**P&T Committee Meeting Minutes**
**GHP Family**
**March 21, 2017**

| **Present:** | **Absent:** |
|---|---|
| Bret Yarczower, MD, MBA – Chair | Kristen Bender, Pharm.D |
| Dean Christian, MD – via phone | Beverly Blaisure, MD |
| Kimberly Clark, Pharm.D. | Keith Boell, DO |
| Kristi Clarke, Pharm. D. – via phone | Holly Bones, Pharm.D. |
| Jamie Dodson, RPh | John Flaherty, Pharm.D. |
| Michael Evans, Pharm.D. B.S. – via phone | Lisa Mazonkey, RPh |
| Tricia Heitzman, Pharm.D. – via phone | Perry Meadows, MD |
| Keith Hunsicker, Pharm.D. | Jonas Pearson, MS, RPh |
| Steven Kheloussi, Pharm.D. – via phone | William Seavey, Pharm.D. |
| Phillip Krebs, R.EEG T. – via phone | Michael Spishock RPh |
| Susan Ledig, MD, MS – via phone | Lori Zaleski, RPh |
| Thomas Morland, MD – via phone | |
| Aubrielle Prater Pharm.D. | |
| Kristen Scheib, Pharm. D. – via phone | |
| Richard Silbert, MD – via phone | |
| Todd Sponenberg, Pharm.D., RPh | |
| Kevin Szczecina, RPh | |
| Elaine Tino, CRNP – via phone | |

**Call To Order:**
Bret Yarczower called the meeting to order at 1:01 p.m., Tuesday, March 21, 2017.

**Review and Approval of Minutes:**
Dr. Bret Yarczower asked for a motion or approval to accept the January 17, 2017 minutes as written. Kevin Szczecina accepted the motion and Todd Sponenberg seconded the motion. None were opposed.

**DRUG REVIEWS:**

**VERMOX/EMVERM** **Aubrielle Prater**
(mebendazole)

Aubrielle Prater provided a review of Vermox and Emverm to the committee for consideration as a pharmacy benefit. Mebendazole is indicated for patients 2 years and older for the treatment of Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworms), Enterobius vermicularis (pinworms), and Trichuris trichiura (whipworms) in single or mixed infections.

Vermox was originally FDA-approved on June 28, 1974, then it was discontinued. Vermox was re-approved October 2016. However, according to the Facts and Comparisons, there are no plans to make the product commercially available; distribution will be limited through a global product donation program. Information pertaining to this product within the monograph is pending revision.

Formulary alternatives: none

**Proposed Recommendations:** Emverm will be a pharmacy benefit. It is recommended that Emverm should be added to the GHP Family formulary at the Brand Tier. Emverm should require a prior authorization with the following criteria:

- Medical record documentation of diagnosis of at least one of the following: Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworms), Enterobius vermicularis (pinworms), or Trichuris trichiura (whipworms)

**QUANTITY LIMIT**:

For *Enterobius vermicularis* (pinworm): maximum number of fills: two (2); quantity limit: 1 tablet per fill
For all other FDA-approved indications: *Ancylostoma duodenale* or *Necator americanus* (hookworms), *Ascaris lumbricoides* (roundworms), and *Trichuris trichiura* (whipworms): maximum number of fills: two (2); quantity limit: 6 tablets (2 tablets per day for 3 days) per fill

**Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

**Approved Recommendations**: Emverm will be a pharmacy benefit. Emverm will be added to the GHP Family formulary at the Brand-Preferred Tier. Emverm will require a prior authorization with the following criteria:

- Medical record documentation of diagnosis of at least one of the following: Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworms), Enterobius vermicularis (pinworms), or Trichuris trichiura (whipworms)

**QUANTITY LIMIT**:

For *Enterobius vermicularis* (pinworm): maximum number of fills: two (2); quantity limit: 1 tablet per fill

For all other FDA-approved indications: *Ancylostoma duodenale* or *Necator americanus* (hookworms), *Ascaris lumbricoides* (roundworms), and *Trichuris trichiura* (whipworms): maximum number of fills: two (2); quantity limit: 6 tablets (2 tablets per day for 3 days) per fill

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

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**CUVITRU** **Keith Hunsicker**
(immune globulin subcutaneous (human) 20% solution)

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Keith Hunsicker provided a review of Cuvitru to the committee for consideration as a medical benefit. Cuvitru is indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older, including common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Formulary alternatives: All covered via the medical benefit: Carimune*, Flebogamma DIF*, Gammagard*, Gammagard S/D*, Gammaplex*, Gammaked*, Gamunex-C*, Hizentra*, Octagam*, Privigen*, Bivigam*, Hyqvia*

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**Proposed Clinical Recommendations:** Cuvitru will be covered as a medical benefit for GHP Family members requiring prior authorization. It is recommended that Cuvitru be added to Medical Benefit Policy 4.0. The prior authorization criteria outlined by MBP 4.0 should apply.

**MBP 4.0 IVIG**

**IVIG is considered to be medically necessary for the following indications when specified criteria are met:**

- **Primary Humoral Immunodeficiencies, including combined immunodeficiencies**
  - Congenital Agammaglobulinemia (X-linked agammaglobulinemia)
  - 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 deficiency; **AND**

2. Medical record documentation of an inability to amount an adequate immunologic 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/$mm^3$; **AND**
     - Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy; **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

  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**
     - 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), a splenectomy;
       **OR**

     - Active bleeding and a platelet count of less than 30,000/$mm^3$; **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

  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 documentation of failure, intolerance, or contraindication to corticosteroids and plasmapheresis; **OR**
  2. Platelet count less than 10,000/$mm^3$ with bleeding

- **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.

- **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**
  The following criteria must be met:

  1. Must be prescribed by a neurologist; AND
  2. Documentation of therapeutic failure on, intolerance to, or contraindication to at least two standard treatments (e.g. cholinesterase inhibitors, azathioprine, corticosteroids) and /or a combination of these treatments for a minimum of 3 months; AND

  Medical documentation of one of the following indications:

  3. Diagnosis of acute myasthenic crisis with decompensation; OR
  4. Use during postoperative period following a thymectomy; OR
  5. Use prior to planned thymectomy

**Note**: For chronic forms of Myasthenia Gravis, treatment with IVIG is considered investigational and is not covered.

- **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 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 12 weeks or longer AND
  3. Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (a minimum of 3 of the following must be documented):
     a. Partial conduction block of one or more motor nerves
     b. Decreased conduction velocity of two or more motor nerves
     c. Prolongation of distal latency of two or more motor nerves
     d. Prolongation or absence of F-wave latencies in two or more motor nerves

Improvement should be apparent after 8 weeks of treatment; otherwise, requests for further treatment will require Medical Director review.

Relapses may require periodic isolated treatments with a single dose of IVIG.

- **Fetal or Neonatal Alloimmune Thrombocytopenia (FAIT)**
  The following criteria must be met:

  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 2 months; AND
  3. Documentation of a diagnosis of multifocal motor neuropathy with conduction block as shown on electrophysiologic study as evidenced by:
     - Conduction block on a single nerve or probable conduction block in two or more nerves
     - Normal sensory nerve conduction in upper limb segments and normal sensory nerve action potential (SNAP) amplitude

  Treatment is limited to one course of therapy defined as 3 months if approved. Requests for further treatment will require Medical Director review.

- **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
  2. Caused by staphylococcal or streptococcal organisms

- **Neonatal sepsis** **(Ia/A)**
  The following criteria must be met:

  1. 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, etc.)
  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 a life threatening condition
  2. Documentation of severe thrombocytopenia and microangiopathic hemolytic anemia
  3. Documentation of failure on, contraindication to, or intolerance to conventional treatment with anticoagulation and steroids
  4. Should be used in combination with plasma exchange

**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)
- systemic lupus erythematosus

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Cuvitru is a subcutaneous immune globulin product indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older, including common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Cuvitru dosing is individualized to the patient depending on patient response. For patients switching from other immune globulin products, the initial Cuvitru dose is determined utilizing a dose conversion chart and the dose of the previous immune globulin product. Clinical trials analyzed the infection rate, antibiotic usage rate, days off work/school/unable to perform normal daily activities due to illness/infection rate, hospitalization rate, and days in hospital due to infections rate. In the North America Study, patient's reported opinions of treatment interference and convenience differed significantly between the intravenous and subcutaneous treatments. There is an associated black box warning due to the risk of thrombosis related to Cuvitru. Cuvitru is one of many immune globulin products. The immune globulin product is selected based on patient specific factors (i.e. avoiding products containing sucrose in patients with renal impairments, avoiding products containing maltose or glucose in patients with diabetes, etc.). Once a patient tolerates an immune globulin product, the tolerated product should not be changed unless there is a compelling reason to do so. Alternative products should only be administered with clinician approval.

