Pharmacy Medical Policy
Intravenous Immunoglobulin

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Policy Number: 310
BCBSA Reference Number: 8.01.05

Related Policies
• See medical policy #422, RSV Immunoprophylaxis (RSV-IVlg)

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 cover intravenous immunoglobulin (IVlg) for the following diagnoses only:

Blood disorders
• Bone marrow transplant patients (for prevention of infection or GVH prevention)\textsuperscript{12, 14, 32}
• Multiple myeloma and immunoproliferative neoplasms\textsuperscript{8}
• Immune neutropenia\textsuperscript{8}
• Multiple myeloma without mention of remission\textsuperscript{8}
• Multiple myeloma in remission\textsuperscript{8}
• Other immunoproliferative neoplasms without mention of remission\textsuperscript{8}
• Other immunoproliferative neoplasms in remission\textsuperscript{8}
• Agranulocytosis\textsuperscript{8}
• Common variable immunodeficiency, severe combined immunodeficiency, Wiskott-Aldrich syndrome, and X-linked (X-linked Agammaglobulinemia & X-linked hyperimmunoglobulinemia M syndrome) immunodeficiency\textsuperscript{14}
• Fetal / Neonatal alloimmune thrombocytopenia\textsuperscript{15}
• Autoimmune (warm antibody) hemolytic anemia who are refractory to prednisone and splenectomy\textsuperscript{17}
• Agammaglobulinemia -primary humoral immunodeficiency\textsuperscript{12, 14}
• Hypogammaglobulinemia -primary humoral immunodeficiency\textsuperscript{12, 14}
• Chronic lymphocytic leukemia (CLL) with frequent infections and\textsuperscript{12, 14}
IgG levels are less than 400mg/dl
- Idiopathic thrombocytopenic purpura (ITP). 12, 24

**Infectious diseases**
- HIV and AIDS 13
- Prevention of infection in HIV-infected children and 12, 14
  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. 7
- Severe Anemia associated with human parvovirus B19.
- Toxic Shock Syndrome

**Neurologic conditions:**
- Guillain-Barré Syndrome (GBS) 15
- Chronic severe myasthenia gravis, 7, 22 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 22
- 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 8, 19
- Peroneal muscular atrophy 8, 19
- Hereditary sensory neuropathy 8, 19
- Idiopathic progressive polyneuropathy 8
- Multiple Sclerosis: for patients with relapsing-remitting disease (not primary or secondary progressive MS) 11, 15
- Chronic inflammatory demyelinating polyneuropathy 15
- Demyelinating polyneuropathy associated with IgM paraproteinemia 20
- Multifocal motor neuropathy in patients with GM1 antibodies and conduction block 15
- Stiff-Person/Men syndrome

**Other:**
- Dermatomyositis/polymyositis which is refractory to treatment with corticosteroids in combination with other immunosuppressive agents.
- Kawasaki syndrome 15, 19
- 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
- Patients with neuromyelitis optica as an alternative for patients with contraindication or lack of response to first-line treatment particularly in children.
- 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)

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 Erythematosus
- 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 BlueSM and Medicare PPO BlueSM 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 Foliacceus, (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:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0850</td>
<td>Injection, cytomegalovirus immune globulin intravenous (human), per vial [Cytogam]</td>
</tr>
<tr>
<td>J1459</td>
<td>Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1556</td>
<td>Injection, immune globulin (Bivigam), 500 mg</td>
</tr>
<tr>
<td>J1557</td>
<td>Injection, immune globulin, (Gammaplex), intravenous, nonlyophilized (e.g., liquid), 500 mg</td>
</tr>
</tbody>
</table>
Injection, immune globulin (Hizentra), 100 mg
Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), nonlyophilized (e.g., liquid), 500 mg
Injection, immune globulin, intravenous, lyophilized (e.g., powder), 500 mg
Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
Injection, immune globulin, (Gammagard liquid), intravenous, nonlyophilized, (e.g., liquid), 500 mg
Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immunoglobulin
Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg
Unclassified biologics (i.e. Asceniv, Cutaquig, Xembify)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the HCPCS codes above if medical necessity criteria are met:

