P&T Committee Meeting Minutes
Commercial/Marketplace/CHIP
April 2024 e-Vote

DRUG REVIEWS

Entyvio Subcutaneous (vedolizumab)

Review:
Entyvio SC is a new subcutaneous formulation of Entyvio (vedolizumab) indicated for the treatment of adult patients with moderately to severe active ulcerative colitis (UC). It is currently not approved for Crohn's disease and patients with CD should continue on Entyvio intravenous infusions.

Entyvio SC prefilled syringe and pen are intended for subcutaneous use under the guidance and supervision of a healthcare professional. Patients or caregivers may self-inject subcutaneous Entyvio after training in subcutaneous injection technique. Following the first two Entyvio intravenous doses (Week 0 and Week 2), Entyvio may be switched to subcutaneous injection at week 6, then every two weeks thereafter. Entyvio may also be switched from intravenous infusion to subcutaneous injection for patients in clinical response or remission beyond Week 6. To switch patients to Entyvio SC, administer the first subcutaneous dose in place of the next scheduled intravenous infusion and every two weeks thereafter. Entyvio SC is supplied as subcutaneous single-dose prefilled pens and single-dose prefilled syringes containing 108 mcg/0.68 mL.

The safety and efficacy of subcutaneous Entyvio was evaluated in a randomized, double-blind, placebo-controlled trial in adult patients with moderately to severely active ulcerative colitis defined as Mayo score of six to twelve with endoscopy subscore of two or three. The baseline Mayo score was between nine to 12 in about 62% and six to eight in about 38% of the overall trial population. The trial included patients who had demonstrated an inadequate response to, loss to response to, or intolerance of at least one 12-week regimen of azathioprine or 6-mercaptopurine, induction with a TNF blocker, or corticosteroids. Patients were permitted to use concomitant stable doses of oral aminosalicylates, oral corticosteroids (prednisone ≤30 mg/day or budesonide ≤9 mg/day), azathioprine or 6-mercaptopurine, probiotics and/or antidiarrheals.

All patients received open-label intravenous Entyvio at Week 0 and Week 2. In order to be randomized to treatment, patients had to be in clinical response at week 6. A total of 162 patients were randomized at Week 6 in a double-blind fashion (2:1) to Entyvio SC 108 mg or placebo every 2 weeks. The primary endpoint was proportion of patients in clinical remission defined as a Mayo score of ≥ 2 points and no individual subscore > 1 point at Week 52. Secondary endpoints included the proportion of patients with improvement of endoscopic appearance of the mucosa at Week 52 and clinical response at both Weeks 6 and 52.

Maintenance of remission at Week 52 in the subgroup of patients who were in remissions at Week 6, was 64% (16/25) in the Entyvio group compared to 20% (3/15) in the placebo group (treatment difference was 44% [95% CI: 9%, 69%]).

The safety profile of Entyvio SC was similar between patients switched to Entyvio SC in the VISIBLE 1 trial and patients in UC and CD clinical trials who received Entyvio as an intravenous infusion except for injection site reactions which were reported with Entyvio SC. Injection site reactions with subcutaneous Entyvio SC in the VISIBLE 1 trial were reported in 9% (10/106) of patients, including injection site erythema, rash, swelling, bruising, and hematoma.

The safety and efficacy of Entyvio has not been established in pediatric patients. Clinical trials of Entyvio did not include sufficient numbers of subjects aged 65 years and over to determine if they respond differently from younger subjects. No overall differences were observed between older and younger

patients and other reported clinical experience has not been identified in responses between elderly and younger patients.

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

Outcome: Entyvio SC is pharmacy benefit and will be added to the Specialty tier or Brand Non-preferred tier for members with a three tier benefit for the Commercial, Marketplace, and GHP Kids formulary. It will require a prior authorization for new starts only. The following prior authorization criteria will apply:

Ulcerative Colitis

- Medical record documentation that Entyvio SC is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderate-to-severe ulcerative colitis **AND**
- Medical record documentation that medication is not being used concurrently with a TNF blocker or other biologic agent **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least one conventional therapy: corticosteroids, aminosalicylates, or immunomodulators (e.g. 6-mercaptopurine or azathioprine)

GPI LEVEL: GPI-12

QUANTITY LIMIT: 2 pen injectors per month

RE-AUTHORIZATION CRITERIA: Entyvio SC is configured as a prior authorization for new starts only. Entyvio SC 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

RPH SIGNOFF REQUIRED: yes

FORMULARY ALTERNATIVES: azathioprine, 6-mercaptopurine

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

Omvoh (mirikizumab-mrkz)

Review:
Omvoh is indicated for the treatment of moderately to severely active ulcerative colitis in adults. Omvoh is a humanized IgG4 monoclonal antibodies that selectively bind the p19 subunit of human interleukin(IL)-23 cytokine and inhibit the interaction with the IL-23 receptor. IL-23 is involved in mucosal inflammation and affects the differentiation expansion and survival of T cell subsets and innate immune cell subsets which represent sources of pro-inflammatory cytokines. Omvoh inhibits the release of pro-inflammatory cytokines and chemokines.

The recommended induction dosage of Omvoh is 300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8. The recommended maintenance dosage of Omvoh is 200 mg subcutaneously (2 consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter. Omvoh for intravenous use is intended for administration by healthcare providers. Omvoh for subcutaneous injection is intended for use under the guidance and supervision of a healthcare professional. It may be self-injected after training in subcutaneous injection technique. Omvoh is supplied as intravenous

infusion solution containing 300 mg/15 mL (20 mg/mL) in a single-dose vial and a subcutaneous injection solution containing 100 mg/mL solution in a single-dose prefilled pen.

