Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Immune Globulins

CG DRUG 09, DRUG.00013

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Intravenous:	
Gamunex-C	Preferred
Octagam	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
Subcutaneous:	
Cuvitru	Non-Preferred
Hizentra	Non-Preferred
HyQvia	Non-Preferred

APPROVAL CRITERIA

Section 1:
Requests for a **non-preferred** immune globulin (Ig) agent may be approved if the following criterion is met:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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** immune globulin (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**:

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. Cuvitru, Hizentra or HyQvia [subcutaneous immune globulin (SCIG)] may be approved for individuals requesting for any of the following indications:
   - A. Difficult vein access that precludes use of an intravenous immune globulin (IVIG); **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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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:
Immune globulin (Ig) therapy may be approved for treatment of individuals with any of the indications:

A. Antenatal alloimmune thrombocytopenia;
   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.

B. Autoimmune mucocutaneous blistering diseases that are refractory, which include: pemphigus vulgaris, pemphigus foliaceous, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita.
C. Autoimmune Neutropenia:
   1. When there is a diagnosis of autoimmune neutropenia; **AND**
   2. Active infection has been excluded as a cause of neutropenia.

D. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
   1. As an *initial trial* (up to 12 weeks) of Ig, when the medical record indicates that the clinical presentation is not consistent with other polyneuropathies (for example, IgM neuropathy, hereditary neuropathy, diabetic neuropathy) and **ONE** of the following clinical and electrodiagnostic criteria are met:
      a. There is proximal muscle weakness or sensory dysfunction caused by neuropathy and nerve conduction studies (NCS) confirm there is electrodiagnostic evidence of a demyelinating neuropathy in at least two limbs; **OR**
      b. There is distal muscle weakness and results of diagnostic testing meet a recognized set of diagnostic criteria as established by the American Academy of Neurology (AAN), or Inflammatory Neuropathy Cause and Treatment (INCAT).
   2. As continued use of Ig after initial trial for CIDP when the following criteria are met:
      a. Clinically significant improvement in neurological symptoms is documented on physical examination; **AND**
      b. Continued need is demonstrated by documentation that attempts on an annual basis to titrate the dose or the interval of therapy result in worsening of symptoms

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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E. Dermatomyositis, refractory:
The presence of dermatomyositis is confirmed by the presence of skin lesions characteristic of dermatomyositis (heliotrope lesions on eyelids, Gottron's papules, erythematous plaques over extensor joints of extremities) **and** at least 4 of the following 8 characteristics:
   1. Weakness in the trunk or proximal extremities
   2. Elevated serum creatinine kinase or aldolase level
   3. Muscle pain not otherwise explained
   4. Characteristic electromyography findings (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
   5. Presence of anti-Jo-1 antibody (histidyl-tRNA synthetase)
   6. Arthralgias or arthritis without joint destruction
   7. Evidence of systemic inflammation such as fever, elevated C-reactive protein, or elevated sedimentation rate
   8. Inflammatory myositis seen on muscle biopsy.

F. Lambert-Eaton myasthenic syndrome treatment:
   1. Muscle weakness, **AND**
   2. Characteristic electromyography; **AND**
   3. Presence of antibodies directed against voltage-gated calcium channels (VGCC).

G. Guillain-Barre Syndrome (acute demyelinating polyneuropathy) as an equivalent alternative to plasma exchange.
H. Human immunodeficiency virus (HIV)-infected children – prevention of opportunistic bacterial infections.
I. Hyperimmunoglobulinemia E syndrome (HIE) :
   1. There is a diagnosis as evidenced by elevated level of serum IgE.
J. Hypogammaglobulinemia and recurrent bacterial infection associated with B-cell chronic lymphocytic leukemia (CLL) that includes both:
   1. Documented history of recurrent bacterial infection or an active infection not responding to antimicrobial therapy; **AND**
   2. Documentation that total IgG is less than 500 mg/dl
K. IgG sub-class deficiency (IgG1, IgG2, IgG3, IgG4) when the following are met:
   1. 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; **AND**
   2. History of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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3. Lack of, or inadequate response to immunization (for example, but not limited to pneumococcal antigen)

L. Immune thrombocytopenia (idiopathic thrombocytopenic purpura [ITP]) in individuals with either of the following:
   1. Symptomatic thrombocytopenia (for example, but not limited to hematuria, petechiae, bruising, gastrointestinal bleeding, gingival bleeding); **OR**
   2. Platelet count less than 20,000 per microliter (mcL) (adult) or 30,000 mcL (child)

