



## Hepagam B® (hepatitis B immune globulin)

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### Medical Guideline Disclaimer

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### Definition

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.

### 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.

## Dosage/Administration

Indication	Dose
Prevention of Hepatitis B recurrence following liver transplantation	<ul style="list-style-type: none"> <li>– <b>Initial dose:</b> 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;</li> <li>– <b>Month 4 onward:</b> 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</li> </ul>
Acute Exposure to Blood Containing HBsAg	<ul style="list-style-type: none"> <li>– 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</li> </ul>
Perinatal Exposure of Infants Born to HBsAg-positive Mothers	<ul style="list-style-type: none"> <li>– 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</li> </ul>
Sexual Exposure to HBsAg-positive Persons	<ul style="list-style-type: none"> <li>– 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</li> </ul>

## Applicable Procedure Codes

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

70504-0052-xx	Hepagam B; 312 iu/ml injection
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## Applicable Diagnosis Codes

ICD-10	ICD-10 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

## References

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