P&T Committee Meeting Minutes
Medicaid
November 21, 2023

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair Amir Antonius, Pharm.D. Emily Antosh, Pharm.D. Kristen Bender, Pharm.D. Kim Castelnovo, RPh Kimberly Clark, Pharm.D. Bhargavi Degapudi, MD Kelly Faust, Pharm.D. Tricia Heitzman, Pharm.D. Keith Hunsicker, Pharm.D. Derek Hunt, Pharm.D. Emily Jacobson, Pharm.D. Kerry Ann Kilkenny, MD Philip Krebs, R.EEG T Briana LeBeau, Pharm.D. Ted Marines, Pharm.D. Lisa Mazonkey, RPh Tyreese McCrea, Pharm.D. Jamie Miller, RPh Mark Mowery, Pharm.D. Austin Paisley, Pharm.D. Kimberly Reichard, Pharm.D. Melissa Sartori, Pharm.D. Kristen Scheib, Pharm.D. Leslie Shumlas, Pharm.D. Aubrielle Smith-Masri Pharm.D. Kirsten Smith, Pharm.D. Michael Spishock, RPh Todd Sponenberg, Pharm.D. Jill Stone, Pharm.D. Luke Sullivan, DO Kevin Szczecina, RPh Amanda Taylor, MD Ariana Wendoloski, Pharm.D. Brandon Whiteash, Pharm.D. Margaret Whiteash, Pharm.D. Birju Bhatt, MD (non-voting participant) Joshua Buffington (pharmacy student) Morgan Casciole (pharmacy resident) Jennifer Lee ((pharmacy student)	Jeremy Bennett, MD Alyssa Cilia, RPh Michael Dubartell, MD Michael Evans, RPh Nichole Hossler, MD Jason Howay, Pharm.D. Kelli Hunsicker, Pharm.D. Perry Meadows, MD Jonas Pearson, RPh William Seavey, Pharm.D. Angela Scarantino Michael Shepherd, MD Robert Strony, MD MBA Jeremy Garris, Pharm.D. (non-voting participant)

Call to Order: Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, November 21, 2023.

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the September 19, 2023 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Vyvgart Hytrulo (Efgartigimod Alfa and Hyaluronidase Injection)

Review: - Vyvgart Hytrulo is a human IgG antibody fragment that binds and reduces IgG in the body to decrease effects of immunoglobulin in the system. The Hyaluronidase in this solution increases permeability of tissue for greater absorption of drug.

- Its FDA labeled indication is for adult patients with generalized Myasthenia Gravis with a positive diagnosis of Anti-acetylcholine receptor antibodies
- Vyvgart Hytrulo is given by a health care professional only, at a dose of 1,008/ 11,200 Units SubQ once weekly for 4 weeks over 30-90 seconds and can repeat, if needed, no sooner than 50 days from first dose of last treatment cycle.
- A Phase 3, Randomized, Open-Label, Parallel-Group Study Vyvgart Hytrulo showed a statistically significant reduction in AChR-Ab levels and IgG levels compared to Vyvgart; 62.2% and 59.7% respectively.
- Vyvgart Hytrulo's place in therapy has not been confirmed by guidelines for MG, however expert consensus and analyzation of the drug places it after trial of other non-biologic medications, unless otherwise indicated.
- The most common adverse events for this drug are infections, specifically upper respiratory infections and urinary tract infections, as well as some injection site reactions.
- Vyvgart Hytrulo also has limited distribution through specialty pharmacies/distributors

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Vyvgart Hytrulo is a medical benefit that will be managed by GHP. The following prior authorization criteria should apply.

For Initial Approval

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Vyvgart Hytrulo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MFGA) II to IV **AND**
- Medical record documentation of Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of 5 or more at baseline **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies OR One (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG)

GPI Level: GPI-12
Authorization Duration: Initial approval will be for 6 months. Subsequent approvals will be for an additional 6 months and will require medical record documentation of the following:

- Medical record documentation of continued disease improvement or lack of disease progression **AND**
- Medical record documentation of positive response to therapy as evidenced by a 2-point reduction from baseline in Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score

Medication will no longer be covered if patient experiences toxicity or worsening of disease.

