Original Effective Date: 05/01/2017
Current Effective Date: 01/31/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C9971-A

Hep B Immune Globulin

PRODUCTS AFFECTED

HepaGam B (Hepatitis B Immune Globulin (Human) Inj Soln, HyperHep B (Hepatitis B Immune Globulin (Human) IM), Nabi- HB (Hepatitis B Immune Globulin (Human) IM)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Prevention of hepatitis B infection recurrence after liver transplantation in HBsAg-positive liver transplant patients, Hepatitis B post-exposure prophylaxis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. PREVENTION OF HEPATITIS B INFECTION RECURRENCE:
1. Documentation of liver transplantation in a member who is HBsAg-positive
   AND
2. Request is for continuation of therapy previously received or started in an institution

B. HEPATITIS B POST-EXPOSURE PROPHYLAXIS:
1. Documentation member requires hepatitis B post-exposure prophylaxis due to ONE of the following:
   (a) Member is unvaccinated, partially vaccinated, or has inadequate anti-HBs antibodies and has been exposed (perinatal or sexual) to someone that is HBsAg positive
   OR
   (b) Member is unvaccinated, partially vaccinated, or has inadequate anti-HBs antibodies and has been exposed (percutaneous {needlestick, bite, sharps}, ocular, oral, or mucus membrane) to HBsAg-positive blood or body fluids that contain blood
   OR
   (c) Member is a non-responder to the hepatitis B vaccine (anti-HBs less than 10 IU per mL after 6 doses or greater) and has been exposed to HbsAg-positive/unknown blood or body fluids that contain blood

CONTINUATION OF THERAPY:
N/A; Use initial authorization criteria

DURATION OF APPROVAL:
Initial authorization: Prevention of Hepatitis B recurrence: 12 months, Post-exposure prophylaxis: Up to 30 days, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
For prevention of hepatitis B infection recurrence after liver transplantation: 18 years of age and older
For post-exposure prophylaxis (HepaGam B, Nabi-HB, HyperHEP B): Infants and older

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous Infusion, Intramuscular

DRUG CLASS:
Immune Serums

FDA-APPROVED USES:

HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] indicated for prevention of Hepatitis B recurrence following liver transplantation in HBsAg-positive liver transplant patients, postexposure prophylaxis in the following settings: acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons, household exposure to persons with acute HBV infection

HyperHep B (Hepatitis B Immune Globulin (Human) injection), indicated for postexposure prophylaxis in the following situations: acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to an HBsAg-positive person, household exposure to persons with acute HBV infection

Nabi-HB, Hepatitis B Immune Globulin (Human) is indicated for treatment of acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute HBV infection in the following settings: acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAG-positive mothers, sexual exposure to HBsAg-positive persons, household exposure to persons with acute HBV infection

Nabi-HB is indicated for intramuscular use only

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

For prevention of hepatitis B infection recurrence after liver transplantation in HBsAg-positive liver transplant patients

20,000 International Units via intravenous (IV) infusion at a rate of 2 mL/minute (decrease to at least 1 mL/min if infusion-related reactions develop). The first dose should be given concurrently with grafting of the transplanted liver. Subsequent doses should be given on the following schedule: once daily on postoperative days 1 through 7, then every 2 weeks starting on postoperative day 14, then every month starting on month 4. The target serum anti-HBs antibody concentration is greater than 500 International Units/L. Regularly monitor the serum anti-HBs concentration before an infusion to track response and to allow for treatment adjustment. If the serum anti-HBs concentration is less than 500 International Units/L within the first week of transplantation, increase the dose to 10,000 International Units IV every 6 hours until the target anti-HBs concentration is reached [HepaGam B package insert]

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Hepatitis B Immune Globulin are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Hepatitis B Immune Globulin include: history of anaphylactic or severe systemic reactions to human globulins, IgA deficient individuals may have the potential to develop IgA antibodies and have an anaphylactoid reaction, IM injections may be contraindicated in patients with coagulation disorders.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
90371	Hepatitis B immune globulin (HBIg), human, for intramuscular use
J1571	Injection, hepatitis b immune globulin (hepagam b), intramuscular, 0.5 ml
J1573	Injection, hepatitis b immune globulin (hepagam b), intravenous, 0.5 ml

AVAILABLE DOSAGE FORMS:
HepaGam B SOLN 312UNIT/ML single dose vial
HyperHEP B SOLN 220UNIT/ML single dose vial
HyperHEP B SOSY 110UNIT/0.5ML syringe
HyperHEP B SOSY 220UNIT/ML syringe
Nabi-HB SOLN 312UNIT/ML single dose vial

REFERENCES

1. HepaGam B (hepatitis B immune globulin intravenous [human]) [prescribing information]. Roswell, GA: Saol Therapeutics Inc; March 2021.
2. HyperHEP B (hepatitis B immune globulin intravenous [human]) [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2022.
3. Nabi-HB (hepatitis B immune globulin intravenous [human]) [prescribing information]. Boca Raton, FL: ADMA Biologics; October 2019.
4. Centers for Disease Control and Prevention (CDC), “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I: Immunization of Infants, Children, and Adolescents,” MMWR Recomm Rep, 2005, 54(RR- 16):1- 31.
5. Centers for Disease Control and Prevention (CDC), “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults,” MMWR Recomm Rep, 2006, 54(RR-16):1-33. [PubMed 17159833]
6. Centers for Disease Control and Prevention (CDC), U.S. Public Health Service, "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis," MMWR Recomm Rep, 2001, 50(RR-11):1-52. [PubMed 11442229]
7. Centers for Disease Control and Prevention. Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students. MMWR 2012;61(No. RR-3):1-12.
8. Centers for Disease Control and Prevention. CDC Guidance For Evaluating Health-Care Personnel For Hepatitis B Virus Protection And For Administering Postexposure Management. MMWR 2013;62(RR-10);1-24.
9. Centers for Disease Control and Prevention. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR 2021;70(No.4);1-187
10. Centers for Disease Control and Prevention. Universal Hepatitis B Vaccination in Adults Aged 19– 59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices - United States, 2022. MMWR 2022;71(No. RR-13):477-483.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Duration of Approval Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Age Restrictions FDA-Approved Uses Appendix Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file