P&T Committee Meeting Minutes
Medicaid
January 18, 2022

Present (via Teams):	**Absent:**
Bret Yarczower, MD, MBA – Chair	Kristen Bender, Pharm.D.
Megan Ammon, Pharm.D.	Holly Bones, Pharm.D.
Emily Antosh, Pharm.D.	Kim Castelnovo, RPh
Jeremy Bennett, MD	Dean Christian, MD
Briana Blaisure, Pharm.D.	Michael Evans, RPh
Alyssa Cilia, RPh	Jason Howay, Pharm.D.
Kimberly Clark, Pharm.D.	Jonas Pearson, RPh
Rajneel Farley, Pharm.D.	Adam Root (non-voting participant)
Kelly Faust Pharm.D.	William Seavey, Pharm.D.
Tricia Heitzman, Pharm.D.	Michael Shepherd, MD
Nichole Hossler, MD	
Emily Hughes, Pharm.D.	
Keith Hunsicker, Pharm.D.	
Kelli Hunsicker, Pharm.D.	
Derek Hunt, Pharm.D.	
Phillip Krebs, R.EEG T	
Tyreese McCrea, Pharm.D.	
Perry Meadows, MD	
Jamie Miller, RPh	
Austin Paisley, Pharm.D.	
Melissa Renn, Pharm.D.	
Kimberly Reichard, Pharm.D.	
Angela Scarantino	
Kristen Scheib, Pharm.D.	
Leslie Shumlas, Pharm.D.	
Richard Silbert, MD	
Aubrielle Smith Pharm.D.	
Michael Spishock, RPh	
Todd Sponenberg, Pharm.D.	
Jill Stone, Pharm.D.	
Robert Strony, MD MBA	
Kevin Szczecina, RPh	
Amanda Taylor, MD	
Brandon Whiteash, Pharm.D.	
Travis Baughn (non-voting participant)	
Nicole Hughes, Pharm.D. (Pharmacy Resident)	
Samantha Matchock, Pharm.D. (Pharmacy Resident)	
MeiLing Montross, Pharm.D. (Pharmacy Resident)	
Alison Walck, Pharm.D. (Pharmacy Resident)	

Call to Order:
Dr. Bret Yarczower called the meeting to order at 1:02 p.m., Tuesday, January 18, 2022

Review and Approval of Minutes, Reviews, Fast Facts, and Updates: Dr. Bret Yarczower asked for a motion or approval to accept the November 2021 minutes as written. Minutes approved unanimously. None were opposed.

DRUG REVIEWS

Nexviazyme (avalglucosidase alfa-ngpt)

Review: Nexviazyme is indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency). Once Pompe disease is suspected, diagnosis is confirmed by blood and genetic testing. Testing includes GAA enzyme activity in the blood and/or other tissue and genetic sequencing. The presence of two pathogenic variants in the GAA gene is sufficient to diagnose Pompe disease. However, some patients may only have one pathogenic variant. In 2015, the US Secretary of Health and Human Services (HSS) approved the recommendation to include GAA deficiency in the Recommended Uniform Screening Panel for newborns. The only other ERT available for Pompe disease is Lumizyme (alglucosidase alfa). Unlike Lumizyme, Nexviazyme was only approved for the treatment of LOPD. Prior to Nexviazyme administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Nexviazyme must be reconstituted and diluted prior to use. Nexviazyme is administered as an IV infusion. Nexviazyme is supplied as a one 100 mg vial in a carton. For patients weighing ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks. For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks. Nexviazyme was studied in randomized, double-blind, multinational, multicenter trial & an open-label, long-term, follow-up phase for up to 5 years. The trial included 100 treatment-naïve patients with LOPD. To be included in the trial, patients had confirmed GAA enzyme deficiency from any tissue source and/or 2 confirmed GAA gene mutations. Patients were randomized in a 1:1 ratio based on baseline forced vital capacity (FVC), gender, age, and country to receive 20 mg/kg of Nexviazyme (n=51) or alglucosidase alfa (n=49) administered intravenously once every two weeks for 49 weeks. In the open-label, long-term, follow-up trial, patients in the alglucosidase alfa arm were switched to Nexviazyme treatment. The primary endpoint was the change in FVC (% predicted) in the upright position from baseline to Week 49. At Week 49, the least squares (LS) mean change in FVC (% predicted) for patients treated with Nexviazyme and alglucosidase alfa was 2.9% and 0.5%, respectively. The estimated treatment difference was 2.4% (95% CI: -0.1, 5.0) favoring Nexviazyme. The key secondary endpoint of Study 1 was the change in total distance walked in 6 minutes (6-Minute Walk Test, 6MWT) from baseline to Week 49. At Week 49, the LS mean change from baseline in 6MWT for patients treated with Nexviazyme and alglucosidase alfa was 32.2 meters and 2.2 meters, respectively. The estimated treatment difference was 30 meters (95% CI: 1.3, 58.7) favoring Nexviazyme. There are warnings for hypersensitivity reactions including anaphylaxis. Nexviazyme also has warnings for infusion-associated reactions. Patients susceptible to fluid overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function for whom fluid restriction is indicated may be at risk of serious exacerbation of their cardiac or respiratory status during Nexviazyme infusion. The most common adverse reactions (≥ 5%) were headache, fatigue, diarrhea, nausea, arthralgia, dizziness, myalgia, pruritus, vomiting, dyspnea, erythema, paresthesia, and urticaria. The safety and effectiveness have been established in pediatric patients 1 year of age and older.

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

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

Outcome: Nexviazyme will be a medical benefit. Nexviazyme will require a prior authorization with the following criteria.

- Medical record documentation of a diagnosis of late-onset Pompe disease supported by:
    - Acid alpha-glucosidase (GAA) assay performed on dried blood spots, skin fibroblasts or muscle biopsy AND

    - Genetic testing showing a mutation in the *GAA* gene
- Medical record documentation of a consultation with a metabolic specialist and/or biochemical geneticist AND
- Medical record documentation of age greater than or equal to 1 year AND
- Medical record documentation of baseline percent-predicted forced vital capacity (% FVC) and 6-minute walk test (6MWT), if age appropriate AND
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme)

Authorization Duration: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require the following:

- Medical record documentation of improvement or stabilization in percent-predicted FVC and/or 6MWT AND
- Medical record documentation that the member is receiving an appropriate dose* based on patient's weight AND
- Medical record documentation that Nexviazyme will not be used in combination with other enzyme replacement therapy (e.g. Lumizyme)

*Note to reviewing pharmacist: For patients weighing ≥30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks. For patients weighing < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks.

