

## Immune Globulins (immunoglobulin) NON-HEMATOLOGY and NON-ONCOLOGY POLICY:

**Asceniv; Bivigam; Flebogamma; Gamunex-C; Gammagard Liquid; Gammagard S/D; Gammaked; Gammaplex; Octagam; Privigen; Panzyga**

### (Intravenous)

Effective Date: 01/01/2020

Review Date: 10/02/2019, 1/3/2019, 1/15/2020, 8/3/2020, 6/10/2021, 5/5/2022, 3/2/2023, 12/21/2023, 01/10/2024

Scope: Medicaid\*, Commercial\*, Medicare-Medicaid Plan (MMP)

\*(Medication only available on the Medical Benefit)

For oncology or hematology indications please refer to NHPRI Immune Globulin (IG) (IVIG, SCIG, IMIG) Policy

### 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]:

| Drug     | Vial size in IgG grams | # of vials    |             |
|----------|------------------------|---------------|-------------|
|          |                        | One time only | per 28 days |
|          |                        | LOAD          | MAINTENANCE |
| Asceniv  | 5                      | 18            | 18          |
| Bivigam* | 5                      | 1             | 1           |
|          | 10                     | 23            | 23          |
|          | 5, 10, 20              | 1             | 1           |

|                               |                   |    |    |
|-------------------------------|-------------------|----|----|
| <b>Flebogamma 10% DIF</b>     | 20                | 11 | 11 |
| <b>Flebogamma 5% DIF</b>      | 2.5, 5, 10        | 1  | 1  |
|                               | 20                | 11 | 11 |
| <b>Gamunex-C</b>              | 1, 2.5, 5, 10, 20 | 1  | 1  |
|                               | 40                | 6  | 6  |
| <b>Gammagard Liquid</b>       | 1, 2.5, 5, 10, 20 | 1  | 1  |
|                               | 30                | 8  | 8  |
| <b>Gammagard S/D*</b>         | 5                 | 1  | 1  |
|                               | 10                | 23 | 23 |
| <b>Gammaked</b>               | 1, 2.5, 5, 10     | 1  | 1  |
|                               | 20                | 11 | 11 |
| <b>Gammaplex (5% and 10%)</b> | 2.5, 5, 10        | 1  | 1  |
|                               | 20                | 11 | 11 |
| <b>Octagam 10%</b>            | 2, 5, 10          | 1  | 1  |
|                               | 20                | 11 | 11 |
| <b>Octagam 5%</b>             | 1, 2.5, 5, 10     | 1  | 1  |
|                               | 25                | 9  | 9  |
| <b>Privigen</b>               | 5, 10, 20         | 1  | 1  |
|                               | 40                | 6  | 6  |
| <b>Panzyga</b>                | 1, 2.5, 5, 10, 20 | 1  | 1  |
|                               | 30                | 8  | 8  |

\*Discontinued by the manufacturer

**B. Max Units (per dose and over time) [Medical Benefit]:**

| <b>Indication</b>  | <b>Billable Units</b> | <b>Per # days<br/>(unless otherwise specified)</b> |
|--|-----------------------|--|
| <b>PID and Supportive Care after Rethymic transplant</b> | 180                   | 21   |
| <b>IgG Subclass Deficiency</b>                           | 90                    | 14   |
| <b>CIDP</b>  | Load: 460             | 5  |
|  | Maintenance: 230      | 21   |
| <b>FAIT</b>  | 230                   | 7  |
| <b>Kawasaki's Disease</b>                                | 460                   | 2 doses only                                       |
| <b>Multifocal Motor Neuropathy</b>                       | 460                   | 28   |
| <b>HIV (Pediatric Patients only)</b>                     | 46                    | 14   |
| <b>Guillain-Barre</b>                                    | 460                   | 5 (for two courses only)                           |

|  |                 |                        |
|--|-----------------|------------------------|
| <b>Myasthenia Gravis</b>   | 460             | 28                     |
| <b>Auto-immune blistering diseases</b>   | 460             | 28                     |
| <b>Bone Marrow or Stem Cell Transplant</b>   | Load:120        | 7(for 90 days)         |
|  | Maintenance:120 |                        |
| <b>Dermatomyositis/Polymyositis</b>  | 460             | 28                     |
| <b>Complications of transplanted solid organ<br/>(kidney, liver, lung, heart and pancreas transplants)</b> | 460             | 28                     |
| <b>Stiff Person</b>  | 460             | 28                     |
| <b>Toxic shock syndrome</b>  | 460             | 5 (for one cycle only) |
| <b>NAIT</b>  | 20              | 2 doses only           |
| <b>Management of Immune Checkpoint Inhibitor<br/>Related Toxicity</b>                                      | 460             | 5 (for one cycle only) |