The safety and efficacy of Omvoh was evaluated in LUCENT-1 and LUCENT-2, two randomized, double-blind, placebo-controlled clinical trials, one induction study and one maintenance study, in adult patients with moderately to severely active ulcerative colitis who had inadequate response, loss of response, or failed to tolerate any of the following: corticosteroids, 6-mercaptopurine, azathioprine, biologic therapy (TNF blocker, vedolizumab), or tofacitinib. The 12-week intravenous induction study (UC-1) was followed by the 40-week subcutaneous randomized withdrawal maintenance study (UC-2).

Warnings include serious hypersensitivity reactions, risk of infections, tuberculosis infection, hepatotoxicity, and increased of risk of infections following live vaccinations. Adverse reactions reported in at least 2% of patients in LUCENT-1 were upper respiratory infections and arthralgia. Infusion-related hypersensitivity reactions were reported by 4 (0.4%) patients treated with Omvoh and 1 (0.3%) patients treated with placebo. During the LUCENT-2 adverse reactions occurring in at least 2% of patients included upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection.

Infections were reported in 145 patients (15%) treated with Velsipity in LUCENT-1 and 93 patients (24%) treated with Velsipity in LUCENT-2. Serious infections included intestinal sepsis, listeria sepsis, pneumonia, and COVID-10 pneumonia.

The safety and efficacy of Omvoh has not been established in pediatric patients. Of the 795 patients treated with Omvoh in LUCENT-1 and LUCENT-2, 64 patients (8%) were 65 years and older, while 10 patients (1%) were 75 years and older. There were not sufficient numbers of geriatric subjects included to determine if they respond differently from younger patients. No clinically meaningful differences in the pharmacokinetics of Omvoh were observed in patients 65 years and older compared to younger patients.

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

Outcome: Omvoh 300 mg/15 mL vial for intravenous infusion will process as a medical benefit. Omvoh 100 mg/mL prefilled pen is a pharmacy benefit and will be added to the Specialty tier or Brand non preferred tier for members with a three tier benefit for Commercial, Marketplace, and GHP Kids formulary. Omvoh vials for intravenous infusion will be added to the medical benefit cost share list. When processed at a Specialty pharmacy, Omvoh vials for IV infusion will process at the Specialty or Brand NP tier for members with a three tier benefit. It will require a prior authorization for new starts only and the following prior authorization criteria will apply:

- Medical record documentation that Omvoh is prescribed by a gastroenterologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of moderately to severely active ulcerative colitis **AND**
- Medical record documentation that Omvoh is not being used concurrently with a tumor necrosis factor (TNF) blocker or other biologic agent **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of three (3) preferred formulary biologics for the treatment of ulcerative colitis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on Entyvio* **AND** infliximab*
- Medical record documentation of Omvoh 300 mg vials as IV infusion (for induction therapy) **OR** Omvoh 100 mg syringes (for maintenance therapy) being prescribed **AND** **(Commercial/Exchange/CHIP Pharmacy Policy Only)**
- Medical record documentation Omvoh 300 mg vials as intravenous (IV) infusion (for induction therapy) **(Medical Policy Only)**

GPI LEVEL: GPI-10

OMVOH 100 MG/ML PREFILLED PEN QUANTITY LIMIT: 2 mL (2 prefilled pens) per 28 days

OMVOH 100 MG/ML PREFILLED PEN RE-AUTHORIZATION CRITERIA: Omvoh is configured as a prior authorization for new starts only. Omvoh 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 105 day break in therapy.

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

OMVOH 300 MG/150 ML IV INFUSION AUTHORIZATION DURATION: Approval will be given for an initial authorization duration of six (6) months

OMVOH 300 MG/150 ML IV INFUSION QUANTITY LIMIT: one-time authorization

- NCRx Quantity Limit: 45 mL per 56 days GPI 14 for Omvoh 300 mg/15 mL vial
- NCRx Quantity limit: 2mL per 28 days GPI 14 for Omvoh 100 mg/mL Prefilled Pen (Facets Rx Count: will convert to Facets count when Jcode becomes available)

RPH SIGN OFF REQUIRED: yes

FORMULARY ALTERNATIVES: azathioprine, balsalazide, mesalamine, sulfasalazine, Humira*/**, adalimumab-fkjb*/**, Hadlima*/**, Yusimry*/**, Rinvoq*/**, Simponi*/**, Xeljanz*/**

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

Miebo (perfluorohexyloctane ophthalmic solution)

Review:
Miebo is a semi-fluorinated alkane indicated for the treatment of the signs and symptoms of dry eye disease. The exact mechanism of action for Miebo in DED is not known but it helps to stabilize the tear film and prevents rapid tear evaporation in patients with meibomian gland dysfunction (MGD). MGD occurs in about 86% of patients with dry eye disease. Treatment guidelines recommend OTC artificial tears first line, followed by pharmacologic treatment with topical antibiotics, topical corticosteroids (limited duration), topical secretagogues, cyclosporine, lifitegrast, oral macrolide or tetracycline antibiotics, punctal occlusion, moisture chambers. At this time, treatment guidelines have not been updated to include Miebo.

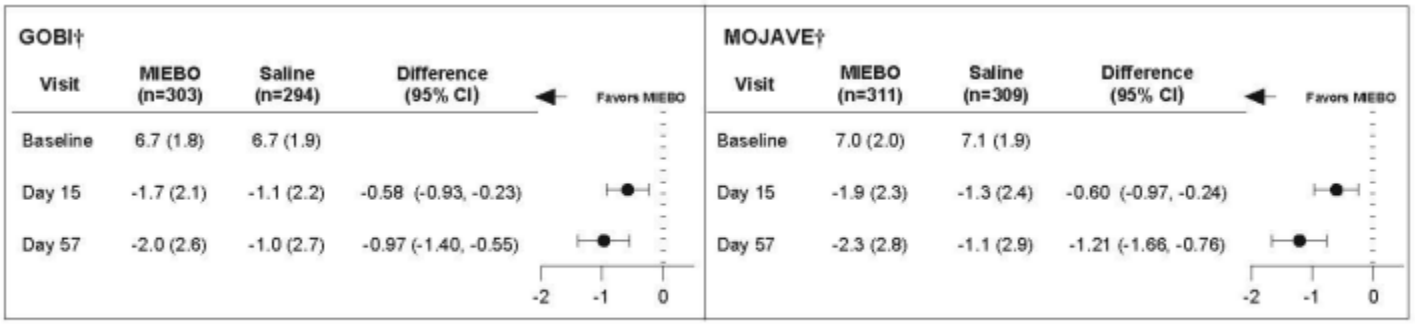
The recommended dosage of Miebo is one drop into affected eye(s) four times daily. Miebo is supplied in multi-dose 5 mL bottles with dropper tips.

