Immune Globulins (immunoglobulin) (Intravenous)

Document Number: MODA-0071

Last Review Date: 10/02/2018
Date of Origin: 07/20/2010

I. Length of Authorization

- Initial and renewal authorization periods vary by specific covered indication.
- Unless otherwise specified, the initial authorization will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Vial size in IgG grams</th>
<th># of vials</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LOAD</td>
<td>per 28 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>One time only</td>
<td>MAINTENANCE</td>
<td></td>
</tr>
<tr>
<td>Bivigam</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>23</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Carimune NF</td>
<td>3,6</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>19</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Flebogamma 10% DIF</td>
<td>5, 10, 20</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Flebogamma 5% DIF</td>
<td>2.5, 5, 10</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Gamunex-C</td>
<td>1, 2.5, 5, 10, 20</td>
<td>1</td>
<td>1</td>
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<tr>
<td></td>
<td>40</td>
<td>6</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Gammagard Liquid</td>
<td>1, 2.5, 5, 10, 20</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Gammagard S/D</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>23</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Gammaked</td>
<td>1, 2.5, 5, 10</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Gammaplex</td>
<td>2.5, 5, 10</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Octagam 10%</td>
<td>2, 5, 10</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>11</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1, 2.5, 5, 10</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
B. Max Units (per dose and over time) [Medical Benefit]:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Billable Units</th>
<th>Per # days (unless otherwise specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PID</td>
<td>184</td>
<td>21</td>
</tr>
<tr>
<td>CIDP</td>
<td>Load: 460</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Maintenance: 230</td>
<td>21</td>
</tr>
<tr>
<td>Immune thrombocytopenia/ITP</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>FAIT</td>
<td>200</td>
<td>7</td>
</tr>
<tr>
<td>Kawasaki’s Disease (Pediatric Patients only)</td>
<td>232</td>
<td>1 dose only</td>
</tr>
<tr>
<td>Multifocal Motor Neuropathy</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>CLL/MM</td>
<td>92</td>
<td>21</td>
</tr>
<tr>
<td>ALL</td>
<td>92</td>
<td>21</td>
</tr>
<tr>
<td>HIV (Pediatric Patients only)</td>
<td>47</td>
<td>28</td>
</tr>
<tr>
<td>Guillain-Barre</td>
<td>460</td>
<td>5 (for one cycle only)</td>
</tr>
<tr>
<td>Myasthenia Gravis</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>Auto-immune blistering diseases</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>Bone Marrow or Stem Cell Transplant</td>
<td>115</td>
<td>7</td>
</tr>
<tr>
<td>Dermatomyositis/Polymyositis</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>Complications of transplanted solid organ (kidney, liver, lung, heart and pancreas transplants)</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>Stiff Person</td>
<td>460</td>
<td>28</td>
</tr>
<tr>
<td>Toxic shock syndrome</td>
<td>460</td>
<td>5 (for one cycle only)</td>
</tr>
<tr>
<td>NAIT</td>
<td>16</td>
<td>2 doses only</td>
</tr>
<tr>
<td>Management of Immune Checkpoint Inhibitor Related Toxicity</td>
<td>460</td>
<td>5 (for one cycle only)</td>
</tr>
</tbody>
</table>

III. Initial Approval Criteria

Site of care specialty infusion program requirements are met (refer to Moda Site of Care Policy).

Coverage is provided in the following conditions:

- Baseline values for BUN and serum creatinine obtained within 30 days of request; AND

Primary immunodeficiency (PID)/Wiskott - Aldrich syndrome †

Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [list not all inclusive]
• Patient’s IgG level is < 200 mg/dL OR both of the following
  o Patient has a history of multiple hard to treat infections as indicated by at least one of the following:
    ▪ Four or more ear infections within 1 year
    ▪ Two or more serious sinus infections within 1 year
    ▪ Two or more months of antibiotics with little effect
    ▪ Two or more pneumonias within 1 year
    ▪ Recurrent or deep skin abscesses
    ▪ Need for intravenous antibiotics to clear infections
    ▪ Two or more deep-seated infections including septicemia: AND
  o The patient has a deficiency in producing antibodies in response to vaccination: AND
    ▪ Titers were drawn before challenging with vaccination: AND
    ▪ Titers were drawn between 4 and 8 weeks of vaccination

