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

(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
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
Gammagard S/D	5	1	1
	10	23	23

Gammaked	1, 2.5, 5, 10	1	1
	20	11	11
Gammaplex	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

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	184	21
IgG Subclass Deficiency	92	14
CIDP	Load: 460	4
	Maintenance: 230	21
Immune thrombocytopenia/ITP	460	28
FAIT	200	7
Kawasaki's Disease (*Pediatric Patients only*)	232	1 dose only
Multifocal Motor Neuropathy	460	28
CLL/MM	92	21
ALL	92	21
HIV (Pediatric Patients only)	47	28
Guillain-Barre	460	5 (*for one cycle only)*
Myasthenia Gravis	460	28
Auto-immune blistering diseases	460	28
Bone Marrow or Stem Cell Transplant	115	7
Dermatomyositis/Polymyositis	460	28
Complications of transplanted solid organ *(kidney, liver, lung, heart and pancreas transplants)*	460	28
Stiff Person	460	28
Toxic shock syndrome	460	5 *(for one cycle only)*
NAIT	16	2 doses only
Management of Immune Checkpoint Inhibitor Related Toxicity	460	5 *(for one cycle only)*
Management of CAR T-Cell-Related Toxicity	115	28

III. Initial Approval Criteria [1-14,69]

Coverage is provided for the following conditions:

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

Primary immunodeficiency (PID)/Wiskott - Aldrich syndrome † [1-14,36,52,54,55,68]

Such as: x-linked agammaglobulinemia, common variable immunodeficiency, transient hypogammaglobulinemia of infancy, IgG subclass deficiency with or without IgA deficiency, antibody deficiency with near normal immunoglobulin levels, and combined deficiencies (severe combined immunodeficiencies, ataxia-telangiectasia, x-linked lymphoproliferative syndrome) [***list not all inclusive***]

- Patient's IgG level is < 200 mg/dL **OR** both of the following
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - 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

IgG Subclass Deficiency ‡ [68,96-98]

- Patient's IgG level is < 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) **[1-14,30,35,37,79]**

For acute disease state:

- To manage acute bleeding due to severe thrombocytopenia (platelet count < 30 X 10^9/L); **OR**
- 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

Chronic Immune Thrombocytopenia (CIT):

- The patient is at increased risk for bleeding as indicated by a platelet count < 30 X 10^9/L; **AND**
- History of failure, contraindication, or intolerance to corticosteroids; **AND**

- Duration of illness > 6 months

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) † (Φ for Gamunex-C) [6-9,12,13,16-20,22-24,40,42,70]

- 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-Barre Syndrome (Acute inflammatory polyneuropathy) † ‡ [2,3,17,19,20,22,28,29,56,68,75]

- 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 rounds 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) [4-6,17,19,20,22,23]

- 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 † ‡ [2,3,25,26.35,87]

- Patient age does not exceed 13 years of age; **AND**
- Patient's IgG level is < 400 mg/dL

Myasthenia Gravis ‡ [51,76,83]

- Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; **AND**
- Patient has an acute exacerbation resulting in impending myasthenic crisis (i.e., respiratory compromise, acute respiratory failure, and/or bulbar compromise); **AND**
- Patient is failing on conventional immunosuppressant therapy alone (e.g., corticosteroids, azathioprine, cyclosporine, mycophenolate, methotrexate, tacrolimus, cyclophosphamide, etc.); **AND**
- Patient will be on combination therapy with corticosteroids or other immunosuppressant (e.g., azathioprine, mycophenolate, cyclosporine, methotrexate, tacrolimus, cyclophosphamide, etc.)

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

Dermatomyositis † / Polymyositis ‡ [10,11,17,19,20,22,63,64,68,80,85]

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

Note: Initial authorization is valid for 3 months

Complications of transplanted solid organ (kidney, liver, lung, heart, pancreas) and bone marrow transplant ‡ [57-60,68]

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

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

Stiff-Person Syndrome ‡ [19,22,62]

- 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 † ‡ [2,3,74]

- 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's IgG level is less than 400 mg/dL

Note: Initial authorization is valid for 3 months

Kawasaki's Disease † [2,3,81]

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

Fetal Alloimmune Thrombocytopenia (FAIT) ‡ [30,35,45,82,88]

- 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) ‡ [33-35,82]

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

Auto-immune Mucocutaneous Blistering Diseases ‡ [32,38,39,65-67,89]

