Division: Pharmacy Policy	Subject: Prior Authorization Criteria IVIG and SCIG
Original Development Date: Original Effective Date: Revision Date:	June 6, 2013; June 19, 2014; November 18, 2014; April 21, 2016; July 20, 2017; September 10, 2020; October 2, 2020, January 13, 2021; September 28, 2021; December 8, 2021; April 12, 2023; September 18, 2023; January 24, 2024, February 28, 2024, May 8, 2024, October 11, 2024

Immune Globulins- IVIG and SCIG

Florida Medicaid Prescribed Drug Services requires prior authorization for all Immune Globulin (IVIG and SCIG) claims.

GENERAL NOTES ON COVERAGE:

Florida Medicaid covers immune globulin therapy that is medically necessary and proven effective for treatment of specific humoral immunodeficiencies and certain covered conditions (listed below).

- The use of immune globulin therapy (including dosage, frequency, site of administration, and duration of therapy) must be clinically appropriate and supported by evidence-based literature.
- Adjustment(s) of dosage, frequency, site of administration, and duration of therapy must be reasonable and appropriate based on condition and severity, alternative available treatments, and previous response to immune globulin therapy.
- The use of immune globulin therapy will not be approved for any use that is considered investigational, is unproven and/or is not supported by evidence-based literature.

GENERAL ELIGIBILITY CRITERIA:

Medically necessary immune globulin is authorized when General Eligibility Criteria (below) and relevant Condition-Specific Criteria are met:

1. Medical record documentation confirms the recipient has been definitively diagnosed (by an appropriate specialist) with one of the Covered Conditions listed below;
2. The diagnosis is confirmed by evidence-based diagnostic criteria (supported by peer-reviewed, published literature) and supportive testing, and clearly documented in clinical notes;
3. The recipient is closely followed by the prescribing specialist, and treatment response has clearly defined endpoints to measure effectiveness;
4. The use (including requested frequency and dosage) of immunoglobulin is supported by evidence-based literature.

LENGTH OF AUTHORIZATION:

Varies per indication, please refer to chart.

CLINICAL NOTES:

Florida Medicaid will cover immune globulin therapy for the following conditions based on specified requirements:

1. **Alloimmune Conditions**
    a. Fetal alloimmune thrombocytopenia (FAIT)
    b. Neonatal alloimmune thrombocytopenia (NAIT)
    c. Neonatal hemochromatosis
    d. Post-transfusion purpura

2. Autoimmune Disorders

a. Acquired red cell aplasia
b. Autoimmune Hemolytic Anemia
c. Autoimmune mucocutaneous blistering diseases
    i. Pemphigus vulgaris
    ii. Pemphigus foliaceus
    iii. Bullous pemphigoid
    iv. Mucous membrane pemphigoid
    v. Epidermolysis bullosa acquisita
d. Autoimmune Neutropenia
e. Immune or idiopathic thrombocytopenic purpura (ITP)
f. Kawasaki Disease
g. Lambert-Eaton myasthenic syndrome

3. Collagen-vascular diseases

a. Dermatomyositis

4. Immunodeficiency Disorders or Diseases caused by Immunodeficiency Disorders

a. HIV-associated thrombocytopenia, pediatric or adult
b. Pediatric Human Immunodeficiency Virus (HIV) Infection
c. Primary Humoral Immunodeficiency Syndromes
    i. CVID (Common Variable Immunodeficiency)
    ii. Congenital agammaglobulinemia
    iii. Hyper IgM syndromes
    iv. Hypogammaglobulinemia
    v. IgM (X-linked Immunodeficiency with Hyperimmunoglobulin)
    vi. Immunodeficiency with thymoma (Good syndrome)
    vii. SCID (Severe Combined Immunodeficiency)
    viii. Selective IgG subclass deficiencies
    ix. Wiscott-Aldrich Syndrome
    x. X-linked Agammaglobulinemia

5. Infectious

a. Enteroviral meningoencephalitis
b. Parvovirus B19 infection, chronic, with severe anemia
c. Staphylococcal toxic shock syndrome
d. Toxic epidermal necrolysis/Stevens Johnson syndrome
e. Toxic shock syndrome or toxic necrotizing fascitis due to group A streptococcus

6. Malignancies

a. B-cell chronic lymphocytic leukemia (CLL)
b. Hematological malignancy patients who are immunosuppressed
c. Multiple Myeloma

d. Bone marrow transplant
e. Paraneoplastic opsoclonus-myoclonus-ataxia associated with neuroblastoma

7. Neurological Disorders

a. Chronic Inflammatory Demyelinating Polyneuropathy
b. Guillain-Barré' Syndrome
c. Multifocal motor neuropathy
d. Myasthenia Gravis
e. Opsoclonus Myoclonus Syndrome
f. Polymyositis
g. Rasmussen's encephalitis
h. Relapsing-Remitting Multiple Sclerosis

8. Transplantation

a. Renal transplantation from live donor with ABO incompatibility or positive crossmatch
b. Solid organ transplant recipients who are iatrogenically immunosuppressed to reduce risk of recurrent bacterial or viral infections
c. Solid organ transplantation recipients prior to transplant to suppress anti-human leukocyte antigens (HLA) antibodies
d. Solid organ transplant recipients for treatment of antibody mediated rejection of solid organ transplants
e. Stem cell or bone marrow transplant recipients receiving an allogeneic or syngeneic transplant.

Condition	Indications
Autoimmune hemolytic anemia, refractory	Warm-type autoimmune hemolytic anemia that does not respond to corticosteroids or splenectomy, or those with contraindications to these treatments **Initial Approval : 5 weeks**
Autoimmune Mucocutaneous Blistering Diseases-pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, epidermolysis bullosa acquisita	1. The diagnosis has been proven by biopsy and confirmed by pathology report; **AND** 2. The condition is rapidly progressing, extensive or debilitating; **AND** 3. Corticosteroids, immuno-suppressive agents have failed or the patient has experienced significant complications from standard treatment, such as diabetes or steroid-induced osteoporosis. **Initial Approval: 6 months**
Bacterial infection in HIV-infected children	Consistent with recommendations of the Working Group on Antiretroviral Therapy of the National Pediatric HIV Resource Center immune globulin is considered medically necessary in children with HIV-infection who meet any of the following criteria: 1. Those with hypogammaglobulinemia, i.e., serum IgG concentration less than 250 mg/dL; 2. Those with recurrent serious bacterial infections, i.e., defined as two or more infections such as bacteremia, meningitis, or pneumonia in a 1-year period; 3. Those who fail to form antibodies to common antigens, such as measles, pneumococcal, and/or Haemophilus influenzae type b vaccine; 4. Those living in areas where measles is highly prevalent and who have not developed an antibody response after two doses of measles, mumps, and rubella virus vaccine live;

	5. Single dose for HIV-infected children who are exposed to measles; 6. HIV-infected children with chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy. **Initial Approval: 1 year**
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Symmetric or focal neurologic deficits with slowly progressive or relapsing course over 2 months or longer (with neurophysiological abnormalities). Note: A meta-analysis comparing the efficacy if immune globulin, plasma exchange, and oral glucocorticoids found equivalence between all three, at least within the first 6 weeks of therapy (Van Schaik et al, 2002). Immune globulin is considered under accepted guidelines as the preferred treatment, particularly in children, when there is difficulty with venous access for plasmapheresis, and those susceptible to the complications of long-term corticosteroid therapy (Orange et al, 2006). Persons typically respond to immune globulin or plasma exchange within the first several weeks of treatment and may demonstrate sustained improvement for many weeks or months. Relapses may require periodic isolated treatments with a single dose of immune globulin or single plasma exchange. If a person responds successfully to infrequent booster treatments of either immune globulin or plasma exchange, it is considered medically necessary to prescribe maintenance therapy with immune globulin to prevent relapse, rather than adding corticosteroids or other immunosuppressants. **Initial Approval: 3 months**
Chronic Lymphocytic Leukemia (CLL)	CLL patients with IgG level less than 600 mg/dL; **AND** 1. One severe bacterial infection within preceding 6 months or 2 or more bacterial infections in 1 year; OR 2. Evidence of specific antibody deficiency. **Initial Approval: 1 year**
Dermatomyositis, Polymyositis (includes juvenile)	Patients presenting at least one item from the 1st criterion (skin lesions) and four items from the 2nd through 9th criteria are said to have dermatomyositis. Patients presenting no items from the 1st criterion and at least four items from the 2nd through 9th criteria are said to have polymyositis. 1. Skin lesions a. Heliotrope rash (red purple edematous erythema on the upper eyelid) b. Gottron's sign (red purple keratotic, atrophic erythema, or macules on the extensor surface of finger joints) c. Erythema on the extensor surface of extremity joints: slightly raised red purple erythema over elbows or knees 2. Proximal muscle weakness (upper or lower extremity and trunk) 3. Elevated serum CK (creatine kinase) or aldolase level 4. Muscle pain on grasping or spontaneous pain 5. Myogenic changes on EMG (short duration, polyphasic motor unit potentials with spontaneous fibrillation potentials) 6. Positive anti-Jo-1 (histadyl tRNA synthetase) antibody 7. Non-destructive arthritis or arthralgias 8. Systemic inflammatory signs (fever: more than 37°C at axilla, elevated serum CRP level or accelerated erythrocyte sedimentation rate (ESR) of more than 20 mm/h by the Westergren method)

	9. Pathological findings compatible with inflammatory myositis (inflammatory infiltration of skeletal evidence of active regeneration may be seen) AND patient has severe active illness AND patient is intolerant or refractory to 1st and 2nd line therapies: 1st line therapy - Corticosteroids (e.g., prednisone); 2nd line therapy - Immunosuppressants (e.g., methotrexate, azathioprine, cyclophosphamide, and cyclosporine). **Initial Approval: 1 year**
Enteroviral meningocephalitis	In severe cases lacking other therapeutic options **Initial Approval: 6 months**
Fetal Alloimmune Thrombocytopenia (FAIT)	At 20 weeks or later of pregnancy, cordocentensis reveals fetal platelets less than 20 x 10^3/µL **OR** Mother has had previous pregnancy affected by FAIT **Initial Approval: approval should cover the pregnancy term**
Guillain Barré syndrome (GBS)	1. Severe GBS with significant weakness such as inability to stand or walk without aid, respiratory or bulbar weakness, or Miller-Fisher syndrome (MFS); AND 2. The disorder has been diagnosed during the first 2 weeks of the illness; AND 3. Immune globulin is initiated within one month of symptom onset. Note: Based on the 2003 American Academy of Neurology (AAN)guidelines, immune globulin should usually be initiated within 2 weeks and no longer than 4 weeks of onset of neuropathic symptoms. **Initial Approval: 5 days**
Hematopoietic Stem Cell Transplant (HSCT) or Bone Marrow Transplant (BMT)	Prophylaxis in allogenic (related donor) or syngeneic (twin donor) transplant recipients within the first 100 days post-transplant After 100 days post-transplant, for patients who are markedly hypogammaglobulinemic (IgG less than 400 mg/dL), who have a primary immunodeficiency disease, or who have Epstein-Barr virus (EBV) or Respiratory Syncytial Virus (RSV) infection Corticosteroid-resistant graft versus host disease (GVHD) in patients 20 years of age or older in the first 100 days post-transplant and who are hypogammaglobinemic (IgG level less than 400 mg/dL) **Initial Approval: 1 year**
HIV-associated thrombocytopenia-Adults	1. Significant bleeding in thrombocytopenic patients or platelet count less than 20,000/µL; AND 2. Failure of RhIG in Rh-positive patients. **Initial Approval: 6 months**
HIV-associated thrombocytopenia-Pediatric	Infants and children less than 13 years of age whose IgG level is less than 400 mg/dL; and 1. Two or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent; **OR** 2. Child has received 2 doses of measles vaccine and lives in a region with a high prevalence of measles; **OR** 3. Child has HIV-associated thrombocytopenia despite anti-retroviral therapy; **OR** 4. Child has chronic bronchiectasis that is suboptimally responsive to antimicrobial and pulmonary therapy; **OR** 5. CD4 cell count is greater than or equal to 200/mm^3 **Initial Approval: 1 year**

