Immune Globulins Prior Authorization Program Summary

This program applies to MN Medicaid.

Targets are SCIG products: Cutaquig, Cuvitru, Hizentra, Hyqvia, Xembify

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

FDA APPROVED INDICATIONS[1-17,31-34]

Route	Agent(s)	Indication(s)
IV Human Immune Globulin	**Asceniv™** 10%	• Treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age)
	Bivigam® 10%	• Treatment of primary humoral immunodeficiency (PI)
	Flebogamma® 5% DIF	• Treatment of primary(inherited) immunodeficiency (PI) in adults and pediatric patients 2 years of age and older
	Flebogamma® 10% DIF	• Treatment of primary (inherited) immunodeficiency (PI) • Treatment of chronic primary immune thrombocytopenia (ITP) age greater than or equal to 2 years
	Gammagard® S/D 5%	• Treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age or older • Prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL) • Prevention and/or control of bleeding in adult chronic idiopathic thrombocytopenic purpura (ITP) patients • Prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients
	Gammaplex® 5%	• Treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older

Route	Agent(s)	Indication(s)
		● Treatment of chronic immune thrombocytopenic purpura (ITP)
	Gammaplex® 10%	● Treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older ● Treatment of chronic immune thrombocytopenic purpura (ITP) in adults
	Octagam® 5%	● Treatment of primary humoral immunodeficiency (PI)
	Octagam® 10%	● Treatment of chronic immune thrombocytopenic purpura (ITP) in adults ● Treatment of dermatomyositis in adults
	Panzyga 10%	● Treatment of primary humoral immunodeficiency in patients 2 years of age and older ● Treatment of chronic immune thrombocytopenia (ITP) in adults ● Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
	Privigen® 10%	● Treatment of primary humoral immunodeficiency (PI) ● Treatment of chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older ● Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) (adults) Limitations of Use: Privigen maintenance therapy in CIDP has not been studied beyond 6 months
IV or SC Human Immune Globulin	**Gamunex-C®** 10%	● Treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older) ● Treatment of idiopathic thrombocytopenic purpura (ITP) in adults and children

Route	Agent(s)	Indication(s)
		● Treatment of chronic inflammatory demyelinating Polyneuropathy (CIDP) in adults
	Gammaked™ 10%	● Treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older ● Treatment of idiopathic thrombocytopenic purpura (ITP) in adults and children ● Treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
	Gammagard™ Liquid 10%	● Replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older ● Maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy (MMN)
SC Human Immune Globulin	**Cutaquig®** 16.5%	● Treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older
	Cuvitru™ 20%	● Replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older
	Hizentra® 20%	● Treatment of primary immunodeficiency (PI) in adults and pediatric patients two years of age or older ● Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP)
	HyQvia™ 10%	● Treatment of primary immunodeficiency (PI) in adults Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than PI
	Xembify® 20% solution	● Treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older

Route	Agent(s)	Indication(s)
IM Human Immune Globulin	**GamaSTAN® S/D** 15-18%	• Prophylaxis following exposure to hepatitis A • To prevent or modify measles in a susceptible person exposed fewer than 6 days previously • To modify varicella • To modify rubella in exposed women who will not consider a therapeutic abortion

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE
Immune Globulins
Immunoglobulin is used to treat a wide variety of diseases, including primary and secondary immunodeficiency states and hematologic and autoimmune disorders. Immunoglobulin is increasingly recognized as a treatment of a variety of medical conditions, not only for its ability to fight infection as a replacement therapy but also for its anti-inflammatory and immunomodulating effects. The appropriate use of immunoglobulin can be life-saving. However, its administration can lead to numerous adverse events and potential additional adverse consequences. Due to finite supply, possible adverse events, and the need for further research in some applications of therapeutic immunoglobulin, it is important for clinicians prescribing immunoglobulin to be familiar with current clinical indications and levels of evidence in support of its use in these conditions.[23]

Primary immunodeficiency
Immunoglobulin replacement therapy via the IV or SC route is required in patients with certain primary immunodeficiency (PI) diseases characterized by absent or deficient antibody production and, in most cases, recurrent or unusually severe infection. Replacement therapy for agammaglobulinemia and hypogammaglobulinemia in well-described immunodeficiencies such as X-linked agammaglobulinemia (XLA) or common variable immunodeficiency (CVID) is necessary and life-saving. Other more genetically complex PIs, however, may also involve defects in antibody function that contribute to an increased susceptibility to infections.[24] Over 300 distinct primary immunodeficiencies have been described to date with new primary immunodeficiencies being discovered at a rapid rate.[35]

Immune globulin is the current mainstay of therapy for patients with PI. Immune globulin protects against infection by providing protective antibodies and humoral immunity. A study in 31 children with X-linked agammaglobulinemia showed that immune globulin reduced the incidence of infection from 0.4 per patient year to 0.06 per patient year ($p<0.001$). In a study of adults with common variable immunodeficiency (CVID), immune globulin reduced the incidence of bacterial pneumonia from 84% before treatment to 11% after treatment with immune globulin.[18]