GPI Level: GPI-12

Require RPH Sign off: Yes

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

Rystiggo (rozanolixizumab-noli)

Review: Rystiggo is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Myasthenia gravis is a primary disorder of neuromuscular transmission characterized by fluctuating motor weakness in ocular, bulbar, limb, and respiratory muscles. In myasthenia gravis, there is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction. Severity of disease can vary between individuals; however, generally it improves with rest and worsens with activity. Pregnancy, infection, surgery, and stress can all be aggravating factors. Most patients (approximately two-thirds) initially present with only ocular muscle weakness, with 85% of patients eventually developing generalized myasthenia gravis (gMG).

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Rystiggo is a medical benefit that will be managed by GHP and will require a prior authorization. The following prior authorization criteria should apply:

- Medical record documentation of age 18 years or older **AND**
- Medical record documentation that Rystiggo is prescribed by or in consultation with a neurologist **AND**
- Medical record documentation of a diagnosis of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) positive **OR** anti-muscle-specific tyrosine kinase (MuSK) antibody positive **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature **AND**
- Medical record documentation of Myasthenia Gravis Foundation of America Clinical Classification (MGFA) Class II to IVa **AND**
- Medical record documentation of a baseline Myasthenia Gravis-Activities of Daily Living (MG-ADL) score greater than or equal to 3 (with at least 3 points being non-ocular) **AND**

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids **AND**
- Medical record documentation of therapeutic failure on intolerance to, or contraindication to at least two (2) non-steroidal immunosuppressive therapies **OR** has failed at least one (1) immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) **AND**
- Medical record documentation of failure on, intolerance to, or contraindication to intravenous immunoglobulin (IVIG).

Formulary Alternatives:
Corticosteroids: dexamethasone, methylprednisolone, prednisone
Cholinesterase inhibitors: pyridostigmine
Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

GPI Level: GPI-12
Authorization Duration: 6 months
Reauthorization Info: Subsequent approvals will be for an additional 6 months and will require:
- Medical record documentation of continued disease improvement or lack of disease progression AND
- Medical record documentation that the member is responding positively to therapy as evidenced by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline**.**

Require RPH Sign off: Yes

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

Vyjuvek (beremagene geperpavec-svdt)

Review: Epidermolysis bullosa (EB) is a rare, inherited connective tissue disorder characterized by abnormalities in the cohesion of the layers of the epidermis that can result in skin blisters, erosions, nonhealing ulceration, and potentially fibrosis in response to friction or skin trauma. Young patients with EB are often described as "butterfly children" because their skin is extremely fragile, like a butterfly's wings. Patients often experience painful chronic wounds and recurring wounds in their skin. Recurrent wounds heal but blister again easily while chronic wounds tend to never heal. Intensely itchy skin is also very common. EB can also have manifestations beyond the skin. Patients may experience blistering, ulcerations, and scarring in visceral mucosal tissues, such as the lining of the gastrointestinal, respiratory, or urinary tracts, which can lead to secondary complications such as anemia, electrolyte abnormalities, cardiomyopathy, strictures and stenoses, and malnutrition leading to growth retardation.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Vyjuvek will be a medical benefit managed by GHP. The following prior authorization criteria will apply:
- Medical record documentation that Vyjuvek is prescribed by or in consultation with a dermatologist who specializes in epidermolysis bullosa (EB) management **AND**
- Medical record documentation of age greater than or equal to 6 months **AND**
- Medical record documentation of diagnosis of dystrophic epidermolysis bullosa (DEB) **AND**
- Medical record documentation of genetic testing confirming mutation(s) in the *COL7A1* gene **AND**

- Medical record documentation of at least one open dystrophic epidermolysis bullosa (DEB) wound **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

GPI Level: GPI-12
Facets Rx Count: 9999
Authorization Duration: 6 months
Reauthorization Info: Subsequent approvals will be for an additional 6 months and will require medical record documentation of clinical response to prior dystrophic epidermolysis bullosa (DEB) wounds treated with Vyjuvek therapy and lack of toxicity.
Require RPH Sign off: Yes

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

Adstiladrin (nadofaragene firadenovec-vncg)

Review: Adstiladrin is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. This is the first and only FDA-approved medication of its kind. Adstiladrin is designed to deliver a copy of a gene encoding a human interferon-alfa 2b (INFα2b) to the bladder urothelium. Intravesical instillation of Adstiladrin results in cell transduction and transient local expression of the INFα2b protein that is anticipated to have anti-tumor effects.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Adstiladrin will be a medical benefit managed by GHP. The following prior authorization criteria will apply:
- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that Adstiladrin is being prescribed by or in consultation with a hematologist, oncologist, or urologist **AND**
- Medical record documentation of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

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 of 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 to Reviewer: There is currently no defined duration of therapy for Adstiladrin. In current clinical trial CS-003, patients without evidence of high-grade recurrence were allowed to continue Adstiladrin treatment every 3 months, with no specified limit.

