IVIG (immune globulin)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2024
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Line of Business: Medicare, Commercial, Medicaid - Kentucky, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Hizentra subcutaneous solution
Gammaked injection solution
Gamunex-C injection solution
Hyqvia subcutaneous solution
Privigen intravenous solution
Cuvitru subcutaneous solution
Panzyga intravenous solution
Cutaquig subcutaneous solution
Xembify subcutaneous solution
Asceniv intravenous solution
Hizentra subcutaneous syringe
Bivigam intravenous solution
Carimune NF Nanofiltered intravenous solution
Flebogamma DIF intravenous solution
GamaSTAN S/D intramuscular solution
Gamunex intravenous solution
Gammagard Liquid injection solution
Gammagard S/D intravenous solution
Octagam intravenous solution
Hizentra subcutaneous syringe
Hizentra subcutaneous solution
GamaSTAN intramuscular solution
GamaSTAN S/D intramuscular solution

Listed Indications

Primary Humoral Immunodeficiency
Idiopathic/Immune Thrombocytopenia Purpura (ITP)
Chronic Lymphocytic Leukemia (CLL, B-cell)
Kawasaki Disease (Mucocutaneous Lymph Node Syndrome)
Bone Marrow Transplant (BMT)
Hematopoietic Stem Cell Transplantation (HSCT)
AIDS/HIV
Infections in Low-Birth Weight Neonates
Toxic Shock Syndrome
Autoimmune Neutropenia
Autoimmune Hemolytic Anemia
Myasthenia Gravis
Guillain-Barre Syndrome
Polymyositis / Dermatomyositis
Multifocal Motor Neuropathy (MMN)
Relapsing-remitting Multiple Sclerosis

Parvovirus B19 Infection, chronic
Chronic Inflammatory Demyelinating Polyneuropathies (CIDP)
Lambert Eaton Myasthenic Syndrome (LEMS)
Allosensitized Solid Organ Transplantation
Autoimmune Blistering Diseases
Hemolytic Disease of the Newborn
Multiple Myeloma
Prevention of Bacterial or Viral Infections in Non-primary Immunodeficiency Members
Stiff-Person Syndrome (Moersch-Woltmann Syndrome)
Systemic Lupus Erythematosus (SLE)

Primary Humoral Immunodeficiency	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has a diagnosis of a primary humoral immunodeficiency disorder such as: • Primary immunoglobulin deficiency syndrome • X-linked immunodeficiency with hyperimmunoglobulin M • Severe combined immunodeficiency disorder • Wiskott-Aldrich syndrome • Common variable immunodeficiency • Congenital agammaglobulinemia (X-linked agammaglobulinemia) **OR** The member has documented hypogammaglobulinemia (defined as serum trough IgG < 600 mg/dL)
Criteria #3	BvsD Coverage Determination may also be required
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Idiopathic/Immune Thrombocytopenia Purpura (ITP)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of

	prior therapy within the past 365 days.
Criteria #2	The member has a diagnosis of Acute ITP with any of the following conditions: • Management of acute bleeding due to severe thrombocytopenia (platelet count < 30,000/µL) • To increase platelet counts prior to invasive major surgical procedures (splenectomy) • Severe thrombocytopenia (platelet count < 20,000/µL), considered to be at risk for intracerebral hemorrhage
Criteria #3	The member has a diagnosis of Chronic ITP and ALL of the following conditions are met: • Prior treatment has included corticosteroids • No concurrent illness/disease explaining thrombocytopenia • Platelet counts persistently at or below 20,000/µL
Criteria #4	BvsD Coverage Determination may also be required
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Chronic Lymphocytic Leukemia (CLL, B-cell)

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has B-cell CLL with either of the following present: • Hypogammaglobulinemia (defined as IgG< 600mg/dL) • Recurrent bacterial infections associated with B-cell CLL.
Criteria #3	BvsD Coverage Determination may also be required
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Kawasaki Disease (Mucocutaneous Lymph Node Syndrome)

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred

	product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with Kawasaki Syndrome within ten days of onset of disease manifestations or is diagnosed after ten days of disease onset and continues to exhibit manifestations of inflammation or evolving coronary artery disease.
Criteria #3	IVIG (immune globulin) is used in combination with high dose aspirin for the prevention of coronary artery aneurysms associated with Kawasaki syndrome.
Criteria #4	BvsD Coverage Determination may also be required
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Bone Marrow Transplant (BMT)