The prevalence of primary immunodeficiencies in the United States is as many as 1:2000 live births.[24] A 20-year survival rate is 64%-67% for males and females respectively. Important signs that may indicate a primary immunodeficiency disease include recurrent, unusual or

difficult to treat infections, poor growth or loss of weight, recurrent pneumonia, ear infections or sinusitis, multiple courses of antibiotics or IV antibiotics necessary to clear infections, recurrent deep abscesses of the organs or skin, a family history of primary immunodeficiency disease, swollen lymph glands or an enlarged spleen, autoimmune disease. Diagnosis of primary immunodeficiencies involves laboratory evaluations (Serum IgA, IgG, and IgM levels, circulating T and B lymphocytes and T cell function), measurement of specific antibodies to vaccines, imaging (CT scan of chest detecting pulmonary abnormalities), histology of lymph nodes (reactive follicular or atypical hyperplasia, and granulomatous inflammation), bronchoscopy (infectious processes), and lymph node biopsy.[25]

Diagnostic criteria discussed by the American Academy of Allergy and Immunology (AAAI) for hypogammaglobulinemia include low IgG level (< 700 mg/dL or more than two standard deviations below the mean) or an inability to mount a significant response to antigenic challenge or both in patients with recurrent bacterial infections coupled with a lack of response to protein or polysaccharide vaccine challenges (i.e., patients who cannot make IgG antibody against diphtheria and tetanus toxoids, pneumococcal polysaccharide vaccine, or both).[22] The European and Pan-American Guidelines, state that, the first criterion for CVID requires IgG levels to be two standard deviations below the mean [for the patient's age]. For most laboratories, the lower limit of normal for IgG is 7 - 8 g/L (700 – 800 mg/dL). Impaired vaccine response is the second and most contentious criterion. The last criterion requiring exclusion of secondary causes is the least contentious. Secondary hypogammaglobulinemia can be caused by a variety of conditions, including gut or renal loss, adverse reactions to drugs, etc.[21] These patients are recommended for immune globulin replacement. The European Society of Immune Deficiencies (ESID) registry has published a working definition for several primary immunodeficiencies including agammaglobulinemia, severe combined immunodeficiency, and CVID. The working definition also includes both laboratory values and clinical symptoms. The working definition is based on more recent registry information than the diagnostic requirements discussed by AAAI and is being used by the ESID however neither definition has been validated.[21]

Treatment guidelines published in 2010 from the National Advisory Committee on Blood and Blood Products and Canadian Blood Services concluded there is sufficient evidence that immunoglobulin therapy reduces the rate of infection and hospitalization in patients with primary immune deficiency, which likely leads to a lower mortality and improved quality of life. These guidelines also recommend when considering primary immune deficiency in patients with autoimmune hematological diseases that quantitative IgA, IgG, and IgM levels be drawn and evaluated prior to beginning therapy with immune globulin. Primary immune deficiency may require indefinite therapy.[29]

Idiopathic thrombocytopenic purpura (ITP)[26]
Immune thrombocytopenia (ITP) is an acquired autoimmune disorder characterized by a low platelet count resulting from platelet destruction and impaired platelet production. ITP can be an isolated primary condition, or it may be secondary to other conditions. ITP remains a diagnosis of exclusion of other causes of thrombocytopenia. The goal of all treatment strategies for ITP is to achieve a platelet count that is associated with adequate hemostasis, rather than a normal platelet count. Bleeding events are often unpredictable and patients with ITP, even in the setting of severe thrombocytopenia, may not exhibit bleeding beyond bruising and petechiae. However, more serious mucosal bleeding may occur, including menorrhagia, epistaxis, gastrointestinal hemorrhage, hematuria, or, rarely, intra-cranial hemorrhage. The decision as to whether a patient can be observed or requires further intervention is highly complex and varies based on comorbidities, medications, and age, which all impact the risk of bleeding. In addition, management approaches may vary based on disease duration, access to care, quality-of-life implications, and patient and provider preferences, among other factors.

An International Working Group consensus panel defines ITP as newly diagnosed (diagnosis to 3 months), persistent (3-12 months from diagnosis), or chronic (lasting for more than 12 months).

Corticosteroids are first- line treatment for ITP. Other treatment options for ITP include thrombopoietin receptor agonists, rituximab, splenectomy, and IVIG or anti-D immunoglobulin.

Kawasaki disease (KD)[30]
Kawasaki disease (KD) is an acute, self-limited febrile illness of unknown cause that predominantly affects children < 5 years of age. KD is characterized by a remittent fever, erythematous rash (often on the trunk), and red swollen lips and tongue. Cardiac complications including coronary artery aneurysm, myocardial infarction, congestive heart failure (CHF), and arrhythmias are the most common cause of death in patients with Kawasaki disease. The diagnosis of classic KD is based on the presence of ≥ 5 days of fever and the presence of ≥ 4 of the 5 following main clinical features:

- Erythema and cracking of lips, strawberry tongue, and/or erythema of oral and pharyngeal mucosa
- Bilateral bulbar conjunctival injection without exudate
- Rash: maculopapular, diffuse erythroderma, or erythema multiforme-like
- Erythema and edema of the hands and feet in acute phase and/or periungual desquamation in subacute phase
- Cervical lymphadenopathy (equal to or greater than 1.5 cm diameter), usually unilateral

The American Heart Association (AHA) guidelines recommend initial therapy include intravenous immune globulin (IVIG) 2 gm/kg administered as a single infusion over 10 to 12 hours and aspirin. Due to concerns for Reyes syndrome, IVIG has been given as a single agent with positive results. There are no studies comparing IVIG and aspirin therapy vs IVIG therapy as a single agent. Randomized, controlled studies, and meta-analyses have confirmed that IVIG reduces the risk of cardiovascular aneurysms. IVIG therapy can be repeated if the patient remains febrile 24-36 hours after the IVIG infusion.

