OREGON HEALTH AUTHORITY

POST-EXPOSURE PROPHYLAXIS WITH HEPATITIS B IMMUNE GLOBULIN (HepaGam B®, Nabi-HB®)	
Last Reviewed	04 April 2019
Last Revised	04-April 2019
This order expires	31 July 2021

No changes from previous version.

I. Oregon Model Immunization Protocol:

1. Screen clients for contraindications and precautions. See warning box in section II.
2. Provide product information and answer any questions.
3. Record all required data elements in the client's permanent health record.
4. See Section II, for age and event-specific HBIG dosing schedules.
5. Give appropriate HBIG dose for age and exposure Intramuscularly (IM). **Aspirate to check for blood return.**[1,2]
6. Initiate Hepatitis B vaccine series as indicated by age and history. Schedule 2nd dose of HBIG one month later for vaccine non-responders and vaccine refusers.[1,2]
7. To request HBIG, see instructions available at http://public.health.oregon.gov/DiseasesConditions/CommunicableDisease/ReportingCommunicableDisease/ReportingGuidelines/Documents/state-supplied-prophy.pdf.
8. Ask client to remain seated on the premises for 15 minutes after HBIG to decrease the risk of injury should they faint.

Health Officer Date

Oregon Health Authority

Health Officer Date

II. Table 1. SCHEUDLE

PRODUCT NAME	VACCINE COMPONENTS	ACCEPTABLE AGE RANGE	DOSE
HepaGam B®[1] or Nabi-HB®[2]	>312 IU/mL anti-HBs Human Plasma	Birth through 12 months	0.5 mL IM
		>12 months of age	0.06 mL/kg IM

LICENSED HBIG: HepaGam B® and Nabi-HB®

HBIG is made from human plasma. Products made from human plasma may contain infectious agents, such as the Creutzfeldt-Jakob disease (CJD) agent, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating or removing certain viruses. Despite these measures, such product can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive transfusions of blood or plasma products may develop signs and or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to VAERS following the process listed in section X.*

HBIG should be given with caution to patients with a history of prior systemic allergic reactions following the administration of IG preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate IM injections, Hepatitis B Immune globulin (Human) should be given only if the expected benefits outweigh the risks.[1,2]

* In addition to VAERS: ALL infections thought by a physician possibly to have been transmitted by HBIG should be reported to the manufacturer:

  - HepaGam B®; Cangene Corporation: 800-768-2304[1]
  - Nabi-HB®; Biotest Pharmaceuticals: 800-458-4244[2]
  - For complete table, see MMR or Varicella immunization protocols.

II. B. Table 2. Recommended intervals between administration of hepatitis B immune globulin preparations and measles- or varicella-containing vaccine:

SUGGESTED INTERVALS BETWEEN ADMINISTRATION OF IMMUNE GLOBULIN PREPARATIONS AND MEASLES- OR VARICELLA-CONTAINING VACCINE[5]

Product/Indication	**Dose (mg IgG/kg) and route[a]**	**Recommended interval before measles- or varicella-containing vaccine[b] administration (months)**
Blood transfusion		
RBCs, washed	10 mL/kg, negligible IgG/kg IV	None
RBCs adenine-saline added	10 mL/kg (10mg IgG/kg) IV	3
Packed RBCs (hematocrit 65%)[c]	10 mL/kg (60mg IgG//kg) IV	6
Whole blood (hematocrit 35%–50%) [c]	10 mL/kg (80-100 mg IgG/kg) IV	6
Plasma/platelet products	10 mL/kg (160mg IgG/kg) IV	7
Botulinum Immune Globulin IV (Human)	1.0 mL.kg (50mg IgG/kg) IV	6