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A48.3</td>
<td>Toxic shock syndrome</td>
</tr>
<tr>
<td>B20</td>
<td>Human immunodeficiency virus [HIV] disease</td>
</tr>
<tr>
<td>B25.0</td>
<td>Cytomegaloviral pneumonitis</td>
</tr>
<tr>
<td>B25.1</td>
<td>Cytomegaloviral hepatitis</td>
</tr>
<tr>
<td>B25.2</td>
<td>Cytomegaloviral pancreatitis</td>
</tr>
<tr>
<td>B25.8</td>
<td>Other cytomegaloviral diseases</td>
</tr>
<tr>
<td>B25.9</td>
<td>Cytomegaloviral disease, unspecified</td>
</tr>
<tr>
<td>B97.6</td>
<td>Parvovirus as the cause of diseases classified elsewhere</td>
</tr>
<tr>
<td>C88.2</td>
<td>Heavy chain disease</td>
</tr>
<tr>
<td>C88.3</td>
<td>Immunoproliferative small intestinal disease</td>
</tr>
<tr>
<td>C88.8</td>
<td>Other malignant immunoproliferative diseases</td>
</tr>
<tr>
<td>C88.9</td>
<td>Malignant immunoproliferative disease, unspecified</td>
</tr>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Multiple myeloma in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
<tr>
<td>C90.20</td>
<td>Extramedullary plasmacytoma not having achieved remission</td>
</tr>
<tr>
<td>C90.21</td>
<td>Extramedullary plasmacytoma in remission</td>
</tr>
<tr>
<td>C90.22</td>
<td>Extramedullary plasmacytoma in relapse</td>
</tr>
<tr>
<td>C90.30</td>
<td>Solitary plasmacytoma not having achieved remission</td>
</tr>
<tr>
<td>C90.31</td>
<td>Solitary plasmacytoma in remission</td>
</tr>
<tr>
<td>C90.32</td>
<td>Solitary plasmacytoma in relapse</td>
</tr>
<tr>
<td>C91.10</td>
<td>Chronic lymphocytic leukemia of B-cell type not having achieved remission</td>
</tr>
<tr>
<td>C91.11</td>
<td>Chronic lymphocytic leukemia of B-cell type in remission</td>
</tr>
<tr>
<td>C91.12</td>
<td>Chronic lymphocytic leukemia of B-cell type in relapse</td>
</tr>
<tr>
<td>D59.0</td>
<td>Drug-induced autoimmune hemolytic anemia</td>
</tr>
<tr>
<td>D59.1</td>
<td>Other autoimmune hemolytic anemias</td>
</tr>
<tr>
<td>D61.2</td>
<td>Aplastic anemia due to other external agents</td>
</tr>
<tr>
<td>D68.61</td>
<td>Antiphospholipid syndrome</td>
</tr>
<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>D69.41</td>
<td>Evans syndrome</td>
</tr>
<tr>
<td>D69.42</td>
<td>Congenital and hereditary thrombocytopenia purpura</td>
</tr>
<tr>
<td>D69.49</td>
<td>Other primary thrombocytopenia</td>
</tr>
<tr>
<td>D69.6</td>
<td>Thrombocytopenia, unspecified</td>
</tr>
<tr>
<td>D70.8</td>
<td>Other neutropenia</td>
</tr>
<tr>
<td>D80.0</td>
<td>Hereditary hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.1</td>
<td>Nonfamilial hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.2</td>
<td>Selective deficiency of immunoglobulin A [IgA]</td>
</tr>
<tr>
<td>D80.3</td>
<td>Selective deficiency of immunoglobulin G [IgG] subclasses</td>
</tr>
<tr>
<td>D80.4</td>
<td>Selective deficiency of immunoglobulin M [IgM]</td>
</tr>
<tr>
<td>D80.5</td>
<td>Immunodeficiency with increased immunoglobulin M [IgM]</td>
</tr>
<tr>
<td>D81.0</td>
<td>Severe combined immunodeficiency [SCID] with reticular dysgenesis</td>
</tr>
<tr>
<td>D81.1</td>
<td>Severe combined immunodeficiency [SCID] with low T- and B-cell numbers</td>
</tr>
<tr>
<td>D81.2</td>
<td>Severe combined immunodeficiency [SCID] with low or normal B-cell numbers</td>
