**P&T Committee Meeting Minutes**
**Commercial/Marketplace/GHP Kids**
**June 2022 e-vote**

## DRUG REVIEWS

### ANJESO (meloxicam injection)

**Review**: Anjeso is an NSAID indicated for use in adults for the management of moderate-to-severe pain. This can be used alone or in combination with non-NSAID analgesics. Due to delayed onset of analgesia, Anjeso alone is not recommended for use when rapid onset of analgesia is required. Most people reach pain relief within 2-3 hours.

The FDA approved dose is 30 mg once daily given undiluted as a slow 15 second IV push bolus. Anjeso should be used for the shortest duration of time consistent with individual patient treatment goals. Patients must be well hydrated before administration of Anjeso. Anjeso is supplied as a single-dose 30 mg/ml ready-to-use vial.

Meloxicam has anti-inflammatory, analgesic, and antipyretic properties. Similar to other NSAIDS, the mechanism of action is not fully understood but involves the inhibition of cyclooxygenase (COX-1 and COX-2). Meloxicam is an inhibitor of prostaglandin synthesis. Prostaglandins are mediators of inflammation and the inhibition of these in peripheral tissues may be the mode of inflammation inhibition. Anjeso is the only FDA approved injectable NSAID with once daily administration.

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:** Anjeso is a medical benefit and will not be added to the Commercial, Marketplace, or GHP Kids pharmacy formulary. It will require a prior authorization. The following prior authorization criteria will apply:

- Medical record documentation of age greater than or equal to 18 years of age **AND**
- Medical record documentation of moderate-to-severe post-operative pain **AND**
- Medical record documentation of prescriber attestation that the patient requires therapy by an intravenous route of administration **AND**
- Medical record documentation that the total daily dose will not exceed 30 mg per day **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three (3) formulary alternative medications, one of which must be oral meloxicam

**AUTHORIZATION DURATION:** Approval will be for one (1) week and will be limited to one (1) treatment course (up to 30 mg per day for up to 7 days total) (Facets RX count 210, Darwin RX count 7).

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

### FYARRO (sirolimus protein-bound particles for injectable suspension (albumin bound))

**Review:** Fyarro is an albumin-bound sirolimus intravenous formulation indicated for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). Fyarro inhibits mechanistic target of rapamycin kinase (mTOR) which controls key cellular functions such as cell survival, growth, and proliferation. Fyarro forms an immunosuppressive complex with immunophilin which inhibits mTOR complex 1 leading to a reduction in cell proliferation, angiogenesis, and glucose uptake. Intravenous administration of Fyarro led to higher tumor accumulation of sirolimus compared to an oral formulation at the same weekly total dose.

Malignant PEComa has no approved treatment regimens, although cytotoxic chemotherapy regimens have shown modest benefits. Prior to the approval of Fyarro, sirolimus, temsirolimus and everolimus showed some promising results in patients with metastatic PECOMS, but the absorption of these agents into the affected cells are variable and don't always provide complete target suppression. NCCN recommends Fyarro as the preferred single-agent for the treatment of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa) (Category 2A, Table 1).

**Table 1. Systemic Therapy Agents and Regimens with Activity in Soft Tissue Sarcoma Subtypes[3]**

| Inflammatory Myofibroblastic Tumor (IMT) with Anaplastic Lymphoma Kinase (ALK) Translocation | Malignant Perivascular Epithelioid Cell Tumor (PEComa) (for locally advanced unresectable or metastatic disease) | Recurrent Angiomyolipoma, Lymphangioleiomyomatosis |
|---|---|---|
| Preferred regimens<br>• ALK inhibitors<br>‣ Crizotinib[78]<br>‣ Ceritinib[79]<br>‣ Brigatinib[80,81]<br>‣ Lorlatinib | Preferred regimens<br>• Albumin-bound sirolimus[82,83]<br><br>Other recommended regimens<br>• Sirolimus[84-87]<br>• Everolimus[88]<br>• Temsirolimus[89,90] | Preferred regimens<br>• Sirolimus[84-87]<br>• Everolimus[88]<br>• Temsirolimus[89,90] |

The recommended dosage of Fyarro is 100 mg/m$^2$ administered as an intravenous infusion over 30 minutes on Days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity. For adverse reactions, the dosage can be reduced to 75 mg/m$^2$, 56 mg/m$^2$, and 45 mg/m$^2$. Patients who are unable to tolerate Fyarro after three dose reductions should discontinue treatment.