**Immune thrombocytopenia/Idiopathic thrombocytopenia purpura (ITP) †**

*For acute disease state:*
• To manage acute bleeding due to severe thrombocytopenia (platelet counts less than 30 X 10^9/L): OR
• To increase platelet counts prior to invasive surgical procedures such as splenectomy. (Platelets less than 100 X 10^9/L): OR
• Patient has severe thrombocytopenia (platelet counts less than 20 X 10^9/L) and is considered to be at risk for intracerebral hemorrhage

**Note:** Authorization is valid for 1 month only and cannot be renewed

*Chronic Immune Thrombocytopenia (CIT):*
• The patient is at increased risk for bleeding as indicated by a platelet count less than 30 X 10^9/L: AND
• History of failure, contraindication, or intolerance to corticosteroids: AND
• Duration of illness > 6 months: AND
• Patient age ≥ 2 years

*Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) †*
• Patient’s disease course is progressive or relapsing and remitting for 2 months or longer: AND
• Patient has abnormal or absent deep tendon reflexes in upper or lower limbs: AND
• Electrodiagnostic testing indicating demyelination:
  o Partial motor conduction block in at least two motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve: OR
  o Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve: OR
  o Abnormal temporal dispersion conduction must be present in at least 2 motor nerves: OR
  o Reduced conduction velocity in at least 2 motor nerves: OR
  o Prolonged distal motor latency in at least 2 motor nerves: OR
  o Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least 1 other nerve: OR
  o Prolonged F wave latency in at least 2 motor nerves: AND
- Cerebrospinal fluid analysis indicates the following:
  - CSF white cell count of <10 cells/mm³; **AND**
  - CSF protein is elevated; **AND**
- Patient is refractory or intolerant to corticosteroids (e.g., prednisolone, prednisone, etc.) given in therapeutic doses over at least three months; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

**Note:** Initial authorization is valid for 3 months

**Guillain-Barre Syndrome (Acute inflammatory polyneuropathy) ‡**
- Patient’s disease is severe (i.e., patient requires assistance to ambulate); **AND**
- Onset of symptoms are recent (i.e., less than 1 month); **AND**
- Patient has abnormal or absent deep tendon reflexes in upper or lower limbs; **AND**
- Approval will be granted for a maximum of 2 rounds of therapy within 6 weeks of onset

**Note:** Authorization is valid for 2 months only and cannot be renewed

**Multifocal Motor Neuropathy †**
- Patient has progressive multi-focal weakness (without sensory symptoms); **AND**
- Complete or partial conduction block or abnormal temporal dispersion conduction must be present in at least 2 nerves with accompanying normal sensory nerve conduction study across the same nerve that demonstrated the conduction block; **AND**
- Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

**Note:** Initial authorization is valid for 3 months

**HIV infected children: Bacterial control or prevention ‡**
- Patient age does not exceed 13 years of age; **AND**
- Patient’s IgG level is less than 400 mg/dL

**Myasthenia Gravis ‡**
- Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
- Patient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
- Patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); **AND**
- Patient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.)
Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

**Dermatomyositis/Polymyositis ‡**

- Patient has severe active disease: **AND**
- Patient has proximal weakness in all upper and/or lower limbs: **AND**
- Diagnosis has been confirmed by muscle biopsy: **AND**
- Patient has failed a trial of corticosteroids (i.e., prednisone): **AND**
- Patient has failed a trial of an immunosuppressant (e.g., methotrexate, azathioprine, etc.): **AND**
  
  Must be used as part of combination therapy with other agents: **AND**
- Patient has a documented baseline physical exam and muscular strength/function

