Pharmacy Policy

Immune Globulin Intravenous, Subcutaneous (IVIG, SCIG)

Policy Number: 9.129  
Version Number: 13.0  
Version Effective Date: 07/17/2017

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary
The Plan will authorize coverage of IVIG, SCIG products when appropriate criteria are met.

Description of Item or Service
Immune globulin intravenous (IVIG) products are of concentrated human immunoglobulins, primarily immunoglobulin G (IgG), that are prepared from pooled plasma collected from a large number of human donors. The donors in a typical pool of plasma have a wide range of antibodies against infectious agents. These products have IgG subclasses similar to that found in normal humans.

‘Human immune globulin therapy provides a broad spectrum of opsonizing and neutralizing immunoglobulin G (IgG) antibodies against a wide variety of bacterial and viral antigen

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There are several immune globulin products available with varied FDA-approved indications. Subcutaneous immune globulin (SCIG) products are only approved for replacement therapy in a limited number of conditions. Currently available products and their FDA-approved indication(s) are listed below:

<table>
<thead>
<tr>
<th>Product</th>
<th>Route</th>
<th>PID</th>
<th>CIPD</th>
<th>CLL</th>
<th>ITP</th>
<th>KD</th>
<th>MMN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivigam</td>
<td>IV</td>
<td>X</td>
<td>X</td>
<td></td>
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</tr>
<tr>
<td>Carimune NF</td>
<td>IV</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Iviviru</strong></td>
<td>SC</td>
<td>X</td>
<td></td>
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<tr>
<td>Flebogamma DIF</td>
<td>IV</td>
<td>X</td>
<td></td>
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</tr>
<tr>
<td>Gammagard Liquid</td>
<td>IV/SC*</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Gammagard S/D</td>
<td>IV</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Gammaked</td>
<td>IV/SC*</td>
<td>X</td>
<td>X</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Gammaplex</td>
<td>IV</td>
<td>X</td>
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<tr>
<td>Gamunex-C</td>
<td>IV/SC*</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Hizentra</td>
<td>SC</td>
<td>X</td>
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<tr>
<td>HyQvia</td>
<td>SC</td>
<td>X</td>
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<tr>
<td>Octagam</td>
<td>IV</td>
<td>X</td>
<td></td>
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<tr>
<td>Privigen</td>
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<td>X</td>
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</tr>
</tbody>
</table>

Notes:
- **PID** – primary humoral immune deficiency including but not limited to the humoral immune defect in the following conditions: common variable immunodeficiency (CVID), X-linked agammaglobulinemia (XLA) (congenital agammaglobulinemia), Wiskott - Aldrich syndrome, severe combined immunodeficiencies (SCID), and measles prophylaxis in individuals with PID who have been exposed to measles or who are at high risk of measles exposure.
- **CLL** – B-cell chronic lymphocytic leukemia for prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections.
- **CIPD** – Chronic inflammatory demyelinating polyneuropathy to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.
- **ITP** – Idiopathic (immune) thrombocytopenic purpura, acute and chronic, when a rapid rise in platelet count is needed to prevent and/or control bleeding or to allow a patient with ITP to undergo surgery.
- **KD** – Kawasaki disease in pediatric patients for the prevention of coronary arteriopathy.
- **MMN** – Multifocal motor neuropathy (MMN) in adults as maintenance therapy to improve muscle strength and disability.

*When administered subcutaneously, these products are only FDA-approved for the treatment of PID; ITP and CIPD should be treated using the intravenous (IV) route.

Comment [VM1]: New drug added
IVIG also is used for many off-label indications. Most evidence for clinical effectiveness of IVIG is anecdotal (i.e., case reports, open series, or cohort studies). Some conditions, however, have been studied in controlled trials. Usually IVIG is indicated only if standard approaches have failed, become intolerable, or are contraindicated.