- Patient has been diagnosed with one of the following:
  - Pemphigus vulgaris
  - Pemphigus foliaceus
  - Bullous Pemphigoid
  - Mucous Membrane Pemphigoid (a.k.a. Cicatricial Pemphigoid)
  - Epidermolysis bullosa aquisita
  - Pemphigus gestationis (Herpes gestationis)
  - Linear IgA dermatosis; **AND**
- Patient has severe disease that is extensive and debilitating; **AND**
- Diagnosis has been confirmed by biopsy; **AND**
- Patient's disease is progressive; **AND**

- Disease is refractory to a trial of conventional therapy with corticosteroids and concurrent immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil, etc.); **AND**
- Patient has a documented baseline on physical exam

Acquired Immune Deficiency secondary to Acute Lymphoblastic Leukemia (ALL) ‡ [35,77,90]

- Used for prevention of infection; **AND**
- Patient's IgG level is less than 400 mg/dL

Acquired Immune Deficiency secondary to Chronic Lymphocytic Leukemia † or Multiple Myeloma † ‡ [2,3,35,68,86]

- Patient's IgG level is <200 mg/dL **OR** both of the following
  - Patient has a history of multiple hard to treat infections as indicated by at least **one** of the following:
    - Four or more ear infections within 1 year
    - Two or more serious sinus infections within 1 year
    - Two or more months of antibiotics with little effect
    - Two or more pneumonias within 1 year
    - Recurrent or deep skin abscesses
    - Need for intravenous antibiotics to clear infections
    - Two or more deep-seated infections including septicemia; **AND**
  - 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 ‡ [44,91,92]

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

Management of Immune-Checkpoint-Inhibitor Related Toxicity ‡ [71,78]

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, dostarlimab, 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
  - Transverse myelitis

- Myocarditis as further intervention if no improvement within 24-48 hours of starting pulse-dose methylprednisolone
- Moderate (G2) or severe (G3-4) Guillain-Barre Syndrome or severe (G3-4) peripheral neuropathy used in combination with pulse-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 pulse-dose methylprednisolone for severe or progressing symptoms or if oligoclonal bands are present
- Moderate, severe, or life-threatening steroid-refractory myalgias or myositis

Management of CAR T-Cell-Related Toxicity ‡ [71,78,84,93,94]

- Patient has been receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, etc.); **AND**
  - Used for the management of G4 cytokine release syndrome 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**
- Used as prophylactic therapy prior to receiving treatment with anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (e.g., axicabtagene ciloleucel, brexucabtagene autoleucel, idecabtagene vicleucel, lisocabtagene maraleucel, tisagenlecleucel, 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 ‡ [95]

- 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/Literature Supported Indication(s); Φ Orphan Drug

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Brand Name/ Formulation	FDA Indication	Contraindications	Product Specs	Comments
Asceniv	PID (≥12yo)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	• **IgA**: ≤200 mcg/mL • **Osmolality**: N/A • **Stabilizer**: Glycine	Other stabilizer used is Polysorbate 80
Bivigam❖ (liquid)	PID (peds ≥6)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	• **IgA**: ≤200 mcg/mL • **Osmolality**: 510 mOsm/kg • **Stabilizer**: glycine	

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) ITP (peds ≥2)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <32 mcg/mL **Osmolarity**: 240 to 370 mOsm/L **Stabilizer**: sorbitol	
Gammagard (liquid)	PID (peds ≥2) MMN (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 policy for criteria
Gammagard S/D ❖ (lyophilized)	PID ITP CLL Kawasaki *(adults/peds for all indx)*	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: <1 mcg/mL (5% solution) **Osmolality**: 636 mOsm/L (5% soln) **Stabilizer**: glycine	Contains some sugar (20mg/mL when prepared)
Gammaked (liquid)	PID (peds ≥2) ITP (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 policy for criteria
Gammaplex 5% (liquid)	PID (peds ≥2) cITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Fructose intolerance	**IgA**: <10 mcg/mL **Osmolality**: 420 to 500 mOsm/kg **Stabilizer**: glycine	Other stabilizer used is Polysorbate 80
Gammaplex 10% (liquid)	PID (adults) 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 (liquid)	PID (peds ≥2) ITP (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 policy for criteria
Octagam 5% (liquid)	PID (peds≥6)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies Corn allergy	**IgA**: ≤200 mcg/mL **Osmolality**: 310 to 380 mOsm/kg **Stabilizer**: maltose	
Octagam 10% (liquid)	ITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: 106 mcg/mL **Osmolality**: 310 to 390 mOsm/kg **Stabilizer**: maltose	
Privigen (liquid)	PID 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	
Panzyga	PID (peds ≥2) cITP (adults)	History of anaphylaxis to IgG IgA-deficient with IgA antibodies	**IgA**: ≤100 mcg/mL **Osmolality**: 240-310 mOsm/kg **Stabilizer**: 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 [1-14,69]

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**
- Patient meets the disease-specific criteria identified below:

Primary Immunodeficiency (PID) [1-14,36,52,54,55,68]

- 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 [68-96-68]

- 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 treatment necessitating continued therapy

Chronic Immune Thrombocytopenia/ITP [1-14,30,35,37,79]

- Disease response as indicated by the achievement and maintenance of a platelet count of ≥ 30 X 10^9/L and at least doubling the baseline platelet count

Chronic Inflammatory Demyelinating Polyneuropathy [1-14,16-20,22-24,40,42,70]

- 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) [56]

- May not be renewed.

