

A Quick Look at Hepatitis B (HepB) Vaccines

Single Antigen (monovalent) Hepatitis B Vaccines

- Engerix-B® & Recombivax HB® approved for use at birth and older
- Heplisav-B® approved for persons aged 18 years and older

Combination Hepatitis B Vaccines

- Pediarix® (DTaP-IPV-HepB) approved for persons aged 6 weeks through 6 years and can be used for any dose of HepB except birth dose
- Twinrix® (Hepatitis A-Hepatitis B) approved for persons aged 18 years and older

Indications for Use and Schedule of Infants (see “Vaccination of Infants”)

- Within 24 hours of birth, begin to administer as a 3-dose series at 0, 1-2, 6-18 months
 - Minimum intervals for a 3 dose HepB series: 4 weeks between dose 1 & 2, 8 weeks between dose 2 & 3, 16 weeks between dose 1 & 3
- Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose (i.e., Pediarix) or for infants weighing less than 2000g
 - When 4 doses are administered, substitute “dose 4” for “dose 3” in minimum interval calculations
- Minimum age for the final (3rd or 4th) dose: 24 weeks
- Use single antigen HepB vaccine for doses administered prior to 6 weeks

Indications for Use and Schedule of Children and Adolescents

- Administer to unvaccinated persons 18 years and younger using the 3-dose schedule (0, 1-2, 6 months)
- Recombivax HB (adult formulation 1.0mL) may be administered to persons aged 11-15 years as a 2-dose schedule (0, 4-6 months)

Hepatitis B Vaccine Types:

Use of Recombivax HB and Engerix-B

- Two manufacturers in the United States, Merck (Recombivax HB) and GlaxoSmithKline Pharmaceuticals (Engerix-B) are available in both pediatric and adult formulations
- Although their antigen content differs, both vaccines are interchangeable except for the 2-dose schedule for adolescents aged 11 through 15 years. Only Recombivax HB is approved for this schedule.
- Recombivax HB (Merck)
 - 5mcg/0.5mL (pediatric dose for persons birth through 19 years of age)
 - 10mcg/1.0mL (adult dose for persons aged 20 years and older or for adolescents 11-15 getting the 2-dose schedule)
 - 40mcg/1.0mL (adult dialysis formulation for persons aged 20 years and older)

Indications for Use and Schedule of Adults

- Administer to unvaccinated persons aged 19 years and older who are at risk for HepB infection (see “Adults at High Risk for Hepatitis B Infection”)
- Unvaccinated persons aged 19 years and older who are not at high risk may also be vaccinated
- When using **Recombivax HB** or **Engerix-B** follow a 3-dose schedule (0, 1-2, 6 months)
- Persons aged 18 years and older may receive a 2-dose series of **Heplisav-B** at least 4 weeks apart
- Persons aged 18 years and older who receive **Twinrix** may receive a 3-dose series (0, 1, 6 months) or a 4-dose series (0, 7, and 21-30 days, followed by a dose at 12 months) for those needing rapid protection from Hepatitis A and B virus

Vaccine Administration

- **Only** administer as an **Intramuscular (IM)** injection in the deltoid of the arm (preferred) or anterolateral thigh
 - If administered via any site other than the deltoid or anterolateral thigh OR if not administered IM, dose **MUST** be repeated
- 1- to 1.5-inch needle; 22-25 gauge
- Use professional judgment when selecting needle length
- Can be given simultaneously with other vaccines

Storage and Handling

- Store in refrigerator unit between **36°-46°F (2°-8°C)**
 - Stand-alone purpose-built storage units preferred
- Do **not** freeze (discard if frozen)
- Keep in original box
- Protect Recombivax HB from light

- Engerix-B (GSK)
 - 10mcg/0.5mL (pediatric dose for persons from birth through 19 years of age)
 - 20mcg/1.0mL (adult dose for persons aged 20 years and older)

Use of Heplisav-B

- The 2-dose HepB vaccine series for adults **only** applies when both doses in the series are Heplisav-B
- A series that consists of a combination of 1 dose of Heplisav-B and a vaccine from a different manufacturer should consist of 3 total doses meeting minimum intervals for the 3-dose schedule (4 weeks between dose 1 & 2, 8 weeks between dose 2 & 3, and 16 weeks between dose 1 & 3)
 - Doses administered at less than the minimum interval should be repeated
 - A series containing 2 doses of Heplisav-B administered at least 4 weeks apart is valid, even if the patient received a single earlier dose from another manufacturer (e.g., 1 dose Engerix, 4 weeks later Heplisav-B, another 4 weeks later Heplisav-B)

