

## Pediatric Hepatitis B Vaccination Guidance during the Supply Shortage

Merck's supply of pediatric hepatitis B vaccine (Recombivax HB®) will continue to be limited through mid-2020. GSK will continue to be able to address supply gaps for pediatric hepatitis B vaccine during this period, using a combination of monovalent pediatric hepatitis B vaccine and its DTaP-HepB-IPV pediatric combination vaccine (Pediatrix).

This increase is sufficient to address the gap in supply related to Merck's manufacturing issue so that infants and young children can continue to receive their recommended hepatitis B vaccine series on time. Importantly, sufficient single-component hepatitis B vaccine will be available to continue to deliver the birth dose of hepatitis B vaccine for infants.

CDC has provided general guidance for pediatric hepatitis B vaccine and an implementation plan that provides options for giving vaccine during this time.

### **Pediatric hepatitis B vaccine general guidance:**

The recommendations for hepatitis B vaccination of infants have **not** changed.

Providers should continue with the recommendations as written in the [Advisory Committee on Immunization Practices \(ACIP\) hepatitis B vaccine recommendations](#).

- Only single-component hepatitis B vaccine should be used for any dose given before 6 weeks of age, including the birth dose.
- During this time, providers should prioritize birth dose vaccination and infant series completion over child and adolescent catch-up vaccination. However, children and adolescents who are at risk for infection as described in the [ACIP hepatitis B vaccine recommendations](#)<sup>1</sup> should be vaccinated.

### For infants whose mothers are hepatitis B surface antigen (HBsAg)-negative:

- Administer single-component hepatitis B vaccine to infants:
  - Weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, within 24 hours of birth
  - Weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, at 1 month of age or when discharged from the hospital
- The third HepB dose can be administered at 6–18 months.
- In populations with high rates of childhood HBV infection (e.g., Alaska Natives, Pacific Islanders, and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), the first dose of HepB vaccine should be administered at birth and the final dose at age 6–12 months.

### For infants whose mothers are HBsAg-positive or hepatitis B status unknown:

- Administer single-component hepatitis B vaccine to infants within 12 hours of birth. Complete the series within 6 months using available single-component or combination vaccine.
  - For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, the birth dose should not be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month.

For considerations of serology testing prior to vaccination, refer to the guidance on persons recommended to receive serologic testing prior to vaccination in the [ACIP hepatitis B vaccine recommendations](#).

For additional information, see the [Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger](#)<sup>2</sup>.

<sup>1</sup> ACIP hepatitis B vaccine recommendations can be found at:

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.PDF>.

<sup>2</sup> Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger can be found at:

<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.



## These sample immunization schedules apply to infants born to hepatitis B surface antigen-negative mothers

### 1. Using Pediarix for all doses after the birth dose

Birth <sup>1</sup>	2 months	4 months	6 months <sup>2</sup>	12–15 months	15–18 months
HepB	Pediarix DTaP-HepB-IPV	Pediarix DTaP-HepB-IPV	Pediarix DTaP-HepB-IPV		
					DTaP <sup>3</sup>
	Hib	Hib	Hib <sup>4</sup>	Hib	

### 2. Using Pediarix and single-component DTaP and IPV

Birth <sup>1</sup>	2 months	4 months	6 months <sup>2</sup>	12–15 months	15–18 months
HepB	Pediarix DTaP-HepB-IPV	DTaP	Pediarix DTaP-HepB-IPV		
		IPV			DTaP <sup>3</sup>
		Hib	Hib <sup>4</sup>	Hib	

### 3. Using Pentacel<sup>®</sup> and single-component HepB vaccine

Birth <sup>1</sup>	2 months	4 months	6 months <sup>2</sup>	12–15 months	15–18 months
HepB	HepB		HepB		
	Pentacel DTaP-IPV/Hib	Pentacel DTaP-IPV/Hib	Pentacel DTaP-IPV/Hib		DTaP <sup>3</sup>
				Hib	

### 4. Completing the hepatitis B series using all single-component vaccines

Birth <sup>1</sup>	2 months	4 months	6 months <sup>2</sup>	12–15 months	15–18 months
HepB	HepB		HepB		
	DTaP	DTaP	DTaP		DTaP <sup>3</sup>
	IPV	IPV	IPV		
	Hib	Hib	Hib <sup>4</sup>	Hib	

<sup>1</sup>For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, vaccine given at birth should NOT be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches 1 month of age. Complete the series within 6 months.

<sup>2</sup>For infants weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, vaccine given at birth DOES count as part of the vaccine series. Two additional doses (for a total of 3 doses) should be administered. A series that includes 4 doses is acceptable, but not required. Complete the series within 6 months.

<sup>3</sup>The 4<sup>th</sup> dose of DTaP may be administered as early as age 12 months, provided at least 6 months have elapsed since the 3<sup>rd</sup> dose.

<sup>4</sup>If using PedvaxHIB a dose at 6 months is not needed.

**These sample immunization schedules apply to infants born to hepatitis B surface antigen-positive or unknown status mothers**

1. Completing the hepatitis B series using Pediarix for all doses after the birth dose

<b>Birth<sup>1</sup></b>	<b>2 months</b>	<b>4 months<sup>2</sup></b>	<b>6 months</b>	<b>12–15 months</b>	<b>15–18 months</b>
HepB	Pediarix DTaP-HepB-IPV	Pediarix DTaP-HepB-IPV	Pediarix DTaP-HepB-IPV		
					DTaP <sup>3</sup>
	Hib	Hib	Hib <sup>4</sup>	Hib	

2. Completing the hepatitis B series using Pentacel

<b>Birth<sup>1</sup></b>	<b>2 months</b>	<b>4 months<sup>2</sup></b>	<b>6 months</b>	<b>12–15 months</b>	<b>15–18 months</b>
HepB	HepB	HepB	HepB		
	Pentacel DTaP-IPV/Hib	Pentacel DTaP-IPV/Hib	Pentacel DTaP-IPV/Hib		DTaP <sup>3</sup>
				Hib	

3. Completing the hepatitis B series using all single-component vaccines

<b>Birth<sup>1</sup></b>	<b>2 months</b>	<b>4 months<sup>2</sup></b>	<b>6 months</b>	<b>12–15 months</b>	<b>15–18 months</b>
HepB	HepB	HepB	HepB		
	DTaP	DTaP	DTaP		DTaP <sup>3</sup>
	IPV	IPV	IPV		
	Hib	Hib	Hib <sup>4</sup>	Hib	

<sup>1</sup>For infants weighing less than 2,000 grams (4 pounds, 6.5 ounces) at birth, vaccine given at birth should NOT be counted as part of the vaccine series. Three additional doses (for a total of 4 doses) should be administered beginning when the infant reaches 1 month of age. Complete the series within 6 months.

<sup>2</sup>For infants weighing 2,000 grams (4 pounds, 6.5 ounces) or more at birth, vaccine given at birth DOES count as part of the vaccine series. Two additional doses (for a total of 3 doses) should be administered. A series that includes 4 doses is acceptable, but not required. Complete the series within 6 months.

<sup>3</sup>The 4<sup>th</sup> dose of DTaP may be administered as early as age 12 months, provided at least 6 months have elapsed since the 3<sup>rd</sup> dose.

<sup>4</sup>If using PedvaxHIB a dose at 6 months is not needed.