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

Saphnelo (anifrolumab-fnia)

Review: Saphnelo is a humanized IgG1k monoclonal antibody that binds to the subunit 1 of the type I interferon receptor (IFNAR). The binding then inhibits type 1 IFN signaling, blocking the activity of type I IFN. Saphnelo induces internalization of IFNAR1 which reduces levels of cell surface IFNAR1 for receptor assembly. IFN responsive gene expression is inhibited by blockade of signaling from the receptor mediated type I IFN. The inhibition blocks plasma cell differentiation and normalizes peripheral T-call subsets. Saphnelo is not currently addressed in guidelines. Saphnelo's approved indication is for patients who are receiving standard therapy. The 2019 European League Against Rheumatism guidelines recommend hydroxychloroquine without regard to severity in SLE. Depending on the severity of disease, glucocorticoids can be used and if patients still do not respond then methotrexate, azathioprine, or mycophenolate can be used. Cyclophosphamide can be used in severe/life-threatening disease or rescue therapy in patients not responding to other immunosuppressive therapies. Add on Benlysta should be considered if patients still do not respond to previously mentioned therapies. Rituximab can also be considered for organ-threatening disease.

- Saphnelo IV infusion 300mg over 30 minutes every 4 weeks can be clinically used in adult patients with symptomatic moderate to severe SLE despite being on standard therapy regimens
    - Patients with severe active lupus nephritis, patients who had severe active central nervous system lupus, and who use other biological agents and cyclophosphamide (needed at least 5 half-live wash-out period prior to enrollment) should not be prescribed Saphnelo at this time.
    - No other biologics or live/live-attenuated vaccines should be co-administered while prescribed Saphnelo.
- Saphnelo should be used in caution with other medications and renal/hepatic disease as it has not been formally studied at this time.
- Clinical trials have demonstrated reduction in disease activity including skin and joint involvement and reduction in OCS use.

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

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

Outcome: Saphnelo will be medical benefit that is GHP managed, requiring prior authorization.

1. Medical record documentation of age greater than or equal to 18 AND
2. Medical record documentation of moderate to severe systemic lupus erythematosus (SLE) AND
3. Medical record documentation that member does not have active lupus nephritis or severe active central nervous system lupus AND
4. Medical record documentation that Saphnelo is being prescribed by a rheumatologist AND
5. Medical record documentation that member is concurrently receiving a stable treatment regimen with corticosteroids, antimalarials, or immunosuppressants AND
6. Medical record documentation that member is <u>not</u> being used concurrently with other biologic agents, including B-cell-targeted therapies.

Authorization Duration: 12 months

Reauthorization criteria: Medical record documentation showing a clinical benefit of one of the following: improvement in functional impairment, decrease in number of exacerbations since starting Saphnelo, decrease in the daily required dose of oral corticosteroids

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

Prevnar 20 (Pneumococcal 20-valent Conjugate Vaccine) and Vaxneuvance (Pneumococcal 15-valent Conjugate Vaccine)

Review:

<u>Prevnar 20:</u> Prevnar 20 is a vaccine indicated for active immunization for the prevention of pneumonia and 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 adults 18 years of age and older. Prevnar 20 protects against 7 additional serotypes compared to Prevnar 13 (8, 10A, 11A, 12F, 15B, 22F, 33F). In October 2021, the Advisory Committee on Immunization Practices (ACIP) approved recommendations for Prevnar 20 and Vaxneuvance for adults 19 to 64

years with certain underlying medical conditions or risk factors and in all adults 65 years and older who have not received a pneumococcal conjugate vaccine or whose previous history is unknown. Efficacy of Prevnar 20 is based in part on the efficacy of Prevnar 13 since the vaccines are manufactured similarly and contain 13 of the same polysaccharide conjugates. Study 1 was a randomized, active-controlled, double blind non-inferiority study evaluating the immunologic non-inferiority of Prevnar 20 to Prevnar 13 and PPSV23 in pneumococcal vaccine naïve adults 18 years or older. Patients were enrolled in 1 of 3 cohorts based on the age of enrollment and were randomized to receive Prevnar 20 or control. Patients 60 years and older were randomly assigned (1:1) to receive Prevnar 20 followed 1 month later with saline placebo or Prevnar 13 followed 1 month later with PPSV23. In adults 60 years and older, immune responses to all 13 matched serotypes elicited by Prevnar 20 were non inferior to Prevnar 13 one month after vaccination. Immune response to 6 out of 7 additional serotypes induced by Prevnar 20 were noninferior to the immune responses induced by PPSV23 one month after vaccination. The effectiveness of Prevnar in adult patients age 50 to 59 years and 18 to 49 years was inferred following comparison of the immune response to each of the 20 vaccine serotypes in each of the age groups to those in patients over 60 years of age. The efficacy of Prevnar 20 in adult patients who were previously vaccinated with a pneumococcal vaccine was evaluated in Study 6, an open label clinical trial in adults 65 years and older who were previously vaccinated with PPSV23 (≥ 1 to ≤ 5 years prior to enrollment) , previously vaccinated with Prevnar 13 (≥6 months prior to enrollment), or previously vaccinated with Prevnar 13 followed by PPSV23 (with PPSV23 vaccination ≥1 year prior to enrollment). Results showed that OPA GMTs in participants who received PPSV23 1 to 5 years prior to Prevnar 20 were diminished compared to OPA GMTs in participants who received Prevnar 13 at least 6 months previously and compared to OPA GMTs in participants who received Prevnar 13 followed by PPSV23, with the last PPSV23 dose given at least 1 year prior to Prevnar 20. There are no black box warnings for Prevnar 20. Warnings include the risk of acute allergic reactions and a contraindication in patients with a severe allergic reaction to a component of Prevnar 20 or diphtheria toxoid and the risk of reduced immune response in patients with altered immunocompetence. The most common adverse reactions reported with Prevnar 20 include pain at injection site, muscle pain, fatigue, headache, and arthralgia and injection site swelling.

Vaxneuvance: Vaxneuvance is a vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older. Vaxneuvance protects against 2 additional serotypes compared to Prevnar 13 (22F, 33F). In October 2021, the Advisory Committee on Immunization Practices (ACIP) approved recommendations for Prevnar 20 and Vaxneuvance for adults 19 to 64 years with certain underlying medical conditions or risk factors and in all adults 65 years and older who have not received a pneumococcal conjugate vaccine or whose previous history is unknown. When Vaxneuvance is used, ACIP recommends it be followed with a dose of PPSV23. The efficacy of Vaxneuvance was evaluated in Study 1, a double-blind, active comparator-controlled study in pneumococcal vaccine-naïve patients 50 years of age and older. Patients were randomized 1:1 to receive Vaxneuvance (n=604) or Prevnar 13 (n=601). The study demonstrated noninferiority for Vaxneuvance to Prevnar 13 for the 13 shared serotypes and statistically significant greater OPA GMTs compared to Prevnar 13 for the shared serotype 3 and the 2 unique serotypes (22F, 33F). Study 3 was a double-blind, active comparator-controlled, descriptive study in pneumococcal vaccine-naïve adults 50 years of age and older. Patients were randomized to receive Vaxneuvance (n=327) or Prevnar 13 (n=325), followed by Pneumovax 23 one year later. Following Pneumovax 23 vaccination, OPA GMTs were numerically similar between the two vaccination groups for the 15 serotypes in Vaxneuvance. Study 4 was a double-blind descriptive study in adult patients aged 18 to 49 years, including those at increased risk of developing pneumococcal disease. Patients were randomized to receive Vaxneuvance (n=1,135) or Prevnar 13 (n=380), followed by Pneumovax 23 six months later. Among those who received Vaxneuvance, 620 participants had one risk factor and 228 participants had two or more risk factors for pneumococcal disease. Following Pneumovax 23 vaccination, OPA GMTs were numerically similar between the two vaccination groups for the 15 serotypes in Vaxneuvance. Study 6 was a double-blind, randomized study in adult patients 50 years of age and older