Idiopathic (or Immune) Thrombocytopenic Purpura (ITP)-Adults	1. Other causes of thrombocytopenia have been ruled out by history and peripheral smear; **AND** Patient is unresponsive to corticosteroid therapy; **AND** Requires management of acute bleeding due to severe thrombocytopenia (platelet counts less than 30,000/µL); **OR** 2. To increase platelet counts prior to invasive major surgical procedures (e.g., splenectomy), **OR** 3. To defer or avoid splenectomy; **OR** 4. In members with severe thrombocytopenia (platelet counts less than 20,000/µL) considered to be at risk for intra-cerebral hemorrhage. **Initial Approval: 5 days**
Idiopathic (or Immune) Thrombocytopenic Purpura (ITP)-Pediatric	Acute ITP: 1. Immune globulin as initial therapy if platelet count less than 20,000/µL, especially when the patient has emergency bleeding or is at risk for severe life-threatening bleeding; **OR** 2. Patients with severe thrombocytopenia (platelet counts less than 20,000/µL) considered to be at risk for intracranial hemorrhage (Note: immune globulin is not indicated if patient has only mild manifestations of bleeding) Chronic ITP: In high-risk patients when the platelet count is low or patient is symptomatic; **AND** 1. Failure of other therapies, **OR** 2. Patient is a high risk for post-splenectomy sepsis. **Initial Approval: 5 days**
Idiopathic (or Immune) Thrombocytopenic Purpura, Chronic Refractory	1. Age of 10 years or older; **AND** 2. Duration of illness of greater than 6 months; **AND** 3. No concurrent illness/disease explaining thrombocytopenia; **AND** 4. Prior treatment with corticosteroids and splenectomy has failed **OR** patient is at high-risk for post-splenectomy sepsis. **Initial Approval: 6 months**
Immune Thrombocytopenic Purpura (ITP) in Pregnancy	1. Refractory to steroids with platelet counts less than 10,000/µL in the 3rd trimester; **OR** 2. Platelet counts less than 30,000/µL associated with bleeding before vaginal delivery or C-section; **OR** 3. Pregnant women who have previously delivered infants with autoimmune thrombocytopenia; **OR** 4. Pregnant women who have platelet counts less than 50,000/µL during the current pregnancy; **OR** 5. Pregnant women with past history of splenectomy **Initial Approval: Should correspond to pregnancy term**
Immunosuppressed Patients	To prevent or modify recurrent bacterial or viral infections in patients with iatrogenically induced, or disease associated immunosuppression (IgG less than 400 mg/dL) with one of the following: 1. Solid organ transplants or extensive surgery with immunosuppression (Note: In particular, immune globulin may be medically necessary in persons undergoing multiple courses of plasmapheresis as a treatment for allograft rejection or for other

	indications; these persons may receive immune globulin at the completion of therapy if their IgG level is less than 400 mg/dL); **OR** 2. Hematological malignancy; **OR** 3. Collagen-vascular disease. **Initial Approval: 1 year**
Kawasaki Disease (Mucocutaneous Lymph Node Syndrome [MCLS])	Diagnosis must be established -- no specific lab test -- diagnosis is established by meeting the following criteria: 1. Fever present for at least 5 days; **AND** 2. **Four of the following 5** conditions are met: a. Mucous membrane changes such as a red tongue and dry fissured lips; b. Swelling of the hands and feet; c. Enlarged lymph nodes in the neck; d. Diffuse red rash covering most of the body; e. Redness of the eyes. **Initial Approval: 1 year**
Lambert-Eaton Myasthenic Syndrome (LEMS)	No response to anti-cholinesterases and dalfampridine (Ampyra); **AND** 1. Used as an alternative to plasma exchange if weakness is severe; **OR** 2. When there is difficulty with venous access for plasmapheresis. **Initial Approval: 3 months**
Myasthenia Gravis	Treatment of acute myasthenic crisis with decompensation (respiratory failure, or disabling weakness requiring hospital admission); **AND** other treatments have been unsuccessful or are contraindicated (e.g., azathioprine, cyclosporine, and cyclophosphamide). Note: For management of acute myasthenic crises, immune globulin is administered over 2 to 5 days. Use of immune globulin as maintenance therapy is considered experimental and investigational. **Initial Approval: 1 year**
Multifocal Motor Neuropathy with Conduction Block	Progressive, symptomatic multifocal motor neuropathy that has been diagnosed on the basis of electrophysiologic findings that rule out other possible conditions that may not respond to immune globulin treatment **Initial Approval: 1 year**
Multiple Myeloma	1. "Plateau Phase" multiple myeloma (greater than 3 months since diagnosis); AND 2. IgG level less than 600 mg/dL; AND 3. Two or more significant infections in last year or a single life-threatening infection; OR Evidence of specific antibody deficiency **Initial Approval: 1 year**
Multiple Sclerosis (MS)-Relapsing-Remitting (not primary or secondary progressive MS)	1. Severe manifestations of relapsing-remitting MS (not primary or secondary progressive MS); **AND** 2. Standard FDA approved therapies (i.e., interferons, glatiramer, etc) have failed, become intolerable, or are contraindicated **Initial Approval: 1 year**
Neonatal Hemochromatosis	Pregnant women who have a history of pregnancy ending with documented neonatal hemochromatosis (Note: Dosage should be 1 mg/kg weekly from the 18th week until the end of pregnancy) **Initial Approval: 6 months**

Division: Pharmacy Policy	Subject: Prior Authorization Criteria IVIG and SCIG
Original Development Date: Original Effective Date: Revision Date:	June 6, 2013; June 19, 2014; November 18, 2014; April 21, 2016; July 20, 2017; September 10, 2020; October 2, 2020; January 13, 2021; September 28, 2021; December 8, 2021; April 12, 2023; September 18, 2023; January 24, 2024; February 28, 2024, May 8, 2024, October 11, 2024

Neonatal Alloimmune Thrombocytopenia (NAIT)	Thrombocytopenia (< 30,000/µL) **AND** Failure, intolerance, or contraindication to platelet transfusion **Initial Approval: 1 month**
Neuroblastoma associated paraneoplastic opsoclonus-myoclonus-ataxia syndrome	Opsoclonus-myoclonus-ataxia syndrome in patients diagnosed with neuroblastoma **Initial Approval: 6 months**
Opsoclonus-myoclonus	Last resort treatment for refractory opsoclonus-myoclonus **Initial Approval: 6 months**
Parvovirus B19 infection (Erythrovirus), Chronic with severe anemia (pure red cell aplasia)	Severe, refractory anemia with documented Parvo B19 (erythrovirus) viremia **Initial Approval: 3 months**
Post-transfusion purpura (PTP)	1. Decreased platelets (usually less than 10,000/µL); ***AND*** 2. Two to 14 days post-transfusion with bleeding. **Initial Approval: 5 days**
Primary Humoral Immunodeficiencies: 1. Selective IgM Immunodeficiency 2. Congenital hypogamma-globulinemia 3. Immunodeficiency with near/normal IgM (absent IgG, IgA) – a.k.a. Hyper IgM syndrome 4. Other deficiency of humoral immunity 5. Combined immunodeficiency disorders (e.g., X-SCID, jak3, ZAP70, ADA, PNP, RAG defects, Ataxia Telangiectasia, DiGeorge syndrome**,** common variable immunodeficiency)	1. Agammaglobulinemia (total IgG less than 200 mg/dL or infants with BTK gene and/or absence of B lymphocytes)); ***OR*** 2. Persistent hypogammaglobulinemia (total IgG less than 400 mg/dL or two standard deviations below the mean for age) with recurrent bacterial infections and/or lack of response to protein or polysaccharide antigens (inability to make IgG antibody against diphtheria and tetanus toxoids, pneumococcal polysaccharide vaccine, or both- see notes below): a. Serum antibody titers to tetanus and/or diphtheria should be obtained prior to immunization with diphtheria and/or tetanus vaccine and 3 to 4 weeks after immunization. The protective level for diphtheria is 0.01 to 0.1 international units/mL and for tetanus greater than 0.1 international units/mL. If post vaccination titers are above these levels, the patients response to protein antigens is normal b. Serum antibody titers to pneumococcus should be measured prior to immunization and 4 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (e.g., Pneumovax). A normal response to pneumococcus for children from 24 months to 5 years of age is a conversion of 50% or more of the serotypes tested. For persons aged 6 years of age and older, a normal response is defined as conversion of 70% of the serotypes tested. A normal response for a single serotype present in a pneumococcal vaccine is defined as the conversion from a non-protective to a protective titer. A protective (normal or adequate) response to each pneumococcal serotype is defined as a titer equal to or greater than 1.3 mcg/mL antibody. (Note: When reported, the conversion factor for nanograms of antibody nitrogen per milliliter (ng N/mL) to antibody micrograms per milliliter is as follows: 160 ng N/mL - 1.0 mcg/mL); or 3. Selective IgG subclass deficiencies (see criteria in section of selective IgG subclass deficiency below); **OR** 4. Normal total IgG levels with severe polysaccharide non-responsiveness and evidence of recurrent severe difficult-to-treat infections (e.g., recurrent otitis media, bronchiectasis, recurrent infections requiring IV antibiotics, multiple antibiotic

