Hep B Immune Globulin
Policy Number: C9971-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
5/1/2017	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
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	RxPA	Q1 2021 20210127C9971-A

PRODUCTS AFFECTED:
Hyperhep B Vial S/D, Nabi-HB Inj, H-Big Vial, Hepagam B Inj

DRUG CLASS:
Immune Serums

ROUTE OF ADMINISTRATION:
Intravenous Infusion, Intramuscular

PLACE OF SERVICE:
Specialty Pharmacy or Buy and Bill
The recommendation is that medications in this policy will be for medical benefit coverage and the product is administered in a place of service that is a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the therapy/member meets the Site of Care exceptions. (See appendix for excerpt from Specialty Medication Administration Site of Care Policy)

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

FDA-APPROVED USES:
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, and Household Exposure to Persons with Acute HBV Infection

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

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

REQUIRED MEDICAL INFORMATION:
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

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

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

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

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

CONTINUATION OF THERAPY:
NA

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

BACKGROUND:

None

APPENDIX:

Molina Healthcare, Inc. covers injectable/infused treatment in a hospital outpatient setting or at a hospital-affiliated infusion suite* when the level of care is determined to be medically necessary. Considerations used to determine if an alternative level of care is not suitable may include the following findings:

1. The member is clinically unstable based on documented medical history and susceptible to complication with drug administration (e.g., cardiopulmonary or renal dysfunction, risk for fluid overload)
2. The requested medication is administered as part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer or with dialysis
3. The member exhibits physical or cognitive impairment and a capable caregiver is not available to assist with safe administration of prescribed medication in the home
4. It is the patient's first dose of the medication or it is being re-initiated after at least 12 months*
5. The member has experienced adverse events with past administration of the drug and cannot be managed by premedication or resources available at an non-hospital facility based location (NHFBL)
6. Documented history of difficulty establishing and maintaining patent vascular access, or is not a candidate for a mode of long-term vascular access during the duration of prescribed treatment

Note: a hospital outpatient setting or a hospital-affiliated infusion suite is expected to have immediate access to specific services of a medical center/hospital setting, including having emergency resuscitation equipment and personnel (ACLS protocol), emergency services, and inpatient admission or intensive care, if necessary

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.

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]