Immune globulin, intravenous
IVIG

Asceniv™, Bivigam®, Cytogam®, Flebogamma DIF®, Gammagard® liquid, Gammagard S/D®, Gamunex-C®, Gammaked®, Gammaplex®, Octagam®, Panzyga®, Privigen®

Place of Service
Office Administration
Home Infusion Administration
Hospital Administration
Infusion Center Administration
Outpatient Facility Administration*
[*Prior authorization required – see section (1)]

HCPCS
Cytogam®: **J0850** per 50 ml vial (2500 mg)
Cytogam®: **90291** per dose
Privigen®: **J1459** per 500 mg
Asceniv™: **J1554** per 500 mg
Bivigam®: **J1556** per 500 mg
Gammaplex®: **J1557** per 500 mg
Gamunex-C®: **J1561** per 500 mg
Gammaked®: **J1561** per 500 mg
Gammagard® S/D: **J1566** per 500 mg
Immune globulin, IV, lyophilized (e.g., powder), NOS: **J1566** per 500 mg
Octagam®: **J1568** per 500 mg
Gammagard® liquid: **J1569** per 500 mg
Flebogamma DIF®: **J1572** per 500 mg
Panzyga®: **J1576** per 500 mg
Immune globulin, IV, non-lyophilized, NOS: **J1599** per 500 mg

Conditions listed in policy (*see criteria for details*)
- Autoimmune mucocutaneous blistering diseases (AMBDs)
- CAR-T induced hypogammaglobulinemia
- Chronic lymphocytic leukemia or small lymphocytic lymphoma
- Chronic inflammatory demyelinating polyneuropathy (CIDP) and variants
- Guillian-Barre syndrome
- Hematopoietic stem cell transplant (includes bone marrow transplantation)
- Hemolytic anemia – autoimmune
- HIV – pediatric
- Hypogammaglobulinemia associated with anti-CD20 monoclonal antibodies
- Immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy
- Kawasaki disease
- Multifocal motor neuropathy
- Multiple myeloma
- Myasthenia gravis
- Polymyositis and dermatomyositis
- Primary immunodeficiency disorders
- Primary immune thrombocytopenia (ITP)
- Solid organ transplants

AHFS therapeutic class: Serums

Mechanism of action: Immune globulin is a sterile, nonpyrogenic solution of globulins containing many antibodies normally present in adult human blood.

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF IVIG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. **Patient is initiating on IVIG or is being re-initiated on IVIG after at least 6 months off therapy.** *Subsequent doses after the first month will require medical necessity for continued use in the hospital outpatient facility site of care.*

2. **Patient is changing IVIG products.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

3. **Patient has experienced a previous severe adverse event to IVIG based on documentation submitted.**

4. **Patient continues to experience moderate to severe adverse events to IVIG based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

5. **Patient is clinically unstable based on documentation submitted.**

6. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for IVIG must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Autoimmune mucocutaneous blistering diseases (AMBDs)

1. Diagnosis of one of the following:
    a. pemphigus foliaceus
    b. pemphigus vulgaris
    c. bullous pemphigoid
    d. cicatricial pemphigoid
    e. epidermolysis bullosa acquisita

    AND
2. Diagnosis is confirmed by lesional tissue biopsy or serology, **AND**
3. Inadequate response to an immunosuppressant and a systemic corticosteroid, or contraindication or intolerance to immunosuppressants and systemic corticosteroids, **AND**
4. Not used in combination with another immunomodulator

Covered Doses
Up to 2 g/kg given intravenously over 3-5 days once monthly

Coverage Period
Initial:
Up to 6 months
First Reauthorization:
Cover for another 12 months if patient has had clinical response (i.e., a reduction in lesions and/or ability to reduce concomitant steroids or immunosuppressants.)
Subsequent authorizations:
Cover yearly based on continued response

ICD-10:
L10.0, L10.2, L12.0, L12.1, L13.8

Chimeric antigen receptor T-cell (CAR-T) therapy induced hypogammaglobulinemia

1. Diagnosis of CAR-T induced hypogammaglobulinemia, **AND**
2. Prescribed by an oncologist or immunologist

Covered Doses
Given intravenously. Dose is highly variable

Coverage Period
Yearly based upon continued response to treatment

ICD-10:
D80.1, D80.0-D83.9

Chronic lymphocytic leukemia or small lymphocytic lymphoma

1. History of hypogammaglobulinemia or recurrent bacterial infections

Covered Doses
Up to 400 mg/kg given intravenously as often as every 3 weeks, or up to 500 g/kg given intravenously every 4 weeks