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:** Fyarro is a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Fyarro will process 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 of age greater than or equal to 18 years **AND**
- Medical record documentation that Fyarro is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa)

**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 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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**MACRILEN (macimorelin)**

**Review:** Macrilen is a growth hormone (GH) secretagogue receptor agonist indicated for the diagnosis of adult growth hormone deficiency (AGHD). Macrilen has a limitation of use stating the safety and diagnostic performance of Macrilen have not been established for subjects with a body mass index (BMI) >40 kg/$m^2$. Patients with organic pituitary disease and a serum insulin-like growth factor (IGF-1) level lower than lower limit of normal for gender and age have confirmed GH deficiency and do not require provocative testing. Patients with equivocal serum IGF-1 require a provocative test demonstrating subnormal response to confirm the diagnosis of GH deficiency.

In addition to the Macrilen test, UpToDate recognizes three other provocative tests to confirm a diagnosis of GH deficiency for adults, which includes the insulin-induced hypoglycemia test, glucagon stimulation test, and combination arginine and GH-releasing hormone (GHRH) test. Currently, UpToDate recommends a Macrilen stimulation test in countries where GH-releasing hormone (GHRH) is not available, including the United States. The 2019 American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) guidelines state the insulin tolerance test (ITT) remains the gold-standard to establish a diagnosis however, the glucagon-stimulation test and macimorelin test could be considered if the ITT is contraindicated or not feasible to be performed.

NCT02558829 was a randomized, open-label, single dose, cross over study comparing the level of agreement between the Macrilen test and insulin tolerance test (ITT) in 157 adult subjects with varying probabilities of growth hormone deficiency and healthy subjects. The ITT was used as the benchmark, meaning if a subject tested negative on the ITT, the indication was absence of disease, and if a subject tested positive on the ITT, the indication was presence of disease. The level of agreement between the results of the ITT and the Macrilen test was used to evaluate the performance of the Macrilen test. The primary outcome measure was the percentage of positive agreement and the percentage of negative agreement. The estimated for negative and positive agreement between the Macrilen test and the ITT in the overall study population were 94% and 74% with lower 95% confidence interval bounds being 85% and 63%, respectively.

There are no documented contraindications or black box warning for Macrilen. Warnings and precautions are significant for QT prolongation, potential for a false positive test result with the use of a strong CYP3A4 Inducer, and potential for a false negative test result in recent onset hypothalamic disease. Drug Interactions are significant for drugs that prolong the QT interval, P450 CYP 3A4 Inducers and drugs that affect growth hormone release. Clinical studies did not include a sufficient number of subjects 65 years and over to determine whether elderly patients respond differently compared to younger subjects. Elderly subjects may require a lower cut-off point for diagnosis since growth hormone secretion normally decreases with age.

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:** Macrilen will be a medical benefit. Macrilen will be added to the medical benefit cost share list when processed on the medical benefit. If processed at a specialty pharmacy, Macrilen will process at the Specialty tier or the Brand Non-preferred tier for members with a three tier benefit. No prior authorization criteria will apply.

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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**PLUVICTO (lutetium Lu 177 vipivotide tetraxetan)**

**Review:** Pluvicto is a radioligand therapeutic agent indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane based chemotherapy. The active moiety, radionuclide lutetium-177, is linked to a moiety that binds prostate-specific membrane antigen (PSMA), a transmembrane protein that is expressed in over 80% of prostate cancers. Upon binding PSMA-expressing cells, Pluvicto delivers radiation to PSMA-expressing cells, as well as surrounding cells, and induces DNA damage which can lead to cell death.

Pluvicto is a radiopharmaceutical that must be administered by healthcare providers with specific training and licensing to administer radiopharmaceuticals. It is administered intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity, at a dosage of 7.4 gigabecquerels (GBq) (200 millicurie [mCi]). In the event of adverse reactions, the dosage may require temporary dose interruption (extending the dosing interval from 6 weeks to 10 weeks), dose reduction, or permanent discontinuation. Treatment delays due to adverse reactions that persist for more than 4 weeks require Pluvicto discontinuation. The dose of Pluvicto may be reduced by 20% to 5.9 GBq once and the dose should not be re-escalated. Patients with continuation of adverse reactions after one dose reduction should discontinue treatment.
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:** Pluvicto is a medical benefit and will be added to the medical benefit cost share list. If processed at a specialty pharmacy, Pluvicto will process 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 Pluvicto 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 prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) **AND**
- Medical record documentation of prior treatment with an androgen-receptor pathway inhibitor 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

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**AUTHORIZATION DURATION:** Approval will be for a one-time authorization of 6 visits (15 months) of 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 labeling.

