

## **VFC Resolution Update: Hepatitis B Vaccine**

#### **Note**

 Red font in the presentation is used to indicate changes to the resolution in comparison to the currently approved version.

## **Purpose of the Resolution**

 The purpose of this resolution is to update the Recommended Vaccination Schedule and Intervals section to reflect updated ACIP recommendations about the use of Hepatitis B vaccine.

# **Eligible Groups**

• All children and adolescents birth through 18 years of age.

# **Recommended Vaccination Schedule and Intervals (1)**

The tables below list the acceptable vaccination schedules for children and adolescents, birth through 18 years of age.

**Table 1. Infants** 

		Single antigen vaccine <sup>1</sup>		Single-antigen <sup>1</sup> and combination vaccine <sup>2,3,4</sup>	
Birth weight	Maternal HBsAg status	Dose	Age	Dose	Age
≥2000 g	Positive	1	Birth (≤12 hrs) <sup>1</sup>	1	Birth (≤12 hrs ) <sup>1</sup>
		2	1-2 months <sup>1</sup>	2	2 months
		3	6 months	3	4 months
				4	6 months
	Unknown	1	Birth (≤12 hrs)¹	1	Birth (≤12 hrs)¹
		2	1-2 months <sup>1</sup>	2	2 months
		3	6 months	3	4 months
				4	6 months
	Negative <sup>5</sup>	1	2 months	1	2 months
		2	3-4 months	2	4 months
		3	6-18 months	3	6 months

## Recommended Vaccination Schedule and Intervals (2)

The tables below list the acceptable vaccination schedules for children and adolescents, birth through 18 years of age.

**Table 1. Infants** 

		Single antigen vaccine <sup>1</sup>		Single-antigen <sup>1</sup> and combination vaccine <sup>2,3,4</sup>	
Birth weight	Maternal HBsAg status	Dose	Age	Dose	Age
<2000 g	Positive	1	Birth (≤ <b>h2</b> s)¹	1	Birth (≤12 hrs)¹
		2	1 month <sup>1</sup>	2	2 months
		3	2-3 months	3	4 months
		4	6 months	4	6 months
	Unknown	1	Birth (≤12 hrs) <sup>1</sup>	1	Birth (≤12 hrs)¹
		2	1 month <sup>1</sup>	2	2 months
		3	2-3 months	3	4 months
		4	6 months	4	6 months
	Negative <sup>5</sup>	1	2 months	1	2 months
		2	3-4 months	2	4 months
		3	6-18 months	3	6 months

### **Recommended Vaccination Schedule and Intervals (3)**

#### Table Notes:

- 1. Only a single antigen hepatitis B vaccine (ENGERIX-B or RECOMBIVAX HB) can be given at <6 weeks of age.
- 2. Pediarix [DTaP-IPV-HepB] is licensed for children 6 weeks through 6 years of age. For adequate immune response, the last dose of hepatitis B vaccine should be given >24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4-week intervals for prevention of pertussis.
- 3. Vaxelis [DTaP-IPV-Hib-HepB] is licensed for children 6 weeks through 4 years of age. For adequate immune response, the last dose of hepatitis B vaccine should be given ≥24 weeks of age and therefore this combination vaccine should not be administered as a complete primary series on an accelerated schedule at 4-week intervals for prevention of pertussis.
- 4. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines.
- 5. Infants born to HBsAg-negative mothers may receive a dose of hepatitis B vaccine before two months of age under individual-based decision-making (also referred to as shared clinical decision-making), including consideration of risks such as a household member who is HBsAg positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common. Infants vaccinated before two months of age under individual-based decision-making may receive up to four doses of hepatitis B vaccine (1 dose of single antigen vaccine followed by 3 doses of combination vaccine).

