Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Immunoglobulins

Override(s)	**Approval Duration**
Prior Authorization	CIDP: Initial requests: 12 weeks All other: 1 year

Medications	
<u>Intravenous</u>:	
Gamunex-C	Preferred
Octagam	Preferred
Asceniv	Non-Preferred
Bivigam	Non-Preferred
Carimune NF	Non-Preferred
Flebogamma DIF	Non-Preferred
Gammagard Liquid	Non-Preferred
Gammagard S/D less IgA	Non-Preferred
Gammaked	Non-Preferred
Gammaplex	Non-Preferred
Panzyga	Non-Preferred
Privigen	Non-Preferred
<u>Subcutaneous</u>:	
Cutaquig	Non-Preferred
Cuvitru	Non-Preferred
Hizentra	Non-Preferred
HyQvia	Non-Preferred
Xembify	Non-Preferred

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Intravenous Immunoglobulin Dosing Limit

Drug	Limit Per Indication
Intravenous Immunoglobulins	**Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):** 1000 mg/kg (may be divided over two days) as frequently as every 3 weeks (DP)† **Guillain-Barré Syndrome:** 400 mg/kg daily for 5 days **OR** 2000 mg/kg administered in divided doses over 2 to 5 days (DP, AHFS) **Idiopathic thrombocytopenic purpura (ITP):** 2000 mg/kg administered in divided doses over 2 to 5 days or 1000 mg/kg every other day for up to 3 doses (DP) **Kawasaki Syndrome:** 2000 mg/kg per dose for up to two doses (AHFS) **OR** 400mg/kg/day for 4 days **Multifocal Motor Neuropathy (MMN):** 2400 mg/kg every 4 weeks (DP)^ **Myasthenia Gravis:** 2000 mg/kg administered in divided doses over 2 to 5 days (DP) **Primary Immunodeficiencies**: 800 mg/kg as frequently as every 3 weeks*
Override Criteria	
†For CIDP initiation of therapy, may approve loading doses of up to 2000 mg/kg in divided doses over 2 to 5 consecutive days ^For MMN, may approve as frequent as every 2 weeks based on response (AHFS) *For primary immunodeficiencies, may approve a higher dose when the treating physician has indicated that it is necessary based on the individual's clinical response	

APPROVAL CRITERIA

Section 1:
Requests for a **non-preferred** immunoglobulin agent may be approved if the following criterion is met:

I. Individual is currently receiving and stabilized on the requested non-preferred agent in addition to one of the approvable diagnoses listed in **Section 3**;

OR
Section 2:
Requests for a **non-preferred** immunoglobulin (Ig) agent may be approved if I, II, III, or IV are met below in addition to one of the approvable diagnoses listed in **Section 3**:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred Ig agent (Gamunex-C or Octagam); **OR**

II. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication, and the requested non-preferred agent does; **OR**

III. The preferred Ig agents are not acceptable due to concomitant clinical condition(s), such as but not limited to the following:
   A. Renal insufficiency/impairment; **OR**
   B. Non-O blood type; **OR**
   C. Severe IgA deficiency; **OR**
   D. Diabetes/prediabetes; **OR**
   E. Cardiovascular disease; **OR**
   F. Hyper-prolinemia; **OR**
   G. Hypernatremia; **OR**
   H. High-risk for thrombosis, such as but not limited to:
      1. Hyperviscosity syndromes (such as cryoglobulinemia, monoclonal gammopathies, polyclonal hyperglobulinemia); **OR**
      2. Hypercoagulable conditions;

   OR

   I. Documented hypersensitivity, as manifested by a severe systemic/allergic or anaphylactic reaction, to any ingredient which is not also present in the requested non-preferred agent; **OR**

OR

IV. Cutaquig, Cuvitru, Hizentra, HyQvia or Xembify [subcutaneous immunoglobulin (SCIG)] may be approved for individuals requesting for any of the following indications:
   A. Difficult vein access that precludes use of an intravenous immunoglobulin (IVIG); **OR**
   B. History of serious systemic reaction to IVIG expected to be avoided by using SCIG; **OR**
   C. History of inconsistent serum levels of immunoglobulin G (IgG) with IVIG.

