a 50% reduction from baseline compared to placebo. Vyepti 300 mg had a statistically significant greater percentage of patients with at least a 75% reduction from baseline compared to placebo.

Study 2 included adults with a history of chronic migraine (15 to 26 headache days per month, of which at least 8 were migraine days). A total of 1072 patients were randomized to receive placebo, Vyepti 100 mg, or Vyepti 300 mg every 3 months for 6 months. Forty-one percent of patients were taking concomitant preventive medication for migraine. Vyepti demonstrated statistically significant improvements compared in the change from baseline in mean monthly migraine days over months 1-3. Secondary endpoints included the percentages of patients with 50% or greater and 75% or greater reductions from baseline in monthly migraine days over months 1-3. Vyepti 100 mg and 300 mg had statistically significant greater percentage of patients with at least a 50% and 75% reduction from baseline compared to placebo.

There are no black box warnings associated with the use of Vyepti. It is contraindicated in patients with serious hypersensitivity to Vyepti or to any of the excipients. The most common adverse reactions reported in clinical studies (incidence  $\geq 2\%$  and 2% or greater than placebo) were nasopharyngitis and hypersensitivity. The safety and effectiveness in pediatric patients have not been established.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Vyepti will be a medical benefit for commercial/exchange/CHIP members. Vyepti will require a prior authorization with the following criteria:

- Prescription written by or in consultation with a neurologist or headache specialist **AND**
- Medical record documentation of the patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of migraine with or without aura, based on the ICHD-III diagnostic criteria **AND**
- Medical record documentation of the number of baseline migraine or headache days per month **AND**
- Medical record documentation of the patient experiencing 4 or more migraines per month **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Aimovig and Emgality **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
  - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox **AND**
  - Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of CGRP antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality)

<b>ICHD-III Diagnostic Criteria <sup>4</sup></b>	
<b><u>Migraine without Aura:</u></b>	<b><u>Migraine with Aura:</u></b>
A) At least five (5) attacks fulfilling criteria B through D below:	A) At least two (2) attacks fulfilling criteria B through C below:
B) Headache lasting 4 to 72 hours (untreated or unsuccessfully treated)	B) One (1) or more of the following fully reversible aura symptoms: <ul style="list-style-type: none"> <li>○ Visual</li> <li>○ Sensory</li> <li>○ Speech and/or language</li> <li>○ Motor</li> <li>○ Brainstem</li> <li>○ Retinal</li> </ul>
C) Headache with at least two (2) of the following characteristics: <ul style="list-style-type: none"> <li>○ unilateral location</li> <li>○ pulsating quality</li> <li>○ moderate to severe pain intensity</li> <li>○ aggravation by or causing avoidance of routine physical activity (e.g. walking or climbing stairs)</li> </ul>	C) At least three (3) of the following: <ul style="list-style-type: none"> <li>○ at least one (1) aura symptom spreads over 5 or more minutes</li> <li>○ two (2) or more aura symptoms occur in succession</li> <li>○ each individual aura symptom lasts 5 to 60 minutes<sup>1</sup></li> <li>○ at least one (1) aura symptom is unilateral<sup>2</sup></li> <li>○ at least one (1) aura symptom is positive<sup>3</sup></li> <li>○ the aura is accompanied, or followed within 60 minutes, by a headache</li> </ul>
D) At least one of the following during the headache: <ul style="list-style-type: none"> <li>○ nausea and/or vomiting</li> <li>○ photophobia and phonophobia</li> </ul>	D) Not better accounted for by another ICHD-3 diagnosis
E) Not better accounted for by another ICHD-3 diagnosis	

**AUTHORIZATION DURATION:** Initial approval will be for three (3) months and subsequent approvals will be for twelve (12) months.

**REAUTHORIZATION CRITERIA:**

- Medical record documentation of continued or sustained reduction in migraine or headache frequency **AND**
- If the request is for Vyepti 300 mg every 3 months, medical record documentation of therapeutic failure on Vyepti 100 mg every 3 months **AND**
- If the request is for use in combination with Botox, all of the following must be met:
  - Medical record documentation of therapeutic failure on a minimum 3 month trial of at least one CGRP antagonist without the concomitant use of Botox **AND**

- Medical record documentation of therapeutic failure on a minimum 6 month trial of Botox without the concomitant use of CGRP antagonist **AND**
- Medical record documentation that Vyepti will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine (e.g. Aimovig, Ajovy, Emgality)

**QUANTITY LIMIT:**

If request is for 100 mg every 3 months:

**Initial 3 months:** Facets Rx count: 100 (C9063); Medaccess 1 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

**Subsequent 12 months:** Facets Rx count: 400 (C9063); Medaccess 1 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

If the request is for 300 mg every 3 months:

**Initial 3 months:** Facets Rx count: 300 (C9063); Medaccess 3 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

**Subsequent 12 months:** Facets Rx count: 1,200 (C9603); Medaccess 3 vial per 90 days; max qty supply:1; min day supply: 84; max day supply: 90

**Additional Recommendations:**

It is recommended to add the following language to Aimovig to both initial and re-authorization criteria for Commercial/Exchange/CHIP (Policy 511.0):

- Medical record documentation that Aimovig will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine (e.g., Ajovy, Emgality, Vyepti)

It is recommended to add the following language to Emgality to both initial and re-authorization criteria for Commercial/Exchange/CHIP (Policy 533.0):

- Medical record documentation that Emgality will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine (e.g., Ajovy, Aimovig, Vyepti)

It is recommended to add the following language to Ajovy to both initial and re-authorization criteria for Commercial/Exchange/CHIP (Policy 532.0):

- Medical record documentation that Ajovy will not be used concomitantly with another CGRP antagonist indicated for the preventive treatment of migraine (e.g., Aimovig, Emgality, Vyepti)

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

**TABRECTA (capmatinib)**

**Review:** Tabrecta is a tyrosine kinase inhibitor that exerts its effect on the mesenchymal-epithelial transition (MET) receptor, a biomarker that has been identified in non-small cell lung cancer as well as other cancer types. It inhibits the phosphorylation of MET as well as MET-mediated phosphorylation of downstream signaling proteins which contribute to proliferation and survival of MET-dependent cancer cells. Tabrecta is the first FDA approved therapy for patients with NSCLC whose tumors have a mutation leading to MET exon 14 (METex14) skipping.

The efficacy of Tabrecta was investigated in GEOMETRY mono-1, a non-randomized, open-label, multi-cohort study in patients with NSCLC with a mutation that leads to METex14 skipping. The study included both treatment naïve (n=28) and previously treated patients(n=69) with most patients receiving platinum based chemotherapy for

their initial treatment. Patients who had previously received treatment targeting MET or hepatocyte growth factor (HGF) were excluded from the study.

Patients received Tabrecta 400 mg twice daily until disease progression or unacceptable toxicity. The primary endpoint assessing overall response rate (RECIST v1.1) found a response rate of 68% in treatment naïve patients and 41% in previously treated patients with a majority of patients having a partial response. The median duration of response was 12.6 months in treatment naïve patients and 9.7 months in previously treated patients.

Tabrecta has warnings and precautions for interstitial lung disease (ILD)/pneumonitis, hepatotoxicity (increases in ALT/AST), photosensitivity, and embryo-fetal harm. Serious adverse events were reported in 51% of patients during the GEOMETRY mono-1 trial, most commonly dyspnea, pneumonia, pleural effusion, physical health deterioration, nausea, and vomiting. The most common adverse events during clinical trials were peripheral edema, nausea, fatigue, vomiting, dyspnea, and decreased appetite.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Outcome:** Tabrecta is a pharmacy benefit and will be added to Oral Oncology Brand Non Preferred Tier (\$0 copay) for the Commercial/Exchange/CHIP formularies. The following prior authorization criteria will apply:

- Medical record documentation that Tabrecta is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping

**QUANTITY LIMIT:** 4 tablets per day, 30 day supply per fill

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

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

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## **RETEVMO (selpercatinib)**

**Review:** Retevmo is the first tyrosine kinase inhibitor (TKI) to selectively inhibit *RET* and the first targeted therapy specific for *RET* gene driven cancers. It is indicated adult patients with metastatic *RET* fusion-positive non-small cell lung cancer (NSCLC), adult and pediatric patients 12 years and older with advanced metastatic *RET*-mutant medullary thyroid cancer (MTC) who require systemic therapy and adult and pediatric patients 12 years and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require system therapy and who are radioactive-iodine refractory (if radioactive iodine is appropriate).

