BlueCross BlueShield of Texas

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Title:

Intravenous Immunoglobulin (IVIG) Therapy

Number:

RX504.003

Effective Date:

03-01-2004

Legislation:

ILLINOIS: None

NEW MEXICO: None

OKLAHOMA:

TEXAS: None

FEDERAL (applies to all Plans): None

Contract:

Each benefit plan or contract defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers have the responsibility for consulting the member's benefit plan or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between a Medical Policy and a member's benefit plan or contract, the benefit plan or contract will govern.

Coverage:

IMMUNODEFICIENT DISORDERS:

The use of Intravenous Immunoglobulin **may be eligible for coverage.** Documentation of disease progression and failed conservative therapy must accompany the request. Immunodeficient disorders eligible for coverage include:

- Premature infants at risk for group B streptococcus infection
- Bone marrow and organ transplant recipients (except corneal), at risk for cytomegalovirus (CMV) and pneumonia due to immunosuppressant agents
- Chronic lymphocytic leukemia, a leukemia associated with hyperplasia and over-activity of lymphoid tissue. (**CAUTION** - this is not the same as acute lymphoblastic leukemia. Refer to the listing of conditions, which are considered investigational.)
- Children, under the age of 16, with acquired immunodeficiency syndrome (AIDS)
- Adults with human immunodeficiency virus (HIV) who are immunosuppressed in association with AIDS or AIDS related complex (ARC)

- Malignancies of various types, especially leukemic illnesses that are vulnerable to recurrent infections secondary to an immunosuppressed system, such as:
  1. Patients with hypogammaglobulinemia of less than 0.6 gm/dl and having two documented serious infections in one year that required hospitalization, may need monthly IVIG therapy
  2. Patients with multiple myeloma with stable plateau phase disease who are at high risk of recurrent infections. (**CAUTION** - this is not the same as multiple myeloma in any other phase. Refer to the listing of conditions, which are considered investigational.);
- Post transfusion purpura (severe)
- Congenital diseases that do not produce sufficient amounts of IgG antibodies, such as:
  1. Children with hypogammaglobulinemia, having more than five infections per year (ear, sinuses, or lungs) who do not demonstrate improvement on antibiotics and/or suppressive antibiotics
  2. High risk hypogammaglobulinemic neonates
  3. Adults with agammaglobulinemia (Bruton's X-linked) who have been diagnosed with chronic infections and have not demonstrated improvement on antibiotics and/or suppressive antibiotics
- Adult patients with deficient gamma globulin (not congenital):
  1. Common variable hypogammaglobulinemia with low, absolute levels of gamma globulin
  2. Deficient antibody synthesis with a normal gross level of antibody, but who fail to make good responses when challenged by vaccines
  3. Subclass-deficient, having failed to make satisfactory specific responses when challenged by vaccines

NOTE: These patients shall have documentation of the following:

- A history of chronic sinus or chest infections that respond poorly to multiple courses of antibiotic treatment or prophylaxis
- An allergy evaluation that is negative, or failure of standard allergy therapy to bring about a reduction in the number of infections in those patients with positive allergy evaluations
- An ear, nose and throat evaluation that fails to reveal structural abnormalities amenable to surgery; or continued, frequent or chronic infections following surgical correction

AUTOIMMUNE DISORDERS:

The use of Intravenous Immunoglobulin **may be eligible for coverage**. Documentation of laboratory monitoring must accompany the request. Autoimmune disorders eligible for coverage include:

- Kawasaki syndrome, usually occurring in infants and children, less than 5 years of age
- Guillain-Barré syndrome; patients with acute symptoms and who are unable to walk have shown improvement following a short course (average length of 30 days) of Ig treatment (IVIG is given as an equivalent alternative to plasma exchange in children and adults.) (**CAUTION** - this is not the same as chronic fatigue syndrome. Refer to the listing of conditions, which are considered investigational.)
- Chronic inflammatory demyelinating polyneuropathy; a destruction of the myelin sheath (covering) of nerves (IVIG acts as an equivalent alternative to plasma exchange in children and adults.)
- Myasthenia gravis (MG): a disease caused by an autoimmune attack on receptors in neuromuscular junctions causing episodic muscle weakness (IVIG is considered in patients with severe MG to treat acute severe decompensation when other treatments have been unsuccessful or are contraindicated.)
- Autoimmune neutropenia: the reduction of the number of certain white blood cells (IVIG may have a role in preventing a severe illness that does not respond to other modalities or when the later are contraindicated.)

- Autoimmune hemolytic anemia (AIHA): a large grouping of anemias involving antibodies working against red blood cell antigens (IVIG may have a role in treating patients with warm-type AIHA that does not respond to corticosteroids.)
- Systemic lupus erythematosus (SLE), vasculitis syndromes, polymyositis and dermatomyositis: characterized by inflammatory and degenerative changes in the muscle and frequently in the skin, leading to weakness and some muscle atrophy (IVIG may be used in patients with severe active illness for whom other interventions have been unsuccessful or intolerable.)
- Idiopathic thrombocytopenic purpura (ITP): when steroids are either ineffective or contraindicated and a rapid rise in the platelet count is needed either preoperatively or to control bleeding
- Neonatal alloimmune thrombocytopenia, severe: when other interventions have failed or are contraindicated. (**CAUTION** - this is not the same as non-immune thrombocytopenia. Refer to the listing of conditions, which are considered investigational.)
- Multiple Sclerosis (MS), relapsing-remitting type only: treatment appears to reduce the occurrence of acute relapse and equally comparable to conventional therapy (interferon-beta). (Treatment of MS with IVIG does not guarantee improvement of baseline neurologic disability or prevent the development of secondary-progressive disease or disability from a relapsing-remitting course) (**CAUTION** - this is not the same as chronic- [primary- or secondary-] progressive multiple sclerosis. Refer to the listing of conditions, which are considered investigational.)

The use of Intravenous Immunoglobulin **is not eligible for coverage** as it is considered **investigational** for the following conditions:

1. Hemolytic transfusion reaction (except post-transfusion purpura)
2. Factor VIII inhibitors, acquired
3. Aplastic anemia
4. Diamond-Blackfan anemia
5. Hemophagocytic syndrome
6. Neonatal hemolytic disease
7. Acquired von Willebrand's syndrome
8. Thrombotic thrombocytopenic purpura
9. Nonimmune thrombocytopenia
10. Hemolytic uremic syndrome
11. Burns
12. Recurrent, spontaneous fetal loss
13. Refractory rheumatoid arthritis, adult and juvenile
14. Asthma and inflammatory chest disease
15. Amyotrophic lateral sclerosis (ALS or Lou Gehrig disease)
16. Antiphospholipid Ab syndrome
17. Inclusion-body myositis
18. Motor neuron syndromes
19. Myelopathy, HTLV-1 associated
20. Progressive lumbosacral plexopathy
21. Paraproteinemic neuropathy
22. Adrenoleukodystrophy
23. Behçet's syndrome
24. Chronic fatigue syndrome
25. Cystic fibrosis
26. Diabetes mellitus
27. Endotoxemia
28. Congenital heart block
29. Membranous nephropathy
30. Nephrotic syndrome
31. Chronic (primary or secondary) progressive multiple sclerosis
32. Recurrent otitis media
33. Euthyroid ophthalmopathy
34. Multiple myeloma
35. Uveitis