Gateway Health
Prior Authorization Criteria

**IVIG and SCIG therapies**

All requests for IVIG and SCIG therapies require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

**IVIG and SCIG therapies Prior Authorization Criteria:**

- Coverage may be provided when the indications and dosing are within the FDA-labeled prescribing information recommendations. Please refer to the drug-specific FDA-approved prescribing information for updated IVIG and SCIG indications and dosing recommendations.
- The following IVIG and SCIG are considered medically necessary when the member meets the following criteria below:
  - **IVIG: 5%**
    - Flebogamma DIF
    - Gammagard S/D
    - Gammaplex
    - Octagam
  - **SCIG:**
    - Cuvitru
    - Gammagard Liquid
    - Gammaked
    - Gamunex-C
    - Hizentra
    - Hyqvia
  - **IVIG: 10%**
    - Bivigam NF
    - Flebogamma DIF
    - Gammagard Liquid
    - Gammaked
    - Gammaplex
    - Gamunex-C
    - Octagam
    - Privigen
  - **IVIG:**
    - Carimune NF

1. **Primary immunodeficiency** (e.g., Congenital agammaglobulinemia, common variable immunodeficiency, hypogammaglobulinemia, Wiskott-Aldrich Syndrome, X-linked agammaglobulinemia, severe combined immunodeficiencies) when the ALL of the following criteria are met:
   - **Adults and pediatrics: All IVIG and SCIG therapies except Octagam 10% (IV)**
   - **Adults only: Hyqvia (SC) and Gammaplex 10% (IV)**
     - Laboratory reports demonstrate IgG level of < 400 mg/dL OR reports demonstrate a lack of ability to produce an antibody response to a protein antigen (e.g., tetanus) or one of the polysaccharide antigens (e.g., pneumococcal polysaccharide or H. Influenza type B)
     - If a member has recurrent bacterial infection and normal IgG levels, a lack of antibody response will be considered adequate to support the diagnosis
     - The member continues to have unexplained recurrent or persistent severe or opportunistic bacterial infections despite adequate treatment
     - Aggressive management of other conditions predisposing to recurrent sinopulmonary infections has been used
     - Increased vigilance has been applied and appropriate antibiotic therapy prescribed for infections
     - Member has had two or more infections per year due to persistent and significant reduction in total IgG or IgG subclasses
2. **Idiopathic thrombocytopenic purpura (ITP) in adults** when the ALL of the following criteria are met:
   - *Carimune NF (IV): Acute and chronic ITP*
   - *Flebogamma DIF 10% (IV): Chronic ITP*
   - *Gammagard S/D 5% (IV): Chronic ITP*
   - *Gammaked 10% (IV): Acute and chronic ITP*
   - *Gammaphor 10% (IV): Chronic ITP*
   - *Gammaphor 5% (IV): Chronic ITP*
   - *Gamunex-C 10% (IV): Acute and chronic ITP*
   - *Octagam 10% (IV): Chronic ITP*
   - **Privigen 10% (IV): Chronic ITP**
     - Other causes of thrombocytopenia have been ruled out by history and peripheral smear
     - Member is unresponsive to corticosteroid therapy
     - Platelet count is < 30,000/mcL with or without active bleeding OR
     - IVIG is being administered to defer or avoid splenectomy
     - Benefit is approved based on the classification of the condition:
       - **Acute ITP:** Benefit approved for five days
       - **Chronic ITP:**
         - Initial: Benefit approved for a maximum of five days
         - Maintenance: Benefit approved for one month and may be reauthorized when platelet counts remain < 30,000/mcL
     - A response to therapy is defined as a platelet count > 30,000/mcL and doubling of the baseline count; a complete response is defined as a platelet count ≥ 100,000/mcL; immune globulin will not be reauthorized in situations where the platelet count is ≥ 100,000/mcL

3. **ITP in pediatrics** when ALL of the following criteria are met:
   - *Carimune NF (IV): Acute and chronic ITP*
   - *Flebogamma DIF 10% (IV): Chronic ITP*
   - *Gammaked 10% (IV): Acute and chronic ITP*
   - *Gammaphor 5% (IV): Chronic ITP*
   - *Gamunex-C 10% (IV): Acute and chronic ITP*
   - **Privigen 10% (IV): Chronic ITP**
     - Initial therapy if platelet count < 30,000/mcL when member has emergency bleeding or is at risk for severe life-threatening bleeding OR
     - Members with severe thrombocytopenia (platelet counts < 20,000/mcL) considered to be at risk for intra-cerebral hemorrhage
     - Benefit approved for five days

4. **Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric members** when the ALL of the following criteria are met:
   - *Gammagard S/D 5% (IV)*
     - Member must be receiving concurrent high-dose aspirin therapy
     - Benefit approved for two weeks and is renewable with documentation that treatment with the first infusion failed
5. **Chronic inflammatory demyelinating polyneuritis (CIDP)** when ALL of the following criteria are met:
   - *Gammaked 10% (IV)*
   - *Gamunex-C 10% (IV)*
     - Member is experiencing symptomatic polyradiculoneuropathy in more than one limb
     - Member has had a progressive or relapsing course over at least two months
     - Member is experiencing at least three of the following and documentation is provided to support one:
       - Partial conduction block of ≥ one motor nerve
       - Reduced conduction velocity of ≥ two motor nerves
       - Prolonged distal latency of ≥ two motor nerves
       - Prolonged F wave latencies of ≥ two motor nerves or absence of F waves
     - Benefit approved for three months

6. **Maintenance therapy to improve muscle strength and disability in adult members with multifocal motor neuropathy (MMN)** when ALL the following criteria are met:
   - *Gammagard Liquid 10% (IV)*
     - Member has progressive, symptomatic MMN (as characterized by limb weakness or motor involvement having a motor nerve distribution in at least two nerves)
     - Electrophysiological findings rule out other possible conditions that may not respond to IVIG
     - Benefit approved for three months

7. **Prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL)** when ALL of the following criteria are met:
   - *Gammagard S/D 5% (IV)*
     - Member has recurrent bacterial infections
     - Member has pretreatment serum IgG < 600 mg/dL OR
     - Member has evidence of specific antibody deficiency
     - Benefit approved for three months and is renewable upon progression of disease

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria, when, in their professional judgment, the requested medication is medically necessary