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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) Inj Soln), 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

A. PREVENTION OF HEPATITIS B INFECTION RECURRENCE:

1. Documentation of liver transplantation in HBsAg-positive liver transplant patients
AND
2. Request is for continuation of therapy previously received in an institution

Drug and Biologic Coverage Criteria

B. HEPATITIS B POST-EXPOSURE PROPHYLAXIS:

1. (a) Hepatitis B post-exposure prophylaxis requiring ONE (1) of the following: In an individual that is unvaccinated, partially vaccinated or has inadequate antibodies due to exposure (perinatal or sexual) with someone that is HBsAg positive,
OR
(b) In an individual that is unvaccinated, partially vaccinated or has inadequate antibodies due to acute exposure to blood containing HBsAg including percutaneous (needlestick, bite, sharps), ocular, oral or mucous membrane exposure to blood or body fluids containing blood,
OR
(c) In an individual as a documented non-responder to the hepatitis B vaccine (anti HBs less than 10mIU per mL after 6 doses or greater) with exposure to an HbsAg-positive/unknown blood or body fluids that contain blood

CONTINUATION OF THERAPY:

NA

DURATION OF APPROVAL:

Initial authorization: Up to 30 days or length of therapy per indication, whichever is shorter

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, Bayhep 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

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Drug and Biologic Coverage Criteria

HyperHep B (Hepatitis B Immune Globulin (Human) Inj Soln), indicated for 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

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, 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:

None

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.

Anaphylactic or severe systematic reactions to parenteral human globulin. IgA deficiency; increased risk of anaphylactoid reaction

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

HCPSC CODE	DESCRIPTION
90371	Hepatitis B immune globulin (HBIG), human, for intramuscular use
J1571	injection, hepatitis b immune globulin (hepagam b), intramuscular, 0.5ml
J1573	injection, hepatitis b immune globulin (hepagam b), intravenous, 0.5ml

AVAILABLE DOSAGE FORMS:

Hyperhep B Vial S/D, Hyperhep B Syr S/D, Nabi-HB Inj, H-Big Vial, Hepagam B Inj, Hepagam B Vial

REFERENCES

1. 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.
2. 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]
3. 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]
4. HepaGam B (hepatitis B immune globulin intravenous [human]) [prescribing information]. Roswell, GA: Saol Therapeutics Inc; March 2021.
5. HyperHEP B (hepatitis B immune globulin intravenous [human]) [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics LLC; December 2020.
6. Nabi-HB (hepatitis B immune globulin intravenous [human]) [prescribing information]. Boca Raton, FL: ADMA Biologics; October 2019.