Chronic lymphocytic leukemia (CLL), bone marrow transplant, pediatric HIV[23]
Chronic lymphocytic leukemia (CLL), bone marrow transplant (BMT), and HIV are all associated with immunosuppression and an increased risk of infection. Immune globulin can provide additional protection against infection by supplementing humoral immunity.

Clinical indications for which IV immunoglobulin (IVIG) have been licensed by the US Food and Drug Administration (FDA) include prevention of bacterial infections in patients with hypogammaglobulinemia and recurrent bacterial infection due to B-cell chronic lymphocytic leukemia (CLL), prevention of infections, pneumonitis, and acute graft-versus-host disease (GVHD) following bone marrow transplantation, and reduction of serious bacterial infection in children infected with HIV.

The administration of immunoglobulin should be restricted to a carefully selected subset of patients with CLL. Patients with CLL, hypogammaglobulinemia, and recurrent bacterial infections should be considered for immunoglobulin replacement.

In the era before highly active antiretroviral treatment (HAART), HIV-infected children with CD4 T cells greater than 200/µL and symptomatic children (CD4 T cells less than 200/µL and a history of AIDS defining illness) were given replacement doses of immunoglobulin to

prevent bacterial (especially pneumococcal) infections, but improvement was seen only in the group with CD4 T cell levels of greater than 200/µL.

Chronic inflammatory demyelinating polyneuropathy[27]
Chronic inflammatory demyelinating polyneuropathy (CIDP, also known as chronic inflammatory demyelinating polyradiculoneuropathy) is an acquired autoimmune disorder directed against the myelin sheath of peripheral nerves and nerve roots. The diagnosis of CIDP should be considered in patients with symmetric or asymmetric polyneuropathy who have a progressive or relapsing-remitting clinical course for more than two months, particularly if the clinical features include positive sensory symptoms, proximal weakness, or areflexia.

Electrophysiologic testing developed by the European Federation of Neurological Societies and the Peripheral Nerve Society (EFNS/PNS) is necessary to confirm the diagnosis. Definitive CIDP diagnosis has at least one of the following criteria based on electrodiagnostic findings:

- Motor distal latency prolongation in 2 nerves
- Reduction of motor conduction velocity in 2 nerves
- Prolongation of F-wave latency in 2 nerves
- Absence of F-wave latency in at least 1 nerve
- Partial motor conduction block of at least 1 motor nerve
- Abnormal temporal dispersion in at least 2 nerves
- Distal CMAP duration increase in at least 1 nerve

EFNS/PNS diagnostic criteria for CIDP also recommends exclusion of other conditions that include:

- Lyme disease, diphtheria, or drug or toxin exposure likely caused the neuropathy
- Hereditary demyelinating neuropathy
- Prominent sphincter disturbance
- Diagnosis of multifocal motor neuropathy
- Other causes of demyelinating neuropathy (e.g., POEMS syndrome, osteosclerotic myeloma, diabetic and nondiabetic lumbosacral radiculoplexus neuropathy)

Initial treatment for CIDP is immune modulating therapy with IVIG, glucocorticoids, or plasma exchange. Considerations that drive the selection of initial therapy include disease severity, comorbid disorders, venous access, potential adverse effects, availability, and cost. Guidelines recommend the use of a corticosteroid or IVIG for patients with moderate to severe CIDP. IVIG should be considered instead of a corticosteroid for patients with pure motor CIDP based on evidence of deterioration in these patients soon after initiation of a corticosteroid.

Multifocal motor neuropathy
Multifocal motor neuropathy (MMN) is a rare neuropathy characterized by progressive asymmetric weakness and atrophy without sensory abnormalities. The disorder is considered to be immune-mediated. The estimated prevalence of MMN is 0.6 to 2 per 100,000. Men are affected more often than women with a ratio of 2.7:1.[36]

The American Association of Electrodiagnostic Medicine (AAEM) has consensus criteria for the diagnosis of Multifocal Motor Neuropathy.[37]

Criteria for definite multifocal motor neuropathy:

- Weakness without objective sensory loss in the distribution of two or more named nerves. During the early stages of symptomatic weakness, the historical or physical finding of diffuse, symmetric weakness excludes multifocal motor neuropathy

- Definite conduction block is present in two or more nerves outside of common entrapment sites*
- Normal sensory nerve conduction velocity across the same segments with demonstrated motor conduction block
- Normal results for sensory nerve conduction studies on all tested nerves, with a minimum of three nerves tested. The absence of each of the following upper motor neuron signs: spastic tone, clonus, extensor plantar response, and pseudobulbar palsy

*Median nerve at wrist; ulnar nerve at elbow or wrist; peroneal nerve at fibular head