Cytomegalovirus IGIV	150 mg/kg maximum IV	6
Hepatitis A[1]		
Contact prophylaxis	0.1 mL/kg (3.3 mg IgG/kg) IM	3
International travel up to 1 month	0.1 mL/kg (3.3 mg IgG/kg) IM	3
International travel up to 2 months	0.2 mL/kg (10mg IgG/kg) IM	3
International travel >2 months	0.2 ml/kg (10mg IgG/kg) IM Repeat 0.2 mL/kg every 2 months IM	3
Hepatitis B IG	0.06 mL/kg (10mg IgG/kg) IM	3
IG IV		
Replacement therapy for immune deficiencies[d]	300-400 mg/kg IV[d]	8
Immune thrombocytopenic purpura treatment	400 mg/kg IV	8
Postexposure varicella prophylaxis	400 mg/kg IV	8
Postexposure measles prophylaxis for **immunocompromised** contacts	400 mg/kg IV	8
Immune thrombocytopenic purpura treatment	1000 mg/kg IV	10

Kawasaki disease	2 g/kg IV	11
Measles prophylaxis IG		
Standard (i.e., nonimmunocompromised) contact	0.50 mL/kg (80 mg IgG/kg) IM	6
Monoclonal antibody to respiratory syncytial virus F protein (e.g., Synagis [MedImmune])[e]	15 mg/kg IM	None
Rabies IG	20 IU/kg (22 mg IgG/kg) IM	4
Tetanus IG	250units (10 mg IgG/kg) IM	3
Varicella IG	125 units/10 kg (60-200 mg IgG/kg) IM, maximum 625 units	5

Footnotes:[6]

Table 3-5, page 37-39, June 2018:
Abbreviations: HIV = human immunodeficiency virus; IG = immune globulin; IgG = immune globulin G; IGIV = intravenous immune globulin; mg IgG/kg = milligrams of immune globulin G per kilogram of body weight; IM = intramuscular; IV = intravenous; RBCs = red blood cells.
(a) This table is not intended for determining the correct indications and dosages for using antibody-containing products. Unvaccinated persons might not be protected fully against measles during the entire recommended interval, and additional doses of IG or measles vaccine might be indicated after measles exposure. Concentrations of measles antibody in an IG preparation can vary by manufacturer's lot. Rates of antibody clearance after receipt of an IG preparation also might vary. Recommended intervals are extrapolated from an estimated half-life of 30 days

for passively acquired antibody and an observed interference with the immune response to measles vaccine for 5 months after a dose of 80 mg IgG/kg.
(b) Does not include zoster vaccine. Zoster vaccine may be given with antibody-containing blood products.
(c) Assumes a serum IgG concentration of 16 mg/mL.
(d) Measles vaccination is recommended for children with mild or moderate immunosuppression from HIV infection, and varicella vaccination may be considered for children with mild or moderate immunosuppression, but both are contraindicated for persons with severe immunosuppression from HIV or any other immunosuppressive disorder.
(e) Contains antibody only to respiratory syncytial virus.

II. C. DIRECTIONS: HEPAGAM B[1]

HepaGam B is supplied in 1.0-mL and 5.0-mL single-dose vials. HepaGam B may be given IV. See package insert for specifics on page 2.

II. D. Table 3. DIRECTIONS: NABI-HB[2]

Nabi-HB is supplied in 1.0-mL and 5.0-mL single-dose vials for IM use only.

CALCULATION FOR ADULT:

(weight of person in pounds) ÷ 2.2046 = weight in kilograms (kg).

(weight of person in kilograms) X 0.06 = dose of 0.06 mL/kg

Example: (150 pounds ÷ 2.2046) = 68.039 X 0.06 mL = 4.2 mL ≅ 4 mL per dose.

Recommended intervals between administration of hepatitis B immune globulin preparations and measles- or varicella-containing vaccine: [3]

Immune globulin	Dose	Interval
Hepatitis B IG	0.06 mL/kg (10 mg IgG/kg) IM	3 months

ACCEPTABLE VOLUME for a single dose of immune globulin (IG) to inject into either the deltoid or vastus lateralis muscle of a normal-weight **adult**.[4]

Deltoid:

- Average 0.5 mL
- Range 0.5–2 mL

Vastus Lateralis:

- Average 1–4 mL
- Range 1–5 mL

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the range.

