

Medical Drug Clinical Criteria

Subject: Immunoglobulins

Document #: CC-0003

Publish Date: 07/15/2026

Status: Revised

Last Review Date: 06/08/2026

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Overview

This document addresses the use of intravenous (IVIG) and Subcutaneous (SCIG) Immunoglobulins (IG). This document does not address the use of GamaSTAN or GamaSTAN S/D. This document also does not address Rho (D) immune globulin and WinRho SD injections for the prevention or treatment of Rh incompatibility.

Immunoglobulin products are prepared from pools of human plasma collected from healthy donors. It is a recognized treatment for a variety of medical conditions, not only for its use in fighting infections, but also for its anti-inflammatory and immunomodulating effects. Immunoglobulins are the cornerstone of therapy for primary immunodeficiencies, reflected in the FDA approval for this use. The FDA has also approved these products for other conditions, as shown in the table below.

Summary of FDA-Approved indications for Immunoglobulins:

Agent	Route	PI	ITP	MMN	CLL	KS	CIDP	DM
Alyglo	IV	x						
Asceniv	IV	x*						
Bivigam	IV	x*						
Cutaquig	SC	x*						
Cuvitru	SC	x*						
Flebogamma DIF 5%	IV	x*						
Flebogamma DIF 10%	IV	x	x* (chronic)					
Gammagard	IV, SC	x*		x			x (IV)	
Gammagard Liquid ERC	IV, SC	x*						
Gammagard S/D	IV	x*	x (chronic)		x	x*		
Gammaked	IV, SC	x*	x* (acute and chronic)				x	
Gammaflex 5%	IV	x*	x* (chronic)					
Gammaflex 10%	IV	x*	x (chronic)					
Gamunex-C	IV, SC	x*	x* (acute and chronic)				x	
Hizentra	SC	x*					x	
Hyqvia	SC	x*					x	
Octagam 5%	IV	x*						
Octagam 10%	IV		x (chronic)					x
Panzyga	IV	x*	x (chronic)				x	
Privigen	IV	x*	x*(chronic)				x	
Qivigy	IV	x						
Xembify	SC	x*						
Yimmugo	IV	x*						

*Includes pediatric indication

PI = Primary (Humoral) Immunodeficiency (including, but not limited to Common Variable Immunodeficiency (CVID), X-linked Agammaglobulinemia, Congenital Agammaglobulinemia, Wiskott-Aldrich Syndrome, Severe Combined Immunodeficiencies); **ITP** = Idiopathic Thrombocytopenic Purpura; **MMN** = Multifocal Motor Neuropathy; **CLL** = B-cell Chronic Lymphocytic Leukemia; **KS** = Kawasaki Syndrome; **CIDP** = Chronic Inflammatory Demyelinating Polyneuropathy; **IV** = Intravenous, **SC** = Subcutaneous; **DM** = Dermatomyositis

Other Uses:

Infection: Immunoglobulins play a role in the treatment and prevention of infection in a variety of clinical scenarios. NCCN recommends IG to prevent infections in certain individuals with chronic lymphocytic leukemia and multiple myeloma. The CDC continues to recommend IG to some children with HIV as well as in the post-exposure prophylaxis of measles, tetanus, and varicella. IG remains first line therapy for Kawasaki disease, a syndrome affecting children which involves fever, rash, and systemic inflammation and vasculitis. The cause of the disease is unknown, but may have an infectious origin. IG is used in the acute phase of the disease to reduce the prevalence of coronary artery abnormalities. While it should ideally be administered within 10 days of onset, the American Heart Association recommends use beyond 10 days in the setting of persistent severe manifestations of the disease.

Transplant: IG has also been used in individuals undergoing blood, bone marrow, or solid organ transplant. The consensus guidelines for infection complications in hematopoietic cell transplant suggest that, while IG should not be routinely used, it may be considered pre- and post- transplant when the patient is hypogammaglobulinemic. For solid organ transplant recipients, IG has been used routinely in desensitization prior to transplant. IG may also be considered in antibody-mediated rejection (AMR). AMR remains a significant problem with lack of standardized treatment and limited therapeutic options. Relevant specialists support this indication; and some transplant centers include IG in protocol for AMR. There is literature and guidelines recommending IG in the setting of AMR as well.

Autoimmune diseases: The anti-inflammatory and immunomodulating effects of IG have shown benefit in many autoimmune conditions such as ITP, autoimmune encephalitis, fetal alloimmune thrombocytopenia, autoimmune neutropenia, skin blistering disease, and dermatomyositis. Polymyositis is a very rare condition, but is thought to be similar to dermatomyositis. In autoimmune encephalitis, the autoimmune response may be triggered by tumors, and it is important to detect tumors promptly for appropriate overall management. Symptoms of AE may also precede the appearance of a tumor, so continued cancer screening is recommended, especially in individuals who have an incomplete response to medical therapy (Zuliani 2019).

Neurologic conditions: IG is also recommended in several neurologic conditions such as Lambert-Eaton myasthenic syndrome (LEMS), myasthenia gravis (MG), chronic inflammatory demyelinating polyneuropathy (CIDP), and multifocal motor neuropathy (MMN). Several of these conditions require electrodiagnostic tests to confirm diagnosis. These tests include nerve conduction studies (NCS) measuring compound muscle action potential (CMAP), repetitive nerve stimulation (RNS), or single fiber electromyography (SFEMG) (see table below). Stiff person syndrome, a rare condition involving progressive muscle stiffness, is thought to have an autoimmune component. First line treatments are often benzodiazepines or baclofen, but IG is recommended in refractory cases. In some individuals with mild to moderate myasthenia gravis, symptoms may be well controlled on acetylcholinesterase inhibition alone (i.e., pyridostigmine), even though it does not treat the underlying cause. However, the cholinergic adverse effects of pyridostigmine are usually dose-limiting. Addition of steroidal and non-steroidal immunosuppressants is the typical clinical course for individuals whose symptoms are not well controlled on pyridostigmine alone, with sufficient trial given to the non-steroidal immunosuppressants due to the lengthy onset of action. (Neurol Clin 2018, Neurology 2016/2020). CIDP is further discussed below.