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member is hypogammaglobulinemic (IgG < 400mg/dL). Note: IVIG (immune globulin) is used to decrease the risk of septicemia and other infections, interstitial pneumonia of infectious or idiopathic etiologies and acute graft-versus-host disease.
Criteria #3	BvsD Coverage Determination may also be required
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Hematopoietic Stem Cell Transplantation (HSCT)

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Pediatric, adolescent, or adult member is within first 100 days of allogenic hematopoietic stem cell transplantation.
Criteria #3	Member is experiencing hypogammaglobulinemia (serum IgG level 90 days afterHSCT is not recommended in absence of hypogammaglobulinemia.

	Note: Routine administration of IVIG (immune globulin) >90 days after HSCT is not recommended in absence of hypogammaglobulinemia.
Criteria #4	BvsD Coverage Determination may also be required
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AIDS/HIV

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	HIV-infected member is younger than 13 years of age and has any of the following conditions: • CD4+ T-cell counts ≥ 200/mm3 • To prevent maternal transmission of HIV infection • IVIG (immune globulin) is used in conjunction with zidovudine or other antiretroviral treatment to prevent serious bacterial infections in HIV-infected members who have hypogammaglobulinemia (serum IgG less than 400 mg/dL).
Criteria #3	BvsD Coverage Determination may also be required
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Infections in Low-Birth Weight Neonates

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Prophylaxis and treatment of infections in high-risk, preterm, low-birth weight members. Note: IVIG (immune globulin) should not be used routinely for prophylaxis or treatment of nosocomial infections in preterm, low-birth weight members.
Criteria #3	BvsD Coverage Determination may also be required
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Toxic Shock Syndrome	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with staphylococcal or streptococcal toxic shock syndrome.
Criteria #3	Infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or the member has persistent oliguria with pulmonary edema.
Criteria #4	BvsD Coverage Determination may also be required
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Autoimmune Neutropenia	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with autoimmune neutropenia
Criteria #3	G-CSF therapy is not appropriate treatment for the member.
Criteria #4	BvsD Coverage Determination may also be required
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Autoimmune Hemolytic Anemia	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.#

	#For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with warm-type autoimmune hemolytic anemia that is refractory to corticosteroid therapy and splenectomy, or for those whom corticosteroid therapy and splenectomy is contraindicated.
Criteria #3	BvsD Coverage Determination may also be required
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Myasthenia Gravis

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with myasthenia gravis and is experiencing acute myasthenic crisis with decompensation (respiratory failure or disabling weakness)
Criteria #3	Other treatments have been unsuccessful or contraindicated (e.g., corticosteroids, azathioprine, cyclosporine, and cyclophosphamide). **Note:** Plasmapheresis may be preferred in members with myasthenic crisis.
Criteria #4	BvsD Coverage Determination may also be required
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Guillain-Barre Syndrome

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member is severely affected by the disease and requires an aid to walk
Criteria #3	BvsD Coverage Determination may also be required
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Polymyositis / Dermatomyositis	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with biopsy proven polymyositis OR dermatomyositis and has failed treatment with corticosteroids and azathioprine or methotrexate.
Criteria #3	BvsD Coverage Determination may also be required
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Multifocal Motor Neuropathy (MMN)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with multifocal motor neuropathy confirmed by electro-physiologic studies that rule out other possible conditions that may not respond to IVIG (immune globulin) therapy.
Criteria #3	BvsD Coverage Determination may also be required
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Relapsing-remitting Multiple Sclerosis	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with relapsing-remitting multiple sclerosis and has failed