### III. Initial Approval Criteria

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Coverage is provided for the following conditions:

- Baseline values for BUN and serum creatinine are obtained within 30 days of request; **AND**
- If requesting non preferred intravenous immune globulin formulations, such as Asceniv, Bivigam, Gammagard S/D, Gammaplex, Privigen or Panzyga the patient must have a failure or intolerance to the following preferred formulations: Gammaked/Gamunex-C, Gammagard liquid, Flebogamma/Flebogamma DIF, or Octagam [for MMP members that are currently on treatment (within the past 365 days) with Asceniv, Bivigam, Gammagard S/D, Gammaplex, Privigen or Panzyga, they can remain on treatment]

#### **Primary immunodeficiency (PID)/†**

Such as: Wiskott - Aldrich syndrome, 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 has an IgG level < 200 mg/dL **OR**
- Patient meets 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 pneumonias within 1 year
    - Recurrent, deep skin or organ abscesses
    - Persistent thrush in mouth or fungal infections on the skin
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia
    - Family history of PID; **AND**
  - 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

#### **IgG Subclass Deficiency †<sup>68,96-98</sup>**

- Patient has an IgG level < 400 mg/dL; **AND**
- Patient has a history of recurrent infections; **AND**
- Patient is receiving prophylactic antibiotic therapy

#### **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:
  - 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**
  - Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
  - Abnormal temporal dispersion conduction must be present in at least 2 motor nerves; **OR**
  - Reduced conduction velocity in at least 2 motor nerves; **OR**

- Prolonged distal motor latency in at least 2 motor nerves; **OR**
- Absent F wave in at least two motor nerves plus one other demyelination criterion listed here in at least 1 other nerve; **OR**
- Prolonged F wave latency in at least 2 motor nerves; **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**
- Patient diagnosis is confirmed using a cerebrospinal fluid analysis; **AND**
- Approval will be granted for a maximum of 2 courses 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 motor 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 <13 years of age; **AND**

- Patient has an IgG level <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† (Φ for Octagam 10%) /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**
- Patient will be on combination therapy with corticosteroids or other immunosuppressants; **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, Polyoma BK virus, etc.)

### **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 has an IgG level < 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:
  - Previous FAIT pregnancy
  - 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

### **Auto-immune 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 acquisita
  - 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 has progressive disease; **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

#### **Toxic Shock Syndrome ‡**

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

#### **Supportive Care after Rethymic transplant ‡ <sup>95</sup>**

- Used as immunoglobulin replacement therapy in pediatric patients with congenital athymia after surgical implantation of Rethymic; **OR**
- Used as re-initiation of treatment 2 months after stopping immunoglobulin replacement therapy in pediatric patients who have an IgG trough level lower than normal range for age

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

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, dostarlimab, tremelimumab, retifanlimab etc.); **AND**
- Patient has one of the following toxicities related to their immunotherapy:
  - Severe (G3) or life-threatening (G4) bullous dermatitis as an adjunct to rituximab
  - Stevens-Johnson syndrome (SJS)
  - Toxic epidermal necrolysis (TEN)
  - Severe (G3-4) myasthenia gravis
  - Demyelinating disease (optic neuritis, transverse myelitis, acute demyelinating encephalomyelitis)



- Myocarditis as further intervention if no improvement within 24-48 hours of starting high-dose methylprednisolone
- Moderate (G2) or severe (G3-4) Guillain-Barré Syndrome or severe (G3-4) peripheral neuropathy used in combination with high-dose methylprednisolone
- Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids
- Severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone
- Encephalitis used in combination with high-dose methylprednisolone for severe or progressing symptoms
- Moderate, severe, or life-threatening steroid-refractory myositis (proximal muscle weakness, neck flexor weakness, with or without myalgias) for significant dysphagia, life-threatening situations, or cases refractory to corticosteroids

