

intravenous immune globulin (IVIG)

Commercial Medical Benefit Drug Policy

For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).

For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

Alyglo 10%
Asceniv (10%)
Bivigam (10%)
Cytogam
Flebogamma DIF (5%)
Flebogamma DIF (10%)
Gammagard liquid (10%)
Gammagard S/D (5%)
Gamunex-C (10%)
Gammaked (10%)
Gammaplex (10%)
Gammaplex (5%)
Octagam (5%)
Octagam (10%)
Panzyga (10%)
Privigen (10%)
Qivigy (10%)
Yimmugo (10%)

Place of Service

Home Infusion Administration
Hospital Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Gammagard Liquid and Octagam will be the preferred IVIG products. Request for all other IVIG products for members newly initiating IVIG therapy will require treatment failure or intolerance to all the preferred drugs or contraindication to all the preferred drugs for certain indications.

Drug Details

USP Category: IMMUNOLOGICAL AGENTS

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

HCPCS:

J0850:Injection, cytomegalovirus immune globulin intravenous (human), per vial

J1459:Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg

J1552:Injection, immune globulin (alyglo), 500 mg

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J1553:Injection, immune globulin (yimmugo), 100 mg
 J1554:Injection, immune globulin (asceniv), 500 mg
 J1556:Injection, immune globulin (bivigam), 500 mg
 J1557:Injection, immune globulin, (gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
 J1561:Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
 J1566:Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
 J1568:Injection, immune globulin, (octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
 J1569:Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
 J1572:Injection, immune globulin, (flebogamma/flebogamma dif), intravenous, non-lyophilized (e.g., liquid), 500 mg
 J1576:Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
 J1599:Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified, 500 mg
 J3590: Qivigy (use as temporary code):

How Supplied:

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

Alyglo 10%: 5, 10, 20 gm (single-use vial)
 Asceniv (10%): 5 gm (single-use vial)
 Bivigam (10%): 5, 10 gm (single-use vial)
 Cytogam: 2500 mg/50 mL vials (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)
 Qivigy (10%): 5, 10 gm (single-use vial)
 Yimmugo (10%): 5, 10, 20 gm (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Autoimmune Mucocutaneous Blistering Diseases (AMBDs)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Variants
- Guillain-Barre Syndrome
- Hematopoietic Stem Cell Transplant (Includes Bone Marrow Transplantation)
- Hemolytic Anemia - Autoimmune
- Kawasaki Disease
- Multifocal Motor Neuropathy (MMN)
- Myasthenia Gravis
- PANDAS / PANS
- Polymyositis and Dermatomyositis

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- Prevention of Bacterial Infection in HIV-Pediatric
- Primary Immune Thrombocytopenia (ITP)
- Primary Immunodeficiency Disorders
- Solid Organ Transplant

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) 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.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

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

1. Patient is starting new therapy with this drug (allowed for the first month). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for the first month). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
 - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.

- b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
- c. Patient is clinically unstable based on documentation submitted.
- d. Patient is physically or cognitively unstable based on documentation submitted

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Autoimmune Mucocutaneous Blistering Diseases (AMBDs)

Meets medical necessity if all the following are met:

Initial

1. Diagnosis of ONE of the following:
 - a. pemphigus foliaceus
 - b. pemphigus vulgaris
 - c. bullous pemphigoid
 - d. cicatricial pemphigoid
 - e. epidermolysis bullosa acquisita
2. Diagnosis is confirmed by lesional tissue biopsy or serology
3. Inadequate response to an immunosuppressant and a systemic corticosteroid, or contraindication or intolerance to immunosuppressants and systemic corticosteroids
4. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Reauthorization

1. Patient is responding to therapy (i.e., a reduction in lesions and/or ability to reduce concomitant steroids or immunosuppressants.)