**Clinical Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Jamie Dodson seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Cuvitru will be covered as a medical benefit requiring prior authorization for GHP Family members. No additional prior authorization criteria should apply.

**Financial Discussion:** No questions or comments.

**Financial Outcome:** Kimberly Clark made a motion to accept the recommendation as written. Todd Sponenberg seconded the motion. None were opposed.

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**Approved Recommendations**: Cuvitru will be covered as a medical benefit requiring prior authorization for GHP Family members. The following prior authorization criteria will apply:

**MBP 4.0 IVIG**

**IVIG is considered to be medically necessary for the following indications when specified criteria are met:**

- **Primary Humoral Immunodeficiencies, including combined immunodeficiencies**
  - Congenital Agammaglobulinemia (X-linked agammaglobulinemia)
  - 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 deficiency; **AND**
2. Medical record documentation of an inability to amount an adequate immunologic 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/$mm^3$; **AND**
   - Medical record documentation of use in conjunction with a corticosteroid or a contraindication to or failure on corticosteroid therapy; **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

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**
   - 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), a splenectomy;
     **OR**
   - Active bleeding and a platelet count of less than 30,000/$mm^3$; **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

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 documentation of failure, intolerance, or contraindication to corticosteroids and plasmapheresis; **OR**
2. Platelet count less than 10,000/$mm^3$ with bleeding

- **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.

- **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**
  The following criteria must be met:

  1. Must be prescribed by a neurologist; AND
  2. Documentation of therapeutic failure on, intolerance to, or contraindication to at least two standard treatments (e.g. cholinesterase inhibitors, azathioprine, corticosteroids) and /or a combination of these treatments for a minimum of 3 months; AND

  Medical documentation of one of the following indications:

  3. Diagnosis of acute myasthenic crisis with decompensation; OR
  4. Use during postoperative period following a thymectomy; OR
  5. Use prior to planned thymectomy

**Note**: For chronic forms of Myasthenia Gravis, treatment with IVIG is considered investigational and is not covered.

- **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 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 12 weeks or longer AND
  3. Physician provided documentation of EMG abnormalities consistent with the diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (a minimum of 3 of the following must be documented):
     a. Partial conduction block of one or more motor nerves
     b. Decreased conduction velocity of two or more motor nerves
     c. Prolongation of distal latency of two or more motor nerves
     d. Prolongation or absence of F-wave latencies in two or more motor nerves

Improvement should be apparent after 8 weeks of treatment; otherwise, requests for further treatment will require Medical Director review.

Relapses may require periodic isolated treatments with a single dose of IVIG.

- **Fetal or Neonatal Alloimmune Thrombocytopenia (FAIT)**
  The following criteria must be met:

  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 2 months; AND
3. Documentation of a diagnosis of multifocal motor neuropathy with conduction block as shown on electrophysiologic study as evidenced by:
    - Conduction block on a single nerve or probable conduction block in two or more nerves
    - Normal sensory nerve conduction in upper limb segments and normal sensory nerve action potential (SNAP) amplitude

Treatment is limited to one course of therapy defined as 3 months if approved. Requests for further treatment will require Medical Director review.

- **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
  2. Caused by staphylococcal or streptococcal organisms

- **Neonatal sepsis** **(Ia/A)**
  The following criteria must be met:

  1. 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, etc.)
  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 a life threatening condition
  2. Documentation of severe thrombocytopenia and microangiopathic hemolytic anemia
  3. Documentation of failure on, contraindication to, or intolerance to conventional treatment with anticoagulation and steroids
  4. Should be used in combination with plasma exchange

**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)
- systemic lupus erythematosus

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

**VEMLIDY** **Aubrielle Prater**
(tenofovir alafenamide)

Aubrielle Prater provided a review of Vemlidy to the committee for consideration as a pharmacy benefit. Vemlidy is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.

Formulary alternatives: entecavir, adefovir dipivozil, Intron-A, Pegasys, Lamivudine HBV, Viread

**Proposed Clinical Recommendations:** Vemlidy will be a pharmacy benefit. It is recommended that Vemlidy should be added to the GHP Family formulary at Brand Tier. Vemlidy should not require a prior authorization.

**QUANTITY LIMIT:** 1 tablet per day

**Clinical Discussion**: FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Vemlidy is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease. The recommended dose of Vemlidy is 25 mg (one tablet) taken orally once daily with food. In the clinical trials comparing Vemlidy to Viread in patients with chronic HBV infection and compensated liver disease the efficacy endpoint was the proportion of subjects with plasma HBV DNA levels < 29 IU/mL at Week 48. In Study 108, the proportion of patients with cirrhosis who achieved this efficacy outcome was 92% (22/24) in the Vemlidy group and 93% (13/14) in the TDF group, there was no significant difference between treatment groups. In Study 110, the proportion of subjects with cirrhosis who achieved HBV DNA < 29 IU/mL at Week 48 was 63% (26/41) in the Vemlidy group and 67% (16/24) in the Vemlidy and TDF groups, there was no significant difference between treatment groups. The most common adverse reactions (incidence ≥ 5%, all grades) were headache, abdominal pain, fatigue, cough, nausea, and back pain. Vemlidy may cause less renal and bone toxicity than Viread. However, this was based on disease-oriented outcomes and the long term clinical significance of this in unknown. Vemlidy has a black box warning for lactic acidosis/severe hepatomegaly with steatosis and post treatment severe acute exacerbation of hepatitis B virus. The warnings and precautions include: risk of development of HIV-1 resistance in patients coinfected with HBV and HIV-1 and new onset or worsening renal impairment. Safety and effectiveness has not been established in patients < 18 years. Vemlidy is not recommended in patients with end stage renal disease (estimated CrCl < 15 mL/min). Vemlidy is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment. Vemlidy is a targeted pro-drug of tenofovir. It has enhanced stability in the plasma, which allows Vemlidy to deliver tenofovir to the

hepatocytes at 1/10th of the dose of Viread, which reduces the levels of tenofovir in the plasma. There is 89% less tenofovir circulating in the plasma with Vemlidy compared to Viread, which results in reduced systemic exposure. UpToDate, recommends tenofovir alafenamide over TDF. If a patient is already on TDF, they recommend patients to switch to tenofovir alafenamide.

**Clinical Outcome:** Keith Hunsicker made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** It is recommended that Vemlidy should be added to the GHP Family formulary on the brand tier. No additional criteria should apply.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Kimberly Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Approved Recommendations**: Vemlidy will be added to the GHP Family formulary on the brand tier.

**QUANTITY LIMIT:** 1 tablet per day

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

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**INFLECTRA** **Keith Hunsicker**
(infliximab-dyyb)

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Keith Hunsicker provided a review of Inflectra to the committee for consideration as a medical benefit. Inflectra is indicated:

Through comparative efficacy and safety trials compared to Remicade:

- Inflectra is a tumor necrosis factor (TNF) blocker indicated for:
    1. Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active **rheumatoid arthritis** (in combination with methotrexate)
    2. Reducing signs and symptoms in patients with active **ankylosing spondylitis**

Through indication extrapolation:

- Inflectra is a tumor necrosis factor (TNF) blocker indicated for:
    1. Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active **Crohn's disease** who have had an inadequate response to conventional AND/OR reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease
    2. Reducing signs and symptoms and inducing and maintaining clinical remission in **pediatric** patients with moderately to severely active **Crohn's disease** who have had an inadequate response to conventional therapy
    3. Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active **ulcerative colitis** who have had an inadequate response to conventional therapy

4. Reducing signs and symptoms of active **psoriatic arthritis**, inhibiting the progression of structural damage, and improving physical function
5. Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) **plaque psoriasis** who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Limitation of Use: Inflectra is not approved for the use in pediatric ulcerative colitis due to orphan drug exclusivity for Remicade.

Formulary alternatives: methotrexate, sulfasalazine, Actemra*, Cimzia*, Enbrel*, Humira*, Orencia*, Otezla*, Simponi*, Xeljanz*

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**Proposed Clinical Recommendations:** Inflectra will be covered as a medical benefit for GHP Family members. It is recommended that Inflectra require prior authorization. Inflectra should be added to Medical Benefit Policy 5.0. It is recommended that MBP 5.0 be edited to read as outlined after the cost effectiveness/final review.