III. Table 4. LICENSED HBIG

PRODUCT NAME	VACCINE COMPONENTS	LATEX	THIMEROSAL
HepaGam B®[1]	Human Plasma	No	No
Nabi-HB®[2]			

IV. A. Table 5. RECOMMENDATIONS FOR USE:

Hepatitis B Immunization Management of Preterm Infants Weighing <2,000 g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status: 2018[5]

Maternal HBsAg Status	Infant Birth Weight	Recommendation[5]
Positive	<2000 g	• Administer HBIG and single-antigen hepatitis B vaccine at separate sites within 12 hrs of birth. • Do not count the birth dose as part of the vaccine series. • Administer 3 additional hepatitis B vaccine doses [total of 4] with single-antigen vaccine at ages 1, 2–3, and 6 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos. • Test for HBsAg and antibody to HBsAg 1–2 mos after completion of the hepatitis B vaccine series, but not before age 9 mos nor within 4 wks of the most recent vaccine dose (i.e., at age 9–12 mos, generally at the next well-child visit).
Unknown	<2000 g	• Test mother for HBsAg. • Administer HBIG and single-antigen hepatitis B vaccine at separate sites within 12 hrs of birth. • Do not count the birth dose as part of the vaccine series. • Administer 3 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1, 2–3, and 6 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos.
Unknown but suspected	<2000 g	• Administer HBIG and single-antigen hepatitis B vaccine at separate sites within 12 hrs of birth. • Infants born to women for whom HBsAg testing results during pregnancy are not available, but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to an HBsAg-positive mother.

Negative	<2000 g	• Delay first dose of hepatitis B vaccine until chronological age of 1 month or hospital discharge, even if the infant weighs less than 2000 g. • Complete the hepatitis B vaccine series with single-antigen vaccine at ages 2 mos and 6–18 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos.

IV. B. Table 6. RECOMMENDATIONS FOR USE: Hepatitis B Immunization Management of Infants Weighing ≥2,000 g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status: 2018[5]

Maternal HBsAg Status	Infant Birth Weight	Recommendation[5]
Positive: Maternal HBsAg, HBV DNA, HBeAg, chronic infection	≥2000 g	• Administer HBIG and single-antigen hepatitis B vaccine at separate sites within 12 hrs of birth. • Administer 2–3 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1–2 and 6 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos. • Test for HBsAg and antibody to HBsAg 1–2 mos after completion of the hepatitis B vaccine series, but not before age 9 mos nor within 4 wks of the most recent vaccine dose (i.e., at age 9–12 mos, generally at the next well-child visit).
Unknown	≥2000 g	•Administer single-antigen hepatitis B vaccine within 12 hrs of birth. • Administer 2 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1–2 and 6 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos.
Unknown but suspected		• The infant should receive both HepB vaccine and HBIG within 12 hours of birth. •Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to an HBsAg-positive mother.

Negative	≥2000 g	• Administer single-antigen hepatitis B vaccine within 24 hrs of birth. • Administer 2–3 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1–2 and 6 mos, or Pediarix® vaccine at ages 2, 4, and 6 mos.

IV C. Table 7. RECOMMENDATIONS FOR POST-EXPOSURE USE of HBIG: [5]

Recommended postexposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus—Advisory Committee on Immunization Practices, United States*

Vaccination and antibody response status of exposed person	Treatment		
	Source HBsAg-positive	Source HBsAg-Negative	Source not tested or status unknown
Unvaccinated	HBIG x 1 Initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated: -Known responder	No treatment	No treatment	No treatment
Known non-responder -after 3 doses	HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg-positive.
-Vaccine refuser -Known non-responder after 6 doses	HBIG x 2 (separated by 1 month)	No treatment	-If known high-risk source, treat as if source were HBsAg-positive.
-Antibody response unknown	Test exposed person for anti-HBs -If adequate*, no treatment -If inadequate*, HBIG x 1 and vaccine booster	No treatment	Test exposed person for Anti-HBs -if adequate*, no treatment -if inadequate*, HBIG x 1 and vaccine booster.