Use of Twinrix

- May use Twinrix for persons aged 18 years and older who need both HepA and HepB vaccine
- A dose of Twinrix contains a standard adult dose of HepB vaccine and a pediatric dose of HepA vaccine
- A dose of Twinrix can be substituted for any dose of the HepB series but not for any dose of the HepA series
- The minimum intervals for a 3-dose series of Twinrix are 4 weeks between dose 1 & 2, 5 months between dose 2 & 3, and 6 months between dose 1 & 3
- Twinrix cannot be used for HepB post-exposure prophylaxis
- When giving Twinrix and single-antigen HepA and HepB, ensure a complete series of each antigen is administered
 - 1 dose of Twinrix + 2 adult doses of single-antigen HepA = complete series of HepA. When administered in this order, use the following minimum intervals:
 - Minimum interval between Twinrix and dose 1 of single-antigen HepA is 4 weeks
 - Minimum interval between dose 1 of single-antigen HepA and dose 2 of single-antigen HepA is 5 months
 - 2 doses of Twinrix + 1 adult dose of single-antigen HepA = complete series of HepA. When administered in this order, use the following minimum interval:
 - Minimum interval between dose 2 of Twinrix and single-antigen HepA dose is 5 months
 - 1 dose of Twinrix + 2 adult doses of single-antigen HepB = complete series of HepB
 - 2 doses of Twinrix + 1 adult dose of single-antigen HepB = complete series of HepB
 - Because Twinrix contains a standard adult dose of HepB vaccine, you can use the same minimum intervals as you would for a single-antigen HepB series when mixing Twinrix and single-antigen HepB
- The 4-dose schedule could benefit persons who need rapid protection from HepA and HepB, such as persons with imminent travel to high-prevalence areas and emergency responders, especially those being deployed to disaster areas overseas

Hepatitis B Vaccine Recommendations:

Vaccination of Infants

- For all medically stable infants weighing greater than or equal to 2,000 grams at birth and born to HepB surface antigen (HBsAg) negative mothers, the first dose of HepB vaccine should be administered within 24 hours of birth; only single-antigen HepB vaccine should be used for the birth dose
- Infants weighing less than 2,000 grams and born to HBsAg-negative mothers should have their first HepB dose delayed to the time of hospital discharge or at chronological age 1 month (even if weight is still less than 2,000 grams)
- All infants born to HBsAg-positive women and women with unknown HBsAg status, should receive HepB vaccine and HepB immune globulin (HBIG) within 12 hours of birth, administered in separate limbs
 - For more information on the management of infants born to mothers who are HBsAg-positive or whose status is unknown, refer to “Prevention of Hepatitis B Virus Infection in the United States” at www.cdc.gov/hepatitis/resources/professionals/mmwr.htm#hepb

- Infants born to mothers with unknown HBsAg status may be breastfed beginning immediately after birth
- Infants who are born to HBsAg-positive mothers and receive postexposure prophylaxis may be breastfed beginning immediately after birth

Vaccination During Pregnancy

- Pregnant women who are identified as being at risk for HepB infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for a sexually transmitted infection, recent or current injection drug use, or having had an HBsAg-positive sex partner) should be vaccinated
- Until safety data are available for Heplisav-B administration during pregnancy, the Advisory Committee on Immunization Practices (ACIP) recommends providers vaccinate with a different manufacturer's vaccine
 - Women who receive Heplisav-B within 28 days before pregnancy or at any time during pregnancy are encouraged to participate in the registry by calling 1-844-443-7734

Vaccination of Dialysis Patients

- HepB vaccination of adult (20 years and older) hemodialysis patients consists of high-dose (40 mcg-1mL) Recombivax HB administered on a 0, 1, and 6 month schedule or high-dose (40mcg-two doses of 20mcg[1mL]) Engerix-B administered on a 0, 1, 2, and 6 month schedule; the Heplisav-B schedule for adult hemodialysis patients (18 years and older) is two 0.5 mL doses, separated by 1 month
- Persons with end-stage renal disease including predialysis, hemodialysis, peritoneal dialysis, and home dialysis who do not respond to an initial vaccine series should be revaccinated with two to four additional doses of HepB vaccine (depending on the brand)
- Hemodialysis patients are considered immune if they have anti-HBs concentrations of at least 10 mIU/mL. The need for booster doses should be assessed by annual anti-HBs testing. A booster dose should be administered when anti-HBs levels decline to less than 10 mIU/mL. Anti-HBs testing 1-2 months following the booster dose to assess response is not recommended.
- If vaccinating using **only** Engerix-B doses or mixing brands, the schedule is a 4-dose series (0, 1, 2, and 6 months)
- If vaccinating using **only** Recombivax HB dialysis formulation, the schedule is a 3-dose series (0, 1, and 6 months)

