Intravenous Immune Globulin (IVIG)

STRIDEsm (HMO) MEDICARE ADVANTAGE


Authorization:
Prior authorization for Harvard Pilgrim StrideSM (HMO) Medicare Advantage is required for intravenous immune globulin (IVIG), administered outside inpatient settings by a qualified physician.

Policy and Coverage Criteria:

FDA-Approved Indications:

Primary Immunodeficiency
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with primary immunodeficiency when documentation confirms ANY of the following diagnoses:

- For individuals with severe combined immunodeficiency (SCID) or congenital agammaglobulinemia (e.g., X-linked or autosomal recessive agammaglobulinemia) based on ANY of the following:
  - Diagnosis confirmed by genetic or molecular testing, or
  - Pretreatment IgG level < 200 mg/dL, or
  - Absence or very low number of T cells (CD3 T cells < 300/microliter) or the presence of maternal T cells in the circulation (SCID only)
- Wiskott-Aldrich syndrome, DiGeorge syndrome, or ataxia-telangiectasia (or other non-SCID combined immunodeficiency) based on ALL of the following:
  - Diagnosis confirmed by genetic or molecular testing (if applicable), and
  - History of recurrent bacterial infections (e.g. pneumonia, otitis media, sinusitis, sepsis, gastrointestinal), and
  - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
- Common variable immunodeficiency (CVID) based on ALL of the following:
  - Age 4 years or older, and
  - Other causes of immune deficiency have been excluded (eg, drug induced, genetic disorders, infectious diseases such as HIV, malignancy), and
  - Pretreatment IgG level < 500 mg/dL or ≥ 2 SD below the mean for age, and
  - History of recurrent bacterial infections, and
  - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A)
- Hypogammaglobulinemia (unspecified), IgG subclass deficiency, selective IgA deficiency, selective IgM deficiency, or specific antibody deficiency based on ALL of the following:
  - History of recurrent bacterial infections, and
  - Impaired antibody response to pneumococcal polysaccharide vaccine (see Appendix A), and
  - ANY of the following pre-treatment laboratory findings:
    - Hypogammaglobulinemia: IgG < 500 mg/dL or ≥ 2 SD below the mean for age
    - Selective IgA deficiency: IgA level < 7 mg/dL with normal IgG and IgM levels
    - Selective IgM deficiency: IgM level < 30 mg/dL with normal IgG and IgA levels
Intravenous Immune Globulin (IVIG)

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals with primary immunodeficiency when documentation confirms all of the following:

- A reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy,
- IgG trough levels are monitored at least yearly and maintained at or above the lower range of normal for age (when applicable for indication),
- The prescriber will re-evaluate the dose of IVIG and consider a dose adjustment (when appropriate).

**Idiopathic Thrombocytopenic Purpura (ITP)**

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for individuals with idiopathic thrombocytopenic purpura (ITP) when documentation confirms the following:

- Newly diagnosed ITP (diagnosed within the past 3 months) or initial therapy when the following criteria are met:
  - Children (< 18 years of age) with ANY of the following:
    - Significant bleeding symptoms (mucosal bleeding or other moderate/severe bleeding) or
    - High risk for bleeding or reason requiring a rapid increase in platelets must be provided (See Appendix B), or
    - Rapid increase in platelets is required* (e.g., surgery or procedure)
  - Adults (≥ 18 years of age) with ANY of the following:
    - Platelet count < 30,000/mcL, or
    - Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding or rapid increase in platelets is required*, and
    - Corticosteroid therapy is contraindicated and IVIG will be used alone or IVIG will be used in combination with corticosteroid therapy

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with chronic/persistent idiopathic thrombocytopenic purpura (≥ 3 months from diagnosis) or ITP unresponsive to first-line therapy when documentation confirms the following:

- Platelet count < 30,000/mcL, or
- Platelet count < 50,000/mcL and significant bleeding symptoms, high risk for bleeding* or rapid increase in platelets is required*, and
- Relapse after previous response to IVIG or inadequate response/intolerance/contraindication to corticosteroid or anti-D therapy

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for adults with refractory ITP after splenectomy when documentation confirms the following:

- Platelet count < 30,000/mcL, or
- Significant bleeding symptoms

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for pregnant women with ITP.
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to three months for individuals with chronic inflammatory demyelinating polyneuropathy (CIDP) when documentation confirms all of the following:

- Disease course is progressive or relapsing/remitting for 2 months or longer
- Moderate to severe functional disability
- The diagnosis was confirmed by electrodiagnostic studies and the evaluation of cerebrospinal fluid (CSF)

Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals with chronic inflammatory demyelinating polyneuropathy (CIDP) when documentation confirms all of the following:

- Significant improvement in disability and maintenance of improvement since initiation of IVIG therapy
- IVIG is being used at the lowest effective dose and frequency

Multifocal Motor Neuropathy (MMN)
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to three months for individuals with multifocal motor neuropathy (MMN) when documentation confirms all of the following:

- Member experienced progressive, multifocal, asymmetrical weakness without objective sensory loss in two or more nerves for at least one month
- The diagnosis was confirmed by electrodiagnostic studies

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals with multifocal motor neuropathy (MMN) when documentation confirms the following:

- Member shows significant improvement in disability and maintenance of improvement have occurred since initiation of IVIG therapy

Kawasaki Syndrome
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for pediatric individuals with Kawasaki Syndrome.

Compilal Uses:
Prophylaxis of Bacterial Infections in HIV-Infected Pediatric Patients
Harvard Pilgrim Stride℠ (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for pediatric individuals with HIV infection when documentation confirms ANY of the following:

- IVIG is prescribed for primary prophylaxis of bacterial infections and pretreatment serum IgG < 400 mg/dL, or
- IVIG is prescribed for secondary prophylaxis of bacterial infections for members with a history of recurrent bacterial infections (> 2 serious bacterial infections in a 1-year period), or
- Member has failed to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine, or
- Member lives in an area where measles is highly prevalent and who have not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live, or
- Member has been exposed to measles and request is for a single dose, or
- Member has chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

**Prophylaxis of Bacterial Infections in Bone Marrow Transplant (BMT)/Hematopoietic Stem Cell Transplant (HSCT) Recipients**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals who are BMT/HSCT recipients when documentation confirms all of the following:
- IVIG is prescribed for prophylaxis of bacterial infections.
- Either of the following:
  - IVIG is requested within the first 100 days post-transplant
  - Member has a pretreatment serum IgG < 400 mg/dL.

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals when a reduction in the frequency of bacterial infections has been demonstrated since initiation of IVIG therapy.

**Dermatomyositis or Polymyositis**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to three months for individuals with dermatomyositis or polymyositis when documentation confirms all of the following:
- Member has at least four of the following:
  - Proximal muscle weakness (upper or lower extremity and trunk)
  - Elevated serum creatine kinase (CK) or aldolase level
  - Muscle pain on grasping or spontaneous pain
  - Myogenic changes on EMG (short-duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
  - Positive anti-Jo-1 (histidyl tRNA synthetase) antibody
  - Non-destructive arthritis or arthralgias
  - Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated ESR of more than 20 mm/h by the Westergren method, or pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen), and
- Standard first-line treatments (corticosteroids) and second-line treatments (immunosuppressants) have been tried but were unsuccessful or not tolerated, or
- Member is unable to receive standard first-line and second-line therapy because of a contraindication or other clinical reason.

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals when documentation confirms significant improvement in disability and maintenance of improvement has been demonstrated since initiation of IVIG therapy.

**Myasthenia Gravis**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for individuals with myasthenia gravis when documentation confirms all of the following:
- Member demonstrates worsening weakness, acute exacerbation, or in preparation for surgery (e.g. diplopia, ptosis, blurred vision, difficulty speaking, difficulty swallowing, difficulty chewing, impaired...
respiratory status, fatigue, and limb weakness. Acute exacerbations include more severe swallowing difficulties and/or respiratory failure
- Pre-operative management (e.g., prior to thymectomy)

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with refractory myasthenia gravis when documentation confirms trial and failure of two or more of standard therapies (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, rituximab).