Criteria for probable multifocal motor neuropathy

- Weakness without objective sensory loss in the distribution of two or more named nerves. During the initial weeks of symptomatic weakness, the presence of diffuse, symmetric weakness excludes multifocal motor neuropathy
- The presence of either:
    - Probable conduction block in two or more motor nerve segments that are not common entrapment sites or
    - Definite conduction block in one motor nerve segment and probable conduction block in a different motor nerve segment, neither of which segments are common entrapment sites
- Normal sensory nerve conduction velocity across the same segments with demonstrated motor conduction block, when this segment is technically feasible for study (that is, this is not required for segments proximal to axilla or popliteal fossa)
- Normal results for sensory nerve conduction studies on all tested nerves, with a minimum of three nerves tested
- The absence of each of the following upper motor neuron signs: spastic tone, clonus, extensor plantar response, and pseudobulbar palsy

Treatment for MMN varies. Some people experience only mild symptoms and do not require treatment. For others, treatment generally consists of intravenous immunoglobulin (IVIg) or immunosuppressive therapy with cyclophosphamide.[42] Cyclophosphamide has shown some effectiveness in some reports, but also some toxicity. Rituximab, beta-interferon, mycophenolate mofetil, cyclosporine, azathioprine, and infliximab have also been tried. More research is necessary to determine the long-term safety and effectiveness of these therapies for the treatment of MMN.[36]

Dermatomyositis and Polymyositis

Polymyositis (PM) and Dermatomyositis (DM) are autoimmune myopathies characterized by inflammation and weakness of proximal muscles with extra muscular manifestations. They are also commonly characterized by progressive muscle weakness, myopathic findings on electromyography, elevated creatine kinase (CK) level in serum, as well as inflammatory infiltrates in muscle biopsy.(41) Other diagnostic tests can be performed, such as testing for myositis-specific autoantibodies however, these tests are positive in 45 to 85 percent of patients; thus, a negative myositis panel does not rule out a diagnosis of DM or PM.(39)

PM is rare in childhood and presents mainly after the second decade of life. The most common time of presentation is between 45 and 60 years of age. DM affects both children and adults with an overall female/male ratio of about 2:1.(43) Individuals with dermatomyositis also develop characteristic skin changes (e.g., butterfly rash, heliotrope eruption, Gottron papules) that, in some cases, may precede muscle weakness. Although PM and DM share some common clinical and histological features such as muscle weakness and inflammatory infiltrates on muscle biopsy, they do have certain differences in both terms of presentation and pathophysiology. From the immunological point of view these two diseases

are different. DM is humorally mediated disease whereas PM is T cell mediated disease.(38,39)

Bohan and Peter criteria are most widely used for diagnosis of polymyositis and dermatomyositis:(39)

- Symmetric proximal muscle weakness
- Typical rash of DM (a distinguishing feature for DM from PM)
- Elevated serum muscle enzymes
- Myopathic changes on electromyography

First line treatment for the muscle involvement associated with DM and PM requires the use of glucocorticoids, particularly prednisone. Treatment for the skin findings associated with dermatomyositis includes sun avoidance, sunscreens, topical glucocorticoids, anti-malarial agents, and mycophenolate mofetil.(38) Intravenous immunoglobulin (IVIG) can be used as adjunct therapy or as a single treatment option for severe or refractory disease. IVIG also serves as a reasonable option of treatment in cases where corticosteroids or immunosuppressants are contraindicated, such as severe infections or neoplasia.(41) Studies have demonstrated the efficacy of glucocorticoids in improving muscle strength and achieving prolonged treatment-free remissions. However, IVIG therapy has been shown to be effective in severe and rapidly progressive or refractory PM and DM in several clinical trials.(43)

Additional treatments for refractory cutaneous DM include systemic immunosuppressants (e.g., azathioprine, cyclosporine, tacrolimus, sirolimus, cyclophosphamide, chlorambucil, Janus kinase [JAK] inhibitors, and rituximab) and dapsone. Due to limited or conflicting evidence in support of the efficacy of these agents and the risks for adverse effects associated with many of these drugs, these treatments are typically reserved for patients who have failed or who are poor candidates for IVIG and mycophenolate mofetil.(41)

Hepatitis A (HAV) [19,20]
Hepatitis A (HAV) is usually transmitted via the fecal-oral route either by person-to-person contact or ingestion of contaminated food or water. Transmission is facilitated by poor personal hygiene, poor sanitation, and intimate contact (e.g., intra-household or sexual exposure). Illicit drug users are the most common source of HAV. The incubation period for HAV infection following exposure to the virus ranges from 15-50 days (average of 28 days). Use in HAV patients is to provide passive immunity for pre-exposure or post-exposure prophylaxis in susceptible individuals who are at risk of or have been exposed to the virus. Immune globulin (GamaSTAN S/D) is used for short-term protection against HAV in unvaccinated patients and is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Measles[6,19,20]
Measles is a highly contagious respiratory disease caused by the measles virus. Measles spread through the air by breathing. Symptoms of measles include fever, runny nose, cough and rash all over the body. Immune globulin (GamaSTAN S/D) is used to prevent or modify symptoms of measles in susceptible persons (unvaccinated and has not had measles) exposed to the disease within 6 days previously.

