P&T Committee Meeting Minutes
Commercial/Marketplace/GHP Kids
February 2023 e-Vote

DRUG REVIEWS

SPEVIGO (spesolimab-sbzo)

Review: Spevigo is the first FDA approved treatment indicated for generalized pustular psoriasis (GPP) flares in adults. GPP is a rare, severe, potentially life-threatening form of psoriasis that is distinct in terms of pathophysiology and genetic factors. The exact etiology of GPP is not known, but the IL-36 pathway appears to play a role in pathogenesis. Spevigo is the first FDA approved IL-36 receptor antagonist that works by binding the IL36 receptor and prevents activation and in turn prevents downstream activation of pro-inflammatory and pro-fibrotic pathways. The precise mechanism between reduced IL36R activity and the treatment of flares of GPP is unknown. A subcutaneous formulation of Spevigo is being evaluated for maintenance treatment for prevention of flares.

Spevigo is administered as a single 900 mg dose by intravenous infusion over 90 minutes at the start of a GPP flare. If the GPP flare symptoms persist, an additional intravenous 900 mg dose (over 90 minutes) may be administered one week after the initial dose. Spevigo is supplied as two single-dose glass vials containing 450 mg/ 7.5 mL (60 mg/mL) of Spevigo.

The efficacy of Spevigo was evaluated in the Effisayil-1 trial, a randomized, double-blind, placebo-controlled study in adult patients with flares of generalized pustular psoriasis (GPP). Patients were included if they had a moderate-to-severe intensity GPP flare, defined as a

- A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [the total GPPPGA score ranges from 0 (clear) to 4 (severe)]
- The presence of fresh pustules (new appearance or worsening of pustules)
- GPPPGA pustulation sub score of at least 2 (mild), and
- At least 5% of body surface area covered with erythema and the presence of pustules.

Patients were randomized (2:1) to receive a single-intravenous dose of 900 mg SPEVIGO (n=35) or placebo (n=18) (administered over 90 minutes) during the double-blind portion of the study. The primary endpoint of the study was proportion of patients with GPPPGA pustulation sub score of 0 (indicating no visible pustules) at week 1 after treatment. Subjects in either treatment group who continued to experience flare symptoms at Week 1 were eligible to receive a single open-label intravenous dose of 900 mg Spevigo. At Week 1, 12 (34%) subjects and 15 subjects (83%) in Spevigo and placebo groups, respectively, received open-label Spevigo. Of the patients who received two doses of Spevigo, 5 (42%) subjects had a GPPPGA pustulation sub score of 0 at Week 2 (one week after the second dose of Spevigo).

Warnings and precautions for Spevigo include increased risk of infection and tuberculosis and hypersensitivity and infusion-related reactions. During the Effisayil-1 trial, the most common reactions were asthenia, fatigue, nausea and vomiting, headache, pruritis and prurigo, infusion site hematoma and bruising, urinary tract infection, bacteremia, bacteriuria, cellulitis, and herpes dermatitis and oral herpes, upper respiratory tract infection, dyspnea, eye edema, and urticaria. Additional adverse reactions that occurred through Week 12 and week 17 were mild to moderate infections, including device-related infection, subcutaneous abscess, furuncle, influenza, otitis externa, vulvovaginal candidiasis, vulvovaginal mycotic infection, latent tuberculosis, and diarrhea and gastritis.

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: Spevigo is a medical benefit and will be added to the medical benefit cost share list. When processed at a specialty pharmacy, Spevigo will be processed at the Specialty tier or Brand Non-Preferred tier for members with a three-tier benefit. The following prior authorization criteria will apply:

- Medical record documentation that Spevigo is prescribed by a dermatologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of generalized pustular psoriasis (GPP) **AND**
- Medical record documentation of a generalized pustular psoriasis (GPP) flare of moderate to severe intensity and all of the following:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high density pustules) **AND**
    - Presence of fresh pustules (new appearance or worsening of pustules) **AND**
    - ≥5% of body surface area covered with erythema and presence of pustules

  AND
- Medical record documentation of a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

GPI LEVEL: GPI-14

QUANTITY LIMIT: 15 milliliters (2 vials)

