# Yukon Immunization Program Manual

## Section 8 - Biological Products

## Hepatitis Vaccines

# SECTION 8 – BIOLOGICAL PRODUCTS

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## Hepatitis A Vaccine Indications

**Recommended and provided free to:**

- Individuals with haemophilia A or B receiving plasma-derived replacement clotting factors and testing negative for anti-HAV IgG/HAV total (combined IgM & IgG) negative. ❸
- Previously unimmunized anti-HCV positive individuals who are anti-HAV IgG/HAV total negative. ❸
- Previously unimmunized individuals chronically infected with Hepatitis B virus who are anti-HAV IgG/HAV total negative. ❸
- Individuals with other chronic liver disease (including cirrhosis and liver transplant candidates or recipients, liver damage from hemachromatosis) who are anti-HAV IgG/HAV total negative.❸
- Users of illicit injection drugs; persons sharing illicit drug snorting, smoking or injecting equipment.
- Men who have sex with men.
- Individuals with sexual life-style risks of infection where there is a likelihood of oral-anal contact.
- Individuals who are HIV positive.❹
- Inmates of correctional facilities in which there is epidemiological evidence of sustained Hepatitis A infection (on order of Medical Officer of Health only).
- Haematopoietic stem cell transplant (HSCT) recipients.
- Individuals receiving repeat blood transfusions or plasma-derived clotting factors.
- Contacts of a confirmed case of hepatitis A: ❶ Household, Close non-household, Daycare, Drug-sharing, Sexual contacts, Other food handlers at the same establishment if the case is a food handler, Patrons of involved food-handling establishment at risk of Hep A as assessed by Public Health staff.

**Recommended but not provided free to:**

- Travelers, military personnel, and others who will work or live in countries with intermediate or high endemic rates of HAV infection, especially when travel or work will involve rural or primitive conditions. ❷
- Persons with multiple sex partners.
- Food handlers.
- Employees who have been directed to receive this immunization, as per employer direction, must pay upfront for the immunization, i.e. Department of Highways & Public Works, City of Whitehorse.
- Zookeepers, veterinarians, and researchers who handle non-human primates; certain workers involved in research on Hepatitis A virus or the production of Hepatitis A vaccine.

❶ One dose of vaccine is to be provided when it is within 14 days after the last exposure to the case while case was in the infectious period. If a client received 1 dose of hepatitis A vaccine more than 24 weeks previously, provide a 2nd dose of hepatitis A vaccine. For more information on post-exposure prophylaxis, see Yukon Communicable Disease Guidelines, Chapter 3: Hep A.

❷ Travelers who opt not to undergo HAV immunization may consider Ig prophylaxis.

❸ That is, those who do not have evidence of past hepatitis A infection. Those who have started a vaccine series who now have positive serology should complete the series regardless of the interval between dose 1 & 2. Those who have not started a vaccine series with a positive anti-HAV IgG or HAV total are considered to have lab evidence of immunity against Hepatitis A.

❹ For individuals who are HIV positive, please contact YCDC for most recent CD4 counts prior to immunization.