The efficacy of Retevmo was investigated in Phase 2 of the LIBRETTO-001 trial, an ongoing, open-label, multicohort trial in patients with advanced solid tumors, including *RET* fusion-positive solid tumors, medullary thyroid cancer and other tumors with *RET* activation.

One cohort evaluated the efficacy of Retevmo patients with advanced or metastatic *RET* fusion-positive NSCLC who were treatment naïve (n=39) or who had progressed on platinum-based chemotherapy (n=105). Patients received Retevmo 160 mg orally twice daily until unacceptable toxicity or disease progression. The primary efficacy outcome evaluating confirmed overall response rate (ORR) showed an 85% overall response rate in treatment naïve patients and a 64% response rate in previously treatment patients. The median duration of response was not estimable for treatment naïve patients and was 17.5 months for previously treated patients and responses lasted at least 6 months for 58% and 81% of treatment naïve and previously treated patients respectively.

A second cohort evaluated the efficacy of Retevmo in evaluated patients with advanced or metastatic *RET*-mutant medullary thyroid cancer who were Cometriq and Caprelsa treatment naïve (n=88) and those who had been previously treated with Cometriq, Caprelsa, or both (n=55). The primary efficacy outcome evaluating confirmed overall response rate (ORR) showed a 73% overall response rate in Cometriq/Caprelsa treatment naïve patients and a 69% response rate in previously treated patients. The median duration of response was 22.0 months and 17.5 months for treatment naïve and previously treated patients, respectively.

A third cohort evaluated Retevmo in patients with *RET* fusion positive thyroid cancer who were radioactive iodine (RAI)-refractory and were systemic treatment naïve (n=8) and patients who were RAI-refractory and had received Lenvima, Nexavar, or both (n=19). All patients had metastatic disease with primary tumor histologies including papillary thyroid cancer (78%), poorly differentiated thyroid cancer (11%), anaplastic thyroid cancer (7%), and Hurthle cell thyroid cancer (4%). The primary efficacy outcome evaluating confirmed overall response rate (ORR) showed a 79% response rate in previously treated patients and a 100% response rate in systemic treatment naïve patients. The median duration of response was 18.4 months in the previously treated patients and not estimable in the systemic treatment naïve patients.

Retevmo contains warnings for hepatic adverse reactions, including increases in AST and ALT, hypertension, QT interval prolongation, hypersensitivity, embryo-fetal toxicity, prolonged wound healing, and serious, including fatal, hemorrhagic events. During clinical trials in patients with *RET* gene fusion or gene mutation positive solid tumors, serious adverse reactions occurred in 33% of patients, most frequently pneumonia. Fatal adverse reactions occurred in 3% of patients, including sepsis, cardiac arrest, and respiratory failure. The most common adverse reactions included laboratory abnormalities (including increased AST, ALT, glucose, creatinine, and cholesterol and decreased albumin, leukocytes, platelets, and calcium), dry mouth, diarrhea, hypertension, rash, and constipation.

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

**Clinical Discussion:** A question was asked if we would know the mutation, if there is no FDA specific approved test. Kim stated that there is another test that can be utilized, so it should be known. No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Outcome:** Retevmo is a pharmacy benefit and will be added to Oral Oncology Brand Non Preferred Tier (\$0 copay) for the Commercial/Exchange/CHIP formularies. The following prior authorization criteria will apply:

### Non-Small Cell Lung Cancer

- Medical record documentation that Retevmo 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 *RET*-fusion positive non-small cell lung cancer (NSCLC)

### Thyroid Cancer

- Medical record documentation that Retevmo is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of advanced metastatic *RET*-mutant medullary thyroid cancer (MTC) **AND** medical record documentation that systemic therapy is required

#### **OR**

- Medical record documentation of advanced or metastatic *RET* fusion-positive thyroid cancer **AND** medical record documentation of both of the following:
  - Documentation that systemic therapy is required **AND**
  - Documentation that patient is radioactive-iodine refractory when radioactive iodine is appropriate

#### **QUANTITY LIMITS:**

- **40 mg capsules:** 2 capsules per day
- **80 mg capsules:** 4 capsules per day

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

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

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### **QINLOCK (ripretinib)**

**Review:** Qinlock is a kinase inhibitor indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib. The recommended dose of Qinlock is 150 mg orally once daily until disease progression or unacceptable toxicity. Qinlock is available in 50 mg tablets and should be dispensed in its original container. The recommended dose reduction for adverse reactions is 100 mg orally once daily. The efficacy of Qinlock was evaluated in an international, multi-center, randomized, double-blind, placebo-controlled trial. Eligible patients had unresectable, locally advanced or metastatic GIST and had received prior treatment with imatinib, sunitinib, and regorafenib. Patients received Qinlock 150 mg or placebo orally once daily until disease progression or unacceptable toxicity. The major efficacy outcome measure was progression-free survival (PFS) based on disease assessment by blinded independent central review (BICR) using modified RECIST 1.1 criteria. The progression free survival was significantly longer for those receiving Qinlock (6.3 months) compared to placebo (1.0 month). Additionally, Qinlock showed a median overall survival of 15.1 months compared to 6.6 months in the placebo group and a reduced risk of death by 64% (HR=0.36).

Qinlock has no boxed warnings, but does have warnings and precautions for palmar-plantar erythrodysesthesia syndrome (PPES), new primary cutaneous malignancies, hypertension, cardiac dysfunction, risk of impaired wound healing, and embryo-fetal toxicity. The most common adverse reactions ( $\geq 20\%$ ), were alopecia, fatigue, nausea,

abdominal pain, constipation, myalgia, diarrhea, decreased appetite, PPES, and vomiting. The safety and effectiveness in pediatric patients have not been established.

Per NCCN, Qinlock is the preferred fourth-line therapy for unresectable or metastatic disease progressive after single agent therapy with imatinib, sunitinib, and regorafenib.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Outcome:** Qinlock will be a pharmacy benefit. It is recommended that Qinlock be added to the Commercial/Exchange/CHIP formularies at the OralOncBrandNP tier. Qinlock will require a prior authorization with the following criteria:

- Prescription written by or in consultation with an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of advanced gastrointestinal stromal tumor (GIST) **AND**
- Medical record documentation of prior treatment with three (3) or more kinase inhibitors, including imatinib

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

**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).

- **90 tablets per 30 days**

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

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## **ZIEXTENZO (pegfilgrastim-bmez)**

**Review:** Ziextenzo is a biosimilar leukocyte colony-stimulating factor that is highly similar to the US-licensed reference product, Neulasta, indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Ziextenzo is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. Ziextenzo acts on hematopoietic cells by binding to cell surface receptors and stimulating proliferation, differentiation commitment, and end-cell functional activation. Ziextenzo is the third FDA-approved pegfilgrastim biosimilar, the first being Fulphila (pefilgrastim-jmdb) and the second being Udenyca (pegfilgrastim-cbqv). None of the pegfilgrastim biosimilar products are interchangeable with Neulasta. Neulasta Onpro offers a “on-body” administration method and is unique to Neulasta. The on-body administration is not available with any of the biosimilar products. Although Ziextenzo does not have an on-body

administration available, the manufacturer of Ziextenzo, Sandoz, offers free in-home injection training via in-home visits (or remote video/tele-visits) where a nurse trainer provides eligible patients detailed instructions on the administration of Ziextenzo.

LA-EP06-104 was a randomized, double-blind, three-way cross over study demonstrated PK and PD similarity between Ziextenzo, Neulasta-EU, and Neulasta-US. PROTECT 1 was a randomized, double-blind, parallel-group, multi-center Phase III comparative study that demonstrated therapeutic equivalence in efficacy, safety, and immunogenicity between Ziextenzo and Neulasta in breast cancer patients treated with myelosuppressive chemotherapy. PROTECT 2 was the pivotal randomized, double-blind, parallel-group, active-controlled multi-center, Phase 3 study that demonstrated therapeutic equivalence in efficacy, safety, and immunogenicity between Ziextenzo and Neulasta for the reduction of severe neutropenia in breast cancer patients treated with myelosuppressive chemotherapy.