**Clinical Discussion:** FDA Approved Indications, Pharmacology/MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Black Box Warnings, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed. For geriatric use, there are no dose adjustments for elderly patients. There were no observed differences in terms of safety and efficacy between elderly patients and younger subjects, however greater sensitivity in elder patients cannot be ruled out. Renal function should be closely monitored.

Inflectra is the only biosimilar to the commercially available infliximab product, Remicade. Inflectra is indicated for the same disease states as Remicade with the exception of pediatric ulcerative colitis. In clinical trials, Inflectra was found to be "equivalent" to Remicade for the indications of rheumatoid arthritis and ankylosing spondylitis. The other approved indications for Inflectra were approved through indication extrapolation. There is limited evidence that may suggest that it is safe and effective to switch from Remicade therapy to Inflectra therapy. Inflectra carries the same black box warning for serious infections and malignancy as well as the same warnings and precautions as Remicade. Anti-TNF therapies are commonly recommended by disease state guidelines, however, currently the guidelines do not prefer one Anti-TNF drug over another. Similarly, the guidelines do not prefer Inflectra over Remicade or vice versa. Geisinger Health System considers patients new to therapy as candidates for a biosimilar product; however, if a patient is stabilized on a biosimilar's reference product, the system prefers to not switch the patient to the biosimilar product. Physician feedback regarding biosimilar products varied and was somewhat hesitant due to unfamiliarity with biosimilar products; however, the concept of preferring the biosimilar product, Inflectra, over the reference product, Remicade, for new start patients was relatively well accepted.

**Clinical Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Jamie Dodson seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Inflectra will be a medical benefit requiring prior authorization for GHP Family members. It is recommended that the criteria outlined by MBP 5.0 apply. MBP 5.0 should be changed to read as the following.

**MBP 5.0**

**For Treatment of Rheumatoid Arthritis:**

- Must be 18 years of age or greater **AND**

- Requesting provider must be a rheumatologist **AND**
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel* **AND**
- Continuation of effective dose of methotrexate during infliximab therapy **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

***Recommended guidelines for use in the treatment of rheumatoid arthritis***

- *3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.*
- *For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.*

**For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:**

- Must be 6 years of age or older; **AND**
- Prescription is written by a gastroenterologist **AND**
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease

**AND**

- One of the following:
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* **OR**
  - Physician documentation of Crohn's disease with actively draining fistulas.

**AND**

- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

***Recommended guidelines for use in the treatment of Crohn's disease or fistulizing Crohn's disease:***

- *5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter*
- *For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.*

**For Treatment of Ulcerative Colitis:**

- Must be at least 6 years of age; **AND**
- Must be prescribed by a gastroenterologist; **AND**
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis **AND**
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (e.g. 6-mercaptopurine or azathioprine **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* OR medical record documentation of age < 18 years **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra* OR medical record documentation of age <18 years

***Recommended guidelines for the use in the treatment of ulcerative colitis***

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

**For Treatment of Ankylosing Spondylitis:**

- Physician documentation of a diagnosis of ankylosing spondylitis **AND**
- Prescribing physician must be a rheumatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel* **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

***Recommended guidelines for use in ankylosing spondylitis***

- *5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter*

**For the treatment of Plaque Psoriasis:**

- Prescribed by a dermatologist **AND**
- Insured individual must be at least 18 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira* AND Enbrel* **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

***Recommended guidelines for the use in the treatment of plaque psoriasis***

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

**For the treatment of Psoriatic Arthritis:**

- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
    - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
- Must be prescribed by a rheumatologist or dermatologist **AND**
- Must be at least 18 years of age **AND**
- Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of **Enbrel*** AND **Humira*** **AND**
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

***Recommended guidelines for the use in the treatment of psoriatic arthritis***

- *5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.*

*Prior authorization Required

**AUTHORIZATION DURATION:** Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy.

**LIMITATIONS:** Inflectra is not approved for the use in pediatric ulcerative colitis due to orphan drug exclusivity for Remicade.

**Financial Discussion:** None

**Financial Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Tricia Heitzman seconded the motion. None were opposed.

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**Approved Recommendations**: Inflectra will be covered as a medical benefit requiring prior authorization for GHP Family members. The following prior authorization criteria will apply:
For Treatment of Rheumatoid Arthritis:

- Must be 18 years of age or greater AND
- Requesting provider must be a rheumatologist AND
- Diagnosis of moderate to severe rheumatoid arthritis according the American College of Rheumatology Criteria for the Classification and Diagnosis of Rheumatoid Arthritis AND
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel* AND
- Continuation of effective dose of methotrexate during infliximab therapy AND
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of rheumatoid arthritis

- 3 mg/kg given as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. Infliximab should be given in combination with methotrexate.
- For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg or treating as often as every 4 weeks.

For Treatment of Crohn's Disease, Pediatric Crohn's Disease, and/or Fistulizing Crohn's Disease:

- Must be 6 years of age or older; AND
- Prescription is written by a gastroenterologist AND
- Medical record documentation of a diagnosis of moderate to severe Crohn's disease AND
- One of the following:
  - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to Humira* OR
  - Physician documentation of Crohn's disease with actively draining fistulas.

  AND
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in the treatment of Crohn's disease or fistulizing Crohn's disease:

- 5 mg/kg given intravenously as an induction regimen at 0, 2, and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter

- For adult members who respond and then lose response, consideration may be given to treatment with 10 mg/kg.

For Treatment of Ulcerative Colitis:
- Must be at least 6 years of age; AND
- Must be prescribed by a gastroenterologist; AND
- Physician provided documentation of a diagnosis of moderate to severe ulcerative colitis AND
- Physician provided documentation of failure on, intolerance to, or contraindication to adequate trials of conventional therapy that include corticosteroids, aminosalicylates and immunomodulators (e.g. 6-mercaptopurine or azathioprine AND
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to at least a 12 week trial of Humira* OR medical record documentation of age < 18 years AND
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra* OR medical record documentation of age <18 years

Recommended guidelines for the use in the treatment of ulcerative colitis
- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For Treatment of Ankylosing Spondylitis:
- Physician documentation of a diagnosis of ankylosing spondylitis AND
- Prescribing physician must be a rheumatologist AND
- Must be at least 18 years of age AND
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Humira* AND Enbrel* AND
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for use in ankylosing spondylitis
- 5mg/kg at 0, 2 and 6 weeks, then every 6 weeks thereafter

For the treatment of Plaque Psoriasis:
- Prescribed by a dermatologist AND
- Insured individual must be at least 18 years of age AND
- Physician provided documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface area involved or disease affecting crucial body areas such as the hands, feet, face, or genitals AND
- Medical record documentation of an inadequate response to, contraindication to, or failure on at least 3 months of Humira* AND Enbrel* AND
- For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for the use in the treatment of plaque psoriasis
- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

For the treatment of Psoriatic Arthritis:
- Physician provided documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:

o Documentation of either active psoriatic lesions or a documented history of psoriasis AND
• Must be prescribed by a rheumatologist or dermatologist AND
• Must be at least 18 years of age AND
• Medical record documentation of an inadequate response to, contraindication to, or failure on 12 weeks of Enbrel* AND Humira* AND
• For new start Remicade requests, medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3 month trial of Inflectra*

Recommended guidelines for the use in the treatment of psoriatic arthritis
- 5 mg/kg as an intravenous infusion followed with additional similar doses at 2 and 6 weeks after the first infusion, then every 8 weeks thereafter.

*Prior authorization Required

AUTHORIZATION DURATION: Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in the signs and symptoms of the treated indication at six (6) months of infliximab therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the treated indication while on infliximab therapy.

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

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**YOSPRALA** **Aubrielle Prater**
(aspirin and omeprazole)

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Aubrielle Prater provided a review of Yosprala to the committee for consideration as a pharmacy benefit. Yosprala is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor, indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk for developing aspirin associated gastric ulcers.