who were randomized to receive Vaxneuvance concomitantly with a seasonal inactivated quadrivalent influenza vaccine (n=600) or Vaxneuvance 30 days after receiving QIV (n=600). GMTs were evaluated 30 days after administration of QIV. Noninferiority was met for the comparison of GMTS for the 15 pneumococcal serotypes in VAXNEUVANCE and for the 4 influenza vaccine strains tested. There are no black box warnings for Vaxneuvance. Warnings are consistent with other conjugated pneumococcal vaccines and include a contraindication in patients with a severe allergic reaction to a component of Vaxneuvance or diphtheria toxoid and the risk of reduced immune response in patients with altered immunocompetence. The safety profile of Vaxneuvance was similar when administered with or without inactivated quadrivalent influenza vaccine.

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

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

Outcome: Prevnar 20 and Vaxneuvance will be covered as medical or pharmacy benefits and will not require a prior authorization. The following age limit should apply: 19 years and older

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

CLASS REVIEW

Rituximab Class Review

Updated Indication (for Rituxan): Rituxan is now indicated for the treatment of pediatric patients aged 6 months and older with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy.

Rituxan was previously indicated for adult patients with Non-Hodgkin's Lymphoma (NHL), adult patients with Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies, Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids, and moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Ruxience and Riabni:
Review: Ruxience and Riabni are biosimilar CD20-directed antibodies that are highly similar to the US-licensed reference product Rituxan, indicated for Non-Hodgkin's Lymphoma (NHL), Chronic Lymphocytic Leukemia (CLL), Rheumatoid Arthritis (RA), Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) and Pemphigus Vulgaris (PV). Ruxience is the third and Riabni is the fourth FDA approved rituximab biosimilar, the first being Truxima (rituximab-abbs). None of the rituximab biosimilars are interchangeable with Rituxan.

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

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

Outcome: Ruxience and Riabni will be medical benefits that will be GHP managed. Ruxience and Riabni should not be added to the GHP Family pharmacy formulary. Because all rituximab biosimilar products offer clinically similar safety and efficacy while also offering significant cost savings, it is recommended that a biosimilar parity

position be adopted as outlined below. Note: MBP 48.0 will require medical PA for Rituxan for diagnoses of CLL, NHL, or MS. The following prior authorization criteria will apply:

Rituxan (rituximab), ~~and~~ Truxima (rituximab-abbs), Ruxience (rituximab-pvvr) and Riabni (rituximab-arrx) will be considered medically necessary 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*, 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).

LIMITATIONS:

If criteria are met, approval will be limited to one course of therapy defined as two infusions, one given on day 1 and another on day 15.

Additional courses may be considered medically necessary if the following criteria are met:

- At least 6 months has elapsed since the previous treatment course; **AND**
- Physician documentation of improvement or lack or progression in the signs and symptoms of rheumatoid arthritis; **AND**
- Physician documentation showing previous treatment course did not result in active infection.

2. **For Chronic Immunothrombocytopenia (ITP):**

All of the following criteria must be met:

- Diagnosis of primary chronic ITP **AND**
- Platelet count of < 30,000/mm^3 with active bleeding; or platelet count < 30,000/mm^3 and a documented history of significant bleeding; or platelet count < 20,000/mm^3 ~~with increased risk of bleeding~~ **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to corticosteroids AND IVIg* AND splenectomy (*prior authorization required)

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).

Authorization Duration*: If patient meets criteria for coverage, authorization will be given for one month of treatment with rituximab.

3. **For Chronic Lymphoid Leukemia:**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C91.10, C91.11 and C91.12. 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 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).

4. **For Microscopic Polyarteritis Nodosa (PAN)**

- Medical record documentation of a diagnosis of microscopic polyarteritis nodosa used in combination with glucocorticoids

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).

5. **For Granulomatosis with Polyangiitis (GPA) *(Wegener's Granulomatosis)* and Microscopic Polyangiitis (MPA)**

- Medical record documentation of a diagnosis of Granulomatosis with Polyangiitis (GPA) (Wegener's granulomatosis) or Microscopic Polyangiitis (MPA) used in combination with glucocorticoids

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).

6. **For Non-Hodgkin Lymphoma**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis codes C82.00 through C85.99 and C86.0 through C88.9. 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 Non-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).

7. **For Multiple Sclerosis (MS)**

Note: Prior authorization is not required for Ruxience, Riabni or Truxima for diagnosis code G35. 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 Multiple Sclerosis

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).

8. **For Refractory Chronic Debilitating Myasthenia Gravis**

- Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis **AND**
- Prescribed by or in consultation with a neuromuscular specialist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy

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).

Note: Corticosteroids: betamethasone, dexamethasone, methylprednisolone, prednisone

Cholinesterase inhibitors: pyridostigmine, neostigmine

Immunosuppressants: azathioprine, mycophenolate, cyclosporine, Rituxan

9. **For Pemphigus Vulgaris (PV)**

- Prescription written by a dermatologist **AND**
- Member is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of moderate to severe pemphigus vulgaris **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on corticosteroids AND a 12-week trial of at least one (1) nonsteroidal immunomodulatory medication (e.g. azathioprine, cyclophosphamide, or mycophenolate).

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).

AUTHORIZATION DURATION:

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

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

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

FAST FACTS

Xywav

Updated Indication: Xywav is now indicated for the treatment of idiopathic hypersomnia (IH) in adult patients.

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

- Medical record documentation of a diagnosis of cataplexy with narcolepsy OR excessive daytime sleepiness with narcolepsy AND
- Medical record documentation that Xywav is prescribed with a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature AND
- Medical record documentation of one of the following:
    - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Xyrem OR
    - Medical record documentation the patient requires a low sodium diet due to a concomitant diagnosis of heart failure, hypertension, or renal impairment AND
- Medical record documentation of one of the following:
    - For cataplexy with narcolepsy, medical record documentation of failure on, intolerance to, or contraindication to one of the following: venlafaxine XR or fluoxetine OR
    - For excessive daytime sleepiness with narcolepsy:
        - For patients 18 years and older, medical record documentation of failure on, intolerance to, or contraindication to one of the following: modafinil AND methylphenidate immediate release or amphetamine/dextroamphetamine immediate release OR
        - For patient 7-17 years, medical record documentation of failure on, intolerance to methylphenidate immediate release or amphetamine/dextroamphetamine immediate release

OR

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

- Medical record documentation of an age greater than or equal to 18 AND
- Medical record documentation that member was evaluated and treated for other etiologies of excessive daytime sleepiness AND
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to modafinil

Outcome: The committee unanimously voted to accept the recommendations.