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

| <b>*For Reference Use Only</b>     |   |  |   |   |
|------------------------------------|---|--|---|---|
| <b>Brand Name/<br/>Formulation</b> | <b>FDA Indication</b>                                       | <b>Contraindications</b>   | <b>Product Specs</b>  | <b>Comments</b>                             |
| Asceniv 10%                        | PID (≥12yo)   | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> ≤200 mcg/mL</li> <li>● <b>Osmolality:</b> 370 to 510 mOsm/kg</li> <li>● <b>Stabilizer:</b> Glycine</li> </ul>                    | Other stabilizer used is Polysorbate 80     |
| Bivigam❖ 10% (liquid)              | PID (peds ≥6)   | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> ≤200 mcg/mL</li> <li>● <b>Osmolality:</b> 370 to 510 mOsm/kg</li> <li>● <b>Stabilizer:</b> glycine</li> </ul>                    |   |
| Flebogamma 5% (liquid)             | PID (peds ≥2)   | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> &lt;50 mcg/mL</li> <li>● <b>Osmolarity:</b> 240 to 370 mOsm/kg</li> <li>● <b>Stabilizer:</b> sorbitol</li> </ul>                 |   |
| Flebogamma 10% (liquid)            | PID (peds ≥2)<br>ITP (peds ≥2)                              | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> &lt;32 mcg/mL</li> <li>● <b>Osmolarity:</b> 240 to 370 mOsm/L</li> <li>● <b>Stabilizer:</b> sorbitol</li> </ul>                  |   |
| Gammagard 10%(liquid)              | PID (peds ≥2)<br>MMN (adults)                               | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> 37 mcg/mL</li> <li>● <b>Osmolality:</b> 240 to 300 mOsm/kg</li> <li>● <b>Stabilizer:</b> glycine</li> </ul>                      | May be used SC (see policy for criteria)    |
| Gammagard S/D 5% ❖ (lyophilized)   | PID<br>ITP<br>CLL<br>Kawasaki<br>(adults/peds for all indx) | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies | <ul style="list-style-type: none"> <li>● <b>IgA:</b> &lt;2.2 mcg/mL (5% solution)</li> <li>● <b>Osmolality:</b> 636 mOsm/L (5% soln)</li> <li>● <b>Stabilizer:</b> glycine</li> </ul> | Contains some sugar (20mg/mL when prepared) |

|                        |   |  |  |  |
|------------------------|---|--|--|--|
| Gammaked 10% (liquid)  | PID (peds ≥2)<br>ITP (peds/adults)<br>CIDP (adults) | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies                         | <b>IgA:</b> 46 mcg/mL<br><b>Osmolality:</b> 258 mOsm/kg<br><b>Stabilizer:</b> glycine          | May be used SC (see policy for criteria) |
| Gammaplex 5% (liquid)  | PID (peds ≥2)<br>cITP (adults)                      | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies<br>Fructose intolerance | <b>IgA:</b> <10 mcg/mL<br><b>Osmolality:</b> 460 to 500 mOsm/kg<br><b>Stabilizer:</b> glycine  | Other stabilizer used is Polysorbate 80  |
| Gammaplex 10% (liquid) | PID (adults)<br>cITP (adults)                       | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies                         | <b>IgA:</b> <20 mcg/mL<br><b>Osmolality:</b> 280 mOsm/kg<br><b>Stabilizer:</b> glycine         | Other stabilizer used is Polysorbate 80  |
| Gamunex-C (liquid)     | PID (peds ≥2)<br>ITP (peds/adults)<br>CIDP (adults) | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies                         | <b>IgA:</b> 46 mcg/mL<br><b>Osmolality:</b> 258 mOsm/kg<br><b>Stabilizer:</b> glycine          | May be used SC (see policy for criteria) |
| Octagam 5% (liquid)    | PID (peds ≥6)                                       | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies<br>Corn allergy         | <b>IgA:</b> ≤100 mcg/mL<br><b>Osmolality:</b> 310 to 380 mOsm/kg<br><b>Stabilizer:</b> maltose |  |
| Octagam 10% (liquid)   | ITP (adults)  | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies                         | <b>IgA:</b> 106 mcg/mL<br><b>Osmolality:</b> 310 to 390 mOsm/kg<br><b>Stabilizer:</b> maltose  |  |
| Privigen (liquid)      | PID<br>cITP (ped ≥15)<br>CIDP (adults)              | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies<br>Hyperprolinemia      | <b>IgA:</b> ≤25 mcg/mL<br><b>Osmolality:</b> 320 mOsm/kg<br><b>Stabilizer:</b> L-proline       |  |
| Panzyga                | PID (peds ≥2)<br>cITP (adults)                      | History of anaphylaxis to IgG<br>IgA-deficient with IgA antibodies                         | <b>IgA:</b> ≤100 mcg/mL<br><b>Osmolality:</b> 0 mOsm/kg<br><b>Stabilizer:</b> Glycine          |  |

- 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.

