Immune Globulin Products

Generic Name: Immune Globulin Replacement Therapy (IVIG) IV/SQ/IM

Therapeutic Class or Brand Name: Asceniv®, Bivigam®, Carimune® NF, Cutaquig®, Cuvitru®, Flebogamma® DIF, GamaSTAN® S/D, Gammagard®, Gammagard® S/D, Gammaked™, Gammaplex®, Gamunex®-C, Hizentra®, HyQvia®, Octagam®, Panzyga®, Privigen®, and Xembify ®. Policy also applies to all other products not listed.

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 2/2/2023

FDA Approved Indication(s)

Brand Name	ROA*	PI*	ITP*	CIDP*	KS*	MMN*	CLL*	VPPX*	DM*
Asceniv®	IV	X							
Bivigam®	IV	X							
Carimune NF®	IV	X	X						
Cutaquig®	SC	X							
Cuvitru®	SC	X							
Flebogamma DIF®	IV	X	X (10% only)						
GamaSTAN S/D	IM							X	
Gammagard Liquid®	IV, SC	X				X (IV only)			
Gammagard S/D®	IV	X	X		X		X		
Gammaked®	IV, SC	X	X (IV only)	X (IV only)					
Gammaplex	IV	X	X						
Gamunex-C®	IV, SC	X	X (IV only)	X (IV only)					
Hizentra®	SC	X		X					
HyQvia®	SC	X							
Octagam®	IV	X (5% only)	X (10% only)						X (10% only)
Panzyga®	IV	X	X	X					
Privigen®	IV	X	X	X					
Xembify®	SC	X							

**ROA: route of administration; PI: primary humoral immunodeficiency; ITP: idiopathic thrombocytopenic purpura; CIDP: chronic inflammatory demyelinating polyneuropathy; KS: Kawasaki syndrome; MMN: multifocal motor neuropathy; CLL: B-cell chronic lymphocytic leukemia; VPPX: viral prophylaxis (for hepatitis A, measles, varicella, rubella); DM: adult dermatomyositis*

Off-Labeled Indications Include: Acquired hypogammaglobulinemia secondary to malignancy; Antibody-mediated rejection (AMR) in cardiac transplantation (treatment); Clostridioides (formerly Clostridium) difficile infection (severe, refractory, and recurrent); Dermatomyositis/polymyositis (refractory); Guillain-Barré syndrome; Hematopoietic cell transplantation with hypogammaglobulinemia (prevention of bacterial infection); HIV-associated thrombocytopenia; Lambert-Eaton myasthenic syndrome; Myasthenia gravis (acute exacerbation)

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criterion I-II are met):

1. Documented diagnosis of one of the following conditions A through G **AND** must meet criteria listed under applicable diagnosis:

A. Immunodeficiency (primary OR acquired) as defined in ONE of the following:

1. Primary Immunodeficiencies
   a) Agammaglobulinemia (X-linked, congenital)
   b) Common variable immunodeficiency (CVID)
   c) Hyper-IgM syndrome
   d) Specific antibody deficiency
      i. Normal IgG levels
      ii. Inadequate antibody response to polysaccharide vaccines (e.g. pneumococcal)
      iii. Recurrent bacterial infections within the past 12 months
   e) Selective immunodeficiency (e.g. selective IgA, IgM, or IgG subclass)
      i. Total or subclass (IgA, IgG, IgM) immune globulin level below normal
      ii. Inadequate antibody response to protein and/or polysaccharide vaccines (e.g. tetanus, pneumococcal)
      iii. Recurrent bacterial infections within the past 12 months
   f) Ataxia-telangiectasia
   g) Severe combined Immunodeficiency (SCID): adenosine deaminase (ADA), JAK3, X-SCID, RAG1/2, DiGeorge syndrome, Wiskott-Aldrich syndrome, Zeta-associated protein 70 (ZAP-70) deficiency
2. Prophylaxis for Human Immunodeficiency Virus (HIV) Infected Children (off-label)
   a) Hypogammaglobulinemia evidenced by serum IgG < 400 mg/dL
   b) Age < 13 years old
   c) Prescribed to prevent serious bacterial infections in a child with human immunodeficiency virus (HIV)

d) Prescribed by or in consultation with an infectious disease specialist

e) Dose does not exceed 400 mg/kg every 2 to 4 weeks OR dose is supported by practice guidelines