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

Mvasi

Updated Indication: Mvasi is a biosimilar for Avastin and recently received the following indications:
• Epithelial ovarian, fallopian tube, or primary peritoneal cancer:
o in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, for stage III or IV disease following initial surgical resection
o in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinumresistant recurrent disease who received no more than 2 prior chemotherapy regimens
o in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by MVASI as a single agent, for platinum-sensitive recurrent disease

Recommendation: No changes are recommended

Outcome: The committee unanimously voted to accept the recommendations.

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

Keytruda

Updated Indication: Keytruda is now indicated:
• For the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC, or III melanoma following complete resection. (Previously this was indicated for adult patients with melanoma with lymph node involvement following complete resection).
• For the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions

Recommendation: There are no changes to the formulary placement of Keytruda. The following changes are recommended to the prior authorization criteria and authorization duration in the Medical Benefit Policy to incorporate the new indications.

Medical Benefit Policy 119.0

1. **Melanoma**
   - Prescription written by a hematologist/oncologist **AND**
   - Medical record documentation of one of the following:

     <u>Unresectable or metastatic melanoma:</u>
     - Medical record documentation that patient is ≥ 18 years of age **AND**
     - A diagnosis of unresectable or metastatic melanoma **AND**

- Keytruda is not being used in combination with any other agents for the treatment of unresectable or metastatic melanoma.

OR

Adjuvant treatment of completely resected ~~metastatic~~ melanoma

- Medical record documentation that patient is ≥ 12 years of age **AND**
- A diagnosis of ~~metastatic~~ Stage IIB, IIC, or III melanoma with ~~lymph node involvement~~, which has been completely resected **AND**
- Keytruda is being used in the adjuvant setting (following lymph node resection) **AND**
- Keytruda is being used as a single agent.

12. **Renal Cell Carcinoma (RCC)**
    - Prescription written by a hematologist/oncologist **AND**
    - Medical record documentation that patient is ≥ 18 years of age **AND**
    - Medical record documentation of one of the following:

Advanced Renal Cell Carcinoma:

- Medical record documentation of a diagnosis of advanced renal cell carcinoma **AND**
- Medical record documentation that Keytruda is being used in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) **AND**
- Medical record documentation that Keytruda in combination with axitinib (Inlyta) OR lenvatinib (Lenvima) is being used as first-line treatment for advanced disease

Note: In clinical trials, advanced disease included newly diagnosed or recurrent Stage IV renal cell carcinoma.

Adjuvant treatment of renal cell carcinoma

- A diagnosis of renal cell carcinoma AND
- Documentation of intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions AND
- Keytruda is being used in the adjuvant setting AND
- Keytruda is being used as a single agent.

Note: In clinical trials, intermediate-high risk category included: pT2 with Grade 4 or sarcomatoid features; pT3, any Grade without nodal involvement (N0) or distant metastases (M0); and high risk included: pT4, any Grade N0 and M0; any pT, any Grade with nodal involvement and M0. The M1 no evidence of disease (NED) category includes patients with metastatic disease who had undergone complete resection of primary and metastatic lesions.

AUTHORIZATION DURATION:

For adjuvant treatment of metastatic melanoma (completely resected melanoma), neoadjuvant/adjuvant treatment of early-stage triple negative breast cancer, and adjuvant treatment of renal cell carcinoma:
Initial approval will be for 6 months. One subsequent approval will be for an additional 6 months and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Keytruda for the adjuvant treatment of metastatic melanoma and renal cell carcinoma should not exceed the FDA-approved treatment duration of 1 year (12 months). Authorization of Keytruda for the treatment of early-stage triple negative breast cancer should not exceed the approved treatment duration of 24 weeks for neoadjuvant therapy and 27 weeks for adjuvant therapy. For requests exceeding the above limit, medical record documentation of the following is required:

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

Outcome: The committee unanimously voted to accept the recommendations.

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

Kyprolis

Updated Indication: Kyprolis is also indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy in combination with daratumumab and hyaluronidase-fihj and dexamethasone.

Recommendation: There are no changes to formulary status or authorization duration at this time. However, it is recommended to update the criteria to included the updated FDA-indication.
Multiple Myeloma:

- Must be prescribed by hematologist or oncologist AND
- Medical record documentation of relapsed or refractory multiple myeloma AND
- Medical record documentation of prior treatment with at least one therapy AND
- Medical record documentation that Kyprolis will be used:
    - As monotherapy OR
    - In combination with dexamethasone OR
    - In combination with dexamethasone and lenalidomide OR
    - In combination with daratumumab (Darzalex) and dexamethasone OR
    - In combination with daratumumab and hyaluronidase-fihj (Darzalex Faspro) and dexamethasone

Outcome: The committee unanimously voted to accept the recommendations.

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

Darzalex Faspro

Updated Indication: Darzalex Faspro is now indicated for multiple myeloma in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Recommendation: There will be no changes to formulary status, authorization duration, or quantity limits at this time. However, it is recommended to make the following updates to the current policy.

- Prescription written by a hematologist/oncologist AND
- Medical record documentation a diagnosis of multiple myeloma AND

If newly diagnosed multiple myeloma (transplant ineligible):

- Medical record documentation that the member is not eligible for stem-cell transplantation (e.g. coexisting conditions, age greater than 65, etc.) AND
- Medical record documentation that Darzalex Faspro will be given in combination with one of the following options:

- Bortezomib (Velcade), melphalan, AND prednisone [VMP] OR
- Lenalidomide (Revlimid) AND dexamethasone

OR

If newly diagnosed multiple myeloma (transplant eligible):

- Medical record documentation that the member is eligible for stem-cell transplantation AND
- Medical record documentation that Darzalex Faspro will be given in combination with bortezomib (Velcade), thalidomide, and dexamethasone (DVTd)

OR

If **relapsed/refractory multiple myeloma:**

- One of the following:
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three prior lines of therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR
  - Medical record documentation that the patient is double-refractory to a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) and an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) OR
  - Medical record documentation of therpaeutic failure on, intolerance to, or contraindication to at least one prior line of therapy including lenalidomide and a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) AND Darzalex Faspro will be prescribed in combination with pomalidomide and dexamethasone OR
  - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least 1 prior therapy including a proteasome inhibitor (including but not limited to Velcade*, Kyprolis*, or Ninlaro*) or an immunomodulatory agent (including but not limited to Pomalyst*, Revlimid*, Thalomid*) AND one of the following:
    - Medical record documentation that Darzalex Faspro will be prescribed in combination with lenalidomide and dexamethasone OR
    - Medical record documentation that Darzalex Faspro will be prescribed in combination with bortezomib and dexamethasone OR
    - Medical record documentation that Darzalex Faspro will be prescribed in combination with carfilzomib (Kyprolis) and dexamethasone

OR

If light-chain (AL) amyloidosis:

- Prescription written by or in consultation with and hematologist/oncologist AND
- Medical record documentation of a diagnosis of light-chain (AL) amyloidosis AND
- Medical Record documentation that the patient does NOT have New York Heart Association (NYHA) Class IIIB (as defined by slight limitation during daily living activity and comfortable at rest) or Class IV heart failure, or mayo cardiac stage IIIB* AND
- Medical record documentation that Darzalex Faspro will be used in combination with bortezomib, cyclophosphamide and dexamethasone

Outcome: The committee unanimously voted to accept the recommendations.