*Adapted from: Professional Resource, Comparison of IVIG Products. Pharmacist's Letter/Prescriber's Letter. December 2016.*

❖Discontinued by the manufacturer

#### 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 : acute kidney injury, thrombosis, hemolysis, hypersensitivity, pulmonary adverse reactions/transfusion related acute lung injury (TRALI), 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**
- 

##### **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

##### **IgG Subclass Deficiency**

- 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 is at a decreased risk of infection as a result of Continued treatment is necessary to decrease the risk of infection

##### **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

### **Myasthenia Gravis**

- May not be renewed.

### **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**
- Continued treatment is necessary to decrease the risk of infection

### **Stiff Person Syndrome**

- Documented improvement from baseline on physical exam

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

- Patient continues to be at an increased risk of infection necessitating continued therapy as evidenced by an IgG level < 400 mg/dL

- 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

#### **Management of Immune Checkpoint Inhibitor related Toxicity ‡**

- May not be renewed.

#### **Supportive Care after Rethymic transplant ‡<sup>95</sup>**

- Renewals for use as initial immunoglobulin replacement therapy will be authorized until all of the following criteria are met:
  - Patient is no longer on immunosuppression (at least 10% of CD3+ T cells are naïve in phenotype); **AND**
  - Patient is at least 9 months post-treatment; **AND**
  - Patient's phytohemagglutinin (PHA) response within normal limits; **OR**
- Renewals for use as re-initiation of treatment after stopping immunoglobulin replacement therapy for patients with an IgG trough level lower than normal range will be continued for 1 year before being retested using the above guidelines

#### Dosing Recommendations:

- 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).
- 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:
  - PID would be excluded from a trial of discontinuation

- HIV-infected children should show satisfactory control of the underlying disease [e.g., undetectable viral load, CD4 counts elevated above 200 or >15% (ages 9 months – 5 years) on antiretroviral therapy, etc.]
- Solid organ transplant, CLL, SLL, ALL and MM patients should not be at an increased risk of infection

## 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/m<sup>2</sup> 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):

| Dosing formulas   |
|---|
| BMI = 703 x (weight in pounds/height in inches <sup>2</sup> ) |
| IBW (kg) for males = 50 + [2.3 (height in inches – 60)]       |
| IBW (kg) for females = 45.5 + [2.3 x (height in inches – 60)] |
| Adjusted body weight = IBW + 0.5 (actual body weight – IBW)   |

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.

| Indication  | Dose  |
|---|---|
| PID and Supportive Care after Rethymic transplant | 200 to 800 mg/kg every 21 to 28 days  |
| CIDP  | 2 g/kg divided over 2-5 days initially, then 1 g/kg administered in 1-2 infusions every 21 days |
| FAIT  | 1 g/kg/week until delivery  |
| Kawasaki’s Disease                                | 1 g/kg to 2 g/kg x 1 dose, may be repeated once if needed                                       |
| Multifocal Motor Neuropathy                       | Up to 2 g/kg divided over 5 days in a 28-day cycle  |

| Indication  | Dose  |
|---|---|
| Pediatric HIV   | 400 mg/kg every 2 to 4 weeks  |
| Guillain-Barre  | 2 g/kg divided over 5 days x 1 course. May be repeated once within 6 weeks of onset if needed |
| Myasthenia Gravis   | 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      |
| Auto-immune blistering diseases   | Up to 2 g/kg divided over 5 days in a 28-day cycle  |
| Dermatomyositis/Polymyositis  | 2 g/kg divided over 2 to 5 days in a 28-day cycle   |
| Bone Marrow or Stem Cell Transplant   | 500 mg/kg once weekly x 90 days, then 500 mg/kg every 3 to 4 weeks                            |
| Complications of transplanted solid organ: (kidney, liver, lung, heart, pancreas) transplant  | 2 g/kg divided over 5 days in a 28-day cycle  |
| Stiff Person Syndrome   | 2 g/kg divided over 5 days in a 28-day cycle  |
| Toxic Shock Syndrome  | 2 g/kg divided over 5 days x 1 course   |
| Neonatal Alloimmune Thrombocytopenia  | 1 g/kg x 1 dose, may be repeated once if needed   |
| Management of Immune Checkpoint Inhibitor Related Toxicity  | 2 g/kg divided over 5 days x 1 course   |
| <p><i>*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.</i></p> |   |