The safety considerations of Ziextenzo are consistent with those of the other pegfilgrastim reference and biosimilar products. Ziextenzo is contraindicated in patients with a history of serious allergic reactions to pegfilgrastim products or filgrastim products. In clinical trials, there were no meaningful differences in safety between Ziextenzo and Neulasta. In PROTECT 1, the most common adverse events included alopecia, nausea, asthenia, vomiting, and neutropenia. In PROTECT 2 the most frequently reported adverse event was bone pain.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Ziextenzo will be a pharmacy or medical benefit requiring prior authorization and will be added to the specialty tier (brand non-preferred tier for members with a 3-tier benefit). It is recommended that the clinical criteria of its reference product, Neulasta, outlined by Policy 162.0 and MBP 59.0 apply and that a “biosimilar first” approach be taken for the pegfilgrastim products as outlined below.

#### Policy 162.0

#### **NEUPOGEN, NEULASTA, FULPHILA, UDENYCA, **ZIEXTENZO**, LEUKINE, ZARXIO, GRANIX AND NIVESTYM**

- **Medical record documentation of a diagnosis of cancer, and when any of the following FDA labeled indications or uses supposed by clinical guidelines are present:**

**Primary Prophylaxis** – For the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

**NOTE:** Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**OR**

For the prevention of FN when the risk of developing FN is less than 20%, but **any** other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or open wounds or active infection
- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin greater than 2.0)
- Renal dysfunction (CrCl less than 50)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

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**NEUPOGEN, NEULASTA, FULPHILA, UDENYCA, ZIEXTENZO, LEUKINE, ZARXIO, AND NIVESTYM**

- **Medical record documentation of any of the following FDA labeled indications or uses supposed by clinical guidelines:**

**Secondary Prophylaxis** – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Treatment of Febrile Neutropenia** – as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Dose Dense Therapy** – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin’s lymphoma

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Stem Cell Transplantation** – when one of the following is met:

- Bone marrow transplant (BMT) –
  - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)

OR

- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
  - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**NOTE: Neulasta, Udenyca, Ziextenzo, and Fulphila are considered off-label for PBPC mobilization.**

**Leukemia or Myelodysplastic Syndromes** – insured individuals with:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Lymphoma** – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Radiation therapy** –

- If prolonged delays secondary to neutropenia are anticipated
- As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**NOTE: Fulphila, Ziextenzo, and Udenyca are considered off-label for radiation injury syndrome; however, the biosimilars are considered medically accepted for this use by the NCCN guidelines.**

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#### **NEUPOGEN, ZARXIO, AND NIVESTYM**

- **Medical record documentation of any of the following FDA labeled indications or uses supposed by clinical guidelines:**

**Severe Chronic Neutropenia** – when the following criteria are met:

- Diagnosis of congenital, cyclic, or idiopathic neutropenia **AND**
  - Documentation of an absolute neutrophil count (ANC) <500 cells/mm<sup>3</sup> on three separate occasions during a 6 month period (for congenital or idiopathic neutropenia) **OR** five consecutive days of ANC <500 cells/mm<sup>3</sup> per cycle (for cyclic neutropenia) **AND**
  - Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months
  - prolonged delays secondary to neutropenia are anticipated.
- 

#### **LEUKINE**

- **Medical record documentation of any of the following FDA labeled indications or uses supposed by clinical guidelines:**

**Delayed Neutrophil Recovery or Graft Failure**

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery\* has not occurred.

\*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm<sup>3</sup> or greater.

**AUTHORIZATION DURATION:** 6 months

**NEULASTA/FULPHILA/UDENYCA/ZIEXTENZO QUANTITY LIMIT:** 0.043mL per day (1 syringe per 14 days)

If an exception is made, Neupogen, Neulasta, Fulphila, Nivestym, Udenyca, Ziextenzo, Leukine, Zarxio, or Granix will be paid for under the member's prescription drug benefit.

#### **EXCLUSIONS:**

There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for "priming" effect; or

- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 days.

Medical Benefit Policy (MBP 59.0)

**DESCRIPTION:**

White blood cell stimulating factors such as granulocyte colony stimulating factors (G-CSF) [e.g., Neupogen (*filgrastim*), Neulasta (*pegfilgrastim*), Nivestym (*filgrastim-aafi*), Fulphila (*pegfilgrastim-jmdb*), Udenyca (*pegfilgrastim-cbqv*), **Ziextenzo (*pegfilgrastim-bmez*)**, Zarxio (*pegfilgrastim-sndz*), and Granix (*tbo-filgrastim*) and granulocyte-macrophage colony stimulating factor (GM-CSF) [e.g., Leukine (*sargramostim*)] are synthetic stimulants and anti-neutropenic agents administered to decrease the incidence and/or severity of infection associated with drug-related myelosuppression and to assist recovery of hematopoietic function in neutropenia.

**CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee**

**Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, Leukine, Granix:**

The use of white blood cell stimulating factor [Neupogen (*filgrastim*), Neulasta (*pegfilgrastim*), Nivestym (*filgrastim-aafi*), Fulphila (*pegfilgrastim-jmdb*), Udenyca (*pegfilgrastim-cbqv*), **Ziextenzo (*pegfilgrastim-bmez*)**, Granix (*tbo-filgrastim*), Zarxio (*filgrastim-sndz*), or Leukine (*sargramostim*)] is considered medically necessary in insured individuals with a diagnosis of cancer, and when any of the following FDA labeled indications or uses supported by clinical guidelines are present:

**1. Primary Prophylaxis** - the prevention of febrile neutropenia (FN) when the risk of FN due to the myelosuppressive chemotherapy regimen is 20% or greater. Those regimens include but are not limited to:

- TC (paclitaxel/cisplatin, or cyclophosphamide/docetaxel or docetaxel/cisplatin or paclitaxel/carboplatin)
- MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
- AC (doxorubicin, cyclophosphamide, docetaxel)
- AT (doxorubicin, paclitaxel)
- TIC (paclitaxel, ifosfamide, mesna, cisplatin)
- VAPEC-B (vincristine, doxorubicin, prednisolone, etoposide, cyclophosphamide, bleomycin)
- DHAP (dexamethasone, cisplatin, cytarabine)

**NOTE:** Regimens not specified in this document must be listed on a nationally recognized guideline stating risk of FN of greater than 20%.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

OR

For the prevention of FN when the risk of developing FN is less than 20%, but any other risk factor listed below is present:

- Age 65 years or greater
- Poor performance status
- Previous history of FN
- Extensive prior radiation or chemotherapy treatment
- Poor nutritional status
- Recent surgery or Open wounds or active infection

- Advanced cancer
- Persistent neutropenia
- Bone marrow involvement by tumor
- Liver dysfunction (bilirubin >2.0)
- Renal dysfunction (CrCl <50)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**Neupogen, Neulasta, Nivestym, Fulphila, Udenyca, Ziextenzo, Zarxio, or Leukine:** May also be considered medically necessary for any of the following:

**2. Secondary Prophylaxis** – prevention of FN when a previous cycle of chemotherapy resulted in a neutropenic complication and for which primary prophylaxis was not received, and a dose reduction will compromise disease-free or overall survival or treatment outcome.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**3. Treatment of Febrile Neutropenia** - as an adjunct to antibiotics in high-risk individuals with FN who are at high risk for infection related complications or when **any** of the following prognostic factors are documented:

- Age 65 years or greater
- Anticipated prolonged and profound neutropenia
- Uncontrolled primary disease
- Pneumonia
- Invasive fungal infection
- Hypotension
- Multi-organ dysfunction
- Hospitalized at the time of development of the fever

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**4. Dose Dense Therapy** – specifically in the treatment of node positive breast cancer, small cell lung cancer, and diffuse aggressive non-Hodgkin’s lymphoma.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, **AND** Fulphila.

**5. Stem Cell Transplantation-** when one of the following is met:

- Bone Marrow Transplant (BMT)
    - Documentation of a non-myeloid malignancy undergoing myeloablative chemotherapy followed by autologous or allogenic bone marrow transplant (G-CSF is given after BMT)
- OR
- Peripheral Blood Progenitor Cell (Mobilization)Transplant (PBPC)
    - Used for mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis. (G-CSF is given prior to and throughout leukapheresis)

Note: Neulasta, Udenyca, **Ziextenzo**, and Fulphila are considered off-label for PBPC mobilization

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, AND Fulphila.