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

Updates

Dexcom and FreeStyle Libre Update

Recommendation: Due to the high approval percentage the following changes are recommended when claims are processed at an in-network pharmacy:

- FreeStyle Libre 14 Day Reader/FreeStyle Libre 2 Reader/FreeStyle Libre Reader
    - Recommend removal of PA, add QL by time to GHP Family of 1 Reader per 730 days
- FreeStyle Libre 14 Day Sensor/FreeStyle Libre 2 Sensor
    - Recommend removal of PA, add QL by ratio to GHP Family of 2 Sensors per 28 days
- FreeStyle Libre Sensor
    - Recommend removal of PA, add QL by ratio to GHP Family of 3 Sensors per 30 days
- Dexcom G6 Transmitter Miscellaneous (GPI 97202012066300, DDID 202418, NDC 08627001601)
    - A single Dexcom G6 transmitter lasts for three months (90 days), starting from the first time you snap it into a sensor--provided that it is used within five months of its shipping date.
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 transmitter per 90 days
- Dexcom G6 Sensor Miscellaneous (GPI 97202012046300, DDID 202419, NDC 08627005303)
    - Dexcom G6 sensors are designed to last for a maximum of 10 days, after which time the Dexcom G6 will require the insertion of a new sensor.
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 sensor per 10 days
- Dexcom G6 Receiver Device (GPI 97202012026200, DDID 202420, NDC 08627009111)
    - Recommended addition to brand preferred tier with no PA, add QL by time of 1 receiver per 730 days

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.

January 2022 P&T DUR/Adherence Update

Recommendation: The January 2022 P&T DUR/Adherence Update was presented to the Committee for review.

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.

Immunomodulator and Oral Oncology Renewal Criteria Removal – GHP Family

Recommendation: After review of prior authorization data from September 1, 2020 through August 31, 2021 it was identified that immunomodulator products and oral oncology products both have a high renewal approval rate. In order to reduce PA burden for low value authorizations, it is recommended that the following changes are made:

ORAL ONCOLOGY

Abiraterone (Zytiga)	Imatinib (Gleevec)	Stivarga
Afinitor Disperz	Imbruvica	Sutent
Alecensa	Inlyta	Tabrecta
Alunbrig	Inqovi	Talzenna
Ayvakit	Iressa	Tasigna
Balversa	Kisqali	Tazverik
Bicalutamide (Casodex)	Koselugo	Temozolomide
Bosulif	Lapatinib (Tykerb)	Tepmetko
Braftovi	Lenvima	Tibsovo
Brukinsa	Lonsurf	Truseltiq
Cabometyx	Lorbrena	Tukysa
Calquence	Lumakras	Turalio
Capecitabine (Xeloda)	Lynparza	Ukoniq
Caprelsa	Mektovi	Venclexta
Cometriq	Nexavar	Vitrakvi
Copiktra	Ninlaro	Vizimpro
Cotellic	Nubeqa	Votrient
Daurismo	Odomzo	Xalkori
Erivedge	Onureg	Xospata
Erleada	Pemazyre	Xpovio
Erlotinib (Tarceva)	Piqray	Xtandi
Everolimus (Afinitor)	Pomalyst	Yonsa
Fotivda	Qinlock	Zejula
Gavreto	Retevmo	Zelboraf
Gilotrif	Revlimid	Zolinza
Ibrance	Rozlytrek	Zydelig
Iclusig	Rubraca	Zykadia
Idhifa	Sprycel	

Medicaid Approval Percentage: 100%

It is recommended that the current authorization duration is removed from the above referenced products and that these medications are instead approved through 12/31/2099.

IMMUNOMODULATORS

Actemra Self-Injectable	Kineret	Simponi
Cimzia	Olumiant	Skyrizi
Cosentyx	Orencia SC	Stelara
Enbrel	Otezla	Taltz
Humira	Rinvoq	Tremfya
Kevzara	Siliq	Xeljanz/Xeljanz XR

Medicaid Approval Percentage: 90%

It is recommended that the initial authorization duration is removed from the above referenced products and that these requests are instead approved for a 12 month duration.

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.

2022 GHP Family Supplemental Formulary

Recommendation: The 2022 GHP Family Supplemental Formulary was presented to the Committee for review.

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.

December Electronic Vote

Due to the volume of full drug reviews, fast facts, and updates that must reviewed by the P&T Committee an additional electronic vote was held from December 20, 2021 to December 24, 2021. Responses were received from 25 members (out of 39) and all voted to approve.

The following was approved for GHP Family:

Drug	Recommendation
Bylvay	Bylvay will be a pharmacy benefit. It is recommended to not add Bylvay to formulary. Bylvay will require a prior authorization with the following criteria: • 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. <u>Authorization Duration</u>: 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

Ascensiv and Xembify	Asceniv and Xembify are medical benefits that will be GHP managed. Asceniv and Xembify should not be added to the GHP Family pharmacy formulary. Asceniv and Xembify should be added to the Medical Benefit Policy 4.0: MBP 4.0 **DESCRIPTION**: Immune Serum Globulins are used to provide passive immunity or to alter the immune response by increasing the recipients' antibody titer and antigen-antibody reaction potential. IgG antibodies help to prevent or modify certain infectious diseases in susceptible individuals. Five major classes of immunoglobulin proteins exist in human serum and other body fluids (IgA, IgD, IgE, IgG, and IgM). Immune globulin is an antibody-containing solution obtained from the pooled plasma of pre-screened, presumably healthy blood donors. Throughout the policy, the term "intravenous immune globulin" and "IVIG" is intended to refer to *all* immune globulin injections, including intravenous, intramuscular and subcutaneous administrations. **CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee** This policy refers to the following intravenous immune globulin drug products: Asceniv Bivigam Carimune NF Cutaquig Cuvitru Flebogamma Flebogamma DIF Gammagard Liquid Gammagard S/D Gammaked Gammaplex Gamunex Gamunex-C Hizentra Hyqvia (Primary Humoral Immunodeficiencies indications only) Octagam Panzyga Privigen Xembify • **For Asceniv (immune globulin intravenous, human – slra) requests:** The following criteria must be met 1. Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least three (3) immune globulin products. **IVIG is considered to be medically necessary for the following, however not limited to, indications when specified criteria are met:** • **Primary Humoral Immunodeficiencies, including combined immunodeficiencies**