Formulary alternatives: lansoprazole, omeprazole, pantoprazole, rabeprazole, aspirin 81 mg, aspirin 325 mg

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**Proposed Clinical Recommendations:** Yosprala will be a pharmacy benefit. It is recommended that Yosprala should not be added to the GHP Family formulary. Yosprala will require a prior authorization with the following criteria:

- Medical record documentation of aspirin, component of Yosprala, being used for secondary prevention of cardiovascular and/or cerebrovascular events as evident by one of the following:
    - History of ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
    - Previous myocardial infarction or unstable angina pectoris
    - Diagnosis of chronic stable angina pectoris
    - History of prior revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is a pre-existing condition for which aspirin is already indicated **AND**

- Medical record documentation of risk of developing aspirin associated gastric ulcers as evident by one of the following:
    - Documentation of member being ≥ 55 years
    - History of gastric ulcers

**Quantity Limit:** 1 tablet per day

**Clinical Discussion:** FDA Approved Indications, Efficacy Evidence, Safety Evidence, Contraindications, Warnings and Precautions, Adverse Events, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Yosprala is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk for developing aspirin associated gastric ulcers. Yosprala should not be used as the initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction, or before percutaneous coronary intervention. It has not been shown to reduce the risk of gastrointestinal bleeding due to aspirin. Yosprala is not interchangeable with the individual components of aspirin and omeprazole. Yosprala is available as delayed-release tablets in 2 different strengths: 81 mg delayed-release aspirin/40 mg immediate-release omeprazole and 325 mg delayed-release aspirin/40 mg immediate-release omeprazole. The recommended dose is one tablet once daily at least 60 minutes before a meal. In the clinical trials, Yosprala significantly reduced the 6-month cumulative incidence of gastric ulcers compared to enteric coated aspirin in Study 1 and 2. The most common adverse reactions in adults (≥ 2%) were: gastritis, nausea, diarrhea, gastric polyps, and non-cardiac chest pain. The warnings/precautions and drug interactions, are combined from established warnings/precautions and drug interactions of both omeprazole and aspirin. Avoid use of NSAIDs, including Yosprala, in pregnant women starting at 30 weeks of gestation (third trimester). Breastfeeding is not recommended during treatment with Yosprala. Yosprala is contraindicated in pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's syndrome. Avoid Yosprala in patients with severe renal impairment (GFR < 10 mL/min) due to the aspirin component. Avoid Yosprala in patients with any degree of hepatic impairment. In cases where low-dose aspirin must be continued, concomitant therapy with a PPI is indicated as maintenance therapy. There is no data that suggest that one PPI is more effective than the other.

**Clinical Outcome:** Kim Clark suggested adding a quantity limit of one tablet per day. Todd Sponenberg made a motion to accept the recommendations as amended. Jamie Dodson seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** It is recommended that Yosprala should not be added to the GHP Family formulary. Yosprala will require a prior authorization with the following criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) formulary alternative proton pump inhibitors (one of which must be omeprazole) with concurrent use of aspirin.

**Formulary alternatives:** omeprazole, pantoprazole, lansoprazole, rabeprazole

**Financial Discussion:** No questions or comments.

**Financial Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

**Approved Recommendations**: Yosprala will be considered non-formulary for GHP Family members. The following prior authorization criteria will apply to requests for Yosprala:

- Medical record documentation of aspirin, component of Yosprala, being used for secondary prevention of cardiovascular and/or cerebrovascular events as evident by one of the following:
    - History of ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
    - Previous myocardial infarction or unstable angina pectoris
    - Diagnosis of chronic stable angina pectoris
    - History of prior revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is a pre-existing condition for which aspirin is already indicated **AND**
- Medical record documentation of risk of developing aspirin associated gastric ulcers as evident by one of the following:
    - Documentation of member being ≥ 55 years
    - History of gastric ulcers **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to at least three (3) formulary alternative proton pump inhibitors (one of which must be omeprazole) with concurrent use of aspirin.

**QUANTITY LIMIT:** one tablet daily

**Formulary alternatives**: omeprazole, pantoprazole, lansoprazole, rabeprazole

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

**GONITRO** **Aubrielle Prater**
(nitroglycerin)

Aubrielle Prater provided a review of Gonitro to the committee for consideration as a pharmacy benefit. Gonitro is a nitrate vasodilator indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.

Formulary alternatives: Nitroglycerin SL tabs, nitroglycerin SL spray, nitroglycerin capsules ER, nitroglycerin transdermal, Nitrostat, Nitro-dur, Nitro-bid

**Proposed Clinical Recommendations:** Gonitro will be a pharmacy benefit. It is recommended that Gonitro should not be added to the GHP Family formulary

**Clinical Discussion:** FDA Approved Indications, Dosing Schedule, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, and Special Population Precautions were discussed.

Gonitro is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease. Gonitro is supplied as a sublingual powder in a packet. It contains 400 mcg of nitroglycerin per packet. The recommended dose at the onset of an attack is one or two packets (400 mcg each) under the tongue. One additional packet may be administered every 5 minutes as needed. No more than three total packets (1200 mcg) are recommended within a 15-minute period. Gonitro may also be used prophylactically 5 to 10 minutes prior to engaging in activities that may precipitate an acute attack. From

the results of the pharmacokinetic study, it is implied that the sublingual absorption is higher following the administration of Gonitro compared to Nitrolingual Pumspray. Gonitro is contraindicated in patients who are taking phosphodiesterase type 5 (PDE-5) inhibitors, such as avanafil, sildenafil, tadalafil, or vardenafil, or soluble guanylate cyclase stimulators (such as riociguat), those who have severe anemia, those with possible increased intracranial pressure (e.g. cerebral hemorrhage or traumatic brain injury), patients allergic to nitroglycerin, other nitrates or nitrites or any excipient, and patients with acute circulatory failure or shock. The warnings and precautions are tolerance, hypotension, hypertrophic obstructive cardiomyopathy, and headache. The safety and effectiveness of nitroglycerin in the pediatric population has not been established. There seems to be no advantage of the nitroglycerin powder packets when compared to the sublingual tablets or translingual sprays.

**Clinical Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Gonitro will be a pharmacy benefit. It is recommended that Gonitro should not be added to the GHP Family formulary. The following criteria should apply:

- Medical record documentation of a reason why the patient cannot use nitroglycerin sublingual tablets and nitroglycerin translingual spray.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Approved Recommendations**: Gonitro will be a pharmacy benefit. It is recommended that Gonitro should not be added to the GHP Family formulary. The following criteria should apply:

- Medical record documentation of a reason why the patient cannot use nitroglycerin sublingual tablets and nitroglycerin translingual spray.

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

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**SPINRAZA** **Keith Hunsicker**
(nusinersen)

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Keith Hunsicker provided a review of Spinraza to the committee for consideration as a medical benefit. Spinraza is indicated for the treatment of pediatric and adult patients with spinal muscular atrophy (SMA). SMA is an autosomal recessive, neurodegenerative disease that causes severe, progressive skeletal muscle atrophy and weakness. Patients with SMA have a mutation in the survival motor neuron (SMN) gene and do not produce enough SMN protein, which plays a critical role in maintaining motor neurons in the spinal cord and lower brain stem.

Specifically, SMA is caused by deletions in the SMN1 gene located on the 5q chromosome. In addition to the SMN1 gene, humans have a SMN2 gene which is identical to the SMN1 gene with the exception of 11 nucleotides. One of the nucleotide differences is a change of cytosine to thymine within exon 7, which causes between 80% to 90% of the transcriptions of the gene to produce a truncated protein which rapidly degrades. Because of this, when a patient does not have a properly functioning SMN1 gene, the SMN2 gene is not able to produce sufficient amounts of protein to compensate for the loss of the SMN1 gene.

It is estimated that SMA presents in the US with an incidence of 8.3 cases per 100,000 live births. 1 in every 54 persons in the United States are thought to be carriers of SMN (carrier frequency can vary by

the ethnicity of the person). As described by Table 1, SMA can affect patients of various ages, and the life-expectancy of patients with the disease varies with the time of onset (and severity) of the disease.

The onset of disease and its associated symptoms ranges from before birth into adulthood. The weakness associated with SMA presents as a symmetric and progressive weakness that affects proximal muscles more than distal. Initially before SMA genetics were understood, SMA was classified by SMA Subtypes (described in Table 1). Now it is noted that the phenotype of SMN1-associated SMA does not divide itself into clear subtypes, yet the subtypes are still useful for prognosis and management.

There are two genotypes of SMA, SMN1-associated and SMN2-associated SMA. SMN1 pathogenic variants do not correlate with severity of the disease. Conversely, SMN2 pathogenic variants correlate with disease severity. Patients can present with up to four copies of SMN2. When three or more copies of SMN2 are present, the patient usually presents a milder phenotype of SMA. It is thought that having a higher quantity of SMN2 copies can compensate for lack of SMN1 expression because of a report of several patients who had homozygous SMN1 deletion with four copies of SMN2 that presented as asymptomatic.