**Guillain-Barre Syndrome (GBS)**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to two months for individuals with Guillain-Barre Syndrome when documentation confirms all of the following:
- Member has severe disease with significant weakness (e.g., inability to stand or walk without aid, respiratory weakness)
- Onset of neurologic symptoms occurred less than 4 weeks from the anticipated start of therapy

**Lambert-Eaton Myasthenic Syndrome (LEMS)**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with Lambert-Eaton Myasthenic Syndrome (LEMS) when documentation confirms all of the following:
- Diagnosis has been confirmed by either of the following:
  - Neurophysiology studies (e.g., electromyography)
  - A positive anti-P/Q type voltage-gated calcium channel antibody test
- Anticholinesterases (e.g., pyridostigmine) and amifampridine (e.g., 3,4-diaminopyridine phosphate, Firdapse) have been tried but were unsuccessful or not tolerated
- Weakness is severe or there is difficulty with venous access for plasmapheresis

Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for reauthorization of up to six months for individuals with Lambert-Eaton Myasthenic Syndrome (LEMS) when documentation confirms member is responding to therapy (i.e., there is stability or improvement in symptoms relative to the natural course of LEMS).

**Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for fetal/neonatal alloimmune thrombocytopenia (F/NAIT).

**Parvovirus B19-Induced Pure Cell Aplasia**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with severe, refractory anemia associated with bone marrow suppression, with parvovirus B19 viremia.

**Stiff-Person Syndrome**
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with stiff-person syndrome when documentation confirms all of the following:
- Diagnosis has been confirmed by anti-glutamic acid decarboxylase (GAD) antibody testing
- Member had an inadequate response to first-line treatment (benzodiazepines and/or baclofen)
Intravenous Immune Globulin (IVIG)  
**Acute Disseminated Encephalomyelitis**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with acute disseminated encephalomyelitis in members who have had an insufficient response to intravenous corticosteroid treatment.

**Autoimmune Mucocutaneous Blistering Disease**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with autoimmune mucocutaneous blistering disease (includes pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa aquisita) when documentation confirms ALL of the following:
- Diagnosis has been proven by biopsy and confirmed by pathology report, and
- Condition is rapidly progressing, extensive or debilitating, and
- Member has failed or experienced significant complications (e.g. diabetes, steroid-induced osteoporosis) from standard treatment (corticosteroids, immunosuppressive agents).

**Autoimmune Hemolytic Anemia**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months when documentation confirms warm-type autoimmune hemolytic anemia for individuals who do not respond or have a contraindication to corticosteroids or splenectomy.

**Autoimmune Neutropenia**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for individuals with autoimmune neutropenia when documentation confirms treatment with granulocyte colony stimulating factor (G-CSF) is not appropriate.

**Hemophagocytic Lymphohistiocytosis (HLH) or Macrophage Activation Syndrome (MAS)**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for treatment of hypogammaglobulinemia in hemophagocytic lymphohistiocytosis (HLH) or macrophage activation syndrome (MAS) when total IgG is less than 400 mg/dL or two standard deviations below the mean for age.

**Hemolytic Disease of Newborn**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for iso-immune hemolytic disease in neonates.

**HIV-Associated Thrombocytopenia**  
Harvard Pilgrim StrideSM (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for treatment of HIV-associated thrombocytopenia for any of the following indications:
- Pediatric members with IgG < 400 mg/dL and one of the following:
  - 2 or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent, or
  - Received 2 doses of measles vaccine and lives in a region with a high prevalence or measles, or
  - HIV-associated thrombocytopenia despite anti-retroviral therapy, or
  - Chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy, or
  - T4 cell count ≥ 200/mm³
- Adult members with significant bleeding, platelet count < 20,000/mcL, and failure of RhIG in Rh-positive individuals
**Intravenous Immune Globulin (IVIG)**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for treatment of severe cases of toxic epidermal necrolysis or Stevens-Johnson Syndrome.

**Toxic Epidermal Necrolysis and Stevens-Johnson Syndrome**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for treatment of severe cases of toxic epidermal necrolysis or Stevens-Johnson Syndrome.

**Toxic Shock Syndrome**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for treatment of staphylococcal or streptococcal toxic shock syndrome when documentation confirms the infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or the member has persistent oliguria with pulmonary edema.

**Systemic Lupus Erythematosus (SLE)**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to six months for treatment of severe, active systemic lupus erythematosus in members who have experienced inadequate response, intolerance or have a contraindication to first- and second-line therapies.

