Immune Globulins (immunoglobulin): Asceniv™; Alyglo™; Bivigam®; Flebogamma®; Gamunex-C®; Gammagard® Liquid; Gammagard® S/D; Gammaked™; Gammaplex®; Octagam®; Privigen®; Panzyga®; Yimmugo® (Intravenous)

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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 annually.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Drug	Vial size in IgG grams	# of vials	
		One time only	per 28 days
		LOAD	MAINTENANCE
Asceniv	5	18	18
Alyglo	5, 10, 20	1	1
Bivigam	5	1	1
	10	23	23
Flebogamma 10% DIF	5, 10, 20	1	1
	20	11	11
Flebogamma 5% DIF	0.5, 2.5, 5, 10	1	1
	20	11	11
Gamunex-C	1, 2.5, 5, 10, 20	1	1
	40	6	6
Gammagard Liquid	1, 2.5, 5, 10, 20	1	1
	30	8	8
	5	1	1

Gammagard S/D	10	23	23
Gammaked	1, 2.5, 5, 10	1	1
	20	11	11
Gammaplex (5% and 10%)	5, 10	1	1
	20	11	11
Octagam 10%	2, 5, 10, 20	1	1
	30	8	8
Octagam 5%	1, 2.5, 5, 10	1	1
	25	9	9
Privigen	5, 10, 20	1	1
	40	6	6
Panzyga	1, 2.5, 5, 10, 20	1	1
	30	8	8
Yimmugo	5, 10, 20	1	1

B. Max Units (per dose and over time) [HCPCS Unit]:

Indication	Billable Units	Per # days *(unless otherwise specified)*
PID and Supportive Care after Rethymic transplant	180	21
IgG Subclass Deficiency	90	14
CIDP	Load: 460	5
	Maintenance: 230	21
Immune thrombocytopenia/ITP	460	28
FAIT	230	7
Kawasaki's Disease	460	2 doses only
Multifocal Motor Neuropathy	460	28
CLL/MM	90	21
ALL	90	21
HIV (Pediatric Patients only)	46	14
Guillain-Barré	460	5 (*for two courses only)*
Myasthenia Gravis	460	28
Auto-immune blistering diseases	460	28
Allogeneic Bone Marrow or Stem Cell Transplant	Load: 120	7 (for 90 days)
	Maintenance: 120	21
Dermatomyositis/Polymyositis	460	28
Complications of transplanted solid organ or bone marrow transplant	460	28
Stiff Person Syndrome	460	28

Toxic Shock Syndrome	460	5 *(for one cycle only)*
NAIT	20	2 doses only
Management of Immune Checkpoint Inhibitor Related Toxicity	460	5 *(for one cycle only)*
Management of CAR T-Cell-Related Toxicity	120	28

III. Initial Approval Criteria [1-16,71]

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

Coverage is provided for the following conditions:

- Patients must have failed, or have a contraindication, or intolerance to ALL other IVIG products prior to consideration of Asceniv™; **AND**

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Up to 3 monthly immunomodulatory courses of intravenous immunoglobulin (IVIG) therapy are recommended for coverage to treat pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) and pediatric acute-onset neuropsychiatric syndrome (PANS) when both of the following are met:

- A clinically appropriate trial of two or more less-intensive treatments (for example, appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short course antibiotic therapy) was either not effective, not tolerated, or did not result in sustained improvement in symptoms (as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex). These trials may be done concurrently; **AND**
- A consultation with and recommendation from a pediatric subspecialist (for example, pediatric neurologist, pediatric psychiatrist, neurodevelopmental pediatrician, pediatric rheumatologist, pediatric allergist/immunologist) as well as the recommendation of the patient's primary care provider (for example, family physician, pediatrician, pediatric nurse practitioner, naturopath). The sub specialist consultation may be a teleconsultation. For adolescents, an adult subspecialist consult may replace a pediatric subspecialist consult

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement.