Note: Initial authorization is valid for 3 months

**Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant ‡**

Coverage is provided for one or more of the following (list not all-inclusive):

- Suppression of panel reactive anti-human leukocyte antigen (HLA) antibodies prior to transplantation
- Treatment of antibody-mediated rejection of solid organ transplantation
- Prevention or treatment of viral infections (e.g., cytomegalovirus, Parvo B-19 virus, and Polyoma BK virus)

**Stiff-Person Syndrome ‡**

- Patient has anti-glutamic acid decarboxylase (GAD) antibodies: **AND**
- Patient has failed at least 2 of the following treatments: benzodiazepines, baclofen, gabapentin, valproate, tiagabine, or levetiracetam: **AND**
- Patient has a documented baseline on physical exam

**Allogeneic Bone Marrow or Stem Cell Transplant ‡**

- Used for prevention of acute Graft-Versus-Host-Disease (aGVHD) or infection: **AND**
- Patient’s BMT was allogeneic: **AND**
- Patient’s IgG level is less than 400 mg/dL

Note: Initial authorization is valid for 3 months

**Kawasaki’s disease (Pediatric) †**

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

**Fetal alloimmune thrombocytopenia (FAIT) ‡**

- Patient has a history of one or more of the following:
  
  o Previous FAIT pregnancy
  o Family history of the disease
Screening reveals platelet alloantibodies

**Note:** Authorization is valid through the delivery date only and cannot be renewed

**Neonatal Alloimmune Thrombocytopenia ‡**

**Note:** Authorization is valid for 1 course (1 month) only and cannot be renewed

**Autoimmune Mucocutaneous Blistering Diseases ‡**

- Patient has been diagnosed with one of the following:
  - Pemphigus vulgaris
  - Pemphigus foliaceus
  - Bullous Pemphigoid
  - Mucous Membrane Pemphigoid (a.k.a. Cicatricial Pemphigoid)
  - Epidermolysis bullosa aquisita
  - Pemphigus gestationis (Herpes gestationis)
  - Linear IgA dermatosis: **AND**
- Patient has severe disease that is extensive and debilitating: **AND**
- Diagnosis has been confirmed by biopsy: **AND**
- Patient’s disease is progressive: **AND**
- Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.): **AND**
- Patient has a documented baseline on physical exam

**Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL) ‡**

- Used for prevention of infection: **AND**
- Patient age is less than 18 years old: **AND**
- Patient’s IgG level is less than 400 mg/dL

**Acquired Immune Deficiency secondary to Chronic lymphocytic leukemia † or Multiple Myeloma ‡**

- Patient’s IgG level is <200 mg/dL OR both of the following
- Patient has a history of multiple hard to treat infections as indicated by at least one of the following:
  - Four or more ear infections within 1 year
  - Two or more serious sinus infections within 1 year
  - Two or more months of antibiotics with little effect
  - Two or more pneumoniases within 1 year
  - Recurrent or deep skin abscesses
  - Need for intravenous antibiotics to clear infections
  - Two or more deep-seated infections including septicemia: **AND**
- The patient has a deficiency in producing antibodies in response to vaccination: **AND**
  - Titers were drawn before challenging with vaccination: **AND**
  - Titers were drawn between 4 and 8 weeks of vaccination
Note: other secondary immunodeficiencies resulting in hypogammaglobulinemia and/or B-cell aplasia will be evaluated on a case-by-case basis

**Toxic Shock Syndrome ‡**

Note: Authorization is valid for 1 course (1 month) only and cannot be renewed

**Management of Immune-Checkpoint-Inhibitor Related Toxicity ‡**

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, etc.); AND
- Patient has one of the following toxicities related to their immunotherapy:
  - Myasthenia gravis refractory to high-dose corticosteroids
  - Severe transverse myelitis
  - Moderate or severe Guillain-Barre Syndrome or peripheral neuropathy toxicity used in combination with pulse-dose methylprednisolone
  - Severe pneumonitis refractory to methylprednisolone after 48 hours of therapy
  - Encephalitis used in combination with pulse-dose methylprednisolone

