



## Prior Authorization Approval Criteria

### Intravenous immunoglobulin and subcutaneous immunoglobulin

**Generic name:** Intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG)

**Brand name:** Refer to table below for IVIG, Vivaglobulin® (SCIG) and Hizentra 20% (SCIG)

**Medication class:** Immune globulin

**FDA approved uses:**

- SCIG: treatment of primary immune deficiencies
- IVIG: please refer to the table below

(IVIG: By brand name and indications)

PID	ITP	BMT	CLL	KD	Pediatric HIV
Carimune NF Flebogamma 5% Gamimune N 10% Gammagard S/D Gammar –P IV Gamunex Iveegam EN Octagam 5% Panglobulin NF Polygam S/D	Carimune NF Gamimune N 10% Gammagard S/D Gamunex Panglobulin NF Polygam S/D	Gamimune N 10%	Gammagard S/D Polygam S/D	Gammagard S/D Iveegam EN Polygam S/D	Gamimune N 10%

PID: primary immune deficiencies

- congenital agammaglobulinemia (X-linked agammaglobulinemia)
- hypogammaglobulinemia
- common variable immunodeficiency\* (please see criteria for use in CVID following this section)
- X-linked immunodeficiency with hyperimmunoglobulin M
- severe combined immunodeficiency
- Wiskott-Aldrich syndrome

ITP: idiopathic thrombocytopenic purpura

BMT: bone marrow transplant

CLL: chronic lymphocytic leukemia

KD: Kawasaki disease

Pediatric HIV: Pediatrics infected with HIV/AIDs, treatment or prevention.

**Off-label uses:**

Blood diseases:

- multiple myeloma and immunoproliferative neoplasms
- agranulocytosis
- autoimmune hemolytic anemia
- Post-transfusion purpura
- Neonatal alloimmune thrombocytopenia

Infectious diseases:

- Solid organ transplant recipients at risk for CMV and pneumonia.
- Parvovirus B19 infection chronic with severe anemia.

Neurologic diseases:

- Guillain Barre Syndrome (400mg/kg/day x 5 days)
- Chronic severe myasthenia gravis (400mg/kg/day ax 5 days)
- hereditary and idiopathic peripheral neuropathy
- idiopathic progressive polyneuropathy
- chronic inflammatory demyelinating polyneuropathy (CIDP)

- multifocal motor neuropathy
- polymyositis
- Moersch-Woitmann syndrome (stiff man syndrome)
- Multiple sclerosis, relapsing remitting, when other therapies are insufficient.

Other:

- Hyper IGE syndrome
- dermatomyositis 2gm/kg/month x 3 months, then must re-assess
- autoimmune mucocutaneous blistering diseases; biopsy proven pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid and epidermolysis bullosa acquisita for patients who have failed conventional therapies or in whom conventional therapies are contraindicated, or in whom conventional therapies would not work fast enough.

**Available dosage forms:** Injection, solution and powder for reconstitution

**Usual dose:**

**SCIG:** Children  $\geq 2$  years and adults: 100-200 mg/kg subcutaneously weekly

- max rate: 20 mL/hour
- doses  $>15$  mL should be divided between sites
- *Treatment may be transitioned to the home/home care setting in the absence of adverse reactions*

**IVIG:** To be infused intravenously over 2-24 hours

- **Pediatric HIV:** 400 mg/kg every 28 days
- **PID:** 200-400 mg/kg every 4 weeks or as per monitored serum IgG concentrations
  - Gammagard® Liquid, Gamunex®, Octagam®: 300-600 mg/kg every 3-4 weeks
- **CLL:** 400 mg/kg/dose every 3 weeks
- **ITP:** Acute: 400 mg/kg/day for 5 days or 1000 mg/kg/day for 1-2 days  
Chronic: 400 mg/kg as needed to maintain platelet count  $>30,000/\text{mm}^3$ ; may increase dose to 800 mg/kg (1000 mg/kg if needed)
- **KD:** Initiate within 10 days of onset: 2 g/kg as a single dose over 10 hrs, or 400 mg/kg/day for 4 days. **Note:** Used in combination with aspirin: 80-100 mg/kg/day in 4 divided doses for 14 days; when fever subsides, dose aspirin at 3-5 mg/kg once daily for  $\geq 6-8$  weeks
- **BMT:** 500 mg/kg beginning on days 7 and 2 pretransplant, then 500 mg/kg/week for 90 days post-transplant

Off-Label

- **Refractory Polymyositis:** 1 g/kg/day x 2 days every month x 4 doses
- **Refractory Dermatomyositis:** 2g/kg/dose every month x 3-4 doses
- **Autoimmune Hemolytic Anemia and Neutropenia:** 1000 mg/kg/dose for 2-3 days
- **Guillain-Barre Syndrome:** 400 mg/kg/day for 5 days
- **CIDP:** variable doses used
  - 400 mg/kg/day for 5 doses once each month
  - 800 mg/kg/day for 3 doses once each month
  - 1000 mg/kg/day for 2 days once each month
- **Myasthenia Gravis:** 2 g/kg divided over 2 days

**Approximate yearly cost**

(based on AWP 2007):

If treating PID: SCIG

\$23,548

IVIG

\$81,900

**Duration of therapy:** Up to 1 year

**Criteria for use:** (bullet points below are all inclusive unless otherwise noted)

- Clinically diagnosed with a medically accepted indication not otherwise excluded by Part D for which immunoglobulin has been shown to be effective.

**Cautions:**

- Anaphylactic reactions can occur, especially with IgA deficient patients

- Possibility of high risk of renal dysfunction: elderly, patients with renal disease, DM, volume depletion, sepsis, paraproteinemia
- Possibility transmission of infectious agents
- Patients should be appropriately hydrated prior to therapy

**Monitoring:** BUN, renal function, urine output, hemoglobin and hematocrit, infusion-related adverse reactions, anaphylaxis.

**Contraindications:** Hypersensitivity to immune globulin, selective IgA deficiency.

**Special considerations:**

- May impair responses to live virus vaccines; separate administration by at least 3 months
- *Subcutaneous weekly treatments provide more constant levels rather than the more pronounced peak and trough patterns observed with I.V. monthly immune globulin treatments*
- Conversion from I.V. to SubQ:
  - Multiply previous I.V. dose by 1.37
  - Divide into a weekly regimen by dividing by the previous I.V. dosing interval (eg, if the dosing interval was every 3 weeks, divide by 3)
  - Adjust the dose over time to achieve desired clinical response or target IgG levels
  - SubQ infusion administration should begin 1 week after the last I.V. dose

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_