Pharmacy Policy Bulletin

Category:	Prior Authorization
Number:	J-114
Subject:	IVIG for Medicare Part D Only
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Policy Applies to: *Medicare* plans only

Background:

Intravenous Immune Globulin (IVIG) is a sterile solution of immunoglobulins prepared from pooled human plasma for intravenous infusion. The solution contains no less than 90% immunoglobulin, which contains a broad range of antibodies that act against bacterial and viral antigens. All IgG subclasses are represented. Also included are trace amounts of IgA and IgM.
This policy will address uses of pooled, broad spectrum intravenous immunoglobulin. This policy will NOT address the use(s) of narrow spectrum intravenous immunoglobulins prepared to work in very specific circumstances (e.g., CMV immunoglobulin).
The use of intravenous immune globulin should be reserved for patients with serious defects of antibody function. The goal is to provide immune globulin to those who lack it.
For those immunodeficiency syndromes in which therapy is guided in part by IgG levels, a serum trough IgG level should be measured before an IVIG infusion and the dose of intravenous immune globulin should be adjusted accordingly. The serum trough IgG level should be measured every month for the first three months of therapy. After the first three months, if therapy is effective, the serum trough IgG level should be measured again at six months (or sooner if clinically indicated). Clinical monitoring takes clear precedence over laboratory monitoring. After the first nine months, if clinical improvement is evident, laboratory monitoring should be done when clinically indicated.
For IgG subclass deficiencies, a serum IgG subclass trough level should be measured every month for the first three months of therapy, then at six months (or sooner if clinically indicated). The dose of IVIG and frequency of administration should be adjusted accordingly; taking into account the IgG subclass levels and the patient's clinical condition.
For functional deficiency, the deficient antibody(ies) should be measured every month for the first three months of therapy, then at six months (or sooner if clinically indicated). The dose of IVIG and frequency of administration should be adjusted accordingly, taking into account the antibody levels and the patient's clinical condition.
Autoimmune mucocutaneous blistering diseases are a group of rare, debilitating and possibly fatal disorders caused by antibodies directed against components of the skin. The diseases are characterized by the formation of extensive blisters evolving to painful erosions on the skin and mucous membranes.
Due to the seriousness of the disease sequelae, early treatment to prevent further morbidity or mortality is necessary. The first line treatment for these diseases is typically corticosteroids alone or in combination with other immunosuppressive agents. Plasmapheresis may be required in severe cases.
When using IVIG to treat neurological disorders, the diagnosis of the disorder must be unequivocal. There must be clinical evidence, including biopsy (muscle-nerve) data when necessary, to support the diagnosis. Other clinical data that may contribute to the diagnosis includes quantitative clinical examinations, electrophysiological motor-sensory nerve conductions (EMG), CSF studies, and other ancillary tests (e.g., serum immunoprotein). Clear diagnostic criteria exist for making a diagnosis in the neurological disorders

considered eligible for coverage under this policy. The reason for choosing IVIG as a treatment is expected to be stated clearly in the medical records.
Once treatment is initiated, the patient's progress is expected to be meticulously documented in the medical record. If there is initial improvement by the second course of treatment and continued treatment is necessary, then objective assessment to monitor the progress is required. Subjective improvement alone is insufficient to continue IVIG.
There must be an attempt made to wean the dosage when improvement has occurred. There must be an attempt to stop the IVIG infusion if improvement is sustained with dosage reduction. If withholding or decreasing IVIG therapy is inappropriate for the purpose of assessing response to therapy, then the medical record is expected to include documentation discussing why therapy cannot be withheld or decreased. If improvement does not occur with IVIG, then infusion should not continue.

Approval Criteria:

Human Immunodeficiency Virus (HIV)
IVIG is covered when indicated for the treatment of patients less than 13 years of age who have entry CD4 lymphocyte counts greater than or equal to 200/mm3, who are clinically symptomatic or asymptomatic, but are immunologically abnormal.

Chronic Lymphocytic Leukemia With Associated Hypogammaglobulinemia
IVIG is covered when indicated for the treatment of patients with an IgG level less than 600 mg/dl, or evidence of specific antibody deficiency, or recurrent bacterial infections.

Bone Marrow Transplantation
IVIG is covered when indicated within the first 100 days after transplantation, for the treatment of patients 20 years of age or older who have had a transplant for a covered indication. Patients may be seropositive for cytomegalovirus (CMV) before transplantation, or may be seronegative, with seronegative donors undergoing allogeneic transplantation.