**6. Leukemia or Myelodysplastic Syndromes** – insured individuals with any of the following conditions:

- Acute myeloid leukemia (AML) receiving induction or consolidation chemotherapy
- Acute lymphoblastic leukemia (ALL) after completion of the first few days of chemotherapy of the initial induction or the first post-remission course
- Myelodysplastic syndrome with less than 15% blasts in the bone marrow, or recurrent neutropenic infections are experienced.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, AND Fulphila.

**7. Lymphoma** – Age 65 years or greater treated with curative chemotherapy, e.g., CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, AND Fulphila.

**8. Radiation therapy** – with any of the following conditions

- If prolonged delays secondary to neutropenia are anticipated.
  - As treatment for radiation injury secondary to doses of 3-10 Grays (Gy) or greater
- Note: Fulphila, Ziextenzo, and Udenyca are not indicated for radiation injury syndrome; however, the biosimilars are considered medically accepted for this indication by the NCCN guidelines.

**AND**

- For requests for Neulasta/Neulasta Onpro, medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Ziextenzo, Udenyca, AND Fulphila.

**Neupogen, Nivestym, and Zarxio:** May also be considered medically necessary for the following:

**9. Severe Chronic Neutropenia** – when the following criteria are met

- Diagnosis of Congenital, Cyclic, or Idiopathic Neutropenia AND
- Documentation of an Absolute Neutrophil Count (ANC) <500 cells/mm<sup>3</sup> on three separate occasions during a 6 month period (for Congenital or Idiopathic Neutropenia) OR five consecutive days of ANC <500 cells/mm<sup>3</sup> per cycle (for Cyclic Neutropenia) AND
- Documentation that the member experienced a clinically significant infection, fever, or oropharyngeal ulcer during the past 12 months.

**Leukine:** May also be considered medically necessary for the following:

**10. Delayed Neutrophil Recovery or Graft Failure**

- Medical record documentation that the member has had an allogeneic or autologous bone marrow transplant and neutrophil recovery\* has not occurred.

\*Note to reviewer: Neutrophil engraftment is defined as the first day of three consecutive days where the neutrophil count (ANC) is 500 cells/mm<sup>3</sup> or greater.

**AUTHORIZATION:** When approved, the duration of the authorization will be for 6 months.

#### **QUANTITY LIMITS:**

- **Ziextenzo:** Facets RX Count: 144 (Q5120 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Udenyca:** Facets RX Count: 144 (Q5111 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Fulphila:** Facets RX Count: 144 (Q5108 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)
- **Neulasta/Neulasta Onpro:** Facets RX Count: 12 (J2505 Units), MedAccess QL: 0.043mL per day (1 syringe per 14 days)

**EXCLUSIONS:** There is insufficient evidence in the published, peer reviewed medical literature to clearly establish that the use of colony stimulating factors (CSF) improves the health outcomes in any of the following indications. The use of CSF's for the following indications is considered not medically necessary and are **NOT COVERED:**

- Routine use as prophylaxis on most chemotherapy regimens; or
- Use as prophylaxis during chemotherapy regimens with a febrile neutropenia risk of less than 20% and no high risk for complications; or
- Use in insured members who are neutropenic but afebrile and not meeting any of the above criteria; or
- Use as an adjunct to antibiotics in uncomplicated febrile neutropenia; or use in relapsed or refractory myeloid leukemia; or
- Use in chemo-sensitization of myeloid leukemias; or
- Use prior to or concurrent with chemotherapy for acute myeloid leukemia; or
- Use prior to or concurrently with chemotherapy for “priming” effect; or
- Use to allow an increase in the dose-intensity of cytotoxic chemotherapy beyond the established dose ranges for these regimens; or
- Use during concomitant chemotherapy and radiation therapy; or
- Continued use if no response is seen within 45 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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#### **FETROJA (cefiderocol)**

**Review:** Fetroja is indicated in patients 18 years of age or older who have limited or no alternative treatment options, for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae* complex. Fetroja is a cephalosporin with activity against Gram-negative aerobic bacteria.

The recommended dosage is 2 grams administered every 8 hours by intravenous (IV) infusion over 3 hours in adults with a creatine clearance of 60 to 119 mL/min. The recommended duration of treatment is 7 to 14 days. The duration should be guided by the severity of infection and the patient's clinical status for up to 14 days. For patients with a creatine clearance of 30 to 59 mL/min, the recommended dose is 1.5 grams every 8 hours. For patients with a creatine clearance of 15 to 29 mL/min, the recommended dose is 1 gram every 8 hours. For patients with end stage renal disease (with or without intermittent hemodialysis), the recommended dose is 0.75 grams every 12 hours. For patients with a creatine clearance greater than or equal to 120 mL/min, the recommended dose is 2 grams every 6 hours.

In a multinational, double-blind trial, 448 adults hospitalized with cUTI (including pyelonephritis) were randomized in a 2:1 ratio to Fetroja 2 grams IV every 8 hours (infused over 1 hour) or imipenem/cilastatin 1g/1g IV every 8 hours (infused over 1 hour) for 7 to 14 days. The response rates for the composite endpoint of the microbiological eradication and clinical response at the TOC visit were higher in the Fetroja arm compared with imipenem/cilastatin. Clinical response rates at the TOC visit were similar between Fetroja and imipenem/cilastatin. Subgroup analyses demonstrated responses consistent with the overall population.

Fetroja is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs. An increase in all-cause mortality was observed in patients treated with Fetroja as compared to best available therapy in a multinational, randomized, open-label trial in critically-ill patients with carbapenem-resistant Gram-negative bacterial infections. The safety and efficacy of Fetroja has not been established for the treatment of nosocomial pneumonia, bloodstream infections, or sepsis. The most common adverse reactions occurring  $\geq 2\%$  of patients treated with Fetroja were diarrhea, infusion site reactions, constipation, rash, candidiasis, cough, elevations in liver tests, headache, hypokalemia, nausea, and vomiting. The safety and efficacy of Fetroja in pediatric patients younger than 18 years of age have not been established.

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

**Clinical Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Financial Discussion:** No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed

**Outcome:** Fetroja will be a medical benefit for commercial, exchange, and CHIP formularies. Fetroja will require a prior authorization.

- Prescription is written by or in consultation with Infectious Disease **AND**
- Medical record documentation that the member is greater than or equal to 18 years of age **AND**
- Medical record documentation of a diagnosis of complicated urinary tract infections (cUTI), including pyelonephritis caused by susceptible Gram-negative microorganisms: *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, and *Enterobacter cloacae complex* **AND**
- Medical record documentation of culture and sensitivity showing the patient's infection is not susceptible to alternative antibiotic treatments **OR** a documented history of previous intolerance to or contraindication to other antibiotics shown to be susceptible on the culture and sensitivity.

**AUTHORIZATION DURATION:** Approval will be given for a duration of 14 days

**QUANTITY LIMIT:** In Medaccess, 8 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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## FAST FACTS

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### **ZEJULA (niraparib)**

**Updated Indication:** Zejula is now indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

There are no changes to the previous indications for Zejula for maintenance treated of recurrent ovarian cancer and for treatment of advanced ovarian cancer after three or more chemotherapies.

**Current formulary status:** OralOnc Brand Non-Preferred tier, requiring a prior authorization

**Recommendation:** No changes are recommended to the formulary placement, authorization duration, and quantity limits of Zejula. It is recommended to make the following changes to Policy 455.0 to incorporate the new indication:

#### **Ovarian Cancer**

- 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**

#### **If the member is in complete/partial response to first-line platinum-based chemotherapy:**

- Medical record documentation of a diagnosis of advanced epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that Zejula is being used as maintenance treatment **AND**
- Medical record documentation that member is in complete or partial response to platinum based chemotherapy **AND**
- Medical record documentation that Zejula is being given at a dosage consistent with FDA- Approved labeling\*

**OR**

#### **If the member has failed three or more treatments:**

- Medical record documentation of diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer **AND**
- 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

**OR**

#### **If the member has Platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy:**

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

\*For first-line treatment of advanced ovarian cancer:

- For patient weight less than 77 kg (170 lbs) **OR** with a platelet count of less than 150,000/ $\mu$ L, the recommended dose is 200 mg (two 100-mg capsules taken orally once daily) .
- For patient weight greater than or equal to 77 kg (170 lbs) **AND** who have a platelet count greater than or equal to 150,000/ $\mu$ L the recommended dose is 300 mg (three 100-mg capsules) taken orally once daily.

