**Prior Authorization DRUG Guidelines**

### Hepatitis B Immune Globulin (Bayhep B, Hepagam B, Hyperhep B S/D, Nabi-HB)

**Effective Date:** 1/28/14  
**Date Developed:** 1/28/14 by Catherine Sanders, MD  
**Last Approval Date:** 1/26/16, 1/24/17, 1/23/18

Hepatitis B Immune Globulin is a blood product derivative used in the treatment of postexposure prophylaxis of hepatitis B. Hepatitis B immune globulin (HBIG) is a nonpyrogenic sterile solution containing immunoglobulin G (IgG) specific to hepatitis B surface antigen (HBsAg). HBIG differs from immune globulin in the amount of anti-HBs. Immune globulin is prepared from plasma that is not preselected for anti-HBs content. HBIG is prepared from plasma preselected for high titer anti-HBs. In the U.S., HBIG has an anti-HBs high titer >1:100,000 by IRA.

### Pre-Authorization Criteria:

Hepatitis B Immune Globulin is indicated for the following conditions:

1. **Passive prophylactic immunity to hepatitis B following:**
   - Acute exposure to blood containing hepatitis B surface antigen (HBsAg) or
   - perinatal exposure of infants born to HBsAg-positive mothers or
   - sexual exposure to HBsAg-positive persons or
   - household exposure to persons with acute HBV infection
2. **Prevention of hepatitis B virus recurrence after liver transplantation in HBsAg-positive transplant patients (Hepagam B only)**

**Note:** Hepatitis B immune globulin is not indicated for treatment of active hepatitis B infection and is ineffective in the treatment of chronic active hepatitis B infection.

### Dosing: Adult:

**Postexposure prophylaxis:** I.M.: 0.06 mL/kg as soon as possible after exposure (ie, within 24 hours of needlestick, ocular, or mucosal exposure or within 14 days of sexual exposure); repeat at 28-30 days after exposure in nonresponders to hepatitis B vaccine or in patients who refuse vaccination  
**Prevention of hepatitis B virus recurrence after liver transplantation (HepaGam B™):** I.V.: 20,000 units/dose according to the following schedule:

- **Anhepatic phase (Initial dose):** One dose given with the liver transplant  
- **Week 1 postop:** One dose daily for 7 days (days 1-7)  
- **Weeks 2-12 postop:** One dose every 2 weeks starting day 14  
- **Month 4 onward:** One dose monthly starting on month 4

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Dose adjustment: Adjust dose to reach anti-HBs levels of 500 units/L within the first week after transplantation. In patients with surgical bleeding, abdominal fluid drainage >500 mL or those undergoing plasmapheresis, administer 10,000 units/dose every 6 hours until target anti-HBs levels are reached.

**Dosing: Pediatric:**
Infants born to HBsAg-positive mothers: I.M.: 0.5 mL as soon after birth as possible (within 12 hours); active vaccination with hepatitis B vaccine may begin at the same time in a different site (if not contraindicated). If first dose of hepatitis B vaccine is delayed for as long as 3 months, dose may be repeated. If hepatitis B vaccine is refused, dose may be repeated at 3 and 6 months.

Infants born to mothers with unknown HBsAg status at birth (CDC, 2005): I.M.: Birth weight <2 kg: 0.5 mL within 12 hours of birth (along with hepatitis B vaccine) if unable to determine maternal HBsAg status within that time
Birth weight ≥2 kg: If the mother is determined to be HBsAg positive, administer 0.5 mL as soon as possible, but within 7 days of birth

Household exposure prophylaxis in infants <12 months: I.M.: 0.5 mL (to be administered if mother or primary caregiver has acute HBV infection).

Postexposure prophylaxis: I.M.: Children ≥12 months: Refer to adult dosing.
Note: HBIG may be administered at the same time (but at a different site) or up to 1 month preceding hepatitis B vaccination without impairing the active immune response

**Dosing: Geriatric:**
Refer to adult dosing.

**Dosing: Renal Impairment:**
No dosage adjustment provided in manufacturer’s labeling.

**Dosing: Hepatic Impairment:**
No dosage adjustment provided in manufacturer’s labeling.

**Dosage Forms: U.S.:**
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
Solution, Injection [preservative free]:
HepaGam B: (1 mL, 5 mL) [contains polysorbate 80]
Solution, Intramuscular:
HyperHEP B S/D: (0.5 mL, 1 mL, 5 mL)
Nabi-HB: (1 mL, 5 mL) [thimerosal free]
BayHep B: (0.5 mL syringe, 1 mL syringe, 1 mL vial, 5 mL vial)

Generic Equivalent Available: U.S.-No

Administration:
I.M.: Postexposure prophylaxis: I.M. injection only in anterolateral aspect of upper thigh and deltoid muscle of upper arm; to prevent injury from injection, care should be taken when giving to patients with thrombocytopenia or bleeding disorders 

I.V.: 
HepaGam B™: Liver transplant: Administer at 2 mL/minute. Decrease infusion to ≤1 mL/minute for patient discomfort or infusion-related adverse events. Actual volume of infusion is dependent upon potency labeled on each individual vial.

Nabi-HB®: Although not FDA-approved for this purpose, Nabi-HB® has been administered intravenously in hepatitis B-positive liver transplant patients (Dickson, 2006)

Exclusions:
Nabi-HB is not FDA approved for prevention of recurrent hepatitis B after liver transplantation in Hepatitis B positive liver transplant patients.

Adverse Reactions:
Serious Reactions: hypersensitivity reaction, anaphylaxis, infusion reactions, hyperviscosity, thromboembolism, viral transmission risk.

References:
7. www.uptodate.com: Hepatitis B immune globulin: Drug Information
8. www.epocrates.com: Hepatitis B immune globulin: Drug Information
REVISION HISTORY:

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