‡ FDA Approved Indication(s), ‡ Compendia/Literature Supported Indication(s)

<table>
<thead>
<tr>
<th>Brand Name/Formulation</th>
<th>FDA Indication</th>
<th>Contraindications</th>
<th>Product Specs</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Bivigam (liquid)        | PID (peds ≥6)  | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | • IgA: ≤200 mcg/mL  
  • Osmolality: 510 mOsm/kg  
  • Stabilizer: glycine | 1.67 gm of sugar per gm of protein |
| Carimune NF (lyophilized) | PID (peds/adults) a/cITP (peds/adults) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | • IgA: 1000-2000 mcg/mL (6% soln)  
  • Osmolality: 192 to 1074 mOsm/kg (depends on diluent and final conc)  
  • Stabilizer: sucrose | |
| Flebogamma 5% (liquid) | PID (peds ≥2) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | IgA: <50 mcg/mL  
  Osmolarity: 240 to 370 mOsm/kg  
  Stabilizer: sorbitol | |
| Flebogamma 10% (liquid) | PID (peds ≥2) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | IgA: <32 mcg/mL  
  Osmolarity: 240 to 370 mOsm/L  
  Stabilizer: sorbitol | |
| Gammagard (liquid)      | PID (peds ≥2) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | IgA: 37 mcg/mL  
  Osmolality: 240 to 300 mOsm/kg  
  Stabilizer: glycine | May be used SC (see policy for criteria |
| Gammagard S/D (lyophilized) | PID ITP CLL Kawasaki (adults/peds for all indx) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | IgA: <1 mcg/mL (5% solution)  
  Osmolality: 636 mOsm/L (5% soln)  
  Stabilizer: glycine | Contains some sugar (20mg/mL when prepared) |
| Gammaked (liquid)       | PID (peds ≥2) | History of anaphylaxis to IgG IgA-deficient with IgA antibodies | IgA: 46 mcg/mL  
  Osmolality: 258 mOsm/kg  
  Stabilizer: glycine | May be used SC (see policy for criteria |
<p>| Gammaplex 5% (liquid)   | PID (peds ≥2) | History of anaphylaxis to IgG | IgA: &lt;10 mcg/mL | Other stabilizer used is Polysorbate 80 |</p>
<table>
<thead>
<tr>
<th><strong>Moda Health Plan, Inc. Medical Necessity Criteria</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Page 8</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IgA-deficient with IgA antibodies or Fructose intolerance</th>
<th>Osmolality: 420 to 500 mOsm/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gammaplex 10% (liquid)</strong></td>
<td><strong>Stabilizer</strong>: glycine</td>
</tr>
<tr>
<td>PID (adults)</td>
<td>eITP (adults)</td>
</tr>
<tr>
<td>History of anaphylaxis to IgG</td>
<td>IgA: &lt;20 mcg/mL</td>
</tr>
<tr>
<td>IgA-deficient with IgA antibodies</td>
<td>Osmolality: 280 mOsm/kg</td>
</tr>
<tr>
<td><strong>Gamunex-C (liquid)</strong></td>
<td><strong>Stabilizer</strong>: glycine</td>
</tr>
<tr>
<td>PID (peds ≥2)</td>
<td>ITP (peds/adults)</td>
</tr>
<tr>
<td>(adults)</td>
<td>CIDP (adults)</td>
</tr>
<tr>
<td>History of anaphylaxis to IgG</td>
<td>IgA: 46 mcg/mL</td>
</tr>
<tr>
<td>IgA-deficient with IgA antibodies</td>
<td>Osmolality: 258 mOsm/kg</td>
</tr>
<tr>
<td><strong>Octagam 5% (liquid)</strong></td>
<td><strong>Stabilizer</strong>: maltose</td>
</tr>
<tr>
<td>PID (peds≥6)</td>
<td>ITP (adults)</td>
</tr>
<tr>
<td>History of anaphylaxis to IgG</td>
<td>IgA: ≤200 mcg/mL</td>
</tr>
<tr>
<td>IgA-deficient with IgA antibodies</td>
<td>Osmolality: 310 to 380 mOsm/kg</td>
</tr>
<tr>
<td>Corn allergy</td>
<td><strong>Other stabilizer used is Polysorbate 80</strong></td>
</tr>
<tr>
<td><strong>Octagam 10% (liquid)</strong></td>
<td><strong>Stabilizer</strong>: maltose</td>
</tr>
<tr>
<td>PID</td>
<td>cITP (peds≥15)</td>
</tr>
<tr>
<td>ITP (adults)</td>
<td>CIDP (adults)</td>
</tr>
<tr>
<td>History of anaphylaxis to IgG</td>
<td>IgA: ≤25 mcg/mL</td>
</tr>
<tr>
<td>IgA-deficient with IgA antibodies</td>
<td>Osmolality: 320 mOsm/kg</td>
</tr>
<tr>
<td>Hyperprolinemia</td>
<td><strong>Stabilizer</strong>: L-proline</td>
</tr>
<tr>
<td><strong>Privigen (liquid)</strong></td>
<td>GREY</td>
</tr>
<tr>
<td>PID</td>
<td>cITP (peds ≥2)</td>
</tr>
<tr>
<td>ITP (adults)</td>
<td>cITP (adults)</td>
</tr>
<tr>
<td>History of anaphylaxis to IgG</td>
<td>IgA: ≤100 mcg/mL</td>
</tr>
<tr>
<td>IgA-deficient with IgA antibodies</td>
<td>Osmolality: 240-310 mOsm/kg</td>
</tr>
</tbody>
</table>