**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

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

**Discussion:** No comments or questions.

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

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

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## **LYNPARZA (olaparib)**

**Updated Indication:** Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor with the following new indications:

- in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
  - a deleterious or suspected deleterious *BRCA* mutation, and/or
  - genomic instability.
- for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Previously, Lynparza was indicated for first-line maintenance treatment of *BRCA*-mutated advanced ovarian cancer, maintenance treatment of recurrent ovarian cancer, treatment of advanced germline *BRCA*-mutated ovarian cancer after 3 or more lines of chemotherapy, treatment of germline *BRCA*-mutated *HER2*-negative metastatic breast cancer, and first-line maintenance treatment of germline *BRCA*-mutated metastatic pancreatic adenocarcinoma.

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

**Recommendation:** No changes are recommended to the formulary placement or the quantity limits of Lynparza. The following changes are recommended to Policy 362 to incorporate the new indications. For GHP Family, the policy is managed by the PDL and the authorization duration can be updated as outlined below:

### **Ovarian Cancer**

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

#### **If the member is in complete/partial response to first-line platinum-based chemotherapy:**

- Medical record documentation of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer **AND**
- Medical record documentation that patient is in complete or partial response to first-line platinum based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance treatment **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of deleterious or suspected deleterious germline or somatic BRCA-mutation (*gBRCAm* or *sBRCAm*) **OR**
  - Medical record documentation of both of the following:
    - Documentation of homologous recombination deficiency (HRD)-positive status with a deleterious or suspected deleterious *BRCA* mutation **OR** genomic instability **AND**
    - Documentation that Lynparza will be prescribed in combination with bevacizumab

**OR**

#### **If the member has failed three or more prior lines of chemotherapy:**

- Medical record documentation of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer **AND**
- Medical record documentation of both of the following:
  - Documentation of deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAm*) as verified by a Food and Drug Administration (FDA) approved test **AND**
  - Documentation of therapeutic failure on, intolerance to, or contraindication to three or more prior lines of chemotherapy

**OR**

#### **If the member has platinum-sensitive recurrent disease and has completed two or more lines of platinum-based chemotherapy**

- Medical record documentation of diagnosis of recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer **AND**
- Medical record documentation that patient is in complete or partial response to platinum-based chemotherapy **AND**
- Medical record documentation that Lynparza will be used as maintenance therapy

### **For Metastatic Breast Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer **AND**
- Medical record documentation that member has been previously treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting **AND**

- If hormone receptor (HR)-positive, medical record documentation that prior treatment included endocrine therapy or documentation that endocrine therapy would be considered inappropriate

#### **For Metastatic Pancreatic Adenocarcinoma**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of deleterious or suspected deleterious *gBRCAm* metastatic pancreatic adenocarcinoma **AND**
- Medical record documentation that member has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

#### **For Metastatic Castration-Resistant Prostate Cancer**

- Medical record documentation that Lynparza is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of progression following prior treatment with Xtandi or Zytiga **AND**
- Medical record documentation that a gonadotropin-releasing hormone (GnRH) analog will be used concurrently **OR** member has had bilateral orchiectomy

**NOTE:** The FDA approved test for Lynparza is the BRACAnalysis CDx™. The FoundationOne CDx™ is also FDA approved for Lynparza for ovarian and prostate cancer.

**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).*

- 100 mg tablets: 4 tablets per day, 28 day supply per fill
- 150 mg tablets: 4 tablets per day, 28 day supply per fill

#### **AUTHORIZATION DURATION:**

**For first-line maintenance of BRCA-mutated advanced ovarian cancer (failure on first-line platinum-based chemotherapy) and for first-line maintenance of HRD-positive advanced ovarian cancer in combination with bevacizumab:**

Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval for Lynparza will be granted for up to an additional 12 months (total of two years of therapy) and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease

For members requesting approval of treatment beyond two (2) years, medical record documentation will be required showing patient has continued evidence of disease and treating healthcare provider believes member can derive further benefit from continuous treatment. Each additional approval will be for a period of 12 months. Members with complete response at two years, will not be granted additional treatment, per the package labeling.

#### **For all other indications:**

Initial approval will be for 12 months or less if the reviewing provider feels it is medical appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or

lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease

**Discussion:** No comments or questions.

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

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

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## **RUBRACA (rucaparib)**

**Updated Indication:** Rubraca is now indicated for the treatment of adult patients with deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

An FDA-approved test for the detection of *BRCA1/BRCA2* mutations in patients with mCRPC is not currently available.

There are no changes to the previous indications for Rubraca in ovarian cancer.

**Current formulary status:** OralOnc Brand Non-Preferred tier, requiring a prior authorization

**Recommendation:** There are no changes recommended to the formulary placement, quantity limits, or authorization duration of Rubraca. The following changes are recommended to Policy 442.0 to incorporate the new indication:

### **For Ovarian Cancer**

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **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 **AND** medical record documentation of Rubraca being used as maintenance treatment after a complete or partial response to platinum-based chemotherapy **OR**
- Medical record documentation of deleterious *BRCA* mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer (as verified by a Food and Drug Administration-approved test) who have been treated with two or more chemotherapies

### **For Prostate Cancer**

- Medical record documentation that Rubraca is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of deleterious *BRCA* mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of prior treatment with androgen receptor-directed therapy and a taxane-based chemotherapy **AND**

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

**NOTE:** For Ovarian Cancer, the Food and Drug Administration approved test is BRACAnalysis CDx, FoundationOne CDx, FoundationFocus CDxBRCA Assay (see <http://www.fda.gov/CompanionDiagnostics>)

**Discussion:** No comments or questions.

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

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

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### TRULICITY (dulaglutide)

**Updated Indication:** Trulicity is now indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.

- Previously, Trulicity was only indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

**Current formulary status:** Trulicity is available on the commercial/exchange formularies at the BrandNP Tier with a quantity limit of 0.072ml/day. The following prior authorization/step therapy criteria apply:

- Medical record documentation of failure on, intolerance to, or contraindication to the use of Victoza AND either Ozempic or Rybelsus

**Recommendation:** No changes are recommended at this time.

**Discussion:** No comments or questions.

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

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

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### INLYTA (axitinib)

**Updated Indication:** Inlyta now has two new indications for the treatment of renal cell carcinoma:

- Inlyta in combination with avelumab (Bavencio) is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
- Inlyta in combination with pembrolizumab (Keytruda) is indicated for the first-line treatment of patients with advanced renal cell carcinoma.

**Current formulary status:** OralOncBrandNP Tier requiring PA, QL applies

**Recommendation:** No changes are recommended to the formulary placement of Inlyta at this time. It is recommended that the following prior authorization criteria changes are made to account for the updated indication. No changes are necessary to the existing authorization duration or quantity limits at this time:

- Medical record documentation that Inlyta is prescribed by an oncologist **AND**
- Medical record documentation of advanced renal cell carcinoma (RCC) **AND**
- Medical record documentation of one of the following:
  - Failure of one prior systemic therapy
  - OR**
  - Use as first-line treatment **AND**
  - Use in combination with pembrolizumab (Keytruda)
  - OR**
  - Use as first-line treatment **AND**
  - Use in combination with avelumab (Bavencio)

**Discussion:** No comments or questions

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

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

## **YERVOY (ipilimumab)**

**Updated Indication:** Yervoy is a human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody now indicated for:

### Non-Small Cell Lung Cancer (NSCLC)

- Treatment of adult patients with metastatic non-small cell lung cancer expressing PD-L1 ( $\geq 1\%$ ) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with nivolumab. (1.6)
- Treatment of adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with nivolumab and 2 cycles of platinum-doublet chemotherapy.

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

**Recommendation:** There are no changes recommended to the formulary placement of Yervoy. It is recommended to add the following prior authorization criteria and authorization duration to Medical Benefit Policy 91.0:

### *Non-Small Cell Lung Cancer (NSCLC)*

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

#### **If the request is for first-line treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ):**

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of PD-L1  $\geq 1\%$  as determined by an FDA-approved test **AND**
- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**
- Medical record documentation that Yervoy will be used for first-line treatment in combination with Opdivo

#### **If the request is for first-line treatment metastatic or recurrent NSCLC:**

- Medical record documentation of a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**

- Medical record documentation that Yervoy will be used for first-line treatment in combination with Opdivo and 2 cycles of platinum-doublet chemotherapy

### **AUTHORIZATION DURATION**

For Unresectable or metastatic melanoma, colorectal cancer and Advanced Renal Cell Carcinoma:

Approval will be for one (1) **6-month** authorization for the FDA-approved maximum of up to four (4) doses of Yervoy. Requests for authorization exceeding these limits will require the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For first line-treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ) and for first-line treatment of metastatic or recurrent NSCLC:

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **18 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.