	Congenital Agammaglobulinemia (X-linked agammaglobulinemia, Bruton's disease) Autosomal recessive agammaglobulinemia Common Variable Immunodeficiency (CVID) Wiskott-Aldrich Syndrome X-linked or autosomal recessive immunodeficiency with hyperimmunoglobulin M Severe Combined Immunodeficiency (SCID) Ataxia-telangectasia DiGeorge syndrome Nijmegen breakage syndrome Gruscelli syndrome NEMO deficiency WHIM (warts, hypogammaglobulinemia, immunodeficiency, and myelokathexis) syndrome X-linked lymphoproliferative disease (in patients with hypogammaglobulinemia or dysgammaglobulinemia and infections) Hypogammaglobulinemia provided the appropriate work up is performed to determine extent (ex. flow cytometry and anamnestic response to recall antigens) Patients with primary immunodeficiencies must meet the following criteria: 1. Medical record documentation/laboratory results of immunoglobulin defic **AND** 2. Medical record documentation of an inability to amount an adequate imm response to inciting antigens; **AND** 3. Medical record documentation of persistent and severe infections • **Idiopathic Thrombocytopenia Purpura (ITP)** 1. Acute ITP when either of the following are present: • Active bleeding and a platelet count of less than 30,000/mm^3; **or** documented history of significant bleeding and a platelet count of less than 30,000/mm^3; **AND** • Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy~~; **OR**~~ **OR** • As a preoperative treatment prior to major invasive surgical procedures **AND** • IVIG be used with corticosteroids when a more rapid increase in platelet count is required **OR** • A platelet count of less than 20,000/mm3 **AND** • Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy 2. Chronic ITP when the following criteria are met:

	• ~~Platelet count less than 30,000/mm^3 in children or less than 20,000/mm^3 in adults; **AND**~~ • Duration of Immune Thrombocytopenia (ITP) greater than 12 months **AND** • No concurrent illness or disease explaining thrombocytopenia; **AND** • Medical documentation of prior treatment with ~~a long course or high dose of~~ corticosteroids (ex, ~~prednisone 1 mg/kg orally for 21 days then tapered off~~ prednisone 2 mg/kg/day for ≤ 6 weeks (for adults) or 4 mg/kg/day for ≤ 7 days (for children)); and a splenectomy, if over 12 months have elapsed from date of initial diagnosis; **OR** • Active bleeding and a platelet count of less than 30,000/mm^3; **or** documented history of significant bleeding and a platelet count of less than 30,000/mm^3 **OR** • A platelet count of less than 20,000/mm3 **OR** • As a preoperative treatment prior to major invasive surgical procedures 3. ITP in pregnancy with medical documentation ~~of any~~ of the following: ~~• Platelet counts less than 10,000/mm^3 during the third trimester~~ ~~• Platelet count of 10,000/mm^3 to 30,000/mm^3 and active bleeding~~ ~~• Platelet counts less than 10,000/mm^3 after steroid failure~~ ~~• Platelet count of 10,000/mm^3 to 30,000/mm^3 and active bleeding after steroid failure~~ ~~• Platelet count of 10,000/mm^3 to 30,000/mm^3 during third trimester and asymptomatic after steroid failure~~ • Active bleeding and a platelet count of less than 30,000/mm3; or documented history of significant bleeding and a platelet count of less than 30,000/mm3; **OR** • A platelet count of less than 20,000/mm3; **OR** • Intent to increase platelet counts to a level considered safe for procedures **AND** • A contraindication to, intolerance to or therapeutic failure on corticosteroid therapy **OR** a more rapid increase in platelets is necessary, as determined by the prescriber* *Note: initial response to corticosteroids usually occurs within 4-14 days and reaches a peak response within 1-4 weeks. Initial response to IVIG usually occurs within 1-3 days and reaches a peak response within 2-7 days. 4. Secondary ITP

	a. *H-pylori*-associated i. Eradication of H-pylori in patients testing positive • **Acquired Hypogammaglobulinemia Secondary to Chronic B-cell Lymphocytic Leukemia or Multiple Myeloma** The following criteria must be met: 1. IgG less than 500 mg/dl, **AND** 2. a documented history of repeated bacterial infection two times in one year or a severe bacterial infection within the last 6 months • **Post-transfusion purpura** The following criteria must be met: 1. Medical record documentation of an onset of severe thrombocytopenia (platelet count less than or equal to 30,000/mm3) occurring 2-14 days post blood product transfusion. • **Kawasaki Disease** The following criteria must be met: 1. Documentation of a diagnosis of Kawasaki disease. 2. Treatment with IVIG is begun within 10 days of the onset of fever. OR 3. Patient has a delayed diagnosis (i.e., later than day 10 of fever) with ongoing systemic inflammation as manifested by elevation of ESR or CRP (CRP>3.0mg/dL) together with either persistent fever without other explanation or coronary artery aneurysms. • **Pediatric HIV infection – Bacterial infection prevention** The following criteria must be met: 1. Indicated in HIV positive children with humoral immunodeficiency AND 2. Entry CD4+ lymphocyte count of 200/mm^3 or greater AND 3. Hypogammaglobulinemia AND one or more of the following: 4. Recurrent serious bacterial infections OR 5. Failure to form antibodies to common antigens OR 6. There is a high risk for measles OR 7. There is a documented bronchiectasis that has not adequately responded to antimicrobial and pulmonary therapy. • **Bone Marrow Transplantation (for lines of business not covered by the transplant vendor only)** The following criteria must be met: 1. The transplant recipient is within the first 100 days after transplant from a matched unrelated donor; OR

	2. Documentation of treatment of Graft vs. Host Disease in a transplant recipient receiving allogenic matched bone marrow transplant with chronic repeated infections or hypogammaglobulinemia (IgG levels less than 400 mg/dL); OR 3. Documentation of autologous transplant with hypogammaglobulinemia (IgG level less than 400 mg/dL) or repeated infections. • **Myasthenia Gravis (Acute use)** The following criteria must be met: 1. Must be prescribed by a neurologist; AND Medical documentation of one of the following indications: 2. Diagnosis of acute myasthenic crisis with decompensation; OR 3. Use during postoperative period following a thymectomy for acute exacerbations; OR 4. Use prior to planned thymectomy OR 5. For short term bridge therapy (one-course of treatment) in patients with acute worsening symptoms with plans to start other immunosuppressive treatments or corticosteroids. *IVIG for any of the above acute indications will be approved for one course of treatment. One course of treatment will be limited to 5 days of IVIG therapy. • **Refractory Chronic Debilitating Myasthenia Gravis** 1. Medical record documentation of refractory Chronic Debilitating Myasthenia Gravis AND 2. Prescribed by or in consultation with a neuromuscular specialist AND 3. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one corticosteroid AND 4. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one cholinesterase inhibitor AND 5. Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least one non-steroidal immunosuppressive therapy • **Dermatomyositis and Polymyositis** All of the following criteria must be met: 1. Diagnosis of dermatomyositis or polymyositis confirmed by biopsy AND 2. Documented evidence of active disease AND 3. Must be prescribed by a neurologist AND 4. Documented evidence that the condition is refractory to both of the following therapies A) First line therapy: corticosteroids (at least 4 months of therapy) B) Second line therapy: at least two immunosuppressants (e.g. cyclosporine, azathioprine, methotrexate, cyclophosphamide)

