OREGON HEALTH AUTHORITY

POST-EXPOSURE PROPHYLAXIS

WITH

HEPATITIS B IMMUNE GLOBULIN (HyperHEP \textsuperscript{®} 1, Nabi-HB \textsuperscript{®} 2)


I. Oregon Immunization Model Standing Order:

1. Screen clients for contraindications. See warning box on page 2.
2. Provide product information, and answer any questions.
3. Record all required data elements in the client’s permanent health record.
5. Give appropriate HBIG dose for age and exposure Intramuscularly (IM). See page 3 for specifics using pre-filled syringe presentation. Aspirate to check for blood return. \textsuperscript{1, 2}
   See package insert for directions.
6. Initiate Hepatitis B vaccine series as indicated by age and history. Schedule 2\textsuperscript{nd} dose of HBIG one month later for vaccine non-responders and vaccine refusers. \textsuperscript{1, 2}
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

Health Officer

Date

This order expires July 31, 2018
II. A. LICENSED HBIG: HyperHEP B® , 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 and/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 and/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* on page 14.

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:

  o HyperHEP B®; Grifoils Therapeutics Inc. 800-520-28071
  o Nabi-HB®; Biotest Pharmaceuticals 800-458-42442
II B. LICENSED HBIG\(^1, 2\) Cont.

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HyperHEP B(^1) S/D(^1)</td>
<td>Human Plasma</td>
<td>Birth through 12 months</td>
<td>0.5 mL IM</td>
</tr>
<tr>
<td>Nabi-HB(^2)</td>
<td></td>
<td>&gt;12 months of age</td>
<td>0.06 mL/kg IM</td>
</tr>
</tbody>
</table>

II. C. DIRECTIONS: HYPER HEP B FOR SYRINGE USE\(^1\)

1. To remove the prefilled syringe from the package, lift syringe by the barrel, NOT the plunger.
2. Twist the plunger rod clockwise until the threads are seated.
3. With the rubber needle shield secured on the syringe tip, push the plunger rod forward a few millimeters to break any friction seal between the rubber stopper and the glass syringe barrel.
4. Remove the needle shield and expel air bubbles immediately prior to the anticipated injection time.
5. Proceed with hypodermic needle puncture.

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6. Aspirate prior to injection to confirm that the needle is not in a vein or artery.

7. Inject the medication.

8. Keeping your hands behind the needle, grasp the guard with free hand and slide forward toward needle until it is completely covered and guard clicks into place. If audible click is not heard, guard may not be completely activated.

9. Discard pre-filled syringe unit in appropriate sharps container.

II. D. DIRECTIONS: NABI-HEP B²

Nabi-HB is supplied in single dose vials.

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 \times 0.06mL = 4.2 mL \approx 4 \text{ mL per dose.}

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.⁴
III. A. RECOMMENDATIONS FOR USE:

Hepatitis B Immunization Management of Preterm Infants Weighing <2,000 g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status: 2007

<table>
<thead>
<tr>
<th>Maternal HBsAg Status</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive</strong></td>
<td>• Administer HBIG* + single-antigen hepatitis B vaccine within 12 hrs of birth.</td>
</tr>
<tr>
<td></td>
<td>• Do not count the birth dose as part of the vaccine series.</td>
</tr>
<tr>
<td></td>
<td>• Administer 3 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1, 2–3, and 6 mos, or hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix®).◊</td>
</tr>
<tr>
<td></td>
<td>• Test for HBsAg and antibody to HBsAg 1–2 mos after completion of &gt; 3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 mos, generally at the next well-child visit). Testing should not be performed before age 9 mos nor within 4 wks of the most recent vaccine dose.</td>
</tr>
<tr>
<td><strong>Unknown</strong></td>
<td>• Administer HBIG + single-antigen hepatitis B vaccine within 12 hrs of birth.</td>
</tr>
<tr>
<td></td>
<td>• Test mother for HBsAg.</td>
</tr>
<tr>
<td></td>
<td>• Do not count the birth dose as part of the vaccine series.</td>
</tr>
<tr>
<td></td>
<td>• Administer 3 additional hepatitis B vaccine doses with single-antigen vaccine at ages 1, 2–3, and 6 mos, or hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix®).◊</td>
</tr>
<tr>
<td><strong>Negative</strong></td>
<td>• Delay first dose of hepatitis B vaccine until age 1 mo or hospital discharge.</td>
</tr>
<tr>
<td></td>
<td>• Complete the hepatitis B vaccine series with single-antigen vaccine at ages 2 mos and 6–18 mos, or hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix®).◊</td>
</tr>
</tbody>
</table>
Hepatitis B immune globulin.

◊ The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

### III B. RECOMMENDATIONS FOR POST-EXPOSURE USE of HBIG:

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

<table>
<thead>
<tr>
<th>Vaccination and antibody response status of exposed person</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Source HBsAg-positive</td>
</tr>
<tr>
<td>Unvaccinated</td>
<td>HBIG x 1</td>
</tr>
<tr>
<td>Previously vaccinated:</td>
<td></td>
</tr>
<tr>
<td>-Known responder</td>
<td>No treatment</td>
</tr>
<tr>
<td>Known nonresponder</td>
<td>BIG x 1 and initiate revaccination</td>
</tr>
<tr>
<td>-after 3 dose</td>
<td></td>
</tr>
<tr>
<td>-Vaccine refuser</td>
<td>HBIG x 2 (separated by 1 month)</td>
</tr>
<tr>
<td>-after 6 doses</td>
<td></td>
</tr>
<tr>
<td>-Antibody response unknown</td>
<td>Test exposed person for anti-HBs</td>
</tr>
<tr>
<td></td>
<td>-If adequate*, no treatment</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- 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; a response <10 mIU/mL is inadequate and is not a reliable indicator of protection.