Serologic Testing:

- Serologic testing for immunity after routine vaccination is not routinely recommended
- Testing for immunity is recommended only for people whose subsequent clinical management depends on knowledge of their immune status
 - Post-vaccination testing is recommended for the following: healthcare and public safety workers at risk of continued exposure to blood on the job, infants born to HBsAg-positive women and infants born to women whose HBsAg status remains unknown (including safely surrendered babies), immune compromised people, and sex or needle-sharing partners of HBsAg-positive people; testing should be performed 1 to 2 months after the last dose of vaccine

Vaccination of Healthcare Personnel (HCP)

- HCP with documentation of receiving a complete, properly spaced series of HepB vaccine **and** who have a positive anti-HBs (antibody to hepatitis B surface antigen) are considered immune to the hepatitis B virus and require no further testing or vaccination
 - A positive anti-HBs is an anti-HBs greater than or equal to 10 mIU/mL
- Persons who cannot provide written documentation of a complete HepB vaccination series should complete the series, then be tested for anti-HBs 1 to 2 months after the final dose
- HCP with documentation of a complete series of HepB vaccine but no documentation of anti-HBs should be tested for anti-HBs.
 - If anti-HBs is 10 mIU/mL or greater, document immunity
 - If anti-HBs is less than 10 mIU/mL, give a challenge dose of HepB vaccine and test for anti-HBs 1-2 months later
 - If anti-HBs is 10 mIU/mL or greater document immunity and no further vaccination or testing needed

- If anti-HBs is less than 10mIU/mL complete 2nd HepB series by giving 2 additional HepB doses and then test for anti-HBs 1-2 months after the last dose
 - If anti-HBs is positive document immunity
 - If anti-HBs is negative further testing and follow up will be needed. For further guidance review the MDHHS document “Option 1-Pre-Exposure Management of Health Care Personnel (HCP) With a Complete Hepatitis B Vaccine Series but Without Post-Vaccination Serology” at www.michigan.gov/immunize > click on Health Care Professionals/Providers Tab
- For postexposure management of HCP, please review the MDHHS document “Option 2-Postexposure Management of Health Care Personnel (HCP) for Hepatitis B Virus Protection” at www.michigan.gov/immunize > click on Health Care Professionals/Providers Tab
- Heplisav-B may be used to revaccinate (including the challenge dose) new HCP who were initially vaccinated with a different manufacturer’s vaccine in the distant past and have anti-HBs less than 10 mIU/mL

Adults at High Risk for Hepatitis B Infection

- Persons with chronic liver disease, HIV infection, sexual exposure risk, current or recent injection drug use, percutaneous or mucosal risk for exposure to blood, incarcerated persons, travel to countries with high or intermediate endemic hepatitis B, and pregnancy (Heplisav-B not currently recommended during pregnancy due to lack of safety data in pregnant women). For an additional breakdown of each high risk category, refer to the HepB notes in the adult immunization schedule at www.cdc.gov/vaccines/schedules/hcp/imz/adult.html.

Contraindications

- An anaphylactic (severe allergic) reaction to a prior dose or a component of HepB vaccines
- Hypersensitivity to yeast

Precautions

- Moderate or severe acute illness with or without fever

Further Points

- When feasible, the same manufacturer’s vaccines should be used to complete the series; however, vaccination should not be deferred when the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable
- For all ages, when the HepB vaccine schedule is interrupted, the vaccine series **does not** need to be restarted
- For other immunocompromised persons (e.g., HIV infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy), the need for booster doses has not been determined
- Long-term immunity has been demonstrated only for people with an anti-HBs result of at least 10 mIU/mL **after completing a full vaccination series**; such a result assures not only seroprotection but long-term protection
- The HepB Vaccine Information Statement (VIS), including information about the Michigan Care Improvement Registry (MCIR), can be found at www.michigan.gov/VIS or your local health department
- Document as “HepB (ped/adol)”, “DTaP-HepB-IPV (Pediarix)”, “HepB (adult)”, “HepB adjuvanted (Heplisav-B)”, “HepA-HepB (Twinrix)”, or “HepB (dialysis)” in MCIR, on the vaccine administration record, and on the immunization record card

Publicly purchased HepB vaccine can be administered to eligible children aged birth through 18 years through the Vaccines for Children (VFC) Program. Eligible children include those who are uninsured, underinsured, Medicaid eligible, Native American or Alaskan Natives. Contact your local health department for more information. HepB vaccine is also available through the Michigan Adult Vaccine Program (MI-AVP) and through Adult Medicaid. For persons covered by Adult Medicaid, private stock should be used and billed to Medicaid. For current HepB vaccine recommendations visit www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.