Characteristic Electrodiagnostic Findings in Selected Neurologic Disorders:

Diagnosis	Typical Electrodiagnostic Findings
MG	• RNS shows progressive decline in CMAP amplitude greater than 10% • SFEMG shows abnormal jitter
LEMS	• NCS show reduced baseline CMAP • RNS or maximal isometric muscle activation show increase in compound muscle action potential (CMAP) amplitude of 60% to ≥100% compared with baseline • SFEMG shows significant jitter and transmission blocking that is improved at higher firing rates
MMN	• NCS show focal demyelination and conduction block

Chronic Inflammatory Demyelinating Polyneuropathy (or polyradiculoneuropathy) (CIDP): CIDP is an acquired, immune-mediated neuropathy which currently lacks consensus on one gold standard for confirming diagnosis via electrophysiologic findings and for determining therapeutic improvement. Clinical trials for the FDA-approved CIDP products utilized the various diagnostic methods and objective measurements, including guidelines

from the 2010 European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS), cerebrospinal fluid analysis, Inflammatory Neuropathy Cause and Treatment (INCAT) scale, Medical Research Council (MRC) scale for muscle strength, and Jamar or Vigorimeter grip strength dynamometer. An American Academy of Neurology (AAN) ad hoc subcommittee also developed criteria for diagnosing CIDP in 1991, albeit originally intended for research purposes. The electrodiagnostic features of the EFNS/PNS (2021) and AAN criteria are below. Clinical trials for the FDA-approved CIDP products also differentiated acute inflammatory demyelinating polyneuropathy (AIDP) from chronic IDP by including only individuals with symptoms lasting greater than 2 months or 8 weeks.

CIDP Typical Electrodiagnostic Findings	
EFNS/PNS	At least one (1) of the following demyelinating parameters are necessary: • $\geq 50\%$ prolongation of motor distal latency above ULN in 2 nerves • $\geq 30\%$ reduction of motor conduction velocity below LLN in 2 nerves • $\geq 20\%$ prolongation of F-wave latency above ULN in 2 nerves, or $\geq 50\%$ if amplitude of distal negative peak CMAP is $< 80\%$ of LLN • Absence of F-waves in 2 nerves, if nerves have amplitudes of distal negative peak CMAPs $\geq 20\%$ of LLN, plus ≥ 1 other demyelinating parameter in ≥ 1 other nerve • Motor conduction block: $\geq 30\%$ amplitude reduction of proximal relative to distal negative peak CMAP, excluding tibial nerve, relative to distal, and distal negative peak CMAP $\geq 20\%$ of LLN in 2 nerves, or in 1 nerve plus ≥ 1 other demyelinating parameter except absence of F-waves in ≥ 1 other nerve • Abnormal temporal dispersion: $> 30\%$ duration $\uparrow$ between proximal and distal negative peak CMAP (at least 100% in the tibial nerve) in ≥ 2 nerves • Distal CMAP duration (interval between onset of the first negative peak and return to baseline of the last negative peak) $\uparrow$ in ≥ 1 nerve plus ≥ 1 other demyelinating parameter in ≥ 1 other nerve
AAN	At least three (3) of the four demyelinating parameters are necessary: • Reduction in conduction velocity in 2 or more nerves: ○ $< 80\%$ of LLN if CMAP amplitude $> 80\%$ of LLN ○ $< 70\%$ of LLN if CMAP amplitude $< 80\%$ of LLN • Partial conduction block in 1 or more nerves: ○ Proximal:distal amplitude ratio < 0.8 with $< 15\%$ increase in CMAP negative peak duration, or abnormal temporal dispersion with proximal:distal amplitude or area ratio < 0.8 with $> 15\%$ increase in CMAP negative peak duration dispersion • Prolonged distal latency in 2 or more nerves: ○ $> 125\%$ of ULN if CMAP amplitude $> 80\%$ of LLN ○ $> 150\%$ of ULN if amplitude $< 80\%$ • Absent or F-wave latencies in 2 or more nerves: ○ $> 120\%$ of ULN if amplitude $> 80\%$ of LLN ○ $> 150\%$ of ULN if CMAP amplitude $< 80\%$ of LLN

Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)/Pediatric Autoimmune Neuropsychiatric Disorder Associated with Group A Streptococci (PANDAS): PANS is an umbrella condition that encompasses PANDAS. Although an association between Group A Streptococcal (GAS) infection and sudden onset of obsessive-compulsive behavior, tic disorders, or other unexplained acute neurologic changes has been proposed, there is no immune globulin that is FDA approved for PANS or PANDAS, and additionally, use is not supported by acceptable drug compendia, such as AHFS and DrugPoints. Per the 2025 American Academy of Pediatrics Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) Clinical Report, “because of the lack of evidence strength for autoimmunity and the potential for adverse effects, including immunocompromise, severe headaches, anaphylaxis, aseptic meningitis, thromboembolic phenomena, hemolysis, renal failure, among other serious reactions, treatment with invasive immunotherapies is not usually recommended.” Furthermore, the AAP states that “these drugs are ideally only used in the context of clinical trials designed to improve our understanding of, and evidence for, effective treatment for PANS.” The PANS/PANDAS Research Consortium published treatment guidelines in the 2017 Journal of Child and Adolescent Psychopharmacology recommending use of high dose immune globulins for moderate to severe cases as part of the treatment algorithm for PANS/PANDAS. Recommendations were based on small randomized controlled trials, case reports, and case studies, including those by Williams, et al. (2016), and Perlmutter, et al. (1999). Study results were conflicting between the Williams, et al. trial and the Perlmutter, et al. study. The Williams, et al. study was a randomized, controlled, double blind trial with 35 children meeting criteria for PANDAS who had moderate to severe OCD. They were treated with IVIG (n=17) or placebo (n=18) for 6 weeks. The primary outcome measures were improvement in Children’s Yale-Brown Obsessive Compulsive Scale (CY-BOCS) and the Clinical Global

Impressions-Improvement (CGI-I). "Responders" were defined, a priori, by a 30% decrease in CY-BOCS total score, and a "much" or "very much" improved rating on CGI-I. During the double-blind phase, the mean decrease in CY-BOCS score was 24% for IVIG and 12% for placebo, with 6 responders (35%) for IVIG vs 4 (22%) for placebo; these differences were not statistically significant. The Perlmutter, et al. trial was also randomized, controlled, double blind trial with 29 children having severe, infection-triggered exacerbations of OCD or tic disorders. Individuals were randomized to plasma exchange (n=10), IVIG over 2 consecutive days (n=9), or placebo to IVIg (n=10). The outcome measures rated symptom severity using standard assessment scales for OCD, tics, anxiety, depression, and global function. Statistically significant improvements were seen at 1 month for IVIG and plasma exchange groups vs placebo across various rating scores for symptom severity. At 1 month, the global change scores for plasma exchange and IVIG groups improved by 48% and 41%, respectively; there was no change in placebo group.