**Policy**

The Plan may authorize coverage of IVIG, SCIG products for members meeting the following criteria:

**Prior Authorization**

A prior authorization request will be required for all prescriptions for IVIG or SCIG. These requests will be approved when criteria below are met:

<table>
<thead>
<tr>
<th>Initial Coverage Criteria – Approval duration (3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Criteria</strong>: All of the following are required:</td>
</tr>
<tr>
<td>1. Request is for an indication for which the medication is FDA approved, or listed below as a covered condition.</td>
</tr>
<tr>
<td>2. The quantity and duration of medication prescribed is consistent with dosing listed in manufacturer package labeling or established clinical literature for the medical condition.</td>
</tr>
<tr>
<td>3. The prescriber is a specialist appropriate for the disease state being treated.</td>
</tr>
<tr>
<td>4. In addition to the above, the condition specific criteria listed below must be met for initial approval.</td>
</tr>
</tbody>
</table>

**Primary Humoral Immunodeficiencies**

- Common variable immunodeficiency (CVID), or unspecified hypogammaglobulinemia
  1. Documented history of significant recurrent or persistent, severe bacterial infections (such as recurrent pneumonias, frequent episodes of bacterial infections such as sinusitis, otitis, bronchitis, skin structure infections, or infections of the gastrointestinal tract) resulting from low IgG; AND
  2. Inadequate response or hypersensitivities to prophylaxis/treatment with antibiotics; AND
  3. Other disorders that may increase susceptibility to infection such as allergy or anatomic defects, have been identified and treated aggressively if present; AND
  4. One of the following is present:
    a. Reduced total serum IgG level
    b. Reduced IgG1 and IgG3 subclass levels or reduced IgG1 alone
    c. Multifocal motor neuropathy (MMN) in adults as maintenance therapy to improve muscle levels of total IgG (CVID only)

- Combined immunodeficiencies with significant hypogammaglobulinemia or antibody production defect (e.g., ataxia-telangiectasia, 1. Incidence of frequent infections (12 months)