The current treatment approach of SMA is providing supportive care with a focus to improve quality of life. Generally, patients with SMA receive respiratory, digestive, and orthopedic support. Early, proactive intervention with these treatments have been correlated with improved survival; however, these treatments do not affect motor function, achievement of motor milestones, or progression of SMA.

Formulary alternatives: None

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**Proposed Clinical Recommendations:** Spinraza will be covered as a medical benefit for GHP Family members. It is recommended that a prior authorization apply. The following prior authorization criteria should apply:

- Prescription is being prescribed by a neurologist or pediatric neurologist **AND**
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
    - Homozygous exon 7 gene deletion OR
    - Homozygous exon 7 conversion mutation OR
    - Compound heterozygous exon 7 mutation

**OR**

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies.

**Clinical Discussion:** FDA Approved Indications, Dosing Schedule, Pharmacology and MOA, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, Special Population Precautions, and Specialist Feedback from Dr. Tom Crawford from The Johns Hopkins Hospital was discussed.

Spinraza is the first and only medication indicated to treat SMA in children and adults. It is an intrathecally injected antisense oligonucleotide and is dosed at 12mg on days 0, 14, 28, 58 and every 4 months thereafter. Spinraza functions by increasing exon 7 inclusion in SMN2 mRNA transcripts, ultimately increasing the production of full length SMN protein, which is necessary for the proper function of motor neurons. In clinical trials, Spinraza has proven to have a statistically and clinically significant improvement in time to death or respiratory intervention and in motor milestone achievement. Clinically, Spinraza is very well tolerated; however, the tolerability of the lumbar puncture procedure necessary to administer Spinraza can vary between patients and may interfere with the dosing of Spinraza as scheduled. The development and clinical trials of Spinraza were without significant barriers and specialists' opinions of the drug are very positive.

**Clinical Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** Spinraza is a medical benefit requiring prior authorization. No additional prior authorization criteria should apply.

**Authorization Duration**: If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of **12 months**. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of **12 months** when the following criteria are met.

- Medical record documentation that member is compliant with prescribed nusinersen regimen.

**Quantity Limit**: Initial approval: One-time initial authorization of three (3) 12mg injections per 30 days; remainder of 12-month authorization duration, Rx Count of 3.
Subsequent approvals: 12-month authorization with Rx Count of 3.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Approved Recommendations**: Spinraza is a medical benefit requiring prior authorization. The following prior authorization criteria should apply:

- Prescription is being prescribed by a neurologist or pediatric neurologist AND
- Medical record documentation of a confirmed diagnosis of 5q Spinal Muscular Atrophy (SMA) by genetic testing with results showing one of the following:
  - Homozygous exon 7 gene deletion OR
  - Homozygous exon 7 conversion mutation OR
  - Compound heterozygous exon 7 mutation

OR

- Medical record documentation of diagnostic testing confirming zero (0) SMN1 copies

**Authorization Duration**: If determined to be medically necessary, Spinraza should be approved for an initial authorization duration of **12 months**. Subsequent authorizations of Spinraza will be determined medically necessary and should be approved for an authorization duration of **12 months** when the following criteria are met.

- Medical record documentation that member is compliant with prescribed nusinersen regimen.

**Quantity Limit**: Initial approval: One-time initial authorization of three (3) 12mg injections per 30 days; remainder of 12-month authorization duration, Rx Count of 3.
Subsequent approvals: 12-month authorization with Rx Count of 3.

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

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**RUBRACA** **Aubrielle Prater**
(rucaparib)

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Aubrielle Prater provided a review of Rubraca to the committee for consideration as a pharmacy benefit. Rubraca is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Patients should be selected for therapy based on an FDA-approved companion diagnostic for Rubraca. Note: This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Formulary alternatives: Lynparza*

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**Proposed Clinical Recommendations:** Rubraca will be a pharmacy benefit. It is recommended that Rubraca should be added to the GHP Family formulary. Rubraca will require a prior authorization with the following criteria**:**

- Prescription must be written by an oncologist/hematologist **AND**
- Medical record documentation of the member being ≥ 18 years **AND**
- Medical record documentation of deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer as verified by an FDA-approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two or more prior lines of chemotherapy

**Note:** The FDA approved test is FoundationFocus $CDx_{BRCA}$
**Quantity Limit:** 4 tablets per day

**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 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

**Clinical Discussion:** FDA Approved Indications, Dosing Schedule, Clinical Evidence of Safety and Efficacy, Adverse Reactions, Dosing Schedule, Monitoring, Safety Profile, Contraindications, Warnings and Precautions, Drug Interactions, Patent Life, Unique Therapeutic Features, Recommendations of National Agencies and Organizations, Distribution, Special Population Precautions and Specialist Feedback from Jenna Carmichael, PharmD, BCOP was discussed.

Rubraca is indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies. Patients should be selected for therapy based on an FDA-approved companion diagnostic for Rubraca. The FDA-approved companion diagnostic test is the FoundationFocus CDxBRCA. Rubraca is a PARP inhibitor. Rubraca is available as 200 mg and 300 mg tablets. The recommended dose is 600 mg (two 300 mg tablets) taken orally twice daily with or without food. If adverse reactions occur, the dose could be reduced or treatment could be interrupted. From a study of, two multicenter, single-arm, open-label trials, patients who received Rubraca 600 mg twice daily, showed an objective response rate of 54%, complete response in 9% of patients, partial response in 45% of patients, and a median duration of response of 9.2 months (investigator-assessed). Independent radiology review response rate was 42% (95% CI [32, 52]), with a median duration of response of 6.7 months (95% CI [5.5, 11.1]). The most common adverse reactions (≥ 20%) were nausea, fatigue (including asthenia), vomiting, anemia, abdominal pain, dysgeusia, constipation, decreased appetite, diarrhea, thrombocytopenia, and dyspnea.

The most common laboratory abnormalities (≥ 35%) were increase in creatinine, increase in ALT, increase in AST, decrease in hemoglobin, decrease in lymphocytes, increase in cholesterol, decrease in platelets, and decrease in absolute neutrophil count. Pregnancy testing is recommended for females of reproductive potential prior to initiating Rubraca. Females should also be advised to use effective contraception during treatment and for 6 months following the final dose of Rubraca. Due to the potential for adverse reactions in the breast-fed infant, women should be advised to not breastfeed during treatment and 2 weeks after the final dose. The only other PARP inhibitor on the market is Lynparza, it is FDA-approved for the treatment of advanced ovarian cancer with known or suspected deleterious germline BRCA mutation (as detected by an FDA-approved test) who received 3 or more prior chemotherapies. Rubraca may cause more grade 3 anemias and increase liver enzymes more than Lynparza, however it can be utilized as a third-line agent compared to a fourth-line agent. NCCN has not provided any recommendations for Rubraca therapy. The distribution of Rubraca is limited to Avella, Biologics, CVS Specialty, and US Bioservices specialty pharmacies.

**Clinical Outcome:** Keith Hunsicker made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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**Proposed Financial Recommendations:** It is recommended that Rubraca be added to the GHP Family formulary on the Brand Tier. No additional criteria should apply.

**Financial Discussion:** No comments or questions.

**Financial Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed.

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**Approved Recommendations**: It is recommended that Rubraca be added to the GHP Family formulary on the Brand Tier. The following criteria should apply.

- Prescription must be written by an oncologist/hematologist **AND**
- Medical record documentation of the member being ≥ 18 years **AND**
- Medical record documentation of deleterious *BRCA* mutation (germline and/or somatic) associated advanced ovarian cancer as verified by an FDA-approved test **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two or more prior lines of chemotherapy

**Note:** The FDA approved test is FoundationFocus $CDx_{BRCA}$
**Quantity Limit:** 4 tablets per day

**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 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

**Note:** The authorization for Lynparza is for 3 months or less if the reviewing provider feels it is medical appropriate. Subsequent approvals will be for an additional 3 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.

**Recommendations:** It is recommended to update the authorization duration for Lynparza. The following changes should apply to the Medicaid policy:
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 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.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed

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

**FAST FACTS:**

**STELARA** **Keith Hunsicker**
(ustekinumab)

**Updated Indication:** Stelara is now indicated for the treatment of adult patients with moderately to severely active Crohn's Disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers. Previously, Stelara was indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy and active psoriatic arthritis alone or in combination with methotrexate. Stelara should be given as a single intravenous infusion using weight-based dosing followed by 90mg subcutaneously every 8 weeks starting 8 weeks after the initial infusion.