Coverage Period
Indefinite

ICD-10:
C91.10, C91.12

Chronic inflammatory demyelinating polyneuropathy (CIDP) and variants

1. Diagnosis of one of the following:
    a. Typical chronic inflammatory demyelinating polyneuropathy (CIDP)
    b. Multifocal acquired demyelinating polyneuropathy
    c. Pure sensory chronic inflammatory demyelinating polyneuropathy
    d. Distal chronic inflammatory demyelinating polyneuropathy
    e. Focal chronic inflammatory demyelinating polyneuropathy
    f. Motor chronic inflammatory demyelinating polyneuropathy

    AND
2. Diagnosis by a neurologist, **AND**
3. Electrodiagnostic testing (nerve conduction studies) shows definite CIDP OR nerve conduction studies show possible CIDP AND 2 of the following to confirm the diagnosis: CSF examination, nerve biopsy, MRI, ultrasound, **AND**
4. Motor or sensory dysfunction of more than 1 limb developing over at least 2 months, **AND**
5. Absent or reduced tendon reflexes in affected limbs or gait ataxia

Covered Doses
Initial:

Up to 2 g/kg given intravenously by IV over up to a 5-day period
Maintenance:
Up to 2 g/kg given intravenously as often as every 2 weeks. For requests more frequent than every 2 weeks, total dose given over a two week period should not exceed 2 g/kg.

Coverage Period
Initial:
Up to 5 days depending on dose (See initial dosing)
Reauthorization:
As needed if patient continues to meet preservice criteria
Maintenance:
Cover yearly as long as patient continues to respond to treatment e.g. control of symptoms (e.g., weakness, sensory loss, imbalance, pain), and/or improvement or maintenance of functional ability.

ICD-10:
G61.81

Guillain-Barre syndrome

1. Diagnosis of Guillain-Barre, **AND**
2. Treatment with IVIG will begin within 4 weeks of onset of neuropathic symptoms

Covered Doses
Up to 400 mg/kg given intravenously daily for 5 days

Coverage Period
Initial: 5 days
Reauthorization: Retreatment with IVIG has not been studied for Guillain-Barre syndrome

ICD-10:
G61.0

Hematopoietic stem cell transplant (includes bone marrow transplantation)

1. Being used for prevention of bacterial infections among allogenic hematopoietic stem cell transpla (HSCT) recipients, **AND**
2. One of the following:
    a. Patient is within 100 days post-allogenic hematopoietic cell transplantation or planned allogenic hematopoietic cell transplantation within 7 days of the first dose, OR
    b. Patient has severe hypogammaglobulinemia (serum immunoglobulin G level less than 400 mg/dl), OR
    c. Patient has chronic GVHD on steroids or has chronic GVHD with pulmonary infection AND IgG level is below normal as defined by the testing laboratory, OR
    d. Patient has positive CMV serology

Covered Doses
Up to 500 mg/kg/week given intravenously. Increased doses or frequency are covered, as needed to maintain serum IgG levels > 400 mg/dL.

Coverage Period

- For patients within 100 days of HSCT, cover up to 100 days post HSCT
- For hypogammaglobulinemia, chronic GVHD, or positive CMV serology and meeting preservice criteria above, cover for 1 year or up to 24 months post-transplant (whichever is less).
- Reauthorization for patients who are less than 24 months post-transplant requires patient is responding to therapy.
- Reauthorization on a yearly basis for patients who are more than 24 months post-transplant requires documented current IgG level <400mg/dl OR patient has chronic GVHD with IgG level that is less than normal as defined by the testing laboratory.

CPT:
38240
ICD-10:
30233Y1

Hemolytic anemia - autoimmune

1. Diagnosis of warm-type autoimmune hemolytic anemia, **AND**
2. Patient has experienced an inadequate response to high dose steroids

Covered Doses
Up to 1 g/kg given intravenously per day for up to 7 days

Coverage Period
Initial: Up to 7 days
Reauthorization: The efficacy and safety of retreatment with IVIG has not been established.