Kawasaki Disease (Mucocutaneous Lymph Node Syndrome)
IVIG is covered when indicated for the treatment of patients with Kawasaki disease, when used in conjunction with aspirin. Treatment should begin within ten days of the onset of illness.

Parvovirus B19 Infection
IVIG is covered when indicated for the treatment of patients with chronic parvovirus B19 infection and severe anemia associated with bone marrow suppression.

Sensitized Renal Transplant Recipients
IVIG is covered when indicated for desensitization of patients with a living donor who harbors or has harbored anti-HLA antibody or isoagglutinins that are donor specific or any patient who has received a renal transplant from a living donor and experiences post-transplant rejection.

Autoimmune Mucocutaneous Blistering Diseases
IVIG is covered when indicated for one of the conditions listed below after having failed conventional therapy OR if conventional therapy is contraindicated OR if the patient has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. In such situations, IVIG therapy would be given along with conventional treatment(s) and the IVIG would be used only until conventional therapy could take effect.

Pemphigus vulgaris
Pemphigus foliaceus
Bullous pemphigoid
Mucous membrane pemphigoid (ciacatrical pemphigoid)

Mucous membrane pemphoid (cicatrical pemphigoid)
Epidermolysis bullosa acquisita
Stevens-Johnson syndrome and toxic epidermal necrolysis

IVIG for the treatment of autoimmune mucocutaneous blistering disease must be used for short-term therapy (not more than four months) and not as maintenance therapy.

Idiopathic Thrombocytopenic Purpura (ITP)
IVIG is covered when a rapid rise in the platelet count is required (e.g., prior to major surgical procedures, to control excessive bleeding, or to defer or avoid splenectomy), OR in patients with severe thrombocytopenia (platelet counts less than 20,000 mm3) considered to be at risk for intracerebral hemorrhage, OR for the management of patients aged 10 years or older who have a duration of illness of less than 6 months, with no concurrent illness or disease explaining their thrombocytopenia. The patient may have had prior treatment with corticosteroids or splenectomy or their platelet counts remain persistently at or below 20,000 mm3.

ITP in Pregnancy
IVIG treatment is covered when indicated for pregnant women who have previously delivered infants with autoimmune thrombocytopenia, OR pregnant women who have platelet counts less than 75,000 mm3 during the current pregnancy, OR pregnant women with a past history of splenectomy.

Guillain-Barre Syndrome
IVIG is covered when the following criteria are met:

1. The patient has diagnosis of acute or chronic Guillain-Barre Syndrome AND
2. The patient has impaired function by objective assessment and/or objective findings on physical exam at the time of initial therapy.

Myasthenia Gravis Syndrome
IVIG is covered when the following criteria are met:

1. The patient has a diagnosis of Myasthenia Gravis Syndrome AND
2. The patient has severely impaired function by objective assessment and/or objective findings on physical exam at the time of initial therapy AND
3. The patient is refractory to other standard therapies (e.g., cholinesterase inhibitors, corticosteroids, azathioprine) given in therapeutic doses over at least 3 months OR is intolerant of/has a contraindication to those standard therapies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
IVIG is covered when the following criteria are met:

1. The patient has a diagnosis of CIDP AND
2. The patient has impaired function by objective assessment and/or objective findings on physical exam at the time of initial therapy.

Multiple Sclerosis
IVIG is covered when the following criteria have been met:

1. The patient has a diagnosis of Multiple Sclerosis AND
2. The patient has impaired function by objective assessment and/or objective findings on physical exam at the time of initial

2. The patient has impaired function by objective assessment and/or objective findings on physical exam at the time of initial therapy AND
3. The patient is refractory to other standard therapies (e.g., interferons) given in therapeutic doses over at least three (3) months, OR is intolerant of/has a contraindication to those standard therapies.

Inflammatory Myopathies
IVIG is covered when the following criteria have been met:

1. The patient has a diagnosis of Dermatomyositis or Polymyositis AND
2. The patient has impaired function by assessment and/or objective findings on physical exam at the time of initial therapy AND
3. The patient is refractory to corticosteroids given in therapeutic doses over at least four (4) months, OR is intolerant of/has a contraindication to corticosteroids**.**

If a physician determines that the administration of IVIG in the patient's home is medically appropriate for a patient with a diagnosis of PID, coverage for IVIG is provided in the home setting under the member's Part B benefit. IVIG provided in the home for a diagnosis other than PID may be covered under the Part D benefit according to aforementioned criteria. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product. Administration and related Home Infusion Therapy services are reimbursed as a health service benefit.

Duration of Authorization:
If approved, authorization should be granted for a period of up to 12 months.

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