Rubella[6,19,20]
Rubella, also known as German Measles, or three-day measles is a contagious viral infection caused by the rubella virus. The virus is spread through the air or close contact. Immune globulin (GamaSTAN S/D) is recommended as post exposure prophylaxis in susceptible

pregnant women who are exposed to a confirmed case of rubella early in pregnancy, and who will not consider terminating the pregnancy under any circumstances. These women should receive immune globulin within 72 hours of rubella exposure.

Varicella[6]
Varicella-zoster virus (VZV), commonly called the chickenpox, is one of eight herpesviruses known to cause human infection and is found worldwide. The virus is spread through airborne particles, droplets in exhaled air, and fluid from the blisters or sores. Symptoms include fever, weakness, rash and usually appear 14-16 days after exposure. Immune globulin (GamaSTAN S/D) is recommended for post exposure prophylaxis when Varicella-Zoster Immune Globulin is unavailable (e.g., cannot be obtained within 96 hours of exposure).

Safety[1-17, 31-34]
All immune globulins contain a boxed warning for thrombosis. Risk factors include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

There is a boxed warning for renal dysfunction and acute renal failure in all immune globulins except Cutaquig, Cuvitru, GamaSTAN S/D, HyQvia, Hizentra, and Xembify. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or in patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG products containing sucrose. Asceniv, Bivigam, Cutaquig, Cuvitru, Flebogamma DIF, Gammagard Liquid, Gammagard S/D, Gammaked, Gammaplex, Gamunex-C, Hizentra, HyQvia, Octagam 5%, Octagam 10%, Panzyga, Privigen, and Xembify do NOT contain sucrose.

Adverse events of immune globulin therapy can be difficult to classify due to the diversity of components in the formulation. Mild adverse events are common and may include low grade fever, headache, nausea, malaise, and myalgia. Infusion related reactions such as urticaria and fever can be prevented by pre-medicating patients with diphenhydramine and acetaminophen. Tension headache is the most common adverse event associated with immune globulin use and ranges in frequency from 26%-61%. Migraine headaches also occur and are more common in patients with a history of migraines.

Aseptic meningitis has been reported in patients receiving high dose immune globulin, with the majority of patients recovering within five days of symptom onset. Anaphylaxis has rarely occurred with immune globulin. Because immune globulin products are derived from donor plasma, the transmission of infectious particles is possible.

Agent	Contraindications
Asceniv 10% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Bivigam 10% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Carimune NF IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin

	• IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Cutaquig 16.5% SCIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin or other components of Cutaquig (polysorbate 80) • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Flebogamma 5% DIF IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Flebogamma 10% DIF IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
GamaSTAN S/D 15-18% IMIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Gammagard S/D 5% IVIG	• History of anaphylactic or severe systemic reactions to the administration of Gammagard S/D < 1µg/mL in a 5% solution
Gammagard liquid 10% SCIG/IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Gammaked Liquid 10% SCIG/IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Gammaplex 5% liquid IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • Patients with hereditary intolerance to fructose, also in infants and neonates for whom sucrose or fructose tolerance has not been established • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Gammaplex 10% Liquid IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Gamunex-C 10% SCIG/IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Hizentra 20% SCIG	• Anaphylactic or severe systemic reactions to human immunoglobulin or inactive ingredients of Hizentra, such as polysorbate 80 • Hyperprolinemia Type I or II (Hizentra contains stabilizer L-proline) • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity

HyQvia 10% SCIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity • Known systemic hypersensitivity to hyaluronidase including Recombinant Human Hyaluronidase of HyQvia • Known systemic hypersensitivity to human albumin (in the hyaluronidase solution)
Octagam 5% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity • Patients with acute hypersensitivity reaction to corn
Octagam 10% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Panzyga 10% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Privigen 10% IVIG	• History of anaphylactic or severe systemic reactions to human immunoglobulin • Hyperprolinemia (Privigen contains the stabilizer L-proline) • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity
Xembify 20% SCIG	• Anaphylactic or severe systemic reactions to human immunoglobulin or inactive ingredients of Xembify such as polysorbate 80 • IgA-deficient patient with antibodies to IgA and a history of hypersensitivity

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Immune Globulins Prior Authorization

TARGET AGENT(S)
Asceniv™ 10% IVIG
Bivigam® 10% IVIG
Cutaquig 16.5% SCIG
Cuvitru™ 20% SCIG
Flebogamma® 5% DIF IVIG
Flebogamma® 10% DIF IVIG
GamaSTAN® S/D, 15-18% IMIG
Gammagard® S/D 5% IVIG
Gammagard™ Liquid 10% SCIG/IVIG
Gammaked™ Liquid 10% SCIG/IVIG
Gammaplex® 5% Liquid IVIG
Gammaplex® 10% Liquid IVIG
Gamunex®-C 10% SCIG/IVIG
Hizentra® 20% SCIG
HyQvia™ 10% SCIG
Octagam® 5% IVIG
Octagam® 10% IVIG
Panzyga 10% IVIG
Privigen™ 10% IVIG
Xembify 20% SCIG