**FORMULARY ALTERNATIVES:** none

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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**PREHEVBRIO (Hepatitis B Vaccine (Recombinant)))**

**Review:** PreHevbrio is a vaccine indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

PreHevbrio contains small (S), middle (pre-S2) and large (pre-S1) hepatitis B surface antigens absorbed on aluminum hydroxide [Al(OH)3] as an adjuvant containing aluminum 0.5mg/mL. PreHevbrio induces antibodies to Hepatitis B surface antigens (HBsAg), with antibody concentrations ≥10 mIU/mL against HBsAG being recognized as conferring protection against hepatitis B virus infection. Other hepatitis B vaccines currently available include Heplisav-B, Engerix-B and Recombivax HB, all of which are single-antigen vaccines. PreHevbrio is the only approved 3-antigen hepatitis B virus (HBV) vaccine for adults in the United States.
Previously, the CDC recommended all infants, unvaccinated people under 19 years of age, and adults in "high risk" groups (healthcare personnel, public safety personnel, incarcerated people, injection-drug users, international travelers to countries with high or intermediate levels of endemic HBV infection, people at risk for infection by sexual exposure, and patients with certain health conditions (chronic liver disease, HIV infection)) be vaccinated against HBV. On November 3, 2021, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) unanimously voted to recommend that all U.S. adults 59 years of age and under should be vaccinated against HBV, regardless of risk. The new recommendation will not become public policy until signed by the CDC's director. Currently the CDC adult immunization schedule for ages 19 years or older, Unites States, 2022, recommends hepatitis B vaccine for adults who meet age requirements (19 through 59 years old), lack documentation of vaccine, or lack evidence of past infection. The CDC recommends that anyone age 60 or older who does not meet risk-based recommendations may still receive hepatitis B vaccination.

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

**Clinical Discussion:** Tricia recommended an additional note to address requests for durations longer than 8 weeks. No additional comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

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

**Outcome:** PreHevbrio will be covered as a medical or pharmacy benefit and will not require prior authorization. PreHevbrio will be covered as a preventive vaccine for a $0 copay. The following age limit should apply:

**AGE LIMIT:** 18 years and older

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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**TARPEYO (budesonide)**

**Review:** Tarpeyo is a corticosteroid (budesonide targeted delayed release) indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

The recommended duration of therapy is 9 months, with a dosage of 16 mg (four 4mg capsules) administered orally once daily. The delayed release capsules should be swallowed whole in the morning, at least 1 hour before a meal. Do not open, crush or chew. When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy. Tarpeyo (budesonide) delayed release capsules 4 mg, are white opaque-coated capsules supplied in bottles of 120 capsules. Safety and efficacy of treatment with subsequent courses of Tarpeyo 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**: No comments or questions. The committee unanimously voted to accept the recommendations as presented. None were opposed.

**Outcome:** Tarpeyo is a pharmacy benefit. Tarpeyo will be added to the Commercial/Exchange/CHIP formularies at the Specialty Tier or BrandNP tier for members with a 3 Tier benefit. The following prior authorization criteria will apply:

- Medical record documentation of age ≥ 18 years **AND**
- Medical record documentation of primary immunoglobulin A nephropathy (IgAN) verified by biopsy **AND**
- Medical record documentation that the medication is prescribed by or in consultation with a nephrologist **AND**
- Medical record documentation that patient is at high risk of disease progression, defined as urine protein-to-creatinine ratio (UPCR) ≥ 1.5 or proteinuria ≥ 1g/day **AND**
- Medical record documentation of eGFR ≥ 35 mL/min/1.73 $m^2$ **AND**
- Medical record documentation that patient has received a stable dose of a RAS Inhibitor (ACE inhibitor or ARB) at a maximally tolerated dose for ≥ 90 days **AND**
- Medical record documentation that a RAS inhibitor (ACE inhibitor or ARB) will be used in combination with Tarpeyo **AND**
- Medical record documentation that patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification **AND**
- Medical record documentation that the member has not previously completed a 9-month treatment course of Tarpeyo **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to a glucocorticoid (e.g., prednisone, methylprednisolone)

**MEDISPAN AUTHORIZATION LEVEL:** GPI-14

**QUANTITY LIMIT:** 120 capsules (1 bottle) per 30 days

**AUTHORIZATION DURATION:** Approval will be for one 10-month treatment cycle (or less if there is medical record documentation of an incomplete course of therapy)