Authorization of Yervoy for the first line-treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ) and for first-line treatment of metastatic or recurrent NSCLC should not exceed the FDA-approved treatment duration of 2 years (24 months) in patients without disease progression. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

For Adjuvant melanoma:

Initial approval will be for **6 months**. Subsequent approvals will be for an additional **12 months** and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if the member experiences unacceptable toxicity or worsening of disease.

**Discussion:** No comments or questions

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

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

### **OPDIVO (nivolumab)**

**Updated Indication:** Opdivo is a programmed death receptor-1 (PD-1) blocking antibody with three new FDA approved indications:

Non-Small Cell Lung Cancer (NSCLC)

- adult patients with metastatic non-small cell lung cancer expressing PD-L1 ( $\geq 1\%$ ) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, as first-line treatment in combination with ipilimumab. (1.3)
- adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy.

### Esophageal Squamous Cell Carcinoma (ESCC)

- patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.

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

**Recommendations:** There are no changes recommended to the formulary placement or the authorization duration of Opdivo for hepatocellular carcinoma. It is recommended to add the following prior authorization criteria to Medical Benefit Policy 126.0:

### *Non-Small Cell Lung Cancer (NSCLC)*

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

#### **If the request is for metastatic NSCLC with progression after platinum-based chemotherapy:**

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) with disease progression while on or after platinum-based chemotherapy **AND**
- Medical record documentation that Opdivo is not being used in combination with any other agents for the treatment of metastatic non-small cell lung cancer (NSCLC)

**OR**

#### **If the request is for first-line treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ):**

- Medical record documentation of a diagnosis of metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of PD-L1  $\geq 1\%$  as determined by an FDA-approved test **AND**
- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**
- Medical record documentation that Opdivo will be used for first-line treatment in combination with Yervoy

#### **If the request is for first-line treatment metastatic or recurrent NSCLC:**

- Medical record documentation of a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of no EGFR or ALK genomic tumor aberrations **AND**
- Medical record documentation that Opdivo will be used for first-line treatment in combination with Yervoy and 2 cycles of platinum-doublet chemotherapy

### *Esophageal Squamous Cell Carcinoma*

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) **AND**
- Medical record documentation of previous trial of fluoropyrimidine- and platinum-based chemotherapy.

### **AUTHORIZATION DURATION:**

#### **\*\*For adjuvant treatment of metastatic melanoma (completely resected melanoma):**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval 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.

Authorization of Opdivo for the adjuvant treatment of metastatic melanoma should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**\*\*For first line-treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ) and for first-line treatment of metastatic or recurrent NSCLC:**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional **18 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.

Authorization of Opdivo for the first line-treatment of metastatic NSCLC expressing PD-L1 ( $\geq 1\%$ ) and for first-line treatment of metastatic or recurrent NSCLC should not exceed the FDA-approved treatment duration of 2 years (24 months) in patients without disease progression. For requests exceeding the above limit, medical record documentation of the following is required:

- Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

**For all other indications:**

Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**Discussion:** No comments or questions

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

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

**POMALYST (pomalidomide)**

**Updated Indication:** Pomalyst is indicated for the treatment of adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in patients with KS who are HIV-negative. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Note: Pomalyst was previously only indicated in combination with dexamethasone, for patients with multiple myeloma (MM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

**Current formulary status:** Pharmacy benefit available at the OralOncBrandNP tier, prior authorization and quantity limits apply

**Recommendation:** There will be no changes to the formulary status at this time. However, it is recommended that the following criteria be added to the policy to reflect the updated indication:

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

- Medical record documentation of Kaposi sarcoma **AND**
  - Medical record documentation of one of the following:
    - Medical record documentation of AIDS-related Kaposi sarcoma **AND**
    - Medical record documentation of progression of Kaposi sarcoma despite the use of antiretroviral therapy **AND**
    - Medical record documentation that antiretroviral therapy will be continued
- OR**
- Medical record documentation that the member is HIV-negative

There will be no changes to quantity limit or authorization duration.

**Discussion:** No comments or questions

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

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

#### **EPCLUSA (sofosbuvir/velpatasvir)**

**Updated Indication:** Epclusa is now approved in age 6 and up, Genotype 1, 2, 3, 4, 5 or 6 Chronic Hepatitis C infection. It was previously approved in adult patients.

**Current formulary status:** sofosbuvir/velpatasvir (Epclusa) tablets : Non-formulary (Commercial/CHIP), Specialty (Exchange), Prior authorization required.

**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 to reflect the updated age and weight. Epclusa's warning in severe renal impairment and ESRD was also removed.

- Medical record documentation of age 6 years or older or weighing 17kg or more **AND**
- ~~Medical record documentation of age greater than or equal to 18 years **AND**~~
- Medical record documentation of concurrent therapy with appropriate dose and duration of **weight-based** ribavirin (1000 mg per day for patients less than 75 kg and 1200 mg for those weighing at least 75 kg), if indicated **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**~~

**AUTHORIZATION DURATION:** according to IDSA/AASLD Guidelines (longer treatment duration is recommended when ribavirin ineligible)

~~AUTHORIZATION DURATION: 12 weeks~~

**Discussion:** No comments or questions

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

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

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## **KEYTRUDA (pembrolizumab)**

**Updated Indication:** Keytruda is now indicated under accelerated approval for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) [ $\geq 10$  mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Keytruda is also now indicated for the treatment of patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation.

Keytruda maintains its previously approved indications for melanoma, non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), head and neck squamous cell cancer (HNSCC), classical Hodgkin Lymphoma (cHL), primary mediastinal large B-cell lymphoma (PMBCL), urothelial carcinoma, microsatellite instability-high cancer (MSI-H), gastric cancer, esophageal cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma (MCC), renal cell carcinoma (RCC), and endometrial carcinoma.

**Current formulary status:** NF (medical benefit requiring PA)

**Recommendation:** No changes are recommended to the tiering or formulary placement of Keytruda at this time. It is recommended that prior authorization criteria are added to the existing Keytruda policy to account for the updated indication. It is recommended that the current 6-month initial and 12-month subsequent authorization durations and associated criteria apply.

### **Tumor Mutational Burden – High (TMB-H) Solid Tumors**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of unresectable or metastatic solid tumors **AND**
- Medical record documentation that tumors are tumor mutational burden-high (TMB-H), defined as greater than or equal to 10 mutations per megabase ( $\geq 10$  mut/Mb), determined by an FDA-approved test **AND**
- Medical record documentation of progression following prior treatment(s) **AND**
- Medical record documentation of no satisfactory alternative treatment options

### **Cutaneous Squamous Cell Carcinoma (cSCC)**

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of recurrent or metastatic cutaneous squamous cell carcinoma **AND**
- Medical record documentation that the patient's disease is not curable by surgery **AND**
- Medical record documentation that the patient's disease is not curable by radiation.

**Discussion:** No comments or questions

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

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

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**DULERA (mometasone furoate/formoterol fumarate dihydrate)**

**Updated Indication:** Dulera is a combination product containing a corticosteroid and a long-acting beta<sub>2</sub>-adrenergic agonist (LABA) indicated for treatment of asthma in patients 5 years of age and older. It is not indicated for the relief of acute bronchospasm.

Previously, Dulera was indicated for treatment of asthma in patients 12 years of age and older

**Current formulary status:** Brand Preferred tier, unrestricted

**Recommendation:** Dulera is currently available without a prior authorization and is not restricted by age. No changes are recommended at this time.

**Discussion:** No comments or questions.

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

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

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**ASMANEX HFA (mometasone furoate)**

**Updated Indication:** Asmanex is a corticosteroid indicated for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. It is not indicated for the relief of acute bronchospasm.