The safety and efficacy of Miebo was evaluated in the GOBI and MOJAVE trials, two randomized, double-masked, saline-controlled trials in 1,217 patients with a history of DED and clinical signs of meibomian gland dysfunction were randomized to Miebo (n=614) or saline 0.6% (n=603).

Total corneal fluorescein staining (tCFS) was recorded at each study visit using a standardized grading system of 0-3 for each of the five areas of the cornea. At days 15 and 57, a statistically significant reduction in tCFS was observed for Miebo compared to saline in both studies (Figure 2). Eye dryness score was rated by patients using a visual analogue scale (VAS) (0=no discomfort, 100=maximal discomfort) at each study visit. The baseline VAS eye dryness average score was 67 in GOBI and 65 in MOJAVE. At days 15 and 57, a statistically significant reduction in VAS eye dryness was observed for Miebo compared to saline in both studies (Figure 3).

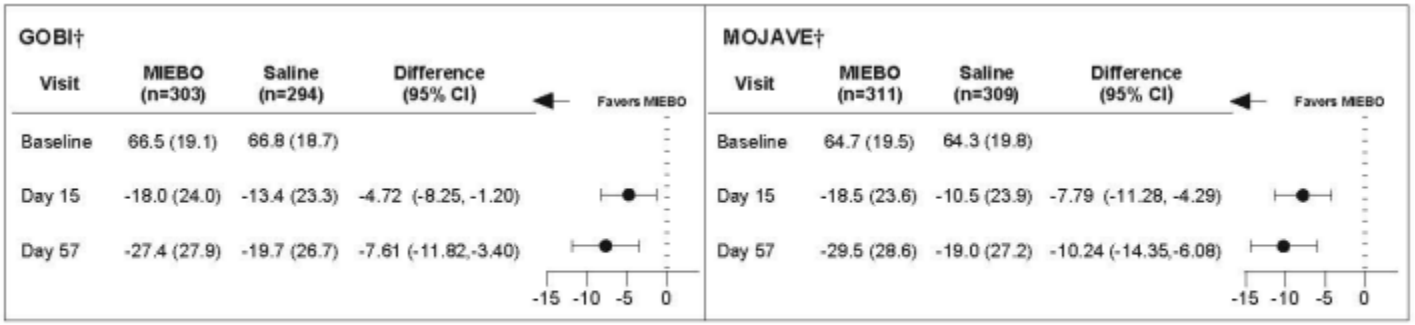
Figure 2. Mean Change (Standard Deviation) from Baseline and Treatment Differences

(Miebo-Saline) in Total Corneal Fluorescein Staining (Study eye) [1]



† A Phase 3, Multi-Center, Randomized, Double-Masked, Saline-Controlled Trial to Evaluate the Effect of NOV03 (Perfluorohexyloctane) on Signs and Symptoms of Dry Eye Disease Associated with Meibomian Gland Dysfunction

Figure 3. Mean Change (Standard Deviation) from Baseline and Treatment Differences (Miebo-Saline) in Eye Dryness Score (Study eye)[1]



† A Phase 3, Multi-Center, Randomized, Double-Masked, Saline-Controlled Trial to Evaluate the Effect of NOV03 (Perfluorohexyloctane) on Signs and Symptoms of Dry Eye Disease Associated with Meibomian Gland Dysfunction

There are no black box warnings or contraindications for Miebo. Patients should not administer Miebo while wearing contact lenses. Lenses should be removed prior to and for at least 30 minutes after administration of Miebo. In clinical trials, the most common ocular adverse reactions was blurred vision. Blurred vision and conjunctival redness was reported in 1-3% of individuals. The safety and efficacy of Miebo in pediatric patients has not been established. In the geriatric population, no overall differences were observed between older and younger patients.

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

Outcome: Miebo is a pharmacy benefit and will not be added to the Commercial, Marketplace, and GHP Kids formularies. The following prior authorization criteria will apply:

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

GPI LEVEL: GPI-12

RPH SIGNOFF REQUIRED: no

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

FAST FACTS

ADBRY (tralokinumab)

Clinical Summary: Adbry is indicated for the treatment of moderate-to-severe atopic dermatitis in patients aged 12 years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It was previously indicated in patients 18 years of age and older.

Updated Dosing:

	Initial Loading Dose	Subsequent Dosage
Adult 18 years and older	600 mg (four 150 mg injections)	300 mg (two 150 mg injections) every other week
Pediatric 12 to 17 years old	300 mg (two 150 mg injections)	150 mg (one 150 mg injection) every other week

- For the initial loading dose of 600 mg, administer each of the four 150 mg injections at different injection sites within the same body area. For the subsequent 300 mg doses, administer the two 150 mg injections at different injection sites within the same body area, rotating the body area with each subsequent set of injections.
- For the initial loading dose of 300 mg, administer the two 150 mg injections at different injection sites within the same body area. For the subsequent 150 mg doses, administer one 150 mg injection, rotating the body area with each subsequent injection.
- Administer subcutaneous injection into the thigh or abdomen, except for the 2 inches (5 cm) around the navel. The upper arm can also be used if a caregiver administers the injection.