All intravenous immunoglobulins are derived from human plasma. Products with higher IgA content pose a greater risk for anaphylactic reactions, especially in patients with IgA deficiencies. All products may predispose patients to nephrotoxicity especially those with sugar-based or proline-based stabilizers. To lower risks, lower concentration products and infusions rates should be used as well as using products with osmolality/osmolarity that is near physiologic range (around 300 mOsm/kg or mOsm/L). Premedications (e.g., acetaminophen, antihistamine, etc) are recommended to reduce the risk of infusion related reactions.


### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

**Note**: unless otherwise specified, renewal authorizations are provided for 1 year

- Patient continues to meet criteria identified in section III: **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions, volume overload, etc.: **AND**
- BUN and serum creatinine have been obtained within the last 6 months and the concentration and rate of infusion have been adjusted accordingly: **AND**
- Patient meets the disease-specific criteria identified below:

**Primary Immunodeficiency (PID)**

- Disease response as evidenced by one or more of the following:
- Decrease in the frequency of infection
- Decrease in the severity of infection

**Chronic Immune Thrombocytopenia/ITP**
- Disease response as indicated by the achievement and maintenance of a platelet count of at least $50 \times 10^9/L$ as necessary to reduce the risk for bleeding

**Chronic Inflammatory Demyelinating Polyneuropathy**
- Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

**Multifocal Motor Neuropathy**
- Renewals will be authorized for patients that have demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

**HIV infected children: Bacterial control or prevention**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient continues to be at an increased risk of infection necessitating continued therapy

**Dermatomyositis/Polymyositis**
- Patient had an improvement from baseline on physical exam and/or muscular strength and function

**Note:** Renewal authorizations are provided for 6 months

**Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection; **AND**
- Patient continues to be at an increased risk of infection necessitating continued therapy

**Stiff Person Syndrome**
- Documented improvement from baseline on physical exam

**Allogeneic Bone Marrow or Stem Cell Transplant**
- Patient’s IgG trough is less than 400 mg/dL
  **Note:** Renewal authorizations are provided for 3 months