Brand (generic)	GPI	Multisource Code
Asceniv 10% IVIG		
5 gm/50 mL	19100020802030	M, N, O, or Y
Bivigam 10% IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
Cutaquig 16.5% SCIG		
1 gm	19100020572021	M, N, O, or Y
1.65 gm	19100020572025	M, N, O, or Y
2 gm	19100020572030	M, N, O, or Y
3.3 gm	19100020572035	M, N, O, or Y
4 gm	19100020572040	M, N, O, or Y
8 gm	19100020572055	M, N, O, or Y
Cuvitru 20% SCIG		
1 gm/5 mL	19100020202050	M, N, O, or Y
2 gm/10 mL	19100020202054	M, N, O, or Y
4 gm/20 mL	19100020202058	M, N, O, or Y
8 gm/40 mL	19100020202062	M, N, O, or Y
10 gm/50 mL	19100020202065	M, N, O, or Y
Flebogamma 5% DIF IVIG		
0.5 gm/10 mL	19100020102020	M, N, O, or Y
2.5 gm/50 mL	19100020102034	M, N, O, or Y
5 gm/100 mL	19100020102038	M, N, O, or Y
10 gm/200 mL	19100020102042	M, N, O, or Y
20 gm/400 mL	19100020102044	M, N, O, or Y
Flebogamma 10% DIF IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y

Brand (generic)	GPI	Multisource Code
20 gm/200 mL	19100020102076	M, N, O, or Y
GamaSTAN S/D 15-18% IMIG		
2 mL vial	19100020002200	M, N, O, or Y
10 mL vial	19100020002200	M, N, O, or Y
Gammagard S/D 5% IVIG		
5.0 gm	19100020102120	M, N, O, or Y
10.0 gm	19100020102130	M, N, O, or Y
Gammagard Liquid 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
30 gm/300 mL	19100020302080	M, N, O, or Y
Gammaked 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
Gammaplex 5% Liquid IVIG		
5 gm/100 mL	19100020102038	M, N, O, or Y
10 gm/200 mL	19100020102042	M, N, O, or Y
20 gm/400 mL	19100020102044	M, N, O, or Y
Gammaplex 10% Liquid IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
Gamunex-C 10% SCIG/IVIG		
1 gm/10 mL	19100020302060	M, N, O, or Y
2.5 gm/25 mL	19100020302064	M, N, O, or Y
5 gm/50 mL	19100020302068	M, N, O, or Y
10 gm/100 mL	19100020302072	M, N, O, or Y
20 gm/200 mL	19100020302076	M, N, O, or Y
40 gm/400 mL	19100020302084	M, N, O, or Y
Hizentra 20% SCIG		
1 gm/5 mL	19100020202050	M, N, O, or Y
1 gm/5 mL prefilled syringe	1910002020E520	M, N, O, or Y
2 gm/10 mL	19100020202054	M, N, O, or Y
2 gm/10 mL prefilled syringe	1910002020E530	M, N, O, or Y
4 gm/ 20 mL	19100020202058	M, N, O, or Y
4 gm/20 mL prefilled syringe	1910002020E540	M, N, O, or Y
10 gm/50 mL	19100020202065	M, N, O, or Y
HyQvia 10% SCIG		
2.5 gm/25 mL	19990002356420	M, N, O, or Y
5.0 gm/50 mL	19990002356425	M, N, O, or Y
10.0 gm/100 mL	19990002356430	M, N, O, or Y
20.0 gm/200 mL	19990002356440	M, N, O, or Y
30.0 gm/ 300 mL	19990002356450	M, N, O, or Y
Octagam 5% IVIG		

Brand (generic)	GPI	Multisource Code
1 gm/20 mL	19100020102030	M, N, O, or Y
2.5 gm/50 mL	19100020102034	M, N, O, or Y
5 gm/100 mL	19100020102038	M, N, O, or Y
10 gm/200 mL	19100020102042	M, N, O, or Y
25 gm/500 mL	19100020102046	M, N, O, or Y
Octagam 10% IVIG		
2 gm/20 mL	19100020102063	M, N, O, or Y
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
30 gm/300 mL	19100020102080	M, N, O, or Y
Panzyga 10% IVIG		
1 gm/10 mL	19100020602020	M, N, O, or Y
2.5 gm/25 mL	19100020602025	M, N, O, or Y
5 gm/50 mL	19100020602030	M, N, O, or Y
10 gm/100 mL	19100020602035	M, N, O, or Y
20 gm/200 mL	19100020602040	M, N, O, or Y
30 gm/300 mL	19100020602045	M, N, O, or Y
Privigen 10% IVIG		
5 gm/50 mL	19100020102068	M, N, O, or Y
10 gm/100 mL	19100020102072	M, N, O, or Y
20 gm/200 mL	19100020102076	M, N, O, or Y
40 gm/400 mL	19100020102090	M, N, O, or Y
Xembify 20% SCIG		
1 gm/5 mL	19100020642020	M, N, O, or Y
2 gm/10 mL	19100020642025	M, N, O, or Y
4 gm/20 mL	19100020642030	M, N, O, or Y
10 gm/50 mL	19100020642040	M, N, O, or Y

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy and ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      i. Information has been provided that indicates the patient has been treated with multiple doses of the requested agent within the past 120 days
      OR
      ii. The prescriber states the patient has been treated with the requested agent within the past 120 days AND is at risk if therapy is changed