*A seroprotective (adequate) level of anti-HBs after completion of a vaccination series is defined as anti-HBs >10 mIU/mL; an antibody level of <10 mIU/mL is inadequate and is not a reliable indicator of protection.[6]

IV.D. Table 8. RECOMMENDATIONS FOR POST-EXPOSURE USE Cont.

Post-exposure Prophylaxis following Sexual Exposure to Hepatitis B

HBIG[1, 2]		Vaccine	
Dose	**Preferred timing**	**Dose**	**Preferred timing**
0.06 mL/kg IM	Single dose within 14 days of last sexual contact.	1.0 mL IM	First dose at separate site at time of HBIG treatment.*

*All susceptible persons whose sex partners have acute hepatitis B infection should receive a single dose of HBIG (0.06 mL/kg) and should **begin the hepatitis B vaccine series if prophylaxis can be started within 14 days** of the last sexual contact or if sexual contact with the infected person will continue. Per package insert, September 2012. Table 1.

IV. E. Table 9. RECOMMENDATIONS FOR POST-EXPOSURE USE, Cont.

Post-exposure Prophylaxis for Other Household Contacts

HBIG: HepaGam B[1] and Nabi-HB[2]			Vaccine	
Dose	**Age**	**Preferred timing of HBIG**	**Dose**	**Preferred timing**
0.5 mL IM	<12 months	Not indicated unless they have identifiable blood exposure to the index patient.	See Hep. B immunization protocol *	First dose at time of HBIG[1, 2] treatment
		Exposures to toothbrushes or razors should be treated as for sexual contact. Administer as soon as possible after exposure and within 24 hours if possible. Administer within 14 days of the last contact or if contact with the infected person will continue.		
0.06 mL/kg IM	>12 months	Administer as soon as possible after exposure and within 24 hours if possible. Administer HepaGam B within 14 days of the last sexual contact or if sexual contact with the infected person will continue.	If the index patient becomes an HBV carrier, then all household contacts should receive hepatitis B vaccine.	Begin the hepatitis B vaccine series, if not contraindicated, within 14 days of the last sexual contact or if sexual contact with the infected person will continue.
Per HepaGam B package insert, September 2012[1]: Postexposure Prophylaxis (2.2) Per Nabi-HB package insert, April 2008[2]: Sexual Exposure to HBsAg-positive Persons, Table 3.				

*If a person cannot or will not receive vaccine even after exposure (e.g., vaccine refuser) two doses of HBIG are a reasonable option, as they are for non-responders. If they refuse vaccine even after an exposure to known HBsAg-positive body fluids, then two doses of HBIG given one month apart are appropriate (CDC correspondence 2016).

IV. F. Table 10. RECOMMENDATIONS FOR POST-EXPOSURE management of healthcare personnel (HCP) after occupational percutaneous and mucosal exposure to blood and body fluids, by HCP hepatitis B vaccination and response status[5]

	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing◊
	Source patient HBsAg status	HCP testing (anti-HBs)	HBIG*	Vaccination	
Documented responder§ after complete series (≥3 doses)	**No action needed**				
Documented nonresponder‡ after 6 doses	Positive/unknown	**	HBIG x2 separated by a month		No
	Negative	**No action needed**			
Response unknown after 3 doses	Positive/unknown	≤10 mIU/mL**	HBIG x 1◊◊	Initiate revaccination	Yes
	Negative	≤10 mIU/mL	None		
	Any result	≥10 mIU/mL	**No action needed**		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	**	HBIG x 1◊◊	Complete vaccination	Yes
	Negative		None	Complete vaccination	Yes

*HBIG should be administered intramuscularly as soon as possible after exposure when indicated. HBIG dosage is 0.06 mL/kg. HBIG is administered by intramuscular injection; an appropriate muscle mass (i.e., deltoid or lateral thigh) should be chosen in which to deliver the large volume of HBIG required, and a needle length appropriate for the client's size should be used. HBIG can be administered simultaneously with Hep B vaccine but at a different injection site.