	hypersensitivities, chronic or recurrent sinusitis) with a documented requirement for antibiotic therapy: a. Patient has unexplained recurrent or persistent severe bacterial infections despite adequate treatment, including all of the following: 1. Aggressive management of other conditions predisposing to recurrent sinopulmonary infections (e.g., asthma, allergic rhinitis); 2. Prophylactic antibiotics; 3. Increased vigilance and appropriate antibiotic therapy for infections; and 4. Immunization with conjugate vaccines in patients who have not responded to polysaccharide vaccines. b. Serum antibody titers to pneumococcus should be measured prior to immunization and 4 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (e.g., Pneumovax); at least 14 polysaccharide antigens should be tested. c. Polysaccharide non-responsiveness is defined as lack of protective antibody titer (specific IgG antibody titer less than 1.3 mcg/ml) in greater than 70 % of antigens tested (more than 50 % in children aged 2 to 5 years). d. Further evidence of infection, including sinus and lung imaging, complete blood counts, C-reactive protein measurement, and erythrocyte sedimentation rate (ESR) determination, may be required to support the need for immune globulin supplementation. e. For children 12 years of age or younger with normal total IgG levels and severe polysaccharide nonresponsiveness, immune globulin should be discontinued, and the medical necessity of immune globulin should be re-evaluated 1 year after initiating therapy and every 2 years thereafter by reassessing immune response to protein and polysaccharide antigens. Immune response should be re-evaluated at least 3 months after discontinuation of immune globulin. Immune globulin should also be discontinued at that time if the number and/or severity of infections have not been reduced, as not all persons with polysaccharide nonresponsiveness benefit from immune globulin. The use of immune globulin may not be beneficial in certain secondary immunodeficiency states; correction of the underlying condition is the preferred approach. **Initial Approval: 1 year**
Rasmussen Encephalitis	For children whose symptoms do not improve with anti-epileptic drugs and corticosteroids **Initial Approval: 1 month**
Selective IgG Subclass Deficiency	1. Deficiency of one or more IgG subclasses to levels less than 2 standard deviations below the age-specific mean (see table below). These levels should be assessed on at least two occasions while the patient is free of infections; **AND** 2. Member has unexplained recurrent or persistent severe bacterial infections despite adequate treatment, including **ALL** the following:

	a. Aggressive management of other conditions predisposing to recurrent sinopulmonary infections (e.g., asthma, allergic rhinitis); b. Prophylactic antibiotics; c. Increased vigilance and appropriate antibiotic therapy for infections; and d. Immunization with conjugate vaccines in patients who have not responded to polysaccharide vaccines; **AND** 3. Member has demonstrated an inability to mount an adequate response to protein and polysaccharide antigens, as determined by the following criteria: a. Member has documented inability to mount an antibody response to protein antigens: Serum antibody titers to tetanus and/or diphtheria should be obtained prior to immunization with diphtheria and/or tetanus vaccine and 3 to 4 weeks after immunization. An inadequate response is defined as a post vaccination titer less than 0.1 international units/mL for diphtheria, and 0.1 international units/mL or less for tetanus; and b. Member has documented inability to mount an adequate antibody response to polysaccharide antigens. Serum antibody titers to at least 14 pneumococcus serotypes should be measured prior to immunization and 4 to 6 weeks after immunization with polyvalent pneumococcal polysaccharide vaccine (e.g., Pneumovax). An inadequate response is defined as lack of protective antibody titer (i.e., specific IgG concentration less than 1.3 mcg/mL) in at least 70 % of serotypes tested (in at least 50 % of serotypes tested in children aged 2 to 5 years) Note: Response to polysaccharide antigens is not reliable in children less than 2 years of age. 4. In children 12 years of age or younger only, 1 year after initiating therapy, immune globulin should be discontinued and the medical necessity of immune globulin should be re-evaluated and every 2 years thereafter by re-assessing immune response to protein and polysaccharide antigens. Immune response should be re-evaluated at least 3 months after discontinuation of immune globulin. Immune globulin should also be discontinued at that time if the number and/or severity of infections have not been reduced, as not all persons with selective IgG subclass deficiencies benefit from immune globulin. **Initial Approval: 1 year**
Staphylococcal Toxic Shock Syndrome	Severe cases of toxic shock syndrome that have not responded to fluids and vasopressors **Initial Approval: 1 month**
Toxic epidermal necrolysis and Stevens-Johnson syndrome	Severe cases of toxic epidermal necrolysis and Stevens-Johnson syndrome **Initial Approval: 3 months**
Toxic shock syndrome or toxic necrotizing fascitis due to group A streptococcus	Patients who are sufficiently ill to require critical care unit support and have documented presence of fascitis and microbiological data consistent with invasive streptococcal infection (culture or Gram stain) **Initial Approval: 1 month**

Division: Pharmacy Policy	Subject: Prior Authorization Criteria IVIG and SCIG
Original Development Date: Original Effective Date: Revision Date:	June 6, 2013; June 19, 2014; November 18, 2014; April 21, 2016; July 20, 2017; September 10, 2020; October 2, 2020; January 13, 2021; September 28, 2021; December 8, 2021; April 12, 2023; September 18, 2023; January 24, 2024; February 28, 2024, May 8, 2024, October 11, 2024

The laboratory's own reference ranges should be used, where available. If the laboratory's reference ranges are not submitted with the immunoglobulin level results, the following standard reference ranges may be applied:

Normal Immunoglobulin Levels (mg/dl)			
AGE	**IgA**	**IgG**	**IgM**
1 - 2 mo	1 - 53	251 - 906	20 - 87
2 - 3 mo	3 - 47	206 - 601	17 - 105
3 - 4 mo	4 - 73	176 - 581	24 - 101
4 - 5 mo	8 - 84	172 - 814	33 - 108
5 - 6 mo	8 - 68	215 - 704	35 - 102
6 - 8 mo	11 - 90	217 - 904	34 - 125
8 mo - 1 yr	16 - 84	294 - 1069	41 - 149
1 - 2 yr	14 - 106	345 - 1213	43 - 173
2 - 3 yr	14 - 123	424 - 1051	48 - 168
3 - 4 yr	22 - 159	441 - 1135	47 - 200
4 - 6 yr	25 - 154	463 - 1236	43 - 196
6 - 9 yr	33 - 202	633 - 1280	48 - 207
9 - 11 yr	45 - 236	608 - 1572	52 - 242
11 yr & up	70 - 312	639 - 1349	56 - 352

Normal IgG Subclass Levels (mg/dl)				
AGE	**IgG1**	**IgG2**	**IgG3**	**IgG4**
cord	435 - 1084	143 - 453	27 - 146	1 - 47
0 - 3 mo	218 - 496	40 - 167	4 - 23	1 - 33
3 - 6 mo	143 - 394	23 - 147	4 - 100	1 - 14
6 - 9 mo	190 - 388	37 - 60	12 - 62	1 - 1
9 mo - 3 yr	286 - 680	30 - 327	13 - 82	1 - 65
3 - 5 yr	381 - 884	70 - 443	17 - 90	1 - 116
5 - 7 yr	292 - 816	83 - 513	8 - 111	1 - 121
7 - 9 yr	442 - 802	113 - 480	15 - 133	1 - 84
9 - 11 yr	456 - 938	163 - 513	26 - 113	1 - 121
11 - 13 yr	456 - 952	147 - 493	12 - 179	1 - 168
13 - 15 yr	347 - 993	140 - 440	23 - 117	1 - 183
15 yr & up	422 - 1292	117 - 747	41 - 129	1 - 291

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

Division: Pharmacy Policy	Subject: Prior Authorization Criteria IVIG and SCIG
Original Development Date: Original Effective Date: Revision Date:	June 6, 2013; June 19, 2014; November 18, 2014; April 21, 2016; July 20, 2017; September 10, 2020; October 2, 2020; January 13, 2021; September 28, 2021; December 8, 2021; April 12, 2023; September 18, 2023; January 24, 2024; February 28, 2024, May 8, 2024, October 11, 2024

Immune globulin therapy is considered experimental and investigational for any of the following conditions (alphabetical):

Hematologic/Oncologic Disorders	Immunologic Disorders	Infectious Disorders	Neurologic Disorders	Rheumatologic Disorders	Other Disorders
Acute lymphoblastic leukemia (ALL)	Cellular immunodeficiencies without IgG deficiencies	Chronic mucocutaneous candidiasis (CMCC)	Amyotrophic lateral sclerosis (ALS)	Behçet's syndrome	Adrenoleukodystrophy
Diamond-Blackfan anemia	Complement deficiencies	Chronic sinusitis	Demyelinating optic neuritis	Inclusion body myositis	Asthma
Red cell aplasia (except as noted above due to parvovirus in the setting of immunocompromise)	Selective IgA deficiency without IgG or IgG subclass deficiency, and impaired antibody response to vaccination	Lyme disease	Epilepsy	Rheumatoid arthritis	Atopic dermatitis
Thrombotic thrombocytopenic pupura		Post-infectious sequelae	Myasthenia gravis-chronic management	Scleroderma	Chronic fatigue syndrome
Hemolytic uremia syndrome		Recurrent otitis media	Primary progressive, secondary progressive or progressive relapsing Multiple Sclerosis	Systemic Lupus Erythematosus (SLE)	Cystic Fibrosis
		Rheumatic fever	Pediatric autoimmune Neuropsychiatric Disorder associated with Streptococcal Infection (PANDAS),	Vasculitides other than Kawasaki Disease	Diabetes Mellitus
			Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS)		Idiopathic environmental illness
			Alzheimer's Disease		Recent onset dilated cardiomyopathy
			Autism		Recurrent fetal loss
					Recurrent Spontaneous Abortion or recurrent spontaneous pregnancy loss

Division: Pharmacy Policy	Subject: Prior Authorization Criteria IVIG and SCIG
Original Development Date: Original Effective Date: Revision Date:	June 6, 2013; June 19, 2014; November 18, 2014; April 21, 2016; July 20, 2017; September 10, 2020; October 2, 2020; January 13, 2021; September 28, 2021; December 8, 2021; April 12, 2023; September 18, 2023; January 24, 2024; February 28, 2024, May 8, 2024, October 11, 2024

Brand of Immune Globulin	FDA-Approved Indications
Alyglo (intravenous)	Primary humoral immunodeficiency
Asceniv (intravenous)	Primary humoral immunodeficiency
Atgam (intravenous)	Renal allograft rejection, aplastic anemia
Bivigam (intravenous)	Primary humoral immunodeficiency
Carimune NF (intravenous)	Primary immunodeficiencies, immune thrombocytopenic purpura
Cutaquig (subcutaneous)	Primary humoral immunodeficiency
Cuvitru (subcutaneous)	Primary immunodeficiencies
Flebogamma (intravenous)	Primary immunodeficiencies, immune thrombocytopenic purpura (10%)
Gammagard liquid (intravenous or subcutaneous)	Primary immunodeficiencies, multifocal motor neuropathy, chronic inflammatory demyelinating polyneuropathy
Gammagard S/D (intravenous)	Primary immunodeficiencies, B-cell Chronic Lymphocytic Leukemia, chronic idiopathic thrombocytopenic purpura, Kawasaki syndrome
Gammaked (intravenous or subcutaneous)	Primary immunodeficiencies, immune thrombocytopenic purpura, chronic inflammatory demyelinating polyneuropathy
Gammaplex (intravenous)	Primary immunodeficiencies, chronic immune thrombocytopenic purpura (10%)
Gamunex-C (intravenous or subcutaneous)	Primary immunodeficiencies, immune thrombocytopenic purpura, chronic inflammatory demyelinating polyneuropathy
Hizentra (subcutaneous)	Primary immunodeficiencies, chronic inflammatory demyelinating polyneuropathy
HyQvia (subcutaneous with recombinant human hyaluronidase)	Primary immunodeficiency, chronic inflammatory demyelinating polyneuropathy
Octagam (intravenous)	Primary immunodeficiencies, idiopathic thrombocytopenic purpura (10%), dermatomyositis (10%)
Panzyga (intravenous)	Primary immunodeficiencies, chronic inflammatory demyelinating polyneuropathy, chronic immune thrombocytopenia
Privigen (intravenous)	Primary immunodeficiencies, chronic inflammatory demyelinating polyneuropathy, immune thrombocytopenic purpura
Xembify (subcutaneous)	Primary immunodeficiencies