| | |
|---|---|
| | **2019 August** |
| **Hepatitis A Vaccine (Inactivated Viral) (Havrix 720® and Havrix 1440®)** **Supplier: GlaxoSmithKline** | |
| **INDICATIONS** | See Hepatitis A Vaccine Indications |
| **INITIAL SERIES ❶ ❹** | **≥ 24 weeks up to and including 18 years of age: ❷❺**<br>**USING HAVRIX® presentation of 720 ELU per 0.5ml**<br>**Dose 1:** 0.5 ml **IM**<br>**Dose 2:** 0.5 ml **IM** 24 weeks - 12 months after dose 1 |
| | **≥ 19 years and older:**<br>**USING HAVRIX® presentation of 1440 ELU per 1.0 ml**<br>**Dose 1:** 1.0 ml **IM**<br>**Dose 2:** 1.0 ml **IM** (**1440 ELU presentation**)<br>**or** 0.5 ml **IM** (**720 ELU presentation**)<br>24 weeks - 12 months after dose 1❸ |
| **REINFORCEMENTS** | Currently no recommendation for booster dose(s). |
| **CONTRAINDICATIONS** | History of an anaphylactic reaction to a previous dose of any hepatitis A vaccine, to any component of HAVRIX ® vaccine or to latex (pre-filled syringe presentation only). |
| **VACCINE COMPONENTS** | Potential allergens: neomycin sulphate, bovine serum albumin.<br>Other components: formaldehyde, aluminium hydroxide, potassium chloride, disodium phosphate, monopotassium phosphate, polysorbate 20, amino acids. |
| **ADVERSE EVENTS** | Tend to be mild and transient.<br>**Local:** Soreness and redness at injection site<br>**Systemic:** Headache, fatigue, fever, malaise, and gastrointestinal symptoms |
| **SPECIAL CONSIDERATIONS** | Active immunization with hepatitis A vaccine is the first choice for protection against hepatitis A for travellers. Given the good serologic response to vaccine after the primary dose, simultaneous administration of Ig is **not** indicated even if the vaccine is given immediately before departure. Ig **may** be used for infants < 24 weeks of age and individuals for whom the vaccine is contraindicated.<br>Post – vaccination testing is not indicated following a Hepatitis A vaccine series |

❶ The hepatitis A vaccines may be used interchangeably, using the age-appropriate dose for the product being given.

❷ HAVRIX® 720 Junior is licensed for persons 1-18 years of age(inclusive). However, NACI indicates hepatitis A vaccine may be provided, beginning at 6 months of age, to infants who are at increased risk of infection or severe hepatitis A. Immune response may be blunted in some children less than 24 weeks of age due to interference with maternally derived antibody. As maternal hepatitis A antibody status is usually not know, contact the Immunization Program Manager to discuss giving Ig to infants less than 24 weeks of age who are at risk of hepatitis A.

❸ Studies have shown that 720 ELISA units provides an effective booster dose in those ≥19 years of age.

❹ For individuals who are HIV positive, please contact YCDC for most recent CD4 counts prior to immunization.

❺ A 1.0 mL of dose of adult formulation of Havrix®1440 should be used for those 16 - 18 years of age to address the licensing gap between Havrix®1440 and Vaqta pediatric when these are the only available products. This recommendation is required because the varied age approvals for Hepatitis A vaccine product lines in Canada. An adult dose (1.0 mL of Havrix®1440) in teens 16 – 18years of age will be immunogenic.

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## Hepatitis B Vaccine: Pre-exposure Indications

Provided free to: ❶❷

- All children ≤ 19 years of age.
- All Community Nursing personnel and Yukon Communicable Disease Control personnel.
- Household contacts of acute Hepatitis B cases or Hepatitis B chronic carriers.
- Sexual contacts of acute Hepatitis B cases or Hepatitis B chronic carriers.
- Users of illicit injectable drugs and their sexual partners.
- Persons sharing illicit drug snorting, smoking or injecting equipment.
- Males who have sexual contact with other males.
- Individuals who are HIV positive ❸❺
- Persons with multiple sexual partners or recent history of a sexually transmitted infection (STI).
- Anti-HCV positive individuals who do not have past or current evidence of hepatitis B infection.
- Individuals with significant chronic liver disease (including cirrhosis, candidates or recipients of liver transplant, and liver damage from hemachromatosis) who do not have past or current evidence of hepatitis B infection. ❸
- Hemophiliacs and others receiving repeated infusions of blood or blood products. Individuals with chronic kidney disease (predialysis, hemodialysis, and peritoneal dialysis clients) and candidates or recipients of a kidney transplant. ❸❹
- Previously unimmunized residents and staff of developmentally challenged known hepatitis B carriers whose behavior or medical condition increases risk to others
- Previously unimmunized children and staff in childcare settings in which there is a child infected with hepatitis B (upon order of Chief Medical Officer of Health).

