MASSACHUSETTS

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Pharmacy Medical Policy
Immunoglobulins Policy

Table of Contents

Policy Number: 310

BCBSA Reference Number: 8.01.05

Related Policies

See medical policy #422, RSV Immunoprophylaxis (RSV-IVIg)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Pharmacy Operations by completing the Prior Authorization Form on the last page of this document.

This medication is covered by the pharmacy benefit. It is also covered under the Home Infusion Therapy benefit.
We may cover intravenous immunoglobulin (IVIg) and subcutaneous IG for the following diagnoses only:

Blood disorders

- Bone marrow transplant patients (for prevention of infection or GVH prevention)
- Multiple myeloma and immunoproliferative neoplasms
- Immune neutropenia
- Multiple myeloma without mention of remission
- Multiple myeloma in remission
- Other immunoproliferative neoplasms without mention of remission
- Other immunoproliferative neoplasms in remission
- Agranulocytosis
- Common variable immunodeficiency, severe combined immunodeficiency, Wiskott-Aldrich syndrome, and X-linked (X-linked Agammaglobulinemia & X-linked hyperimmunoglobulinemia M syndrome) immunodeficiency
- Fetal / Neonatal alloimmune thrombocytopenia
- Autoimmune (warm antibody) hemolytic anemia who are refractory to prednisone and splenectomy
- Agammaglobulinemia -primary humoral immunodeficiency
- Hypogammaglobulinemia -primary humoral immunodeficiency
- Chronic lymphocytic leukemia (CLL) with frequent infections and

IgG levels are less than 400mg/dl
- Idiopathic thrombocytopenic purpura (ITP).

Infectious diseases
- HIV and AIDS
- Prevention of infection in HIV-infected children and IgG levels are less than 400mg/dl
- Prior to solid organ transplant, treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ
- Solid organ transplant recipients at risk for cytomegalovirus infections and pneumonia.
- Severe Anemia associated with human parvovirus B19.
- Toxic Shock Syndrome

Neurologic conditions:
- Guillain-Barré Syndrome (GBS)
- Chronic severe myasthenia gravis, for severe exacerbations causing disability
- Myasthenic crisis/exacerbations (i.e., an acute episode of respiratory muscle weakness) in patients with a contraindication to plasma exchange
- Severe refractory Myasthenia gravis in patients with chronic debilitating disease despite treatment with cholinesterase inhibitors, or complications from or failure of corticosteroids and/or azathioprine.
- Hereditary and idiopathic peripheral neuropathy
- Peroneal muscular atrophy
- Hereditary sensory neuropathy
- Idiopathic progressive polyneuropathy
- Multiple Sclerosis: for patients with relapsing-remitting disease (not primary or secondary progressive MS)
- Chronic inflammatory demyelinating polyneuropathy
- Demyelinating polyneuropathy associated with IgM paraproteinemia
- Multifocal motor neuropathy in patients with GM1 antibodies and conduction block
- Stiff-Person/Man syndrome

Other:
- Dermatomyositis/polymyositis which is refractory to treatment with corticosteroids in combination with other immunosuppressive agents.
- Kawasaki syndrome
- Prior to solid organ transplant; treatment of patients at high risk of antibody-mediated rejection, including highly sensitized patients, and those receiving an ABO incompatible organ, Effective January 2007
- Following solid organ transplant; treatment of antibody-mediated rejection. Effective January 2007.
- Patients with neuromyelitis optica as an alternative for patients with contraindication or lack of response to first-line treatment.
- Patients with severe, progressive autoimmune mucocutaneous blistering diseases that include pemphigus vulgaris (L10.0), pemphigus foliaceus (L10.2) bullous pemphigoid (L12.0) and mucous membrane pemphigoid (L12.1) who have failed treatment with conventional agents such as corticosteroids, azathioprine and cyclophosphamide.
- Ataxia telangiectasia
- Wegener's granulomatosis
- Eaton-Lambert myasthenic syndrome who have failed to respond to anticholinesterase medications and/or corticosteroids.
- Antiphospholipid syndrome
- Hemolytic disease of the fetus and newborn (aka erythroblastosis fetalis)
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS) and Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)

We do not cover intravenous immunoglobulin in the following conditions:

Blood disorders
- Acquired factor VIII inhibitors
- Acute lymphoblastic leukemia
- Aplastic anemia
- Diamond-Blackfan anemia
- Hemophagocytic syndrome
- Nonimmune thrombocytopenia
- Red cell aplasia
- Thrombotic thrombocytopenic purpura.