Current Formulary Status: Pharmacy Benefit available at the Specialty tier, Prior Authorization required.

Recommendation: There are no recommended changes to formulary status, quantity limits, or authorization duration at this time. It is recommended to update policy 701.0 to include the new FDA approved age range:

- Medical record documentation of a diagnosis of moderate to severe atopic dermatitis **AND**
- Medical record documentation that Adbry is prescribed by or in consultation with an allergist, dermatologist, or immunologist **AND**
- Medical record documentation of age greater than or equal to 12 ~~18~~ **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on an adequate trial of phototherapy (UVA/UVB treatment) **AND**
- Medical record documentation of one of the following:
  - Therapeutic failure on an adequate trial of at least one medium (or higher) potency topical corticosteroid **OR**
  - For members with an intolerance or contraindication to topical corticosteroids or for members in whom topical corticosteroids are inadvisable, therapeutic failure on, intolerance to, or contraindication to a topical calcineurin inhibitor

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals for the medication will be for 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 patient experiences toxicity or worsening of disease.

QUANTITY LIMIT (add to letter ONLY): 6 mL per 28 days

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

BESPONSA (inotuzumab ozogamicin)

Clinical Summary: Besponsa is now indicated for the treatment of relapsed or refractory CD22-positive B-Cell precursor acute lymphoblastic leukemia (ALL) in pediatric patients 1 year and older. Previously, it was approved for this same indication in adults. There are no changes to the dosing regimen for pediatric patients.

Besponsa was evaluated in a multicenter, single-arm, open-label study in 53 pediatric patients 1 year to <18 years of age with relapsed or refractory CD22-positive B-cell precursor ALL. There were 2 dose levels: initial dose of 1.4mg/m^2/cycle in 12 patients and 1.8mg/m^2/cycle in 41 patients. Efficacy was established based on Complete Remission (CR) Rate [defined as < 5% blasts in the bone marrow and the absence of peripheral blood leukemic blasts, full recovery of peripheral blood counts (platelets ≥ 100 × 10^9/L and ANC ≥ 1 × 10^9/L) and resolution of any extramedullary disease], duration of CR, and proportion of patients with minimal residual disease (MRD) negative CR [defined as leukemic cells comprising < 1 × 10-4 (< 0.01%) of bone marrow nucleated cells by flow cytometry or by PCR].

Amongst all the patients, 22/53 (42%, 95% CI 28.1-55.9%) patients achieved CR. The median duration of CR was 8.2 months (95% CI: 2.6-NE). The MRD negativity rate in patients with CR was 21/22 [95.5% (95% CI: 77.2-99.9)] based on flow cytometry and 19/22 [86.4% (95% CI: 65.1-97.1)] based on RQ-PCR. There are no changes to the safety considerations.

Current Formulary Status: Besponsa is a medical benefit requiring prior authorization.

Recommendation: No formulary placement changes recommended, however, it is recommended to update the PA criteria.

MBP 160 Besponsa
Acute Lymphoblastic Leukemia (ALL)

- Prescription written by a hematologist/oncologist AND
- Medical record documentation that patient is ≥1 year of age **AND**
- Medical record documentation of a diagnosis of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL)

Auth Duration: An initial authorization duration of 3 cycles (3 months) should be approved.
Reauthorization: One subsequent authorization will be for an additional 3 cycles (3 months) and will require medical record documentation of the following:

- Medical record documentation that patient is not receiving hematopoietic stem cell transplant (HSCT) **AND**
- Medical record documentation that patient has achieved complete remission or complete remission with incomplete hematologic recovery and minimal residual disease (MRD) **AND**
- Medical record documentation that the patient is not experiencing 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.

BRUKINSA (zanubrutinib)

Clinical Summary: Brukinsa is a kinase inhibitor previously indicated for the treatment of adult patients with:

- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Waldenstrom's macroglobulinemia (WM)
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen
- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

It is also now indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), in combination with Obinutuzumab, after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Updated Dosing for New indication: There is no change in dosing for the new indication. The recommended dosage of Bruskinsa is 160mg taken orally twice daily or 320mg taken orally once daily until disease progression or unacceptable toxicity.

Current Formulary Status: Oral oncology brand non preferred tier requiring a prior authorization for new starts only with a quantity limit of 4 tablets per day

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 indication:

Mantle Cell Lymphoma

- 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 mantle cell lymphoma **AND**
- Medical record documentation of therapeutic failure on or intolerance to one prior therapy

Waldenström's macroglobulinemia

- 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 Waldenström's macroglobulinemia

Marginal Zone Lymphoma (MZL)

- 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 relapsed or refractory marginal zone lymphoma (MZL) **AND**
- Medical record documentation of therapeutic failure on or intolerance to one prior anti-CD20-based regimen

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)

Follicular Lymphoma

- 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 relapsed or refractory Follicular Lymphoma **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two prior therapies **AND**
- Medical record documentation that Brukinsa is being used in combination with a Obinutuzumab

QUANTITY LIMITS: 4 capsules per day, 30 days supply per fill

MEDISPAN AUTHORIZATION LEVEL: GPI-12

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

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

CRESEMBA (Isavuconazonium sulfate)

Clinical Summary: Cresemba is an azole antifungal indicated for the treatment of Invasive aspergillosis and Invasive mucormycosis in adults.

Cresemba VIAL is now approved for pediatric patients 1 year of age and older and Cresemba CAPSULES are now approved for pediatric patients 6 years of age and older who weigh 16 kilograms and greater. Cresemba capsules are now available as a 74.5 mg dose in addition to the 186 mg dose. Cresemba IV is 372 mg/vial; there are no updated dosages for injection.