Recommended but not provided free to:

- All Health Care Workers
- All employees who have been directed to receive this immunization, as per employer direction, must pay upfront for the immunization i.e. City of Whitehorse, Department of Highways & Public Works
- Persons visiting countries with high HBV endemic areas and/or having sexual or blood contact with local residents regardless of length of stay.

❶ Starting in 1994 YT has had either a school based or infant hepatitis B immunization program; therefore, many individuals born in 1983 through present day are immunized. If no records are available and the client is unable to recall receiving hepatitis B vaccine, proceed with hepatitis B vaccination as per indication.

❷ Pre-vaccination testing for HBsAg, anti-Hbc and anti-HBs is recommended for persons at high risk of having been infected (i.e., IDU, STW, individuals with HCV or chronic liver disease, and persons born in countries of high hepatitis B prevalence).

❸ **Routine Serology to determine protective status for hepatitis B is not recommended, except** in the following situations: Infants born to HBsAg positive mothers, health care workers and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids, sex partners of persons with chronic HBV infection, chronic liver, chronic renal & HIV infection. If anti-HBs is < 10IU/L but is detectable, provide one dose of vaccine and retest 4 weeks after this dose. If level is ≥ 10 following this dose, no further vaccine is required. When anti-HBs is <10 IU/L after this one dose, complete the second vaccine series and retest 4 weeks after the last dose. Do not complete more than 2 complete Hepatitis B series.

❹ Hemodialysis clients require a specific hepatitis B vaccine dosage and series. See Section 5, Immunization of Special Populations, Chronic Kidney Disease.

❺ For individuals who are HIV positive, please contact YCDC for most recent CD4 counts prior to immunization.

| 2019 August | |
|---|---|
| **Hepatitis B Vaccine (Engerix®-B)**<br>**Pediatric presentation 10 mcg/0.5 ml; Adult presentation 20mcg/1.0 ml**<br>**Supplier: GlaxoSmithKline** | |
| **INDICATIONS** | **INITIAL SERIES ❶❷❸❹❺❻** |
| **(1)** See Hepatitis B Vaccine Pre-exposure Indications<br>**(2)** See Hepatitis B Vaccine Post-exposure Indications<br>**(3)** Use when there is a contraindication to RecombivaxHB® or when RecombivaxHB® is not available | (1) (2) & (3)<br>Infants from birth, children, and adolescents to 19 years of age inclusive<br>(except the routine infant program and neonates who will be contacts of chronic carriers)<br>3 dose schedule:<br>Give 0.5 ml **IM** (10 mcg) at 0, 4 weeks and 24 weeks❷<br><br>Eligible adults ≥20 years of age<br>3 dose schedule:<br>Give 1.0 ml **IM** (20 mcg) at 0, 4 weeks and 24 weeks |
| **(4)** Adolescents ≥11 years of age, but ≤15 years of age at the initiation **and** completion of series. | (4)<br>**2 dose schedule:**<br>Give 1.0 ml **IM** (20 mcg) at 0 and 24 weeks (Use **adult dose** formulation)❼ |
| **REINFORCEMENTS** | None |
| **CONTRAINDICATIONS** | History of anaphylactic reaction to a previous dose of any hepatitis B vaccine or to any component of Engerix®-B. |
| **VACCINE COMPONENTS** | Aluminum hydroxide, and traces of yeast. Thimerosal ❷ |
| **ADVERSE EVENTS** | Fever (≤37.7°C) and mild short-term soreness at injection site. |

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## Hepatitis B Vaccine (Engerix®-B)
## Pediatric presentation 10 mcg/0.5 ml; Adult presentation 20mcg/1.0 ml

**Supplier: GlaxoSmithKline**

❶ Engerix®-B & RecombivaxHB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the respective product. There must be a minimum of 24 weeks between doses 1 and 2 whenever both products are used in a 2-dose series.

❷ The single dose pediatric formulation (10 mcg/0.5 ml vial) and the adult single dose (20 mcg/1.0 ml) formulation are thimerosal-free.