</tr>
<tr>
<td>D81.6</td>
<td>Major histocompatibility complex class I deficiency</td>
</tr>
<tr>
<td>D81.7</td>
<td>Major histocompatibility complex class II deficiency</td>
</tr>
<tr>
<td>D81.89</td>
<td>Other combined immunodeficiencies</td>
</tr>
<tr>
<td>D81.9</td>
<td>Combined immunodeficiency, unspecified</td>
</tr>
<tr>
<td>D82.0</td>
<td>Wiskott-Aldrich syndrome</td>
</tr>
<tr>
<td>D83.0</td>
<td>Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function</td>
</tr>
<tr>
<td>D83.2</td>
<td>Common variable immunodeficiency with autoantibodies to B- or T-cells</td>
</tr>
<tr>
<td>D83.8</td>
<td>Other common variable immunodeficiencies</td>
</tr>
<tr>
<td>D83.9</td>
<td>Other specified immunodeficiencies</td>
</tr>
<tr>
<td>D84.8</td>
<td>Immunodeficiency, unspecified</td>
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<tr>
<td>D89.82</td>
<td>Autoimmune lymphoproliferative syndrome [ALPS]</td>
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<tr>
<td>G11.3</td>
<td>Cerebellar ataxia with defective DNA repair</td>
</tr>
<tr>
<td>G25.82</td>
<td>Stiff-man syndrome</td>
</tr>
<tr>
<td>G35</td>
<td>Multiple sclerosis</td>
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<tr>
<td>G36.0</td>
<td>Neuromyelitis optica [Davic]</td>
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<tr>
<td>G60.0</td>
<td>Hereditary motor and sensory neuropathy</td>
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<tr>
<td>G60.2</td>
<td>Neuropathy in association with hereditary ataxia</td>
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<tr>
<td>G60.3</td>
<td>Idiopathic progressive neuropathy</td>
</tr>
<tr>
<td>G60.8</td>
<td>Other hereditary and idiopathic neuropathies</td>
</tr>
<tr>
<td>G60.9</td>
<td>Hereditary and idiopathic neuropathy, unspecified</td>
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<tr>
<td>G61.0</td>
<td>Guillain-Barre syndrome</td>
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<tr>
<td>G61.81</td>
<td>Chronic inflammatory demyelinating polyneuritis</td>
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<tr>
<td>G61.89</td>
<td>Other inflammatory polyneuropathies</td>
</tr>
<tr>
<td>G62.89</td>
<td>Other specified polyneuropathies</td>
</tr>
<tr>
<td>G64</td>
<td>Other disorders of peripheral nervous system</td>
</tr>
<tr>
<td>G70.00</td>
<td>Myasthenia gravis without (acute) exacerbation</td>
</tr>
<tr>
<td>G70.01</td>
<td>Myasthenia gravis with (acute) exacerbation</td>
</tr>
<tr>
<td>G70.80</td>
<td>Lambert-Eaton syndrome in disease classified elsewhere</td>
</tr>
<tr>
<td>L10.0</td>
<td>Pemphigus vulgaris</td>
</tr>
<tr>
<td>L10.1</td>
<td>Pemphigus vegetans</td>
</tr>
<tr>
<td>L10.2</td>
<td>Pemphigus foliaceous</td>
</tr>
<tr>
<td>L10.3</td>
<td>Brazilian pemphigus [fogo selvagem]</td>
</tr>
<tr>
<td>L10.4</td>
<td>Pemphigus erythematosus</td>
</tr>
<tr>
<td>L10.5</td>
<td>Drug-induced pemphigus</td>
</tr>
<tr>
<td>L10.81</td>
<td>Paraneoplastic pemphigus</td>
</tr>
</tbody>
</table>
L10.89 Other pemphigus
L10.9 Pemphigus, unspecified
L12.0 Bullous pemphigoid
L12.1 Cicatricial pemphigoid
L12.8 Other pemphigoid
L12.9 Pemphigoid, unspecified
M30.3 Mucocutaneous lymph node syndrome [Kawasaki]