Contraindications:

Due to the various immunoglobulin preparations, agents have different contraindications. All immunoglobulins are either contraindicated or have warnings for severe hypersensitivity reactions in IgA deficient patients who have antibodies against IgA. Gammagard S/D contains <1ug/mL of IgA, and Gammagard Liquid ERC contains ≤2ug/mL of IgA, and may be better tolerated by a limited number of patients who have reacted to IG preparations with higher IgA. However, the concentration of IgA that will not provoke a reaction is unknown. Privigen and Hizentra are contraindicated in patients with hyperprolinemia because they contain L-proline. Hyqvia is also contraindicated in patients with hypersensitivity to hyaluronidase or human albumin. Per label, Gammaplex 5% is contraindicated in patients with a hereditary intolerance to fructose and in infants and neonates for whom sucrose or fructose tolerance has not been established, but the same contraindication is not noted in the label for Gammaplex 10%. Per label Octagam 5% is contraindicated in patients with an acute hypersensitivity reaction to corn because it contains maltose; however, Octagam 10% also contains maltose, but the same contraindication is not labeled for this agent.

Black Box Warnings:

Immunoglobulins (SC and IV) have a black box warning for thrombosis. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, IG should be administered at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity

Intravenous Immunoglobulins (IVIG) have a black box warning for renal dysfunction and acute renal failure. Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. For patients at risk of renal dysfunction or acute renal failure, administer IG at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Immunoglobulins

Requests for Immunoglobulin therapy may be approved if the following criteria are met:

- I. **Individual is using for treatment of one of the following primary immunodeficiencies (AAAAI/ACAAI 2015):**
 - A. For initial requests:
 1. Primary humoral immunodeficiency including congenital agammaglobulinemia, X-linked immunodeficiency, or Wiskott-Aldrich syndrome [WAS]) when:
 - a. The initial, pre-treatment total serum IgG is below the lower limit of the age adjusted laboratory reference range, or more than two standard deviations below the age adjusted mean; **AND**

- b. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy) as causes of hypogammaglobulinemia;

OR

- 2. Primary humoral immunodeficiency common variable immunodeficiency (CVID) when:
 - a. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
 - b. There is a lack of, or inadequate response to immunization (for example, but not limited to tetanus or pneumococcal antigen); **AND**
 - c. The initial, pre-treatment total serum IgG is below the lower limit of the age adjusted laboratory reference range, or more than two standard deviations below the age adjusted mean; **AND**
 - d. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy, PLE) as causes of hypogammaglobulinemia;

OR

- 3. IgG sub-class deficiency (IgG1, IgG2, IgG3, IgG4) when:
 - a. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
 - b. There is a lack of, or inadequate response to immunization (for example, but not limited to tetanus or pneumococcal antigen); **AND**
 - c. The initial, pre-treatment levels of one or more serum IgG subclasses are below the lower limit of the age adjusted laboratory reference range or are more than two standard deviations below the age adjusted mean;

OR

- 4. Hyperimmunoglobulinemia E syndrome (HIE) when the following criteria are met:
 - a. Confirmation of elevated level of serum IgE; **AND**
 - b. Individual has clinical features including:
 - i. Recurrent sinopulmonary and skin infections; **AND**
 - ii. Chronic eczematous dermatitis;

OR

- 5. Specific Antibody Deficiency (SAD) when:
 - a. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
 - b. There is a lack of, or inadequate response to pneumococcal polysaccharide antigen; **AND**
 - c. There are normal concentrations of IgG, IgA, IgM, and IgG subclasses;

OR

- 6. Severe combined immunodeficiency [SCID] when:
 - a. Either of the following:
 - i. The initial, pre-treatment total serum IgG is below the lower limit of the age adjusted laboratory reference range, or more than two standard deviations below the age adjusted mean; **OR**
 - ii. CD3+ T cell count of less than 300 cells /mm³, or there is presence of maternal T cells in the circulation; **AND**
 - b. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy) as causes of hypogammaglobulinemia.

B. Continuation requests for treatment of primary immunodeficiencies:

- 1. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease;

Approval Duration for Primary Immunodeficiency:

Initial requests: 1 year

Continuation requests: 1 year

OR

II. Individual is using for one following secondary immunodeficiencies:

A. For initial requests:

- 1. B-cell chronic lymphocytic leukemia (CLL) with the following (NCCN 2A):
 - a. A history of recurrent bacterial infection or an active infection not responding to antimicrobial therapy; **AND**
 - b. Hypogammaglobulinemia shown by total IgG less than 500 mg/dl;

OR

- 2. Multiple myeloma with the following: (NCCN 2A)
 - a. History of a clinically severe infection or active clinically severe infection, OR

- b. Hypogammaglobulinemia shown by functional IgG less than 400 mg/dL (i.e., polyclonal functional IgG may be estimated by subtracting M [monoclonal] spike value from total IgG);

OR

- 3. Human immunodeficiency virus (HIV)-infected children, to prevent opportunistic bacterial infection in individuals with hypogammaglobulinemia (IgG less than 400mg/dL) or recurrent infections (IDSA/CDC 2023);

OR

- 4. Secondary hypogammaglobulinemia or agammaglobulinemia following chimeric antigen receptor (CAR) T cell treatment (NCCN 2A/Label);

OR

- 5. Immune checkpoint inhibitor (i.e., CTLA-4 inhibitors, PD-1 inhibitors, PD-L1 inhibitors)-related toxicities with the following (NCCN 2A):
 - a. The offending agent has been interrupted or discontinued; **AND**
 - b. Individual has had a trial and inadequate response or intolerance to corticosteroids; **AND**
 - c. Individual has one of the following immune checkpoint inhibitor-related toxicities:
 - i. Myocarditis
 - ii. Severe or life-threatening bullous dermatitis
 - iii. Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)
 - iv. Hemolytic anemia
 - v. Severe or very severe aplastic anemia
 - vi. Thrombocytopenia
 - vii. Severe or life-threatening myositis
 - viii. Severe or progressing encephalitis
 - ix. Demyelinating disease (i.e., optic neuritis, transverse myelitis, acute demyelinating encephalomyelitis [ADEM])
 - x. Severe pneumonitis;

OR

- 6. Parvovirus B19 chronic infection and severe anemia associated with bone marrow suppression (NCCN 2A).