**Current formulary status:** Brand Non-Preferred, unrestricted

**Recommendation:** No changes are recommended to the formulary placement of Asmanex HFA.

**Discussion:** No comments or questions.

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

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

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**ALUNBRIG (brigatinib)**

**Updated Indication:** Alunbrig is now indicated for treatment of adult patients with ALK+, metastatic non-small cell lung cancer (NSCLC) as detected by an FDA approved test.

- Previously, Alunbrig was only indicated for ALK+, metastatic NSCLC patients who had failed on Xalkori.

**Current formulary status:** Alunbrig is a pharmacy benefit on the OralOncBrandNP Tier requiring prior authorization and quantity limits apply

**Recommendation:** No changes are recommended to formulary placement at this time. Recommend updating the prior authorization criteria to the following:

- Medical record documentation that Alunbrig is prescribed by an oncologist **AND**
- Medical record documentation of a diagnosis of ALK-positive, metastatic non-small cell lung cancer

**AUTHORIZATION DURATION:** 12 months

**QUANTITY LIMIT:** 6 tablets per day (30 day supply per fill)

**Discussion:** No comments or questions.

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

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

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### **TECENTRIQ (atezolizumab)**

**Updated Indication:** Tecentriq is now indicated, in combination with bevacizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Previously, Tecentriq was indicated for urothelial carcinoma, non-small cell lung cancer, locally advanced or metastatic triple-negative breast cancer, and small cell lung cancer. No changes have been made to these indications.

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

**Recommendation:** No changes are recommended to the formulary placement or authorization duration of Tecentriq. It is recommended to add the following prior authorization criteria to Medical Benefit Policy 144.0 to incorporate the new indication.

#### **Unresectable or Metastatic Hepatocellular Carcinoma (HCC)**

- Prescription written by an oncologist **AND**
- Medical record documentation of diagnosis of unresectable or metastatic hepatocellular carcinoma (HCC) **AND**
- Medical record documentation that Tecentriq will be given in combination with bevacizumab **AND**
- Medical record documentation that patient has not received prior systemic treatment for hepatocellular carcinoma

**Discussion:** No comments or questions.

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

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

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**AVASTIN (bevacizumab)**

**Updated Indication:** Avastin is now indicated in combination with Tecentriq for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

**Current formulary status:** Medical Benefit, unrestricted

**Recommendation:** Currently, Avastin is available as a medical benefit without a prior authorization and no changes are recommended to formulary placement of Avastin at this time.

**Discussion:** No comments or questions.

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

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

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## UPDATES

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### PROCYSBI POLICY UPDATE

Procysbi is a pharmacy benefit available at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit. Procysbi requires a prior authorization with the following criteria.

- Medical record documentation that member is > 1 years of age **AND**
- Medical record documentation of a diagnosis of nephropathic cystinosis **AND**
- Medical record documentation that medication is prescribed by a nephrologist, geneticist, or metabolic specialist **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Cystagon

**DAY SUPPLY LIMIT:** 34 day supply per fill

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

- Medical record documentation of a diagnosis of nephropathic cystinosis **AND**
- Medical record documentation of age greater than or equal to 1 year **AND**
- Medical record documentation that Procysbi is prescribed by a nephrologist **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of intolerance to Cystagon and one of the following:
    - If intolerance is gastrointestinal-related, medical record documentation of therapeutic failure on 4 months of Cystagon and a proton-pump inhibitor (e.g. omeprazole, esomeprazole) **OR**
    - If intolerance is not gastrointestinal-related, justification supported by peer-review literature citing well-designed clinical trials that the member's intolerance will be improved by switching therapy to Procysbi
  - OR**
  - Medical record documentation of therapeutic failure on Cystagon as defined by all of the following:
    - Medical record documentation of failure to achieve WBC cystine levels < 1 nmol half-cystine/mg protein on maximally tolerated dose of Cystagon **AND**
    - Claims history or attestation from the provider that the patient is adherent to Cystagon at an every 6 hour dosing interval

**Discussion:** No comments or questions.

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

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

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### XCOPRI QUANTITY LIMIT UPDATE

The maximum dosage formulation of Xcopri is 200 mg tablets. To allow for the maximum dosage of 400 mg daily, the following update is recommended to the current quantity limits.

**QUANTITY LIMITS:** 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).*

- **50 mg, 100 mg, 150 mg:** 1 tablet per day
- **200 mg, Maintenance Pack:** 2 tablets per day
- **Titration Pack:** 28 tablets per 180 days

**Recommendation:** Update QL for 200 mg tables to 2 per day.

**Discussion:** No comments or questions.

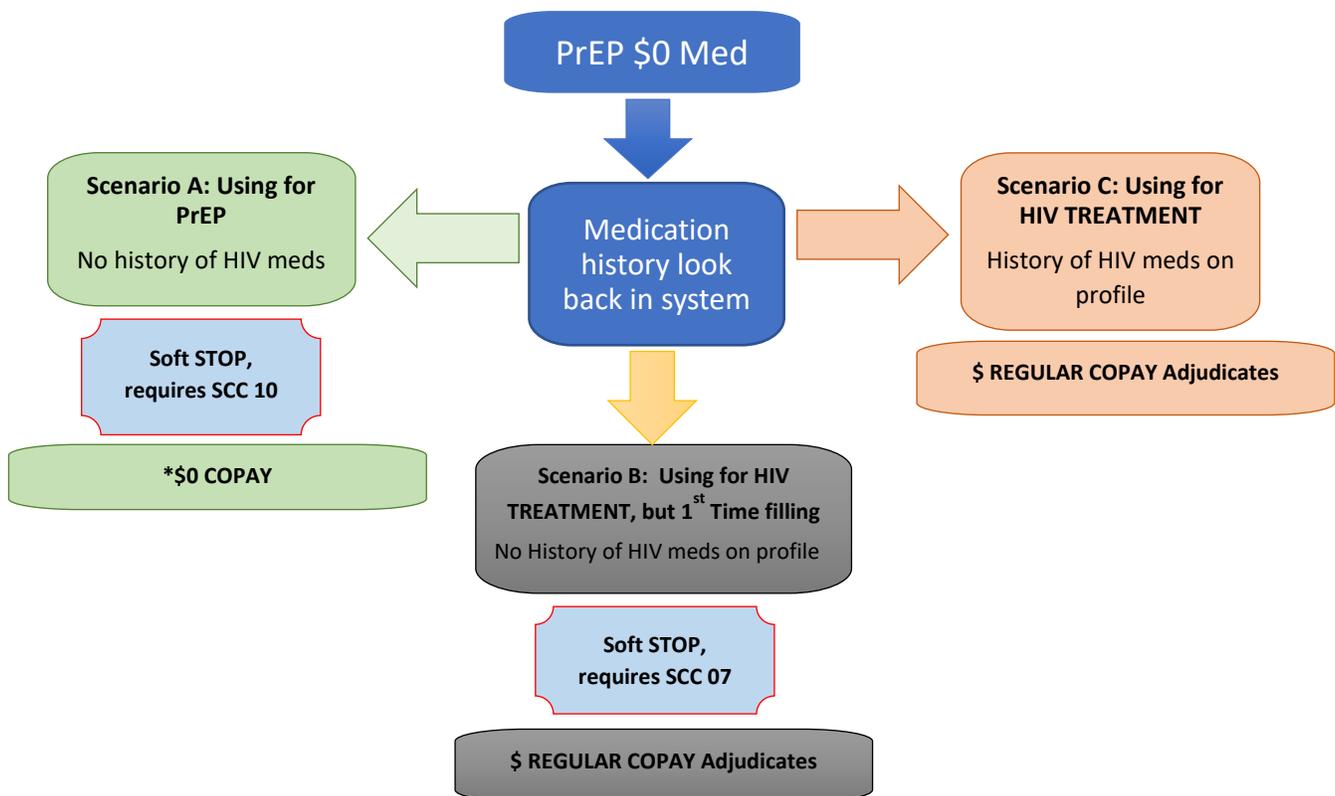
**Outcome:** The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

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## HIV PRE-EXPOSURE PROPHYLAXIS

In June of 2019 the United States Preventive Task Force (USPSTF) approved a category A recommendation for coverage of HIV pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy for persons who are at high risk of HIV acquisition. In order to comply with the USPSTF recommendation, it is recommended for Truvada 200-300 mg tablet, Emtriva 200 mg tablet, and tenofovir 300 mg capsule to be covered for \$0 cost sharing when used for PrEP. The following logic will be configured in the claims system to determine whether members are utilizing these agents for HIV treatment of HIV PrEP effective 7/1/2020:



\*Before assigning \$0 copay, soft stop PrEP meds intended to be \$0 with POS:

- If for HIV preexposure prophylaxis, resubmit with SCC10. If for HIV treatment, resubmit with SCC07
- If medications on HIV TX LOOKBACK DRUGS FOR EHB LIST are found, do not soft stop; proceed regular copay

**Discussion:** No comments or questions.

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

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

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## **XELJANZ/XELJANZ XR**

Xeljanz recently added a black box warning for increased rate of all-cause mortality in patients 50 years of age and older with at least one cardiovascular risk factor who were treated for rheumatoid arthritis with Xeljanz 10 mg twice daily (correlates to Xeljanz XR 22 mg) compared to those treated with Xeljanz 5 mg twice daily or TNF blockers in a large ongoing post-marketing safety study. To ensure the appropriate dosage is being prescribed, it is recommended to add the following prior authorization criteria to Policy 273.0 for Xeljanz and Xeljanz XR.