M. Kawasaki Syndrome:
   1. Within 10 days of onset; **AND**
   2. Treatment for no more than 5 days

N. Multifocal Motor Neuropathy (MMN) for either of the following:
   1. As an *initial* trial (up to 4 weeks) to treat MMN, when **ONE** of the following criteria are met:
      a. There is asymmetric weakness that predominantly affects distal muscles (without upper motor neuron signs) **AND** nerve conduction studies confirm a demyelinating neuropathy is present (conduction block, slowing, or abnormal temporal dispersion in at least one nerve); **OR**
      b. Clinical history and exam do not suggest upper motor neuron disease (no bulbar weakness, no upper motor neuron signs) and labs show that GM-1 antibody titers are elevated; **OR**
      c. After the initial exam and electrodiagnostic testing clinical presentation suggests MMN but the diagnosis remains uncertain
   2. Continued use of Ig after initial trial for MMN when the following criteria are met:
      a. Clinical results document an improvement in strength and function within three weeks of the start of the infusion period; **AND**
      b. Continued need is demonstrated by documentation that attempts on an annual basis to titrate the dose or the interval of therapy result in worsening of symptoms

O. Myasthenia Gravis;
   1. History and physical examination characteristic of myasthenia gravis and at least one of the following:
      a. The presence of antibodies against one or more neuromuscular junction protein (for example, the acetylcholine receptor (AChR-Ab) or muscle-specific tyrosine kinase (MuSK-Ab)); **or**
      b. Characteristic findings on repetitive nerve stimulation or single-fiber electromyography.

P. Neonates -Treatment of severe hyperbilirubinemia.;

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Q. Parvovirus B19 chronic infection and severe anemia associated with bone marrow suppression.
R. Polymyositis:
The diagnosis is confirmed by the presence of at least 4 of the following 8 characteristics:
1. Weakness in the trunk or proximal extremities
2. Elevated serum creatinine kinase or aldolase level
3. Muscle pain not otherwise explained
4. Characteristic electromyography findings (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials)
5. Presence of anti-Jo-1 antibody (histidyl-tRNA synthetase)
6. Arthralgias or arthritis without joint destruction
7. Evidence of systemic inflammation such as fever, elevated C-reactive protein, or elevated sedimentation rate
8. Inflammatory myositis seen on muscle biopsy.

S. 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. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy, PLE) as causes of hypogammaglobulinemia; **AND**
4. 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.

T. Primary humoral immunodeficiency – Other (for example, congenital agammaglobulinemia, X-linked immunodeficiency, severe combined immunodeficiency [SCID], or Wiskott-Aldrich syndrome [WAS]) when:
1. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy) as causes of hypogammaglobulinemia; **and**
2. 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.

U. Secondary hypogammaglobulinemia or agammaglobulinemia following chimeric antigen receptor (CAR) T cell treatment;
V. Stiff-person syndrome not controlled by other therapies;

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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W. Toxic shock syndrome caused by staphylococcal or streptococcal organisms refractory to several hours of aggressive therapy;
X. Transplantation when any of the following are met:
    1. Hematopoietic stem cell transplant for either of the following:
        a. 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); **OR**
        b. Secondary hypoglobulinemia in individuals who are immunosuppressed (for example status-post bone marrow transplant) and have a documented total IgG less than 500 mg/dl
    2. Solid organ transplantation for either of the following:
        a. Prior to medically necessary 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); **OR**
        b. Transplant recipients at risk for CMV;

Immune Globulin may <u>NOT</u> be approved for the following:

A. For the indications listed above when criteria are not met.
B. For all other indications not listed above, including but not limited to:
    1. Alzheimer's disease;
    2. Immune optic neuropathy;
    3. Multiple sclerosis;
    4. Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci (PANDAS),

Note: Intravenous immunoglobulins have black box warnings for renal dysfunction, acute renal failure, osmotic nephrosis, and death. Use caution in individuals predisposed to acute renal failure and administer at the minimum concentration available and the minimum rate of infusion practicable in such individuals. Higher rates of renal failure were associated with IGIV products containing sucrose. Carimune NF is currently the only available agent on the market containing sucrose.

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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State Specific Mandates		
State N/A	Date N/A	Mandate details (including specific bill if applicable) N/A

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

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