ICD-10:
D59.1

HIV - pediatric

1. Age less than 13 years, **AND**
2. Symptomatic HIV or history of recurrent infections, **AND**
3. CD4+ count > 200/mm^3

Covered Doses
Up to 400 mg/kg given intravenously as often as every 4 weeks

Coverage Period
Indefinite

ICD-10:
B20

Hypogammaglobulinemia associated with anti-CD20 monoclonal antibodies

1. History of hypogammaglobulinemia or recurrent bacterial infections, **AND**
2. Patient has received treatment with an anti-CD20 monoclonal antibody (e.g., rituximab, Arzerra, Gazyva)

Covered Doses
Up to 400 mg/kg given intravenously as often as every 3 weeks, or up to 500 g/kg given intravenously every 4 weeks

Coverage Period
1 year

ICD-10:
D80.1

Immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy

1. Being treated with an immune-checkpoint inhibitor, **AND**
2. Treatment of the following immunotherapy-related toxicities secondary to immune-checkpoint inhibitor therapy:
    a. Severe pneumonitis refractory to methylprednisolone
    b. Severe myasthenia gravis
    c. Moderate or severe Guillain-Barré Syndrome or severe peripheral neuropathy in combination with pulse-dose methylprednisolone
    d. Encephalitis in combination with pulse-dose methylprednisolone
    e. Transverse myelitis
    f. Severe inflammatory arthritis refractory to high-dose corticosteroids
    g. Severe bullous dermatitis
    h. Stevens-Johnson syndrome or toxic epidermal necrolysis
    i. Severe myocarditis, pericarditis, arrhythmias, impaired ventricular function, or conduction abnormalities refractory to pulse-dose methylprednisolone
    j. Moderate or severe myalgias or myositis refractory to corticosteroids

Covered Doses
Up to 2 gm/kg total dose

Coverage Period:
Once per treatment course

ICD-10:
J70.2, J70.4, G70.00, G70.01, G61.0, G61.1, G61.81, G61.82, G61.89, G61.9, G03.8, G03.9, G04.81, G04.89, G04.90-G04.91, G56.80-G56.83, G56.90-G56.93, G57.80-G57.83, G57.90-G57.93, G90.09, I44.0, I44.1-I44.3, I44.30, I44.39, I47.0, I45.0, I45.10, I45.19, I45.2-I45.6, I45.81, I45.89, I45.9, I49.9, L13.8, L13.9, L51.1, L51.2, M06.4, M60.80, M60.811, M60.812, M60.819, M60.821, M60.822, M60.829, M60.831, M60.832, M60.839, M60.841, M60.842, M60.849, M60.851, M60.852, M60.859, M60.861, M60.862, M60.869, M60.871, M60.872, M60.879, M60.88, M60.89, M60.9, M79.1

Kawasaki disease

1. Patient is now on or will be on combination treatment with high dose aspirin (80-100 mg/kg day)

Covered Doses
Up to 2 g/kg given intravenously as a single dose
OR
Up to 400 mg/kg given intravenously once daily for 4 consecutive days

Coverage Period
Initial:

- If giving as a single dose, authorize for 2 doses (one initial and one for possible retreatment)
- If giving as a multiple dose regimen, authorize for 8 doses (4 initial and 4 for possible retreatment). Check dose to make sure only authorizing for 400 mg/kg once daily.

Reauthorization beyond the first retreatment: Subsequent retreatments after the first retreatment have not been evaluated for efficacy or safety.

ICD-10:
M30.3

Multifocal motor neuropathy

1. Diagnosis by a neurologist, confirmed by electrodiagnostic testing (nerve conduction studies), **AND**
2. Asymmetric weakness and/or atrophy without sensory dysfunction for at least one month

Covered Doses
Up to 2.4 gm/kg/month

Coverage Period
Yearly, based on continued response

ICD-10:
G61.82

Multiple myeloma

1. Greater than or equal to 2 significant infections within the last year or a single life-threatening infection

Covered Doses
Up to 500 mg/kg given intravenously every month

Coverage Period
Yearly

ICD-10:
C90.00-C90.02

Myasthenia gravis

1. Diagnosis of myasthenia gravis, **AND**
2. Prescribed by a neurologist, **AND**
3. Patient has experienced an inadequate response or has an intolerance or contraindication to at least one of the following: a corticosteroid, mycophenolate, azathioprine, cyclosporine, or cyclophosphamide