### **Recommendations:**

#### **For treatment of rheumatoid arthritis**

An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- 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 Rheumatoid Arthritis) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- 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 **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record recommendation that Xeljanz/Xeljanz XR is being dosed consistent with FDA-approved labeling\*

#### **QUANTITY LIMIT:**

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

- Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill.
- Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

#### **For treatment of psoriatic arthritis**

An exception for coverage of Xeljanz or Xeljanz XR may be made for members who meet the following criteria:

- Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following: o Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**

- Medical record documentation of an inadequate response to or intolerance to a 3-month trial of methotrexate or another disease-modifying antirheumatic drug (DMARD) **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a rheumatologist or dermatologist **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is being prescribed in combination with non-biologic disease modifying antirheumatic drug (DMARD) therapy (including but not limited to methotrexate, sulfasalazine, and/or leflunomide) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira\* **AND** Cosentyx\* **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record recommendation that Xeljanz/Xeljanz XR is being dosed consistent with FDA-approved labeling\*

**QUANTITY LIMIT:**

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

- Xeljanz 5 mg: 2 tablets per day, 30 day supply per fill.
- Xeljanz XR 11 mg: 1 tablet per day, 30 day supply per fill

**For treatment of ulcerative colitis**

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

- Medical record documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Medical record documentation that Xeljanz or Xeljanz XR is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira\* **AND**
- Medical record documentation that Xeljanz is not being used concurrently with a tumor necrosis factor (TNF) blocker, potent immunosuppressant (e.g. azathioprine and cyclosporine), or other biologic agent

**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).*

- Xeljanz 5 mg or 10 mg\*: 2 tablets per day, 30 day supply per fill.
- Xeljanz XR 11 mg or 22 mg\*: 1 tablet per day, 30 day supply per fill

**\*NOTE:** Xeljanz 10 mg twice daily and Xeljanz XR 22 mg once daily are only indicated for the treatment of ulcerative colitis induction treatment and in cases of loss of response to maintenance treatment. The maximum recommended dosage for rheumatoid arthritis and psoriatic arthritis are Xeljanz 5 mg twice daily or Xeljanz XR 11 mg once daily.

**Discussion:** No comments or questions.

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

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

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## ACYCLOVIR CREAM/OINTMENT

### **Review:**

Acyclovir cream: Treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents (12 years and older)

Acyclovir ointment: Indicated for the management of initial genital herpes and in limited non-life threatening mucocutaneous herpes simplex virus infections in immunocompromised patients.

Unsupported uses: Although included as an FDA-approved use in the manufacturer's prescribing information for the management of initial genital herpes, the CDC discourages topical antiviral therapy for genital herpes infection due to minimal clinical benefit.

Per UpToDate, there is no role for topical antiviral therapy in the treatment of genital herpes. In an analysis that compared the results of three randomized trials in patients with primary genital HSV, the effects of IV and oral acyclovir were greater than topical treatment in reduction of viral shedding, time to complete healing of lesions, and reduction of new lesion formation. Oral therapy reduced viral shedding by 80% and topical therapy only reduced shedding by 55%. Also, oral therapy reduced new lesion formation and topical therapy did not.

**Current Formulary Status:** Acyclovir cream and acyclovir ointment are on generic tier and require a prior authorization

**Recommendation:** It is recommended to remove the prior authorization on the acyclovir ointment. Also, it is recommended to remove the genital herpes section from the policy. Acyclovir cream and Denavir cream will still require a prior authorization with the following criteria:

### **For the treatment of Cold Sores:**

- An exception for the coverage of **acyclovir cream** may be made for members who meet the following criteria:
  - Medical record documentation of a diagnosis of Cold Sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older AND
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Abreva (OTC), valacyclovir, AND famciclovir (famciclovir only if age greater than or equal to 18 years)
- An exception for the coverage of **Denavir Cream** may be made for members who meet the following criteria:
  - Medical record documentation of a diagnosis of cold sores (Herpes Simplex 1 or Herpes Labialis) in patients 12 years of age and older AND
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to:
    - Abreva (OTC), acyclovir cream (prior authorization required), valacyclovir, AND famciclovir (famciclovir only if age greater than or equal to 18 years)

**QUANTITY LIMIT:** For acyclovir Cream: A quantity limit of 1 co-pay per package applies  
For Denavir Cream: A quantity limit of 1 co-pay per package applies

**Discussion:** No comments or questions.

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

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

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## ACYCLOVIR CREAM/OINTMENT

**Review:** The ability of Abilify Mycite to improve patient compliance has not been established. Abilify Mycite offers no advantage in efficacy over aripiprazole tablets and Abilify Maintena. Abilify Maintena is an alternative form of aripiprazole for patients who have trouble with compliance issues.

**Recommendation:** It is recommended to add the following reauthorization criteria to the Commercial Policy 619.0 for Abilify Mycite.

**Authorization Duration:** Initial authorizations for Abilify Mycite will be approved for a period of 12 months. Reauthorizations will be for a period of 12 months each provided the following criteria are met:

- Claims history and attestation from the provider showing the patient is adherent to Abilify Mycite **OR** continued need to monitor drug ingestion **AND**
- Medical record documentation of one of the following:
  - For schizophrenia and bipolar I disorder:
    - Medical record documentation of reason why aripiprazole oral tablets **AND** Abilify Maintena cannot be used
  - OR**
  - For major depressive disorder (MDD)
    - Medical record documentation of reason why aripiprazole oral tablets cannot be used

**Discussion:** No comments or questions.

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

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

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## SOVALDI AND HARVONI QUANTITY LIMIT UPDATE

Based on updated formulations, in line with FDA approved recommendations, it is necessary to update quantity limits for HCV drugs Sovaldi and Harvoni.

**Quantity Limit Recommendations:** It is recommended to update the quantity limits in the policy to the following (underlined):

Sovaldi 200mg pellets: QL: 56 packets per 28 days.

Sovaldi 150mg pellets: QL: 28 packets per 28 days

Sovaldi 200mg tablets, QL: 28 tablets /28 days

Sovaldi 400mg tablets, QL: 28 tablets /28 days

Ledipasvir-sofosbuvir 90mg-400mg tablets: QL: 28 tablets /28 days

Harvoni 37.5mg-150mg pellets: QL: 28 pellets / 28 days

Harvoni 45-200mg pellets: QL: 56 pellets / 28 days.

Harvoni 45mg-200mg tablets: QL: 28 tablets / 28 days

Harvoni 90mg-400mg tablets, QL: 28 tablets /28 days (brand with generic review)

**Discussion:** No comments or questions.

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

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

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## **QUARTERLY CASE AUDIT RESULTS**

The Quarterly Case Audit was held on June 4<sup>th</sup>, 2020 utilizing data from 1st quarter 2020. No recommendations of formulary changes were made at this time. Will continue to look for opportunities to create more drug specific policies at future quarterly case audit meetings.

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**The clinical portion of the reviews were approved by 22 of 35 voting members. No response was received from the remaining 13 members.**

**The financial portion of the reviews were approved by 22 of 35 voting members. No response was received from the remaining 13 members.**

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Meeting adjourned at 4:47 pm

### **Future Scheduled Meetings**

The next bi-monthly scheduled meeting will be held virtually on Tuesday, September 15, 2020 at 1:00 pm.