

AAMC Standardized Immunization Form 2023

Hepatitis B Vaccine – Frequently Asked Questions

(Information from the CDC)

1. What are the hepatitis B vaccines licensed for use in the United States?

Four hepatitis B vaccines and two combination hepatitis B vaccines are currently licensed in the U.S.

Hepatitis B vaccines:

Trade Name – Licensure Date	Abbreviation	Number of Doses	Minimum Age
RECOMBIVAX HB® (1986)	1A-HepB	3 doses	Birth through adult
ENGERIX-B® (1989)	1A-HepB	3 doses	Birth through adult
HEPLISAV-B® (2017)	HepB-CpG	2 doses	Adult ≥18 years
PREHEVBRIO® (2022)	3A-HepB	3 doses	Adult ≥18 years

Hepatitis B combination vaccines:

- PEDIARIX®: Combined hepatitis B, diphtheria, tetanus, acellular pertussis (DTaP) and inactivated poliovirus (IPV) vaccine. Cannot be administered before 6 weeks of age or after 7 years of age.
- TWINRIX® and TWINRIX® Junior: Combined hepatitis A and hepatitis B vaccine. Recommended for use in persons 1 year of age and older who are at increased risk for both HAV and HBV infections.

2. What are the recommended schedules for hepatitis B vaccination?

The vaccination schedule most often used for children and adults is three doses given at 0, 1, and 6 months. Alternate schedules have been approved for certain vaccines and/or populations. A new formulation, Heplisav-B (HepB-CpG), is approved to be given as two doses one month apart.

3. If there is an interruption between doses of hepatitis B vaccine, does the vaccine series need to be restarted?

No. The series does not need to be restarted but the following should be considered:

- If the vaccine series was interrupted after the first dose, the second dose should be administered as soon as possible.
- The second and third doses should be separated by an interval of at least 8 weeks.
- If only the third dose is delayed, it should be administered as soon as possible.

4. Is it harmful to administer an extra dose of hepatitis B vaccine or to repeat the entire vaccine series if documentation of the vaccination history is unavailable or the serology test is negative?

No, administering extra doses of single-antigen hepatitis B vaccine is not harmful.

5. Can Heplisav-B or PreHevbrio be used to complete a vaccination series started with Engerix-B or Recombivax HB?

Doses of Engerix-B or Recombivax-HB single antigen hepatitis B (1A-HepB) vaccines are considered interchangeable. However, there are limited data on the safety and immunogenicity effects when doses of Heplisav-B (HepB-CpG) or PreHevbrio (3A-HepB) vaccine are interchanged with HepB products from other manufacturers. When feasible, the same manufacturer's vaccines should be used to complete the series. However, vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable.

6. Can the HepB-CpG vaccine be used to complete a hepatitis B vaccine series started with Engerix-B or Recombivax HB?

- The 2-dose HepB vaccine series only applies when both doses consist of HepB-CpG administered at least 4 weeks apart.
- If one dose of HepB-CpG is used in a vaccine series in combination with two doses of Engerix-B or Recombivax HB, adhere to the 3-dose schedule minimum intervals of 4 weeks between doses #1 and #2, 8 weeks between doses #2 and #3, and 16 weeks between doses #1 and #3.
- However, if HepB-CpG is used as dose #2 of a vaccine series beginning with Engerix-B or Recombivax HB as dose #1, a provider has the option of administering the next dose of HepB-CpG a minimum of 4 weeks from the previous dose to complete the 3-dose series.

7. Who should receive post-vaccination testing?

Testing for vaccine-induced immunity is advised for certain persons whose subsequent clinical management depends on knowledge of their immune status. This includes health care workers (and health care students/trainees) and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids. This also includes persons who are immunocompromised.

8. When should post-vaccination testing be done?

Post-vaccination testing for anti-HBs levels (i.e. quantitative serum titers of antibodies [HBsAb] against Hepatitis B Surface Antigen [HBsAg]) should be performed 4-8 weeks after completion of the vaccine series. **An anti-HBsAg titer ≥ 10 mIU/mL is considered a correlate of vaccine-induced protection for people who have completed an approved vaccination series.** If testing is performed more than 2 months after the last dose of vaccine, any negative anti-HBs serum titers are uninterpretable. In these situations, the individual should consult with their health care provider regarding boosting or completing a second hepatitis B vaccine series before rechecking the serum titers.

9. Can anti-HBs levels following vaccination decline over time?

Yes. Following vaccination, anti-HBs levels decline over time. Immunocompetent people who achieve an anti-HBs level ≥ 10 mIU/mL 1–2 months after completing the hepatitis B vaccine series remain protected (presumably because of persistent cellular immunity), even if anti-HBs levels decline to < 10 mIU/mL beyond that time.

10. How long does protection from hepatitis B vaccine last?

Studies indicate that immunologic memory remains intact for at least 30 years among healthy people who initiated hepatitis B vaccination at > 6 months of age. The vaccine confers long-term protection against clinical illness and chronic hepatitis B virus infection. Cellular immunity appears to persist even though antibody levels might become low or decline below detectable levels. Booster doses of vaccine are not recommended once the health care worker (or health care student/trainee) has developed protective antibodies (an anti-HBs level ≥ 10 mIU/mL 1–2 months after completing the hepatitis B vaccine series).

11. If a nonimmune person had a high-risk exposure to hepatitis B virus and became infected, how long does it take to test HBsAg-positive after exposure?

HBsAg will be detected in an infected person's blood an average of four weeks (range: 1-9 weeks) after exposure to the virus. About half of patients will no longer be infectious by seven weeks after onset of hepatitis symptoms, and all patients who do not remain chronically infected will be HBsAg negative by 15 weeks after onset of symptoms.

12. Can Hepatitis B vaccine be given during pregnancy or lactation?

Yes, Hepatitis B vaccine contains no live virus, so neither pregnancy nor lactation should be considered a contraindication to vaccination of women. Until additional safety data are available for Heplisav-B (HepB-CpG) and PreHevbrio (3A-HepB) vaccines, providers should use Engerix-B or Recombivax HB single antigen (1A-HepB) vaccines to vaccinate pregnant women needing hepatitis B vaccination.

REFERENCES:

1. Hepatitis B Questions and Answers for Health Care Professionals
<https://www.cdc.gov/hepatitis/hbv/hbvfaqhtm#D3>
2. Heplisav-B (HepB-Cpg) Vaccine – Advisory Committee on Immunization Practices (ACIP) Recommendations
<https://www.cdc.gov/vaccines/schedule/vacc-updates/heplisav-b.pdf>
3. Schillie S, Harris A, Link-Gelles, R, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No.15);455-8.