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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**VIJOICE (alpelisib)**

**Review:** Vijoice is an oral kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. Vijoice inhibits phosphatidylinositol-3-kinase (PI3K), predominantly PI3Kα. Activating mutations in the gene encoding for the catalytic α-subunit of PI3K (PIK3CA) have been found to induce overgrowths and malformations which comprise PROS disorders. In inducible mouse models of Congenital Lipomatous Overgrowth, Vascular Malformations, Epidermal Nevi, Scoliosis/Skeletal and Spinal syndrome (CLOVES), a phenotype of PROS, Vijoice resulted in prevention or improvement of organ abnormalities associated with the disease. Results depended on when treatment was started and the findings reversed after withdrawal of Vijoice.

The recommended dosage of Vijoice for adult patients is 250 mg orally once daily until disease progression or unacceptable toxicity. The recommended initial dosage of Vijoice in pediatric patients is 50 mg once daily until disease progression or unacceptable toxicity. In patients 6 years and older, the dose can be increased up to 125 mg once daily after 24 weeks of treatment at the initial dosage for response optimization. Pediatric patients who subsequently turn 18 years old can consider a gradual dose increase up to 250 mg. Adult patients requiring a dosage reduction can reduce the dose to 125 mg once daily and subsequently 50 mg once daily if need. Pediatric patients 6 years and older can reduce the dose to 50 mg once daily. All patients unable to tolerate 50 mg once daily should discontinue Vijoice.

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:** Vijoice is a pharmacy benefit and will be added to the Specialty tier or Brand Non-preferred tier for members with a three-tier benefit on the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will be required:

- Medical record documentation of age greater than or equal to 2 years **AND**
- Medical record documentation of diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS) **AND**
- Medical record documentation of mutation in the catalytic α-subunit of PI3K (PIK3CA) gene **AND**
- Medical record documentation of severe or life-threatening disease which requires systemic treatment

**MEDISPAN AUTHORIZATION LEVEL:** GPI-12

**QUANTITY LIMIT:**

50 mg tablets: 1 tablet per day, 28 day supply per fill
125 mg tablets: 2 tablets per day, 28 day supply per fill
250 mg Therapy Pack (200 mg and 50 mg tablets): 2 tablets per day, 28 day supply/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 patient experiences toxicity or worsening of disease.

**FORMULARY ALTERNATIVES:** none

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

## FAST FACTS

## CABENUVA/VOCABRIA/EDURANT (cabotegravir/rilpivirine)

**Clinical Summary:**
Cabenuva: New dosage regimen of every 2-month gluteal intramuscular injections that allows patients to proceed directly to injection dosing without the use of oral cabotegravir and oral rilpivirine lead-in dosing. Now indicated for treatment of HIV-1 infection in adults and adolescent 12 years of age and older and weighing at least 35kg. Previously indicated in adult patients with an oral lead-in dose with Vocabria and Edurant and then every month thereafter.

Vocabria: Expands the use of Vocabria in combination with Edurant as an oral, short-term treatment regimen followed by Cabenuva injection dosing regimen administered monthly or every two months for the treatment of HIV-1 virus infection in adolescents 12 years of age and older and weighing at least 35 kg. Previously indicated for HIV-treatment in combination with Edurant for short-term treatment of HIV-1 infection in adults.

Edurant: Expands the use of Edurant in combination with Vocabria as an oral, short-term treatment regimen, followed by monthly Cabenuva injection dosing regimen for the treatment of HIV-1 virus infection in adolescents 12 years of age and older and weighing at least 35 kg. Previously indicated for HIV-treatment in combination with Edurant for short-term treatment of HIV-1 infection in adults.

**Current formulary status:**
Cabenuva is a medical benefit, no prior authorization required
QLs: 600 mg/900 mg Kit: 6 mL per 180 days, 400 mg/600 mg Kit: 4 mL per 28 days
Vocabria is a pharmacy benefit on the Brand preferred tier, no PA required, QL 1 tablet per day
Edurant is a pharmacy benefit on the Brand preferred tier, no PA required, QL 1 tablet per day

**Recommendation:** There are no changes recommended to the formulary placement of Cabenuva, Vocabria or Edurant

**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.

## LUPRON (leuprolide acetate for depot suspension)

**Clinical Summary:** Lupron Depot 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, and 45 mg for 6-month administration are indicated for the treatment of advanced prostatic cancer. Previously, they were indicated for the palliative treatment of advanced prostatic cancer.

