Immunoglobulins

Override(s)	Approval Duration
Prior Authorization	Secondary Immunodeficiency: 6 months In the Context of Transplant: 6 months Autoimmune encephalitis: Initial requests: 12 weeks Continuation requests: 1 year Immune thrombocytopenia (idiopathic thrombocytopenia purpura [ITP]): 6 months Mucocutaneous blistering diseases: Initial requests: 6 months Continuation requests: 1 year Neutropenia: 6 months Dermatomyositis or Polymyositis: Initial requests: 6 months Continuation requests: 1 year Lambert-Eaton myasthenic syndrome: Initial requests: 12 weeks Continuation requests: 1 year Guillain-Barre Syndrome: 1 course of therapy (5 days) Myasthenia Gravis: Initial requests: 12 weeks Continuation requests: 1 year Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Initial requests: 12 weeks Continuation requests: 1 year Multifocal Motor Neuropathy (MMN): Initial requests: 12 weeks Continuation requests: 1 year Stiff-person Syndrome:

	Initial requests: 12 weeks Continuation requests: 1 year Myelin Oligodendrocyte Glycoprotein (MOG) related Neuromyelitis Optica Spectrum (NMOSD): Initial requests: 6 months Continuation requests: 1 year Cancer-related CMV pneumonia: 6 months All other: 1 year

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

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)† **Chronic Lymphocytic Leukemia (CLL):** 500 mg/kg monthly (NCCN) **Dermatomyositis (DM):** 2000 mg/kg administered in divided doses over 2 to 5 days every 4 weeks (Octagam 10% label) **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

All requests require documentation provided for diagnosis.

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** (AAAAI/ACAAI 2015)**:**

A. Primary humoral immunodeficiency including congenital agammaglobulinemia, X-linked immunodeficiency 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 the following criteria are met:
   1. Confirmation of elevated levels of serum IgE; **AND**
   2. Individual has clinical features including:
      a. Recurrent sinopulmonary and skin infections; **AND**
      b. Chronic eczematous dermatitis;

OR

E. Specific Antibody Deficiency (SAD) when:
   1. There is a history of recurrent sinopulmonary infections requiring antibiotic therapy; **AND**
   2. There is a lack of, or inadequate response to pneumococcal polysaccharide antigen; **AND**
   3. There are normal concentrations of IgG, IgA, IgM, and IgG subclasses;

OR

F. Severe combined immunodeficiency [SCID] when:
   1. Either of the following:
      a. 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; **OR**
      b. CD3+ T cell count of less than 300 cells /mm^3, *or* there is presence of maternal T cells in the circulation; **AND**

2. There is no evidence of renal (nephrotic syndrome) and gastrointestinal (for example, protein losing enteropathy) as causes of hypogammaglobulinemia;

Approval Duration for Primary Immunodeficiency: 1 year

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

B. Multiple myeloma with the following: (NCCN 2A)
   1. History of a clinically severe infection or active clinically severe infection; **OR**
   2. Hypogammaglobulinemia shown by total IgG less than 400 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/Tecartus PI);

OR

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

Approval Duration for Secondary Immunodeficiency: 6 months

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 or cPRA [corrected PRA]) levels to human leukocyte antigens (HLA) (AAAAI 2016), **or** in individuals with a history of high levels of donor-specific antibodies (DSA) (KDIGO 2020, ISHLT 2022); **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 2022);