3. B-Cell Chronic Lymphocytic Leukemia Infection Prophylaxis
   a) Diagnosis of B-Cell CLL
   b) Prescribed to prevent bacterial infections
   c) Member must meet one of the following
      i. Hypogammaglobulinemia
      ii. Recurrent bacterial infections
   d) Prescribed by or in consultation with hematologist, oncologist, or immunologist
4. Multiple Myeloma Infections Prophylaxis (off-label)
   a) Diagnosis of multiple myeloma with stable disease
   b) Hypogammaglobulinemia
   c) Prescribed to prevent bacterial infections
   d) Prescribed by or in consultation with hematologist, oncologist, or immunologist
5. Post-Hematopoietic Cell Transplant Infection Prophylaxis (off-label)
   a) Prescribed to prevent bacterial infection in allogenic hematopoietic stem cell transplant (HSCT) recipients
   b) Severe hypogammaglobulinemia with serum IgG < 400 mg/dL
   c) Dose does not exceed 500 mg/kg weekly

B. Immune-mediated hematologic disorder as defined in ONE of the following:

1. Autoimmune Hemolytic Anemia (off-label)
   a) Inadequate response to alternative therapies (i.e. steroids, immunosuppressive agents, plasmapheresis, rituximab, and/or splenectomy)
   b) Dose does not exceed 1 gram/kg daily for up to 7 days
2. Fetal/Neonatal Alloimmune Thrombocytopenia (FAIT) (off-label)
   a) Diagnosis of fetal/neonatal alloimmune thrombocytopenia
   b) Dose does not exceed 2 gram/kg weekly
3. Idiopathic Thrombocytopenia (ITP)
   a) Diagnosis of acute or chronic ITP
      i. Acute ITP

(a) Rapid increase in platelet count is necessary – active bleeding or prior to invasive procedure (i.e. surgery, epidural anesthesia, etc.)

ii. Chronic ITP

(a) Low platelet count as defined by ONE of the following:

(i) Children: < 30,000 cells/mm^3

(ii) Adults: < 20,000 cells/mm^3

(iii) Adults with signs or symptoms of bleeding: < 30,000 cells/mm^3

b) ITP in pregnancy and at least ONE of the following is met:

i. Platelet counts < 10,000 cells/mm^3 in the third trimester, despite a trial of systemic corticosteroids unless contraindicated or not tolerated.

ii. Platelet counts < 30,000 cells/mm^3 that are associated with bleeding before vaginal delivery or Cesarean section (C-section).

4. Parvovirus B19 Infection and Severe Anemia (off-label)

a) Diagnosis of anemia secondary to chronic parvovirus B19 infection

b) Severe anemia defined as Hgb < 10 or Hct < 30.

C. Neuromuscular disorder as defined in ONE of the following:

1. Inflammatory Demyelinating Polyneuropathy (IDP)

a) Diagnosis of acute or chronic IDP [CIDP]

i. Acute IDP/Guillain-Barré Syndrome (GBS) and ONE of the following is met:

(a) Deteriorating pulmonary function tests (PFTs).

(b) Rapid deterioration with symptoms for < 2 weeks.

(c) Rapidly deteriorating ability to ambulate.

(d) Inability to walk independently for 10 meters (30 feet)

ii. Chronic IDP and ALL of criteria are met:

(a) Significant functional disability.

(b) Documentation of slowing of nerve conduction velocity on electromyography (EMG) or nerve conduction study (NCS)

(c) Documentation of elevated spinal fluid protein on lumbar puncture OR nerve biopsy confirming the diagnosis

b) Prescribed by or in consultation with a neurologist.