B. Continuation requests for treatment of secondary immunodeficiencies:

- 1. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease;

Approval Duration for Secondary Immunodeficiency:

Initial requests: 1 year

Continuation requests: 1 year

OR

III. **Individual is using in the context of transplant for one of the following:**

A. Hematopoietic stem cell transplant (HCT) for either of the following:

- 1. Allogeneic bone marrow transplant (BMT) recipients, in the first 100 days after transplantation, to reduce the risk of graft-versus-host disease associated with interstitial pneumonia (infectious or idiopathic) and infections (cytomegalovirus infections, varicella-zoster virus infection, and recurrent bacterial infection) (DrugPoints B IIa); **OR**
- 2. Prevention of bacterial infections in individuals who are immunosuppressed after allogeneic HCT transplant), when there is severe hypogammaglobulinemia (IgG less than 400 mg/dl) (AHFS, ASBMT 2009);

OR

B. Solid organ transplantation including either of the following:

- 1. Desensitization prior to a solid organ transplantation for suppression of panel reactive anti-HLA antibodies in individuals with high panel reactive antibody (PRA or cPRA [corrected PRA]) levels to human leukocyte antigens (HLA) (AAAAI 2016), or in individuals with a history of high levels of donor-specific antibodies (DSA) (KDIGO 2020, ISHLT 2022); **OR**
- 2. Transplant recipients at risk for CMV (TTS 2018, DP B lib); **OR**
- 3. Transplant recipients experiencing antibody-mediated rejection with donor-specific antibodies (KDIGO 2009, ISHLT 2022);

Approval Duration in the context of transplant: 6 months

OR

IV. **Individual is using for treatment of one the following autoimmune diseases:**

- A. Immune-mediated encephalitis, including paraneoplastic and autoimmune encephalitis (AE) when the following criteria are met (Zuliani 2019, Lancaster 2016):
1. Individual has been evaluated for possible neoplasm associated with encephalitis; **AND**
 2. As an initial trial (up to 12 weeks) when diagnosis is confirmed by the following:
 - a. Detection of a specific autoantibody associated with AE, including but not limited to:
 - i. NMDAR, LGI1, Caspr2, AMPAR, GABA-A or GABA-B receptor, IgLON5, DPPX, GlyR, mGluR1, mGluR2, mGluR5, Neurexin 3-alpha, or dopamine-2 receptor (D2R); **AND**
 - b. Clinical presentation includes neurological symptoms (for example, memory deficits, seizures, movement disorders, speech disturbances, behavioral changes, or psychiatric symptoms); **AND**
 - c. Alternative etiologies of encephalitis syndrome have been ruled out, such as infectious etiologies, other neurological disorders, or other autoimmune conditions.
 3. Continued use of Ig after initial trial when the following criteria are met:
 - a. There are clinically significant improvements in symptoms on physical examination; **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals, or previous discontinuation resulted in relapse); **AND**
 - c. Cancer screening continues;

Approval Duration for AE:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

- B. Immune thrombocytopenia (idiopathic thrombocytopenic purpura [ITP]) with either of the following:
1. Active bleeding (for example, but not limited to hematuria, petechiae, bruising, gastrointestinal bleeding, gingival bleeding); **OR**
 2. Platelet count less than 30,000 mcL (ASH 2019);

Approval Duration for ITP: 6 months

OR

- C. Fetal alloimmune thrombocytopenia with the following: (ACOG 2019)
1. Antibodies to paternal platelet antigen are found in maternal serum; **AND**
 2. One of the following is demonstrated:
 - a. There has been a previously affected pregnancy; **OR**
 - b. There is a family history of maternofetal alloimmune thrombocytopenia; **OR**
 - c. Fetal blood sample shows thrombocytopenia;

Approval Duration for fetal alloimmune thrombocytopenia: 6 months

OR

- D. Isoimmune hemolytic disease of the newborn, treatment of severe hyperbilirubinemia (AAP 2022);

Approval Duration for isoimmune hemolytic disease of the newborn: 6 months

OR

- E. Warm-type autoimmune hemolytic anemia (wAIHA) when the following criteria are met (Jäger 2020)
1. Individual has had a trial and inadequate response or intolerance to a corticosteroid; **AND**
 2. Individual has had a trial and inadequate response or intolerance to one other treatment option, such as rituximab, azathioprine, cyclosporine, mycophenolate, or splenectomy; **AND**
 3. Individual is transfusion dependent; **AND**
 4. Immune globulin is used as adjunct to other supportive therapies;

Approval Duration for warm-type autoimmune hemolytic anemia (wAIHA): 6 months

OR

- F. Autoimmune mucocutaneous blistering diseases (including pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita) when the following criteria are met (AAAAI 2016, Murrell 2020):
1. Individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as corticosteroids or immunosuppressive agents.

2. As continued use after initial trial for autoimmune mucocutaneous blistering diseases when the following criteria are met:
 - a. There is clinically significant improvements in symptoms on physical examination; **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for mucocutaneous blistering diseases:

Initial requests: 6 months

Continuation requests: 1 year

OR

- G. Autoimmune neutropenia when active infection has been excluded as a cause of neutropenia (AAAAI 2016, DP B lib);

Approval Duration for neutropenia: 6 months

OR

- H. Dermatomyositis or polymyositis when the following criteria are met: (AHFS, AAAAI 2016)

1. For initial requests:

- a. Individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments, including corticosteroids and non-steroidal immunosuppressive agents; **AND**
- b. Diagnosis is confirmed by the presence of at least 4 of the following 8 characteristics (Tanimoto 1995):
 - i. Weakness in the trunk or proximal extremities;
 - ii. Elevated serum creatinine kinase or aldolase levels;
 - iii. Muscle pain not otherwise explained;
 - iv. Characteristic electromyography findings (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials);
 - v. Presence of anti-Jo-1 antibody (histidyl-tRNA synthetase);
 - vi. Arthralgias or arthritis without joint destruction;
 - vii. Evidence of systemic inflammation such as fever, elevated C-reactive protein, or elevated sedimentation rate;
 - viii. Inflammatory myositis seen on muscle biopsy;

AND

- c. If using for dermatomyositis, there are skin lesions characteristic of dermatomyositis (such as heliotrope lesions on eyelids, Gottron's papules, erythematous plaques over extensor joints of extremities) present.

2. As continued use after initial trial for dermatomyositis or polymyositis when the following criteria are met:

- a. There is clinically significant improvements in symptoms on physical examination; **AND**
- b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for dermatomyositis or polymyositis:

Initial requests: 6 months

Continuation requests: 1 year

OR

V. Individual is using for treatment of one of the following neurologic diseases:

- A. Lambert-Eaton myasthenic syndrome when the following criteria are met: (AAAAI 2016)

1. For initial requests:

- a. Individual is experiencing muscle weakness, **AND**
- b. Diagnosis confirmed by one of the following:
 - i. Characteristic electrodiagnostic findings using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing, or single fiber electromyography (SFEMG); **OR**
 - ii. Presence of antibodies directed against voltage-gated calcium channels (VGCC).

