Medical Policy:

Hepagam B® (hepatitis B immune globulin)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.148	February 29, 2024	

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Hepagam B is an Immune globulin containing antibodies against hepatitis B surface antigen; provides passive immunity to patients exposed to the HBV

Length of Authorization

Coverage will be provided for 12 months.

Dosing Limits [Medical Benefit]

Indication	Dose
Prevention of Hepatitis B recurrence following liver transplantation	– **Initial dose:** 20,000 iu IV concurrent with grafting of the transplanted liver; week 1, postoperative dose: 20,000 iu IV once daily on days 1 to 7 postoperative; weeks 2 to 12, postoperative dose: 20,000 iu IV every 2 weeks starting on day 14; – **Month 4 onward:** 20,000 iu IV once a month; dosing is intended to attain serum levels of antibodies to hepatitis B surface antigen (anti-HBs) greater than 500 international units/L

Acute Exposure to Blood Containing HBsAg	– 0.06 mL/kg IM as a single dose as soon as possible and preferably within 7 days of exposure; give a second dose 1 month later to known non-responders to hepatitis B vaccine or in those who refuse vaccination
Perinatal Exposure of Infants Born to HBsAgpositive Mothers	– 0.5 mL IM within 12 hours of birth plus appropriate hepatitis B vaccine series; if hepatitis B vaccine is delayed for as long as 3 months, then give hepatitis B immune globulin and repeat at 3 months; if hepatitis B vaccine is refused, then give hepatitis B immune globulin and repeat at 3 and 6 months
Sexual Exposure to HBsAg-positive Persons	– 0.06 mL/kg IM as a single dose and initiate hepatitis B vaccine series within 14 days of sexual contact or if sexual contact will continue

Guideline

I. Initial Approval Criteria

Hepagam B *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Prevention of Hepatitis B recurrence following Liver Transplantation in HBsAg-positive liver transplant patients**
2. **Postexposure Prophylaxis in the following settings:**
    A. Acute Exposure to Blood Containing HBsAg
    B. Perinatal Exposure of Infants Born to HBsAg-positive Mothers
    C. Sexual Exposure to HBsAg-positive Persons
    D. Household Exposure to Persons with Acute HBV Infection

Limitations/Exclusions

Hepagam B is not considered medically necessary for when any of the following selection criteria is met:

1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

Patient continues to meet INITIAL APPROVAL CRITERIA.

Applicable Procedure Codes

Code	Description
J1571	Injection, Hepatitis B immune globulin (Hepagam B), intramuscular, 1 billable unit = 0.5 ml
J1573	Injection, Hepatitis B immune globulin (Hepagam B), intravenous, 1 billable unit = 0.5 ml

Applicable NDCs

Code	Description
70504-0052-xx	Hepagam B; 312 iu/ml injection

ICD-10 Diagnoses

Code	Description
T86.4	Complications of liver transplant
T86.40	Unspecified complication of liver transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.89	Complications of other transplanted tissue
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
T86.899	Unspecified complication of other transplanted tissue
T86.9	Complication of unspecified transplanted organ and tissue
T86.90	Unsp complication of unspecified transplanted organ and tissue
T86.91	Unspecified transplanted organ and tissue rejection
T86.92	Unspecified transplanted organ and tissue failure
T86.93	Unspecified transplanted organ and tissue infection
T86.99	Other complications of unspecified transplanted organ and tissue
Z29.1	Encounter for prophylactic immunotherapy
Z29.8	Encounter for other specified prophylactic measures
Z29.9	Encounter for prophylactic measures, unspecified
Z48.2	Encounter for aftercare following organ transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.28	Encounter for aftercare following multiple organ transplant
Z48.288	Encounter for aftercare following multiple organ transplant
Z94.4	Liver transplant status

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/29/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	6/27/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	7/6/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/15/2019	Annual review

References

1. Product Information: HepaGam B® intravenous intramuscular injection, hepatitis B immune globulin (human) intravenous intramuscular injection. Cangene bioPharma, Inc. (per FDA), Baltimore, MD, 2012.