❸ A minimum of 4 weeks must pass between dose 1 and 2. Dose 3 must be given at least 16 weeks after the 1st dose and 8 weeks after the 2nd dose. If the immunization series is interrupted after the 1st dose, the 2nd dose should be administered as soon as possible. If only the 3rd is delayed, administer as soon as possible. If years have lapsed between the 1st and 2nd dose, it may be prudent to assess antibody response post series, especially if the client is at significant risk.

❹ Hemodialysis clients require a specific hepatitis B vaccine dosage and series (see Hepatitis B Vaccine Program for Chronic Kidney Disease Clients).

❺ **Routine serology to determine protective status for hepatitis B is not recommended, except** in the following situations: Infants born to HBsAg positive mothers, health care workers and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids, sex partners of persons with chronic HBV infection, chronic liver, chronic renal & HIV infection. If anti-HBs is < 10IU/L but is detectable, provide one dose of vaccine and retest 4 weeks after this dose. If level is ≥ 10 following this dose, no further vaccine is required. When anti-HBs is <10 IU/L after this one dose, complete the second vaccine series and retest 4 weeks after the last dose. Do not complete more than 2 complete Hepatitis B series.

❻ High risk infants who receive a birth dose of Hepatitis B vaccine and/or HBIg can complete their vaccine series with INFANRIX hexa® at 8 weeks, 16 weeks and 24 weeks of age.

Infants who have been given doses of Hepatitis B vaccine at birth **and** 4 weeks of age should be given PEDIACEL® vaccine at 8 weeks, 16 weeks and 24 weeks of age, and a 3rd dose of Hepatitis B vaccine at 24 weeks of age. These infants weighing < 2000 grams at birth will require a 4th dose of Hepatitis B vaccine at 32 weeks of age.

❼ There must be a minimum of 24 weeks between doses 1 and 2.

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| **Hepatitis B Vaccine Pre-Exposure (RecombivaxHB®)**<br>**Pediatric presentation: (5 mcg/0.5 ml); Adult presentation: (10 mcg/ 1mL); both thimerosal free**<br>**Supplier: Merck Frosst** |

| INDICATIONS | INITIAL SERIES ❶❷❸❹❼ |
|---|---|
| **(1)** Infants, weighing < 2000 grams at birth, whose father or other primary caregiver or household contact has chronic hepatitis B infection. | **(1) 4 dose schedule:**<br>Give 0.5ml **IM** (5mcg) at birth<br>Give INFANRIX hexa ® **IM** at 8 weeks,16 weeks and 24 weeks of age ❺ |
| **(2)** Infants who are part of the routine Hepatitis B program and receiving PEDIACEL® in the primary series | **(2) 3 dose schedule:**<br>Give 0.5 ml **IM** (5 mcg) at 8 weeks, 16 weeks and 24 weeks of age. |
| **(3)** Infants, weighing < 2000 grams at birth, who are receiving PEDIACEL® and whose father or other primary caregiver or household contact has chronic hepatitis B infection. | **(3) 4 dose schedule:**<br>Give 0.5ml **IM** (5mcg) at birth, 4 weeks, 24 weeks **and** 32 weeks of age |
| **(4)** Infants and children and adolescents to19 years of age inclusive (except the routine infant program, neonates who will be contacts of chronic carriers, and those in indication 5). | **(4) 3 dose schedule:**<br>Give 0.5 ml **IM** (5 mcg) at 0, 4 weeks and 24 weeks |
| **(5)** Adolescents ≥11years of age, but ≤15 years of age **at time of initiation & completion of series.** | **(5) 2 dose schedule:**<br>Give 1.0 ml **IM** (10 mcg) at 0 and 24 weeks❻ |
| **(6)** Eligible adults ≥20 years of age.<br>See Hepatitis B Vaccine Pre-exposure Indications<br>See Hepatitis B Vaccine Post-exposure Indications | **(6) 3 dose schedule:**<br>Give 1.0 ml **IM** (10 mcg) at 0, 4 weeks and 24 weeks. |