Covered Doses
Up to 2 g/kg given intravenously per month

Coverage Period
Initial: 3 months
Reauthorization: Yearly based upon continued response to treatment

ICD-10:
G70.00, G70.01

Polymyositis and dermatomyositis

1. Inadequate response to treatment with high dose corticosteroids (equivalent to prednisone 40-60 mg/d or highest tolerated dose), **AND**
2. Inadequate response, intolerable side effect, or contraindication to an immunosuppressant (i.e., azathioprine, methotrexate, tacrolimus, cyclosporin A, mycophenolate, cyclophosphamide)

Covered Doses
Up to 2 gm/kg total given intravenously each month

Coverage Period
Yearly based upon continued response to treatment

ICD-10:
M33.00- M33.02, M33.09-M33.12, M33.19, M33.90-M33.92, M33.99, M36.0
M33.20-M33.22, M33.29

Primary immunodeficiency disorders

1. Diagnosis of ONE of the following primary immunodeficiency disorders
    a. Common variable hypogammaglobulinemia
    b. Congenital agammaglobulinemia (e.g., X-linked agammaglobulinemia, BTK deficiency)
    c. Ectodermodysplasia with immunodeficiency (IKBKG: Inhibitor of kB kinase g chain, NEMO (nuclear factor kB essential modulator) deficiency, IKBA/IKBKB GOF mutation)
    d. Variable immunodeficiency with hyper-IgM (e.g., AID deficiency, UNG deficiency, INO90 deficiency, MSH6 deficiency)
    e. WHIM: Warts, hypogammaglobulinemia, immunodeficiency, myelokathexis
    f. Severe combined immunodeficiency (SCID)
    g. Wiskott-Aldrich Syndrome
    h. Combined immunodeficiency (CID) [e.g., IL21 deficiency, Wiskott-Aldrich Syndrome, WIP deficiency, Arp2/3-mediated filament branching defect, RIDDLE (Radiosensitivity, Immune Deficiency, Dysmorphic features, Learning difficulties) syndrome, ICF (immunodeficiency with centromeric instability and facial anomalies), FILS syndrome, Ligase I deficiency, MYSM1 deficiency, Roifman syndrome, Tricho-Hepato-Enteric Syndrome (THES), Wiedemann-Steiner syndrome]
    i. Di George's syndrome
    j. Hyper IgE syndrome (e.g., IL6 receptor deficiency)
    k. AIPS-Caspase 8
    l. CD70 deficiency, CD20 deficiency, SAP deficiency (XLP1), X-linked magnesium EBV and neoplasia (XMEN)
    m. P14/LAMTOR2 deficiency
    n. PLAID (PLCγ2 associated antibody deficiency and immune dysregulation)
    o. GOOD syndrome

AND

2. One of the following:
    a. IgG <200 mg/dL, OR
    b. All or the following:
        i. Member has a history of recurrent bacterial infections, AND
        ii. Inability to respond to IgG antibody production after antigenic challenge against diphtheria and tetanus toxoids or pneumococcal polysaccharide vaccine, AND
        iii. Decreased IgG concentrations (<500mg/dL or below normal as defined by testing laboratory) documented on two or more occasions OR diagnosed by an allergist or immunologist if IgG concentrations are not decreased (>500mg/d or normal as defined by the testing laboratory)

Covered Doses
200-800 mg/kg given intravenously no more often than every 3-4 weeks, and not to exceed 2 doses per month

Coverage Period
Yearly based upon continued response to treatment

ICD-10:
D80.0, D80.1, D80.3, D80.5, D80.6, D80.7, D81.0-D81.2, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.3, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9

Primary immune thrombocytopenia (ITP)

1. One of the following:
    a. Acute primary ITP and a rapid increase in platelets is required for surgery, invasive procedure, or acute bleeding episode, OR
    b. Chronic primary ITP and platelet count is less than 30 X 10^9/L (<30,000/mm^3)

Covered Doses and Coverage Period:
Acute ITP: Up to 2 g/kg given intravenously over 2-5 days for 5 doses total
Chronic ITP: Up to 2 g/kg IV dose per month for up to 12 doses over up to 12 months

