

Medical Policy

Immune Globulins

Last review date: **1/1/2026**

Prior review date: **7/1/2025**

Applicable Products	
Alyglo (immune globulin intravenous, human-stwk)	Gammaked (immune globulin injection – human)
Asceniv (immune globulin intravenous, human – slra)	Gammaplex (immune globulin intravenous - human)
Bivigam (immune globulin intravenous - human)	Gamunex-C (immune globulin injection – human)
Cutaquig (immune globulin subcutaneous - human)	Hizentra (immune globulin subcutaneous - human)
Cuvitru (immune globulin subcutaneous - human)	HyQvia (immune globulin infusion – human)
Flebogamma (immune globulin intravenous - human)	Octagam (immune globulin intravenous - human)
Gamastan (immune globulin - human)	Panzyga (immune globulin intravenous, human - ifas)
Gammagard (immune globulin infusion – human)	Privigen (immune globulin intravenous - human)
Gammagard S/D (immune globulin intravenous - human)	Xembify (immune globulin subcutaneous, human – klhw)

Initial Approval Criteria

Coverage may be approved if all of the following are met:

- Drug specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Alyglo, Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma, Gammagard, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam, Privigen, Xembify

Patient has a diagnosis of one of the following:

- Primary immunodeficiency
 - Hypogammaglobulinemia, unspecified
 - Selective IgM immunodeficiency
 - Other selective immunoglobulin deficiencies
 - X-linked agammaglobulinemia
 - X-linked immunodeficiency with hyper IgM
 - Combined immunodeficiency (SCID)
 - Common variable immunodeficiency (CVID)

- Hypogammaglobulinemia
- Wiskott-Aldrich Syndrome; **OR**
- Secondary immunodeficiency
 - Solid organ transplant
 - Extensive surgery
 - Allograft rejection
 - Hematological malignancy
 - Extensive burns
 - Collagen-vascular disease
 - Chronic lymphoid leukemia (CLL); **OR**
- Hematologic condition
 - Primary thrombocytopenia
 - Idiopathic Thrombocytopenic Purpura (ITP)
 - ITP in pregnancy and fetal alloimmune thrombocytopenia
 - Neonatal alloimmune thrombocytopenia
 - Post-transfusion purpura
 - Autoimmune hemolytic anemia
 - Immune-mediated neutropenia
 - Anemia due to pure red cell aplasia secondary to chronic parvovirus b19 infection
 - Anemia due to pure red cell aplasia, immunologic subtype
 - Allogeneic bone marrow or stem cell transplant
 - Complications of transplanted solid organ (e.g. Heart, kidney, liver, lung, pancreas) or bone marrow transplant
 - Human immunodeficiency virus infection (HIV)

Gammagard, Gammaked, Gamunex-C, Hizentra, HyQvia, Panzyga, Privigen

Patient has a diagnosis of Chronic inflammatory demyelinating polyneuropathy (CIDP) and has all of the following:

- Progressive or relapsing motor and/or sensory dysfunction; **AND**
- Hyporeflexia or areflexia; **AND**
- Nerve conduction studies strongly supportive of demyelination

Gamastan

Must be used for ONE of the following:

- Prophylaxis of hepatitis A within two weeks of exposure to hepatitis A; **OR**
- Prevention or modification of measles (rubeola) in a susceptible person (non-vaccinated and no previous diagnosis of measles) exposed fewer than 6 days previously; **OR**
- Passive immunization against varicella in immunosuppressed members when promptly given when Varicella-Zoster Immune Globulin (Human) is unavailable; **OR**
- Reduction of infection and fetal damage due to rubella in early pregnancy in an exposed, susceptible woman who will not consider a therapeutic abortion

Renewal Criteria

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Patient has demonstrated clinical response; **AND**
- Absence of unacceptable toxicity

Length of Authorization

Gamastan – **1 month**

All others – **12 months**

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.