## VI. Billing Code/Availability Information

### HCPCS code & NDC:

| Drug    | Manufacturer   | J-Code or CPT Code   | 1 Billable Unit Equivalent | IgG (grams) per SDV | NDC |
|---------|----------------|----------------------|----------------------------|---------------------|-----|
| Asceniv | ADMA Biologics | J1554<br>or<br>90283 | 500mg                      | 5                   | N/A |

|                             |                            |                      |        |                       |               |
|-----------------------------|----------------------------|----------------------|--------|-----------------------|---------------|
| Bivigam❖                    | Biotest<br>Pharmaceuticals | J1556                | 500 mg | 5                     | 59730-6502-XX |
|                             |                            | or<br>90283          |        | 10                    | 59730-6503-XX |
| Carimune NF❖                | CSL Behring AG             | J1566                | 500 mg | 6                     | 44206-0417-XX |
|                             |                            |                      |        | 12                    | 44206-0418-XX |
| Flebogamma 10% DIF          | Instituto Grifols,<br>S.A. | J1572<br>or<br>90283 | 500 mg | 5, 10, 20             | 61953-0005-XX |
| Flebogamma 5% DIF           |                            |                      |        | 2.5, 5, 10, 20        | 61953-0004-XX |
| Gamunex-C                   | Grifols<br>Therapeutics    | J1561                | 500 mg | 1, 2.5, 5, 10, 20, 40 | 13533-0800-XX |
| Gammagard Liquid            | Baxalta                    | J1569<br>or<br>90283 | 500 mg | 1, 2.5, 5, 10, 20, 30 | 00944-2700-XX |
| Gammagard S/D Less<br>IGA ❖ | Baxalta                    | J1566<br>or<br>90283 | 500 mg | 5                     | 00944-2656-XX |
|                             |                            |                      |        | 10                    | 00944-2658-XX |
| Gammaked                    | Grifols<br>Therapeutics    | J1561                | 500 mg | 1, 2.5, 5, 10, 20     | 76125-0900-XX |
| Gammaplex 5%                | Bio Products<br>Laboratory | J1557<br>or<br>90283 | 500 mg | 5, 10, 20             | 64208-8234-XX |
| Gammaplex 10%               |                            |                      |        | 5, 10, 20             | 64208-8235-XX |
| Octagam 10%                 | Octapharma USA<br>Inc      | J1568<br>or<br>90283 | 500 mg | 2, 5, 10, 20          | 68982-0850-XX |
| Octagam 5%                  |                            |                      |        | 1, 2.5, 5, 10, 25     | 68982-0840-XX |
| Privigen                    | CSL Behring<br>LLC         | J1459<br>or<br>90283 | 500 mg | 5                     | 44206-0436-XX |
|                             |                            |                      |        | 10                    | 44206-0437-XX |
|                             |                            |                      |        | 20                    | 44206-0438-XX |
|                             |                            |                      |        | 40                    | 44206-0439-XX |



|  |                    |                      |        |                       |               |
|--|--------------------|----------------------|--------|-----------------------|---------------|
| Panzyga  | Octapharma USA Inc | J1576<br>or<br>90283 | 500mg  | 1, 2.5, 5, 10, 20, 30 | 68982-0820-XX |
| Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified | N/A                | J1599                | 500 mg | N/A                   | N/A           |
| ❖ <i>Discontinued by the manufacturer</i>  |                    |                      |        |                       |               |

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## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description                         |
|--------|--|
| A48.3  | Toxic shock syndrome                       |
| B20    | Human immunodeficiency virus (HIV) disease |
| B25.0  | Cytomegaloviral pneumonitis                |
| B25.1  | Cytomegaloviral hepatitis                  |
| B25.2  | Cytomegaloviral pancreatitis               |
| B25.8  | Other cytomegaloviral diseases             |
| B25.9  | Cytomegaloviral disease, unspecified       |