Approval Duration in the context of transplant: 6 months

OR

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

A. Immune-mediated encephalitis, including paraneoplastic and autoimmune encephalitis (AE) when the following criteria are met (Zuliani 2019, Lancaster 2016):
   1. Individual has been evaluated for possible neoplasm associated with encephalitis; **AND**
   2. As an *initial* trial (up to 12 weeks) when diagnosis is confirmed by the following:
      a. Detection of a specific autoantibody associated with AE, including but not limited to:
         i. NMDAR, LGI1, Caspr2, AMPAR, GABA-A or GABA-B receptor, IgLON5, DPPX, GlyR, mGluR1, mGluR2, mGluR5, Neurexin 3-alpha, or dopamine-2 receptor (D2R); **AND**
      b. Clinical presentation includes neurological symptoms (for example, memory deficits, seizures, movement disorders, speech disturbances, behavioral changes, or psychiatric symptoms); **AND**
      c. Alternative etiologies of encephalitis syndrome have been ruled out, such as infectious etiologies, other neurological disorders, or other autoimmune conditions.
   3. Continued use of Ig after initial trial when the following criteria are met:
      a. There are clinically significant improvements in symptoms on physical examination; **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 previous discontinuation resulted in relapse); **AND**
      c. Cancer screening continues.

Approval Duration for AE:
Initial requests: 12 weeks
Continuation requests: 1 year

OR

B. Immune thrombocytopenia (idiopathic thrombocytopenic purpura [ITP]) with either of the following:
   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 2019);

Approval Duration for ITP: 6 months

OR

C. Fetal alloimmune thrombocytopenia with the following: (ACOG 2019)
   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

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

OR

E. Autoimmune mucocutaneous blistering diseases (including pemphigus vulgaris, pemphigus foliaceous, bullous pemphigoid, mucous membrane pemphigoid, and epidermolysis bullosa acquisita) when the following criteria are met (AAAAI 2016, Murrell 2020):
   1. For initial requests, individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as corticosteroids or immunosuppressive agents**.**
   2. As continued use after initial trial for autoimmune mucocutaneous blistering diseases when the following criteria are met:
      a. There is clinically significant improvements in symptoms on physical examination; **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);

Approval Duration for mucocutaneous blistering diseases:
Initial requests: 6 months
Continuation requests: 1 year

OR

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

Approval Duration for neutropenia: 6 months

OR

G. Dermatomyositis or polymyositis when the following criteria are met: (AHFS, AAAAI 2016)
   1. For initial requests:

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

AND

c. 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.

2. As continued use after initial trial for dermatomyositis or polymyositis when the following criteria are met:
    a. There is clinically significant improvements in symptoms on physical examination; **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);

Approval Duration for dermatomyositis or polymyositis:
Initial requests: 6 months
Continuation requests: 1 year

OR

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

A. Lambert-Eaton myasthenic syndrome when the following criteria are met: (AAAAI 2016)
    1. For initial requests:
        a. Individual is experiencing muscle weakness; **AND**
        b. Diagnosis confirmed by one of the following:
            i. Characteristic electrodiagnostic findings using nerve conduction tests, repetitive nerve stimulation (RNS), exercise testing, or single fiber electromyography (SFEMG); **OR**

ii. Presence of antibodies directed against voltage-gated calcium channels (VGCC).

2. As continued use after initial trial for Lambert-Eaton myasthenic syndrome 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);

Approval Duration for Lambert-Eaton myasthenic syndrome:
Initial requests: 12 weeks
Continuation requests: 1 year

OR

B. Guillain-Barre Syndrome (acute demyelinating polyneuropathy) when: (Drugpoints B IIa)
   1. Individual's clinical presentation is characteristic of Guillain-Barre Syndrome, including (Willison 2016):
      a. Progressive weakness in the legs and/or arms; **AND**
      b. Absent or depressed tendon reflexes (i.e., areflexia) in affected limbs; **AND**
   2. Initial treatment with immune globulin occurs within eight (8) weeks of onset of symptoms (AAN 2016); **AND**
   3. Individual is not on concomitant plasmapheresis therapy; **AND**
   4. Treatment for no more than 5 days (i.e., one course of therapy);

Approval Duration for Guillain-Barré Syndrome: 1 course of therapy (5 days)