◊Should be performed 1–2 months after the last dose of the Hep B vaccine series (and 4–6 months after administration of HBIG to avoid detection of passively administered anti-HBsAb) using a quantitative method that allows detection of the protective concentration of anti-HBsAb (≥10 mIU/mL).

§A responder is defined as a person with anti-HBsAb ≥10 mIU/mL after ≥3 doses of Hep B vaccine.

‡A non-responder is defined as a person with anti-HBsAb <10 mIU/mL after ≥6 doses of Hep B vaccine.

** HCP who have anti-HBsAb <10 mIU/mL, or who are unvaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after exposure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc

◊◊ If a person cannot or will not receive vaccine even after exposure (e.g., vaccine refuser) two doses of HBIG are a reasonable option, as they are for non-responders. If they refuse vaccine even after an exposure to known HBsAg-positive body fluids, then two doses of HBIG are appropriate (CDC correspondence, 2016).

V.CONTRAINDICATIONS [1,2]

1. Previous anaphylactic reaction to any human immune globulin.
2. Nabi-HB contains 40 µg/mL of IgA. Individuals who are deficient in IgA have the potential to develop antibodies against IgA and anaphylactic reactions.
3. 3.HepaGam B contains less than 40 µg/mL of IgA. Individuals who are deficient in IgA have the potential to develop antibodies against IgA and anaphylactic reactions.

VI.PRECAUTIONS AND WARNINGS[1,2]

1. HepaGam B may cause interference with blood glucose testing.
2. HepaGam B may be given IV.
3. Nabi-HB should not be administered intravenously because of the potential for serious reactions. **Injections should be IM, with care given to aspirate before injection to make sure the tip of the needle is not in a blood vessel.**
4. Use the deltoid muscle of the upper arm or lateral thigh muscle for injection.
5. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered.

VII. SIDE EFFECTS AND ADVERSE REACTIONS[1,2]

1. Local pain and tenderness at the injection site.
2. Urticaria and angioedema may occur.
3. Anaphylactic reactions, although rare, have been reported following the injection of human immune globulin preparations.

VIII.OTHER CONSIDERATIONS

1. **Drug Interactions:** Live virus vaccines should be deferred until approximately 3 months after HBIG administration. No interactions with other products are known.[1]
2. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[10]
3. **Pregnancy:** No studies have been conducted with HBIG in pregnant women. it is not known if HBIG can affect reproduction capacity. HBIG should be given to a pregnant woman only if clearly indicated.[1,2]
4. **Nursing Mothers**: All classes of immunoglobulins can be detected in breast milk. Immunoglobulins from the mother help to support the infant's health.[13]
5. **CDC. PEP:** Post-Exposure Prophylaxis Consultation: 888-448-4911, 9 a.m. – 2 a.m. Eastern time, 7 days a week. http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/ 02-16-2017
6. No data available on overdosage. Clinical experience suggests that there might be pain and tenderness at the injection site.[1,2]
7. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, Hepatitis B Immune globulin (Human) should be given only if the expected benefits outweigh the risks.[1,2]

IX. Table 11. STORAGE AND HANDLING

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
HepaGam B® [1]	Store at 2°–8°C (36˚F–46˚F)	Do not use if product has been frozen. Report to health educator.	Use within 6 hours of opening.
Nabi-HB[2]			

X. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html .

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971-673-0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocols

REFERENCES*

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11. Hepatitis B. In*: Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds.13th ed. Washington, DC: Public Health Foundation, 2015; 149–74. Available at: www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb.pdf. Accessed 04 April 2019.

12. Chiara C, Aldrovandi GM: Breast Milk: Proactive immunomodulation and mucosal protection against viruses and other pathogens. Future Virology: 2013;8(11):1127–8. Available at: www.medscape.com/viewarticle/814970_2. Accessed 04 April 2019.

*Copy and paste links as needed