| ICD-10  | ICD-10 Description   |
|---------|--|
| D69.41  | Evans syndrome   |
| D80.0   | Hereditary hypogammaglobulinemia   |
| D80.1   | Nonfamilial hypogammaglobulinemia  |
| D80.3   | Selective deficiency of immunoglobulin G [IgG] subclasses                                      |
| D80.5   | Immunodeficiency with increased immunoglobulin M [IgM]   |
| D80.7   | Transient hypogammaglobulinemia of infancy   |
| D81.0   | Severe combined immunodeficiency [SCID] with reticular dysgenesis                              |
| D81.1   | Severe combined immunodeficiency [SCID] with low T- and B-cell numbers                         |
| D81.2   | Severe combined immunodeficiency [SCID] with low or normal B-cell numbers                      |
| D81.6   | Major histocompatibility complex class I deficiency  |
| D81.7   | Major histocompatibility complex class II deficiency   |
| D81.89  | Other combined immunodeficiencies  |
| D81.9   | Combined immunodeficiency, unspecified   |
| D82.0   | Wiskott-Aldrich syndrome   |
| D82.1   | DiGeorge's syndrome  |
| D83.0   | Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function |
| D83.2   | Common variable immunodeficiency with autoantibodies to B- or T-cells                          |
| D83.8   | Other common variable immunodeficiencies   |
| D83.9   | Common variable immunodeficiency, unspecified  |
| D89.810 | Acute graft-versus-host disease  |
| D89.812 | Acute on chronic graft-versus-host disease   |
| G03.8   | Meningitis due to other specified causes   |
| G03.9   | Meningitis, unspecified  |
| G04.81  | Other encephalitis and encephalomyelitis   |
| G04.89  | Other myelitis   |
| G04.90  | Encephalitis and encephalomyelitis, unspecified  |
| G04.91  | Myelitis, unspecified  |
| G25.82  | Stiff-man syndrome   |
| G56.80  | Other specified mononeuropathies of unspecified upper limb                                     |



| ICD-10  | ICD-10 Description   |
|---------|--|
| G56.81  | Other specified mononeuropathies of right upper limb       |
| G56.82  | Other specified mononeuropathies of left upper limb        |
| G56.83  | Other specified mononeuropathies of bilateral upper limbs  |
| G56.90  | Unspecified mononeuropathy of unspecified upper limb       |
| G56.91  | Unspecified mononeuropathy of right upper limb             |
| G56.92  | Unspecified mononeuropathy of left upper limb              |
| G56.93  | Unspecified mononeuropathy of bilateral upper limbs        |
| G57.80  | Other specified mononeuropathies of unspecified lower limb |
| G57.81  | Other specified mononeuropathies of right lower limb       |
| G57.82  | Other specified mononeuropathies of left lower limb        |
| G57.83  | Other specified mononeuropathies of bilateral lower limbs  |
| G57.90  | Unspecified mononeuropathy of unspecified lower limb       |
| G57.91  | Unspecified mononeuropathy of right lower limb             |
| G57.92  | Unspecified mononeuropathy of left lower limb              |
| G57.93  | Unspecified mononeuropathy of bilateral lower limbs        |
| G61.0   | Guillain-Barre syndrome                                    |
| G61.1   | Serum neuropathy   |
| G61.81* | Chronic inflammatory demyelinating polyneuritis            |
| G61.82  | Multifocal motor neuropathy                                |
| G61.89  | Other inflammatory polyneuropathies                        |
| G61.9   | Inflammatory polyneuropathy, unspecified                   |
| G62.89  | Other specified polyneuropathies                           |
| G70.00  | Myasthenia gravis without (acute) exacerbation             |
| G70.01  | Myasthenia gravis with (acute) exacerbation                |
| G90.09  | Other idiopathic peripheral autonomic neuropathy           |
| J70.2   | Acute drug-induced interstitial lung disorders             |
| J70.4   | Drug-induced interstitial lung disorders, unspecified      |
| L10.0   | Pemphigus vulgaris   |
| L10.2   | Pemphigus foliaceus  |