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| **REINFORCEMENTS** | None. |
| **CONTRAINDICATIONS** | History of anaphylactic reaction to a previous dose of any hepatitis B vaccine, to any component of RecombivaxHB® or to latex**.** |
| **VACCINE COMPONENTS** | Aluminum hydroxide, formaldehyde, yeast, and thimerosal when the 3 mL vial presentation is used. |
| **ADVERSE EVENTS** | Fever (≤37.7°C) and mild short-term soreness at injection site. |

**(continued on next page)**

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## Hepatitis B Vaccine Pre-Exposure (RecombivaxHB®)

**Pediatric presentation: (5 mcg/0.5 ml); Adult presentation: (10 mcg/ 1mL); both thimerosal free**

**Supplier: Merck Frosst**

❶ Engerix®-B & RecombivaxHB® are interchangeable at any dose, using age-specific dosage and recommended schedule for the respective product**.** There must be a minimum of 24 weeks between doses 1 and 2 whenever **both** products are used in a 2-dose series.

❷ A minimum of 4 weeks must pass between dose 1 and 2. Dose 3 must be given at least 16 weeks after the 1st dose and 8 weeks after the 2nd dose. If the immunization series is interrupted after the 1st dose, the 2nd dose should be administered as soon as possible. If only the 3rd is delayed, administer as soon as possible. If years have lapsed between the 1st and 2nd dose, it may be prudent to assess antibody response post series, especially if the client is at significant risk.

❸ Hemodialysis clients require a specific hepatitis B vaccine dosage and series (see Hepatitis B Vaccine Program for Chronic Kidney Disease Clients)

❹ A 0.5 ml (5mcg) Recombivax HB® dose represents a double dose for infants and children < 11 years of age, as per product monograph.

❺ Infants who have been given doses of Hepatitis B vaccine at birth and 4 weeks of age should be given PEDIACEL® vaccine at 8 weeks, 16 weeks and 24 weeks of age, and a 3rd dose of Hepatitis B vaccine at 24 weeks of age. These infants weighing < 2000 grams at birth will require a 4th dose of Hepatitis B vaccine at 32 weeks of age.

❻ While a second dose can be given 16 weeks – 24 weeks following the first dose, the dose is suggested at 24 weeks for consistent timing with other vaccine programs administered in the school setting.

❼ **Routine serology to determine protective status for hepatitis B is not recommended, except** in the following situations: Infants born to HBsAg positive mothers, health care workers and public safety workers at high risk for continued percutaneous or mucosal exposure to blood or body fluids, sex partners of persons with chronic HBV infection, chronic liver, chronic renal & HIV infection. If anti-HBs is < 10IU/L but is detectable, provide one dose of vaccine and retest 4 weeks after this dose. If level is ≥ 10 following this dose, no further vaccine is required. When anti-HBs is <10 IU/L after this one dose, complete the second vaccine series and retest 4 weeks after the last dose. Do not complete more than 2 complete Hepatitis B series.

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## Hepatitis B Vaccine Post-Exposure Indications

Provided free to:

- Infant born to **known** HBsAg + mother. **Give HBIg and hepatitis B vaccine at birth.** ❷
- Infant born to a mother who is at high risk for hepatitis B infection (intravenous drug use or sex trade work) and her infectious status at delivery is unknown or negative (possible window period); **give HBIg and hepatitis B vaccine at birth**. ❷
- Infants born to mother who has risk factors (other than IDU and/or STW) for hepatitis B infection and her infectious status at delivery is unknown or negative (possible window period). **Give hepatitis B vaccine at birth.** ❷
- Infant whose father or other primary care giver or household contact has chronic hepatitis B infection. **Give hepatitis B vaccine at birth.** ❷
- Infants from birth to <12 months of age if father or other primary caregiver are at high risk for hepatitis B infection and their infectious status is unknown or negative (possible window period). **Give hepatitis B vaccine at birth.** ❷
- Infant < 12 months of age whose mother has **acute** hepatitis B. ❶❷
- Household contacts (including infants) ❷of acute case or chronic carrier. ❶
- Sex with a person who has **acute or chronic** hepatitis B infection. ❶❸❹
- Percutaneous or mucosal exposure in the community (i.e. sexual assault, needle sticks) and household contacts with percutaneous or mucosal exposure (i.e. sharing of toothbrushes or razors) of **acute or chronic** hepatitis B infection. ❶❹