Current Formulary Status: Capsules: Pharmacy Benefit, Non-Formulary, Prior Authorization required; **Vials:** Pharmacy or Medical Benefit, Prior Authorization Required

Recommendation: There are no recommended changes to the formulary placement or auth duration. Recommendation is to update the approved age, weight and quantity limits in Commercial Policy 386.0 for Cresemba capsules.

Commercial Policy 386.0 Cresemba Capsules

Treatment of Aspergillosis and Mucormycosis

- Medical record documentation of age greater than or equal to ~~18 years~~ 6 years of age and older and weighing 16 kg or greater **AND**
- Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis **OR** for the treatment of invasive mucormycosis.

Prophylaxis of Aspergillosis and Candida

- Medical record documentation of age greater than or equal to ~~18~~ 6 years of age and older and weighing 16 kg or greater **AND**
- Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AN**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole.

AUTHORIZATION DURATION: 3 months.
Reauthorization will be based on the following criteria:

- Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba **AND**
- Medical record documentation that the appropriate dose is being prescribed (2 capsules per day) for 186 mg capsules OR
- Medical record documentation that the appropriate dose is being prescribed for 74.5 mg capsule based on age and weight (see chart below)

MEDISPAN AUTHORIZATION LEVEL: GPI-12

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 186 mg capsule: 2 capsules per day
- QL FOR LETTER ONLY: 74.5 mg capsule: max QL is 5 capsules per day.
  - 2 capsules per day (16 kg to < 18 kg of body weight)
  - 3 capsules per day (18 kg to < 25 kg body weight)
  - 4 capsules per day (25 kg to < 32 kg of body weight)
  - 5 capsules per day (body weight of 32 kg or greater)

Dosage Form	Age	Body Weight	Quantity Limit	Loading dose	Maintenance Dose
Cresemba 74.5 mg capsules	6 to less than 18 years of age	16 kg to less than 18 kg	loading dose: 12 capsules maintenance dose: 2 capsules daily	Two capsules (149 mg) orally every 8 hours for 6 doses (48 hours)	Two capsules (149 mg) orally once daily
		18 kg to less than 25 kg	loading dose: 18 capsules maintenance dose: 3 capsules daily	Three capsules (223.5 mg) orally every 8 hours for 6 doses (48 hours)	Three capsules (223.5 mg) orally once daily
		25 kg to less than 32 kg	loading dose: 24 capsules maintenance dose: 4 capsules daily	Four capsules (298 mg) orally every 8 hours for 6 doses (48 hours)	Four capsules (298 mg) orally once daily
		great than or equal to 32 kg	loading dose: 30 capsules maintenance dose: 5 capsules daily	Five 74.5 mg capsules (372 mg) orally every 8 hours for 6 doses (48 hours)	Five 74.5 mg capsules (372 mg) orally once daily

Recommended Dosage for CRESEMBA in Adult Patients		
Dosage Form	**Loading Dose**	**Maintenance Dose**
Cresemba 186 mg Capsules	Two 186 mg capsules (372 mg) orally every 8 hours for 6 doses (48 hours)	Two 186 mg capsules (372 mg) orally once daily
Cresemba 74.5 mg capsules	Five 74.5 mg capsules (372 mg) orally every 8 hours for 6 doses (48 hours)	Five 74.5 mg capsules (372 mg) orally once daily

Medical Benefit Policy MBP 134.0 Cresemba IV

- Medical record documentation that the patient is ~~18 years~~ 1 year of age or older **AND**
- Medical record documentation that Cresemba is being used for the treatment of invasive aspergillosis OR for the treatment of invasive mucormycosis **OR**
- Medical record documentation that Cresemba is prescribed by an oncologist, hematologist, infectious disease specialist, or transplant service provider **AND**
- Medical record documentation of use for prophylaxis of invasive Aspergillus or Candida infections in patients at high risk of developing these infections due to being severely immunocompromised **AND**
- Medical record documentation that member requires treatment with an anti-cancer medication that interacts with posaconazole

AUTHORIZATION DURATION: Authorization duration should be for a length of 3 months. Reauthorization will be based on the following criteria:

- Medical record documentation of a culture and sensitivity showing the isolates are susceptible to Cresemba **AND**
- Medical record documentation that the appropriate dose is being prescribed (1 vial/day)

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

EDURANT (rilpivirine)/ EDURANT PED (rilpivirine)

Clinical Summary: Edurant is now indicated for the treatment of HIV-1 infection in treatment-naïve patients aged 2 years and older, weighing at least 14 kg, with HIV-1 RNA less than or equal to 100,000 copies/mL. Previously, this was indicated for the treatment of HIV-1 infection in treatment-naïve patients aged 12 years and older, weighing at least 35 kg, with HIV-1 RNA less than or equal to 100,000 copies/mL, as well as being indicated in combination with Vocabria for short-term treatment of HIV-1 infection in adults and adolescents aged 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure with no known or suspected resistance to either cabotegravir or rilpivirine.

This medication also has a new formulation, Edurant Ped, which is available as a 2.5 mg tablet for oral suspension, while Edurant is still available as a 25 mg tablet. The updated dosing of Edurant is as follows:

- Pediatric patients aged ≥2 years and weighing ≥14 kg to <20 kg: 5 (2.5 mg) tablets once daily
- Pediatric patients aged ≥2 years and weighing ≥20 kg to <25 kg: 6 (2.5 mg) tablets once daily
- Pediatric patients aged ≥2 years and weighing ≥25 kg: 1 (25 mg) tablet once daily

The safety and efficacy of Edurant and Edurant Ped in treatment-naïve pediatric patients aged 6 to less than 12 years of age with HIV-1 infection weighing at least 17 kg were assessed in TMC278-C213 Cohort 2, an open-label, single-arm, Phase 2 trial. This trial included 18 subjects, 17 completed the study at 48 weeks, and 1 subject discontinued the study early due to reaching virologic endpoint. At 48-Week analysis, 13/18 patients had HIV-1 RNA <50 copies/mL, while 3/18 patients had HIV-1 RNA c50 copies/mL, and the other 2/18 patients had missing viral load data at Week 48 but their post-Week 48 viral load was <50 copies/mL.