Section 3:
Requests for Immunoglobulin therapy may be approved if the following criteria are met:

I. **Individual is using for treatment of one of the following primary immunodeficiencies:**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

A. Primary humoral immunodeficiency including congenital agammaglobulinemia, X-linked immunodeficiency, severe combined immunodeficiency [SCID], or Wiskott-Aldrich syndrome [WAS]) when:
   1. The initial, pre-treatment total serum IgG is below the lower limit of the age adjusted laboratory reference range, or more than two standard deviations below the age adjusted mean; **AND**
   2. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy) as causes of hypogammaglobulinemia;

OR

B. Primary humoral immunodeficiency common variable immunodeficiency (CVID) when:
   1. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
   2. There is a lack of, or inadequate response to immunization (for example, but not limited to tetanus or pneumococcal antigen); **AND**
   3. The initial, pre-treatment total serum IgG is below the lower limit of the age adjusted laboratory reference range, or more than two standard deviations below the age adjusted mean; **AND**
   4. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy, PLE) as causes of hypogammaglobulinemia;

OR

C. IgG sub-class deficiency (IgG1, IgG2, IgG3, IgG4) when:
   1. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
   2. There is a lack of, or inadequate response to immunization (for example, but not limited to tetanus or pneumococcal antigen); **AND**
   3. The initial, pre-treatment levels of one or more serum IgG subclasses are below the lower limit of the age adjusted laboratory reference range or are more than two standard deviations below the age adjusted mean;

OR

D. Hyperimmunoglobulinemia E syndrome (HIE) when there is a diagnosis as evidenced by elevated level of serum IgE (AAAAI/ACAAI 2015);

OR

II. **Individual is using for one following secondary immunodeficiencies:**

A. B-cell chronic lymphocytic leukemia (CLL) with the following (NCCN 2A):
   1. A history of recurrent bacterial infection or an active infection not responding to antimicrobial therapy; **AND**
   2. Hypogammaglobulinemia shown by total IgG is less than 500 mg/dl;

OR

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

B. Multiple myeloma with the following: (NCCN 2A)
   1. History of a clinically severe infection or active clinically severe infection; **AND**
   2. Hypogammaglobulinemia shown by total IgG less than 500 mg/dL;

OR

C. Human immunodeficiency virus (HIV)-infected children, to prevent opportunistic bacterial infection in individuals with hypogammaglobulinemia (IgG less than 400mg/dL) or recurrent infections (IDSA/CDC 2013);

OR

D. Secondary hypogammaglobulinemia or agammaglobulinemia following chimeric antigen receptor (CAR) T cell treatment (Kymriah/Yescarta PI);

OR

E. Parvovirus B19 chronic infection and severe anemia associated with bone marrow suppression (NCCN 2A);

OR

III. **Individual is using in the context of transplant for one of the following:**

A. Hematopoietic stem cell transplant (HCT) for either of the following:
   1. Allogeneic bone marrow transplant (BMT) recipients, in the first 100 days after transplantation, to reduce the risk of graft-versus-host disease associated with interstitial pneumonia (infectious or idiopathic) and infections (cytomegalovirus infections, varicella-zoster virus infection, and recurrent bacterial infection) (DrugPoints B IIa); **OR**
   2. Prevention of bacterial infections in individuals who are immunosuppressed after allogenic HCT transplant, when there is severe hypogammaglobulinemia (IgG less than 400 mg/dl) (AHFS, ASBMT 2009);

OR

B. Solid organ transplantation including either of the following:
   1. Desensitization prior to a solid organ transplantation for suppression of panel reactive anti-HLA antibodies in individuals with high panel reactive antibody (PRA) levels to human leukocyte antigens (HLA) (AAAAI 2016); **OR**
   2. Transplant recipients at risk for CMV (TTS 2018, DP B IIb); **OR**
   3. Transplant recipients experiencing antibody-mediated rejection with donor-specific antibodies (KDIGO 2009, ISHLT 2010);

OR

IV. **Individual is using for treatment of one the following autoimmune diseases:**

A. Immune thrombocytopenia (idiopathic thrombocytopenic purpura [ITP]) with either of the following:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

1. Active bleeding (for example, but not limited to hematuria, petechiae, bruising, gastrointestinal bleeding, gingival bleeding); **OR**
2. Platelet count less than 30,000 mcL (ASH 2011);

OR

B. Fetal alloimmune thrombocytopenia with the following: (ACOG 2016)
   1. Antibodies to paternal platelet antigen are found in maternal serum; **AND**
   2. One of the following is demonstrated:
      a. There has been a previously affected pregnancy; **OR**
      b. There is a family history of maternofetal alloimmune thrombocytopenia; **OR**
      c. Fetal blood sample shows thrombocytopenia;