❶ Refer to Yukon Immunization Program, Section 16, Blood & Body Fluid Management for complete guidelines to assess need for HBIg and hepatitis B vaccine. These guidelines do not include post exposure to newborns. For newborn exposure see, Hepatitis B Vaccine Post Exposure (Recombivax HB).

❷ Post-vaccination testing (HBsAg and anti-HBs) of infants must be performed 4 weeks after completion of the hepatitis B vaccine series. If HBsAg is found, the infant is likely to become a chronic carrier. If the infant is negative for HBsAg and anti-HBs, a 2nd series of hepatitis B vaccine should be given and serological testing repeated 4 weeks post-series. See❶.

❸ For steady long-term sexual partners of chronic HBV carriers, test for HBsAg, anti-HBc and anti- HBs see section 16, chapter 4, p.21, Table 4 **Section 16 - Blood Body Fluid Exposure Management**

❹ Post-vaccination testing should be performed 4 weeks after completion of the hepatitis B vaccine series for **steady** sexual partners of HBV chronic carriers, household contacts of acute and chronic carriers, sexual assault victims and those with percutaneous or mucosal exposures.
See ❶.

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## Hepatitis B Vaccine Post-Exposure Indications Yukon & HBIg Availability

**Yukon & HBIg availability**

HBIG for post exposure prophylaxis is located in the following rural community facilities throughout the territory:

**Dawson City Hospital, Old Crow Health Center, and Watson Lake Hospital**

When you receive the HBIg there will be a transfer log enclosed. It must be completed and faxed to the WGH Lab when either a client has received HBIg or the Lot has expired. Arrangements for the timely administration of HBIg will be made on a case by case basis via Yukon Communicable Disease Control or the Chief Medical Officer of Health. Should HBIg not be stocked in the community requesting it, arrangements will be made by YCDC to have it provided from/to the most feasible location. See Yukon Communicable Disease Guidelines, **Hepatitis B**, How to Access HBIg.

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## Hepatitis B Vaccine Higher Dose Schedule

The following immunocompromised individuals may respond sub-optimally to hepatitis B vaccine and therefore require higher doses of the antigen to elicit an adequate immune response. This includes those with:

- Congenital immunodeficiency
- Hematopoietic stem cell transplant (HSCT) recipients❶
- Solid organ transplant candidates and recipients
- HIV infection

See Section 5 of the Yukon Immunization Manual for complete list of clients who are indicated.

Individuals with advanced liver disease (e.g., cirrhosis, physician-diagnosed advanced liver disease related to hepatitis C infection) who are non-responsive to the initial hepatitis B vaccine series (standard dosing), should be immunized as per the 'Hepatitis B Vaccine Higher Dose Schedule' for the second series. If a Fibroscan® result is available, consider F3 or 4 as indicative of advanced liver disease.

This higher dose schedule is defined as follows:

| | ENGERIX®-B | | | RECOMBIVAX HB®❸ | | |
|---|---|---|---|---|---|---|
| **Age** | **Dose** | **Volume** | **Schedule** | **Dose** | **Volume** | **Schedule** |
| 0-15 years | 20mcg | 1.0mL | 0, 1 and 6 months | 10mcg | 1.0mL | 0, 1 and 6 months |
| 16-19 years❷ | 40mcg | 2.0 mL | 0, 1, 2 and 6months | 10mcg | 1.0 mL | 0, 1 and 6 months |
| ≥20 years ❷ | 40mcg | 2.0 mL | 0, 1, 2 and 6months | 40mcg | ❸ | 0, 1 and 6 months |

**Post-vaccination serology:** Measure anti-HBs at 1-6 months after completion of the vaccine series to ensure that an adequate immune response has been achieved. If anti-HBs is ≥ 10 IU/L, consider immune. If anti-HBs is < 10 IU/L, provide a second vaccine series and re-assess anti-HBs 4 weeks later. If anti-HBs remains < 10 IU/L, consider as a non-responder and susceptible to hepatitis B.