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

Primary Immunodeficiency (PID) † [1-16,38,54,56,57,70,103]

Such as: Wiskott-Aldrich syndrome, x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, 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 the 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 ‡ [57,70,98-100]

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

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) † (**Φ** for Gammaplex) [2,5-9,11-13,32,37,39,81]

For acute ITP:

- Used to manage acute bleeding due to severe thrombocytopenia (platelet count < 30 X 10^9/L); **OR**
- Used to increase platelet counts prior to invasive surgical procedures such as splenectomy (platelet count < 100 X 10^9/L); **OR**
- Patient has severe thrombocytopenia (platelet count < 20 X 10^9/L)

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

For chronic ITP:

- Patient is at increased risk for bleeding as indicated by a platelet count < 30 X 10^9/L; **AND**
- Patient has a history of failure, contraindication, or intolerance to corticosteroids; **AND**
- Duration of illness > 6 months

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) † (**Φ** for Gamunex-C) [4,6,7,12,13,18-22,24-26,42,44,72,116]

- Patient's disease course is progressive or relapsing and remitting for >2 months; **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 2 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 motor 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 2 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-Barré Syndrome (Acute inflammatory polyneuropathy) ‡ [19,21,22,24,30,31,58,70,77,115]

- Patient has severe disease (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 (CSF) 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 † (**Φ** for Gammagard Liquid) [4,19,21,22,24,25]

- Patient has progressive, focal, asymmetric limb weakness (without sensory symptoms) for >1 month; **AND**
- Patient has complete or partial conduction block or abnormal temporal dispersion conduction in at least 2 motor nerves; **AND**
- Patient has normal sensory nerve conduction on all nerves tested; **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 ‡ [27,28,37,89]

- Patient ≤ 13 years of age; **AND**
- Patient has an IgG level < 400 mg/dL

Myasthenia Gravis ‡ [53,78,85]

- 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 ‡** [11,19,21,22,24,65,66,70,82,87]

- 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 ‡ [59-62,70,102]

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 ‡ [21,24,64,114]

- Patient has anti-glutamic acid decarboxylase (GAD) antibodies; **AND**
- Patient has failed ≥ 2 of the following treatments: benzodiazepines (e.g., diazepam, clonazepam, alprazolam, lorazepam, oxazepam, temazepam, etc.), anti-spasticity agents (e.g., baclofen, tizanidine, etc.) or anti-epileptics (e.g., gabapentin, valproate, tiagabine, levetiracetam, etc.); **AND**
- Patient has a documented baseline on physical exam

Allogeneic Bone Marrow or Stem Cell Transplant ‡ [76,102,113]

- Used for prevention of acute Graft-Versus-Host-Disease (aGVHD) or infection; **AND**
- Patient's bone marrow (BMT) or hematopoietic stem cell (HSCT) transplant was allogeneic; **AND**
- Patient has an IgG level < 400 mg/dL

Note: Initial authorization is valid for 3 months

Kawasaki's Disease † [5,83]

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

Fetal Alloimmune Thrombocytopenia (FAIT) ‡ [32,37,47,84,90]

- 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 (NAIT) ‡ [35-37,84]

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

Autoimmune Mucocutaneous Blistering Diseases ‡ [34,40,41,67-69,91,110-112]

- 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 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

Acquired Immune Deficiency Secondary to Acute Lymphoblastic Leukemia (ALL) ‡ or Multiple Myeloma ‡ [37,70,79,92,106]

- Used for prevention of infection; **AND**
- Patient has an IgG level < 400 mg/dL

Acquired Immune Deficiency Secondary to Chronic Lymphocytic Leukemia † ‡ or Small Lymphocytic Lymphoma ‡ [5,37,70,88,103,107]

- Patient has an IgG level < 200 mg/dL; **OR**
- Patient has an IgG level < 500 mg/dL**; AND**
  - Patient has recurrent sinopulmonary infections requiring IV antibiotics or hospitalization; **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 the mouth or fungal infections on the skin
    - 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 ‡ [46,93,94]

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

Management of Immune-Checkpoint-Inhibitor Related Toxicity ‡ [73,80]

- 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

Management of CAR T-Cell-Related Toxicity ‡ [73,80,86,95,96,104,105]

