INTRAVENOUS IMMUNE GLOBULIN (IVIG) FOR IMMUNODEFICIENCY DISORDERS CHECKLIST

Medicare Local Coverage Determination (LCD) - L34007

See a separate checklist for Intravenous Immune Globulin for Neurological and Other Disorders.

Effective Date: For services performed on or after 08/13/2019

Intravenous Immune Globulin (IVIG) is a solution of human immunoglobulin specifically prepared for intravenous infusion. It contains a broad range of antibodies that specifically act against bacterial and viral antigens. The use of intravenous immune globulin should be reserved for patients with serious defects of antibody function. The goal is to provide immunoglobulin G (IgG) antibodies to those who lack them.

Affected patient populations are those with immunodeficiency disorders (discussed below) and neurological and other disorders (see a separate checklist).

COVERAGE INDICATIONS/ LIMITATIONS/SPECIFIC REQUIREMENTS

IVIG may be medically necessary for:

- management of acute bleeding due to severe thrombocytopenia with platelet count < 30,000/uL
- patients with severe thrombocytopenia (platelet count < 20,000/uL), with documented risk for intracerebral or other hemorrhage, including co-morbidities: hypertension, peptic ulcer disease.
- increasing platelet counts prior to invasive surgical procedures, e.g., splenectomy.

Limitation: IVIG is not covered for:

- children with platelet counts > 30,000/uL that are asymptomatic or have only minor purpura
- adults with a platelet count > 50,000/uL

Children with Human Immunodeficiency Virus (HIV) Disease who do not have ITP:

To reduce significant bacterial infections when:

A: All three primary criteria are met:

- Age < 13 years;
- IG level < 400 mg/dL;
- Entry CD4+ lymphocyte count is ≥ 200/mm3; and

B: One of the below secondary criteria is met:

- Two or more bacterial infections in a 1-year period despite antibiotic chemoprophylaxis with TMP-SMZ or another active agent.
- A region with a high prevalence of measles, the child received two doses of measles vaccine.
- The child with chronic bronchiectasis whose immunological response is suboptimal to antimicrobial and pulmonary therapy.
- The child with symptomatic or asymptomatic HIV, lacks an ability to produce an antibody response to immunization with protein or carbohydrate antigens.

Dosages according to FDA drug label for each specific indication.

Note: No established dosing regimen for off-label indications.

Dual Diagnosis:

- (B20) Human immunodeficiency virus [HIV] disease, and
- (Z91.89) Other specified personal risk factors, not elsewhere classified or (Z78.9) Other specified health status.

GENERAL DOCUMENTATION REQUIREMENTS

- History and physical; supporting rationale (current within the last 12 months) to initiate intra-venous immune globulin therapy and the continued need thereof, including but not limited to:
- Physician's orders (with dose, frequency, administration route and duration; written within 30 days prior date of service); progress note(s) including the necessity for initiation and continuation of IVIG.
- Documentation supporting the qualifying diagnoses
- A copy of applicable lab and procedure test results
- An accurate weight (in kilograms) documented prior to each infusion for dosage determination
- Medication administration records

ICD-10-CM diagnosis code(s) supporting medical necessity submitted with each claim; see above dual code requirements for certain conditions.

Coding:

- Specific documentation indicated in the section above
- HCPSC Codes: J1459, J1555, J1556, J1561, J1566, J1568, J1569, J1572, J1575

Checklist completed by: Date:

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