	conventional therapy (e.g., Betaseron, Avonex, Rebif, Copaxone, etc.).
Criteria #3	BvsD Coverage Determination may also be required
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Parvovirus B19 Infection, chronic	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member has chronic Parvovirus B19 infection with severe anemia associated with bone marrow suppression.
Criteria #3	BvsD Coverage Determination may also be required
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Chronic Inflammatory Demyelinating Polyneuropathies (CIDP)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member is diagnosed with CIDP and has not responded to corticosteroid treatment.
Criteria #3	One of the following clinical/electro-diagnostic criteria are met: • There is electro-diagnostic evidence of demyelinating neuropathy in at least two limbs, resulting in muscle weakness or sensory dysfunction OR • There is muscle weakness and diagnostic testing was conducted in accordance with American Academy of Neurology (AAN) diagnostic criteria. **Note:** IVIG (immune globulin) treatment either used alone or following therapeutic plasma exchange.
Criteria #4	BvsD Coverage Determination may also be required
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Lambert Eaton Myasthenic Syndrome (LEMS)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Member has diagnosis of Lambert Eaton myasthenic syndrome confirmed by electro-physiologic studies.
Criteria #3	Member has not responded to diaminopyridine (DAP), azathioprine, corticosteroids, or anticholinesterases (e.g. pyridostigmine).
Criteria #4	BvsD Coverage Determination may also be required
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Allosensitized Solid Organ Transplantation	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Allosensitized members who are awaiting solid organ transplant.
Criteria #3	BvsD Coverage Determination may also be required
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Autoimmune Blistering Diseases	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has a biopsy-proven diagnosis of an autoimmune blistering disease such as:

	• epidermolysis bullosa acquisista • bullous pemphigoid • gestational pemphigoid • pemphigus vulgaris • pemphigus follaceus • mucous membrane pemphigoid • linear IgA disease, etc.
Criteria #3	The member has tried and failed conventional therapy or has contraindications to conventional therapy, or the member has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. **Note:** IVIG (immune globulin) should be given along with conventional treatment(s) and used only until conventional therapy could take effect.
Criteria #4	BvsD Coverage Determination may also be required
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Hemolytic Disease of the Newborn

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	Neonate is diagnosed with isoimmune hemolytic disease. Note: IVIG (immune globulin) is used in conjunction with phototherapy to reduce the number of exchange perfusions.
Criteria #3	BvsD Coverage Determination may also be required
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Multiple Myeloma

Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has recurrent serious or life-threatening infections, OR The member is experiencing

	hypogammaglobulinemia (IgG less than or equal to 400mg/dL)
Criteria #3	BvsD Coverage Determination may also be required
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Prevention of Bacterial or Viral Infections in Non-primary Immunodeficiency Members	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	IVIG (immune globulin) is used in conjunction with appropriate anti-infective therapy to prevent or modify acute bacterial or viral infections and one of the following: • Member is experiencing iatrogenically induced (i.e., immunosuppressant therapy) or disease associated immunosuppression such as members undergoing major surgery (e.g. cardiac transplants) **OR** • Member is diagnosed with a hematologic malignancy (i.e. multiple myeloma), extensive burns, or collagen-vascular disease
Criteria #3	BvsD Coverage Determination may also be required
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Stiff-Person Syndrome (Moersch-Woltmann Syndrome)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has a diagnosis of stiff-person syndrome (Moersch-Woltmann Syndrome)
Criteria #3	Other interventions (diazepam therapy) have been unsuccessful or are intolerable or are contraindicated.
Criteria #4	BvsD Coverage Determination may also be required
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Systemic Lupus Erythematosus (SLE)	
Does the member meet all of the following criteria?	
Criteria #1	For **medical benefit** requests the following are preferred products: Flebogamma DIF, Gammagard, Gammagard S/D, Gammaked, Gamunex-C, Hizentra, Octagam, Privigen and Xembify. For **Medicare Part D** requests, Humana's preferred product is Gamunex-C. For **non-preferred** product requests the member must have had prior therapy or intolerance with a preferred product.# #For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.
Criteria #2	The member has active and chronic SLE that is refractory to standard corticosteroid therapy or in members with hemolytic anemia or thrombocytopenia.
Criteria #3	BvsD Coverage Determination may also be required
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Background

This is a prior authorization policy about IVIG (immune globulin).

Key points around IVIG (immune globulin) include:

- When a patient has a rapidly progressive disease where a clinical response cannot be affected quickly enough using conventional agents, immune globulin can be given along with conventional treatment(s).The continued administration of immune globulin is not considered medically necessary once conventional therapy takes effect.
- Subcutaneous administration of immune globulin is an alternative to intravenous therapy for patients who meet the medical necessity criteria for intravenous immune globulin.
- Once IVIG (immune globulin) treatment is initiated, there should be adequate documentation of progress and clinical monitoring.
- Administration of IVIG (immune globulin) should not exceed the recommended rate of infusion, which is 4 mg/kg/hr.Vital signs should be monitored continuously during infusion of IVIG (immune globulin) and the patient observed throughout the infusion.
- Urine output and renal function (BUN and serum creatinine) should be assessed prior to and at appropriate intervals during IVIG (immune globulin) therapy.To minimize the risk of acute renal, patients should be adequately hydrated prior to IVIG (immune globulin) administration.Patients at risk for developing acute renal failure include those with any preexisting renal insufficiency, diabetes mellitus, volume depletion, sepsis, or paraproteinemia, those receiving nephrotoxic drugs and those over the age of 65 years.
- Patients with thrombotic risk factors, including advanced age, hypertension, Cerebrovascular disease, coronary artery disease, diabetes mellitus, high serum levels of a monoclonal protein, a history of prolonged immobilization, and/or a history of thrombotic episodes should be evaluated before IVIG (immune globulin) administration due to the risk of developing thrombotic events.