	• **Guillain-Barre Syndrome/Ascending Paralysis** The following criteria must be met: 1. ~~Adults with a~~ A diagnosis of either acute or chronic Guillain-Barre syndrome; AND 2. Must be prescribed by a neurologist; AND 3. IVIG will be initiated within 2 weeks but no longer than 4 weeks of neuropathic symptom onset if acute onset; AND 4. No plan for combining IVIG with plasma exchange or sequential plasma exchange and IVIG. • **Chronic Inflammatory Demyelinating Polyneuropathy** All of the following criteria must be met: 1. Must be prescribed by a neurologist; AND 2. Documented evidence of focal or symmetric neurologic deficits that are slowly progressive or relapsing over 2 months or longer AND 3. Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy with the presence of at least ONE of the following: a. Motor distal latency prolongation ≥ 50% above ULN in two nerves (excluding median neuropathy at the wrist from carpal tunnel syndrome), OR b. Reduction of motor conduction velocity ≥ 30% below LLN in two nerves, OR c. Prolongation of F-wave latency ≥ 30% above ULN in two nerves (≥ 50% if amplitude of distal negative peak CMAP <80% of LLN values), OR d. Absence of F-waves in two nerves if these nerves have distal negative peak CMAP amplitudes ≥ 20% of LLN + ≥ 1 other demyelinating parameter in ≥ 1 other nerve, OR e. Partial motor conduction block: ≥ 50% amplitude reduction of the proximal negative peak CMAP relative to distal, if distal negative peak CMAP ≥ 20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥ 1 other nerve, OR f. Abnormal temporal dispersion (>30% duration increase between the proximal and distal negative peak CMAP) in ≥ 2 nerves, OR g. Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) increase in ≥ 1 nerve (median ≥ 6.6 ms, ulnar ≥ 6.7 ms, peroneal ≥ 7.6 ms, tibial ≥ 8.8 ms) + ≥ 1 other demyelinating parameter in ≥ 1 other nerve

	Improvement should be apparent after 3 months of treatment; otherwise, requests for further treatment will require Medical Director review. • **Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT)** The following criteria must be met: 1. History of previous fetus or newborn with serologically confirmed Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT) with thrombocytopenia **OR** 2. History of previous fetus or newborn with serologically confirmed Fetal or Neonatal Alloimmune Thrombocytopenia (FNAIT) with intracranial hemorrhage **OR** 3. History of previous fetus or newborn with thrombocytopenia or intracranial hemorrhage of unknown etiology **AND** documentation a complete diagnostic workup was performed* *Note, a complete diagnostic workup, per ACOG guidelines may include: • Maternal anti-HPA antibody screening and cross matching with paternal platelets at 12, 24 and 32 weeks OR • Paternal incompatibility for human platelet antigen OR • A single antibody screening study including the crossmatching of paternal and maternal platelets at 30 weeks gestation ~~1.There has been a history of a previous pregnancy affected by FAIT and the father is homozygous for HPA-1a; OR~~ ~~2.At 20 weeks, cordocentesis reveals fetal platelets less than 100,000uL; OR~~ ~~3.Neonate with severe thrombocytopenia, who is at high risk of developing intracranial hemorrhage and washed irradiated maternal platelets are not available, have not been successful, have become intolerable, or are contraindicated~~ • **Multifocal Motor Neuropathy** The following criteria must be met: 1. Must be prescribed by a neurologist; AND 2. Medical documentation of progressive symptoms for a minimum of 1 month; AND 3. Asymmetric limb weakness in at least two nerves AND 4. No objective sensory abnormalities except for minor vibration sense abnormalities in the lower limb AND 5. Documentation of a diagnosis of multifocal motor neuropathy with conduction block as shown on electrophysiologic study as evidenced by: • Definite Conduction block on a single nerve OR • Probable Conduction block in at least two nerves

OR

- Probable Conduction block in at least one nerve AND at least two (2) of the following:

    i. Elevated IgM anti-ganglioside GM1 antibodies

    ii. Increased CSF protein

    iii. increased T2-signal intensity on MRI of brachial plexus with diffuse nerve swelling

    iv. Objective clinical improvement following IVIG treatment

- **CMV Interstitial Pneumonia in Allogenic Bone Marrow Transplant or HSCT patients** (Ib/A)

  The following criteria must be met:
  1. Medical record documentation of CMV pneumonia
  2. Medical record documentation that IVIG is being used in combination with or patient has a contraindication to ganciclovir

- **Toxic shock syndrome** (III/C)

  The following criteria must be met:
  ~~1. Used in conjunction with conventional therapy~~

  1. Medical record documentation of severe disease and failure on, intolerance to, or contraindication to conventional therapy, which may include, but is not limited to surgical debridement, fluid replacement, vasopressors or antibiotic therapy **AND**
  2. Caused by staphylococcal ~~or streptococcal~~ organisms

OR

  3. Medical record documentation of Streptococcal Toxic Shock Syndrome (TSS)

~~- **Neonatal sepsis** (Ia/A)~~

~~The following criteria must be met:~~
~~Used in conjunction with conventional therapy~~

- **Graves' Ophthalmopathy** (Ib/A)

  The following criteria must be met:
  1. Medical record documentation of failure on, contraindication to, or intolerance to conventional treatment (corticosteroids)
  2. Prescription must be written by an ophthalmologist

- **Autoimmune Mucocutaneous Blistering Diseases (pemphigus, pemphigoid, pemphigus vulgaris, pemphigus foliaceus, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis** (III/C)

	The following criteria must be met: **1.** Diagnosis must be substantiated by biopsy; AND **2.** Failure or contraindication to two or more conventional therapies (corticosteroids, azathioprine, cyclophosphamide, etc.); OR **3.** Have rapidly progressive disease in which a clinical response could not be quickly achieved utilizing conventional therapy. IVIG would be given in conjunction with conventional therapy and only until such time as conventional therapy could take effect Note: IVIG for the treatment of autoimmune mucocutaneous blistering disease must be used only for short-term therapy and not as maintenance therapy. • **Solid Organ Transplant** The following criteria must be met: Prevention of acute humoral rejection • Medical record documentation that patient is at high risk for antibody-mediated rejection, including highly sensitized patients or receiving ABO incompatible organ OR Treatment of acute humoral rejection • Medical record documentation of antibody-medicated rejection • **Rasmussen's Encephalitis** **(IIb/B)** The following criteria must be met: 1. Medical record documentation that short-term amelioration of encephalitis is needed prior to definitive surgical therapy 2. Medical record documentation of intractable focal motor seizures and progressive neurologic deterioration • **Stiff-Person Syndrome** **(Ib/A)** The following criteria must be met: 1. Prescription written by a neurologist 2. Medical record documentation of failure on, intolerance to, or contraindication to all standard therapies (muscle relaxants, benzodiazepines, and gabapentin-related medications) • **Eaton-Lambert myasthenic syndrome** **(Ib/A)** All of the following criteria must be met: 1. Prescription written by a neurologist 2. Medical record documentation of failure on, contraindication to, or intolerance to other treatments including corticosteroids or other immunosuppressants, cholinesterase inhibitors, and 3,4-diaminopyridine.