There have been no changes to the recommended dosing. Lupron Depot must be administered under the supervision of a physician. Lupron Depot 7.5 mg is given once every 4 weeks. Lupron Depot 22.5 mg is given once every 12 weeks. Lupron Depot 30 mg is given once every 16 weeks. Lupron Depot 45 mg is given once every 24 weeks.

There were no additional studies completed to support this update in indication. Also, there are no changes to the safety considerations.

**Current formulary status:** Lupron Depot is currently a medical benefit and does not require a prior authorization. If Lupron Depot processes through a specialty pharmacy, it will process at the Specialty tier or the Brand Non-Preferred tier for members with a three tier benefit. Lupron Depot does not require a prior authorization.

**Recommendation:** There are no formulary changes 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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**OZEMPIC (semaglutide)**

**Clinical Summary:** Ozempic was approved for a new dose of 2mg once weekly. Previously, the maximum dose of Ozempic was 1mg once weekly. Ozempic is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). Ozempic is also indicated to reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease.

A new dosage form of Ozempic was approved to allow for 2mg once weekly dosing. Ozempic is now available in single-patient-use pen that deliver 2mg per injection: Ozempic 8mg/3mL.

Ozempic has a new warning/precaution for Acute Gallbladder Disease – If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated.

**Current formulary status:** Ozempic is on the preferred brand tier with the following quantity limits:

- Ozempic 0.25mg or 0.5mg/dose (2mg/1.5mL): 0.06 mL per day
- Ozempic 1mg/dose (2mg/1.5mL): 0.11 mL per day
- Ozempic 1mg/dose (4mg/3mL): 0.11 mL per day
- Ozempic 2mg/dose (8mg/3mL): 0.11 mL per day

**Recommendation:** There are no changes recommended to formulary placement of Ozempic 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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**SOLOSEC (secnidazole)**

**Clinical Summary:** Solosec is now indicated to treat bacterial vaginosis and trichomoniasis in children ≥ 12 years old. Previously it was only indicated for use in adults.

**Current formulary status:** Non-formulary

**Recommendation:** No changes to formulary status. Age in policy should be updated to "age greater than or equal to 12 years"

**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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**TIBSOVO (ivosidenib)**

**Clinical Summary:** Tibsovo is now indicated for the treatment of newly diagnosed AML in combination with azacitidine in adults who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. Previously, it was approved for treatment of newly diagnosed AML as monotherapy in adults who are 75 years or older (or who have comorbidities that preclude use of intensive induction chemotherapy), relapsed/refractory AML in adult patients, and locally advanced/metastatic cholangiocarcinoma in adult patients.

There were no changes to dosing or safety considerations for the new indication.

**Current formulary status:** Tibsovo is a pharmacy benefit available at Brand Non-Preferred Tier (Oral Oncology Tier). Tibsovo requires prior authorization.

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

Newly Diagnosed AML:

- Medical record documentation that Tibsovo is prescribed by a hematologist or oncologist AND
- Medical record documentation of newly diagnosed acute myeloid leukemia **AND**
- Medical record documentation that Tibsovo will be used as monotherapy or in combination with azacitidine **AND**
- Medical record documentation of an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation of one of the following:
    - Medical record documentation of age greater than or equal to 75 years **OR**
    - Medical record documentation of age greater than or equal to 18 years **AND** comorbidities† that preclude the use of intensive induction 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.

**TRIUMEQ/TRIUMEQ PD (abacavir, dolutegravir, and lamivudine)**

**Clinical Summary:** Triumeq/Triumeq PD is now indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 10 kg. Triumeq PD is a new dosage form. Triumeq was previously indicated for the treatment of HIV-1 infection in adults and in pediatric patients weighing at least 40 kg.

The updated dosing for Triumeq/Triumeq PD is as follows:

- Pediatric patients weighing 10kg to less than 14kg: 4 tablets of Triumeq PD once daily
- Pediatric patients weighing 14kg to less than 20kg: 5 tablets of Triumeq PD once daily
- Pediatric patients weighing 20kg to less than 25kg: 6 tablets of Triumeq PD once daily
- Pediatric patients weighing greater than or equal to 25kg and adults: 1 tablet of Triumeq once daily

Prior to initiating Triumeq or Triumeq PD, it is recommended that patients be screened or tested for the following: HLA-B*5701 allele due to the abacavir component of the drug, Hepatitis B infection, pregnancy in adolescents and adults of childbearing potential. The following are other dosage considerations. Triumeq and Triumeq PD should not be interchanged based on a milligram-per-milligram basis. If dosing with certain UGT1A or CYP3A inducers, the dosage of dolutegravir should be adjusted. Because Triumeq and Triumeq PD are fixed-dose tablets and cannot be dose adjusted, they are not recommended in patients with creatinine clearance less than 30mL/min or in patients with hepatic impairment.

