VENTURA COUNTY
HEALTH CARE PLAN

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

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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 (HB_sAg). HBIG differs from immune globulin in the amount of anti-HB_s. Immune globulin is prepared from plasma that is not preselected for anti-HB_s content. HBIG is prepared from plasma preselected for high titer anti-HB_s. In the U.S., HBIG has an anti-HB_s 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:
   a. Acute exposure to blood containing hepatitis B surface antigen (HB_sAg) or
   b. perinatal exposure of infants born to HB_sAg-positive mothers or
   c. sexual exposure to HB_sAg-positive persons or
   d. household exposure to persons with acute HBV infection
2. Prevention of hepatitis B virus recurrence after liver transplantation in HB_sAg-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
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

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

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:

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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 I: Immunization of Infants, Children, and Adolescents," *MMWR Recomm Rep*, 2005, 54(RR-16):1-31.
3. 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. Cohen V, Jellinek SP, Teperikidis L, et al, "Room-Temperature Storage of Medications Labeled for Refrigeration," *Am J Health-Syst Pharm*, 2007, 64(16):1711-15. [PubMed 17687059]
5. Dickson RC, Terrault NA, Ishitani M, et al, "Protective Antibody Levels and Dose Requirements for IV 5% Nabi Hepatitis B Immune Globulin Combined With Lamivudine in Liver Transplantation for Hepatitis B-Induced End Stage Liver Disease," *Liver Transpl*, 2006, 12(1):124-33. [PubMed 16382463]
6. Tung BY and Kowdley KV, "Hepatitis B and Liver Transplantation," *Clin Infect Dis*, 2005, 41(10):1461-6. [PubMed 16231258]
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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