**Auto-Immune Mucocutaneous Blistering Diseases**
- Documented improvement from baseline on physical exam

**Note:** Renewal authorizations are provided for 6 months

**Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia or Multiple Myeloma**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection: AND
- Patient continues to be at an increased risk of infection necessitating continued therapy

**Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL)**
- Disease response as evidenced by one or more of the following:
  - Decrease in the frequency of infection
  - Decrease in the severity of infection: AND
- Patient continues to be at an increased risk of infection necessitating continued therapy

**Management of Immune Checkpoint Inhibitor related Toxicity ‡**
- May not be renewed.

**Note:** Renewal authorizations are provided for 6 months

<table>
<thead>
<tr>
<th>Dosing Recommendations:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient’s dose should be reduced to the lowest necessary to maintain benefit for their condition. Patients who are stable, or who have reached the maximum therapeutic response, should have a trial of dose reduction (e.g., 25-50% reduction in dose every 3 months).</td>
</tr>
<tr>
<td>• Patients who have tolerated dose reduction and continue to show sustained improvement (i.e. remission) should have a trial of treatment discontinuation; with the following exceptions:</td>
</tr>
<tr>
<td>- PID would be excluded from a trial of discontinuation</td>
</tr>
<tr>
<td>- HIV-infected children should show satisfactory control of the underlying disease [e.g., undetectable viral load, CD4 counts elevated above 200 or &gt;15% (ages 9 months – 5 years) on antiretroviral therapy, etc.]</td>
</tr>
<tr>
<td>- Solid organ transplant, CLL, and MM patients should not be at an increased risk of infection</td>
</tr>
</tbody>
</table>

**V. Dosage/Administration**

Dosing should be calculated using adjusted body weight if one or more of the following criteria are met:

- Patient’s body mass index (BMI) is 30 kg/m² or more; OR
- Patient’s actual body weight is 20% higher than his or her ideal body weight (IBW)
Use the following dosing formulas to calculate the adjusted body weight (round dose to nearest 5 gram increment in adult patients):

<table>
<thead>
<tr>
<th>Dosing formulas</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI = 703 x (weight in pounds/height in inches²)</td>
</tr>
<tr>
<td>IBW (kg) for males = 50 + [2.3 (height in inches – 60)]</td>
</tr>
<tr>
<td>IBW (kg) for females = 45.5 + [2.3 x (height in inches – 60)]</td>
</tr>
<tr>
<td>Adjusted body weight = IBW + 0.5 (actual body weight – IBW)</td>
</tr>
</tbody>
</table>