Rheumatologic diseases
- Behcet's syndrome
- Inclusion body myositis, because it does not work in this disorder
- Rheumatoid arthritis and other connective tissue diseases including systemic lupus erythematosus
- Scleroderma
- Systemic Lupus Erythematosis
- Other vasculitides besides Kawasaki disease; including vasculitis associated with anti-neutrophil cytoplasmic antibodies (ANCA; e.g., polyarteritis nodosa), Goodpasture's syndrome, and vasculitis associated with other connective tissue diseases.

Neurologic conditions
- Epilepsy
- Multiple sclerosis: primary progressive or secondary progressive types, because it has not been shown to offer additional health benefits to patients with these types of MS
- Paraneoplastic syndromes excluding Eaton-Lambert syndrome.

Infectious
- Chronic sinusitis
- Recurrent otitis media.

Other
- Adrenoleukodystrophy
- Asthma
- Chronic fatigue syndrome
- Cystic fibrosis
- Diabetes mellitus
- Hemolytic uremic syndrome
- Idiopathic lumbosacral flexopathy
- Recurrent fetal loss
- Recurrent Spontaneous Abortion
- Epidermolysis bullosa aquisita
- Recurrent spontaneous pregnancy loss
- Idiopathic environmental illness
- Myasthenia gravis in patients responsive to immunosuppressive treatment
- Post-infectious sequelae
- Organ transplant rejection
- Uveitis
- Demyelinating optic neuritis
- Recent onset dilated cardiomyopathy
- Other disorders not listed above.

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members
Coverage Indications, Limitations, and/or Medical Necessity

Effective October 1, 2002, IVIg is covered for the treatment of biopsy-proven (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita for the following patient subpopulations:

- Patients who have failed conventional therapy. Medicare Administrative Contractors (MACs) have the discretion to define what constitutes failure of conventional therapy;
- Patients in whom conventional therapy is otherwise contraindicated. Contractors have the discretion to define what constitutes contraindications to conventional therapy; or
- Patients with rapidly progressive disease in whom a clinical response could not be affected quickly enough using conventional agents. In such situations IVIg therapy would be given along with conventional treatment(s) and the IVIg would be used only until the conventional therapy could take effect.

In addition, IVIg for the treatment of autoimmune mucocutaneous blistering diseases must be used only for short-term therapy and not as a maintenance therapy. Contractors have the discretion to decide what constitutes short-term therapy.

National Coverage Determination (NCD) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3)

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, see link below:

Link to Specialty Pharmacy List

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS Codes

HCPCS codes:	Code Description
C9072	Injection, immune globulin asceniv , 500 mg
J0850	Injection, cytomegalovirus immune globulin intravenous (human), per vial [Cytogam]
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin Bivigam , 500 mg

J1557	Injection, immune globulin, Gammaplex, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1558	Injection, immune globulin Xembify, 100 mg
J1559	Injection, immune globulin Hizentra, 100 mg
J1561	Injection, immune globulin, Gamunex / Gamunex-C / Gammaked , nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), 500 mg [Carimune, Panglobulin]
J1568	Injection, immune globulin, Octagam, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, Gammagard liquid, intravenous, nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, Flebogamma/Flebogamma Dif, intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, Hyqvia, 100 mg immuneglobulin
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
J3590	Unclassified biologics (i.e. Asceniv, Cutaquig, Panzyga)

Other Information
Preferred Home Infusion Therapy Network
Referring providers are encouraged to use these preferred Home Infusion providers to obtain these medications.