# **Recommended Vaccination Schedule and Intervals (5)**

#### **Table 2. Children and Adolescents**

Age	Schedule <sup>1,6</sup>
Children (1 through 10 years)	0, 1, and 6 month's 0, 2, and 4 month's 0, 1, 2, and 12 month's
Adolescents (11 through 18 years)	0, 1, and 6 months 0, 1, and 4 months 0, 2, and 4 months 0, 12, and 24 months 0 and 46 months 0, 1, 2, and 12 months 0, 7 days, 2-80 days, 12 months

#### **Recommended Vaccination Schedule and Intervals (6)**

#### **Table Notes:**

- Children and adolescents not vaccinated at birth may be vaccinated according to any of the schedules indicated, except as noted. Selection of a schedule should consider the need to optimize compliance with vaccination.
- 2. Pediatric/adolescent formulation.
- 3. A two-dose schedule of Recombivax-HB Adult Formulation is (10 micrograms) is licensed for adolescents aged 11 through 15 years. When scheduled to receive the second dose, adolescents aged > 15 years should be switched to a three-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.
- 4. A four-dose schedule of Engerix B is licensed for all age groups.
- 5. Twinrix can be administered to persons 18 years of age before travel or any other potential exposure on an accelerated schedule at 0, 7, and 21-30 days, followed by a dose at 12 months.
- 6. Use of brand names is not meant to preclude the use of other comparable US licensed vaccines.

#### **Recommended Vaccination Schedule and Intervals (7)**

#### Interrupted schedules and minimum dosing intervals

- When the HepB vaccine schedule is interrupted, the vaccine series does not need to be restarted. If
  the series is interrupted after the first dose, the second dose should be administered as soon as
  possible, and the second and third doses should be separated by an interval of at least eight weeks.
   If only the third dose has been delayed, it should be administered as soon as possible.
- The final dose of vaccine must be administered at least eight weeks after the second dose and should follow the first dose by at least 16 weeks; the minimum interval between the first and second doses is four weeks. Inadequate doses of hepatitis B vaccine or doses received after a shorter-than recommended dosing interval should be re-administered, using the correct dosage or schedule.
- Vaccine doses administered ≤4 days before the minimum interval or age are considered valid.
   Because of the unique accelerated schedule for Twinrix, the four-day guideline does not apply to the first three doses of this vaccine when administered on a 0 day, 7 day, 21-30 day, and 12 month schedule.
- In infants, administration of the final dose is not recommended before age 24 weeks (164 days).

### Recommended Vaccination Schedule and Intervals (8)

#### Revaccination

Revaccination (i.e., booster dose, challenge dose, or revaccination with a complete series) is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, or adolescents. Revaccination when anti-HBs is <10 mIU/mL is recommended for the following:

- Infants born to HBsAg-positive mothers. HBsAg-negative infants with anti-HBs <10 mIU/mL should be re-vaccinated with a single dose of HepB vaccine and receive post vaccination serologic testing 1-2 months later. Infants whose anti-HBs remains <10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose.</li>
  - Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs
     <10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by post vaccination serologic testing (PVST) performed 1-2 months after the final dose of vaccine.</li>
- <u>Hemodialysis patients</u>. For hemodialysis patients, 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 <10 mIU/mL.

### **Recommended Vaccination Schedule and Intervals (9)**

#### Revaccination

- Other immunocompromised persons. 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. When anti-HBs levels decline to <10 mIU/mL, annual anti-HBs testing and booster doses should be considered for persons with an ongoing risk for exposure.</li>
- Persons with postvaccination serologic testing results that do not demonstrate protection. This includes children and adolescents through age 18 years who are chronic hemodialysis patients, HIV-infected, otherwise immunocompromised (e.g., hematopoietic stem-cell transplant recipients or persons receiving chemotherapy), or sex partners of HBsAg-positive persons. Persons in these groups found to have anti-HBs concentrations of <10 mIU/mL after the primary vaccine series should be revaccinated.</p>

### **Dosage, Contraindications, Precautions**

#### **Recommended dosage**

Refer to package inserts available at: <u>Vaccines Licensed for Use in the United States | FDA</u>

#### **Contraindications and Precautions**

Contraindications can be found in the package inserts available at: <u>Vaccines</u> Licensed for Use in the United States | FDA

#### **Statement Regarding Update Based on Published Documents**

• [If an ACIP recommendation or notice regarding hepatitis B vaccination immunization is published within 6 months following this resolution, the relevant language above (except in the eligible groups sections) will be replaced with the language in the recommendation and incorporated by reference to the publication URL.]