The safety and efficacy of Edurant and Edurant Ped in treatment naïve pediatric patients aged 2 to 6 years of age is supported by evidence from adequate and well-controlled studies of Edurant in adults with additional population pharmacokinetic data from adults and pediatric patients aged 6 years and older.

The most common adverse reactions occurring in ≥2% of patients for this patient population for Edurant and Edurant Ped were in line with the known adverse reactions of Edurant. No new warnings, contraindications, or black box warnings were identified.

Current Formulary Status: Pharmacy Benefit on the Preferred Brand Tier, with a quantity limit of 1 tablet per day

Recommendation: It is recommended to add Edurant Ped 2.5 mg tablets for oral suspension to the formulary at the Preferred Brand Tier (to match formulary placement Edurant) with a quantity limit of 6 tablets per day when it becomes commercially available.

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

ICLUSIG (ponatinib)

Clinical Summary: Iclusig (ponatinib) is now approved for the treatment of adult patients with newly diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL), in combination with chemotherapy. This indication is approved under accelerated approval based on minimal residual disease (MRD)-negative complete remission (CR) at the end of induction. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.
Iclusig was previously approved for the treatment of adult patients for the following conditions:

- As monotherapy in Ph+ ALL for whom no other kinase inhibitors are indicated
- T315I-positive Ph+ ALL or T315I-positive CML (chronic phase, accelerated phase, or blast phase)
- Chronic phase CML with resistance or intolerance to at least two prior kinase inhibitors.
- Accelerated phase or blast phase CML for whom no other kinase inhibitors are indicated.

Updated Dosing for New indication: 30 mg orally once daily; the dose may be reduced (i.e. 15 mg) after achievement of complete remission, to lessen toxicity

Current Formulary Status: Iclusig is a pharmacy benefit on specialty tier or brand non-preferred tier for members with a three- tier benefit, requiring prior authorization with a quantity limit.

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

- Medical record documentation that Iclusig is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
    - Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND**
    - Medical record documentation that Iclusig will be given in combination with chemotherapy
      OR
    - Medical record documentation of T315I mutation positive chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
      OR
    - Medical record documentation of a diagnosis of accelerated or blast phase chronic myeloid leukemia (CML) **OR** Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) **AND**
    - Medical record documentation of resistance or intolerance to all other indicated tyrosine kinase inhibitors, including but not limited to bosutinib, dasatinib, imatinib, and nilotinib
      OR

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

QUANTITY LIMIT: *No QLs need to be entered within the authorization unless the requested quantity exceeds the QL.*

- QL FOR LETTER ONLY: 1 tablet per day, 30 day supply per fill

RE-AUTHORIZATION CRITERIA: Iclusig is configured as a prior authorization for new starts only. Iclusig 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

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

RYBREVANT (amivantamab-vmjw)

Clinical Summary: Rybrevant was previously indicated as a single agent for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease progressed on or after platinum-based chemotherapy.

Rybrevant is now also indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test.

The dosing for Rybrevant as first-line treatment does vary from the dosing in previously treated NSCLC. Rybrevant is also now indicated in combination with carboplatin and pemetrexed, whereas was indicated only as monotherapy previously. The dosing for first line treatment of locally advanced or metastatic NSCLC with EGFR exon 20 insert mutations is summarized in Table 1.

Table 1. Recommended Dosage for Rybrevant for First-line Treatment of NSCLC with Exon 20 Mutations in Combination with Carboplatin and Pemetrexed

Body weight at Baseline[a]	Recommended Dose	Dosing Schedule
Less than 80 kg	1400 mg	Weekly (total of 4 doses) from Weeks 1 to 4 • Week 1 - split infusion on Day 1 and Day 2 • Weeks 2 to 4 - infusion on Day 1 • Weeks 5 and 6 – no dose
	1750 mg	Every 3 weeks starting at Week 7 onwards
Greater than or equal to 80 kg	1750 mg	Weekly (total of 4 doses) for Weeks 1 to 4 • Week 1 - split infusion on Day 1 and Day 2 • Weeks 2 to 4 - infusion on Day 1 • Weeks 5 and 6 – no dose
	2100 mg	Every 3 weeks starting at Week 7 onwards

[a] Dose adjustments not required for subsequent body weight changes.

Current Formulary Status: Rybrevant is a medical benefit requiring prior authorization. If processed at a specialty pharmacy, Rybrevant will process at the Specialty tier or Brand non-preferred tier for members with a three tier benefit.

Recommendation: There are no changes recommended to the formulary placement or authorization duration of Rybrevant. It is recommended to update the following criteria as a result of the new indication:

MBP 239.0 Rybrevant (amivantamab-vmjw)
Rybrevant (amivantamab-vmjw) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Medical record documentation that Rybrevant 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 with locally advanced or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as determined by an FDA approved test* **AND**
- One of the following:
    - Medical record documentation of disease progression on or following prior treatment with a platinum-based chemotherapy AND that Rybrevant will be used as a single agent

    OR
    - Medical record documentation that Rybrevant is being used as first line treatment AND that Rybrevant will be used in combination with carboplatin and pemetrexed

AUTHORIZATION DURATION: Initial approval will be for **6 months or less** if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **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.

***NOTE:** The FDA approved test for Rybrevant to detect the presences of EGFR exon 20 insertion mutations is the Guardant360® CDx

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

TAGRISSO (osimertinib)

Clinical Summary: Tagrisso is a kinase inhibitor now indicated in combination with pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Updated Dosing for New indication: Locally advanced or metastatic NSCLC: 80 mg orally once daily administered in combination with pemetrexed and platinum-based chemotherapy, with or without food, until disease progression or unacceptable toxicity due to Tagrisso.