Multifocal Motor Neuropathy [1-14,17,19,20,22,23]

- 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 [25,26.35,87]

- 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 [51,76,83]

- May not be renewed.

Dermatomyositis/Polymyositis [17,19,20,22,63,64,68,80]

- 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 [57-60,68]

- 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 treatment necessitating continued therapy

Stiff Person Syndrome [19,22,62]

- Documented improvement from baseline on physical exam

Allogeneic Bone Marrow or Stem Cell Transplant [74]

- Patient's IgG trough is less than 400 mg/dL

Note: Renewal authorizations are provided for 3 months

Kawasaki's Disease [5,81]

- May not be renewed.

Fetal Alloimmune Thrombocytopenia (FAIT) [31,36,46,83,88]

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

Neonatal Alloimmune Thrombocytopenia [33-35,82]

- May not be renewed.

Auto-Immune Mucocutaneous Blistering Diseases [32,38,39,65-67,89]

- 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), or Multiple Myeloma [35,68,77,90]

- 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 treatment necessitating continued therapy

Toxic Shock Syndrome [44,91,92]

- May not be renewed.

Management of Immune Checkpoint Inhibitor related Toxicity [71,78]

- May not be renewed.

Management of CAR T-Cell-Related Toxicity [71,78,84]

- Patient is still receiving 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

Supportive Care after Rethymic transplant ‡ [95]

- 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, and MM patients should not be at an increased risk of infection

V. Dosage/Administration [1-14,22,23,30,39,51,56,61,62,74,76-78,81,82,87-92,97]

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 + 0.5 (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
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
FAIT	1 g/kg/week until delivery

Indication	Dose
Kawasaki's Disease (Pediatric Patients)	1 g/kg to 2 g/kg x 1 course
Multifocal Motor Neuropathy	Up to 2 g/kg divided over 5 days in a 28-day cycle
Acquired immune deficiency: CLL, MM and ALL	400 mg/kg every 3 to 4 weeks
Pediatric HIV	400 mg/kg every 2 to 4 weeks
Guillain-Barre	2 g/kg divided over 5 days x 1 course
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) and bone marrow transplant	2 g/kg divided over 5 days in a 28-day cycle
Stiff Person	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
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

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 *(Effective 07/01/2023)* J1599 *(Discontinue use on 07/01/2023)*	500mg	1, 2.5, 5, 10, 20, 30	68982-0820-XX
Injection, immune globulin, intravenous, non-lyophilized (e.g.,	N/A	J1599	500 mg	N/A	N/A

liquid), not otherwise specified					

***** *90283 – immune globulin (IgIV), human, for intravenous use*

****** *(HOPPS-Hospital Outpatient Prospective Payment System Use Only)*

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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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
G90.09	Other idiopathic peripheral autonomic neuropathy
I30.8	Other forms of acute pericarditis
I30.9	Acute pericarditis, unspecified

ICD-10	ICD-10 Description
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
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]
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
O26.43	Herpes gestationis, third trimester
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
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

ICD-10	ICD-10 Description
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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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/LCA):

Jurisdiction(s): N	**NCD/LCD/Article Document (s):** A57778
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57778&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): F	NCD/LCD/Article Document (s): A57194
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57194&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): H, L	NCD/LCD/Article Document (s): A56786
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56786&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): E	NCD/LCD/Article Document (s): A57187
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57187&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 5, 8	NCD/LCD/Article Document (s): A57554
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57554&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): J, M	NCD/LCD/Article Document (s): A56718
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56718&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): ALL	NCD/LCD/Article Document (s): 250.3
https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=158&ncdver=1&bc=0	

Jurisdiction(s): 15	NCD/LCD/Article Document (s): A56779
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56779&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): E, F	NCD/LCD/Article Document (s): A54641, A54643
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a54641&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a54643&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): E, F	NCD/LCD/Article Document (s): A54660, A54662
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a54660&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a54662&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 6, K	NCD/LCD/Article Document (s): A52446
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52446&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 15	NCD/LCD/Article Document (s): A57160
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57160&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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, 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