



MEDICAL PAYMENT and PRIOR-AUTHORIZATION POLICY

Policy Name:	Clinical Pharmacy Coverage: Intravenous Immunoglobulin (IVIG)
Policy Number:	
Approved By:	Medical Management
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Application:	All participating and non-participating practitioners and facilities
Page Number(s):	1 of 6

Disclaimer

Gateway HealthSM's (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern and/or otherwise influence medical decisions.

POLICY STATEMENT:

This policy describes the criteria for which Intravenous Immunoglobulin (IVIG) is medically necessary and appropriate and therefore covered by Gateway Health.

(PA HealthChoices Agreement currently in effect; National Committee for Quality Assurance (NCQA) Standards and Guidelines for the Accreditation of Health Plans, UM 13: Procedures for Pharmaceutical Management)

DEFINITIONS:

Medical necessity: A service or benefit is medically necessary if it is compensable under the MA program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to prevent the onset of an illness, condition, or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.
- The service or benefit will assist the member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the member and those functional capacities that are appropriate for members of the same age.

PROCEDURES

Coverage*:

- Coverage is provided for Primary Immunodeficiency in patients whom severe impairment of antibody capacity is present in the following conditions: Congenital agammaglobulinemia, Hypogammaglobulinemia, Common Variable Immunodeficiency, Wiskott-Aldrich Syndrome, X-linked Immunodeficiency with Hyper-IgM, Severe Combined Immuno-deficiencies, Deficient qualitative or Quantitative Antibody Production where the member has a history of at least one bacterial infection directly attributable to this deficiency.
 - The initial maintenance dose does not exceed 400 mg/kg and Laboratory reports demonstrate IgG level of less than 400 mg/dL OR reports demonstrate a lack of ability to produce an antibody response to a protein antigen (i.e. tetanus) or one of the polysaccharide antigens (i.e. pneumococcal polysaccharide or H. Influenza type B). If a patient has recurrent bacterial infection and normal IgG levels, a lack of antibody response will be considered adequate to support the diagnosis
 - The patient continues to have unexplained recurrent or persistent severe or opportunistic bacterial infections despite adequate treatment
 - Aggressive management of other conditions predisposing to recurrent sinopulmonary infections has been used
 - Increased vigilance has been applied and appropriate antibiotic therapy prescribed for infections
 - Patient has had two or more infections per year due to persistent and significant reduction in total IgG or IgG subclasses
- Coverage is provided for idiopathic thrombocytopenic purpura (ITP) in adults when the following criteria are met:
 - Other causes of thrombocytopenia have been ruled out by history and peripheral smear
 - Platelet count is less than or equal to 30,000/mcL without active bleeding and the member is remaining unresponsive to corticosteroid therapy
 - Management of acute bleeding due to severe thrombocytopenia – defined as a platelet count less than 30,000/mcL with active bleeding without a trial of corticosteroid therapy
- Coverage is provided for pediatric ITP when the following criteria are met:
 - IVIG as initial therapy if platelet count less than 30,000/mcL when member has emergency bleeding or is at risk for severe life-threatening bleeding OR
 - Persons with severe thrombocytopenia (platelet counts less than 20,000/mcL) considered to be at risk for intra-cerebral hemorrhage
- Coverage is provided for Kawasaki disease when the following criteria are met:
 - Fever present for at least five days
 - Treatment is being initiated within ten days of onset of fever
 - Must be on concurrent aspirin therapy
 - At least four of the following conditions are met:

- Mucous membrane changes such as strawberry tongue and dry fissured lips without discrete lesions
 - Changes in the extremities such as edema of the hands and feet
 - Enlarged lymph nodes in the neck
 - Diffuse red rash covering most of the body
 - Redness of the eyes
- Coverage is provided for Human Immunodeficiency Virus (HIV) infection when the following criteria are met:
 - Patient is younger than 14 years old
 - Evidence of either qualitative or quantitative humoral immunologic defects
 - Current bacterial infections despite appropriate antimicrobial prophylaxis
- Coverage is provided for Chronic Inflammatory Demyelinating Polyneuritis (CIDP) when the following criteria are met:
 - Patient is experiencing symptomatic polyradiculoneuropathy in more than one limb
 - Patient has had a progressive or relapsing course over at least two months
 - Patient is experiencing at least three of the following and documentation is provided to support one.
 - Partial conduction block of greater than or equal to one motor nerve
 - Reduced conduction velocity of greater than or equal to two motor nerves
 - Prolonged distal latency of greater than or equal to two motor nerves
 - Prolonged F wave latencies of greater than or equal to two motor nerves or absence of F waves
- Coverage is provided for Multifocal neuropathy when ALL the following criteria are met:
 - Patient has progressive, symptomatic multifocal motor neuropathy (as characterized by limb weakness or motor involvement having a motor nerve distribution in at least two nerves).
 - Electrophysiological findings rule out other possible conditions that may not respond to IVIG.
- Coverage is provided for the following biopsy-proven conditions:
 - Pemphigus vulgaris
 - Pemphigus foliaceus
 - Bullous pemphigoid
 - Mucous membrane pemphigoid , benign mucous membrane pemphigoid, with or without mention of ocular movement
 - Epidermolysis bullosa acquisita
 - When at least one of the following criteria are met:
 - Failed conventional therapy. A failure in therapy can be defined as rapidly progressive, extensive, or debilitating disease despite treatment and dose optimization with conventional therapies such as glucocorticoids (e.g., prednisone, prednisolone, methylprednisolone) and/or immunosuppressive agents (e.g., azathioprine, cyclophosphamide, methotrexate, or mycophenolate mofetil).