OR

C. Isoimmune hemolytic disease of the newborn, treatment of severe hyperbilirubinemia (AAP 2004);

OR

D. Autoimmune mucocutaneous blistering diseases (including pemphigus vulgaris, pemphigus foliaceous, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita) when individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as corticosteroids or immunosuppressive agents (AAAAI 2016);

OR

E. Autoimmune neutropenia when active infection has been excluded as a cause of neutropenia (AAAAI 2016, DP B IIb);

OR

F. Dermatomyositis or polymyositis when: (AAAAI 2016)
   1. Individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as corticosteroids and immunosuppressive agents; **AND**
   2. Diagnosis is confirmed by the presence of at least 4 of the following 8 characteristics (Tanimoto 1995):
      a. Weakness in the trunk or proximal extremities
      b. Elevated serum creatinine kinase or aldolase levels
      c. Muscle pain not otherwise explained
      d. Characteristic electromyography findings (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
      e. Presence of anti-Jo-1 antibody (histidyl-tRNA synthetase)
      f. Arthralgias or arthritis without joint destruction
      g. Evidence of systemic inflammation such as fever, elevated C-reactive protein, or elevated sedimentation rate
      h. Inflammatory myositis seen on muscle biopsy

   AND

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

3. If using for dermatomyositis, there are skin lesions characteristic of dermatomyositis (such as heliotrope lesions on eyelids, Gottron's papules, erythematous plaques over extensor joints of extremities) present;

OR

V. **Individual is using for treatment of one of the following neurologic diseases:**

A. Lambert-Eaton myasthenic syndrome when: (AAAAI 2016)
   1. Individual is experiencing muscle weakness; **AND**
   2. Diagnosis confirmed by one of the following:
      a. Characteristic electrodiagnostic findings using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing, or single fiber electromyography (SFEMG); **OR**
      b. Presence of antibodies directed against voltage-gated calcium channels (VGCC);

OR

B. Guillain-Barre Syndrome (acute demyelinating polyneuropathy) (Drugpoints B IIa);

OR

C. Myasthenia Gravis when (AAAAI 2016, Neurol Clin 2018, Neurology 2016):
   1. Individual's clinical presentation is characteristic of myasthenia gravis; **AND**
   2. The diagnosis is confirmed by one of the following:
      a. The presence of antibodies against the acetylcholine receptor (AChR-Ab) or muscle-specific tyrosine kinase (MuSK-Ab); **OR**
      b. Characteristic electrodiagnostic findings using repetitive nerve stimulation (RNS) or single fiber electromyography (SFEMG);

   AND

   3. Individual is using for one of the following:
      a. Exacerbation of myasthenia gravis or acute myasthenic crisis; **OR**
      b. Short-term therapy as immunosuppressive treatment is taking effect; **OR**
      c. Maintenance therapy of myasthenia gravis when individual has had an inadequate response to, is intolerant of, or has a contraindication to **all** of the following:
         i. Pyridostigmine; **AND**
         ii. Corticosteroids; **AND**
         iii. Non-steroidal immunosuppressants.
         Inadequate response to non-steroidal immunosuppressants is defined as unchanged or worsening symptoms despite *one* of the following:
         - At least a twelve (12) month trial of azathioprine or mycophenolate; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

- At least a two (2) month trial of cyclosporine, cyclophosphamide, tacrolimus, or methotrexate;

OR

D. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):
   1. As an *initial trial* (up to 12 weeks) when the following criteria are met:
      a. There is muscle weakness or sensory dysfunction caused by neuropathy in more than one limb for at least two (2) months; **AND**
      b. Evidence of a demyelinating neuropathy confirmed by **one** of the following:
         i. Per the EFNS/PNS guidelines, individual has **one** of the following electrodiagnostic findings (EFNS/PNS 2010):
            - Prolongation of motor distal latency in 2 nerves
            - Reduction of motor conduction velocity in 2 nerves
            - Prolongation of F-wave latency in 2 nerves
            - Absence of F-waves in at least 1 nerve
            - Partial motor conduction block in at least 1 nerve
            - Abnormal temporal dispersion in at least 2 nerves
            - Distal compound muscle action potential (CMAP) duration increase in at least 1 nerve; **OR**

         ii. Per the AAN guidelines, individual has **three (3)** of the following electrodiagnostic findings (AAN 1991):
            - Reduced conduction velocity in at least 2 nerves
            - Partial conduction block in at least 1 nerves
            - Prolonged distal motor latency in at least 2 nerves
            - Absent or prolonged F-wave latency in at least 2 nerves;