   OR
   B. If requesting IVIG or SCIG, ONE of the following:

i. The patient has a diagnosis of primary immunodeficiency AND ONE of the following:
    a. The patient has a total IgG less than 200 mg/dL at baseline prior to immune globulin therapy
    OR
    b. The patient has abnormal Bruton tyrosine kinase (BTK) gene/absence of BTK protein
    OR
    c. The patient has an absence of B lymphocytes
    OR
    d. ALL of the following:
        1. ONE of the following:
            A. The patient has selective IgG subclass deficiency [Defined as deficiency of 1 or more IgG subclasses (e.g., IgG1, IgG2, IgG3, or IgG4) by more than 2 standard deviations (SD) below age-specific mean, assessed on 2 separate occasions during infection free period]
            OR
            B. The patient has specific antibody deficiency (SAD) with normal levels of both immunoglobulin and total IgG subclasses
            OR
            C. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy
            OR
            D. The patient has another Primary immunodeficiency [e.g., Common variable immunodeficiency (CVID), X-linked immunodeficiency, severe combined immunodeficiency (SCID), combined immunodeficiency syndromes (e.g., Ataxia Telangiectasia (A-T), DiGeorge syndrome, Wiskott-Aldrich Syndrome)]
        AND
        2. The patient has a lack of response or inability to mount an adequate response to protein and/or polysaccharide antigens (e.g., inability to make IgG antibody against either diphtheria and tetanus toxoids, or pneumococcal polysaccharide vaccine, or both)
        AND
        3. The patient has evidence of recurrent, persistent, severe, difficult-to-treat infections (e.g., recurring otitis media, bronchiectasis, recurrent infections requiring IV antibiotics) despite aggressive prophylactic management and treatment with antibiotics

OR

ii. The patient has a diagnosis of B-cell Chronic lymphocytic leukemia AND ONE of the following:
    a. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy

OR

b. The patient has history of recurrent bacterial infections requiring antibiotics and/or hospitalization

OR

iii. The patient has a diagnosis of idiopathic thrombocytopenia purpura (ITP) and ONE of the following:
    a. The patient's medication history includes ONE conventional therapy (e.g., corticosteroids) for ITP AND ONE of the following:
        1. The patient has had an inadequate response to ONE conventional therapy (e.g., corticosteroids) for ITP
        OR
        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy (e.g., corticosteroids) for ITP

    OR

    b. The patient has an intolerance or hypersensitivity to ONE conventional therapy (e.g., corticosteroids)

    OR

    c. The patient has an FDA labeled contraindication to ALL conventional therapy (e.g., corticosteroids)

    OR

    d. The patient is currently being treated with the requested agent as indicated by ALL of the following:
        1. A statement by the prescriber that the patient is currently taking the requested agent
        AND
        2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
        AND
        3. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR

    e. The prescriber has provided documentation that conventional therapy (e.g., corticosteroids) for ITP cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

OR

iv. The requested agent will be used for the prevention of bacterial infection in HIV-infected children AND ALL of the following:
    a. The patient is < 13 years old
    AND
    b. CD4 count is > 200/µL
    AND
    c. The patient has hypogammaglobulinemia defined as total IgG < 700 mg/dL OR more than 2 standard deviations below mean for the patient's age at baseline prior to immune globulin therapy

OR

v. The patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) AND ALL of the following:

a. The patient has progressive symptoms present for at least 2 months

AND

b. The patient has progressive or relapsing motor sensory impairment of more than one limb

AND

c. The patient has electrodiagnostic findings indicating at least ONE of the following are present:
    1. Motor distal latency prolongation in 2 nerves

    OR

    2. Reduction of motor conduction velocity in 2 nerves

    OR

    3. Prolongation of F-wave latency in 2 nerves

    OR

    4. Absence of F-waves in at least 1 nerve

    OR

    5. Partial motor conduction block of at least 1motor nerve

    OR

    6. Abnormal temporal dispersion in at least 2 nerves

    OR

    7. Distal CMAP duration increase in at least 1 nerve

AND

d. The prescriber is a specialist (e.g., neurologist) in the area of the patient's diagnosis or has consulted with a specialist in the area of the patient's diagnosis

OR

vi. The patient has a diagnosis of multifocal motor neuropathy AND BOTH of the following:
    a. The diagnosis was confirmed by ALL of the following:
        1. Weakness with slowly progressive or stepwise progressive course over at least 1 month

        AND

        2. Asymmetric involvement of two or more nerves

        AND

        3. Absence of motor neuron signs and bulbar signs

    AND

    b. The prescriber is a specialist (e.g., neurologist) in the area of the patient's diagnosis or has consulted with a specialist in the area of the patient's diagnosis

OR

vii. The patient has a diagnosis of Kawasaki disease

OR

viii. The patient has a diagnosis of Guillain-Barre syndrome

OR

ix. The requested agent will be used for prevention of infection or graft vs host disease following bone marrow transplantation AND the bone marrow transplant was within the last 100 days

OR

x. The patient has a diagnosis of dermatomyositis and BOTH of the following:
    a. ONE of the following:
        1. The patient's medication history includes ONE conventional therapy [e.g., corticosteroids (e.g.,

prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis AND ONE of the following:

A. The patient has had an inadequate response to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis

OR

B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for dermatomyositis

OR

2. The patient has an intolerance or hypersensitivity to ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

OR

3. The patient has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) and immunosuppressants (e.g., azathioprine, mycophenolate)]