**Recommendation:** It is recommended that the following indication is added to the existing Stelara policies for GHP Family:
For Crohn's disease (CD)

- Prescription must be written by a gastroenterologist **AND**
- Member must be at least 18 years of age **AND**
- Medical record documentation of moderately to severely active Crohn's disease **AND**
- Medical record documentation of an intolerance to, contraindication to, or therapeutic failure on a minimum 3-month trial of three (3) of the following medications: Humira*, Cimzia*, Entyvio*, infliximab (Remicade or Inflectra) *, or Tysabri* **AND**
- Medical record documentation of Stelara 130mg vials as IV infusion (for induction therapy) **OR** Stelara 90mg syringes (for maintenance therapy) being prescribed.

*Prior authorization required

**Note to reviewer:** Stelara 45mg syringe is not indicated for use in Crohn's disease.

**Authorization Duration:** If determined to be medically necessary, Stelara should be approved for an initial authorization duration of **6 months**. After the initial 6-month maintenance approval, subsequent approvals for coverage will be for a duration of **12 months** requiring medical record documentation of continued or sustained improvement in the signs and symptoms of Crohn's disease while on Stelara therapy.

**Quantity limit**:

Initial Authorization:

- One-time authorization of up to four 130mg vials for induction infusion (to be entered by medical).
- Rx Count of two (2) 90mg syringes for remainder of the initial 6-month authorization (to be entered by pharmacy).

Subsequent Authorizations:

- Rx count of six (6) 90mg syringes per 12-month authorization

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Todd Sponenberg seconded the motion. None were opposed.

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

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**ILARIS** **Aubrielle Prater**
(canakinumab)

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**Updated Indication:** Ilaris is an interleukin-1β blocker indicated for the treatment of:

- Periodic Fever Syndromes:
  - Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including:
    - Familial Cold Autoinflammatory Syndrome (FCAS)
    - Muckle-Wells Syndrome
  - Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients.
  - Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients.
  - Familial Mediterranean Fever (FMF) in adult and pediatric patients.
- Active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

NOTE: Ilaris was previously FDA-approved for CAPS and SJIA

**Recommendation:** The current medical policy for Ilaris (MBP 77.0) should be updated to reflect the new indication. The following prior authorization criteria should be added to the current policy:

**Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) when the following criteria are met:

- Physician provided documentation of diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) supported by documentation of genetic testing to identify the *TNFRSF1A* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.

**Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) when the following criteria are met:

- Physician provided documentation of diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) supported by documentation of elevated immunoglobulin D level or genetic testing to identify the *MVK* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.

**Familial Mediterranean Fever (FMF)**
Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Familial Mediterranean Fever (FMF) when the following criteria are met:

- Physician provided documentation of diagnosis of Familial Mediterranean Fever (FMF) as confirmed by genetic testing to identify the *MEFV* gene mutation.
- Must be prescribed by an immunologist, rheumatologist, or allergist.
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on colchicine.

AUTHORIZATION DURATION (for all indications): The initial approval will be for a time period of 6 months, requiring medical record documentation of improvement in signs and symptoms of disease. Ilaris will then require approval on a yearly basis.

The following criteria should be removed from the current Ilaris Medical Policy (MBP 77.0) for CAPS… and "Patient must be evaluated by expert in a contracted Center of Excellence as chosen by Geisinger Health Plan Medical Director in collaboration with the requesting physician."

**Other Recommendations:**
**Arcalyst:** The Arcalyst policy for should be updated for GHP Family. The criteria, "Patient must be evaluated by expert in field as chosen by Geisinger Health Plan Medical Director…" or "Patient must be evaluated by expert in a contracted Center of Excellence as chosen by Geisinger Health Plan Medical Director in collaboration with the requesting physician.…" should be removed from GHP Family Policy.
**Kineret:** The Kineret policy should be updated for GHP Family. The criteria,
"Patient must be evaluated by an expert in a contracted Center of Excellence as chosen by Geisinger Health Plan Medical Director in collaboration with the requesting physician" should be removed from the GHP Family Policy.

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as modified. Kim Clark seconded the motion. None were opposed.

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

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**ENBREL** **Kimberly Clark**
(etanercept)

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**Updated Indication:** Enbrel is a tumor necrosis factor (TNF) blocker which is now indicated for the treatment of plaque psoriasis (PsO) in patients 4 years or older. Previously indicated for patients 18 years of age or older

**Recommendation:** It is recommended that the pediatric psoriasis indication is added to the existing Enbrel policy with the following criteria:

- Prescription must be written by a dermatologist **AND**
- Member must be at least 4 years of age **AND**
- Medical record documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% of body surface area involved or disease involving crucial body areas such as the hands, feet, face, or genitals **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to topical corticosteroids

**AUTHORIZATION DURATION**:
For Treatment of Moderate to Severe Plaque Psoriasis:
Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or lack of progression in signs and symptoms of psoriasis on six (6) months of etanercept therapy is required.

After the initial six (6) month approval, subsequent approvals will be for a duration of one (1) year, requiring medical record documentation of continued or sustained improvement in the signs and symptoms of psoriasis while on etanercept therapy.

**Discussion**: No questons or comments.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

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

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**IMBRUVICA** **Aubrielle Prater**
(imbrutinib)

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**Updated Indication:** Imbruvica is a kinase inhibitor now indicated for the treatment of patients with Marginal Zone Lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy. Note: Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**Recommendations:** The current Imbruvica policy (1242.0F) should be updated to reflect the new indication. The following prior authorization criteria should be added to the current policy:
…**OR**

- Medical record documentation of Marginal Zone Lymphoma who have received at least one prior anti-CD20-based therapy

**Quantity Limit**: 4 capsules per day

**Authorization duration**: Each treatment period will be defined as 12 months. Re-review will occur every 12 months. Imbruvica will no longer be covered if there is medical record documentation of disease progression.
**Discussion:** No other questions or comments.

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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

**OPDIVO** **Keith Hunsicker**
(nivolumab)

**Updated Indication:** Opdivo is now indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing therapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Previously, Opdivo's indications only included: BRAF V600 wildtype and mutation positive metastatic melanoma, metastatic melanoma in combination with ipilimumab, metastatic non-small cell lung cancer after progression on or after platinum-based chemotherapy, advanced renal cell carcinoma, classical Hodgkin lymphoma, and recurrent or metastatic squamous cell carcinoma of the head and neck.

**Recommendations:** It is recommended the Opdivo policy be updated to include the new urothelial carcinoma indicatin as follows:

**For Urothelial Carcinoma**

1.Prescription written by a hematologist/oncologist **AND**
2.Medical record documentation that patient > 18 years of age **AND**
3.Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma **AND** one of the following:

a. Disease progression during or following platinum-containing chemotherapy **OR**
b. Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy **AND**

4.Medical record documentation that Opdivo is NOT being used in combination with any other agents

**Discussion**: No questions or comments.

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed.

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

**LATUDA** **Aubrielle Prater**
(lurasidone)

**Updated Indication:** Latuda is now indicated for the treatment of:

- Schizophrenia in adults and adolescents (13 to 17 years) and

- Depressive episodes associated with Bipolar I Disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

Note: Previously, Latuda was FDA-approved for the treatment of schizophrenia in adult patients.

**Recommendations:** No changes recommended.

**Discussion**: No questions or comments

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed.

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

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**TARCEVA** **Keith Hunsicker**
(erlotinib)

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**Updated Indication:** Tarceva is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. Tarceva is also indicated as first-line treatment of patients with locally advanced, unresectable, or metastatic pancreatic cancer in combination with gemcitabine. Limitation of use: Safety and efficacy of Tarceva have not been established in patient with NSCLC whose tumors have other EGFR mutations, and Tarceva is not recommended for use in combination with platinum-based chemotherapy.

**Recommendations:** It is recommended that the existing NSCLC prior authorization criteria are changed to the following:

**Non-Small Cell Lung Cancer**

- Must be prescribed by a hematologist/oncologist **AND**
- Medical record documentation of metastatic non-small cell lung cancer **AND**
- Medical record documentation that Tarceva is being used as first line treatment OR maintenance treatment OR second line or greater treatment after progression on at least one prior chemotherapy regimen **AND**
- Medical record documentation of one of the following EGFR mutations as detected by an FDA approved test
    - Exon 19 deletion **OR**
    - Exon 21 (L858R) substitution

No changes are recommended to the existing Pancreatic Cancer prior authorization criteria or quantity limits. It is recommended that the authorization duration is increased to an initial approval of 12 months and subsequent approvals of 12 months.