Preferred Home Infusion Therapy Provider Contact Information:
Accredo Health Group Phone: 1 866-759-1557 For Hemophilia therapies only, 1-866-712-5007 Website: www.accredo.com
Caremark, LLC. Phone: 1-866-846-3096 Website: www.caremark.com
Coram™ Specialty Infusion Services Phone: 1-800-678-3442 For Hemophilia therapies only, 1-888-699-7440 Website: www.coramhc.com

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Prior Authorization Information

Oupatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

Policy History

Date	Action
7/2022	Renamed policy to be inclusive of IV and SubQ products.
12/2021	BCBSA National medical policy review. No changes to policy statements. New references added.
2/2021	Updated to add PANDAS & PANS in line with state mandate.
1/2021	Coding information clarified.
12/2020	BCBSA National medical policy review. No changes to policy statements. New references added.
10/2020	Clarified coding information
4/2020	Updated to add Asceniv to the policy.
11/2019	Updated to add Xembify to the policy.
7/2019	Updated to add Cutaquig to the policy.
1/2019	Clarified coding information.
8/2018	Updated to include Association coverage statement for Neuromyelitis Optica & Blistering disease.
10/2017	Clarified coding information plus updated to change Walgreens Specialty Name.
7/2017	Updated to add AllCare to Pharmacy Specialty list.
6/2017	Updated address for Pharmacy Operations.
1/2016	Updated to add new HCPCS code J1575.
10/2015	Updated to included revised language for Pharmacy only medications.
7/2015	Update to include Retail billing.
6/2015	Updated to include Bivigam, Cytogam, Gammaplex, Hizentra and HyQvia and to align ICD codes.
2/2015	Updated to include a couple HCPCS codes and one ICD code.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
1/2014	Updated ExpressPAth Language.
1/2013	Updated 1/2013 to include new FDA products Gammaked ™ and Gamunex ®-C.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
11/2011	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2010	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
10/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.

9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2009	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
10/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
10/2009	Updated to reflect UM requirements.
1/2009	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/2008	Reviewed - Medical Policy Group - Plastic Surgery and Dermatology. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
9/2007	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

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Endnotes

1. Revised 9/95 based on TEC (Technology Evaluation Center) 6/95 assessment of medical literature from 1991 to 1995 addressing IVIg for SLE-related cytopenia, vasculitis, pericarditis, and pleural effusions in patients who were not controlled by immunosuppressives or cytotoxic agents.
2. Revised 9/95 to include the 2/95 TEC evaluation of medical literature from 1991-4/95 assessing IVIg to improve the functional status of patients with inclusion body myositis who have not responded to prednisone or other immunosuppressives.
3. Revised 10/95 based on 1994 TEC evaluation of medical literature from 1991-1994 assessing IVIG to stop progression of muscle weakness or to decrease frequency or severity of relapses in MS..
4. Revised 10/95 based on a 1994 TEC evaluation of medical literature from 1991-1994 assessing IVIg to improve functional capacity or to reduce pain in patients with RA refractory to NSAIDS and either cytotoxic or disease-modifying antirheumatic drugs.