M31.30 Wegener's granulomatosis without renal involvement
M31.31 Wegener's granulomatosis with renal involvement
M33.00 Juvenile dermatomyositis, organ involvement unspecified
M33.01 Juvenile dermatomyositis with respiratory involvement
M33.02 Juvenile dermatomyositis with myopathy
M33.09 Juvenile dermatomyositis with other organ involvement
M33.10 Other dermatomyositis, organ involvement unspecified
M33.11 Other dermatomyositis with respiratory involvement
M33.12 Other dermatomyositis with myopathy
M33.19 Other dermatomyositis with other organ involvement
M33.20 Polymyositis, organ involvement unspecified
M33.21 Polymyositis with respiratory involvement
M33.22 Polymyositis with myopathy
M33.29 Polymyositis with other organ involvement
M33.90 Dermatopolymyositis, unspecified, organ involvement unspecified
M33.91 Dermatopolymyositis, unspecified with respiratory involvement
M33.92 Dermatopolymyositis, unspecified with myopathy
M33.99 Dermatopolymyositis, unspecified with other organ involvement
M36.0 Dermato(poly)myositis in neoplastic disease
P55.0 Rh isoimmunization of newborn
P55.1 ABO isoimmunization of newborn
P55.8 Other hemolytic diseases of newborn
P55.9 Hemolytic disease of newborn, unspecified
P61.0 Transient neonatal thrombocytopenia
R75 Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
T86.00 Unspecified complication of bone marrow transplant
T86.01 Bone marrow transplant rejection
T86.03 Bone marrow transplant infection
T86.09 Other complications of bone marrow transplant
T86.10 Unspecified complication of kidney transplant
T86.11 Kidney transplant rejection
T86.13 Kidney transplant infection
T86.19 Other complication of kidney transplant
T86.20 Unspecified complication of heart transplant
T86.21 Heart transplant rejection
T86.23 Heart transplant infection
T86.290 Cardiac allograft vasculopathy
T86.298 Other complications of heart transplant
T86.30 Unspecified complication of heart-lung transplant
T86.31 Heart-lung transplant rejection
T86.33 Heart-lung transplant infection
T86.39 Other complications of heart-lung transplant
T86.40 Unspecified complication of liver transplant
T86.41 Liver transplant rejection
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T86.43</td>
<td>Liver transplant infection</td>
</tr>
<tr>
<td>T86.49</td>
<td>Other complications of liver transplant</td>
</tr>
<tr>
<td>T86.5</td>
<td>Complications of stem cell transplant</td>
</tr>
<tr>
<td>T86.810</td>
<td>Lung transplant rejection</td>
</tr>
<tr>
<td>T86.812</td>
<td>Lung transplant infection</td>
</tr>
<tr>
<td>T86.818</td>
<td>Other complications of lung transplant</td>
</tr>
<tr>
<td>T86.819</td>
<td>Unspecified complication of lung transplant</td>
</tr>
<tr>
<td>T86.90</td>
<td>Unspecified complication of unspecified transplanted organ and tissue</td>
</tr>
<tr>
<td>T86.91</td>
<td>Unspecified transplanted organ and tissue rejection</td>
</tr>
<tr>
<td>T86.93</td>
<td>Unspecified transplanted organ and tissue infection</td>
</tr>
<tr>
<td>T86.99</td>
<td>Other complications of unspecified transplanted organ and tissue</td>
</tr>
<tr>
<td>Z48.290</td>
<td>Encounter for aftercare following bone marrow transplant</td>
</tr>
<tr>
<td>Z94.81</td>
<td>Bone marrow transplant status</td>
</tr>
</tbody>
</table>