2. As continued use after initial trial for Lambert-Eaton myasthenic syndrome when the following criteria are met:

- a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not); **AND**
- b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for Lambert-Eaton myasthenic syndrome:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

- B. Guillain-Barré Syndrome (acute demyelinating polyneuropathy) when: (Drugpoints B IIa)
 - 1. Individual's clinical presentation is characteristic of Guillain-Barre Syndrome, including (Willison 2016):
 - a. Progressive weakness in the legs and/or arms; **AND**
 - b. Absent or depressed tendon reflexes (i.e., areflexia) in affected limbs; **AND**
 - 2. Initial treatment with immune globulin occurs within eight (8) weeks of onset of symptoms (AAN 2016); **AND**
 - 3. Individual is not on concomitant plasmapheresis therapy; **AND**
 - 4. Treatment for no more than 5 days (i.e., one course of therapy);

Approval Duration for Guillain-Barré Syndrome: 1 course of therapy (5 days)

OR

- C. Myasthenia Gravis when the following criteria are met: (AAAAI 2016, Neurol Clin 2018, Neurology 2016/2020)
 - 1. For initial requests:
 - a. Individual's clinical presentation is characteristic of myasthenia gravis; **AND**
 - b. The diagnosis is confirmed by one of the following (Juel 2007):
 - i. The presence of antibodies against the acetylcholine receptor (AChR-Ab) or muscle-specific tyrosine kinase (MuSK-Ab); **OR**
 - ii. Characteristic electrodiagnostic findings using repetitive nerve stimulation (RNS) or single fiber electromyography (SFEMG); **AND**
 - c. Individual is using for one of the following:
 - i. Exacerbation of myasthenia gravis or acute myasthenic crisis; **OR**
 - ii. Short-term therapy as immunosuppressive treatment is taking effect; **OR**
 - iii. Maintenance therapy of myasthenia gravis when individual has had an inadequate response to, is intolerant of, or has a contraindication to **all** of the following:
 - Pyridostigmine; **AND**
 - Corticosteroids; **AND**
 - Non-steroidal immunosuppressants. Inadequate response to non-steroidal immunosuppressants is defined as unchanged or worsening symptoms despite *one* of the following:
 - At least a twelve (12) month trial of azathioprine or mycophenolate; **OR**
 - At least a two (2) month trial of cyclosporine, cyclophosphamide, tacrolimus, or methotrexate.
 - 2. As continued use after initial trial for myasthenia gravis when the following criteria are met:
 - a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not); **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for myasthenia gravis:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

- D. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):

1. As an *initial trial* (up to 12 weeks), when the following criteria are met:
 - a. Diagnosis has been verified by all of the following:
 - i. Clinical presentation aligned with one of the following (EFNS/PNS 2010):
 - 1) Typical CIDP; defined as chronically progressive, stepwise, or recurrent symmetric proximal and distal weakness and sensory dysfunction of all extremities, developing over at least 2 months and absent or reduced tendon reflexes in all extremities; **OR**
 - 2) Atypical CIDP; defined as in typical CIDP but with one of the following: predominately distal, asymmetric, focal, pure motor, or pure sensory);
 - AND**
 - ii. Characteristic electrodiagnostic findings (prolongation of motor distal latency, reduction of motor conduction velocity, prolongation of F-wave latency, absence of F-waves, motor conduction block, abnormal temporal dispersion, and distal compound muscle action potential (CMAP) duration increase) in at least one nerve (EFNS/PNS 2010);
 - AND**
 - iii. Other causes of neuropathy (including but not limited drug or toxin induced neuropathy, Lyme disease, IgM neuropathy, hereditary neuropathy, prominent sphincter disturbance, multifocal motor neuropathy, and diabetic neuropathy) have been ruled out (EFNS/PNS 2010).
 - b. Individual demonstrates objective functional impairment from CIDP (including but not limited to requiring support to walk or upper limb symptoms affecting or preventing ability to perform certain functions [such as zips and buttons, washing or brushing hair, using a knife and fork together, or handling small coins]).
2. As continued use after initial trial for CIDP when the following criteria are met:
 - a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not); **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for CIDP:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

- E. Multifocal Motor Neuropathy (MMN) for either of the following:
1. As an *initial trial* (up to 12 weeks) to treat MMN, when diagnosis is confirmed by all of the following criteria: (EFNS/PNS 2010, AANEM 2003):
 - a. Stepwise or slowly progressive, focal, asymmetric limb weakness for at least one (1) month; **AND**
 - b. Motor involvement of at least two (2) nerves; **AND**
 - c. Sensory nerve conduction studies are normal, with the exception of minor vibration loss in the lower limbs; **AND**
 - d. Absence of *all* of the following upper motor neuron signs, **or** presence of such can be explained by a comorbid condition (for example, history of stroke):
 - i. Spastic tone
 - ii. Clonus
 - iii. Extensor plantar response
 - iv. Pseudobulbar palsy.
 2. Continued use of Ig after initial trial for MMN when the following criteria are met:
 - a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not); **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for MMN:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

F. Stiff-person syndrome when the following criteria are met (AAAAI 2016):

1. For initial requests:
 - a. Individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as benzodiazepines or baclofen (AAAAI 2016).
2. Continued use of Ig after initial trial when the following criteria are met:
 - a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not); **AND**
 - b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals);

Approval Duration for stiff-person syndrome:

Initial requests: 12 weeks

Continuation requests: 1 year

OR

G. Myelin Oligodendrocyte Glycoprotein (MOG)- related Neuromyelitis Optica Spectrum Disorder (NMOSD) for either of the following (Hacohen 2019):

1. As an *initial* trial for the diagnosis of MOG-related neuromyelitis optica spectrum disorder (NMOSD); **AND**
 - a. Individual is confirmed to be seropositive for myelin oligodendrocyte glycoprotein (MOG) antibodies; **AND**
 - b. Individual is *seronegative* for aquaporin-4 (AQP4) antibodies; **AND**
 - c. Individual is using for one of the following:
 - i. As induction treatment for an acute episode after an inadequate response to, intolerance, or contraindication to corticosteroids; **OR**
 - ii. Individual has further relapse after maintenance treatment with corticosteroids *and* non-steroidal immunosuppressants.
2. Continued maintenance use after initial treatment for MOG-related NMOSD when the following criteria is met:
 - a. Individual has experienced a clinical response with immune globulin (for example, a reduction in frequency of relapse);

Approval Duration for MOG-related NMOSD:

Initial requests: 6 months

Continuation requests: 1 year

OR

VI. **Individual is using for treatment of one of the following miscellaneous indications:**

- A. Measles (rubeola) post-exposure prophylaxis: (AHFS)
 1. Individual is using for post-exposure prophylaxis to prevent or modify measles (rubeola); **AND**
 2. Administered within 6 days of exposure and not given concomitantly with a vaccine containing the measles virus; **AND**
 3. Eligible, exposed, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 8 months after immunoglobulin administration (CDC 2013); **AND**
 4. Used in the following individuals considered at risk for severe disease and complications (CDC 2013):
 - a. No evidence of measles immunity, in particular in pregnant women; **OR**
 - b. Severely immunocompromised individuals;