REFERENCES:

1. Jongen JL, van Doorn PA, van der Meche FG. High-dose intravenous immunoglobulin therapy for myasthenia gravis. J Neurol. 1998;245(1):26-31.
2. Bradley DJ, Glode MP. Kawasaki disease. The mystery continues. West J Med. 1998;168(1):23-29.
3. Sicherer SH, Winkelstein JA. Primary immunodeficiency diseases in adults. JAMA. 1998;279(1):58-61.
4. Tangel M, Hartung HP, Marx P, Gold R. Intravenous immunoglobulin treatment of neurological autoimmune diseases. J Neurol Sci. 1998;153(2):203-214.
5. Otten A, Bossuyt PM, Vermeulen M, Brand A. Intravenous immunoglobulin treatment in hematological diseases. Eur J Haematol. 1998;60(2):73-85.
6. Fabris F, Cordiano I, Girolami A. High-dose intravenous immune globulin and the response to splenectomy in patients with idiopathic thrombocytopenic purpura. N Engl J Med. 1997;337(15):1088-1089.
7. Comi G, Nemni R, Amadio S, et al. Intravenous immunoglobulin treatment in multifocal motor neuropathy and other chronic immune-mediated neuropathies. Mult Scler. 1997;3(2):93-97.
8. Stiehm ER. Human intravenous immunoglobulin in primary and secondary antibody deficiencies. Pediatr Infect Dis J. 1997;16(7):696-707.
9. Dalakas MC. Intravenous immune globulin therapy for neurologic diseases. Ann Intern Med. 1997;126(9):721-730.
10. Dickler HB, Gelfand EW. Current perspectives on the use of intravenous immunoglobulin. Adv Intern Med. 1996;41:641-680.
11. Rosti L. High-dose intravenous immunoglobulins. J Perinat Med. 1996;24(5):539.
12. Cunningham-Rundles C. Established and new uses of intravenous immunoglobulin. Mt Sinai J Med. 1992;59(4):335-340.
13. Klassen LW, Calabrese LH, Laxer RM. Intravenous immunoglobulin in rheumatic disease. Rheum Dis Clin North Am. 1996;22(1):155-173.
14. National Institutes of Health. Intravenous Immunoglobulin Consens Statement. 1990;8(5):1-23.
15. Canadian Paediatric Society, Infectious Diseases and Immunization Committee. Intravenous immune globulin use in children. Can Med Assoc J. 1992;146(2):121-124.
16. Garvey MA, Giedd J, Swedo SE. PANDAS: The search for environmental triggers of pediatric neuropsychiatric disorders. Lessons from rheumatic fever. J Child Neurol. 1998;13(9):413-423.
17. Swedo SE, Leonard HL, Mittleman BB, et al. Identification of children with pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections by a marker associated with rheumatic fever. Am J Psychiatry. 1997;154(1):110-112.
18. Bril V, Allenby K, Midroni G, et al. IVIG in neurology--evidence and recommendations. Can J Neurol Sci. 1999;26(2):139-152.
19. Horiuchi I, Yamada T, Imaiso Y, et al. [A case of stiff-man syndrome with an antineuronal autoantibody against an 80 kDa protein]. Rinsho Shinkeigaku. 1998;38(10-11):936-940.
20. Liblau R, Benyahia B, Delattre JY. The pathophysiology of paraneoplastic neurological syndromes. Ann Med Interne (Paris). 1998;149(8):512-520.
21. Sevrin C, Moulin T, Tatu L, et al. 'Stiff-man' syndrome treated with intravenous immunoglobulins (letter). Rev Neurol (Paris). 1998;154(5):431.
22. Stayer C, Meinck HM. Stiff-man syndrome: An overview. Neurologia. 1998;13(2):83-88.
23. Saiz A, Arias M, Fernandez-Barreiro A, et al. Diagnostic usefulness of glutamic acid decarboxylase antibodies in stiff-man syndrome. Med Clin (Barc). 1998;110(10):378-381.
24. Liguori R, Cordivari C, Lugaresi E, Montagna P. Botulinum toxin A improves muscle spasms and rigidity in stiff-person syndrome. Mov Disord. 1997;12(6):1060-1063.
25. Levin KH. Paraneoplastic neuromuscular syndromes. Neurol Clin. 1997;15(3):597-614.
26. Fonseca LF, Noce TR, Teixeira ML, Early-onset acute transverse myelitis following hepatitis B vaccination and respiratory infection: Case report. Arq Neuropsiquiatr. 2003;61(2A):265-268.
27. Barker RA, Marsden CD. Successful treatment of stiff man syndrome with intravenous immunoglobulin. J Neurol Neurosurg Psychiatry. 1997;62(4):426-427.
28. Centers for Disease Control and Prevention (CDC). Availability of immune globulin intravenous for treatment of immune deficient patients -- United States, 1997-1998. MMWR Morb Mortal Wkly Rep. 1999;48(8):159-162.
29. Lisak RP. Intravenous immunoglobulins in multiple sclerosis. Neurology. 1998;51(6 Suppl 5):S25-S29.
30. Sorensen PS, Wanscher B, Jensen CV, et al. Intravenous immunoglobulin G reduces MRI activity in relapsing multiple sclerosis. Neurology. 1998;50(5):1273-1281.
31. Achiron A, Gabbay U, Gilad R, et al. Intravenous immunoglobulin treatment in multiple sclerosis. Effect on relapses. Neurology. 1998;50(2):398-402.
32. Sorensen PS. Intravenous immunoglobulin G therapy: Effects of acute and chronic treatment in multiple sclerosis. Mult Scler. 1996;1(6):349-352.
33. Poehlau D, Federlein J, Postert T, et al. Intravenous immunoglobulin (IVIG) treatment for patients with primary or secondary progressive multiple sclerosis -- outline of a double- blind randomized, placebo-controlled trial. Mult Scler. 1997;3(2):149-152.
34. Sorensen PS, Wanscher B, Schreiber K, et al. A double-blind, cross-over trial of intravenous immunoglobulin G in multiple sclerosis: Preliminary results. Mult Scler. 1997;3(2):145-148.

35. Fazekas F, Deisenhammer F, Strasser-Fuchs S, et al. Treatment effects of monthly intravenous immunoglobulin on patients with relapsing-remitting multiple sclerosis: Further analyses of the Austrian Immunoglobulin in MS study. Mult Scler. 1997;3(2):137-141.
36. Fazekas F, Deisenhammer F, Strasser-Fuchs S, et al. Randomised placebo-controlled trial of monthly intravenous immunoglobulin therapy in relapsing-remitting multiple sclerosis. Austrian Immunoglobulin in Multiple Sclerosis Study Group. Lancet. 1997;349(9052):589-593.
37. American College of Obstetricians and Gynecologists (ACOG), Committee on Practice Bulletins -- Obstetrics. Thrombocytopenia in pregnancy. ACOG Practice Pattern No. 6. Washington, DC: ACOG; September 1999.
38. Ohlsson A, Lacy JB. Intravenous immunoglobulin for suspected or subsequently proven infection in neonates. Cochrane Database Syst Rev. 2010;(3):CD001239.
39. Ohlsson A, Lacy JB. Intravenous immunoglobulin for preventing infection in preterm and/or low-birth-weight infants. Cochrane Database Syst Rev. 2004;(1):CD000361.
40. University HealthSystem Consortium (UHC), Technology Assessment Program of the Clinical Practice Advancement Center. Technology assessment: Intravenous immunoglobulin preparations. Oak Brook, IL: UHC; March 1999.
41. University HealthSystem Consortium (UHC). Immune globulin intravenous (IGIV) - update. Drug Monograph. Oak Brook, IL: UHC; 2006.
42. University of Michigan Health Center (UMHC), Department of Pediatrics and Communicable Diseases. Intravenous Immunoglobulin is effective therapy for acute idiopathic thrombocytopenic purpura. Evidence-Based Pediatrics Website. Ann Arbor, MI: UMHC; January 25, 1999. Available at: http://www.med.umich.edu/pediatrics/ebm/cats/itp.htm. Accessed June 24, 2002. .
43. University of Pittsburgh Medical Center, Department of Pharmacy Services. IVIG Guidelines for Use. Pittsburgh, PA: University of Pittsburgh Medical Center; 1998. Available at: http://www.upmc.edu/druginfo/InternalAccess/Documents/ShortForms/iv_immunoglobulin_products.htm. Accessed June 24, 2002.
44. Association of British Neurologists (ABN). Guidelines for the Use of Intravenous Immunoglobulin in Neurologic Diseases. London, UK: ABN; March 2002. Available at: http://www.theabn.org/downloads/IVIgGuidelines.pdf. Accessed June 24, 2002.
45. European Agency for the Evaluation of Medicinal Products, Committee for Proprietary Medicinal Products (CPMP), Blood Products Working Party. Core SPC for human normal immunoglobulin for intravenous administration (IVIg). London, UK: CPMP; June 2000. Available at: http://www.emea.eu.int/pdfs/human/bpwg/085995en.pdf. Accessed June 24, 2002.
46. American Society for Reproductive Medicine (ASRM). Intravenous immunoglobulin (IVIG) and recurrent spontaneous pregnancy loss. A Practice Committee Report. Washington, DC: ASRM; July 1998. Available at: http://www.asrm.org/Media/Practice/ivig.html. Accessed June 24, 2002.
47. Chapel HM, Spickett GP, Ericson D, et al. The comparison of the efficacy and safety of intravenous versus subcutaneous immunoglobulin replacement therapy. J Clin Immunol. 2000;20(2):94-100.
48. Gaspar J, Gerritsen B, Jones A. Immunoglobulin replacement treatment by rapid subcutaneous infusion. Arch Dis Child. 1998;79(1):48-51.
49. Stiehm ER, Casillas AM, Finkelstein JZ, et al. Slow subcutaneous human intravenous immunoglobulin in the treatment of antibody immunodeficiency: Use of an old method with a new product. J Allergy Clin Immunol. 1998;101(6 Pt 1):848-849.
50. Nigro G, D'Eufemia P, Zervini M, et al. Parvovirus B19 infection in a hypogammaglobulinemic infant with neurologic disorders and anemia: Successful immunoglobulin therapy. Pediatr Infect Dis J. 1994;13:1019-1021.
51. American Academy of Pediatrics (AAP), Committee on Infectious Diseases. Immune globulin intravenous. In: 2006 Red Book: Report of the Committee on Infectious Diseases. 27th ed. Elk Grove Village, IL: AAP; 2006:57-60.
52. Kimata H. High-dose intravenous gammaglobulin treatment of hyperimmunoglobulinemia E syndrome. J Allergy Clin Immunol. 1995;95:771-774.
53. Bain PG, Motomura M, Newsom-Davis J, et al. Effects of intravenous immune globulin on muscle weakness and calcium-channel autoantibodies in the Lambert-Eaton myasthenic syndrome. Neurology. 1996;47:678-683.
54. Fasano MB. Risks and benefits of intravenous immunoglobulin treatment in children. Curr Opin Pediatr. 1995;7:688-694.
55. Clegg A, Bryant J, Milne R. Disease modifying agents in multiple sclerosis. Health Technol Assess. 2000;4(9):1-101.
56. Center for Medicare and Medicaid Services (CMS). Intravenous immune globulin for autoimmune mucocutaneous blistering diseases. Decision Memorandum. CPG-00109N. Baltimore, MD: CMS; January 22, 2002. Available at: http://cms.hhs.gov/coverage.8b3-kkk2.asp. Accessed July 1, 2002.
57. Fanaroff AA, Korones SB, Wright LL, et al. A controlled trial of intravenous immune globulin to reduce nosocomial infections in very-low-birth-weight infants. N Engl J Med. 1994;330(16):1107-1113.
58. Plasma Exchange/Sandoglobulin Guillain-Barré Syndrome Trial Group. Randomized trial of plasma exchange, intravenous immunoglobulin, and combined treatments in Guillain-Barré syndrome. Lancet. 1997;349:225-230.
59. Oates-Whitehead RM, Baumer JH, Haines L, et al. Intravenous immunoglobulin for the treatment of Kawasaki disease in children. Cochrane Database Syst Rev. 2003;(4):CD004000.
60. Wu HM, Tang JL, Sha ZH, et al. Interventions for preventing infection in nephrotic syndrome. Cochrane Database Syst Rev. 2004;(2):CD003964.
61. Hughes RAC, Swan AV, van Doorn PA. Intravenous immunoglobulin for Guillain-Barré syndrome. Cochrane Database Syst Rev. 2010;(6):CD002063.