The warnings and precautions for Triumeq and Triumeq PD has been updated to include that the different formulation are not interchangeable. Triumeq and Triumeq PD are not interchangeable on a milligram-per-milligram basis. If a pediatric patient switches from the tablets for oral suspension to the tablets, the dosage must be adjusted.

**Current formulary status:** Triumeq is a pharmacy benefit on the brand tier with a quantity limit.

**Recommendation:** No changes recommended to the formulary placement of Triumeq at this time. It is recommended that Triumeq PD be added to the brand tier with a quantity limit of 6 tablets 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.

## UPDATES

## NUCALA

**Background:** Nucala is now available in a 40 mg/0.4 mL prefilled syringe for use in children aged 6 to 11 years. There is no change to the recommended dosage for pediatric patients, but previously this dosage was not available as a prefilled syringe and was only available by using 0.4 mL from a 100 mg single-dose vial for reconstitution. The pediatric dosage for severe eosinophilic asthma for patients 6 to 11 years of age is 40 mg administered subcutaneously once every 4 weeks.

The 100 mg/mL prefilled autoinjectors and 100 mg/mL prefilled syringes are still only for use in adults and adolescents aged 12 years and older and patients may self-inject or the patient caregiver may inject those products. The 40 mg/0.4 mL prefilled syringe is only for use in children 6 to 11 years and must be administered by a healthcare provider or the patient caregiver if the healthcare provider determines it is appropriate.

**Current Formulary Status:** Nucala 100 mg vial for reconstitution: Medical benefit, requires prior authorization; Quantity Limit: 1 vial (100mg) per 28 days (for eosinophilic asthma or CRSwNP), 3 vials (300mg) per 28 days (for EGPA or HES)

Nucala 100 mg Prefilled Syringe/Autoinjector: Pharmacy benefit, Specialty tier or Brand NP tier for members with a 3 tier benefit, requires a prior authorization, Quantity Limit: 1 prefilled syringe or autoinjector (100mg) per 28 days (for eosinophilic asthma or CRSwNP), 3 prefilled syringes or autoinjectors (300mg) per 28 days (for EGPA or HES)

**Recommendation:** Nucala 0.4 mg/mL can be a medical benefit if administered by a healthcare professional or a pharmacy benefit if administered by a caregiver. It should be added to formulary to match the placement of the Nucala 100 mg vials, prefilled syringes, and autoinjectors.

For Medical: Nucala 0.4 mg/mL should be added to the medical benefit cost share list. When processed at a specialty pharmacy: Specialty tier or Brand NP tier for members with three tier benefit. Add to policy MBP 141.0

For Pharmacy: Nucala 0.4 mg/mL should be added to the Specialty tier or Brand NP tier for members with a three tier benefit. Add to policy 592.0.

The following quantity limits and changes should be made to Medical Benefit Policy 141.0 for Nucala Vials and Commercial Policy 592.0 for Nucala for Self-Administration:

**MBP 141.0**
**Quantity Limit:** 100 mg vials: 1 vial (100mg) per 28 days (for eosinophilic asthma or CRSwNP), 3 vials (300mg) per 28 days (for EGPA or HES)
40 mg/mL prefilled syringe: 1 prefilled syringe (40 mg) per 28 days (for eosinophilic asthma for patients 6-11 years of age)

**Commercial Policy 592.0**
**Severe Eosinophilic Asthma**

- Medical record documentation of age greater than or equal to ~~12 years~~ 6 years **AND**

**QUANTITY LIMIT:** *QL must be entered within the authorization.*

- QL FOR LETTER & AUTHORIZATION: 100 mg prefilled syringe/autoinjector: 1 prefilled syringe or 1 autoinjector (100 mg) per 28 days
  40 mg prefilled syringe: 1 prefilled syringe (40 mg) per 28 days

**Discussion:** No comments or questions.

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

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

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**Voting responses were received from 30 of 49 members. The vote was unanimously approved.**

**Future Scheduled Meetings**

The next bi-monthly scheduled meeting will be held on July 19th, 2022 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.