**There is no benefit to further vaccination. If an exposure to blood or body fluids occurs, the client will require HBIg.**

**NOTE:** If post-vaccination serology was done more than 6 months after completion of the vaccine series, results may not be predictive of actual protection. Consider as immune those with anti-HBs ≥ 10 IU/L.

**However, if anti-HBs < 10 IU/L one of the following scenarios should be followed:**

- anti-HBs is undetectable - provide a second series and retest 4 weeks later.
- anti-HBs is read as "detectable" but < 10 IU/L - provide one dose of vaccine and retest 4 weeks later.
  - If level after the above dose is still < 10 IU/L - complete the second vaccine series and retest 4 weeks later.
  - If level after the above dose is ≥ 10 IU/L, consider immune.

If anti-HBs remains < 10 IU/L after 2 vaccine series - consider as a non-responder and susceptible to hepatitis B.

**If a client that would normally be a candidate for higher dose vaccine has already started but did not complete a normal dose series, the series should be completed with the normal dose and post-vaccination serology done as above to determine response. If anti-HBs is <10 IU/L, the second vaccine series should be at the higher dose.**

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## Hepatitis B Vaccine Higher Dose Schedule

Periodic monitoring for the presence of anti-HBs may be recommended by the specialist, for Immunocompromised persons and persons with chronic renal disease, taking into account the severity of the immunocompromised state and whether or not the risk for hepatitis B infection is still present. Booster doses should be offered if anti-HBs titres fall below 10 IU/L. If a higher vaccine dose was indicated for the initial vaccine series, a higher HB vaccine dose should be used for all subsequent immunizations.

❶ For HSCT clients contact Immunization Program Manager.
❷ If any dose in the series is given as ENGERIX®-B vaccine, the client will require a 4-dose series.
❸ Volume will depend on formulation of Recombivax HB® vaccine: HB 40 mcg = 1.0 mL; HB 10 mcg = 4 mL

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## Hepatitis B Vaccine Program for Chronic Kidney Disease Clients

Chronic hemodialysis clients are at high risk for HBV infection because the process of hemodialysis requires vascular access for prolonged periods. In an environment where multiple clients receive dialysis concurrently, repeated opportunities exist for person-to-person transmission of infectious agents, directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces or hands of personnel. Furthermore, hemodialysis clients are immunosuppressed, which increases their susceptibility to infection.

**ELIGIBILITY:**
All pre-dialysis, hemodialysis and peritoneal dialysis clients in hospital, community, home or self-care settings are eligible for this program. Vaccine administration often occurs at the dialysis facility; please verify if this has occurred prior to immunization and enter the appropriate immunization records into Panorama.

PRE-DIALYSIS AND DIALYSIS CLIENTS ❶❷

| | ENGERIX®-B | | | RECOMBIVAX HB® | | |
|---|---|---|---|---|---|---|
| **Age** | **Dose** | **Volume** | **Schedule** | **Dose** | **Volume** | **Schedule** |
| 0-15 years | 20 mcg | 1.0 mL | 0, 1 and 6 months | 10 mcg❹ | 1.0 mL | 0, 1 and 6 months |
| 16-19 years ❻ | 40 mcg | 2.0 mL | 0, 1, 2 and 6 months | 10 mcg❹ | 1.0 mL | 0, 1, and 6 months |
| ≥ 20 years of age❻ | 40 mcg | 2.0 mL | 0, 1, 2 and 6 months | 40 mcg❸ | 1.0 mL | 0, 1 and 6 months |