Require RPH Sign off: Yes

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

TPOXX (Tecovirimat)

Review: Tecovirimat (Tpoxx) is the first drug approved for the treatment of human smallpox disease caused by the variola virus. It works by targeting and inhibiting the activity of the orthopoxviral VP37 protein (encoded by and highly conserved in all members of the orthopoxvirus genus) and blocks its interaction with cellular Rab9 GTPase and TIP47, which prevents the formation of egress-competent enveloped virions necessary for cell-to-cell and long-range dissemination of virus. It was first approved in 2018 as an oral dosage form and is indicated for the treatment of smallpox disease in pediatric and adult patients weighing greater than 13 kg. Tecovirimat (Tpoxx) also became FDA approved intravenously in 2022 as an option for patients unable to take the oral formulation and can be used in patients weighing as little as 3 kg. Tecovirimat (Tpoxx) is not commercially available and is part of the Strategic National Stockpile and was approved under the FDA's Animal Rule. This rule allows approval of drugs based upon well-controlled animal efficacy studies when the agent treats or prevents serious or life-threatening conditions and when human efficacy studies are not ethical and field trials are not feasible. Currently there is an off-label indication for use in the treatment of Mpox using an EA-IND (Emergency Use Authorization Investigational New Drug) which was approved in May 2023. The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, is now sponsoring the Study of Tecovirimat for Human Mpox Virus (STOMP). The STOMP trial is designed to assess whether tecovirimat is safe and effective for treating Mpox in people with the disease.

Clinical Discussion: The committee unanimously voted to accept the recommendations.

Financial Discussion: The committee unanimously voted to accept the recommendations.

Outcome: Tecovirimat (Tpoxx) will be non-formulary, as it is not commercially available. If Tecovirimat (Tpoxx) becomes commercially available, it will be added to formulary as both a medical and pharmacy benefit without requiring prior authorization. It will be added to the brand non-preferred tier.

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

Fast Facts

Prevnar20

Updated Indication: Prevnar 20 is now indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older. Previously this indication was for adult patients 18 years of age and older. Prevnar 20 is also now indicated for active immunization for the prevention of otitis media

caused by S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age. There are no changes to the Prevnar 20 indication for active immunization for the prevention of pneumonia caused by S. pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 18 years of age and older.

Recommendation: No changes are recommended. Patient included in the new indications will be required to receive the vaccine through their prescriber through the VFC program.

Outcome: The committee unanimously voted to accept the recommendation.

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

Updates

Medical Benefit Policy Updates

Recommendation: It is recommended to retire Medical Benefit Policy (MBP) 223.0 Blenrep (belantamab mafodotin-blmf).

Outcome: The committee unanimously voted to accept the recommendation

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

Aponvie

Recommendation: It is recommended to add Medicaid to MBP 299.0 with the prior authorization included below. Aponvie (aprepitant) will be considered medically necessary when **ALL** of the following criteria are met:

- Medical record documentation that the member is 18 years of age or older **AND**
- Medical record documentation of use for prevention of post-operative nausea and vomiting (PONV) **AND**
- Medical record documentation that the medication is prescribed by a surgeon or anesthesiologist

AUTHORIZATION DURATION: Approved requests will be for a One-time authorization for one administration of Aponvie

QUANTITY LIMITS: One vial (32mg/4.4mL) per 1 day supply (Facets RX count: 32)

Outcome: The committee unanimously voted to accept the recommendation

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

October ELECTRONIC VOTE

An electronic vote was held from October 16, 2023, to October 25, 2023. Responses were received from 28 members (out of 49 members) and all voted to approve. Additional evidence of the criteria used to make this decision can be found in the drug review presented to the committee.

Elrexfio (elranatamab-bcmm)

Review**:** Elrexfio is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adults with relapsed or refractory multiple myeloma (R/R MM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. Elrexfio binds BCMA on plasma cells, plasmablasts, and multiple myeloma cells and CD3 on T-cells leading to cytolysis of the BCMA-expressing cells. Elrexfio-activated T-cells caused proinflammatory cytokine release and resulted in multiple myeloma cell lysis.