**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:**

<table>
<thead>
<tr>
<th>Provider</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accredo Health Group</td>
<td>Phone: 1-877-988-0058 Website: <a href="http://www.accredo.com">www.accredo.com</a></td>
</tr>
<tr>
<td>Caremark, LLC</td>
<td>Phone: 1-866-846-3096 Website: <a href="http://www.caremark.com">www.caremark.com</a></td>
</tr>
<tr>
<td>Coram™ Specialty Infusion Services</td>
<td>Phone: 1-800-678-3442 Website: <a href="http://www.coramhc.com">www.coramhc.com</a></td>
</tr>
<tr>
<td>Home Solutions</td>
<td>Falmouth Location: Phone: 1-508-548-4266 or toll free 1-800-244-1227</td>
</tr>
<tr>
<td></td>
<td>Canton Location: Phone: 1-617-989-0888 or toll free at 1-888-660-1660 Website: <a href="http://www.infusionreferral.com">www.infusionreferral.com</a></td>
</tr>
</tbody>
</table>

**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

**Managed Care Authorization Instructions**
- Prior authorization is required for all outpatient sites of service
• For all outpatient sites of service requesting retail pharmacy exceptions, physicians may fax or mail the attached form to the address above.

**PPO and Indemnity Authorization Instructions**
• Prior authorization is required when this medication is processed under the home infusion therapy benefit.
• Prior authorization is not required when drugs are not part of Pharmacy only program and is purchased by the physician and administered in the office in accordance with this medical policy.
• Physicians may also fax or mail the attached form for retail pharmacy exceptions to the address above.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/2020</td>
<td>Updated to add Asceniv to the policy.</td>
</tr>
<tr>
<td>11/2019</td>
<td>Updated to add Xembify to the policy.</td>
</tr>
<tr>
<td>7/2019</td>
<td>Updated to add Cutaquig to the policy.</td>
</tr>
<tr>
<td>1/2019</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>8/2018</td>
<td>Updated to include Association coverage statement for Neuromyelitis Optica &amp; Blistering disease.</td>
</tr>
<tr>
<td>10/2017</td>
<td>Clarified coding information plus updated to change Walgreens Specialty list.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Updated to add AllCare to Pharmacy Specialty list.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated address for Pharmacy Operations.</td>
</tr>
<tr>
<td>1/2016</td>
<td>Updated to add new HCPCS code J1575.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Updated to included revised language for Pharmacy only medications.</td>
</tr>
<tr>
<td>7/2015</td>
<td>Update to include Retail billing.</td>
</tr>
<tr>
<td>6/2015</td>
<td>Updated to include Bivigam, Cytogam, Gammaplex, Hizentra and HyQvia and to align ICD codes.</td>
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<tr>
<td>2/2015</td>
<td>Updated to include a couple HCPCS codes and one ICD code.</td>
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<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>1/2014</td>
<td>Updated ExpressPAth Language.</td>
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<tr>
<td>1/2013</td>
<td>Updated 1/2013 to include new FDA products Gammaked™ and Gamunex®-C.</td>
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<td>Date</td>
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<tr>
<td>10/2009</td>
<td>Updated to reflect UM requirements.</td>
</tr>
</tbody>
</table>

References

15. 1998 TEC Assessments; Tab 19.
30. 1998 TEC Assessments; Tab 14.


73. Kozlowski T, Andreoni K. Limitations of rituximab/IVIg desensitization protocol in kidney transplantation: is this better than a tincture of time? Ann Transplant. Apr-Jun 2011;16(2):19-25. PMID 21716181


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/acpcj/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.


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.


22. Previous criteria summarized in the current form: vital capacity less than 1L; dysphagia associated with aspiration; inability to ambulate 100 feet without assistance.


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.


30. Based upon the 2004 BCBSA National Policy 8.01.05. Bone marrow transplant patients (for prevention of infection or GVH prevention.)


32. Based upon the 2004 BCBSA National Policy 8.01.05. Bone marrow transplant patients (for prevention of infection or GVH prevention.)

33. Based upon the 2004 BCBSA National Policy 8.01.05. Recurrent Spontaneous 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:
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.

<table>
<thead>
<tr>
<th>Company name:</th>
<th>Contact Name:</th>
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<td>Provider #:</td>
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<th>Telephone:</th>
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<tbody>
<tr>
<td>PCP name/address:</td>
<td>Telephone:</td>
</tr>
</tbody>
</table>

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