



# Medication Management Clinical Practice Guidelines

TITLE:	NEWBORN HEPATITIS B IMMUNE GLOBULIN & VACCINE PROPHYLAXIS SCHEDULE	NUMBER:	80.28
Sponsor:	Drugs & Therapeutics Committee	Page:	1 of 4
Approved by:	Medical Advisory Committee	Approval Date:	March 5, 2019
		Effective Date:	March 26, 2019
Applies To:	Medical staff, Nursing, Pharmacy, Nurse Practitioners		

## GUIDELINES

### **A. Infants Born to Hepatitis B surface antigen POSITIVE Mothers:**

Infants born to Hepatitis B surface antigen **positive** mothers should receive Hepatitis B Immune Globulin **and** Hepatitis B vaccine to prevent perinatal transmission.

An order by an authorized prescriber is required for both Hepatitis B Immune Globulin and Hepatitis B vaccine.

### **Hepatitis B Immune Globulin\***

Dose: 0.5 mL intramuscularly immediately **after birth**. Efficacy decreases rapidly after 48 hours.

- Hepatitis B Immune Globulin **and** Hepatitis B vaccine may be given together, but at different sites (preferably different limbs).
- If exceptional circumstances prevent immediate administration of Hepatitis B Immune Globulin **and** Hepatitis B vaccine, give at the first possible opportunity. Do not delay unnecessarily.
- Obtain Hepatitis B Immune Globulin from Blood Bank.

**Note:** *\*Hepatitis B Immune Globulin preparations (HyperHEP B<sup>®</sup> S/D, HepaGam B<sup>®</sup>) are solutions of hepatitis B Ig for IM administration, prepared from pooled human plasma from screened donors with a high level of antibody to hepatitis B surface antigen. Hepatitis B Ig provides immediate short-term passive immunity. The two products are considered interchangeable.*

## Hepatitis B Vaccine

Dose: 0.5 mL intramuscularly as soon as possible and ideally **within 12 hours of birth**.

- Give second and third dose of vaccine series 1 and 6 months after first dose.
- Give fourth dose is required for infants with a birth weight of less than 2000 grams.
- Obtain inpatient dose(s) of Hepatitis B vaccine from Pharmacy or after hours from Birth Unit Pyxis Medstation.
- See Table I for vaccine dosing schedule

If a mother is identified as being Hepatitis B surface antigen-positive more than 7 days after delivery, the newborn should only receive Hepatitis B vaccine as efficacy of Hepatitis B Immune Globulin is unknown if given after 7 days.

- Infants born to HB-infected mothers should not be tested for HBsAg (to see if infant infected) and anti-HBs (to see if the infant is protected), prior to 9 months of age, in order to avoid detection of passive anti-HBs from HBIG administered at birth and to maximize the likelihood of detecting late HB virus infection. Testing should be conducted at least 1 month and no more than 4 months after the last dose of vaccine is administered, but not prior to 9 months of age. If HBsAg is present, the child will likely become a chronic carrier. If the infant is a vaccine non-responder (negative for both HBsAg and anti-HBs), additional doses of vaccine should be given with repeated serologic testing for antibody response.
- Neonates weighing less than 2000 grams born to infected mothers should have an individual schedule that includes Hepatitis B Immune globulin plus at least four doses of hepatitis B vaccine, and assessment of antibody response after the series had been completed.

<b>TABLE I</b>				
<b>Hepatitis B Vaccine Dosing Schedule</b>				
<b>Infants Born to Hepatitis B Surface Antigen POSITIVE Mothers</b>				
	<b>Infants less than 2000 grams</b>		<b>Infants 2000 grams or greater</b>	
<b>Mother HbsAg positive</b>	1 <sup>st</sup> dose	within 12 hours of birth (with Hepatitis B Immune globulin)	1 <sup>st</sup> dose	within 12 hours of birth (with Hepatitis B Immune globulin)
	2 <sup>nd</sup> dose	1 month after first dose	2 <sup>nd</sup> dose	1 month after first dose
	3 <sup>rd</sup> dose	2-3 months after first dose	3 <sup>rd</sup> dose	6 months after first dose
	4 <sup>th</sup> dose	6-7 months after 1 <sup>st</sup> dose		
<b>Dose</b>	Recombivax HB® 5 micrograms (0.5 mL) Engerix-B® 10 micrograms (0.5 mL)		Recombivax HB® 5 micrograms (0.5 mL) Engerix-B® 10 micrograms (0.5 mL)	

Note: Recombivax® and Engerix-B® can be used interchangeably even though their antigen content is not the same.

**B. Infants Born to Hepatitis B surface antigen NEGATIVE Mothers:**

If mother is Hepatitis B Surface Antigen **negative**, but other risk factors have deemed prophylaxis necessary (at the physicians discretion),

- See Table II for dosing schedule.
- Vaccine is administered in a 3-dose schedule: the second and third dose of the vaccine series are due 1 and 6 months after the first dose.

<b>TABLE II</b>					
<b>Hepatitis B Vaccine Dosing Schedule</b>					
<b>Infants Born to Hepatitis B Surface Antigen NEGATIVE Mothers</b>					
<b>Infants less than 2000 grams</b>			<b>Infants 2000 grams or greater</b>		
<b>Mother HbsAg negative</b>	1 <sup>st</sup> dose	at 2000 grams or upon discharge (whichever is sooner)		1 <sup>st</sup> dose	at birth
	2 <sup>nd</sup> dose	1 month after first dose		2 <sup>nd</sup> dose	1 month after first dose
	3 <sup>rd</sup> dose	6 months after first dose		3 <sup>rd</sup> dose	6 months after first dose
<b>Dose</b>	Recombivax HB® 5 micrograms (0.5 mL) Engerix-B® 10 micrograms (0.5 mL)			Recombivax HB® 5 micrograms (0.5 mL) Engerix-B® - 10 micrograms (0.5 mL)	

Note: Recombivax® and Engerix-B® can be used interchangeably even though their antigen content is not the same.

**REFERENCES**

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4. Canadian Immunization Guide Evergreen Edition: Accessed April 10, 2017  
<http://www.phac-aspc.gc.ca/publicat/cig-gci/p05-01-eng.php#hepa>
5. Pickering LK, Baker CJ, Long SS, McMillan JA, eds. *Red Book: 2009 Report of the Committee on Infectious Diseases*, 28<sup>th</sup> ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009. – hard copy on file.
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**Related Documents**

**Forms**

Consent to Treatment and Investigative Procedures - Form ID IWKCOOP

**IWK Policies Replaced**

(none)

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**Version History**

<b>Major Revisions (e.g. Standard 4 year review)</b>	<b>Minor Revisions (e.g. spelling correction, wording changes, etc.)</b>
July 3, 2012	June 2, 2015
March 5, 2019	April 2017
	Sept. 5/17 – updated & renamed as a Guideline, rewording page 2, bullet 2