Subsequent reauthorization for acute or chronic ITP requires the following:

- Patient had a prior response to IVIG, defined as platelet count >30 x 10^9/L, AND
- Either of the following: Patient has continued thrombocytopenia (defined as platelet count <30 x 10^9/L) or patient is scheduled for surgery or invasive procedure

ICD-10:
D69.3

Solid organ transplant

1. Documented solid organ transplant, including pre/perioperative prevention or for treatment of antibo mediated rejection of allograft

Covered Doses
Given intravenously. Dose is highly variable

Coverage Period
Initial: 16 weeks per treatment course

ICD-10:
Z94.0, Z94.1, Z94.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for IVIG (intravenous immune globulin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):
Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Alopecia universalis
- Aplasia – Pure red blood cell
- Asthma
- Atopic dermatitis
- Autoinflammatory syndrome
- Burn patients
- Chronic fatigue syndrome
- Chronic granulomatous disease (CGD)

- Clostridium difficile colitis in adults
- Complement deficiency
- Crohn's disease
- Cystic fibrosis
- Epidermodysplasia verruciformis (EV)
- Epstein-barr induced cerebellar ataxia
- Familial hemophagocytic lymphohistiocytosis (FHL)
- Gastroenteritis
- Hemolytic uremic syndrome
- Hemophagocytic syndrome
- Hemophilia
- Herpes simplex encephalitis (HSE)5
- HIV in Adults
- Hopkin's Syndrome
- Immunodeficiency, polyendocrinopathy, X-linked (IPEX)
- In vitro –fertilization (Adjunct)
- Isaac's syndrome
- Isolated IgG4 deficiency
- Juvenile rheumatoid arthritis
- Leukocyte adhesion deficiency (LAD)
- Lymphoproliferative disorder-post transplant
- Lysinuric protein intolerance
- Malaria
- Mendelian susceptibility to mycobacterial disease (MSMD)
- Multiple sclerosis
- Myocarditis
- Neonatal infection
- Nephropathy
- Ocular cicatricial pemphigoid
- Otitis media
- Paraneoplastic neurological syndrome
- Paraproteinaemic demyelinating neuropathy
- Recurrent spontaneous pregnancy loss
- Rheumatic fever-acute
- Rheumatoid arthritis
- RH immunizations
- Rotavirus infection
- Selective IgA deficiency
- Sepsis
- Stevens Johnson's syndrome
- Stiff man/person syndrome
- Still's Disease
- Systemic lupus erythematosus
- Systemic vasculitis
- Toxic epidermal necrolysis
- Thrombocytopenia – antenatal/neonatal
- Streptococcal toxic shock syndrome
- Urticaria delayed pressure

- Varicella Zoster exposure
- Vasculitis leukocyctoclastic
- Wegener's Granulomatosis

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

IVIG usual concentration: 5% = 5 gm/100ml, 10%= 10 gm/100ml, 20%, 20 gm/100ml

Asceniv™ (10%): 5 gm (single-use vial)
Bivigam® (10%): 5, 10 gm (single-use vial)
Cytogam®: 2500 mg/50 mL vials (single-use vial)
Flebogamma DIF® (5%): 0.5, 2.5, 5, 10, 20 gm (single-use vial)
Flebogamma DIF® (10%): 5, 10, 20 gm (single-use vial)
Gammagard® liquid (10%): 1, 2.5, 5, 10, 20, 30 gm (single-use bottle)
Gammagard S/D® (5%): 5, 10 gm (single-use bottle)
Gamunex-C® (10%): 1, 2.5, 5, 10, 20, 40 gm (single-use bottle)
Gammaked® (10%): 1, 2.5, 5, 10 ,20 gm (single-use bottle)
Gammaplex® (10%): 5, 10, 20 gm (single-use bottle)
Gammaplex® (5%): 5, 10, 20 gm (single-use bottle)
Octagam® (5%): 1, 2.5, 5, 10, 25 gm (single-use bottle)
Octagam® (10%): 2, 5, 10, 20 gm
Panzyga® (10%): 1, 2.5, 5, 10, 20, 30 gm (single-use bottle)
Privigen® (10%): 5, 10, 20, 40 gm (single-use vial)

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(7) Policy Update

Date of last revision: 2Q2024

Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following revision.