5. Revised 10/95 based on a 1994 TEC evaluation of medical literature from 1991-1994 assessing IVIG to improve neurologic function in CIDP, either as first-line therapy, or for acute exacerbations in patients refractory or intolerant of prednisone or azathioprine.
6. Revised 10/95 based on a 1994 TEC evaluation of medical literature assessing IVIG to reduce fetal loss in women with recurrent fetal loss (sequence of 3 or more miscarriages), with or without antiphospholipid antibodies.
7. Revised 3/96 to include CMS (Centers for Medicare and Medicaid services) regulations published in the February/March 1996 issue of the Medicare Health Resources.
8. Revised 2/97 to include CMS (Centers for Medicare and Medicaid services) regulations published in the February/March 1997 issue of the Medicare Health Resources.
9. Revised 9/97 to include CMS regulations (Centers for Medicare and Medicaid services) published in the June/July 1997 Medicare B Health Resources.
10. Added based on recommendations made by the Massachusetts Neurological Society.
11. Based on the July 1998 TEC (Technology Evaluation Center) analysis of the literature on IVIg for MS. Health outcomes considered by TEC included prevention of disease progress and disability, improving baseline neuro disability, and reducing acute relapse.
    Also see the July/August 1997 ACP Journal Club commentary:
    http://www.acponline.org/journals/acpjc/julaug97
    Regarding the article: Fazekas F et al., Austrian Immunoglobulin in Multiple Sclerosis Study Group. Randomized placebo-controlled trial of monthly intravenous immunoglobulin therapy in relapsing-remitting multiple sclerosis. Lancet. 1997 Mar 1;349:589-93.
12. FDA-approved uses as of July, 1998.
13. Off-label use in the treatment of AIDS and HIV as required by law.
14. Label use based on National Blue Cross Blue Shield policy 8.01.05, issued 12/15/98.
15. Off-label use based on National Blue Cross Blue Shield policy 8.01.05, issued 12/15/98.
16. Investigational use based on National Blue Cross Blue Shield policy 8.01.05, issued 12/15/98.
17. Based on recommendations from Walt Kagan, MD, Massachusetts Society of Clinical Oncologists.
18. Based upon a September 1999 Medicare B HealthResource Newsletter.
19. Medicare policy is developed separately from BCBSMA policy. While BCBSMA policy is based upon scientific evidence, Medicare policy incorporates scientific evidence with local expert opinion, and governmental regulations from CMS (Centers for Medicare and Medicaid Services) and the U.S Congress. While BCBSMA and Medicare policies may differ, our Medicare HMO Blue and Medicare PPO Blue members must be offered the same services as Medicare offers. In many instances, BCBSMA policies offer more benefits than does Medicare policy.
20. Based on recommendations from David Weinberg, MD, Massachusetts Neurologic Association, 1/2000 MPG Neurology meeting.
21. Medical Policy Group, August 2000.
22. Previous criteria summarized in the current form: vital capacity less than 1L; dysphagia associated with aspiration; inability to ambulate 100 feet without assistance.
23. Medical Policy Group, January 2000.
24. Idiopathic Thrombocytopenic Purpura: A Practice Guideline Developed by Explicit Methods for the American Society of Hematology
25. See the 1998 ASRM (American Society of Reproductive Medicine) Practice Committee Report on Intravenous Immunoglobulin and Spontaneous Pregnancy Loss.
26. Based on the June 2002 Medicare B Resource Newsletter. See also the CMS /Medicare websites at www.cms.gov and www medicare.gov.
27. Based upon the 2002 Blue Cross Blue Shield Association policy 8.01.05. IVIG for myasthenic crisis is considered medically necessary. Myasthenic crisis is an off-label indication.
28. Based upon the 2002 Blue Cross Blue Shield Association National policy 8.01.05.
29. Based upon the 2004 Blue Cross Blue Shield Association policy 2.01.01.
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31. Consensus statement on the use of intravenous immunoglobulin therapy in the treatment of autoimmune mucocutaneous blistering diseases. Arch Dermatol.2003;139:1051-1059.
32. Based upon the 2004 BCBSA National Policy 8.01.05. Bone marrow transplant patients (for prevention of infection or GVH prevention.)

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33. Based upon the 2004 BCBSA National Policy 8.01.05. Recurrent Spontanous Abortion.
34. Based on Blue Cross Blue Shield National policy 8.01.05 Intravenous Immune Globulin Therapy issued 4/06.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%2 prior%20auth%20instruction%20prn.pdf

Home Infusion Therapy
Prior Authorization Form

Please complete and fax with the physician's prescription to: (888) 641-5355. If the patient is a BCBSMA employee, please fax the form to: (617)246-4013.

Company name:		Contact Name:			
Phone #:		Provider #:			
Fax#		Address:			
Patient name:		Address:			
Patient_ID#:		DOB:____/____/____		Diagnosis:	
Prescribing Physician/addr:	_____			Telephone:	
PCP name/address:	_____			Telephone:	

Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No

Place of Service ☐ **Home** ☐ **SNF** ☐ **MD office** ☐ **other (specify)**_____

Primary Therapy

Primary drug name: _____ Approximate duration: ____/____/____ to ____/____/____

Dose: _____

Frequency: _____ Route of Administration: pump: Y N

Other Therapy

Other drug name: _____ Approximate duration: ____/____/____ to ____/____/____

Dose: _____

Frequency _____ Route of Administration: pump: Y N

☐ If this is a "drug only" authorization request, indicate other services the nursing agency is providing:

_____

Nursing provided by: _____ Contact: _____

Phone: _____ Fax: _____

Request for 7 Day Coverage : Date of occurrence: _____ request dates:_____

Occurrence type: ☐ Hospitalization ☐ Death ☐ Change of Therapy

Physician signature:_____ **Date:**_____

OR Copy of prescription REQUIRED with this request