Recommendation**:** Elrexfio is a medical benefit managed by GHP. The following prior authorization criteria will apply.

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Elrexfio is prescribed by a hematologist or oncologist AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 the member experiences unacceptable toxicity or worsening of disease.

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

Talvey (talquetamab-tgvs)

Review: Talvey is a first-in-class bispecific T-cell engaging antibody that binds to the CD3 receptor expressed on the surface of Tcells and G protein–coupled receptor, family C, group 5, member D (GPRC5D), a novel multiple myeloma (MM) target that is highly expressed on the surface of MM cells and non-malignant plasma cells, as well as cells within some healthy tissues, such as epithelial cells of the skin and tongue.

Recommendation: Talvey is a medical benefit managed by GHP. The following prior authorization criteria will apply.

- Medical record documentation of age greater than or equal to 18 years AND
- Medical record documentation that Talvey is prescribed by a hematologist or oncologist AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of treatment with at least four (4) prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

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 the member experiences unacceptable toxicity or worsening of disease.

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

Bylvay

Updated Indication: Bylvay (odevixibat) is now indicated in the treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome.

Recommendation: There are no changes recommended to formulary placement of Bylvay but the following updates to the policy are recommended:

Progressive Familial Intrahepatic Cholestasis (PFIC)

- Prescription written by or consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation of diagnosis of progressive familial intrahepatic cholestasis (PFIC) confirmed by genetic testing **AND**
- Medical record documentation of the presence of moderate to severe pruritus **AND**
- Medical record documentation of age greater than or equal to 3 months **AND**
- Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight **AND**
- Medical record documentation of concurrent use or therapeutic failure on, intolerance to, or contraindication to ursodiol.

*** Note to reviewing pharmacist:** The recommended dosage of Bylvay for PFIC is 40 mcg/kg once daily. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg (6000 mcg). See https://bylvay.com/pdf/021066_Bylvay_Dosing_Guide.pdf

OR

Alagille Syndrome

- Medical record documentation of a diagnosis of Alagille Syndrome (ALGS) **AND**
- Medical record documentation of the presence of moderate to severe pruritis **AND**
- Medical record documentation that member is 12 months of age or older **AND**
- Medical record documentation that Bylvay is prescribed by or in consultation with a hepatologist or gastroenterologist **AND**
- Medical record documentation that member is receiving an appropriate dose* based on patient's weight **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to ursodiol and one of the following: cholestyramine, rifampin, or naltrexone.

*** Note to reviewing pharmacist:** The recommended dosage of Bylvay for Alagille Syndrome is shown in the table below:

Table 2. Recommended Dosage for ALGS in Patients aged 12 months and older (120 mcg/kg/day)

Body Weight (kg)	Once Daily Dosage (mcg)
7.4 and below	600
7.5 to 12.4	1,200
12.5 to 17.4	1,800
17.5 to 25.4	2,400
25.5 to 35.4	3,600
35.5 to 45.4	4,800
45.5 to 55.4	6,000
55.5 and above	7,200

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 the following:

• Medical record documentation of improvement in pruritus and/or reduction in serum bile acid **AND**
• Medical record documentation that the member is receiving an appropriate dose* based on the patient's weight

Alternatives: Per Statewide PDL

- Progressive Familial Intrahepatic Cholestasis: ursodiol
- Alagille Syndrome: cholestyramine, rifampin, naltrexone, sertraline

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

Jemperli

Updated Indication: Jemperli is now indicated, in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA approved test, or microsatellite instability-high (MSI-H).

Recommendation: The following prior authorization criteria and changes should be added to MBP 236.0:
Endometrial Cancer

- Medical record documentation that Jemperli 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 one of the following:
    - Medical record documentation of a diagnosis of recurrent or advanced endometrial cancer AND
        - Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test AND
        - Medical record documentation of disease progression on or following prior treatment with a platinum-containing regimen AND
        - Medical record documentation that member is not a candidate for curative surgery or radiation

OR

    - Medical record documentation of primary advanced or recurrent endometrial cancer AND

- Medical record documentation that Jemperli will be used in combination with carboplatin and paclitaxel for 6 doses, followed by Jemperli as a single agent AND
- Medical record documentation of mismatch repair deficient (dMMR) as determined by an FDA approved test **OR** microsatellite instability-high (MSI-H)