OR

C. Myasthenia Gravis when the following criteria are met (AAAAI 2016, Neurol Clin 2018, Neurology 2016/2020):
   1. For initial requests:
      a. Individual's clinical presentation is characteristic of myasthenia gravis; **AND**
      b. The diagnosis is confirmed by one of the following (Juel 2007):
         i. The presence of antibodies against the acetylcholine receptor (AChR-Ab) or muscle-specific tyrosine kinase (MuSK-Ab); **OR**
         ii. Characteristic electrodiagnostic findings using repetitive nerve stimulation (RNS) or single fiber electromyography (SFEMG);

      AND
      c. Individual is using for one of the following:
         i. Exacerbation of myasthenia gravis or acute myasthenic crisis; **OR**

ii. Short-term therapy as immunosuppressive treatment is taking effect; **OR**
iii. 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:
- Pyridostigmine; **AND**
- Corticosteroids; **AND**
- 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**
  - At least a two (2) month trial of cyclosporine, cyclophosphamide, tacrolimus, or methotrexate.

2. As continued use after initial trial for myasthenia gravis 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);

Approval Duration for myasthenia gravis:
Initial requests: 12 weeks
Continuation requests: 1 year

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 2021):
            - 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 2021); **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) ;

Approval Duration for CIDP:
Initial requests: 12 weeks
Continuation requests: 1 year

OR

E. Multifocal Motor Neuropathy (MMN) for either of the following:
   1. As an *initial* trial (up to 12 weeks) to treat MMN, when diagnosis is confirmed by all of the following criteria (EFNS/PNS 2010, AANEM 2003):
      a. Stepwise or slowly progressive, focal, asymmetric limb weakness for at least one (1) month; **AND**
      b. Motor involvement of at least two (2) nerves; **AND**
      c. Sensory nerve conduction studies are normal, with the exception of minor vibration loss in the lower limbs; **AND**
      d. Absence of *all* of the following upper motor neuron signs, **or** presence of such can be explained by a comorbid condition (for example, history of stroke):
         i. Spastic tone
         ii. Clonus
         iii. Extensor plantar response
         iv. Pseudobulbar palsy
   2. Continued use of Ig after initial trial for MMN 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);

Approval Duration for MMN:
Initial requests: 12 weeks
Continuation requests: 1 year

OR

F. Stiff-person syndrome when the following criteria are met (AAAAI 2016):
   1. For initial requests:
      a. Individual has had an inadequate response to, is intolerant of, or has a contraindication to other treatments such as benzodiazepines or baclofen (AAAAI 2016).
   2. Continued use of Ig after initial trial 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);

Approval Duration for stiff-person syndrome:
Initial requests: 12 week
Continuation requests: 1 year

OR

G. Myelin Oligodendrocyte Glycoprotein (MOG)- related Neuromyelitis Optica Spectrum Disorder (NMOSD) for either of the following (Hacohen 2019):
   1. As an *initial* trial for the diagnosis of MOG-related neuromyelitis optica spectrum disorder (NMOSD); **AND**
      a. Individual is confirmed to be seropositive for myelin oligodendrocyte glycoprotein (MOG) antibodies; **AND**
      b. Individual is *seronegative* for aquaporin-4 (AQP4) antibodies; **AND**
      c. Individual is using for one of the following:
         i. As induction treatment for an acute episode after an inadequate response to, intolerance, or contraindication to corticosteroids; **OR**
         ii. Individual has further relapse after maintenance treatment with corticosteroids *and* non-steroidal immunosuppressants.
   2. Continued maintenance use after initial treatment for MOG-related NMOSD when the following criteria is met:

a. Individual has experienced a clinical response with immune globulin (for example, a reduction in frequency of relapse);

Approval Duration for MOG-related NMOSD:
Initial requests: 6 months
Continuation requests: 1 year

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**
   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 less than 500mg/dL) (NCCN 2A).

Approval Duration for cancer-related CMV pneumonia: 6 months

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

I. Alzheimer's disease;
II. Immune optic neuropathy, with the exception of MOG-related NMOSD;
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 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.

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