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IVIG, SCIG
<table>
<thead>
<tr>
<th>Initial Coverage Criteria – Approval duration (3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiGeorge syndrome, nuclear factor κB essential modifier deficiency (NEMO)</td>
</tr>
<tr>
<td>• Hyper-IgM syndromes, X-linked or autosomal recessive</td>
</tr>
<tr>
<td>• Severe combined immunodeficiency (SCID)</td>
</tr>
<tr>
<td>• Wiskott-Aldrich syndrome</td>
</tr>
<tr>
<td>• X-linked agammaglobulinemia</td>
</tr>
<tr>
<td>B-Cell Chronic Lymphocytic Leukemia (CLL) for Prevention of Bacterial Infections</td>
</tr>
<tr>
<td>Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) or Polyradiculoneuropathy</td>
</tr>
<tr>
<td>Idiopathic (Immune) Thrombocytopenic Purpura [ITP] or Immune Thrombocytopenia [IT]</td>
</tr>
<tr>
<td>Kawasaki Disease</td>
</tr>
<tr>
<td>Multifocal Motor Neuropathy (MMN)</td>
</tr>
<tr>
<td>Other uses of IVIG with supportive evidence</td>
</tr>
<tr>
<td>Autoimmune Mucocutaneous Blistering Diseases (Pemphigus Vulgaris, Pemphigus Foliaceus, Bullous Pemphigoid, Mucous)</td>
</tr>
</tbody>
</table>
### Initial Coverage Criteria – Approval duration (3 months)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membrane Pemphigoid (Cicatricial Pemphigoid, and Epidermolysis Bullosa Acquisita)</td>
<td>Due to rapid, debilitating or progressive severity of disease</td>
</tr>
<tr>
<td>Dermatomyositis or Polymyositis</td>
<td>1. Inadequate response or contraindication to the use of systemic corticosteroids and an immunosuppressive agent (azathioprine, cyclophosphamide, dapsone, methotrexate, etc.)</td>
</tr>
<tr>
<td>Cytomegalovirus (CMV) Interstitial Pneumonia in Patients with Hematopoietic Cell Transplantation [HCT]</td>
<td>1. Therapy is intended for the prevention and treatment of cancer related CMV infection and not as a preemptive or prophylaxis therapy.</td>
</tr>
<tr>
<td>Solid Organ Transplantation (Heart, Intestinal, Kidney, or Liver)</td>
<td>1. Therapy is required for desensitization prior to, or immediately following solid organ transplantation</td>
</tr>
<tr>
<td>Guillain-Barré Syndrome (GBS)</td>
<td>1. Presence of neuropathic symptoms (weakness, inability to stand or walk without assistance, respiratory or bulbar weakness); AND Therapy with IVIG is initiated within 2 weeks and no longer than 4 weeks of onset of the neuropathic symptoms; OR 2. The patient has had a relapse, but had an initial response to IVIG</td>
</tr>
<tr>
<td>Hematopoietic Cell Transplantation (HCT)</td>
<td>1. History of HCT within the previous year; AND 2. There is a significant risk of having frequent and/or severe bacterial infections despite antibiotic therapy</td>
</tr>
<tr>
<td>Human Immunodeficiency Virus (HIV)-Associated Thrombocytopenia</td>
<td>1. Current use of combination antiretroviral therapy (cART) for HIV infection; OR 2. Presence of clinically significant bleeding complications</td>
</tr>
<tr>
<td>Prevention of Recurrent Bacterial Infections in HIV patients (children)</td>
<td>1. Age is less than 13 years; AND 2. Current use of combination antiretroviral therapy (cART) for HIV infection; AND 3. One of the following: a. Hypogammaglobulinemia (IgG &lt; 400 mg/dL); OR b. Functional antibody deficiency is demonstrated by poor specific antibody titers; OR c. Functional antibody deficiency is demonstrated by the patient having recurrent (two or more per year), serious bacterial infections [e.g., bacteremia, meningitis, pneumonia] despite administration of cART and appropriate antimicrobial prophylaxis</td>
</tr>
<tr>
<td>Multiple Myeloma</td>
<td>1. The disease is in a stable (plateau phase) (&gt;3 months from diagnosis); AND 2. There has been severe bacterial recurrent bacterial infections (past 12 months)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Initial Coverage Criteria – Approval duration</th>
<th>Approval duration (3 months)</th>
</tr>
</thead>
</table>

| Multiple Sclerosis                          | 1. A diagnosis of multiple sclerosis with acute severe exacerbation; AND  
2. An inadequate response, intolerance or contraindication to use of the following: oral/IV corticosteroids, or Plasma exchange, or Acthar; OR  
1. A diagnosis of multiple sclerosis in a post-partum female and treatment intended to prevent relapse; AND  
2. The patient is not currently receiving disease modifying treatment for MS (interferon-beta, glatiramer, fingolimod, etc) |
| Myasthenia Gravis                           | 1. A diagnosis of Myasthenia Gravis with acute exacerbation; OR  
2. Treatment in required for stabilization of myasthenia gravis before surgery; OR  
3. The patient has been started on an immunosuppressive drug (e.g., azathioprine, cyclosporine, cyclophosphamide, mycophenolate mofetil) and is waiting for full effect; OR  
4. The patient has responded to a previous course of IVIG therapy, but weakens (relapses) and has no response to other medications; OR  
5. An inadequate response to systemic corticosteroid, or azathioprine, or other immunosuppressive agent |
| Passive Immunization for Varicella (Chickenpox) (Post-Exposure Prophylaxis). | 1. HIV-infected and age is less than 13 years old; AND  
2. VariZIG (varicella zoster immune globulin IM injection) is not available; AND  
3. The patient does not have evidence of immunity to varicella (i.e., patient does not have a history of the disease or age-appropriate vaccination); OR  
1. Non HIV-infected child; AND  
2. VariZIG (varicella zoster immune globulin IM injection) is not available; AND  
3. The patient does not have evidence of immunity to varicella (i.e., patient does not have a history of the disease or age-appropriate vaccination); AND  
4. The patient is pregnant or immune compromised |
| Pure Red Blood Cell Aplasia (PRCA) Secondary to Chronic (Persistent) Parvovirus B19 Infection | 1. Presence of clinically significant anemia or transfusion dependent anemia; AND  
2. The patient has a chronic immunodeficient condition (e.g., HIV infection, solid organ transplants [e.g., renal, liver], chemotherapy for hematologic malignancy) |
| Pure Red Blood Cell Aplasia (PRCA), Immunologic Subtype | 1. An inadequate response, intolerance, or contraindication to the use of a systemic corticosteroid and either cyclophosphamide or cyclosporine |
| Stiff-Person Syndrome (Moersch-Woltman Syndrome). | 1. An inadequate response, intolerance, or contraindication to use of standard medical therapy such as baclofen, diazepam, clonidine, phenytoin, corticosteroids. |
| Fetal or neonatal alloimmune Thrombocytopenia | 1. Fetal platelets are <100,000/UI; OR  
2. The patient has a previous history of pregnancy affected by fetal alloimmune thrombocytopenia  
3. Neonate requires increase in platelet level due to high risk of intracranial hemorrhage |