Covered Doses:

Up to 2 g/kg given intravenously over 3-5 days per month

Coverage Period:

intravenous immune globulin (IVIg)

Initial: 6 months

Reauthorization: 1 year

ICD-10:

L10.0, L10.2, L12.0, L12.1, L13.8

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Variants

Meets medical necessity if all the following are met:

Initial

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
2. Diagnosis by a neurologist
3. Meets ONE of the following:
 - a. Electrodiagnostic testing (nerve conduction studies) shows definite CIDP
 - b. Nerve conduction studies show possible CIDP AND 2 of the following to confirm the diagnosis: CSF examination, nerve biopsy, MRI, ultrasound
4. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Reauthorization

1. Patient is responding to therapy [i.e. control of symptoms (e.g., weakness, sensory loss, imbalance, pain)], improvement or maintenance of functional ability]

Covered Doses:

Initial: Not to exceed 2 g/kg given intravenously over up to a 5-day period

Reauthorization: Not to exceed 2 g/kg given intravenously over 2 weeks

Coverage Period:

Initial: Up to 5 days

Reauthorization: 1 year

ICD-10:

G61.81

Guillain-Barre Syndrome

Meets medical necessity if all the following are met:

1. Treatment with IVIG will begin within 4 weeks of onset of neuropathic symptoms

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2. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 400 mg/kg given intravenously daily for 5 days

Coverage Period:

5 days

Retreatment with IVIG has not been studied for Guillain-Barre syndrome

ICD-10:

G61.0

Hematopoietic Stem Cell Transplant (Includes Bone Marrow Transplantation)

Meets medical necessity if all the following are met:

Initial

1. Being used for prevention of bacterial infections among allogenic hematopoietic stem cell transplant (HSCT) recipients
2. Meets 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
 - b. Patient has severe hypogammaglobulinemia (serum immunoglobulin G level less than 400 mg/dl)
 - 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
 - d. Patient has positive CMV serology
3. **Effective 6/1/2026:** Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Reauthorization

1. Meets one of the following:
 - a. Patient is less than 24 months post-transplant and is responding to therapy
 - b. Patients is more than 24 months post-transplant and meets one of the following:
 1. Current IgG level of less than 400 mg/dl
 2. Patient has chronic GVHD with IgG level that is less than normal as defined by the testing laboratory

Covered Doses:

Initial: Not to exceed 500 mg/kg given intravenously weekly

Increased doses or frequency are covered, as needed to maintain serum IgG levels > 400 mg/dL.

Coverage Period:

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Initial

- For patients within 100 days of HSCT: Cover up to 100 days post HSCT
- For hypogammaglobulinemia, chronic GVHD, or positive CMV serology: 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: Cover for remaining time that adds up to 24 months total
- For patients who are more than 24 months post-transplant: 1 year

ICD-10:

Z52.011, Z52.091, Z94.81, Z94.84

Hemolytic Anemia - Autoimmune

Meets medical necessity if all the following are met:

1. Diagnosis of warm-type autoimmune hemolytic anemia
2. Patient has experienced an inadequate response to high dose steroids
3. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

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

Coverage Period:

Up to 7 days

The efficacy and safety of retreatment with IVIG has not been established.

ICD-10:

D59.11

Kawasaki Disease

Meets medical necessity if all the following are met:

1. Patient is now on or will be on combination treatment with high dose aspirin (80-100 mg/kg per day)
2. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 2 g/kg given intravenously as a single dose per treatment course for 2 treatment courses

OR

Not to exceed 400 mg/kg given intravenously once daily for 4 consecutive days per treatment course for 2 treatment courses

Coverage Period:

One time

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Reauthorization beyond the first retreatment have not been evaluated for efficacy or safety.

ICD-10:

M30.3

Multifocal Motor Neuropathy (MMN)

Meets medical necessity if all the following are met:

1. Diagnosis by a neurologist, confirmed by electrodiagnostic testing (nerve conduction studies)
2. Asymmetric weakness and/or atrophy without sensory dysfunction for at least one month
3. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 2.4 gm/kg given intravenously every 4 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

G61.82

Myasthenia Gravis

Meets medical necessity if all the following are met:

1. Prescribed by a neurologist
2. 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
3. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 2 g/kg given intravenously per month

Coverage Period:

Initial: 3 months

Reauthorization: Yearly, based on continued response to therapy

ICD-10:

G70.00, G70.01

PANDAS / PANS

Meets medical necessity if all the following are met:

1. Moderate-to-severe disease (e.g., symptoms interfere with daily activities, occupying 50%-70% of waking hours)
2. Patient has a history of antibiotic use or is currently taking prophylactic antibiotics
3. Inadequate response, intolerable side effect, or contraindication to glucocorticoids or NSAIDS

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4. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 2 gm/kg total given intravenously monthly

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

D89.89, D89.9, G04.81

Polymyositis and Dermatomyositis

Meets medical necessity if all the following are met:

1. Inadequate response to treatment with high dose corticosteroids (equivalent to prednisone 40-60 mg/d or highest tolerated dose)
2. Inadequate response, intolerable side effect, or contraindication to an immunosuppressant (i.e., azathioprine, methotrexate, tacrolimus, cyclosporin A, mycophenolate, cyclophosphamide)
3. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 2 gm/kg total given intravenously each month

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

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

Prevention of Bacterial Infection in HIV-Pediatric

Meets medical necessity if all the following are met:

1. Age is less than 13 years
2. Symptomatic HIV or history of recurrent infections
3. IgG is less than 400 mg/dL
4. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Not to exceed 400 mg/kg given intravenously every 4 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

B20

Primary Immune Thrombocytopenia (ITP)

Meets medical necessity if all the following are met:

Initial

1. Meets ONE of the following:
 - a. Acute primary ITP and a rapid increase in platelets is required for surgery, invasive procedure, or acute bleeding episode
 - b. Chronic primary ITP and platelet count is less than $30 \times 10^9/L$ ($<30,000/mm^3$)
2. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Reauthorization

1. Meets ALL of the following:
 - a. Patient had a prior response to IVIG, defined as platelet count of greater than $30 \times 10^9/L$
 - b. Meets one of the following:
 1. Patient has continued thrombocytopenia (defined as platelet count of less than $30 \times 10^9/L$)
 2. Patient is scheduled for surgery or invasive procedure

Covered Doses:

Acute ITP: Up to 2 g/kg given intravenously over 2-5 days for 5 doses total

Chronic ITP: Up to 2 g/kg given intravenously per month for up to 12 doses

Coverage Period:

Acute ITP: 1 time

Chronic ITP: 1 year

ICD-10:

D69.3

Primary Immunodeficiency Disorders

Meets medical necessity if all the following are met:

1. Meets ONE of the following (a) or (b):
 - a. Diagnosis of primary immunodeficiency (There are over 500 Primary immunodeficiency diseases which can be found at the Immune Deficiency Foundation website) and meets ONE of the following:
 - i. IgG <200 mg/dL
 - ii. Meets ALL of the following:
 1. Member has a history of recurrent bacterial infections
 2. Inability to respond to IgG antibody production after antigenic challenge against diphtheria and tetanus toxoids or pneumococcal polysaccharide vaccine
 3. Decreased IgG concentrations (<500 mg/dL or below normal as defined by testing laboratory) documented on two or more occasions OR diagnosed by an allergist or

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immunologist if IgG concentrations are not decreased (>500mg/d or normal as defined by the testing laboratory)

- b. Diagnosis of IgG Subclass Deficiency, and meets ALL of the following:
 - i. History of recurrent infections requiring antibiotic therapy
 - ii. Pre-treatment levels of one or more serum IgG subclasses are below the lower limit of the age-adjusted laboratory reference range
 - iii. Inability to respond to IgG antibody production after antigenic challenge against diphtheria and tetanus toxoids or pneumococcal polysaccharide
2. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Up to 800 mg/kg given intravenously every 3-4 weeks, and not to exceed 2 doses per month

Coverage Period:

Yearly, based on continued response to therapy

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

Solid Organ Transplant

Meets medical necessity if all the following are met:

1. Documented solid organ transplant (e.g., pre/perioperative prevention or for treatment of antibody-mediated rejection of allograft)
2. Request for a non-preferred product requires an inadequate response, intolerable side effect, or contraindication to two preferred products (e.g. Gammagard Liquid 10%, Octagam 5%, Octagam 10%)

Covered Doses:

Given intravenously. Dose is highly variable

Coverage Period:

16 weeks per treatment course

ICD-10:

Z94.0, Z94.1, Z94.4

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Review History

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- Added new IVIG product Qivigy (FDA approval 9/2025)
- Updated Yimmugo's HCPCS to J1553, effective 4/1/2026.
- Hematopoietic Stem Cell Transplant: **Effective 6/1/2026**, will require step therapy with preferred IVIG products, Gamagard Liquid and Octagam (Rationale: Cost effective therapeutic alternatives available)
- For oncology-related indications, medical necessity criteria can be found here: [Blue Shield Oncology-Related Medication Policies](#).
- For PPO, Direct Contract HMO, and when applicable, ASO, and Shared Advantage: Please access Evolent's [CarePro Provider Portal](#) to submit your request.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*