62. Alejandria MM, Lansang MA, Dans LF, Mantaring JBV. Intravenous immunoglobulin for treating sepsis and septic shock. Cochrane Database Syst Rev. 2002;(1):CD001090.
63. Gray O, McDonnell GV, Forbes RB. Intravenous immunoglobulins for multiple sclerosis. Cochrane Database Syst Rev. 2003;(3):CD002936.
64. Brocklehurst P. Interventions for reducing the risk of mother-to-child transmission of HIV infection. Cochrane Database Syst Rev. 2002;(1):CD000102.
65. Gajdos P, Chevret S, Toyka K. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database Syst Rev. 2008;(1):CD002277.
66. Alcock GS, Liley H. Immunoglobulin infusion for isoimmune haemolytic jaundice in neonates. 2002;(3):CD003313.
67. Bain PG, Motomura M, Newsom-Davis J, et al. Effects of intravenous immunoglobulin on muscle weakness and calcium-channel autoantibodies in the Lambert-Eaton myasthenic syndrome. Neurology. 1996;47:678-683.
68. Maddison P, Newsom-Davis J. Treatment for Lambert-Eaton myasthenic syndrome. Cochrane Database Syst Rev. 2005;(2):CD003279.
69. Daya S, Gunby J, Clark D A. Intravenous immunoglobulin therapy for recurrent spontaneous abortion: A meta-analysis. Am J Reprod Immunol. 1998;39(2):69-76.
70. Jenson HB, Pollock BD. Meta-analyses of the effectiveness of intravenous immune globulin for prevention and treatment of neonatal sepsis. Pediatrics. 1997:99(2):E2.
71. Ballow M. Primary immunodeficiency disorders: Antibody deficiency. J Allergy Clin Immunol. 2002;109(4):581-591.
72. U.S. Pharmacopoeial Convention. Immune globulin intravenous (human) (systemic). USP-DI. Drug Information for the Healthcare Professional. Greenwood Village, CO: Micromedex; 2007.
73. Schuval SJ. Treatment of antibody deficiency syndromes. Pediatrics Rev. 2000;21(10):358-359.
74. Sorensen RU, Moore C. Antibody deficiency syndromes. Pediatr Clin North Am. 2000;47(6):1225-1252.
75. American Academy of Pediatrics, Committee on Children with Disabilities. Technical report: The pediatrician's role in the diagnosis and management of autistic spectrum disorder in children. Pediatrics. 2001;107(5):e85. Available at: http://www.pediatrics.org/cgi/content/full/107/5/e85. Accessed July 9, 2002.
76. American Academy of Pediatrics (AAP). Immune globulins. In: 2000 Red book: Report of the Committee on Infectious Diseases. 25th ed. G Peter, ed. Elk Grove Village, IL: AAP;2000:39-41.
77. Gajdos P, Chevret S, Clair B, et al. Clinical trial of plasma exchange and high dose immunoglobulin in myasthenia gravis. Ann Neurol. 1997;41(6):789-796.
78. Ronager J, Ravnborg M, Hermansen I, Vorstrup S. Immunoglobulin treatment versus plasma exchange in patients with chronic moderate to severe myasthenia gravis. Artif Organs. 2001;25(12):967-973.
79. Wolfe GI, Barohn RJ, Foster BM, et al. Randomized, controlled trial of intravenous immunoglobulin in myasthenia gravis. Muscle Nerve. 2002;26(4):549-552.
80. Cilliers AM, Manyemba J, Saloojee H. Anti-inflammatory treatment for carditis in acute rheumatic fever. Cochrane Database Syst Rev. 2003;(2):CD003176.
81. Jordan S, Cunningham-Rundles C, McEwan R. Utility of intravenous immune globulin in kidney transplantation: Efficacy, safety, and cost implications. Am J Transplant. 2003;3(6):653-664.
82. Glotz D, Antoine C, Julia P, et al. Desensitization and subsequent kidney transplantation of patients using intravenous immunoglobulins (IVIg). Am J Transplant. 2002;2(8):758-760.
83. Jordan SC. Management of the highly HLA- sensitized patient. A novel role for intravenous gammaglobulin. Am J Transplant. 2002;2(8):691-692.
84. Sonnenday CJ, Ratner LE, Zachary AA, et al. Preemptive therapy with plasmapheresis/intravenous immunoglobulin allows successful live donor renal transplantation in patients with a positive cross-match. Transplant Proc. 2002;34(5):1614-1616.
85. Al-Uzri AY, Seltz B, Yorgin PD, et al. Successful renal transplant outcome after intravenous gamma-globulin treatment of a highly sensitized pediatric recipient. Pediatr Transplant. 2002;6(2):161-165.
86. Glotz D, Antoine C, Haymann JP, et al. Intravenous immunoglobulins and kidney transplantation in patients with anti-HLA antibodies. Adv Nephrol Necker Hosp. 2000;30:221-233.
87. Montgomery RA, Zachary AA, Racusen LC, et al. Plasmapheresis and intravenous immune globulin provides effective rescue therapy for refractory humoral rejection and allows kidneys to be successfully transplanted into cross-match-positive recipients. Transplantation. 2000;70(6):887-895.
88. Jordan SC, Quartel AW, Czer LS, et al. Posttransplant therapy using high-dose human immunoglobulin (intravenous gammaglobulin) to control acute humoral rejection in renal and cardiac allograft recipients and potential mechanism of action. Transplantation. 1998;66(6):800-805.
89. Wadstrom J, Gannedahl G, Bersztel A, et al. Successful kidney transplantation after suppression of HLA alloantibodies with intravenous immunoglobulin in a highly sensitized patient. Transplant Proc. 1995;27(6):3463-3464.
90. Glotz D, Haymann JP, Niaudet P, et al. Successful kidney transplantation of immunized patients after desensitization with normal human polyclonal immunoglobulins. Transplant Proc. 1995;27(1):1038-1039.

91. Glotz D, Haymann JP, Sansonetti N, et al. Suppression of HLA-specific alloantibodies by high-dose intravenous immunoglobulins (IVIg). A potential tool for transplantation of immunized patients. Transplantation. 1993;56(2):335-337.
92. Mouthon L. [Treatment of ANCA-positive systemic vasculitis with intravenous immunoglobins] Rev Med Interne. 1999;20 Suppl 4:431s-435s.
93. Levy Y, George J, Fabbrizzi F, et al. Marked improvement of Churg-Strauss vasculitis with intravenous gammaglobulins. South Med J. 1999;92(4):412-414.
94. Jordan SC. Treatment of systemic and renal-limited vasculitic disorders with pooled human intravenous immune globulin. J Clin Immunol. 1995;15(6 Suppl):76S-85S.
95. Reinhold-Keller E, Tatsis E, Gross WL. [ANCA-associated vasculitis (Wegener's granulomatosis, Churg-Strauss syndrome, microscopic polyangiitis). 3. Therapeutic Procedure] Z Rheumatol. 1995;54(5):303-309.
96. Armentia A, Fernandez A, Sanchez P, et al. Asthma and vasculitis. Response to intravenous immunoglobulins. Allergol Immunopathol (Madr). 1993;21(2):47-52.
97. Hamilos DL, Christensen J. Treatment of Churg-Strauss syndrome with high-dose intravenous immunoglobulin. J Allergy Clin Immunol. 1991;88(5):823-824.
98. Levy Y, Sherer Y, George J, et al. Serologic and clinical response to treatment of systemic vasculitis and associated autoimmune disease with intravenous immunoglobulin. Int Arch Allergy Immunol. 1999;119(3):231-238.
99. Cordonnier C, Chevret S, Legrand M, et al. Should immunoglobulin therapy be used in allogeneic stem-cell transplantation? A randomized, double-blind, dose effect, placebo-controlled, multicenter trial. Ann Intern Med. 2003;139:8-18.
100. British Columbia Ministry of Health Services, Provincial Blood Coordinating Office. IVIG utilization management handbook. 1st ed. Vancouver, BC: British Columbia Ministry of Health Services; April 2002. Available at: http://www.bloodlink.bc.ca/documents/ivighandbook2.pdf. Accessed June 30, 2003.
101. Larcombe J. Urinary tract infection in children. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; July 2009.
102. Nicholas R, Chataway J. Multiple sclerosis. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; June 2008.
103. Hughes RAC, Wijdicks EFM, Barohn R, et al. Practice parameter: Immunotherapy for Guillian-Barre syndrome. Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2003;61:736-740. Available at: http://www.neurology.org/cgi/content/abstract/61/6/736. Accessed March 10, 2004.
104. Massachusetts General Hospital, Transfusion Committee. Consensus indications for IV IgG. Boston, MA: Massachusetts General Hospital; February 2003. Available at: http://www.mgh.harvard.edu/labmed/lab/bts/IV%20IgG%20Guidelines.pdf. Accessed April 29, 2004.
105. Buckley RH. Immunoglobulin G subclass deficiency: Fact or fancy? Curr Allergy Asthma Rep. 2002;2(5):356-360.
106. Buckley RH. IgG subclass deficiency. In: Clinical Focus on Primary Immune Deficiencies. Issues and Information on Current Topics. Towson, MD: Immune Deficiency Foundation; December 1998;1(3):1-4.
107. Fleisher TA. Evaluation of suspected immunodeficiency. Med Lab Observ. 2003;35(2):1-2,12,14,19.
108. Maguire GA, Kumararatne DS, Joyce HJ. Are there any clinical indications for measuring IgG subclasses? Ann Clin Biochem. 2002;39:374-377.
109. Salcedo J, Keates S, Pothoulakis C, et al. Intravenous immunoglobulin therapy for severe *Clostridium difficile* colitis. Gut. 1997;41(3):366-370.
110. Leung DY, Kelly CP, Boguniewicz M, et al. Treatment with intravenously administered gamma globulin of chronic relapsing colitis induced by *Clostridium difficile* toxin. J Pediatr. 1991;118(4 (Pt 1)):633-637.
111. Ohlsson A, Lacy J. Intravenous immunoglobulin for preventing infection in preterm and/or low-birth-weight infants. Cochrane Database Syst Rev. 2004;(1):CD000361.
112. Fanaroff AA, Korones SB, Wright LL, et al. A controlled trial of intravenous immune globulin to reduce nosocomial infections in very-low-birth-weight infants. National Institute of Child Health and Human Development Neonatal Research Network. N Engl J Med. 1994;330(16):1107-1013.
113. Kinney J, Mundorf L, Gleason C, et al. Efficacy and pharmacokinetics of intravenous immune globulin administration to high-risk neonates. Am J Dis Child. 1991;145(11):1233-1238.
114. Malik S, Giacoia GP, West K. The use of intravenous immunoglobulin (IVIG) to prevent infections in bronchopulmonary dysplasia: Report of a pilot study. J Perinatol. 1991;11(3):239-244.
115. Buemi M, Pettinato G, Palella S, et al. Treatment of the nephritic syndrome in elderly with human intravenous immunoglobulins. Contrib Nephrol. 1993;105:172-179.
116. Hebert AA, Bogle MA. Intravenous immunoglobulin prophylaxis for recurrent Stevens-Johnson syndrome. J Am Acad Dermatol. 2004;50(2):286-288.
117. Campione E, Marulli GC, Carrozzo AM, et al. High-dose intravenous immunoglobulin for severe drug reactions: efficacy in toxic epidermal necrolysis. Acta Derm Venereol. 2003;83(6):430-432.
118. Metry DW, Jung P, Levy ML. Use of intravenous immunoglobulin in children with Stevens-Johnson syndrome and toxic epidermal necrolysis: Seven cases and review of the literature. Pediatrics. 2003;112(6 Pt 1):1430-1436.
119. Sidwell RU, Swift S, Yan CL, et al. Treatment of toxic epidermal necrolysis with intravenous immunoglobulin. Int J Clin Pract. 2003;57(7):643-645.

