

Reference number(s)
4806-A

Jurisdiction Specific Medicare Part B HepaGam B

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
HepaGam B	hepatitis B immune globulin intravenous [human]

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.

- Prevention of hepatitis B recurrence following liver transplant in hepatitis B surface antigen-positive liver transplant patients
- Post-exposure prophylaxis including:
 - Acute exposure to hepatitis B antigen-positive blood, plasma, or serum (parenteral exposure, direct mucus membrane contact, oral ingestion, etc.)
 - Perinatal exposure of infants born to hepatitis B antigen-positive mothers
 - Sexual exposure to hepatitis B antigen-positive persons
 - 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 listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Coverage Criteria

Post-Exposure Prophylaxis

Authorization of 1 month may be granted for post-exposure prophylaxis in any of the following settings when the requested medication will be administered intramuscularly:

- Acute exposure to blood containing hepatitis B surface antigen (HBsAg)
- Perinatal exposure of infants born to hepatitis B surface antigen-positive mothers
- Sexual exposure to hepatitis B surface antigen-positive persons
- Household exposure to persons with acute hepatitis B infection

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 members when the requested medication will be administered intravenously.

Continuation Of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Post-Exposure Prophylaxis

Authorization for members who are requesting authorization for continuation of therapy of post-exposure prophylaxis of hepatitis B must meet all requirements in the coverage criteria.

Prevention of Hepatitis B Recurrence Following Liver Transplant

Authorization for 6 months may be granted for prevention of hepatitis B recurrence following liver transplant when all of the following criteria are met:

- The member is currently receiving therapy with HepaGam B.
- The requested medication is being administered intravenously.
- The member is receiving benefit from therapy. Benefit is defined as an objective response to therapy.

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References

1. Immune Globulins LCD (L34771) Version R22 Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed June 14, 2024.
2. Billing and Coding: Immune Globulins (A57554) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed June 14, 2024.
3. HepaGam B [package insert]. Hoboken, NJ: Kamada Inc.; September 2022.