**Discussion**: No questions or comments.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as amended. Todd Sponenberg seconded the motion. None were opposed.

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

**STRIBILD** **Aubrielle Prater**
(elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate)

**Updated Indication:** Stribild is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older weighing at least 35 kg who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Stribild. Note: Stribild was previously approved for adult patients only.

**Recommendations:** No changes are recommended.

**Discussion**: No comments or questions

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Kim Clark seconded the motion. None were opposed.

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

**POLICY UPDATES:**

**FORTEO** **Aubrielle Prater**

**Recommendation:** It is recommended that the criteria in the Forteo policies be updated for GHP Family to reflect the following changes:

- There is no medical record documentation of increased baseline risk of osteosarcoma [Paget's disease, open epiphyses (pediatric or young adult patients), prior radiation therapy involving the skeleton, unexplained elevations of alkaline phosphatase] **AND**
- **For women:**
    - There is medical record documentation of a diagnosis of osteoporosis **AND**
    - There is medical record documentation of postmenopausal status **AND**
    - There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonates **OR**
    - There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score –2.5 or below with documented risk factors)

**OR**

- **For men:**
    - There is medical record documentation of a diagnosis of osteoporosis **AND**
    - There is medical record documentation of an attempt of therapy with or contraindication to bisphosphonate therapy **OR**
    - There is medical record documentation of a previous osteoporotic fracture or high risk of fracture (T-score <-2.5).

Note: There are no changes to authorization duration and quantity limit recommended.

**Discussion**: No comments or questions.

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Kevin Szczecina seconded the motion. None were opposed

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

**POLICY UPDATES** **Kimberly Clark**

**Evzio**

Discussion: Recommend that Evzio policy is updated to require prior use of all formulary agents within the same therapeutic class prior to approval.

Existing Policy Criteria:

- Medical record documentation of a reason why the patients cannot use generic naloxone 1 mg/mL or 0.4 mg/mL syringes

Recommendation:

- Medical record documentation of a reason why the patients cannot use generic naloxone syringes **AND** Narcan Nasal Spray**

  No changes are recommended to other existing policy criteria.

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**Nuedexta**

Discussion: Recommend that policy is created to improve efficiency and ensure consistency between prior authorization reviewers.

Existing Policy Criteria: None available

Recommendation:

- Medical record documentation of a diagnosis of pseudobulbar affect (PBA)

  QUANTITY LIMIT: 2 capsules per day

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**Byetta**

Discussion: Recommend that Byetta policy is updated to require prior use of all formulary agents within the same therapeutic class prior to approval. Also, recommend addition of quantity limit based on Food and Drug Administration (FDA) approved maximum dosage per day.

Existing Policy Criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza*

Recommendation:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Victoza* **AND** Tanzeum*

No changes are recommended to other existing policy criteria.

QUANTITY LIMIT: 5 mcg pen (0.04 mL per day), 10 mcg pen (0.08 mL per day)

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**Binosto**

Discussion: Recommend that Binosto policy is updated to require prior use of all formulary agents within the same therapeutic class prior to approval.

Existing Policy Criteria:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to generic alternatives in tablet form: ibandronate **AND** alendronate

Recommendation:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to generic alternatives in tablet form: ibandronate **AND** alendronate **AND** risedronate

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**Tazorac Cream/Gel**

Discussion: Recommend that policy is updated to clarify the number of alternative therapies a member must attempt prior to approval of Tazorac and to updated policy to require failure on

Existing Policy Criteria:

- There is medical record documentation of a diagnosis of psoriasis or acne vulgaris and
- There is medical record documentation that Tazorac is being prescribed by a dermatologist, and
- There is medical record documentation of a contraindication to, intolerance to, or therapeutic failure on one formulary alternative for a diagnosis of psoriasis or three formulary alternatives for a diagnosis of acne vulgaris

Recommendation:

**Acne:**

- Medical record documentation of a diagnosis of acne, acne vulgaris, adult onset acne **AND**
- Medical record documentation that Tazorac is being prescribed by a dermatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to three formulary medications for the treatment of acne.

**Plaque psoriasis:**

- Medical record documentation of a diagnosis of plaque psoriasis **AND**
- Medical record documentation that Tazorac is being prescribed by a dermatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to one topical anti-psoriatic therapy **AND** at least 2 to 3 months of methotrexate or phototherapy

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**Amlodipine/Olmesartan**

Discussion: Recommend that amlodipine/olmesartan (generic Azor) policy is updated to require prior use of all formulary agents within the same therapeutic class prior to approval.

Existing Policy Criteria:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to amlodipine used in combination with losartan **AND** amlodipine used in combination with irbesartan

Recommendation:

- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to amlodipine used in combination with losartan **AND** amlodipine used in combination with irbesartan **AND** amlodipine used in combination with valsartan

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**ProAir/Proventil**

Discussion: Recommend that policy is created to improve efficiency and ensure consistency between prior authorization reviewers.

Existing Policy Criteria: None available.

Recommendation:

- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Ventolin HFA

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**Diclegis**

Discussion: Based on a high rate of approval (80.77% during 4$^{th}$ quarter, 2016), it is recommended that the prior authorization requirement for Diclegis is lifted as it is the only medication with Food and Drug Administration (FDA) approval for the treatment of nausea and vomiting of pregnancy.

Recommendation:

- Remove prior authorization requirement.
- QUANTITY LIMIT: 4 tablets per day, maximum 9 month supply per year

Outcome: Kevin Szczecina made a motion to accept the recommendations as amended. Keith Hunsicker seconded the motion. None were opposed.

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

**HEPATITIS C POLICY UPDATES** **Kristi Clarke**

**Recommendation:** It is recommended that the following changes be made to the respective Hepatitis C Policies:

**HCV Direct Acting Antivirals**

Remove:

~~Medical record documentation of no signs and symptoms of decompensated liver disease AND~~

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**Daklinza**

Update:

Medical record documentation of Genotype 3 and concurrent therapy with Sovaldi ~~**AND**~~**OR**
Medical record documentation of the member receiving an Food and Drug Administration (FDA) approved medication regimen that is inside the parameters of use approved by the FDA or supported in the widely used compendia available **AND**

Remove:

~~Medical record documentation of rationale for not using Sovaldi used in combination with peginterferon and ribavirin if clinically appropriate in those with genotype 3 cirrhosis (F4 Metavir score)~~

Add:

Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Eplusa, if appropriate

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**Sovaldi**

Update:

Medical record documentation of Genotype 3: Concurrent therapy with Daklinza if noncirrhotic or post liver transplant **OR**

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed

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

**QUANTITY LIMITS** **Kevin Szczecina**

**Recommendation:** It is recommended the following quantity limits be approved:

| Brand Name | Generic Name | Dosage | QL to be added |
|---|---|---|---|
| **NRTI** | | | |
| Lamivudine 100 mg tablet (HBV) | lamivudine | 100 mg daily (HBV) | 30/30 days |
| **Protease Inhibitor** | | | |
| Prezista 150 mg tablet | darunavir | Based on weight | 180/30 days |
| Prezista 75 mg tablet | darunavir | Based on weight | 60/30 days |
| **Entry Inhibitor** | | | |
| Selzentry 20 mg/mL | maraviroc | 300 mg BID (600 mg BID with potent CYP3A inducers | 1800 mL/30 days |

**Discussion**: No comments or questions.

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed

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

**PSORIATIC ARTHRITIS** **Kevin Szczecina**

**Recommendation:** Per UpToDate, in patients with axial symptoms that do not respond adequately to treatment with NSAIDs, such as those with prolonged morning stiffness and severe pain, interfering with function, a TNF inhibitor rather than a traditional nonbiologic DMARD is recommended. The choice of agent and dosing are the same as those used for peripheral arthritis. Members with moderate to severe peripheral psoriatic arthritis who are resistant to initial NSAID therapy alone are usually treated with a conventional disease-modifying antirheumatic drug (DMARD), such as methotrexate (MTX). It is recommended that the criteria in the policies for Enbrel and Humira be changed to (see underlined section):

1. Medical record documentation of a diagnosis of moderately to severely active psoriatic arthritis which must include the following:
   - Documentation of either active psoriatic lesions or a documented history of psoriasis **AND**
2. Must be prescribed by a rheumatologist or dermatologist **AND**
3. Member must be at least 18 years of age **AND**
4. For peripheral disease: Medical record documentation of intolerance to, contraindication to, or therapeutic failure on methotrexate **AND** an adequate trial of at least two (2) formulary NSAIDS **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy

**OR**

For axial disease: Medical record documentation of intolerance to, contraindication to, or therapeutic failure to an adequate trial of at least two (2) formulary NSAIDS **OR** medical record documentation of a therapeutic failure on or intolerance to prior biologic therapy **AND**

5. Medical record documentation that Humira is being dosed at a maximum of 40 mg every other week **OR** medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing that exceeds FDA approved labeling.