AUTHORIZATION DURATION: Initial approval will be for one dose of 900 mg (2 vials) for one week. A subsequent approval of Spevigo will be given for 900 mg (2 vials) if the following criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity **AND** all of the following criteria:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high density pustules) **AND**
    - Spevigo will be administered no sooner than 1 week after the initial dosage was administered

  AND
- Medical record documentation that member has not already received two doses of Spevigo for treatment of the current generalized pustular psoriasis (GPP) flare

Treatment of new generalized pustular psoriasis (GPP) flares will require reevaluation of coverage for a new initial approval for one dose of 900 mg (2 vials) for a duration of one week and the following criteria will be required:

- Medical record documentation the member is being treated for a new generalized pustular psoriasis (GPP) flare of moderate to severe intensity **AND** all of the following:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 3 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high density pustules) **AND**
    - Presence of fresh pustules (new appearance or worsening of pustules) **AND**
    - ≥ 5% of body surface area covered with erythema and presence of pustules **AND**
    - At least 12 weeks have elapsed since the last dose of Spevigo

One subsequent approval of Spevigo for the treatment of persistent symptoms of repeat generalized pustular psoriasis (GPP) flare will be given for 900 mg (2 vials) for a duration one week if the following reauthorization criteria are met:

- Medical record documentation that member is experiencing persistent symptoms of an acute generalized pustular psoriasis (GPP) flare of moderate to severe intensity **AND** all of the following criteria:
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score ≥ 2 (moderate to severe) **AND**
    - Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) pustulation subscore ≥ 2 (moderate to very high density pustules) **AND**
    - Spevigo will be administered no sooner than 1 week after the initial dosage was administered

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

KRAZATI (adagrasib)

Review: Krazati is indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who had received at least one prior systemic therapy. This indicated was an accelerated approval based on objective response rate (ORR) and duration of response (DOR). The FDA approved test for the KRAS G12C Biomarker for Krazati is Agilent Resolution ctDx FIRST assay. Krazati is an irreversible inhibitor of KRAS G12C that binds mutant KRAS protein in its inactive state and prevents downstream signaling without affecting wild-type KRAS G12C. Krazati inhibits tumor cell growth and viability in cells harboring KRAS G12C mutations and results in tumor regression in KRAS G12C-mutated tumor xenograft models with minimal off-target activity. NCCN recommends Krazati after at least one line of therapy if no previous KRAS G12Ctargeted therapy (Category 2A/2B). They recommend not switching between Lumakras and Krazati at the time of progression since they have a similar mechanism of action.

The recommended dosage of Krazati is 600 mg orally twice daily until disease progression or unacceptable toxicity. In the event of adverse reactions, a maximum of two dose reductions to 400 mg twice daily and 600 mg once daily are permitted. If patients are unable to tolerate 600 mg once daily, Krazati should be permanently discontinued. Krazati is supplied as 200 mg tablets in bottles of 120 and 180 tablets.

The efficacy of Krazati was evaluated in KRYSTAL-1, a single-arm, open-label expansion cohort study in patients with locally advanced or metastatic KRAS G12C-mutated NSCLC who had previously received treatment with a platinum-based regimen and an immune checkpoint inhibitor, and ECOG Performance status of 0 or 1, and at least one measurable lesion defined by RECIST v1.1. Patients were treated with 600 mg twice daily until acceptable toxicity or disease progression. Efficacy was assessed based on objective response rate and duration of response. Results are shown in Table 5.

Warnings and Precautions for Krazati include gastrointestinal adverse reactions, QTc interval prolongation, hepatotoxicity, and interstitial lung disease and pneumonitis. During the KRYSTAL-1 trial, serious adverse reactions occurred in 57% of patients treated with Krazati, including pneumonia, dyspnea, renal impairment, sepsis, hypoxia, pleural effusion, respiratory failure, anemia, cardiac failure, hyponatremia, hypotension, muscular weakness, pyrexia, dehydration, diarrhea, mental status changes, pulmonary embolism, and pulmonary hemorrhage. Fatal adverse reactions occurred in 11% of patients, including pneumonia, respiratory failure, sudden death, cardiac failure, cerebrovascular accident, mental status change, pulmonary embolism, and pulmonary hemorrhage. Permanent discontinuation, dose interruptions, and dose reductions occurred in 13%, 77% and 28% of patients respectively. The most common adverse reactions were diarrhea, nausea, fatigue, vomiting, musculoskeletal pain, hepatotoxicity, renal impairment, dyspnea, edema, decreased appetite, cough, pneumonia, dizziness, constipation, abdominal pain, and QTc interval prolongation. The most common laboratory abnormalities