This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>PID</td>
<td>200 to 800 mg/kg every 21 to 28 days</td>
</tr>
<tr>
<td>CIDP</td>
<td>2 g/kg divided over 2-5 days initially, then 1 g/kg administered in 1-2 infusions every 21 days</td>
</tr>
<tr>
<td>ITP</td>
<td>2 g/kg divided over 5 days or 1 g/kg once daily for 2 consecutive days in a 28-day cycle</td>
</tr>
<tr>
<td>FAIT</td>
<td>1 g/kg/week until delivery</td>
</tr>
<tr>
<td>Kawasaki’s Disease (Pediatric Patients)</td>
<td>1 g/kg to 2 g/kg x 1 course</td>
</tr>
<tr>
<td>Multifocal Motor Neuropathy</td>
<td>Up to 2 g/kg divided over 5 days in a 28-day cycle</td>
</tr>
<tr>
<td>Acquired immune deficiency: CLL, MM and ALL</td>
<td>400 mg/kg every 3 to 4 weeks</td>
</tr>
<tr>
<td>Pediatric HIV</td>
<td>400 mg/kg every 2 to 4 weeks</td>
</tr>
<tr>
<td>Guillain-Barre</td>
<td>2 g/kg divided over 5 days x 1 course</td>
</tr>
<tr>
<td>Myasthenia Gravis</td>
<td>1-2 g/kg divided as either 0.5 g/kg daily x 2 days or 0.4 g/kg daily x 5 days x 1 course</td>
</tr>
<tr>
<td>Auto-immune blistering diseases</td>
<td>Up to 2 g/kg divided over 5 days in a 28-day cycle</td>
</tr>
<tr>
<td>Dermatomyositis/Polymyositis</td>
<td>2 g/kg divided over 2 to 5 days in a 28-day cycle</td>
</tr>
<tr>
<td>Bone Marrow or Stem Cell Transplant</td>
<td>500 mg/kg once weekly x 90 days, then 500 mg/kg every 3 to 4 weeks</td>
</tr>
<tr>
<td>Complications of transplanted solid organ: (kidney, liver, lung, heart, pancreas) transplant</td>
<td>2 g/kg divided over 5 days in a 28-day cycle</td>
</tr>
<tr>
<td>Stiff Person</td>
<td>2 g/kg divided over 5 days in a 28-day cycle</td>
</tr>
<tr>
<td>Toxic shock syndrome</td>
<td>2 g/kg divided over 5 days x 1 course</td>
</tr>
<tr>
<td>Indication</td>
<td>Dose</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>----------------------------------------------------</td>
</tr>
<tr>
<td>Neonatal Alloimmune Thrombocytopenia</td>
<td>1 g/kg x 1 dose, may be repeated once if needed</td>
</tr>
<tr>
<td>Management of Immune Checkpoint Inhibitor Related Toxicity</td>
<td>2 g/kg divided over 5 days x 1 course</td>
</tr>
</tbody>
</table>

*Dosing for IVIG is highly variable depending on numerous patient specific factors, indication(s), and the specific product selected. For specific dosing regimens refer to current prescribing literature.***

VI. **Billing Code/Availability Information**

**HCPCS code & NDC:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>J-Code</th>
<th>1 Billable Unit Equivalent</th>
<th>IgG (grams) per SDV</th>
<th>NDC</th>
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</thead>
<tbody>
<tr>
<td>Bivigam</td>
<td>Biotest Pharmaceuticals</td>
<td>J1556</td>
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<td>5</td>
<td>59730-6502-XX</td>
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<tr>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Carimune NF</td>
<td>CSL Behring AG</td>
<td>J1566</td>
<td>500 mg</td>
<td>6</td>
<td>44206-0417-XX</td>
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<td>12</td>
</tr>
<tr>
<td>Flebogamma 10% DIF</td>
<td>Instituto Grifols, S.A.</td>
<td>J1572</td>
<td>500 mg</td>
<td>5, 10, 20</td>
<td>61953-0005-XX</td>
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<tr>
<td>Flebogamma 5% DIF</td>
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<td></td>
<td></td>
<td>2.5, 5, 10, 20</td>
<td>61953-0004-XX</td>
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<tr>
<td>Gamunex-C</td>
<td>Grifols Therapeutics</td>
<td>J1561</td>
<td>500 mg</td>
<td>1, 2.5, 5, 10, 20, 40</td>
<td>13533-0800-XX</td>
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<tr>
<td>Gammagard Liquid</td>
<td>Baxalta</td>
<td>J1569</td>
<td>500 mg</td>
<td>1, 2.5, 5, 10, 20, 30</td>
<td>00944-2700-XX</td>
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<tr>
<td>Gammagard S/D Less IGA</td>
<td>Baxalta</td>
<td>J1566</td>
<td>500 mg</td>
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<td>00944-2656-XX</td>
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<tr>
<td>Gammaked</td>
<td>Grifols Therapeutics</td>
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<td>500 mg</td>
<td>1, 2.5, 5, 10, 20</td>
<td>76125-0900-XX</td>
</tr>
<tr>
<td>Gammmaplex 5%</td>
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<td>J1557</td>
<td>500 mg</td>
<td>5, 10, 20</td>
<td>64208-8234-XX</td>
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<tr>
<td>Gammmaplex 10%</td>
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<td>5, 10, 20</td>
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<td>Octagam 10%</td>
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<td>J1568</td>
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<td>68982-0850-XX</td>
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<tr>
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<td>1, 2.5, 5, 10, 25</td>
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<td>Privigen</td>
<td>CSL Behring LLC</td>
<td>J1459</td>
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### VII. References


### Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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</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>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>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------</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>C90.10</td>
<td>Plasma cell leukemia not having achieved remission</td>
</tr>
<tr>
<td>C90.11</td>
<td>Plasma cell leukemia in remission</td>
</tr>
<tr>
<td>C90.12</td>
<td>Plasma cell leukemia in relapse</td>
</tr>
<tr>
<td>C90.00</td>
<td>Acute lymphoblastic leukemia not having achieved remission</td>
</tr>
<tr>
<td>C90.01</td>
<td>Acute lymphoblastic leukemia, in remission</td>
</tr>
<tr>
<td>C90.02</td>
<td>Acute lymphoblastic leukemia, in relapse</td>
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<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>D69.41</td>
<td>Evans syndrome</td>
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<tr>
<td>D69.42</td>
<td>Congenital and hereditary thrombocytopenic purpura</td>
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<tr>
<td>D69.49</td>
<td>Other primary thrombocytopenia</td>
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<tr>
<td>D69.59</td>
<td>Other secondary thrombocytopenia</td>
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<tr>
<td>D80.0</td>
<td>Hereditary hypogammaglobulinemia</td>
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<tr>
<td>D80.1</td>
<td>Nonfamilial hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.3</td>
<td>Selective deficiency of immunoglobulin G [IgG] subclasses</td>
</tr>
<tr>
<td>D80.5</td>
<td>Immunodeficiency with increased immunoglobulin M [IgM]</td>
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<tr>
<td>D80.7</td>
<td>Transient hypogammaglobulinemia of infancy</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>
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<tr>
<td>D81.2</td>
<td>Severe combined immunodeficiency [SCID] with low or normal B-cell numbers</td>
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<tr>
<td>D81.6</td>
<td>Major histocompatibility complex class I deficiency</td>
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<tr>
<td>D81.7</td>
<td>Major histocompatibility complex class II deficiency</td>
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<tr>
<td>D81.89</td>
<td>Other combined immunodeficiencies</td>
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<tr>
<td>D81.9</td>
<td>Combined immunodeficiency, unspecified</td>
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<tr>
<td>D82.0</td>
<td>Wiskott-Aldrich syndrome</td>
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<td>D82.1</td>
<td>DiGeorge's syndrome</td>
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<tr>
<td>D83.0</td>
<td>Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function</td>
</tr>
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<td>D83.2</td>
<td>Common variable immunodeficiency with autoantibodies to B- or T-cells</td>
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<td>D83.8</td>
<td>Other common variable immunodeficiencies</td>
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<td>D83.9</td>
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<tr>
<td>D89.810</td>
<td>Acute graft-versus-host disease</td>
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<td>D89.812</td>
<td>Acute on chronic graft-versus-host disease</td>
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<td>G03.8</td>
<td>Meningitis due to other specified causes</td>
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<td>G04.81</td>
<td>Other encephalitis and encephalomyelitis</td>
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<td>Bone marrow transplant rejection</td>
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<td>Bone marrow transplant failure</td>
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<td>Bone marrow transplant infection</td>
</tr>
<tr>
<td>T86.09</td>
<td>Other complications of bone marrow transplant</td>
</tr>
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<td>T86.10</td>
<td>Unspecified complication of kidney transplant</td>
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*G61.81 is not payable when associated with diabetes mellitus, dysproteinemias, renal failure, or malnutrition*

### Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

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Jurisdiction(s): 15  
NCD/LCD/Article Document(s): L35891

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NCD/LCD/Article Document(s): A54641, A54643

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NCD/LCD/Article Document(s): A54660, A54662

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NCD/LCD/Article Document(s): A52446

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