2. Dermatomyositis and Polymyositis (FDA approved Octagam® 10%, remainder off-label)

a) Diagnosis of dermatomyositis or polymyositis.

b) Failure of a course of systemic corticosteroid unless contraindicated or clinically significant adverse effects are experienced.

3. Myasthenia Gravis (MG)/Lambert Eaton Myasthenia Syndrome (LEMS) (off-label)
   a) Diagnosis of myasthenia gravis (MG) or Lambert Eaton Myasthenia Syndrome (LEMS).
   b) Member meets one of the following
      i. Acute crisis (i.e. respiratory failure, swallowing difficulties, inability to ambulate).
      ii. Failure of one of the following (pyridostigmine, azathioprine, cyclosporine, or systemic corticosteroid) unless contraindicated or experienced clinically significant adverse effects.
4. Multifocal Motor Neuropathy (MMN)
   a) Documented diagnosis of multifocal motor neuropathy.
   b) Dose does not exceed 2.4 gram/kg monthly.
5. Paraneoplastic Neurological Syndrome (off-label)
   a) Diagnosis of Opsoclonus-myoclonus ataxia syndrome [OMS] in pediatric neuroblastoma patients with significant functional impairment.
      i. Failure of an adequate course (at least 3 to 7 days) of systemic corticosteroids unless contraindicated or experienced clinically significant adverse effects.
   b) Diagnosis of Stiff-Person Syndrome
      i. Failure of one of the following (diazepam, baclofen, clonazepam, valproic acid, clonidine) unless contraindicated or experienced clinically significant adverse effects.
6. Pemphigoid-refractory Immunobullous Disease (off-label)
   a) Diagnosis of one of the following:
      i. Bullous Pemphigoid.
      ii. Mucous Membrane Pemphigoid.
      iii. Pemphigus Foliaceus.
      iv. Pemphigus Vulgaris.
   b) Failure of an adequate course of systemic corticosteroid OR immunosuppressant (azathioprine, mycophenolate, cyclophosphamide) unless contraindicated or experienced clinically significant adverse effects
7. Systemic Lupus Erythematosus (SLE) (off-label)
   a) Diagnosis of severe active systemic lupus erythematous.

b) Failure of an adequate course of systemic corticosteroid OR immunosuppressant (azathioprine, mycophenolate, cyclophosphamide) unless contraindicated or experienced clinically significant adverse effects.

D. Solid Organ Transplant (off-label)

1. Prescribed for the prevention or treatment of antibody-mediated rejection
   a) Prevention: Prior to solid organ transplant and in the perioperative period, for patients at high risk for AMR, including highly sensitized patients, and those receiving an ABO-incompatible organ.
   b) Treatment: Following solid organ transplant and confirmed antibody-mediated rejection by either biopsy or presence of panel reactive antibodies (PRAs).

E. Kawasaki Syndrome

1. Diagnosis of Kawasaki Syndrome.
2. Therapy is initiated within first 10 days of diagnosis.
3. Prescribed concurrently with aspirin therapy unless contraindicated or experienced clinically significant adverse effects.

F. Pediatric Intractable Epilepsy (off-label)

1. In candidates for surgical resection OR when other interventions (i.e. anticonvulsant medications, systemic corticosteroids, etc.) are ineffective or not tolerated

G. Viral Prophylaxis for Hepatitis A, Measles, Varicella, Rubella Viruses

1. Request is for intramuscular formulation (GammaSTAN S/D)
2. Request is for one of the following indications
   a) Hepatitis A
      i. Meets ONE of the following:
         (a) Exposure in the past 2 weeks AND does not have clinical manifestation of hepatitis A
         (b) At high risk for exposure – travel to areas where Hepatitis A is common
      ii. Hepatitis A vaccine is contraindicated or unavailable
   b) Measles
      i. Exposure within the past 6 days.
      ii. Has not had receiving measles vaccine.
      iii. Has not previously had measles.
      iv. Measles vaccines is contraindicated or unavailable.
   c) Varicella
      i. Lacks immunity to varicella