**Discussion**: No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed

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

## DIABETIC TESTING SUPPLIES — Kevin Szczecina

**Recommendation:**
In an effort to increase consistency while reviewing prior authorization requests for nonpreferred diabetes testing supplies for GHP Family members it is recommended the following criteria be approved:

**Diabetes Testing Supplies**

- Medical record documentation of Type I, Type II, or gestational diabetes **AND**
- Medical record documentation of a contraindication to, intolerance to, or therapeutic failure on a Lifescan product **OR**
- Medical record documentation of use of an insulin pump requiring a specific monitor brand **OR**
- Medical record documentation of the requirement of a feature not available from a Lifescan Product (i.e speech capability).

**Discussion**: No comments or questions.

**Outcome:** Kim Clark made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed

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

## NON-CALORIC ORAL DIETARY SUPPLEMENTS — Kevin Szczecina

**Recommendation:** In an effort to increase consistency while reviewing prior authorization requests for nonformulary oral dietary supplements for GHP Family members, it is recommended the following criteria be approved:

**Non-caloric Oral Dietary Supplments**

- Medical record documentation that the requested product is not meant to increase or replace caloric intake (ie. Enaure, Infamel [coverd as a DME benefit]) **AND**
- Medical record documentation of a description of the member's clinical condition that clearly outlines why the nutritional needs cannot be met through dietary modification **AND**

- The product must be labeled and used for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements to avert the development of serious physical or mental disabilities or to promote normal development or function **AND**
- For supplements that are outside the parameters of use approved by the FDA or accepted standards of care or current nationally recognized guidelines the provider must provide documentation as recognized in a national compendium **AND**
- Medical record documentation of a therapeutic failure on, intolerance to or contraindication to up to three formulary alternatives if available

**Discussion**: No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Keith Hunsicker seconded the motion. None were opposed

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

**GOLD CARD POLICY** **Jamie Dodson**

**Recommendation:** It is recommended the following policy be approved:

**PROCEDURE:**

**General Gold Card Criteria**

1. Prescriber must be a par provider or contracted with the GHP mental health network **AND**
2. Prescriber must be in the contracted network at least 6 months **AND**
3. Prescriber must agree in writing to the following:
    a. Follow plan approved prior authorization criteria **AND**
    b. Retrospective audits
        i. By signing an agreement, the prescriber agrees to send necessary medical record documentation within 5 business days of request from health plan **AND**
4. Prescriber must meet volume threshold **AND**
5. Prescriber must have a denial rate lower than the maximum denial rate threshold "Denial Threshold" (**AND**
6. There must be a corresponding medical claim, that is received by or submitted to GHP, to support prescription

**Specific Gold Card Criteria**

1. All General criteria must be met **AND**
2. Gold card status is drug specific and currently only applicable to the following drugs:
    a. GHP reserves the sole right to add or remove drugs from the list of drugs that can be Gold Carded.
    b. Formulary Suboxone and buprenorphine products ("Gold Carded Drugs")
        i. Volume threshold = minimum 26 requests, for a prescriber, over the past 6 months **AND**

ii. Denial Threshold = Prescriber has no greater than a 5% denial rate over the past 6 months

**Obtaining Gold Card Status**

1. GHP Pharmacy Department will conduct monthly data reviews to identify any prescriber that meets both the General and Specific Gold Card criteria and is not already established as a Gold Card prescriber.
    a. Prescribers that meet the criteria through reporting, will be notified via telephone as well as in writing.
        i. Prescribers are to sign and return the agreement within 7 business days.
    b. If approved as a Gold Card prescriber, the approval duration will be for 12 months from the date of approval. Eligibility after the initial 12-month period will be determined as specified in this Policy.
        i. Subsequent approvals will be determined through random chart audits that ensure the prescriber continues to follow the plan approved prior authorization criteria.
    c. Once the signed agreement is received by GHP the prescriber will be entered into the Gold Card prescribers SQL database.
        i. Table elements will include
            1. Prescriber NPI
            2. Prescriber Name
            3. Gold Carded Drug Group
            4. Gold Card Start Date
            5. Gold Card Review Date
                a. Calculated as 11 months from the start date
            6. Gold Card End Date
                a. Calculated as 12 months from the start date
            7. Audit Complete Date
            8. Audit Score
            9. Audit Outcome
2. A prescriber can send a letter of request to GHP Pharmacy Department, requesting to obtain Gold Card Status.
    a. GHP Pharmacy Department will run a report for the requesting prescriber to determine if the eligibility criteria is met.
    b. The prescriber will be notified of the decision verbally within 3 business days of the receipt of the request and in writing within 7 business days of receipt of the request.
        i. If the prescriber is approved for the Gold Card, then the written notification will contain the required agreement to be signed and returned.
        ii. If the prescriber is not approved for the Gold Card, then the written notification will contain specific language as to why they were denied.

**Random Chart Audits Process**

1. Prior to the Gold Card expiration, a random chart audit, for each Gold Card prescriber, will be done to ensure the prescriber is still meeting GHP's prior authorization criteria.
    a. GHP Pharmacy Department will pull 10 random members that have been obtaining Gold Carded Drugs from a Gold Carded Prescriber within the approval period.
    b. GHP will notify the prescriber verbally, and in writing, with the charts that are needed for review.
        i. If the charts are not received within 5 business from the request the prescribers Gold Card status will be rescinded and the provider will not be eligible for the Gold Card program for 12 months from the date the rescinding notification is sent.
            1. After the 12 months have expired, the prescriber will be eligible to request Gold Card status and go through the process to obtain Gold Card status again.
        ii. If the charts are received within 5 business days then the audit will be conducted by a GHP Pharmacist.
    c. The audit score must be at least 90% (9 out of 10 charts must meet all current clinical criteria) to maintain the Gold Card status.
    d. The prescriber will be notified verbally, and in writing, of the outcome of the audit.
        i. If approved, the prescriber will need to sign and send in an updated agreement.
            1. Once the signed agreement is received, the prescriber will be entered into the Gold Card prescribers database with the new start date.
        ii. If denied
            1. The prescriber will be notified of the exact reason for denial.
            2. The prescriber's Gold Card status will be rescinded and the provider will not be eligible for the Gold Card program for 12 months
                a. After the 12 months have expired, the prescriber will be eligible to request Gold Card status and go through the process to obtain Gold Card status again.

2. Audit details will be captured in the Gold Card prescribers Audit Excel file
    a. Details to include
        i. Member Number
        ii. Member Name
        iii. Prescriber NPI
        iv. Prescriber Name
        v. Date of the audit
        vi. Result
            1. 1 = Pass
            2. 0 = Fail
        vii. Notes regarding the findings
    b. The overall score for a prescriber will be calculated to determine the audit outcome (Pass or Fail).
3. The Audit Complete Date, Audit Score, and Audit Outcome (Pass or Fail) will be entered into the Gold Card prescribers database.

***Geisinger Health Plan reserves the right to revoke a prescriber's Gold Card status at any time for any reason, including but not limited to, A Fraud Waste or Abuse finding or investigation, Clinical outcome concerns, or Service and/or Care Complaints or Grievances against a prescriber.***

**Discussion**: No comments or questions.

**Outcome:** Kevin Szczecina made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed

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

**FORMULARY UPDATES** **Kevin Szczecina**

**Recommendation:** In an effort to increase member satisfaction and decrease prior authorization volume the following changes are recommended:

| Medication | Proposed Change |
|---|---|
| Drysol (aluminum chloride) | Add to formulary on Generic Tier |
| L-methylfolate 7.5 mg, 15 mg tablet | Add to formulary on Generic Tier, QL of 1/day |
| Dutasteride 0.5 mg capsule | Add to formulary on Generic Tier |
| Colchicine 0.6 mg tablet | Add to formulary on Generic Tier, QL of 3/day |

**Discussion**: No comments or questions.

**Outcome:** Todd Sponenberg made a motion to accept the recommendations as written. Aubrielle Prater seconded the motion. None were opposed

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

Meeting adjourned at 4:35 pm.

**Future Scheduled Meetings**
May 16, 2017 at 1:00 HCN3A & 3B Conference room

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.