120. Mayorga C, Torres MJ, Corzo JL, et al, Posadas S, Jurado A, Blanca M. Improvement of toxic epidermal necrolysis after the early administration of a single high dose of intravenous immunoglobulin. Ann Allergy Asthma Immunol. 2003;91(1):86-91.
121. Bachot N, Roujeau JC. Intravenous immunoglobulins in the treatment of severe drug eruptions. Curr Opin Allergy Clin Immunol. 2003;3(4):269-274.
122. Prins C, Vittorio C, Padilla RS, et al, Saurat JH, French LE. Effect of high-dose intravenous immunoglobulin therapy in Stevens-Johnson syndrome: A retrospective, multicenter study. Dermatology. 2003;207(1):96-99.
123. Tan A, Tan HH, Lee CC, Ng SK. Treatment of toxic epidermal necrolysis in AIDS with intravenous immunoglobulins. Clin Exp Dermatol. 2003;28(3):269-271.
124. Wolff K, Tappeiner G. Treatment of toxic epidermal necrolysis: The uncertainty persists but the fog is dispersing. Arch Dermatol. 2003;139(1):85-86.
125. Trent JT, Kirsner RS, Romanelli P, Kerdel FA. Analysis of intravenous immunoglobulin for the treatment of toxic epidermal necrolysis using SCORTEN: The University of Miami Experience. Arch Dermatol. 2003;139(1):39-43.
126. Bachot N, Revuz J, Roujeau JC. Intravenous immunoglobulin treatment for Stevens-Johnson syndrome and toxic epidermal necrolysis: A prospective noncomparative study showing no benefit on mortality or progression. Arch Dermatol. 2003;139(1):33-36.
127. Prins C, Kerdel FA, Padilla RS, et al. TEN-IVIG Study Group. Toxic epidermal necrolysis-intravenous immunoglobulin. Treatment of toxic epidermal necrolysis with high-dose intravenous immunoglobulins: Multicenter retrospective analysis of 48 consecutive cases. Arch Dermatol. 2003;139(1):26-32.
128. Tristani-Firouzi P, Petersen MJ, Saffle JR, et al. Treatment of toxic epidermal necrolysis with intravenous immunoglobulin in children. J Am Acad Dermatol. 2002;47(4):548-552.
129. Umapathi T, Hughes RAC, Nobile-Orazio E, Léger JM. Immunosuppressive treatment for multifocal motor neuropathy. Cochrane Database Syst Rev. 2005;(3):CD003217.
130. Reid S, Chalder T, Cleare A, et al. Chronic fatigue syndrome. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; September 2007.
131. Karussis D. Abramsky O. Is the routine use of intravenous immunoglobulin treatment in neurologic disorders justified? Arch Neurol. 1999;56(8):1028-1032.
132. Rodnitzky RL. Is IVIG effective in myasthenia gravis? Summary and Comment. Journal Watch Neurology. 2002;6. Available at: http://neurology.jwatch.org/cgi/content/full/2002/1206/6. Accessed October 27, 2004.
133. Bussiere M, and the University of Western Ontario (UWO) Evidence Based Neurology Group. There is no difference in the functional outcome of patients with a myasthenic exacerbation treated with either IVIg or plasma exchange. London, ON: UWO; December 2001. Available at: http://www.uwo.ca/cns/ebn/CATs/nm-mg-ivig-pe-therapy.htm. Accessed October 27, 2004.
134. American Academy of Pediatrics (AAP), Committee on Infectious Diseases. Immune globulin intravenous. In: Red Book: 2003 Report of the Committee on Infectious Diseases. 26th ed. LK Pickering, ed. Elk Grove Village, IL: AAP; 2003:56-59.
135. Majumdar S, Mockenhaupt M, Roujeau J-C, Townshend A. Interventions for toxic epidermal necrolysis. Cochrane Database Syst Rev. 2002;(4):CD001435.
136. Kirtschig G, Murrell D, Wojnarowska F, Khumalo N. Interventions for mucous membrane pemphigoid/cicatricial pemphigoid and epidermolysis bullosa acquisita: A systematic literature review. Archiv Dermatol. 2002;138(3):380-384.
137. NHS Centre for Reviews and Dissemination. The effectiveness of interventions used in the treatment/management of chronic fatigue syndrome and/or myalgic encephalomyelitis in adults and children. York, UK: Centre for Reviews and Dissemination; 2002.
138. Gottstein R, Cooke RW. Systematic review of intravenous immunoglobulin in haemolytic disease of the newborn. Arch Dis Child Fetal Neonatal Ed. 2003;88(1):F6-F10.
139. van Koningsveld R, Schmitz PI, Meche FG, et al. Effect of methylprednisolone when added to standard treatment with intravenous immunoglobulin for Guillain-Barre syndrome: Randomised trial. Lancet. 2004;363(9404):192-196.
140. Dalakas MC. Intravenous immunoglobulin in autoimmune neuromuscular diseases. JAMA. 2004;291(19):2367-2375.
141. Buyon JP, Rupel A, Clancy RM. Neonatal lupus syndromes. Lupus. 2004;13(9):705-712.
142. Hoekstra PJ, Minderaa RB, Kallenberg CG. Lack of effect of intravenous immunoglobulins on tics: A double-blind placebo-controlled study. J Clin Psychiatry. 2004;65(4):537-542.
143. Robinson J, Hartling L, Vandermeer B, et al. Intravenous immunoglobulin for presumed viral myocarditis in children and adults. Cochrane Database Syst Rev. 2005;(1):CD004370.
144. Tanimoto K, Nakano K, Kano S, et al. Classification criteria for polymyositis and dermatomyositis. J Rheumatol. 1995;22(4):668-674.
145. Cernadas C, Pichon Riviere A, Augustovski F. Assessment of treatment with immunoglobulines in recurrent miscarriage [summary]. Report ITB No. 5. Buenos Aires, Argentina: Institute for Clinical Effectiveness and Health Policy (IECS); 2003.
146. Dodel RC, Du Y, Depboylu C, et al. Intravenous immunoglobulins containing antibodies against beta-amyloid for the treatment of Alzheimer's disease. J Neurol Neurosurg Psychiatry. 2004;75(10):1472-1474.
147. Broughton SS, Meyerhoff WE, Cohen SB. Immune-mediated inner ear disease: 10-year experience. Semin Arthritis Rheum. 2004;34(2):544-548.
148. Roed HG, Langkilde A, Sellebjerg F, et al. A double-blind, randomized trial of IV immunoglobulin treatment in acute optic neuritis. Neurology. 2005;64:804-810.