         OR

         iii. Cerebrospinal fluid (CSF) analysis shows albuminocytologic dissociation or elevated CSF protein with a white blood cell count of less than 10/mm^3 (EFNS/PNS 2010); **AND**
      c. Other polyneuropathies such as IgM neuropathy, hereditary neuropathy, and diabetic neuropathy have been ruled out;

   OR

   2. As *continued use* after initial trial for CIDP when the following criteria are met:
      a. There is clinically significant and objective improvement in neurological symptoms on physical examination (for example, an objective change in patient function that is clinically meaningful, such as patient can now work or perform tasks that they previously could not; **AND**
      b. Continued need is demonstrated by clinical effect (for example, patient has a positive response and stable on current dose, or worsening of symptoms occurs from a dose decrease or increase in dose intervals) ;

OR

E. Multifocal Motor Neuropathy (MMN) for either of the following:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

1. As an *initial* trial (up to 12 weeks) to treat MMN, when clinical presentation combined with electrodiagnostic testing, labs, or diagnostic criteria suggest or confirm MMN; **OR**
2. Continued use of Ig after initial trial for MMN when the following criteria are met:
   a. Individual experienced improvement in strength and function after the initial trial; **AND**
   b. Continued need is demonstrated by attempts on an annual basis to titrate the dose or the interval of therapy result in worsening of symptoms;

OR

F. Stiff-person syndrome when individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as benzodiazepines or baclofen (AAAAI 2016);

OR

VI. **Individual is using for treatment of one of the following miscellaneous indications:**

A. Measles (rubeola) post-exposure prophylaxis: (AHFS)
   1. Individual is using for post-exposure prophylaxis to prevent or modify measles (rubeola); **AND**
   2. Administered within 6 days of exposure and not given concomitantly with a vaccine containing the measles virus; **AND**
   3. Eligible, exposed, non-immune individuals will receive a vaccine containing the measles virus greater than or equal to 8 months after immunoglobulin administration (CDC 2013); **AND**
   4. Used in the following individuals considered at risk for severe disease and complications (CDC 2013):
      a. No evidence of measles immunity, in particular in pregnant women; **OR**
      b. Severely immunocompromised individuals;

OR

B. Varicella post-exposure prophylaxis: (AHFS)
   1. Individual is using as post-exposure prophylaxis of varicella infection in susceptible individuals (such as, immunocompromised); **AND**
   2. The varicella-zoster immune globulin (human) (VZIG) is unavailable;

OR

C. Tetanus: (AHFS)
   1. Individual is using as treatment or post-exposure prophylaxis of tetanus when tetanus immune globulin (TIG) is unavailable;

OR

D. Kawasaki Syndrome when:
   1. Treatment initiated within 10 days of onset; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

2. Treatment Initiated beyond 10 days of onset if individual has unexplained persistent fever, or coronary artery abnormalities with evidence of ongoing inflammation (such as elevated erythrocyte sedimentation rate [ESR] or C-reactive protein [CRP]) (AHA 2017); **AND**
3. Treatment for no more than 5 days (AFHS);

OR

E. Toxic shock syndrome caused by staphylococcal or streptococcal organisms (AAP 2018, AHFS);

OR

F. Treatment of cancer-related CMV pneumonia if individual has hypogammaglobulinemia (IgG <500mg/dL) (NCCN 2A).

Requests for Immunoglobulin may **not** be approved for the following:

I. Alzheimer's disease;
II. Immune optic neuropathy;
III. Multiple sclerosis;
IV. Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS);
V. Treatment to prevent recurrent spontaneous abortion in pregnant women with a history of recurrent spontaneous abortion (ASRM 2012);
VI. When the above criteria are not met and for all other indications.

Note:
Immunoglobulins (SC and IV) have a black box warning for thrombosis. Risk factors may include advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors. For patients at risk of thrombosis, IG should be administered at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity

Intravenous Immunoglobulins (IVIG) have a black box warning for renal dysfunction and acute renal failure. Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients with immune globulin intravenous (IGIV) products. Patients predisposed to renal dysfunction include those with any degree of pre-existing renal

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. For patients at risk of renal dysfunction or acute renal failure, administer IG at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.
Carimune NF is the only IVIG that contains sucrose.

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Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

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