OR

- B. Varicella post-exposure prophylaxis: (AHFS)
 1. Individual is using as post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised); **AND**
 2. The varicella-zoster immune globulin (human) (VZIG) is unavailable;

OR

- C. Tetanus: (AHFS)

1. Individual is using as treatment or post-exposure prophylaxis of tetanus when tetanus immune globulin (TIG) is unavailable;

OR

D. Kawasaki Syndrome when:

1. Treatment initiated within 10 days of onset; **OR**
2. Treatment Initiated beyond 10 days of onset if individual has unexplained persistent fever, or coronary artery abnormalities with evidence of ongoing inflammation (such as elevated erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP]) (AHA 2017);

AND

3. Treatment for no more than 5 days (AHFS);

OR

E. Toxic shock syndrome caused by staphylococcal or streptococcal organisms (AAP 2018, AHFS);

OR

F. Treatment of cancer-related CMV pneumonia if individual has hypogammaglobulinemia (IgG less than 500mg/dL) (NCCN 2A).

Approval Duration for cancer-related CMV pneumonia: 6 months

Requests for Immunoglobulin therapy may not be approved for the following:

- I. Alzheimer's disease; **OR**
- II. Immune optic neuropathy, with the exception of MOG-related NMOSD; **OR**
- III. Multiple sclerosis; **OR**
- IV. Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS) (AAP 2025, Perlmutter 1999, Williams 2016); **OR**
- V. Treatment to prevent recurrent spontaneous abortion in pregnant women with a history of recurrent spontaneous abortion (ASRM 2012); **OR**
- VI. When the above criteria are not met and for all other indications.

Step Therapy

Note: When an immunoglobulin is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferred¹ agent or agents.

IG products and selected properties[†]

Agent	Route	Osmolality (mOsm/kg)	Sodium	IgA (µg/mL)	Stabilizer or regulator
Alyglo 10%	IV	not stated	not stated	≤ 100	Glycine
Asceniv 10%	IV	370 – 510π	100 to 140 mmol/L	<200	Glycine and polysorbate 80
Bivigam 10%	IV	370 – 510	100 to 140 mmol/L	≤200	Glycine and polysorbate 80
Cutaquig 16.5%	SC	310 – 380	<30 mmol/L	≤600	Maltose
Cuvitru 20%	SC	280 – 292	none	80	Glycine
Flebogamma DIF 5%	IV	240 – 370	trace	<50	D-sorbitol
Flebogamma DIF 10%	IV	240 – 370	trace	<100	D-sorbitol
Gammagard 10%	IV, SC	240 – 300	none	37	Glycine
Gammagard Liquid ERC	IV, SC	240 – 300	none	≤2	Glycine
Gammagard S/D 5%	IV	636	8.5 mg/mL	<1	Glucose and glycine
Gammaked 10%	IV, SC	258	trace	46	Glycine
Gammaplex 5%	IV	420 – 500	30 to 50 mmol/Lπ/±	<10	D-sorbitol, glycine, and polysorbate 80
Gammaplex 10%	IV	280	<30 mmol/L	<20	Glycine and polysorbate 80
Gamunex-C 10%	IV, SC	258	trace	46	Glycine

Hizentra 20%	SC	380 π/±	trace	≤50	L-proline and polysorbate 80
Hygvia 10%	SC	240 – 300	none	37	Glycine
Octagam 5%	IV	310 – 380	≤30 mmol/L	≤200	Maltose
Octagam 10%	IV	310 – 380	≤30 mmol/L	106	Maltose
Panzyga 10%	IV	240 – 310	trace	100	Glycine
Privigen 10%	IV	240 – 440	trace	≤25	L-proline
Qivigy 10%	IV	240	not stated	≤50	Glycine
Xembify 20%	SC	280 – 404	none	contains IgA (not defined)	Glycine and polysorbate 80
Yimmugo 10%	IV	280 – 380	not stated	≤300	Glycine and polysorbate 80

† Per FDA Package Insert, unless otherwise noted; †Immune Deficiency Foundation (2021); *AAAAI (2016).

Commercial

Non-preferred Intravenous Immunoglobulins (IVIG) Step Therapy

A list of the preferred intravenous immunoglobulin(s) is available [here](#).

Requests for a non-preferred intravenous immunoglobulin agent may be approved when the following criteria are met:

- I. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred intravenous Ig agents; **OR**
- II. Documentation is provided that the preferred Ig agents are not acceptable due to concomitant clinical condition(s), which requires an Ig agent with specific properties. Examples include, but not limited to the following:
 - A. Severe IgA deficiency (<7 mg/dL of IgA), or IGA deficiency with antibodies against IgA, requiring agent with very low IGA content; **OR**
 - B. Hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; **OR**
 - C. Clinically significant reaction, including, but not limited to, hemolysis or renal dysfunction/impairment, that may be lessened by use of a non-preferred agent with different properties; **OR**
- III. The preferred agents are not FDA-approved and do not have accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.

Non-preferred Subcutaneous Immunoglobulins (SCIG) Step Therapy

A list of the preferred subcutaneous immunoglobulin(s) is available [here](#).

Requests for a non-preferred subcutaneous immunoglobulin (SCIG) agent may be approved when the following criteria are met:

- I. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred SCIGagents;
- OR**
- II. Documentation is provided that the preferred SCIG agent is not acceptable due to concomitant clinical condition(s), which requires an Ig agent with specific properties. Examples include, but not limited to the following:
 - A. Severe IgA deficiency (<7 mg/dL of IgA), or IgA deficiency with antibodies against IgA, requiring agent with very low IgA content; **OR**
 - B. Hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; **OR**
 - C. Clinically significant reaction, including, but not limited to, hemolysis or renal dysfunction/impairment, that may be lessened by use of a non-preferred agent with different properties;
- OR**

- III. The preferred SCIG agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.

Medicare

Non-preferred Intravenous Immunoglobulins (IVIG) Step Therapy

A list of the preferred intravenous immunoglobulin(s) is available [here](#).

Requests for a non-preferred intravenous immunoglobulin agent may be approved when the following criteria are met:

- I. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred intravenous Ig agents; **OR**
- II. Documentation is provided that the preferred Ig agents are not acceptable due to concomitant clinical condition(s), which requires an Ig agent with specific properties. Examples include, but not limited to the following:
 - A. Severe IgA deficiency (<7 mg/dL of IgA), or IGA deficiency with antibodies against IgA, requiring agent with very low IGA content; **OR**
 - B. Hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; **OR**
 - C. Clinically significant reaction, including, but not limited to, hemolysis or renal dysfunction/impairment, that may be lessened by use of a non-preferred agent with different properties; **OR**
- III. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.