149. Bartolomei F, Boucraut J, Barrie M, et al. Cryptogenic partial epilepsies with anti-GM1 antibodies: A new form of immune-mediated epilepsy? Epilepsia. 1996;37(10):922-926.
150. Bakker J, Metz L. Devic's neuromyelitis optica treated with intravenous gamma globulin (IVIG). Can J Neurol Sci. 2004;31(2):265-267.
151. Mutch LS, Johnston DL. Late presentation of opsoclonus-myoclonus-ataxia syndrome in a child with stage 4S neuroblastoma. J Pediatr Hematol Oncol. 2005;27(6):341-343.
152. Garvey MA, Snider LA, Leitman SF, et al. Treatment of Sydenham's chorea with intravenous immunoglobulin, plasma exchange, or prednisone. J Child Neurol. 2005;20(5):424-429.
153. Bearden CM, Agarwal A, Book BK, et al. Rituximab inhibits the in vivo primary and secondary antibody response to a neoantigen, bacteriophage phiX174. Am J Transplant. 2005;5(1):50-57.
154. Jordan SC, Vo AA, Tyan D, et al. Current approaches to treatment of antibody-mediated rejection. Pediatr Transplant. 2005;9(3):408-415.
155. Asia-Pacific IVIG Advisory Board. Expert consensus statements on the use of IVIG in neurology. 1st ed. Singapore: Asia-Pacific IVIG Advisory Board Inc.; November 2004.
156. Fergusson D, Hutton B, Sharma M, et al. Use of intravenous immunoglobulin for treatment of neurologic conditions: A systematic review. Transfusion. 2005;45(10):1640-1657.
157. Rayment R, Brunskill SJ, Stanworth S, et al. Antenatal interventions for fetomaternal alloimmune thrombocytopenia. Cochrane Database Syst Rev. 2005;(1):CD004226.
158. Empson M, Lassere M, Craig J, Scott J. Prevention of recurrent miscarriage for women with antiphospholipid antibody or lupus anticoagulant. Cochrane Database Syst Rev. 2005;(2):CD002859.
159. van Schaik IN, van den Berg LH, de Haan R, Vermeulen M. Intravenous immunoglobulin for multifocal motor neuropathy. Cochrane Database Syst Rev. 2005;(2):CD004429.
160. Choy EHS, Hoogendijk JE, Lecky B, Winer JB. Immunosuppressant and immunomodulatory treatment for dermatomyositis and polymyositis. Cochrane Database Syst Rev. 2005;(3):CD003643.
161. Liu Z, Albon E, Hyde C. The effectiveness and cost effectiveness of immunoglobulin replacement therapy for primary immunodeficiency and chronic lymphocytic leukaemia: A systematic review and economic evaluation. DPHE Report No. 54. Birmingham, UK: West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, University of Birmingham (WMHTAC); 2005.
162. Orange JS, Hossny EM, Weiler CR, et al. Use of intravenous immunoglobulin in human disease: A review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol 2006;117:S525-S553.
163. Darabi K, Abdel-Wahab O, Dzik WH. Current usage of intravenous immune globulin and the rationale behind it: The Massachusetts General Hospital data and a review of the literature. Transfusion. 2006;46(5):741-753.
164. Porter TF, LaCoursiere Y, Scott JR. Immunotherapy for recurrent miscarriage. Cochrane Database Syst Rev. 2006;(2):CD000112.
165. Overell JR, Hsieh ST, Odaka M, et al. Treatment for Fisher syndrome, Bickerstaff's brainstem encephalitis and related disorders. Cochrane Database Syst Rev. 2007:(1):CD004761.
166. Allen D, Lunn MPT, Niermeijer J, Nobile-Orazio E. Treatment for IgG and IgA paraproteinaemic neuropathy. Cochrane Database Syst Rev. 2007;(1):CD005376.
167. Orellana JC, Pogonza RE, Lopez-Olivo MA, et al. Intravenous immunoglobulin for juvenile idiopathic arthritis. Cochrane Database Syst Rev. 2006;(4):CD006191.
168. Lunn MPT, Nobile-Orazio E. Immunotherapy for IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathies. Cochrane Database Syst Rev. 2006;(2):CD002827.
169. Volmink J, Marais B. HIV: Mother-to-child transmission. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; January 2007.
170. Alejandra M. Dengue haemorrhagic fever or dengue shock syndrome in children. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; updated June 2008.
171. Madjok R, Wu O. Systemic lupus erythematosus. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; December 2008.
172. Parr J. Autism. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; May 2009.
173. Duckitt K, Qureshi A. Recurrent miscarriage. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; April 2007.
174. Comite d' Evaluation et de Diffusion des Innovations Technologiques (CEDIT). Intravenous immunoglobulines - systematic review, primary research, expert panel, working group. Update. Paris, France; CEDIT; 2007.
175. Meyer N, Ferraro V, Mignard MH, Adamski H, Chevrant-Breton J. Pyoderma gangrenosum treated with high-dose intravenous immunoglobulins: Two cases and review of the literature. Clin Drug Investig. 2006;26(9):541-546.
176. Jolles S, Hughes J. Use of IGIV in the treatment of atopic dermatitis, urticaria, scleromyxedema, pyoderma gangrenosum, psoriasis, and pretibial myxedema. Int Immunopharmacol. 2006;6(4):579-591.
177. Feasby T, Banwell B, Benstead T, et al. Guidelines on the use of intravenous immune globulin for neurologic conditions. Transfus Med Rev. 2007;21(2 Suppl 1):S57-S107.
178. Mikati MA, Shamseddine AN. Management of Landau-Kleffner syndrome. Paediatr Drugs. 2005;7(6):377-389.

179. Kang HC, Kim HD, Lee YM, Han SH. Landau-Kleffner syndrome with mitochondrial respiratory chain-complex I deficiency. Pediatr Neurol. 2006;35(2):158-161.
180. de Menezes MS. Landau-kleffner syndrome. eMedicine Pediatric Neurology. San Francisco, CA: eMedicine.com; updated March 20, 2007. Available at: http://www.emedicine.com/neuro/topic182.htm. Accessed August 18, 2008.
181. Whitington PF, Kelly S. Outcome of pregnancies at risk for neonatal hemochromatosis is improved by treatment with high-dose intravenous immunoglobulin. Pediatrics. 2008;121(6):e1615-e1621.
182. Chen S, Pi D, Ansari M, et al. Polyclonal intravenous immunoglobulin in patients with immune thrombocytopenic purpura: Clinical systematic review. Technology Report. HTA Issue 108. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008.
183. Ho C, Membe S, Cimon K, et al. Subcutaneous versus intravenous immunoglobulin for primary immunodeficiencies: Systematic review and economic evaluation. Technology Report. HTA Issue 98. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008.
184. Blackhouse G, Xie F, Campbell K, et al. Intravenous immunoglobulin for treatment of idiopathic thrombocytopenic purpura: Economic and health service impact analyses. Technology Report. HTA Issue 112. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); 2008.
185. Elovaara I, Apostolski S, van Doorn P, et al. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases: EFNS task force on the use of intravenous immunoglobulin in treatment of neurological diseases. Eur J Neurol. 2008;15(9):893-908.
186. Hughes RA, Donofrio P, Bril V, et al.; ICE Study Group. Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): A randomised placebo-controlled trial. Lancet Neurol. 2008;7(2):136-144.
187. Jann S, Bramerio MA, Facchetti D, Sterzi R. Intravenous immunoglobulin is effective in patients with diabetes and with chronic inflammatory demyelinating polyneuropathy: Long term follow-up. J Neurol Neurosurg Psychiatry. 2009;80(1):70-73.
188. Achiron A, Kishner I, Dolev M, et al. Effect of intravenous immunoglobulin treatment on pregnancy and postpartum-related relapses in multiple sclerosis. J Neurol. 2004;251(9):1133-1137.
189. Dudesek A, Zettl UK. Intravenous immunoglobulins as therapeutic option in the treatment of multiple sclerosis. J Neurol. 2006;253 Suppl 5:V50-V58.
190. Haas J, Hommes OR. A dose comparison study of IVIG in postpartum relapsing-remitting multiple sclerosis. Mult Scler. 2007;13(7):900-908.
191. Anderson D, Ali K, Blanchette V, et al. Guidelines on the use of intravenous immune globulin for hematologic conditions. Transfus Med Rev. 2007;21(2 Suppl 1):S9-S56.
192. Osborne BJ, Volpe NJ. Optic neuritis and risk of MS: Differential diagnosis and management. Cleve Clin J Med. 2009;76(3):181-190.
193. Levy SE, Mandell DS, Schultz RT. Autism. Lancet. 2009;374(9701):1627-1638.
194. Gupta AA, Tyrrell P, Valani R, et al. Experience with hemophagocytic lymphohistiocytosis/macrophage activation syndrome at a single institution. J Pediatr Hematol Oncol. 2009;31(2):81-84.
195. Eftimov F, Winer JB, Vermeulen M, et al. Intravenous immunoglobulin for chronic inflammatory demyelinating polyradiculoneuropathy. Cochrane Database Syst Rev. 2009;(1):CD001797.
196. Fortin PM, Tejani AM, Bassett K, Musini VM. Intravenous immunoglobulin as adjuvant therapy for Wegener's granulomatosis. Cochrane Database Syst Rev. 2009;(3):CD007057.
197. Goebel A, Baranowski A, Maurer K, et al. Intravenous immunoglobulin treatment of the complex regional pain syndrome: A randomized trial. Ann Intern Med. 2010;152(3):152-158.
198. Raanani P, Gafter-Gvili A, Paul M, et al. Immunoglobulin prophylaxis in hematological malignancies and hematopoietic stem cell transplantation. Cochrane Database Syst Rev. 2008;(4):CD006501.
199. Liu JP, Nikolova D, Fei Y. Immunoglobulins for preventing hepatitis A. Cochrane Database Syst Rev. 2009:(2):CD004181.
200. Díaz-Manera J, Rojas-García R, Illa I. Treatment strategies for myasthenia gravis. Expert Opin Pharmacother. 2009;10(8):1329-1342.
201. Tranchant C. Therapeutic strategy in myasthenia gravis. Rev Neurol (Paris). 2009;165(2):149-154.
202. Morozumi S, Kawagashira Y, Iijima M, et al. Intravenous immunoglobulin treatment for painful sensory neuropathy associated with Sjögren's syndrome. J Neurol Sci. 2009;279(1-2):57-61.
203. Donofrio PD, Berger A, Brannagan TH 3rd, et al. Consensus statement: The use of intravenous immunoglobulin in the treatment of neuromuscular conditions report of the AANEM ad hoc committee. Muscle Nerve. 2009;40(5):890-900.
204. O'Horo J, Safdar N. The role of immunoglobulin for the treatment of Clostridium difficile infection: A systematic review. Int J Infect Dis. 2009;13(6):663-667.
205. Abougergi MS, Broor A, Cui W, Jaar BG. Intravenous immunoglobulin for the treatment of severe Clostridium difficile colitis: An observational study and review of the literature. J Hosp Med. 2010;5(1):E1-E9.
206. Stephenson MD, Kutteh WH, Purkiss S, et al. Intravenous immunoglobulin and idiopathic secondary recurrent miscarriage: A multicentered randomized placebo-controlled trial. Hum Reprod. 2010;25(9):2203-2209.
207. Abougergi MS, Kwon JH. Intravenous immunoglobulin for the treatment of Clostridium difficile infection: A review. Dig Dis Sci. 2011;56(1):19-26.