- Patient has received treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**
  - Used for the management of G4 cytokine release syndrome (CRS) that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); **OR**
  - Patient has hypogammaglobulinemia as confirmed by serum IgG levels <600 mg/dL and serious or recurrent infections; **OR**
- Patient has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); **AND**
  - Used for the management of G4 cytokine release syndrome (CRS) that is refractory to high-dose corticosteroids and anti-IL-6 therapy (e.g., tocilizumab); **OR**
  - Patient has hypogammaglobulinemia as confirmed by serum IgG levels <400 mg/dL; **OR**
- Used as prophylactic therapy prior to receiving treatment with anti-CD19 or BCMA-targeted CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, ciltacabtagene autoleucel, etc.); **AND**
  - Patient has hypogammaglobulinemia as confirmed by serum IgG levels ≤400 mg/dL and serious, persistent, or recurrent bacterial infections

Supportive Care after Rethymic transplant ‡ [97]

- 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

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Brand Name/ Formulation	**FDA Indication**	**Contraindications**	**Product Specs**	**Comments**
Asceniv 10%	PID (≥12yo)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	• **IgA**: ≤200 mcg/mL • **Osmolality**: 370 to 510 mOsm/kg • **Stabilizer**: Glycine	Other stabilizer used is Polysorbate 80
Alyglo 10%	PID (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	• **IgA**: ≤100 mcg/mL • **Osmolality**: N/A • **Stabilizer**: Glycine	
Bivigam 10% (liquid)	PID (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	• **IgA**: ≤200 mcg/mL • **Osmolality**: 370 to 510 mOsm/kg • **Stabilizer**: glycine	
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) cITP (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 10% (liquid)	PID (peds ≥2) MMN (adults) CIDP (adults)	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 SCIG policy for criteria)
Gammagard S/D 5%(lyophilized)	PID (peds ≥2) cITP (adult) CLL Kawasaki (peds)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: ≤2.2 mcg/mL **Osmolality**: 636 mOsm/L **Stabilizer**: glycine	Contains some sugar (20mg/mL when prepared)
Gammaked 10% (liquid)	PID (peds ≥2) aITP or cITP (peds/adults) CIDP (adults)	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 SCIG policy for criteria)
Gammaplex 5% (liquid)	PID (peds ≥2) cITP (peds/adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Fructose intolerance	**IgA**: <10 mcg/mL **Osmolality**: 460 to 500 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Gammaplex 10% (liquid)	PID (peds ≥2) cITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <20 mcg/mL **Osmolality**: 280 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Gamunex-C 10% (liquid)	PID (peds ≥2) aITP or cITP (peds/adults) CIDP (adults)	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 SCIG policy for criteria)
Octagam 5% (liquid)	PID (peds ≥6)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Corn allergy	**IgA**: ≤100 mcg/mL **Osmolality**: 310 to 380 mOsm/kg **Stabilizer**: maltose	

Octagam 10% (liquid)	cITP (adults) Dermatomyositis (adult)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 106 mcg/mL **Osmolality**: 310 to 380 mOsm/kg **Stabilizer**: maltose	
Panzyga 10% (liquid)	PID (peds ≥2) cITP (adults) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: ≤100 mcg/mL **Osmolality**: 240 to 310 mOsm/kg **Stabilizer**: glycine	
Privigen 10% (liquid)	PID (peds ≥3) cITP (ped ≥15) CIDP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Hyperprolinemia	**IgA**: ≤25 mcg/mL **Osmolality**: 320 mOsm/kg **Stabilizer**: L-proline	
Yimmugo 10% (liquid)	PID (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: ≤300 mcg/mL **Osmolality**: 280 to 380 mOsm/kg **Stabilizer**: N/A	Does not contain carbohydrate stabilizers (e.g., sucrose, maltose) or preservatives
– 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.* *- Product package inserts* *- Characteristics of Immunoglobulin Products Used to Treat Primary Immunodeficiencies (PI). Immune Deficiency Foundation. April 2020*				

IV. Renewal Criteria [1-16,57,71]

Coverage can be renewed based upon the following criteria:

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

- Patient continues to meet indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: renal dysfunction and acute renal failure, thrombosis, hemolysis, severe hypersensitivity reactions, pulmonary adverse reactions/transfusion-related acute lung injury (TRALI), hyperproteinemia, increased serum viscosity, hyponatremia, aseptic meningitis syndrome, hypertension, 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) [1-16,38,54,56,57,70]

- 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 [70,98,100]

- 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

Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) [2,5-9,11-13,32,37,39,81]

- Acute ITP:
  - May not be renewed.
- Chronic ITP:
  - Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 109/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy [4,6,7,12,13,18-22,24-26,42,44,72,116]

- 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.)

Guillain-Barre Syndrome (Acute inflammatory polyneuropathy) [58]

- May not be renewed.

Multifocal Motor Neuropathy [1-14,19,21,22,24,25]

- 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 [27,28,37,89]

- 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 as evidenced by an IgG level < 400 mg/dL

Myasthenia Gravis [53,78,85]

- May not be renewed.

Dermatomyositis/Polymyositis [19,21,22,24,65,66,70,82]

- 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 [59-62,70,102]

- 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 [21,24,64]

- Documented improvement from baseline on physical exam

Allogeneic Bone Marrow or Stem Cell Transplant [76,102]

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

Note: Renewal authorizations are provided for 3 months

Kawasaki's Disease [5,83]

- May not be renewed.

Fetal Alloimmune Thrombocytopenia (FAIT) [33,38,48,85,90]

- Authorization is valid through the delivery date only and cannot be renewed

Neonatal Alloimmune Thrombocytopenia [35-37,84]

- May not be renewed.

Autoimmune Mucocutaneous Blistering Diseases [34,40,41,67-69,91,110-112]

- Documented improvement from baseline on physical exam

Note: Renewal authorizations are provided for 6 months

Acquired Immune Deficiency Secondary to Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), Small Lymphocytic Lymphoma (SLL), or Multiple Myeloma (MM) [37,70,79,92]

- 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

Toxic Shock Syndrome [46,93,94]

- May not be renewed.

Management of Immune Checkpoint Inhibitor Related Toxicity [73,80]

- May not be renewed.

Management of CAR T-Cell-Related Toxicity [73,80,86,104,105]

- Patient has received treatment with anti-CD19 CAR T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**
    - Patient has serum IgG levels <600 mg/dl; **OR**
- Patient is has received treatment with BCMA-targeted CAR T-cell therapy (e.g., idecabtagene vicleucel, ciltacabtagene autoleucel, etc.); **AND**
    - Patient has serum IgG levels <400 mg/dL

Supportive Care after Rethymic transplant ‡ [97]

- 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 [1-16,24,25,32,41,53,58,63,64,76,78-80,83,84,89-94,99,101,102,106,110,111,116]

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^2 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^2)
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 + 0.4 (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
IgG Subclass Deficiency	300 to 400 mg/kg every 14 days
CIDP	2 g/kg divided over 2-5 days initially, then 1 g/kg administered in 1-2 infusions every 21 days
ITP	2 g/kg divided over 5 days or 1 g/kg once daily for 2 consecutive days in a 28-day cycle
Fetal Alloimmune thrombocytopenia (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
Acquired immune deficiency: CLL, SLL, MM, and ALL	400 mg/kg every 3 to 4 weeks
HIV Infected Children	400 mg/kg every 2 to 4 weeks
Guillain-Barré	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
Allogeneic 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) and bone marrow transplant	2 g/kg divided over 5 days in a 28-day cycle

Indication	Dose ¤
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 (NAIT)	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
Management of CAR T-Cell-Related Toxicity	400-500 mg/kg every 28 days
¤ *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:

Drug	Manufacturer	HCPCS Code	1 Billable Unit Equivalent	IgG (grams) per SDV	NDC
Asceniv*	ADMA Biologics	J1554	500 mg	5	69800-0250-XX
Alyglo	GC Biopharma	J1552 *(Effective 01/01/2025)* J1599 *(Discontinue use on 01/01/2025)*	500 mg	5, 10, 20	61476-0104-XX
Bivigam*	ADMA Biologics	J1556	500 mg	5	69800-6502-XX
				10	69800-6503-XX
Flebogamma 10% DIF*	Instituto Grifols, S.A.	J1572	500 mg	5, 10, 20	61953-0005-XX
Flebogamma 5% DIF*				0.5, 2.5, 5, 10, 20	61953-0004-XX
Gamunex-C	Grifols Therapeutics	J1561	500 mg	1, 2.5, 5, 10, 20, 40	13533-0800-XX
Gammagard Liquid*	Baxalta	J1569	500 mg	1, 2.5, 5, 10, 20, 30	00944-2700-XX
Gammagard S/D*	Baxalta	J1566	500 mg	5	00944-2656-XX
				10	00944-2658-XX

Gammaked*	Grifols Therapeutics	J1561	500 mg	1, 2.5, 5, 10, 20	76125-0900-XX
Gammaplex 5%*	Bio Products Laboratory	J1557	500 mg	5, 10, 20	64208-8234-XX
Gammaplex 10%*				5, 10, 20	64208-8235-XX
Octagam 10%*	Octapharma USA Inc	J1568	500 mg	2, 5, 10, 20, 30	68982-0850-XX
Octagam 5%*				1, 2.5, 5, 10, 25	68982-0840-XX
Privigen*	CSL Behring AG	J1459	500 mg	5	44206-0436-XX
				10	44206-0437-XX
				20	44206-0438-XX
				40	44206-0439-XX
Panzyga*	Octapharma USA Inc	J1576	500mg	1, 2.5, 5, 10, 20, 30	68982-0820-XX
Yimmugo	Biotest AG	J1599	N/A	5, 10, 20	83372-0605-XX
Injection, immune globulin, intravenous, non-lyophilized (e.g., liquid), not otherwise specified	N/A	J1599	500 mg	N/A	N/A
**90283 – immune globulin (IgIV), human, for intravenous use*					

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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
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C90.00	Multiple Myeloma not having achieved remission
C90.01	Multiple Myeloma in remission
C90.02	Multiple Myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.00	Acute lymphoblastic leukemia not having achieved remission
C90.01	Acute lymphoblastic leukemia, in remission
C90.02	Acute lymphoblastic leukemia, in relapse

ICD-10	ICD-10 Description
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
D69.42	Congenital and hereditary thrombocytopenic purpura
D69.49	Other primary thrombocytopenia
D69.59	Other secondary thrombocytopenia
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
D82.8	Immunodeficiency associated with other specified major defects
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
D89.834	Cytokine release syndrome, grade 4
D89.839	Cytokine release syndrome, grade unspecified
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

ICD-10	ICD-10 Description
G25.82	Stiff-man syndrome
G56.80	Other specified mononeuropathies of unspecified upper limb
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
G62.0	Drug-induced polyneuropathy
G62.89	Other specified polyneuropathies
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
H46.9	Unspecified optic neuritis
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified
I40.8	Other acute myocarditis
I40.9	Acute myocarditis, unspecified
J70.2	Acute drug-induced interstitial lung disorders
J70.4	Drug-induced interstitial lung disorders, unspecified

ICD-10	ICD-10 Description
L10.0	Pemphigus vulgaris
L10.2	Pemphigus foliaceous
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
L13.9	Bullous disorder, unspecified
L51.1	Stevens-Johnson syndrome
L51.2	Toxic epidermal necrolysis [Lyell]
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
M60.80	Other myositis, unspecified site