| ICD-10 | ICD-10 Description  |
|--------|---|
| L12.0  | Bullous pemphigoid  |
| L12.1  | Cicatricial pemphigoid  |
| L12.30 | Acquired epidermolysis bullosa, unspecified                     |
| L12.31 | Epidermolysis bullosa due to drug                               |
| L12.35 | Other acquired epidermolysis bullosa                            |
| L12.5  | Other acquired epidermolysis bullosa                            |
| L13.8  | Other specified bullous disorders                               |
| M06.4  | Inflammatory polyarthropathy                                    |
| M30.3  | Mucocutaneous lymph node syndrome [Kawasaki]                    |
| M33.00 | Juvenile dermatomyositis, organ involvement unspecified         |
| M33.01 | Juvenile dermatomyositis with respiratory involvement           |
| M33.02 | Juvenile dermatomyositis with myopathy                          |
| M33.03 | Juvenile dermatomyositis without myopathy                       |
| M33.09 | Juvenile dermatomyositis with other organ involvement           |
| M33.10 | Other dermatomyositis, organ involvement unspecified            |
| M33.11 | Other dermatomyositis with respiratory involvement              |
| M33.12 | Other dermatomyositis with myopathy                             |
| M33.13 | Other dermatomyositis without myopathy                          |
| M33.19 | Other dermatomyositis with other organ involvement              |
| M33.20 | Polymyositis, organ involvement unspecified                     |
| M33.21 | Polymyositis with respiratory involvement                       |
| M33.22 | Polymyositis with myopathy                                      |
| M33.29 | Polymyositis with other organ involvement                       |
| M33.90 | Dermatopolymyositis, unspecified, organ involvement unspecified |
| M33.91 | Dermatopolymyositis, unspecified with respiratory involvement   |
| M33.92 | Dermatopolymyositis, unspecified with myopathy                  |
| M33.93 | Dermatopolymyositis, unspecified without myopathy               |
| M33.99 | Dermatopolymyositis, unspecified with other organ involvement   |
| M36.0  | Dermato(poly)myositis in neoplastic disease                     |

| ICD-10  | ICD-10 Description                                 |
|---------|--|
| O26.40  | Herpes gestationis, unspecified trimester          |
| O26.41  | Herpes gestationis, first trimester                |
| O26.42  | Herpes gestationis, second trimester               |
| O26.43  | Herpes gestationis, third trimester                |
| P61.0   | Transient neonatal thrombocytopenia                |
| T86.00  | Unspecified complication of bone marrow transplant |
| T86.01  | Bone marrow transplant rejection                   |
| T86.02  | Bone marrow transplant failure                     |
| T86.03  | Bone marrow transplant infection                   |
| T86.09  | Other complications of bone marrow transplant      |
| T86.10  | Unspecified complication of kidney transplant      |
| T86.11  | Kidney transplant rejection                        |
| T86.12  | Kidney transplant failure                          |
| T86.13  | Kidney transplant infection                        |
| T86.19  | Other complication of kidney transplant            |
| T86.20  | Unspecified complication of heart transplant       |
| T86.21  | Heart transplant rejection                         |
| T86.22  | Heart transplant failure                           |
| T86.23  | Heart transplant infection                         |
| T86.290 | Cardiac allograft vasculopathy                     |
| T86.298 | Other complications of heart transplant            |
| T86.30  | Unspecified complication of heart-lung transplant  |
| T86.31  | Heart-lung transplant rejection                    |
| T86.32  | Heart-lung transplant failure                      |
| T86.33  | Heart-lung transplant infection                    |
| T86.39  | Other complications of heart-lung transplant       |
| T86.40  | Unspecified complication of liver transplant       |
| T86.41  | Liver transplant rejection                         |
| T86.42  | Liver transplant failure                           |

| ICD-10  | ICD-10 Description                                       |
|---------|--|
| T86.43  | Liver transplant infection                               |
| T86.49  | Other complications of liver transplant                  |
| T86.810 | Lung transplant rejection                                |
| T86.811 | Lung transplant failure                                  |
| T86.812 | Lung transplant infection                                |
| T86.818 | Other complications of lung transplant                   |
| T86.819 | Unspecified complication of lung transplant              |
| T86.890 | Other transplanted tissue rejection                      |
| T86.891 | Other transplanted tissue failure                        |
| T86.892 | Other transplanted tissue infection                      |
| T86.898 | Other complications of other transplanted tissue         |
| T86.899 | Unspecified complication of other transplanted tissue    |
| Z48.21  | Encounter for aftercare following heart transplant       |
| Z48.22  | Encounter for aftercare following kidney transplant      |
| Z48.23  | Encounter for aftercare following liver transplant       |
| Z48.24  | Encounter for aftercare following lung transplant        |
| Z48.280 | Encounter for aftercare following heart-lung transplant  |
| Z48.290 | Encounter for aftercare following bone marrow transplant |
| Z94.0   | Kidney transplant status                                 |
| Z94.1   | Heart transplant status                                  |
| Z94.2   | Lung transplant status                                   |
| Z94.3   | Heart and lungs transplant status                        |
| Z94.4   | Liver transplant status                                  |
| Z94.81  | Bone marrow transplant status                            |
| Z94.83  | Pancreas transplant status                               |
| Z94.84  | Stem cells transplant status                             |