were decreased lymphocytes, albumin, platelets, sodium, magnesium, potassium, and hemoglobin and increased AST and ALT, creatinine, and lipase.

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: Krazati is a pharmacy benefit and will be added to the Oral Oncology Brand NP tier for Commercial, Marketplace, and GHP Kids. The following prior authorization criteria will apply:

- Medical record documentation that Krazati is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of a KRAS-G12C mutation, as determined by an FDA approved test **AND**
- Medical record documentation of at least one prior systemic therapy

RE-AUTHORIZATION CRITERIA: Krazati will be configured as a prior authorization for new starts only. Krazati will no longer be covered if it is identified that the member is not receiving appropriate follow-up care from the prescribing specialist or if the member has greater than or equal to a 90 day break in therapy.

- Medical record documentation that the member is receiving appropriate follow-up care from the prescribing specialist

GPI LEVEL: GPI-12

QUANTITY LIMIT: 6 tablets per day, 30 day supply per fill

FORMULARY ALTERNATIVES: Lumakras*

RPH SIGNOFF REQUIRED: Yes

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

FAST FACTS

BRUKINSA (zanubrutinib)

Clinical Summary: Brukinsa is now indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Previously indications for Brukinsa included mantle cell lymphoma (MCL), Waldenström's macroglobulinemia (WM), and relapsed/refractory marginal zone lymphoma (MZL) in patients who received at least one anti-CD20 based regimen.

The dosage of Brukinsa for the new indication is consistent with all other indications; 160 mg taken orally twice daily or 320 mg once daily until disease progression or unacceptable toxicity.

Current Formulary Status: Oral Oncology Brand Non-Preferred tier, requires a prior authorization

Recommendation: No changes are recommended to the formulary placement, authorization duration, or quantity limits. The following additional criteria are recommended for Commercial Policy 608.0 to incorporate the new indications:

Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Brukinsa is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

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.

FIRDAPSE (amifamprine)

Clinical Summary: On September 29, 2022, Firdapse was approved for use in pediatric patients age 6 to less than 17 years with Lambert-Eaton myasthenic syndrome (LEMS). This approval now permits use of Firdapse in patients six years of age and above.

Current Formulary Status: Pharmacy benefit requiring prior authorization; specialty tier or brand non preferred for members with a 3 tier benefit.

Recommendation: There are no changes recommended to the formulary placement or auth duration of Firdapse. The following changes are recommended to the prior authorization criteria in Commercial Policy 544.0 to incorporate the change regarding age:

- Medical record documentation of age greater than or equal to 6 years **AND**
- Medical record documentation that Firdapse is prescribed by a neurologist **AND**
- Medical record documentation of a diagnosis of Lambert-Eaton myasthenic syndrome confirmed by one of the following:
    - Medical record documentation of post-exercise facilitation test showing increase in compound muscle action potential (CMAP) amplitude of at least 60% compared to pre-exercise baseline value **OR**

    - Medical record documentation of high-frequency repetitive nerve stimulation (RNS) showing increase in compound muscle action potential CMAP) of at least 60% **OR**
    - Medical record documentation of positive anti-P/Q voltage-gated calcium channel antibody test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to pyridostigmine

Discussion: No comments or questions.

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

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

KEYTRUDA (pembrolizumab)

Clinical Summary: Keytruda is now indicated as a single agent, for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer.

The dosage for the adjuvant treatment of NSCLC is 200 mg every 3 weeks and 400 mg every 6 weeks until disease progression, unacceptable toxicity, or up to 12 months.

Current Formulary Status: Medical Benefit, requires a prior authorization. When processed at a Specialty pharmacy, Keytruda processes at the Specialty tier or Brand NP tier.