Current Formulary Status: Tagrisso is currently on formulary and is a specialty medication requiring a prior authorization on policy 405.0.

Recommendation: The following criteria will be added to Commercial Policy 405.0:

Metastatic or locally advanced Non-Small Cell Lung Cancer (NSCLC)

- Medical record documentation that Tagrisso is prescribed by a hematologist or oncologist **AND**

- ~~Medical record documentation of metastatic non-small cell lung cancer (NSCLC)~~ **~~AND~~**
- Medical record documentation of an epidermal growth factor receptor (EGFR) exon 19 deletion, EGFR exon 21L858R mutation, or EGFR T790 mutation **AND**
- Medical record documentation of one of the following:
  - Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
  - Medical record documentation of epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation **AND**
  - Medical record documentation that Tagrisso is being used as first-line treatment **AND**
  - Medical record documentation that Tagrisso is being used a monotherapy

OR

  - Medical record documentation of metastatic non-small cell lung cancer (NSCLC) **AND**
  - Medical record documentation of epidermal growth factor receptor (EGFR) T790 mutation positive disease **AND**
  - Medical record documentation that Tagrisso is being used a monotherapy
  - Medical record documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib) **AND**

OR

  - Medical record documentation of metastatic or locally advanced non-small cell lung cancer (NSCLC) **AND**
  - Medical record documentation of epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation **AND**
  - Medical record documentation that Tagrisso is being used as first-line treatment **AND**
  - Medical record documentation that Tagrisso is being used in combination of pemetrexed and platinum-based chemotherapy

- ~~If member has epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R mutation: Medical record documentation that Tagrisso is being used as first-line treatment~~ ~~OR~~
- ~~If member has epidermal growth factor receptor (EGFR) T790 mutation positive disease: Medical record documentation of failure on or intolerance to prior tyrosine kinase inhibitor therapy with Iressa (gefitinib), Gilotrif (afatinib), or Tarceva (erlotinib)~~

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

TARPEYO (budesonide)

Clinical Summary: Tarpeyo is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. Previously, Tarpeyo was 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. Previous indication was approved under accelerated approval based on a reduction in proteinuria since Tarpeyo's effect on slowing kidney function decline was unknown as studies were ongoing.

Updated Dosing for New Indication: The recommended dose and duration of therapy has not changed. 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.

Current Formulary Status: Tarpeyo is a pharmacy benefit on the Commercial/Exchange/CHIP formularies at the Specialty Tier or BrandNP tier for members with a 3 Tier benefit.

Recommendation: Tarpeyo is a pharmacy benefit. It is recommended that Tarpeyo remain on the Commercial/Exchange/CHIP formularies at the Specialty Tier or BrandNP tier for members with a 3 Tier benefit. The following prior authorization criteria should be updated based on the new indication:

- 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 that patient is at risk of disease progression, defined as 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)

GPI 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.

WEGOVY (semaglutide)

Clinical Summary: Wegovy is now approved to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight.

The recommended dosage for Wegovy for the new indication is the same as dosage for weight loss in adults. Initiate at 0.25 mg once weekly for 4 weeks. Then follow the dosage escalation schedule, titrating every 4 weeks to achieve the maintenance dosage. The maintenance dosage of Wegovy in adults is either 2.4 mg (recommended) or 1.7 mg once weekly.

The efficacy of Wegovy on major adverse cardiovascular events (MACE) when added to current standard of care, which included management of CV risk factors and individualized healthy lifestyle counseling (including diet and physical activity) was determined in a multi-national, multi-center, placebo-controlled, double-blind trial (Study 1: NCT03574597). The primary endpoint, MACE, was the time to first occurrence of a three-part composite outcome which included cardiovascular death, non-fatal myocardial

infarction, and non-fatal stroke. All patients were 45 years or older, with an initial BMI of 27 kg/m2 or greater and established cardiovascular disease (prior myocardial infarction, prior stroke, or peripheral arterial disease). Patients with a history of type 1 or type 2 diabetes were excluded. Concomitant CV therapies could be adjusted, at the discretion of the investigator, to ensure participants were treated according to the current standard of care for patients with established cardiovascular disease. In this trial, 17,604 patients were randomized to Wegovy or placebo. Mean baseline body weight was 97 kg and mean BMI was 33 kg/m2. At baseline, prior myocardial infarction was reported in 76% of randomized individuals, prior stroke in 23%, and peripheral arterial disease in 9%. Heart failure was reported in 24% of patients. At baseline, cardiovascular disease and risk factors were managed with lipid-lowering therapy (90%), platelet aggregation inhibitors (86%), angiotensin converting enzyme inhibitors or angiotensin II receptor blockers (74%), and beta blockers (70%). A total of 10% had moderate renal impairment (eGFR 30 to <60 mL/min/1.73m2) and 0.4% had severe renal impairment eGFR <30 mL/min/1.73m2. In total, 96.9% of patients completed the trial, and vital status was available for 99.4% of patients. The median follow-up duration was 41.8 months. A total of 31% of Wegovy-treated patients and 27% of placebo-treated patients permanently discontinued study drug. For the primary analysis, a Cox proportional hazards model was used to test for superiority. Type 1 error was controlled across multiple tests.

Wegovy significantly reduced the risk for first occurrence of MACE. The estimated hazard ratio (95% CI) was 0.80 (0.72, 0.90). The reduction of MACE with Wegovy was not impacted by age, sex, race, ethnicity, BMI at baseline, or level of renal function impairment.

Current Formulary Status: Wegovy is an excluded medication.

Recommendation: No changes recommended to the formulary placement of Wegovy at this time. It would remain excluded.