- Patients should also be monitored for clinical signs and symptoms of hemolysis and adverse pulmonary reactions.
- Because IVIG (immune globulin) is prepared from pooled human plasma, there is the potential risk for transmission of human viruses including viral hepatitis, HIV, and Creutzfeldt-Jakob disease.
- Contraindications to IVIG (immune globulin) therapy include previous anaphylactic or severe systemic reactions to IVIG (immune globulin) and IgA deficient patients with antibodies against IgA and a history of hypersensitivity.

IVIG (immune globulin) is a sterile, non-pyrogenic solution of globulins containing many antibodies normally present in adult human blood. It is officially designated in the United States as IGIV but is commonly referred to as IVIG. Immune globulin intramuscular (IGIM), immune globulin intravenous (IGIV), and immune globulin subcutaneous (IGSC) are used as replacement therapy in individuals with primary immunodeficiency diseases. They provide a broad spectrum of IgG antibodies against a wide variety of bacterial and viral agents. IGIM and IGIV are also used to provide passive immunity in susceptible patients exposed to certain infectious diseases when there is no vaccine available for active immunization against the disease, when the susceptible patient is allergic to a vaccine component, or when there is insufficient time for active immunization to stimulate antibody production. In addition, certain IVIG (immune globulin) preparations are also used as replacement therapy in patients with antibody-deficiency syndromes, treatment of autoimmune diseases such as idiopathic thrombocytopenia purpura, and Kawasaki disease.
There are multiple IVIG (immune globulin) products from multiple manufacturers that are commercially available. It is made from large pools of human plasma. To prevent the transmission of human viruses, blood donors are screened and the manufacturing process employs several methods of viral inactivation. IVIG (immune globulin) products differ according to the viral inactivation process, sugar content, IgA content, dosage from (lyophilized or solution), dosage strength (5% or 10%) and storage requirements. Product selection is based on availability of IVIG (immune globulin) and patient characteristics. Examples of current FDA approved IVIG (immune globulin) products include Asceniv, Bivigam, Carimune NF, Cutaquig 16.5%, Flebogamma 5%, Gamastan S/D, Gamunex-C 10%, Gammagard S/D, Gammagard Liquid 10%, Gammaked, Gammaplex 5%, Gammaplex 10%, , Octagam 5%, Panzyga 10%, Privigen. Gammagard Liquid 10%, Hizentra 20%, Gammaked 10%, Gamunex-C, HyQvia 10%, Xembify 20%, and Cuvitru 20% are examples of a commercially available product for subcutaneous administration.

Each product may have different FDA approved indications; thus, specific product information, product availability, and patient characteristics should be taken into account when selecting therapy. Some of the main FDA approved indications include the treatment of primary immune deficiency disorder, prevention of bacterial infection in patients with hypogammaglobulinemia due to B cell chronic lymphocytic leukemia, prevention of coronary artery aneurysms in Kawasaki disease, and increasing platelet count in idiopathic thrombocytopenic purpura to prevent bleeding.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

IVIG; immune globulin; Asceniv; Bivigam; Carimune NF; Cutaquig; Cuvitru; Flebogamma; Gamastan; Gamunex; Gammagard S/D; Gammagard Liquid; Polygam S/D; Octagam; Vivaglobin; Hizentra; Gammaked; Gamunex-C; HyQvia; Panzyga, primary immune deficiency disorder, prevention of bacterial infection hypogammaglobulinemia chronic lymphocytic leukemia, Kawasaki disease, idiopathic thrombocytopenic purpura; bone marrow/stem cell transplant; HIV/AIDS; hepatitis; inflammatory; multiple sclerosis; autoimmune; intravenous; subcutaneous; pharmacy

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