- **Multiple Sclerosis (relapsing/remitting type)**

  All of the following criteria must be met:
  1. Must be prescribed by a neurologist; **AND**
  2. Medical record documentation of RRMS **AND**
  3. Medical record documentation of current MS exacerbation **AND**
  4. Medical record documentation of therapeutic failure on, contraindication to, or intolerance to an appropriate trial of high dose corticosteroids

Improvement should be apparent after 2 courses of monthly treatment, otherwise, requests for further treatment will require Medical Director review of supporting documentation of expected outcome.

Note: IVIG is considered investigational for primary or progressive multiple sclerosis and will not be covered.

- **Warm Antibody Autoimmune hemolytic anemia** **(III/D)**

  The following criteria must be met:
  1. Refractory to or contraindicated to corticosteroids and immunosuppressive agents
  2. Refractory to splenectomy

- **Parvovirus B19 Infection**

  All of the following criteria must be met
  1. Prescribed by or in consultation with an infectious disease specialist, immunologist, hematologist, or transplant specialist
  2. Medical record documentation of chronic immunodeficient condition (HIV, solid organ transplant ect)
  3. Medical record documentation of chronic parvovirus B19 infection
  4. Medical record documentation of severe anemia as defined by hemoglobin < 8 g/dL

- **Catastrophic Antiphospholipid Syndrome (CAPS)** **(III/C)**

  All of the following criteria must be met:
  1. Documentation of patient with antiphospholipid syndrome (APS) with multiorgan failure (evidence of involvement of three or more organs, systems, and/or tissues AND
  2. Development of manifestations simultaneously or in less than one week AND
  3. Confirmation by histopathology of small vessel occlusion in at least one organ or tissue AND
  4. Medical record documentation Intravenous Immunoglobulin (IVIG) will be used in combination with conventional therapies (eg. anticoagulation and corticosteroids) AND

	5. Laboratory confirmation of the presence of antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, and/or anti-beta2-glycoprotein I antibodies) OR o All four criteria are met, except for only two organs, systems and/or sites of tissues involvement OR o All four criteria are met, except for laboratory confirmation OR o Criteria 1, 2, and 4 are met OR o Criteria 1,3, and 4 and the development of a third event in more than a week but less than a month, despite anticoagulation **AUTHORIZATION DURATION:** Each treatment period will be defined as 6 months or less, unless otherwise stated (e.g. Chronic Inflammatory Demyelinating Polyneuropathy, Multiple Sclerosis, and Multifocal Motor Neuropathy). Re-review will occur every 6 months or less, dependent on the indication. Documentation of clinical response to therapy is required after initiation of therapy. If initial benefit is seen and continued therapy is deemed necessary, documentation of objective monitoring must be seen. Clinical improvement is superior to laboratory monitoring. IVIG will no longer be covered if there is a medical record documentation of disease progression. **LIMITATIONS: When approved, IVIG will be administered in a setting determined by the Plan, in consultation with the requesting physician to be the most clinically appropriate and/or medically necessary.** **Initial Dosing:** Dosing should be calculated using adjusted body weight (ABW) if one or more of the following criteria are met: • Patient's body mass index (BMI) is 30 kg/m^2 or more • Patient's actual body weight is 20% higher than his or her ideal body weight (IBW) Dosing formulas: • BMI = weight in kg / height in $meters^2$ • IBW (kg) for males = 50 + [2.3 (height in inches – 60)] • IBW (kg) for females = 45.5 + [2.3 * (height in inches – 60)] • ABW = IBW + 0.5 (actual body weight – IBW) Geisinger Health Plan considers some conditions other than those listed under Indications to be **Experimental, Investigational or Unproven** and **NOT Medically Necessary**. These conditions include: • Alzheimer's disease • amyotrophic lateral sclerosis • atopic dermatitis • autism • chronic fatigue syndrome

	• chronic mucocutaneous candidiasis (CMCC) • complex regional pain syndrome (CRPS) • epilepsy • inclusion body myositis • Lyme disease • neuromyelitis optica (NMO) (Devic's Disease) • optic neuritis • paraproteinemic demyelinating neuropathy (PDN) • post-polio syndrome • recurrent spontaneous miscarriage • rheumatic fever • secondary progressive multiple sclerosis (SPMS)
Tecentric	Medical Benefit, managed by GHP requires prior authorization. No changes are needed to the formulary placement of Tecentriq. The following changes are recommended to Medical Benefit Policy: **2. Non-Small Cell Lung Cancer:** • Prescription written by an oncologist **AND** • Medical record documentation of a diagnosis of non-small cell lung cancer meeting one of the following situations: o Medical record documentation of disease progression during or following platinum-containing chemotherapy OR o Medical record documentation of disease progression on at least one FDA-approved therapy targeting EGFR or ALK if the patient has EGFR or ALK genomic tumor aberrations (e.g. mutation, deletion, insertion, etc.) OR o Medical record documentation of a non-squamous histologic subtype **AND** o Medical record documentation that Tecentriq will be given as first-line treatment **AND** o Medical record documentation that Tecentriq will be given in combination with bevacizumab, paclitaxel, AND carboplatin **OR** paclitaxel protein-bound AND carboplatin **AND** o Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration. OR o Medical record documentation that Tecentriq will be given as first-line treatment for metastatic disease **AND** o Medical record documentation that tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of

	the tumor area [IC ≥ 10%]) as determined by an FDA-approved test **AND** ○ Medical record documentation that the patient does not have an EGFR or ALK genomic tumor aberration. OR ○ Medical record documentation of stage II to IIIA disease AND ○ Medical record documentation of use as adjuvant treatment following resection and platinum-based therapy **AND** ○ Medical record documentation that tumors have PD-L1 expression on ≥1% of tumor cells as determined by an FDA-approved test **AND** ○ Medical record documentation that Tecentriq is being given as a single agent. ****For adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy:** One approval will be given for 12 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease. Authorization of Tecentriq for adjuvant treatment of stage II to IIIA non-small cell lung cancer (NSCLC) following resection and platinum-based chemotherapy should not exceed the FDA-approved treatment duration of 1 year (12 months) in patients. For requests exceeding the above limit, medical record documentation of the following is required: • Peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

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

Meeting adjourned at 3:49 pm

Future Scheduled Meetings
The next bi-monthly scheduled meeting will be held on March 15, 2022 at 1:00 p.m.

All of these meetings are scheduled to be held at Geisinger Health Plan, Hughes Center North and South Buildings; 108 Woodbine Lane; Danville, PA 17821 or will be held virtually