Non-preferred Subcutaneous Immunoglobulins (SCIG) Step Therapy

A list of the preferred subcutaneous immunoglobulin(s) is available [here](#).

Requests for a non-preferred subcutaneous immunoglobulin (SCIG) agent may be approved when the following criteria are met:

- I. Documentation is provided that individual has had a trial and inadequate response or intolerance to two preferred subcutaneous Ig agents; **OR**
- II. Documentation is provided that the preferred SCIG agent is not acceptable due to concomitant clinical condition(s), which requires an Ig agent with specific properties. Examples include, but not limited to the following:
 - A. Severe IgA deficiency (<7 mg/dL of IgA), or IgA deficiency with antibodies against IgA, requiring agent with very low IgA content; **OR**
 - B. Hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; **OR**
 - C. Clinically significant reaction, including, but not limited to, hemolysis or renal dysfunction/impairment, that may be lessened by use of a non-preferred agent with different properties; **OR**
- III. The preferred SCIG agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.

¹Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Intravenous Immunoglobulin Quantity Limits

Drug	Limit Per Indication
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Intravenous Immunoglobulins	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): 1000 mg/kg (may be divided over two days) as frequently as every 3 weeks (DP) [†] Chronic Lymphocytic Leukemia (CLL): 500 mg/kg monthly (NCCN) Dermatomyositis (DM): 2000 mg/kg administered in divided doses over 2 to 5 days every 4 weeks (Octagam 10% label) Guillain-Barré Syndrome: 400 mg/kg daily for 5 days OR 2000 mg/kg administered in divided doses over 2 to 5 days (DP, AHFS) Idiopathic thrombocytopenic purpura (ITP): 2000 mg/kg administered in divided doses over 2 to 5 days or 1000 mg/kg every other day for up to 3 doses (DP) Kawasaki Syndrome: 2000 mg/kg per dose for up to two doses (AHFS) OR 400mg/kg/day for 4 days Multifocal Motor Neuropathy (MMN): 2400 mg/kg every 4 weeks (Gammagard label) [^] Myasthenia Gravis: 2000 mg/kg administered in divided doses over 2 to 5 days (DP) Primary Immunodeficiencies: 800 mg/kg as frequently as every 3 weeks*
Override Criteria	
[†] For CIDP initiation of therapy, may approve loading doses of up to 2000 mg/kg in divided doses over 2 to 5 consecutive days [^] For MMN, may approve as frequent as every 2 weeks based on response (AHFS) *For primary immunodeficiencies, may approve a higher dose when the treating physician has indicated that it is necessary based on the individual's clinical response	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

90283	Immune globulin, (IgIV), human, for intravenous use
90284	Immune globulin, (SCIg), human, for use in subcutaneous infusions, 100 mg each

HCPCS

J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1551	Injection, immune globulin (Cutaquig), 100 mg
J1552	Injection, immune globulin (Alyglo), 500 mg
J1553	Injection, immune globulin (Yimmugo), 100 mg
J1554	Injection, immune globulin (Asceniv), 500 mg
J1555	Injection, immune globulin (Cuvitru), 100 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin (Xembify), 100 mg
J1559	Injection, immune globulin (Hizentra), 100 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 [Carimune NF, Gammagard S/D]
J1568	Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard Liquid/Gammagard Liquid ERC), non-lyophilized (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g., liquid), 500 mg

J1575	Injection, immune globulin/hyaluronidase, (HyQvia), 100 mg immune globulin
J1576	Injection, immune globulin (Panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1577	Injection, immune globulin (Qivigy), 100 mg
Q2052	Services, supplies and accessories used in the home for the administration of intravenous immune globulin (IVIG)
S9338	Home infusion therapy; immunotherapy, administrative services, professional pharmacy services, care coordination, all necessary supplies and equipment, per diem

ICD-10 Diagnosis

All diagnoses

Document History

Revised: 06/08/2026

Document History:

- 06/08/2026 – Select Review: Clarify continuation requests for secondary immunodeficiencies. Update SCIG step therapy to remove requirement for trial or intolerance of IV products. Wording and formatting changes. Coding Reviewed: Updated description for HCPCS J1569 effective 7/1/26. Removed HCPCS NOC C9399, J1599 and J3590 effective 6/30/26 and added J1577 effective 7/1/26. 03/26/2026 – Step therapy table updates. Coding Update: Removed Yimmugo from HCPCS NOC C9399 and J3590 effective 3/31/26 and added J1553 effective 4/1/26. Added J1599 for Qivigy. Removed Gammagard Liquid ERC from HCPCS NOC C9399 and J3590 and added to J1569.
- 03/09/2026 – Select Review: Add continuation criteria and update approval duration for primary and secondary immunodeficiencies. Add approval duration for fetal alloimmune thrombocytopenia, isoimmune hemolytic disease of the newborn, and warm-type autoimmune hemolytic anemia (wAIHA). Wording and formatting updates. Coding Reviewed: No changes.
- 02/01/2026 – Step therapy table updates.
- 01/02/2026 – Coding Update: Added HCPCS J1572.
- 12/22/2025 – Coding Update: Added Gammagard Liquid ERC to HCPCS NOC C9399 and J3590.
- 11/14/2025 – Annual Review: Update criteria for CIDP. Add indication for immune checkpoint inhibitor-related toxicities per guidelines. Add indication for warm-type autoimmune hemolytic anemia. Add new agents Gammagard Liquid ERC and Qivigy to clinical criteria and step therapy properties table. Coding Reviewed: Added HCPCS NOC C9399 for Yimmugo and Qivigy. Added Qivigy to HCPCS NOC J3590. Added HCPCS Q2052. Removed HCPCS J1572 effective 1/1/26.
- 05/16/2025 – Select Review: Update step therapy criteria to remove grandfathering allowance and add specific overrides for non-preferred agents and existing users. Coding Reviewed: Updated description for HCPCS J1561.
- 04/01/2025 – Step therapy table updates.
- 01/17/2025 – Step therapy table updates.
- 11/15/2024 – Annual Review: Update criteria for use in multiple myeloma. Step therapy update. Coding Reviewed: Add HCPCS J1552 effective 1/1/2025 and delete HCPCS J1599 for Alyglo.
- 10/23/2024 – Step therapy table updates.
- 08/16/2024 – Select Review: Add new agent Yimmugo to document. Coding Reviewed: Added HCPCS J3590 for Yimmugo (immune globulin intravenous, human-dira). Removed HCPCS J1460 and J1560, these intramuscular immunoglobulins products are addressed in CC-0039; removed CPT 90281. Updated coding description for: J1558 (removed Effective 7/1/2020 wording); J1561 (added Gamunex).
- 07/01/2024 – Step therapy table updates.
- 03/11/2024 – Select Review: Add new agent Alyglo to document. Update summary of FDA indications for Gammagard liquid and Hyqvia. Coding Reviewed: Added HCPCS J1599 for Alyglo.
- 03/29/2024 – Step therapy table updates.
- 11/17/2023 – Annual Review: Update criteria to add indication for specific antibody deficiency. Update criteria to expand on indication for severe combined immune deficiency. Wording, formatting, and reference updates. Coding Reviewed: No changes.
- 03/13/2023 – Select Review: Update criteria to clarify initiation requests for various indications. Coding Reviewed: No changes. Effective 7/1/2023 Added HCPCS J1576. Deleted HCPCS J1599.
- 11/18/2022 – Annual Review: Update criteria to add continuation criteria for Autoimmune mucocutaneous blistering diseases, Dermatomyositis or polymyositis, Lambert-Eaton myasthenic syndrome, Myasthenia