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Re-authorization Criteria – Approval duration (1 year for PID, 6 months or less for other conditions)

Documentation of the following:
1. The condition being treated has clinically improved evidenced by documentation in medical records and requires continued therapy; AND
2. The quantity and duration of medication prescribed is consistent with dosing listed in manufacturer package labeling or established clinical literature for the prescribed indication.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>90283</td>
<td>Immune Globulin (IgIV), human, for intravenous use</td>
</tr>
<tr>
<td>90284</td>
<td>Immune globulin (SCIG), human, for use in subcutaneous infusions, 100 mg, each</td>
</tr>
<tr>
<td>J1459</td>
<td>Injection, immune globulin (Privigen), intravenous, non-lyophilized (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, non-lyophilized (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1559</td>
<td>Injection, immune globulin (Hizentra), 100 mg</td>
</tr>
<tr>
<td>J1561</td>
<td>Injection, immune globulin, (Gamunex/Gamunex-C/Gammaked), intravenous, non-lyophilized (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1566</td>
<td>Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg</td>
</tr>
<tr>
<td>J1568</td>
<td>Injection, immune globulin, (Octagam), intravenous, non-lyophilized (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1569</td>
<td>Injection, immune globulin, (Gammagard), intravenous, non-lyophilized, (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1572</td>
<td>Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, non-lyophilized (e.g., liquid),500 mg</td>
</tr>
<tr>
<td>J1599</td>
<td>Injection, immune globulin, intravenous, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg</td>
</tr>
<tr>
<td>J1562</td>
<td>Injection, immune globulin(Vivaglobin), 100mg</td>
</tr>
<tr>
<td>J1575</td>
<td>Injection, immune globulin/kyaluronidase, (Hyqvia), 100mg immunoglobulin</td>
</tr>
</tbody>
</table>

Limitations

The Plan will not approve coverage of IVIG/SCIG in the following instances:

- When the criteria above are not met.

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IVIG/SCIG

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When IVIG or SCIG is prescribed for condition(s) in which there is insufficient clinical evidence to support its use and/or if the request is for one for the following:

- Adrenoleukodystrophy
- Alzheimer’s Disease (AD)
- Amyotrophic Lateral Sclerosis
- Anemia, Aplastic
- Asthma
- Atopic Dermatitis
- Autism
- BK Virus Associated Nephropathy (BKVAN) in Kidney Transplant Patient
- Chronic Fatigue Syndrome
- Chronic Myasthenia Gravis
- Complex Regional Pain Syndrome (Reflex Sympathetic Dystrophy)
- Crohn’s Disease
- Cystic Fibrosis
- Cytomegalovirus (CMV) Disease Prophylaxis in Hematopoietic Cell Transplantation (HCT) Recipients
- Cytomegalovirus (CMV) Infection, Preemptive Therapy for Cytomegalovirus (CMV) Infection or Treatment of Cytomegalovirus (CMV) Disease, in Allogeneic Hematopoietic Cell Transplantation (HCT) Recipients
- Cytomegalovirus (CMV) Infections, Prophylaxis or Treatment in Solid Organ Transplantation, (e.g., Heart, Kidney) for Prophylaxis
- Diabetes Mellitus, Immunotherapy
- Epilepsy, Pediatric Intractable
- Fibromyalgia Syndrome
- Graft Versus Host Disease (GVHD), Acute [Within First 100 days After Hematopoietic Cell Transplantation (HCT)]
- Graft Versus Host Disease (GVHD), chronic, Prevention in Hematopoietic Cell Transplantation (HCT) Recipient
- Heart Block, Congenital (Prevention)
- Heart Failure, Chronic
- Hematopoietic Cell Transplantation (HCT) in Allogeneic Recipients from Human Leukocyte Antigen (HLA)-Identical Sibling Donors
- Human Immunodeficiency Virus (HIV) Infection, Adults, for Prophylaxis of Infections
- Immune Globulin M (IgM) Paraproteinemic Demyelinating Neuropathy or Other Paraproteinemic Demyelinating Neuropathies
- In Vitro Fertilization (IVF)
- Infantile Spasms (West Syndrome)
o Marburg Variant Multiple Sclerosis (MS)
o Multiple Sclerosis (MS), Primary or Secondary Progressive, Relapsing Remitting for the Prevention of Relapses
o Nephropathy, Membranous
o Organomegaly, Endocrinopathy, Monoclonal Gammopathy, and Skin Changes (POEMS) Syndrome
o Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infection (PANDAS)
o Post-Polio Syndrome
o Recurrent Spontaneous Pregnancy Loss (RSPL) [Including Antiphospholipid Antibody-Positive Women]
o Selective Immune Globulin A (IgA) Deficiency as the Sole Immunologic Abnormality
o Systemic Lupus Erythematosus (SLE)
o Systemic Sclerosis (Scleroderma)
o Thrombocytopenia, Heparin-Induced (HIT)
o Thrombotic Thrombocytopenic Purpura (TTP)/Hemolytic Uremic Syndrome (HUS)
o Urticaria, Chronic Autoimmune
o Uveitis, Noninfectious
o Other Disorders not listed above

Clinical Background Information and References

1. Carimune NF lyophilized [prescribing information]. Kankakee, IL: CSL Behring LLC (manufactured by CSL Behring AG, Bern, Switzerland); September 2013.
2. Flebogamma 5% or 10% DIF solution [prescribing information]. Los Angeles, CA: Grifols Biologicals, Inc (manufactured by Instituto Grifols, SA, Barcelona, Spain); September 2013.
4. Gammagard S/D freezed dry IgA ≤ 2.2 mcg/mL or ≤ 1 mcg/mL in a 5% solution [prescribing information]. Westlake Village, CA: Baxter Healthcare Corporation; December 2011.
6. Gammaplex solution [prescribing information]. Raleigh, NC: BPL Inc. (manufactured by Bio Products Laboratory, Hertfordshire, UK); September 2013.
8. Octagam liquid [prescribing information]. Hoboken, NJ: Octapharma USA, Inc (manufactured by Octapharma Pharmaeutika Produktionsges.m.b.H., Vienna, Austria); September 2013.
9. Privigen 10% liquid [prescribing information]. Kankakee, IL: CSL Behring LLC (manufactured by CSL Behring AG, Bern, Switzerland); September 2013.