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

Reblozyl

Updated Indication: Reblozyl is now indicated for:

- Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.
- Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions.
- Anemia failing an erythropoiesis stimulating agent (ESA) and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).
    - Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia

Recommendation: It is recommended to update the following criteria as a result of the new indication. **Medical Benefit Policy 210.0 Reblozyl (luspatercept-aamt)**

1. Anemia due to Beta thalassemia

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of beta thalassemia **AND**
- Medical record documentation that patient requires regular* red blood cell (RBC) transfusions **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

2. Anemia due to myelodysplastic syndromes or myelodysplastic/myeloproliferative neoplasm

For ESA-refractory disease:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of diagnosis of myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) with one of the following:
    - Documentation of greater than or equal to 15% ring sideroblasts **OR**
    - Documentation of greater than or equal to 5% ring sideroblasts AND an SF3B1 mutation

AND

- Medical record documentation of very low to intermediate risk disease per the Revised International Prognostic Scoring System (IPSS-R) **AND**
- Medical record documentation that patient requires 2 or more red blood cell units over 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record documentation of therapeutic failure, intolerance to, or contraindication to an erythropoiesis stimulating agent **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

For ESA-naïve disease:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of myelodysplastic syndromes with or without ring sideroblasts **AND**
- Medical record documentation of very low to intermediate risk disease per the Revised International Prognostic Scoring System (IPSS-R) **AND**
- Medical record documentation that patient requires an average of at least 2 red blood cell units per 8 weeks **AND**
- Medical record documentation of baseline number of transfusions and red blood cell (RBC) units required for the previous six (6) months **AND**
- Medical record recommendation that Reblozyl is being dosed consistent with FDA-approved labeling**.

AUTHORIZATION DURATION: Approval will be given for an **initial duration of six (6) months** or less if the reviewing provider feels it is medically appropriate. After the initial six (6) month approval, subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a decrease in red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

Ongoing subsequent approvals will be for a **duration of six (6) months** or less if the reviewing provider feels it is medically appropriate, requiring medical record documentation of:

- a sustained reduction of red blood cell (RBC) transfusion burden from baseline **AND**
- Reblozyl being dosed consistent with the FDA-approved labeling**

LIMITATIONS: Reblozyl will no longer be covered if the patient does not experience a decrease in transfusion burden after nine (9) weeks of treatment (administration of three (3) doses) at the maximum dose level or if unacceptable toxicity occurs at any time.

NOTES:

*In clinical trials For Beta Thalassemia, “regular red blood cell transfusions” was considered to be 6 to 20 red blood cell units per 24 weeks with no transfusion-free period greater than 35 days.

**Per current labeling: For Beta Thalassemia: 1mg/kg every 3 weeks increasing to a maximum of 1.25mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.25mg/kg every 3 weeks

For MDS associated anemia ~~-RS and MDS/MPN-RS-T~~: 1mg/kg every 3 weeks increasing to a dose of 1.33 mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen , then increasing up to a maximum of 1.75mg/kg every 3 weeks after two doses if a reduction in transfusion burden is not seen. Dose should not exceed 1.75mg/kg every 3 weeks

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

Medical Benefit Policy Updates

Discussion: During the process of annual review, it was determined Enbrel would be another acceptable preferred agent to include in the alternative list for the indication of Rheumatoid Arthritis

Recommendation: The following changes have been recommended to be made with annual review.

MBP 48.0 Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx)

Rituxan (rituximab), Truxima (rituximab-abbs), Ruxience (rituximab-pvvr), and Riabni (rituximab-arrx) will be considered medically necessary for commercial, exchange, CHIP and Medicaid lines of business when all of the following criteria are met:

1. For Rheumatoid Arthritis:
   All of the following criteria must be met:
   - Physician documentation of a diagnosis of moderate to severe rheumatoid arthritis in accordance with the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis; **AND**
   - At least 18 years of age or older; **AND**
   - Prescription written by a rheumatologist; **AND**
   - Medical record documentation that an effective dose of methotrexate will be continued during rituximab therapy; **AND**
   - Medical record documentation that Rituxan is not being used concurrently with a TNF blocker **AND**
   - Physician documentation of an inadequate response to 12 weeks of therapy with Humira*, Enbrel*, Rinvoq*, OR Xeljanz*

   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.

Meeting adjourned at 4:02 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on January 16, 2024 at 1:00 p.m.

Meetings will be held virtually via phone/Microsoft Teams