**Toxic Necrotizing Fasciitis due to Group A Streptococcus**

Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage considers the use of Intravenous Immune Globulin (IVIG) as reasonable and medically necessary for up to one month for treatment fasciitis due to invasive streptococcal infection.

**Covered services must be:**

- Reasonable and medically necessary based on the member’s condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member’s medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.

**Recommended Dosage:**

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication</th>
<th>FDA-approved loading dose (if applicable)</th>
<th>FDA-approved directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asceniv&lt;sup&gt;®&lt;/sup&gt;</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>Give 300mg to 800 mg/kg IV once every 3 to 4 weeks</td>
</tr>
<tr>
<td>Bivigam&lt;sup&gt;®&lt;/sup&gt;</td>
<td></td>
<td></td>
<td>• dose adjustments may be required in patients who fail to maintain trough total IgG concentrations of at least 500 mg/ dL with a target of 600 mg/dL.</td>
</tr>
<tr>
<td>Carimune&lt;sup&gt;®&lt;/sup&gt; NF</td>
<td></td>
<td></td>
<td>Starting with the second infusion, adjust the dose proportionally, targeting a trough of ≥ 600 mg/dL, based on the previous trough and the associated dose.</td>
</tr>
<tr>
<td>Carimune NF</td>
<td>Acute immune thrombocytopenic purpura</td>
<td>N/A</td>
<td>400 mg/kg IV daily for 2 to 5 days</td>
</tr>
</tbody>
</table>

HPHC Medical Policy

Intravenous Immune Globulin (IVIG)

Harvard Pilgrim Stride<sup>SM</sup> (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim Stride<sup>SM</sup> (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.
<table>
<thead>
<tr>
<th>Product</th>
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<th>FDA-approved loading dose (if applicable)</th>
<th>FDA-approved directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carimune NF</td>
<td>Chronic immune thrombocytopenic purpura</td>
<td>N/A</td>
<td>In adults and children, if after induction therapy the platelet count falls to less than 30,000/µL and/or the patient manifests clinically significant bleeding, 0.4 g/kg of body weight may be given as a single infusion. If an adequate response does not result, the dose can be increased to 0.8–1 g/kg of body weight given as a single infusion.</td>
</tr>
<tr>
<td>Flebogamma DIF 5%</td>
<td>Primary (inherited) immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Flebogamma DIF 10%</td>
<td>Primary immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Flebogamma DIF 10%</td>
<td>Primary immune thrombocytopenia (ITP)</td>
<td>N/A</td>
<td>1 gram/kg once daily for 2 consecutive days.</td>
</tr>
<tr>
<td>Gammagard Liquid</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gammagard Liquid</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>Starting SC dose in grams 1.37 x (600 mg/kg DIVIDED BY # of weeks between IV doses). Adjust SC dose according to patient response, maximum of 106 mL per week</td>
</tr>
<tr>
<td>Gammagard Liquid</td>
<td>Multifocal motor neuropathy</td>
<td>N/A</td>
<td>2.4 grams/kg IV per month</td>
</tr>
<tr>
<td>Gammagard S/D</td>
<td>Primary immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gammagard S/D</td>
<td>B-cell chronic lymphocytic leukemia</td>
<td>N/A</td>
<td>400 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gammagard S/D</td>
<td>Idiopathic immune thrombocytopenic purpura (ITP)</td>
<td>N/A</td>
<td>1 gram/kg IV every other day for up to three separate doses</td>
</tr>
<tr>
<td>Gammagard S/D</td>
<td>Kawasaki syndrome</td>
<td>N/A</td>
<td>1 gram/kg IV as a single dose OR 400 mg/kg IV daily for 4 consecutive days</td>
</tr>
<tr>
<td>Gammaked</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gammaked</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>Starting SC dose in grams 1.37 x (600 mg/kg DIVIDED BY # of weeks between IV doses).</td>
</tr>
<tr>
<td>Product</td>
<td>Indication</td>
<td>FDA-approved loading dose (if applicable)</td>
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</tr>
<tr>
<td>Gammaked</td>
<td>Idiopathic thrombocytopenic purpura</td>
<td>N/A</td>
<td>Adjust SC dose according to patient response, maximum of 100 mL per week</td>
</tr>
<tr>
<td></td>
<td>Chronic inflammatory demyelinating polyneuropathy (CIDP)</td>
<td>2 g/kg (20 mL/kg) given in divided doses over two to four consecutive days</td>
<td>1 g/kg IV once daily for 2 consecutive days OR 400 mg/kg IV once daily for 5 days</td>
</tr>
<tr>
<td>Gammaplex</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>800 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gammaplex</td>
<td>Chronic immune thrombocytopenic purpura (ITP)</td>
<td>N/A</td>
<td>1 g/kg IV once daily for 2 consecutive days</td>
</tr>
<tr>
<td>Gamunex-C</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Gamunex-C</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>Starting SC dose in grams 1.37 x (600 mg/kg DIVIDED BY number of weeks between IV doses. ADJUST SC dose according to patient response, maximum of 100 mL per week</td>
</tr>
<tr>
<td>Octagam 5%</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Octagam 10%</td>
<td>Chronic immune thrombocytopenic purpura</td>
<td>N/A</td>
<td>1 g/kg IV daily for 2 days</td>
</tr>
<tr>
<td>Panzyga</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>600 mg/kg IV once every 3 weeks</td>
</tr>
<tr>
<td>Panzyga</td>
<td>Chronic immune thrombocytopenia</td>
<td>N/A</td>
<td>2 g/kg, divided into two daily doses of 1 g/kg (10 mL/kg) given on two consecutive days</td>
</tr>
<tr>
<td>Privigen</td>
<td>Primary humoral immunodeficiency</td>
<td>N/A</td>
<td>800 mg/kg IV once every 3 weeks</td>
</tr>
</tbody>
</table>
Intravenous Immune Globulin (IVIG)