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

WILATE (human plasma-derived von Willebrand factor)

Clinical Summary: In December 2023, Octapharma was granted an expansion to their label for the use of Wilate. This approval now allows for the use of Wilate for the routine prophylaxis in reducing the frequency of bleeding episodes in adults and children aged 6 years and older with any type of von Willebrand disease.

Wilate's new indication is supported by the WIL-31 study, a prospective, non-controlled, international, multicenter phase 3 trial that investigated the efficacy and safety of wilate® prophylaxis over 12 months in people aged 6 and older with severe VWD of any type.

All WIL-31 patients received on-demand treatment with wilate® during a previous six-month, prospective, observational study (WIL-29). Patients who experienced at least six bleeding episodes (BEs), excluding menstrual bleeds, with at least two of these BEs treated with a VWF-containing product, were eligible to enter WIL-31. Patients in WIL-31 received Wilate prophylaxis two to three times per week at a dose of 20-40 IU/kg, for 12 months.

The clinical trial's primary purpose was to investigate whether prophylaxis with Wilate lowered the mean total annualized bleeding rate (ABR) by more than 50% compared to the six months of on-demand treatment. Secondary goals were to measure spontaneous ABR and treatment-emergent adverse events.

Researchers reported an 84% reduction in the mean total ABR compared with on-demand treatment during the prior study. The median spontaneous ABR decreased by 95%. Importantly, no serious drug-related adverse events or thrombotic events were observed during the study.

Guide for dosing Wilate for routine prophylaxis to reduce the frequency of bleeding episodes is provided below. It is important to note that exact dosing should be defined by the severity of the patient's VWD and by the patient's clinical status and response.

Current Formulary Status:

Pharmacy benefit: Prior authorization required (currently no policy in place)

Medical benefit: prior authorization required (on commercial medical admin policy) if NOT given in one of the following settings: office (location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis); inpatient hospital; on campus outpatient hospital; emergency room; ambulatory surgical center

Recommendation:
Pharmacy benefit: Prior authorization required if being used in the outpatient setting for VWD or Hemophilia A

The following prior authorization criteria apply to commercial/exchange/CHIP:

For the treatment of Von Willebrand disease:

1. Medical record documentation of a diagnosis of Von Willebrand disease AND
2. Medical record documentation that Wilate is being prescribed for outpatient use in the outpatient setting AND
3. Medical record documentation of use for routine prophylaxis to reduce the frequency of bleeding episodes, treatment and control of bleeding episodes or for perioperative management AND
4. If request is for routine prophylaxis, medical record documentation of age greater than or equal to 6 years AND
5. Medical record documentation of failure, contraindication or intolerance to desmopressin acetate in patients 2 years of age and older with VWD type 1, 2A, 2M, or 2N. (DDAVP is not recommended in type 2B VWD and is contraindicated in type 3 VWD)

For the treatment of Hemophilia A:

1. Medical record documentation of a diagnosis of hemophilia A (a documented factor VIII deficiency) AND
2. Medical record documentation that the antihemophilic agent will be used for outpatient use in the outpatient setting AND
3. Medical record documentation that Wilate is being prescribed for routine prophylaxis to reduce the frequency of bleeding episodes or for on-demand treatment and control of bleeding episodes AND
4. If request is for routine prophylaxis, medical record documentation of age greater than or equal to 12 years

MEDISPAN AUTHORIZATION LEVEL: GPI-12

AUTHORIZATION DURATION: open ended

Additional Recommendation:
Add note to Commercial Antihemophilic Agents for Hemophilia A policy 514.0 that Wilate is addressed in its own policy.

Medical benefit: prior authorization required (on commercial medical admin policy) if NOT given in one of the following settings: office (location other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness

or injury on an ambulatory basis); inpatient hospital; on campus out patient hospital; emergency room; ambulatory surgical center.

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

UPDATES

Iyuzeh Update

Discussion: Iyuzeh was previously reviewed at March 2024 P&T. Recommendations for prior authorization criteria matched Vyzulta, another non-preferred agent.

Recommendation: It is recommended that step-therapy be added to Iyuzeh to match Vyzulta, Iyuzeh will be added to Commercial Policy 506.0 for Vyzulta with the following criteria:

Commercial Policy 506.0

- Electronic step therapy of on-line prescription drug claims history showing 15 days use of latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost within the previous 180 days. If this electronic step is met, the claim will automatically adjudicate **OR**
- Medical record documentation of intolerance to, contraindication to, or therapeutic failure on latanoprost (generic Xalatan), tafluprost (generic Zioptan), **AND** travoprost

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

Medical policy update – Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

The following updates were proposed based on OncoHealth's review to capture rituximab's use in other standard of care oncology disease states. These changes will affect MBP 48.0:

3. **For Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, and Chronic Lymphoid Leukemia:**
   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.00 through C91.02, C91.10 through C91.12, or C91.40 through C91.42. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:
   - Medical record documentation of a diagnosis of Acute Lymphoblastic Leukemia, Hairy Cell Leukemia, or Chronic Lymphocytic Leukemia (CLL)

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

7. **For Hodgkin Lymphoma**
   Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C81.00 through C81.09. In the event of a request for the rituximab reference product (i.e. Rituxan), OR in the event a requestor would like a medical necessity review completed, the following criteria would apply:
   - Medical record documentation of a diagnosis of Hodgkin Lymphoma

   AND
   - For rituximab reference product requests (i.e. Rituxan), medical record documentation of a therapeutic failure on, intolerance to, or contraindication to rituximab-pvvr (Ruxience) AND rituximab-arrx (Riabni) AND rituximab-abbs (Truxima).

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 27 of 50 members. The vote was unanimously approved.

The next bi-monthly scheduled meeting will be held on May 21st, 2024 at 1:00 p.m.

Meeting will be held virtually via phone/Microsoft Teams.