208. Ishii A, Hayashi A, Ohkoshi N, et al. Clinical evaluation of plasma exchange and high dose intravenous immunoglobulin in a patient with Isaacs' syndrome. J Neurol Neurosurg Psychiatry. 1994;57(7):840-842.
209. Perlmutter SJ, Leitman SF, Garvey MA, et al. Therapeutic plasma exchange and intravenous immunoglobulin for obsessive-compulsive disorder and tic disorders in childhood. Lancet. 1999;354(9185):1153-1158.
210. Hoekstra PJ, Minderaa RB, Kallenberg CG. Lack of effect of intravenous immunoglobulins on tics: A double-blind placebo-controlled study. J Clin Psychiatry. 2004;65(4):537-542.
211. Isobe Y, Sugimoto K, Shiraki Y, et al. Successful high-titer immunoglobulin therapy for persistent parvovirus B19 infection in a lymphoma patient treated with rituximab-combined chemotherapy. Am J Hematol. 2004;77(4):370-373.
212. Aries PM, Hellmich B, Gross WL. Intravenous immunoglobulin therapy in vasculitis: Speculation or evidence? Clin Rev Allergy Immunol. 2005;29(3):237-245.
213. Myers KA, Baker SK. Late-onset seropositive Isaacs' syndrome after Guillain-Barré syndrome. Neuromuscul Disord. 2009;19(4):288-290.
214. Eleftheriou D, Brogan PA. Vasculitis in children. Best Pract Res Clin Rheumatol. 2009;23(3):309-323.
215. Ishii N, Hashimoto T, Zillikens D, Ludwig RJ. High-dose intravenous immunoglobulin (IVIG) therapy in autoimmune skin blistering diseases. Clin Rev Allergy Immunol. 2010;38(2-3):186-195.
216. Jolles S. A review of high-dose intravenous immunoglobulin (hdIVIg) in the treatment of the autoimmune blistering disorders. Clin Exp Dermatol. 2011;26(2):127-131.
217. Kim JY, Park KD, Richman DP. Treatment of myasthenia gravis based on its immunopathogenesis. J Clin Neurol. 2011;7(4):173-183.
218. Bird SJ. Treatment of myasthenia gravis. UpToDate [online serial]. Waltham, MA: UpToDate; last reviewed January 2012.
219. Barker AF. Treatment of bronchiectasis in adult. UpToDate [online serial]. Waltham, MA: UpToDate; last reviewed September 2011.
220. Dedeoglu F, Kim S, Sundel R. Management of Henoch-Schönlein purpura. UpToDate [online serial]. Waltham, MA: UpToDate; last reviewed September 2011. .
221. Parambil JG, Tavee JO, Zhou L, et al. Efficacy of intravenous immunoglobulin for small fiber neuropathy associated with sarcoidosis. Respir Med. 2011;105(1):101-105.
222. Freedman AS, Friedberg JW. Initial treatment of follicular lymphoma. UpToDate [online serial]. Waltham, MA: UpToDate; updated September 2011.
223. Freedman AS, Friedberg JW. Treatment of relapsed or refractory follicular lymphoma. UpToDate [online serial]. Waltham, MA: UpToDate; updated September 2011.
224. Trucco SM, Jaeggi E, Cuneo B, et al. Use of intravenous gamma globulin and corticosteroids in the treatment of maternal autoantibody-mediated cardiomyopathy. J Am Coll Cardiol. 2011;57(6):715-723.
225. INIS Collaborative Group, Brocklehurst P, Farrell B, King A, et al. Treatment of neonatal sepsis with intravenous immune globulin. N Engl J Med. 2011;365(13):1201-1211.
226. Lemmon JK, Knutsen AP. IgG subclass deficiency. UpToDate [online serial]. Waltham, MA: UpToDate; May 11, 2012.
227. American College of Obstetricians and Gynecologists (ACOG). Antiphospholipid syndrome. ACOG Practice Bulletin No. 118. Washington, DC: American College of Obstetricians and Gynecologists (ACOG); January 2011.
228. Keeling D, Mackie I, Moore GW, et al, British Committee for Standards in Haematology. Guidelines on the investigation and management of antiphospholipid syndrome. Br J Haematol 2012;157(1):47–58.
229. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with obsessive-compulsive disorder. J Am Acad Child Adolesc Psychiatry 2012;51(1):98-113.
230. Krull KR. Attention deficit hyperactivity disorder in children and adolescents: Treatment with medications. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012a.
231. Krull KR. Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012b.
232. Searight HR, Burke JM. Adult attention deficit hyperactivity disorder. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012.
233. Katon W, Ciechanowski P. Initial treatment of depression in adults. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012a.
234. Katon W, Ciechanowski P. Treatment of resistant depression in adults. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012b.
235. Schwarz MI. The diffuse alveolar hemorrhage syndromes. UpToDate [online serial]. Waltham, MA: UpToDate; updated December 2012.
236. Patwa HS, Chaudhry V, Katzberg H, et al. Evidence-based guideline: Intravenous immunoglobulin in the treatment of neuromuscular disorders: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012;78(13):1009-1015.
237. Pichichero ME. PANDAS: Pediatric autoimmune neuropsychiatric disorder associated with group A streptococci. UpToDate [online serial]. Waltham, MA: UpToDate; updated October 2012.
238. Tan J, Smith CH, Goldman RD. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections. Can Fam Physician. 2012;58(9):957-959.

239. Perlmutter SJ, Leitman SF, Garvey MA, et al. Therapeutic plasma exchange and intravenous immunoglobulin for obsessive-compulsive disorder and tic disorders in childhood. Lancet. 1999;354(9185):1153-1158.
240. Martino D, Defazio G, Giovannoni G. The PANDAS subgroup of tic disorders and childhood-onset obsessive-compulsive disorder. J Psychosom Res. 2009;67(6):547-557.
241. Shulman ST. Pediatric autoimmune neuropsychiatric disorders associated with streptococci (PANDAS): Update. Curr Opin Pediatr. 2009;21(1):127-130.
242. Marconi D, Limpido L, Bersani I, et al. PANDAS: A possible model for adult OCD pathogenesis. Riv Psichiatr. 2009;44(5):285-298.
243. Horton TM, Steuber CP. Overview of the treatment of acute lymphoblastic leukemia in children. UpToDate [online serial]. Waltham, MA: UpToDate; updated October 2012.
244. Larson RA. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. UpToDate [online serial]. Waltham, MA: UpToDate; updated October 2012.
245. Kakkis E, Wraith E. Complications and management of the mucopolysaccharidoses. UpToDate [online serial]. Waltham, MA: UpToDate; updated October 2012.
246. Bronkhorst MW, Bouwman LH. Mannose-binding lectin deficiency. UpToDate [online serial]. Waltham, MA: UpToDate; updated October 2012.
247. Alijotas-Reig J. Treatment of refractory obstetric antiphospholipid syndrome: The state of the art and new trends in the therapeutic management. Lupus. 2013;22(1):6-17.
248. Hughes R, Cusack C, Murphy GM, Kirby B. Solar urticaria successfully treated with intravenous immunoglobulin. Clin Exp Dermatol. 2009;34(8):e660-e662.
249. Llamas-Velasco M, Argila DD, Eguren C, et al. Solar urticaria unresponsive to intravenous immunoglobulins. Photodermatol Photoimmunol Photomed. 2011;27(1):53-54.
250. Adamski H, Bedane C, Bonnevalle A, et al. Solar urticaria treated with intravenous immunoglobulins. J Am Acad Dermatol. 2011;65(2):336-340.
251. Elmets CA. Photosensitivity disorders (photodermatoses): Clinical manifestations, diagnosis, and treatment. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
252. Gajdos P, Chevret S, Toyka KV. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database Syst Rev. 2012;12:CD002277.
253. Bascic-Kes V, Kes P, Zavoreo I, et al Ad Hoc Comittee of the Croatian Society for Neurovascular Disorders, Croatian Medical Association. Guidelines for the use of intravenous immunoglobulin in the treatment of neurologic diseases. Acta Clin Croat. 2012;51(4):673-683.
254. Bird SJ. Treatment of myasthenia gravis. Last reviewed December 2013. UpToDate Inc. Waltham, MA.
255. Fortin PM, Tejani AM, Bassett K, Musini VM. Intravenous immunoglobulin as adjuvant therapy for Wegener's granulomatosis. Cochrane Database Syst Rev. 2013;1:CD007057.
256. Lunn MP, Nobile-Orazio E. Immunotherapy for IgM anti-myelin-associated glycoprotein paraprotein-associated peripheral neuropathies. Cochrane Database Syst Rev. 2012;5:CD002827.
257. Ruzhansky K, Brannagan TH. Intravenous immunoglobulin for treatment of neuromuscular disease. Neurol Clin Pract. 2013;3(5):440-445.
258. Drulovic J, Andrejevic S, Bonaci-Nikolic B, Mijailovic V. Hashimoto's encephalopathy: A long-lasting remission induced by intravenous immunoglobulins. Vojnosanit Pregl. 2011;68(5):452-454.
259. Olmez I, Moses H, Sriram S, et al. Diagnostic and therapeutic aspects of Hashimoto's encephalopathy. J Neurol Sci. 2013;331(1-2):67-71.
260. He L, Li M, Long XH, et al. A case of Hashimoto's encephalopathy misdiagnosed as viral encephalitis. Am J Case Rep. 2013;14:366-369.
261. Rubin DI. Hashimoto's encephalopathy. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
262. Wong KS, Connan K, Rowlands S, et al. Antenatal immunoglobulin for fetal red blood cell alloimmunization. Cochrane Database Syst Rev. 2013;5:CD008267.
263. Modlin JF. Epidemiology, pathogenesis, treatment, and prevention of enterovirus and parechovirus infections. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
264. Joao C. Immunoglobulin is a highly diverse self-molecule that improves cellular diversity and function during immune reconstitution. Med Hypotheses. 2007;68(1):158-161.
265. Schmidt-Hieber M, Schwarck S, Stroux A, et al. Prophylactic i.v. Igs in patients with a high risk for CMV after allo-SCT. Bone Marrow Transplant. 2009;44(3):185-192.
266. Sexton DJ, Pien BC. Immune reconstitution inflammatory syndrome. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
267. Gavhed D, Laurencikas E, Akefeldt SO, Henter JI. Fifteen years of treatment with intravenous immunoglobulin in central nervous system Langerhans cell histiocytosis. Acta Paediatr. 2011;100(7):e36-e39.
268. Edeer-Karaca N, Gulez N, Aksu G, Kutukculer N. Common variable immunodeficiency: Familial inheritance and autoimmune manifestations in two siblings. Turk J Pediatr. 2010;52(1):89-93.
269. Michet CJ. Treatment of relapsing polychondritis. Last reviewed December 2013. UpToDate Inc. Waltham, MA.

270. Ohlsson A, Lacy JB. Intravenous immunoglobulin for suspected or proven infection in neonates. Cochrane Database Syst Rev. 2013;7:CD001239.
271. Noguchi Y, Tsuchiyama T, Matsumoto T, et al. Two distinct types of neuropathy associated with Sjogren's syndrome developed in one patient. The importance of the selection of an appropriate therapeutic regimen. Rinsho Shinkeigaku. 2003;43(9):539-543.
272. De Toni Franceschini L, Amadio S, Scarlato M, et al. A fatal case of Churg-Strauss syndrome presenting with acute polyneuropathy mimicking Guillain-Barre syndrome. Neurol Sci. 2011;32(5):937-940.
273. Brass SD, Helfgott SM. Diagnosis and treatment of vasculitic neuropathy. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
274. Rajkumar SV. Treatment and prognosis of Waldenstrom macroglobulinemia. Last reviewed December 2013. UpToDate Inc., Waltham, MA.
275. Orange JS, Ballow M, Stiehm ER, et al. Use and interpretation of diagnostic vaccination in primary immunodeficiency: A working group report of the Basic and Clinical Immunology Interest Section of the American Academy of Allergy, Asthma & Immunology. J Allergy Clin Immunol. 2012;130(3 Suppl):S1-S24.