OR

4. The patient is currently being treated with the requested agent as indicated by ALL of the following:

A. A statement by the prescriber that the patient is currently taking the requested agent

AND

B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent

AND

C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

OR

5. The prescriber has provided documentation that ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

b. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, immunologist) or has consulted with a specialist in the area of the patient's diagnosis

xi. The patient has a diagnosis of polymyositis and BOTH of the following:

a. ONE of the following:

1. The patient's medication history includes conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis AND ONE of the following:
    A. The patient has had an inadequate response to conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis
    OR
    B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis

    OR
2. The patient has an intolerance or hypersensitivity ONE conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

    OR
3. The patient has an FDA labeled contraindication to ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)]

    OR
4. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

    OR
5. The prescriber has provided documentation that ALL conventional therapy [e.g., corticosteroids (e.g., prednisone) or immunosuppressants (e.g., azathioprine, mycophenolate)] for polymyositis cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

b. The prescriber is a specialist in the area of the patient's diagnosis (e.g., immunologist, rheumatologist) or has consulted with a specialist in the area of the patient's diagnosis

OR

xii. The patient has another FDA approved indication for the requested agent and route of administration
OR
xiii. The patient has another indication that is supported in compendia for the requested agent and route of administration

AND

2. If requesting IMIG, ONE of the following:
   A. The patient has a diagnosis of hepatitis A AND BOTH of the following:
      i. The patient requires pre-exposure or post-exposure prophylaxis (exposure is within the previous 14 days)
      AND
      ii. ONE of the following:
         a. The patient cannot be vaccinated due to age (<12 months)
         OR
         b. The patient has a vaccination allergy OR has refused vaccination
         OR
         c. The patient is an infant born to a mother with acute hepatitis A infection

   OR

   B. The patient has a diagnosis of measles AND ALL of the following:
      i. The patient has been exposed to measles within the past 6 days
      AND
      ii. The patient is unvaccinated
      AND
      iii. The patient has NOT previously had measles

   OR

   C. The patient has a diagnosis of rubella AND BOTH of the following:
      i. The patient is pregnant
      AND
      ii. The patient requires post exposure prophylaxis within 72 hours of exposure to reduce the risk of infection and fetal damage

   OR

   D. The patient has a diagnosis of varicella AND ALL of the following:
      i. The patient is immunocompromised
      AND
      ii. The patient requires post exposure prophylaxis
      AND
      iii. Varicella zoster immune globulin is not available (cannot obtain vaccine within 96 hours of exposure)

   OR

   E. The patient has another FDA approved indication for the requested agent and route of administration
   OR
   F. The patient has another indication that is supported in compendia for the requested agent and route of administration

AND

3. If the patient has an FDA approved indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

5. ONE of the following:
    A. The requested dose does not exceed the maximum FDA labeled dose or the compendia supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN 1 or 2a level of evidence) for the requested indication
    OR
    B. The prescriber has provided information in support of therapy with the requested dose for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2A level of evidence, or NCCN 1 or 2a recommended

Length of Approval:

Indication	Length of Approval
Measles, Rubella, Varicella	One time
Guillain-Barre Syndrome	3 months
Hepatitis A	3 months
Kawasaki disease	3 months
Prevention of infection following bone marrow transplant	3 months
Privigen for CIDP	6 months
All other indications	12 months

Renewal Evaluation
Target Agent(s) will be approved when ALL of the following are met:
1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
    AND
2. ONE of the following:
    A. The patient was previously approved for short term use of the requested agent (i.e., ≤ 6 months) (refer to length of approval table) AND the prescriber has provided information supporting continued use of the requested agent
    OR
    B. The patient was previously approved for more than 6 months AND ONE of the following:
        i. The patient has had clinical improvement or stabilization with the requested agent (e.g., IgG level has improved from pre-treatment levels with the requested agent, reduction in the number and/or severity of difficult to treat infections, reduction in seizure frequency)
        OR
        ii. The prescriber has provided information in support of continued use of the requested agent

    AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent
    AND
4. ONE of the following:
    A. The requested dose does not exceed the maximum FDA labeled dose or the compendia supported dose for the requested indication
    OR
    B. The prescriber has provided information in support of the requested dose for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval:

Indication	Length of Approval
Measles, Rubella, Varicella	One time
Guillain-Barre Syndrome	3 months
Hepatitis A	3 months
Kawasaki disease	3 months
Prevention of infection following bone marrow transplant	3 months
Privigen for CIDP	6 months
All other indications	12 months

Primary Humoral Immune Deficiency Testing Table
Serum antibody titers to tetanus and/or diphtheria • Initial serum antibody titer to be collected prior to immunization, and then collected again 3-4 weeks after immunization • Inadequate response is defined as < 4-fold increase in antibody titer and lack of protective antibody level (as defined by laboratory)
Serum antibody titer to pneumococcus • Initial serum antibody titer to be collected prior to immunization and then collected again 3-6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (Pneumovax 23) • Inadequate response is defined as failure to increase baseline titer at least 2-fold or failure to generate a protective antibody titer (defined as IgG concentration > 1.3 mcg/mL • Overall failure is failure in 12 or more serotypes (50% or more) in a child under 6 years of age or failure in 7 or more serotypes (30%) in patients age 6 years or older