ii. Varicella-Zoster Immune Globulin is unavailable

iii. Varicella vaccine is contraindicated or unavailable

d) Rubella

i. Pregnant women

ii. Exposure to rubella

2. Prescribed by or in consultation with a specialist (hematologist, oncologist, neurologist, or immunologist)

EXCLUSION CRITERIA

Hypersensitivity to immune globulin or any component of the formulation; IgA deficiency (with anti-IgA antibodies and history of hypersensitivity [excluding Gammagard® S/D]);hyperprolinemia (Hizentra®, Privigen®); severe thrombocytopenia or coagulation disorders where IM injections are contraindicated (GamaSTAN® S/D); hypersensitivity to corn (Octagam 5%®); hereditary intolerance to fructose (Gammaplex 5%®); infants/neonates for whom sucrose or fructose tolerance has not been established (Gammaplex 5%®); hypersensitivity to hyaluronidase, human albumin, or any component of the hyaluronidase formulation (HyQvia®).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- When prior authorization is approved, immune globulins may be authorized for the dose as stated in product package insert although dosage is highly variable:

Medication	Indication	Dosing Regimen (Prescribing Information)
Asceniv®	PI	300 to 800 mg/kg IV every 3 to 4 weeks
Bivigam®	PI	300 to 800 mg/kg IV every 3 to 4 weeks
Carimune NF®	ITP	0.4 gram/kg IV daily consecutively on day 2 to 5
	PI	0.4 to 0.8 gram/kg IV every 3 to 4 weeks
Cutaquig®	PI	Switching from immunoglobulin IV: $\frac{\text{IGIV dose (grams)} \times 1.40}{\text{No. of weeks between doses}}$ = Initial weekly dose
Cuvitru®	PI	IV to SC: initial weekly dose= $\frac{\text{IGIV/HYQVIA dose (grams)} \times 1.30}{\text{No. of weeks between doses}}$
Flebogamma 5%	PI	300 to 600 mg/kg IV every 3 to 4 weeks
Flebogamma 10%®	PI	300 to 600 mg/kg IV every 3 to 4 weeks
	ITP	1 gram/kg IV daily for 2 consecutive days

GamaSTAN S/D®	Hepatitis A	Recent exposure: 0.1 mL/kg High risk for exposure: < 1 month: 0.1 mL/kg; 1 to 2 months: 0.2 mL/kg; >2 months: Repeat dose of 0.2 mL/kg every 2 months
	Measles	0.25 mL/kg IM once
	Rubella	0.55 mL/kg IM once
	Varicella	0.6 to 1.2 mL/kg IM once
Gammagard® Liquid	MMN	0.5 to 2.4 gram/kg IV monthly
	PI	Intravenous: 300 to 600 mg/kg every 3 to 4 weeks Subcutaneous: weekly dose= $\frac{\text{IGIV dose (grams) x 1.37}}{\text{No. of weeks between doses}}$
Gammagard S/D®	CLL	400 mg/kg IV every 3 to 4 weeks
	ITP	1 gram/kg IV, maximum 3 doses on alternate days
	KS	1 gram/kg once or 400 mg/kg daily for 4 consecutive days
	PI	300 to 600 mg/kg every 3 to 4 weeks
Gammaked®	CIDP	Loading dose: 2 gram/kg IV in divided doses over 2 to 4 consecutive days Maintenance dose: 1 gram/kg IV every 3 weeks
	ITP	1 gram/kg IV daily on 2 consecutive days OR 0.4 gram/kg IV daily on 5 consecutive days
	PI	Intravenous: 300 to 600 mg/kg every 3 to 4 weeks Subcutaneous: Weekly dose= $\frac{\text{IGIV dose (grams) x 1.37}}{\text{No. of weeks between doses}}$
Gammaplex®	ITP	1 gram/kg IV daily for 2 consecutive days
	PI	300 to 800 mg/kg IV every 3 to 4 weeks
Gamunex-C®	CIDP	2 gram/kg IV given in divided doses over 2 to 4 consecutive days
	ITP	1 gram/kg daily on 2 consecutive days OR 0.4 gram/kg IV daily on 5 consecutive days
	PI	Intravenous: 300 to o600 mg/kg every 3 to 4 weeks Subcutaneous: Weekly dose= $\frac{\text{IGIV dose (grams) x 1.37}}{\text{No. of weeks between doses}}$
Hizentra®	CIDP	0.2 to 0.4 gram/kg SC weekly
	PI	IV to SC: Weekly dose= $\frac{\text{IGIV dose (grams) x 1.37}}{\text{No. of weeks between doses}}$ Administer at regular interval from daily up to every 2 weeks
HyQvia®	PI	IG therapy naïve or switching from SC: 300 to 600 mg/kg every 3 to 4 weeks Switching from IGIV: same dose and frequency
Octagam 5%®	PI	300 to 600 mg/kg every 3 to 4 weeks
Octagam 10%®	ITP	1 gram/kg IV daily for 2 consecutive days