Recommendation: No changes are recommended to the formulary placement of Keytruda. The following criteria should be added to Medical Benefit Policy 119.0 for Keytruda to incorporate the new indication. The authorization duration should be updated to include the new indication.

Stage IB (T2a ≥ 4 cm), II, or IIIa Non-Small Cell Lung Cancer

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation that patient is ≥ 18 years of age **AND**
- Medical record documentation of Stage IB (T2a ≥ 4 cm), II, or IIIa non-small cell lung cancer (NSCLC) **AND**
- Keytruda is being used in the adjuvant setting following resection and platinum-based chemotherapy **AND**
- Keytruda is being used as a single agent

AUTHORIZATION DURATION:
For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, adjuvant treatment of renal cell carcinoma, adjuvant treatment of non-small cell lung cancer:

Initial approval will be for 6 months. One subsequent approval 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. Authorization of Keytruda for the adjuvant treatment of metastatic melanoma, renal cell carcinoma, and non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy.

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

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.

OXLUMO (lumasiran)

Clinical Summary: Oxlumo is now indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower plasma oxalate levels in pediatric and adult patients. Previously, it was approved to lower urinary oxalate levels in pediatric and adult patients.

Current Formulary Status: Medical benefit requiring prior authorization

Recommendation: No changes are recommended at this time based on updated indication.

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.

RUBRACA (rucaparib)

Clinical Summary: Rubraca is indicated for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

The recommended dose of Rubraca is 600 mg (two 300 mg tablets) taken orally twice daily with or without food, for a total daily dose of 1,200 mg. Continue treatment until disease progression or unacceptable toxicity.

Current Formulary Status: Pharmacy benefit requiring prior authorization.

Recommendation: Recommend the following prior authorization additions to policy 442.0:

- 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 a diagnosis of a deleterious BRCA mutation (germline and/or somatic)- associated 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.

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.

TECENTRIQ (atezolizumab)

Clinical Summary: Tecentriq is a programmed death-ligand 1 (PD-L1) blocking antibody that is now indicated for the treatment of unresectable or metastatic Alveolar Soft Part Sarcoma (ASPS) in adults and pediatric patients aged 2 years and older. Previously, Tecentriq was indicated for the treatment of Non-Small Cell Lung Cancer (NSCLC), Small Cell Lung Cancer (SCLC), Hepatocellular Carcinoma (HCC), melanoma, and has had its indication for Urothelial Carcinoma removed.

Current Formulary Status: Medical benefit that requires a prior authorization. When processed at a specialty pharmacy, it is on the Specialty Tier or Brand Non-Preferred Tier.

Recommendation: No changes are recommended to the formulary placement or authorization duration of Tecentriq. It is recommended that the following prior authorization criteria be added to Medical Benefit Policy 166.0 to incorporate the updated indication:

~~**Locally Advanced or Metastatic Urothelial Carcinoma:**~~

- ~~Prescription written by an oncologist **AND**~~
- ~~Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND**~~
- ~~Medical record documentation of one of the following:~~
  - ~~Patient is not eligible for cisplatin-containing therapy **AND**~~
  - ~~Tumors express PD-L1 (greater than or equal to 5%) as determined by an FDA-approved test~~

~~**OR**~~

- ~~Patient is not eligible for any platinum-containing chemotherapy (regardless of PD-L1 status)~~

Alveolar Soft Part Sarcoma (ASPS)

- Prescription written by an oncologist **AND**
- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of unresectable or metastatic alveolar soft part sarcoma (ASPS)

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.

TUKYSA (tucatinib)

Clinical Summary: Tukysa (tucatinib) is now indicated in combination with trastuzumab for the

treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Previously, Tukysa was approved in combination with trastuzumab and capecitabine for the 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. This combination is the first FDA-approved treatment indicated for HER2-positive metastatic colorectal cancer.

Current Formulary Status: Tukysa is a pharmacy benefit on specialty tier or brand non-preferred tier for members with a three- tier benefit, requiring prior authorization for new starts only with a quantity limit of 4 tablets per day, 30- day supply per fill.