Harvard Pilgrim Stride℠ considers Intravenous Immune Globulin (IVIG) as experimental/investigational and not medically necessary for all other indications.

Exclusions:

Coding:

Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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), 500mg</td>
</tr>
<tr>
<td>J1557</td>
<td>Injection, immune globulin, (gammaplex), intravenous, non-hyphenlyophilized (e.g., liquid), 500 mg</td>
</tr>
<tr>
<td>J1561</td>
<td>Injection, immune globulin, (Gamunex-c/Gammaked), nonlyophilized (e.g. liquid), 500 mg</td>
</tr>
<tr>
<td>J1568</td>
<td>Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg</td>
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<td>J1572</td>
<td>Injection, immune globulin, (Flebogamma / Flebogamma DIF), intravenous, nonlyophilized (e.g, liquid), 500 mg</td>
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Appendices:

Appendix A: Impaired Antibody Response to Pneumococcal Polysaccharide Vaccine

- Age 2 years and older: impaired antibody response demonstrated to vaccination with a pneumococcal polysaccharide vaccine
- Not established for children less than 2 years of age
- Excludes the therapy initiated in the hospital setting

Appendix B: Examples of Risk Factors for Bleeding (not all inclusive)

- Undergoing a medical or dental procedure where blood loss is anticipated
- Comorbidity (e.g., peptic ulcer disease, hypertension)
- Mandated anticoagulation therapy
- Profession or lifestyle predisposes patient to trauma (e.g., construction worker, fireman, professional athlete)

References:

Medicare Advantage Plan. Providers are responsible for reviewing materials. These policies are intended to provide National and Local Coverage Determinations.

Harvard Pilgrim

Intravenous Immune Globulin (IVIG)


HPHC Medical Policy

Intravenous Immune Globulin (IVIG)

Harvard Pilgrim StrideSM (HMO) policies are based on medical science and relevant information including current Medicare coverage (including National and Local Coverage Determinations), Harvard Pilgrim medical policies, and Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan materials. These policies are intended to provide benefit coverage information and guidelines specific to the Harvard Pilgrim StrideSM (HMO) Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.
Conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will provide benefit coverage information and guidelines specific to the Harvard Pilgrim Medicare Advantage Plan. Providers are responsible for reviewing the CMS Medicare Coverage Center guidance; in the event that there is a conflict between this document and the CMS Medicare Coverage Center guidance, the CMS Medicare Coverage Center guidance will control.


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Approved by Medical Policy Committee: 2/16/21
Approved by Clinical Policy Operational Committee: 5/20; 3/21
Policy Effective Date: 03/08/21
Initiated: 3/20