ICD-10	ICD-10 Description
M60.811	Other myositis, right shoulder
M60.812	Other myositis, left shoulder
M60.819	Other myositis, unspecified shoulder
M60.821	Other myositis, right upper arm
M60.822	Other myositis, left upper arm
M60.829	Other myositis, unspecified upper arm
M60.831	Other myositis, right forearm
M60.832	Other myositis, left forearm
M60.839	Other myositis, unspecified forearm
M60.841	Other myositis, right hand
M60.842	Other myositis, left hand
M60.849	Other myositis, unspecified hand
M60.851	Other myositis, right thigh
M60.852	Other myositis, left thigh
M60.859	Other myositis, unspecified thigh
M60.861	Other myositis, right lower leg
M60.862	Other myositis, left lower leg
M60.869	Other myositis, unspecified lower leg
M60.871	Other myositis, right ankle and foot
M60.872	Other myositis, left ankle and foot
M60.879	Other myositis, unspecified ankle and foot
M60.88	Other myositis, other site
M60.89	Other myositis, multiple sites
M60.9	Myositis, unspecified
M79.10	Myalgia, unspecified site
M79.11	Myalgia of mastication muscle
M79.12	Myalgia of auxiliary muscles, head and neck
M79.18	Myalgia, other site
O26.40	Herpes gestationis, unspecified trimester
O26.41	Herpes gestationis, first trimester
O26.42	Herpes gestationis, second trimester
O26.43	Herpes gestationis, third trimester
O36.8210	Fetal anemia and thrombocytopenia, first trimester, not applicable or unspecified
O36.8211	Fetal anemia and thrombocytopenia, first trimester, fetus 1

ICD-10	ICD-10 Description
O36.8212	Fetal anemia and thrombocytopenia, first trimester, fetus 2
O36.8213	Fetal anemia and thrombocytopenia, first trimester, fetus 3
O36.8214	Fetal anemia and thrombocytopenia, first trimester, fetus 4
O36.8215	Fetal anemia and thrombocytopenia, first trimester, fetus 5
O36.8219	Fetal anemia and thrombocytopenia, first trimester, other fetus
O36.8220	Fetal anemia and thrombocytopenia, second trimester, not applicable or unspecified
O36.8221	Fetal anemia and thrombocytopenia, second trimester, fetus 1
O36.8222	Fetal anemia and thrombocytopenia, second trimester, fetus 2
O36.8223	Fetal anemia and thrombocytopenia, second trimester, fetus 3
O36.8224	Fetal anemia and thrombocytopenia, second trimester, fetus 4
O36.8225	Fetal anemia and thrombocytopenia, second trimester, fetus 5
O36.8229	Fetal anemia and thrombocytopenia, second trimester, other fetus
O36.8230	Fetal anemia and thrombocytopenia, third trimester, not applicable or unspecified
O36.8231	Fetal anemia and thrombocytopenia, third trimester, fetus 1
O36.8232	Fetal anemia and thrombocytopenia, third trimester, fetus 2
O36.8233	Fetal anemia and thrombocytopenia, third trimester, fetus 3
O36.8234	Fetal anemia and thrombocytopenia, third trimester, fetus 4
O36.8235	Fetal anemia and thrombocytopenia, third trimester, fetus 5
O36.8239	Fetal anemia and thrombocytopenia, third trimester, other fetus
O36.8290	Fetal anemia and thrombocytopenia, unspecified trimester, not applicable or unspecified
O36.8291	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 1
O36.8292	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 2
O36.8293	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 3
O36.8294	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 4
O36.8295	Fetal anemia and thrombocytopenia, unspecified trimester, fetus 5
O36.8299	Fetal anemia and thrombocytopenia, unspecified trimester, other fetus
P61.0	Transient neonatal thrombocytopenia
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XS	Complication of immune effector cellular therapy, sequela
T80.89XA	Other complications following infusion, transfusion and therapeutic injection, initial encounter
T80.89XS	Other complications following infusion, transfusion and therapeutic injection, sequela
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
E	A57187, A54660, A54641	Noridian Healthcare Solutions, LLC
F	A54643, A57194, A54662	Noridian Healthcare Solutions, LLC
H, L	A56786	Novitas Solutions, Inc.
J, M	A56718	Palmetto GBA
N	A57778	First Coast Service Options, Inc.
5, 8	A57554	Wisconsin Physicians Service Insurance Corporation
6, K	A59105	National Government Services, Inc. (NGS)
15	A56779, A57160	CGS Administrators, LLC
ALL	250.3	ALL

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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