Reference number(s)
4017-A

JURISDICTION SPECIFIC MEDICARE PART B

HEPAGAM B (hepatitis B immune globulin intravenous [human])

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications uses are listed below:

A. Prevention of hepatitis B recurrence following liver transplant in hepatitis B surface antigen-positive liver transplant patients
B. Post-exposure prophylaxis including:
    1. Acute exposure to hepatitis B antigen-positive blood, plasma, or serum (parenteral exposure, direct mucus membrane contact, oral ingestion, etc.)
    2. Perinatal exposure of infants born to hepatitis B antigen-positive mothers
    3. Sexual exposure to hepatitis B antigen-positive persons
    4. Household exposure to persons with acute hepatitis B virus infection

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. The information contained in the medical record should include all relevant diagnostic laboratory studies, prior history of bleeding, infection, disease progression, prior medical/surgical therapies and any other information essential in establishing that the patient meets the coverage indicators set forth in the NCD and LCD.
B. An accurate weight in kilograms should be documented prior to the infusion since the dosage is based on mg/kg dosage.
C. Indications for administration of immune globulin must be fully documented in the patient's medical record.

Physicians or other providers filing Medicare claims for administration of immune globulin therapy at the request of another provider assume full responsibility as to the medical necessity for immune globulin under terms and conditions of NCD and LCD. These providers must also be able to meet documentation requirements given above, either directly through their own medical records or indirectly through records obtained from the referring physician.

III. CRITERIA FOR APPROVAL

A. Prevention of Hepatitis B Recurrence Following Liver Transplant

Authorization of 6 months may be granted for prevention of hepatitis B recurrence following liver transplant in hepatitis B surface antigen-positive liver transplant patients.

B. Post-Exposure Prophylaxis

Authorization of 6 months may be granted for post-exposure prophylaxis in any of the following settings:

1. Acute exposure hepatitis B surface antigen-positive blood, plasma or serum (parenteral exposure, direct mucous membrane contact, oral ingestion, etc.)
2. Perinatal exposure of infants born to hepatitis B surface antigen-positive mothers
3. Sexual exposure to hepatitis B surface antigen-positive persons
4. Household exposure to persons with acute hepatitis B infection

IV. REFERENCES

1. Intravenous Immune Globulin (IVIG) LCD (L35093) Version R17. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
2. Billing and Coding: Intravenous Immune Globulin (IVIG) (A56786) Version R11. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
3. HepaGam B [package insert]. Roswell, GA: Saol Therapeutics, Inc.; June 2018.