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46. Newburger JW, Takahashi M, Gerber MA, et al; Committee on Rheumatic Fever, Endocarditis and Kawasaki Disease; Council on Cardiovascular Disease in the Young; American Heart Association; American Academy of Pediatrics. Diagnosis, treatment, and long-term management of Kawasaki disease: a statement for

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70. Tomblyn M, Chiller T, Einsele H, et al; Center for International Blood and Marrow Research; National Marrow Donor program; European Blood and Marrow Transplant Group; American Society of Blood and Marrow Transplantation; Canadian Blood and Marrow Transplant Group; Infectious Diseases Society of America; Society for Healthcare Epidemiology of America; Association of Medical Microbiology and Infectious Disease Canada; Centers for Disease Control and Prevention. Guidelines for preventing infectious complications among hematopoietic cell transplantation recipients: A global perspective. Biol Blood Marrow Transplant. 2009;15:1143-1238.
73. Gamimune N, 10% [prescribing information]. Elkhart, IN: Bayer Corporation; October 2008.

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97. VariZIG for intramuscular injection [prescribing information]. Winnipeg, Canada: Cangene Corporation; December 2012.


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136. Caro XJ, Winter EF, Dumas AJ. A subset of fibromyalgia patients have findings suggestive of chronic inflammatory demyelinating polyneuropathy and appear to respond to IVlg. *Rheumatology (Oxford).* 2008;47:208-211.


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/13/2006</td>
<td>07/13/2006</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/13/2008</td>
<td>P&amp;T Annual Review, no significant changes</td>
<td>07/01/2008</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/12/2009</td>
<td>P&amp;T Annual Review, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) added to FDA indications, approval durations revised for select off-label indications</td>
<td>07/01/2009</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/11/2010</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>07/01/2010</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/10/2011</td>
<td>P&amp;T Annual Review, MS acute severe exacerbation, MS post-partum to prevent relapses added to indications; specialist requirement added to multiple indications; approval durations revised for select off-label indications; Miller Fisher Syndrome, Myasthenia gravis crisis, Autoimmune</td>
<td>07/01/2011</td>
<td>P&amp;T Committee</td>
</tr>
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IVIG.SCIG

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/2011</td>
<td>Policy applied to Commercial.</td>
</tr>
<tr>
<td>03/08/2012</td>
<td>P&amp;T Annual Review, Primary immune deficiency – requirement for pre-dose IgG was removed; Idiopathic thrombocytopenia (ITP) – changes made to reflect American Society of Hematology guidelines regarding platelet count requirements for adults and children, for pregnant women, requirement for platelet count and trial of steroid was removed; Multiple sclerosis – added coverage for children and adolescents, several neurologic diseases were added to exclusions; added criteria for Hizentra.</td>
</tr>
<tr>
<td>07/01/2012</td>
<td></td>
</tr>
<tr>
<td>08/22/2012</td>
<td>Policy applied to NH Medicaid</td>
</tr>
<tr>
<td>12/01/2012</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>03/14/2013</td>
<td>P&amp;T Annual Review, added Bivigam (IVIG) to policy.</td>
</tr>
<tr>
<td>07/01/2013</td>
<td></td>
</tr>
<tr>
<td>12/13/2013</td>
<td>Policy applied to ConnectorCare/Qualified Health Plan</td>
</tr>
<tr>
<td>04/01/2014</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>03/13/2014</td>
<td>P&amp;T Annual Review, a pulmonologist was added to acceptable specialist for treatment of primary humoral immunodeficiency; additional</td>
</tr>
<tr>
<td>07/01/2014</td>
<td></td>
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</tbody>
</table>

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<tr>
<td>03/12/2015</td>
<td>P&amp;T Annual Review, reformatted policy, added Chronic Myasthenia Gravis to list of excluded conditions, added HyQvia to policy</td>
<td>07/01/2015</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>03/10/2016</td>
<td>P&amp;T Annual Review, general formatting, no criteria changes</td>
<td>07/06/2016</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/09/2017</td>
<td>P&amp;T Annual Review, added new drug Cuvitru (SCIG) to the policy; added new available JCodes.</td>
<td>07/17/2017</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
</tbody>
</table>

Next Review Date

03/08/2017

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
9.015 Quantity Limitation Policy

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Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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