- Contraindication to conventional therapy, including glucocorticoids and/or immunosuppressive agents. (If a contraindication to a single therapy is identified, another therapy should be tried if possible).
 - Have rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In these situations, IVIG therapy would be given along with conventional treatment(s) and the IVIG would be used only until conventional therapy could take effect.
- Coverage is provided for Hematopoietic Stem Cell Transplantation (HSCT) given the following criteria:
 - Patient at least 20 years old or older
 - HSCT is not Autologous
 - Therapy is being initiated within the first 100 days post-transplant
 - After 100 days post-transplant IVIG is indicated for treatment of recipients who are markedly hypogammaglobulinemic (IgG level less than 400 mg/dL) , who have a primary immunodeficiency disease, or who have CMV, EBV, or RSV infection
 - Meets one of the following criteria:
 - IVIG is medically necessary for treatment of steroid resistant graft vs. host disease (GVHD)in persons receiving matched HLA allogenic Bone marrow transplant
 - IVIG is medically necessary for prophylaxis treatment against infection in persons with Hypogammaglobulinemia (IgG level less than 400mg/dL)
 - Coverage is provided for pediatric HIV type-1 infection when the following criteria is met:
 - Patient less than 14 years of age.
 - CD-4 lymphocyte count \geq 200/mcL
 - IgG level less than 400mg/dL
 - Current bacterial infections despite appropriate antimicrobial prophylaxis
 - Coverage is provided for Active Chronic Lymphocytic Leukemia given the following criteria:
 - Progressive disease, as demonstrated by rapidly increasing white cells in the blood, and/or rapidly enlarging lymph nodes, spleen, or liver. Hypogammaglobulinemia (IgG less than 600 mg/dL) and recent history of bacterial infection(s) attributed to low IgG
 - Hypogammaglobulinemia (IgG less than 600 mg/dL) and/or evidence of specific antibody deficiency

*Additional unapproved indications that are otherwise supported by recognized compendia will be reviewed on a case by case basis.

Coverage Duration:

- Intravenous immunoglobulin in the treatment of Primary immunodeficiency including: CVID, X-Linked Agammaglobulinemia, SCID, X-Linked Hyper-IgM Deficiency and IgG subclass deficiency.
 - Benefit approved for three months and is renewable in the presence of an IgG level of 400mg/dL or lower with a history of infections.

- Idiopathic thrombocytopenia purpura (ITP):
 - Pediatric
 - Benefit approved for five days in pediatric patients with platelet count less than 30,000/mcL and moderate membrane bleeding (89% of pediatric patients recover spontaneously).
 - Adult
 - Acute: Benefit approved for five days
 - Chronic:
 - Initial: Benefit approved for 1-2 gram/kg total dose over two to five days
 - Maintenance: Benefit approved for 1-2 grams per kg every two to six weeks based on platelet counts. Approve for one month.
- Kawasaki disease
 - Benefit approved for two weeks in the presence of the criteria for the disease. There are no studies indicating the benefit of prolonged use after the tenth day. Repeated treatment has been used when the first infusion failed. IVIG should not be infused within three months of any live vaccinations, such as MMR. Concurrent aspirin therapy should also be used in these patients.
- Hematopoietic stem cell transplantation (HSCT)
 - Benefit approved for three months in the prevention of infection and is renewable if physician feels infection is still a threat to patient and inadequate levels of Immunoglobulins are being produced.
- Chronic Lymphocytic Leukemia (CLL)
 - Benefit approved for three months and is renewable upon progression of disease. Aggressive therapy in early stages is usually ineffective, but some type of treatment is usually recommended when patient experiences anemia and/or low platelet count, weakness, fatigue, painful lymph node swelling, fever, or repeated infections.
- Pediatric HIV Type 1 infection
 - Benefit approved for three months and is renewable upon request of physician.
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - Benefit approved for three months
 - Initial: Up to 2 gram/kg in two to five divided doses
 - Maintenance: 0.4-1 gram/kg every four to six weeks
- Multifocal Motor Neuropathy (MMN)
 - Benefit approved for three months
 - Initial: Up to 2 gram/kg in two to five divided doses
 - Maintenance: 0.4-1 gram/kg every two to six weeks

- Autoimmune mucocutaneous blistering disease/dermatological conditions (including pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, Mucous membrane pemphigoid/cicatrcial pemphigoid, and epidermolysis bullosa acquisita)
 - Benefit approved for three months:
 - Initial dosing: Up to 2 g/kg in two to five divided doses
 - Maintenance 0.4-2g/kg in divided doses over three to five days, every three to four weeks, up to three months

Exclusions:

IVIG is not covered for any diagnoses or indications other than those specifically identified in this policy.