III.C. RECOMMENDATIONS FOR POST-EXPOSURE USE Cont.

Post-exposure Prophylaxis following Sexual Exposure to Hepatitis B

<table>
<thead>
<tr>
<th>HBIG&lt;sup&gt;1, 2 *&lt;/sup&gt;</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dose</strong></td>
<td><strong>Recommended timing</strong></td>
</tr>
<tr>
<td>0.06 mL/kg IM&lt;sup&gt;0&lt;/sup&gt;</td>
<td>Single dose within 14 days of last sexual contact.</td>
</tr>
</tbody>
</table>

<sup>*</sup>HBIG = Hepatitis B Immune Globulin (Human)

<sup>0</sup>IM = Intramuscularly

<sup>§</sup>The first dose can be administered the same time as the HBIG dose but at a different site; subsequent doses should be administered as recommended for specific vaccine.

<sup>‡</sup>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.<sup>1</sup>
### III. D. RECOMMENDATIONS FOR POST-EXPOSURE USE, Cont.

#### Post-exposure Prophylaxis for Other Household Contacts

<table>
<thead>
<tr>
<th>HBIG*</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>Age</td>
</tr>
<tr>
<td>0.5 mL</td>
<td>&lt;12 months</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>0.06 mL/kg IM◊</td>
<td>&gt;12 months</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Per package insert, September 2012 Table 2.¹

* HBIG = Hepatitis B Immune Globulin (Human)

◊ IM = Intramuscularly

§ The first dose can be administered the same time as the HBIG dose but at a different site; subsequent doses should be administered as recommended for specific vaccine.
‡If the first dose of hepatitis B vaccine is delayed for as long as 3 months, then a 0.5-mL dose of HBIG should be given at 3 months of age.

** If Hepatitis B vaccine is refused, then a 0.5-mL dose of HBIG should be repeated at 3 and 6 months of age.

◊◊ 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.¹, CDC correspondence 2016
### III. E. 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

<table>
<thead>
<tr>
<th>HCP personnel status</th>
<th>Postexposure testing</th>
<th>Postexposure prophylaxis</th>
<th>Postvaccination serologic testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Source patient HBsAg status</td>
<td>HCP testing (anti-HBs)</td>
<td>HBIG* Vaccination</td>
</tr>
<tr>
<td>Documented responder after complete series (≥3 doses)</td>
<td>No action needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documented nonresponder after 6 doses</td>
<td>Positive/unknown</td>
<td>**</td>
<td>HBIG x2 separated by a month</td>
</tr>
<tr>
<td>Negative</td>
<td>No action needed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response unknown after 3 doses</td>
<td>Positive/unknown</td>
<td>≤10 mIU/mL**</td>
<td>HBIG x 100</td>
</tr>
<tr>
<td>Negative</td>
<td>≤10 mIU/mL</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Any result</td>
<td>≥10 mIU/mL</td>
<td>No action needed</td>
<td></td>
</tr>
<tr>
<td>Unvaccinated/incompletely vaccinated or vaccine refusers</td>
<td>Positive/unknown</td>
<td>**</td>
<td>HBIG x 100</td>
</tr>
<tr>
<td>Negative</td>
<td>None</td>
<td>Complete vaccination</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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**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.¹, CDC correspondence 2016
IV. CONTRAINDICATIONS 1, 2

1. Previous anaphylactic reaction to any human immune globulin.

V. PRECAUTIONS AND WARNINGS 1, 2

1. HBIG 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.** This is not a vaccine.

2. Use the deltoid muscle of the upper arm or lateral thigh muscle for injection.

3. An individual decision as to which muscle is injected must be made for each patient based on the volume of material to be administered.

VI. 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.
VII. 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 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. EST Seven days a week. [http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/](http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/) 02-16-2017¹¹

6. No data available on overdosage. Clinical experience suggests that there might be pain and tenderness at the injection site.¹, ²

7. HBIG should be given with caution in patients with a history of prior systemic allergic reactions following the administration of human immune globulin preparations.¹, ²

8. 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
VIII. 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).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HyperHEP B® 1</td>
<td>Store at 2°–8°C (36°F–46°F)</td>
<td>Do not use if product has been frozen. Report to health educator.</td>
<td>No natural rubber latex. Use immediately.</td>
</tr>
<tr>
<td>Nabi-HB²</td>
<td></td>
<td></td>
<td>No natural rubber latex. Use within 6 hours of opening.</td>
</tr>
</tbody>
</table>

IX. ADVERSE EVENTS REPORTING

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

1. Save a copy of the report number for your records
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

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 standing order is available at: http://1.usa.gov/OregonStandingOrders

Original: 07 -2017
REFERENCES*


8. CDC. Appendix B. Postexposure prophylaxis to prevent hepatitis B virus infection. MMWR 2006;55:30–1. Available at:


*Copy and paste links as needed*