Gravis, and Stiff-person syndrome. Add approval durations for various indications. Update multiple myeloma criteria per NCCN guidelines to allow for use with history of infections or low IgG levels. Add dosing limits for DM, CLL, and Stiff-person syndrome per label and/or compendia. Wording, formatting, and reference updates. Coding Reviewed: No changes.

- 09/30/2022 – Step therapy table updates.
- 07/25/2022 – Step therapy table updates. Administrative update to add documentation.
- 11/19/2021 – Annual Review: Update criteria to add paraneoplastic encephalitis indication. Update the CIDP criteria to remove the word “partial” from the motor conduction block for the EFNS/PNS diagnostic criteria per guideline update. Updated references. Coding Reviewed: No changes. Effective 7/1/2022 Added HCPCS J1551 for Cutaquig. Removed HCPCS J3490, J3590, C9399.
- 11/20/2020 – Annual Review: Update criteria for hyperimmunoglobulinemia E syndrome to include clinical features of disease. Update criteria for multiple myeloma to update minimum threshold for IgG levels per NCCN 2A update. Update criteria for solid organ transplant to allow for corrected PRA and history of high DSA levels per guidelines. Update IG criteria to allow for new indication of autoimmune encephalitis. Clarify use of previous agents for dermatomyositis and polymyositis. Update criteria for Guillain-Barre syndrome to include clinical presentation features, treatment guidance, and approval duration. Update criteria for multifocal motor neuropathy to expand on diagnostic requirements, and requirements for continuation of use, and clarify approval duration. Update IG criteria to allow for new indication of MOG-related NMOSD. Update non-approvable criteria to allow exceptions for MOG-related NMOSD under immune optic neuropathy. Add administrative note for use in cancer-related CMV pneumonia. Wording and formatting changes. Coding Reviewed: Added HCPCS C9072 for Asceniv (Effective 1/1/2021). Effective 4/1/2021 Added HCPCS J1554 for Asceniv. Removed C9072. Removed term Asceniv from J1599.
- 05/15/2020 – Select Review: Update criteria for myasthenia gravis to include specific drug failures, and add failure of pyridostigmine as requirement. Update criteria for CIDP to include requirement regarding disease duration, specific electrodiagnostic criterion, and objective measures for continuation. Remove annual evaluation of clinical effect requirement from CIDP criteria, and clarify language for clinical effect. Clarify initial approval duration for CIDP. Coding Reviewed: Added HCPCS J1558 for Xembify (Effective 7/1/2020), Delete the term Xembify 6/30/2020- J3490, J3590, C9399
- 11/15/2019 – Annual Review: Add new product Xembify (subcutaneous immunoglobulin) to clinical criteria and step therapy. Update criteria for use in Kawasaki disease to include coronary artery abnormalities. Minor wording and formatting changes. Coding reviewed: Added Xembify to J3490, J3590, C9399.
- 09/23/2019 - Administrative update to add drug specific quantity limit.
- 06/10/2019 – Select Review: Add new products, Asceniv (intravenous immunoglobulin) and Cutaquig (subcutaneous immunoglobulin) to indication table and as potential preferred products in step therapy. Coding reviewed: Added new HCPCS J3490, J3590, and C9399 for Cutaquig, Asceniv drug is listed under J1599
- 11/16/2018 – Annual Review: Initial review of Immunoglobulin clinical criteria. Clarify definition of “refractory” in certain indications. Add use in Multiple Myeloma and CMV pneumonia per NCCN recommendations. Update HIV indication to apply to hypogammaglobulinemic patients. Update definition of hypogammaglobulinemia to IgG <400mg/dL per guidelines. Add use in antibody-mediated rejection per guidelines. Update definition of ITP per guidelines and for consistency with other agents. Update criteria in Myasthenia Gravis to include use in exacerbation or refractory disease. Simplify and clarify diagnostic criteria in neurologic conditions. Bring post- exposure prophylaxis of certain infections in scope. Add references for off label indications and other wording and formatting changes. HCPCS Coding review: no change. ICD-10 Coding review: no change.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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CC-0003 Immunoglobulins

Commercial Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
02/01/2025	Intravenous: Gamunex-C Octagam Subcutaneous: Cutaquig Hizentra Xembify	Intravenous: Alyglo Asceniv Bivigam Flebogamma DIF Gammaked Gammagard Gammagard S/D Gammaplex Panzyga Privigen Yimmugo Subcutaneous: Cuvitru HyQvia

05/01/2026	Intravenous: Gamunex-C Octagam Subcutaneous: Cutaquig Hizentra Xembify	Intravenous: Alyglo Asceniv Bivigam Flebogamma DIF Gammaked Gammagard Gammagard Liquid ERC Gammagard S/D Gammaplex Panzyga Privigen Qivigy Yimmugo Subcutaneous: Cuvitru HyQvia
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Medicaid Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
N/A	N/A	N/A

Medicare Medical Benefit

Effective Date	Preferred Agents	Non-Preferred Agents
04/1/2025	Intravenous: Gamunex-C Octagam Subcutaneous: Cutaquig Hizentra Xembify	Intravenous: Alyglo Asceniv Bivigam Flebogamma DIF Gammaked Gammagard Gammagard S/D Gammaplex Panzyga Privigen Yimmugo Subcutaneous: Cuvitru HyQvia

05/01/2026	Intravenous: Gamunex-C Octagam Subcutaneous: Cutaquig Hizentra Xembify	Intravenous: Alyglo Asceniv Bivigam Flebogamma DIF Gammaked Gammagard Gammagard Liquid ERC Gammagard S/D Gammaplex Panzyga Privigen Qivigy Yimmugo Subcutaneous: Cuvitru HyQvia
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