Octagam 10%®	DM	2 gram/kg divided in equal doses over 2-5 consecutive days every 4 weeks
Panzyga®	PI	300 to 600 mg/kg IV every 3 to 4 weeks
	ITP	1 gram/kg IV daily for 2 consecutive days
	CIDP	Loading dose: 1 gram/kg BID for 2 consecutive days Maintenance dose: 1-2 g/kg every 3 weeks divided in 2 doses given over 2 consecutive days
Privigen®	CIDP	Loading dose: 2 gram/kg IV in divided doses over 2 to 5 consecutive days Maintenance dose: 1 gram/kg IV every 3 weeks
	ITP	1 gram/kg IV for 2 consecutive days
	PI	200 to 800 mg/kg IV every 3 to 4 weeks
Xembify®	PI	IV to SC: Weekly dose= $\frac{\text{IGIV dose (grams)} \times 1.37}{\text{No. of weeks between doses}}$ OR previous SC weekly dose administered in regular intervals from daily up to every week

APPROVAL LENGTH

- **Authorization:** See table below
- **Re-Authorization:** Must submit an updated letter of medical necessity or progress notes showing the criteria for the applicable indication are met and that the medication is effective (i.e. disease stability, decrease in infections, improvement of functional impairment, etc.)

Indication	Approval Duration
Immunodeficiency	
Primary immunodeficiencies	12 months
Prophylaxis for HIV infected children	12 months
B-cell CLL infection prophylaxis	12 months
Multiple myeloma infection prophylaxis	12 months
Post-HSCT infection prophylaxis	12 months
Immune mediated hematologic disorders	
Autoimmune hemolytic anemia	6 months
Fetal/neonatal alloimmune thrombocytopenia	Weekly dose until delivery
Idiopathic thrombocytopenia (ITP) • Acute/chronic • Pregnancy	 6 months Monthly dose until delivery
Parvovirus B19 infection and severe anemia	6 months
Neuromuscular disorder	
Inflammatory demyelinating polyneuropathy (IDP) • Acute/GBS • Chronic	 3 months 6 months
Dermatomyositis and polymyositis	3 months

Myasthenia gravis/Lambert-Eaton myasthenic syndrome (LEMS)	6 months
Multifocal motor neuropathy (MMN)	6 months
Paraneoplastic neurologic syndrome • Opsoclonus-myoclonus ataxia • Stiff-Person Syndrome	 One dose (up to a 2-week window) Monthly dose for 3 months
Pemphigoid-refractory immunobullous disease	Monthly dose x 6 months
Systematic lupus erythematosus (SLE)	Monthly dose x 6 months
Solid Organ Transplant	
Prevention	3 months: up to 4 doses pre-transplant, then weekly dose for 4 weeks post-transplant (Not to exceed 8 total doses)
Treatment	One dose per rejection episode (up to a 2-week window)
Kawasaki Syndrome	One-time approval for up to a 2-week window
Pediatric intractable epilepsy	Monthly dose for 6 months
Viral prophylaxis	
Hepatitis A	6 months
Measles, Varicella, Rubella	One-time approval

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