*\*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):

|   |   |
|---|---|
| <b>Jurisdiction(s):</b> N   | <b>NCD/LCD/Article Document (s):</b> L34007 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34007&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34007&amp;bc=gAAAAAAAAAAAAAA==</a> |   |
| <b>Jurisdiction(s):</b> F   | <b>NCD/LCD/Article Document (s):</b> L34074 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34074&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34074&amp;bc=gAAAAAAAAAAAAAA==</a> |   |
| <b>Jurisdiction(s):</b> L; H  | <b>NCD/LCD/Article Document (s):</b> L35093 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35093&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35093&amp;bc=gAAAAAAAAAAAAAA==</a> |   |
| <b>Jurisdiction(s):</b> E   | <b>NCD/LCD/Article Document (s):</b> L34314 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34314&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34314&amp;bc=gAAAAAAAAAAAAAA==</a> |   |
| <b>Jurisdiction(s):</b> 5, 8  | <b>NCD/LCD/Article Document (s):</b> L34771 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34771&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34771&amp;bc=gAAAAAAAAAAAAAA==</a> |   |
| <b>Jurisdiction(s):</b> J, M  | <b>NCD/LCD/Article Document (s):</b> L34580 |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34580&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34580&amp;bc=gAAAAAAAAAAAAAA==</a> |   |

|   |   |
|---|---|
| <b>Jurisdiction(s): ALL</b>   | <b>NCD/LCD/Article Document (s): 250.3</b>          |
| <a href="https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=158&amp;ncdver=1&amp;DocID=250.3&amp;bc=gAAAABAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=158&amp;ncdver=1&amp;DocID=250.3&amp;bc=gAAAABAAAAAAAA%3d%3d&amp;</a> |   |
| <b>Jurisdiction(s): 15</b>  | <b>NCD/LCD/Article Document (s): L35891</b>         |
| <a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35891&amp;bc=gAAAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35891&amp;bc=gAAAAAAAAAAAAAAAA==</a>   |   |
| <b>Jurisdiction(s): E</b>   | <b>NCD/LCD/Article Document (s): A54641, A54643</b> |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54641&amp;bc=gAAAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54641&amp;bc=gAAAAAAAAAAAAAAAA==</a>   |   |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54643&amp;bc=gAAAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A54643&amp;bc=gAAAAAAAAAAAAAAAA==</a>   |   |
| <b>Jurisdiction(s): E</b>   | <b>NCD/LCD/Article Document (s): A54660, A54662</b> |
| <a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A54660&amp;bc=gAAAAAAAAAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A54660&amp;bc=gAAAAAAAAAAAAAAAA%3d%3d&amp;</a>                   |   |
| <a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A54662&amp;bc=gAAAAAAAAAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A54662&amp;bc=gAAAAAAAAAAAAAAAA%3d%3d&amp;</a>                   |   |
| <b>Jurisdiction(s): 6, K</b>  | <b>NCD/LCD/Article Document (s): A52446</b>         |
| <a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52446&amp;bc=gAAAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52446&amp;bc=gAAAAAAAAAAAAAAAA==</a>   |   |

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

| <b>Jurisdiction</b> | <b>Applicable State/US Territory</b>   | <b>Contractor</b>  |
|---------------------|--|--|
| E (1)               | CA, HI, NV, AS, GU, CNMI               | Noridian Healthcare Solutions, LLC                       |
| F (2 & 3)           | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC                       |
| 5                   | KS, NE, IA, MO                         | Wisconsin Physicians Service Insurance Corporation (WPS) |
| 6                   | MN, WI, IL                             | National Government Services, Inc. (NGS)                 |
| H (4 & 7)           | LA, AR, MS, TX, OK, CO, NM             | Novitas Solutions, Inc.                                  |
| 8                   | MI, IN                                 | Wisconsin Physicians Service Insurance Corporation (WPS) |

| <b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b> |   |  |
|--|---|--|
| <b>Jurisdiction</b>  | <b>Applicable State/US Territory</b>  | <b>Contractor</b>                        |
| N (9)  | FL, PR, VI  | First Coast Service Options, Inc.        |
| J (10)   | TN, GA, AL  | Palmetto GBA, LLC                        |
| M (11)   | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                        |
| L (12)   | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                  |
| K (13 & 14)  | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS) |
| 15   | KY, OH  | CGS Administrators, LLC                  |