Recommendation: There are no changes recommended to formulary placement of Tukysa at this time. However, it is recommended to update the prior authorization criteria in the current policy to include the following:

HER2-positive metastatic breast cancer

- Medical record documentation that Tukysa is precribed by a hematologist/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

OR

RAS wild type, HER2-positive metastatic colorectal cancer

- Medical record documentation that prescription is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of RAS wild-type HER2-positive unresectable or metastatic colorectal cancer **AND**
- Medical record documentation that Tukysa will be given in combination with trastuzumab **AND**
- Medical record documentation of prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy

Discussion: No comments or questions.

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

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

VEMLIDY (tenofovir alafenamide)

Clinical Summary: Vemlidy is now indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 12 years of age and older with compensated liver disease. Previously, Vemlidy was only indicated for adults.

Current Formulary Status: Vemlidy is a pharmacy benefit on the brand preferred tier with a quantity limit of 1 tablet per day. No prior authorization is required.

Recommendation: There are no changes recommended to the formulary placement 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.

VRAYLAR (cariprazine)

Clinical Summary: Vraylar is now indicated for the treatment of major depressive disorder as adjunctive therapy to antidepressants in adults. It was previously approved for the treatment of schizophrenia, manic/mixed episodes associated with bipolar I disorder, and depressive episodes associated with bipolar I disorder in adult patients.

Current Formulary Status: Vraylar is a pharmacy benefit on the Brand Non-preferred Tier requiring prior authorization.

Recommendation: No changes to formulary placement are recommended at this time. It is recommended to add the new indication as follows:

Major Depressive Disorder

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation of a diagnosis of major depressive disorder (MDD) AND
- Medical record documentation that the patient is using Vraylar as adjunctive therapy AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of combination therapy with aripiprazole and an antidepressant AND
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of combination antidepressant therapy (such as a selective serotonin reuptake inhibitor [SSRI] and bupropion or a serotonin and norepinephrine reuptake inhibitor [SNRI] and bupropion) OR
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least a 4-week trial of an antidepressant with augmentation therapy (including, but not limited to lithium, valproate, carbamazepine, and lamotrigine)

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.

ZEJULA (niraparib)

Clinical Summary: Zejula is now indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube,

or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Zejula was previously indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Zejula also remains 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. The indication for the treatment of advanced homologous recombination deficiency (HRD) positive ovarian cancer after greater than three lines of chemotherapy was removed.

Patients selected for the maintenance treatment of recurrent ovarian cancer with Zejula is based on the presence of deleterious or suspected deleterious germline BRCA mutations. An FDA-approved test for the detection of deleterious or suspected deleterious germline BRCA mutations is not currently available. The recommended dosage for the maintenance treatment of recurrent germline BRCA-mutated ovarian cancer is 300mg orally once daily. Treatment is continued until disease progression or unacceptable adverse reaction.

Current Formulary Status: Zejula is a pharmacy benefit requiring a prior authorization with a quantity limit. It is on the oral oncology brand non-preferred tier ($0 copay).

Recommendation: No changes recommended to the formulary placement or authorization duration of Zejula at this time. However, it is recommended to update policy 455.0 to include the following changes:

- ~~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:**~~

First-line maintenance treatment of advanced 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
- Medical record documentation 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 first-line platinum-based chemotherapy AND
- Medical record documentation that Zejula is being given at a dosage consistent with Food and Drug Administration (FDA)-approved labeling*

OR

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

- ~~Medical record documentation 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:**~~

Maintenance treatment of recurrent germline BRCA-mutated 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
- Medical record documentation of deleterious or suspected deleterious germline BRCA-mutated 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 of receiving at least 2 prior platinum-containing regimens AND

- Medical record documentation of a complete or partial response to the most recent platinum based chemotherapy AND
- Medical record documentation that Zejula is being given at a dosage consistent with Food and Drug Administration (FDA)-approved labeling (300mg once daily)

*__NOTE__: For the 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/µL, 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/µL the recommended dose is 300 mg (three 100-mg capsules) taken orally 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.

Voting responses were received from 33 of 50 members. The vote was unanimously approved.

Future Scheduled Meetings

The next bi-monthly scheduled meeting will be held on March 21st, 2023 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.