**Post-vaccination serology:** measure anti-HBs 4 weeks after completion of a primary series. If anti- HBs is <10 IU/L, the client is a non-responder. Provide a second vaccine series and assess anti- HBs. If anti-HBs is <10 IU/L, the client, as a non-responder to 2 vaccine series, is susceptible to hepatitis B. **There is no benefit to further vaccination. If an exposure to blood or body fluids occurs, the client will require HBIg.**

❶ All doses of hepatitis B vaccine should be administered in the deltoid by the **IM** route, or for infants < 12 months of age, in the vastus lateralis.
❷ Pre-dialysis clients and dialysis clients receive the same dose volume of hepatitis B vaccine because there is no discrete level of renal function that correlates well with vaccine immunogenicity.
❸ Special formulation for adult dialysis clients (40mcg/1.0 mL).
❹ Use adult formulation (10mcg/1.0ml).
❺ Use thimerosal-free Recombivax HB® or pediatric Engerix®-B formulation. Dosage for this age group is based on NACI guidelines.
❻ If any dose in the series is given as Engerix®-B, a **4 dose series** is required.

**2019 August**

## Hepatitis A and B Vaccine Combined (Inactivated Viral) (Twinrix®)

**Supplier: GlaxoSmithKline**

| INDICATIONS | INITIAL SERIES ❶❷❸ |
|---|---|
| **(1) Persons ≥ 19 years old**<br><br>**See Hepatitis A Vaccine: Indications & Hepatitis B Vaccine: Indications for usage recommendations.** | **(1) Persons 19 years of age and older:**<br>**3 dose schedule:**<br>Give 1.0 ml **IM** at 0, 4 weeks and 24 weeks<br><br>**Alternate rapid dosing schedule (3 +1 reinforcement):**<br>**Give 1.0 mL IM at 0, 7 and 21 days (+reinforcement 1 year after dose 1).** |
| **REINFORCEMENTS** | **(1)** None (3 dose at regular intervals complete)<br>• **For alternate rapid dosing schedule:** Give 1.0 mL **IM** 12 months after dose 1. |
| **CONTRAINDICATIONS** | History of anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B-containing vaccine, to any component of Twinrix® vaccine, or to latex. |
| **VACCINE COMPONENTS** | Neomycin sulfate, formaldehyde, aluminum hydroxide, aluminum phosphate, 2-phenoxyethanol, polysorbate 20, and traces of yeast. |
| **ADVERSE EVENTS** | **Local:** rarely, redness, swelling and pain<br>**Systemic:** fever (≤ 37.7° C), headache, malaise, fatigue, nausea |

❶ Each 1.0 ml dose contains Havrix® 720 ELU and Engerix®-B 20 mcg

❷ If a client is to be given monovalent hepatitis A vaccine in place of a dose (or doses) of Twinrix®, the following vaccines may be used: HAVRIX®, VAQTA®, AVAXIM™, or AVAXIM™ Pediatric, administering the age-specific dosage for the particular product. If a client is to be given monovalent hepatitis B vaccine in place of a dose (or doses) of Twinrix®, the following vaccines may be used: Engerix®-B or RecombivaxHB® administering the age-specific dosage and number of doses for the particular product.

❸ The preferred injection site for children and adults is the deltoid muscle. For those <12 months of age, the preferred site is the vastus lateralis. The vaccine should **not** be administered in the gluteal region.

❹ Twinrix ® is licensed for persons ≥1 year of age. However, numerous studies have demonstrated the immunogenicity and safety of hepatitis A vaccine for infants at 6 months of age. Immune response may be blunted in some children less than 6 months of age due to interference with maternally derived antibody. As maternal hepatitis A antibody status is usually not known, give Ig to all infants < 6 months of age who are at risk for hepatitis A. Consult Immunization Program Manager to discuss giving Ig to infants < 6 months of age who are at risk for hepatitis A.

| 2019 August | |
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| **Hepatitis A and B Vaccine Combined (Inactivated Viral) (Twinrix Junior®)**<br>**Supplier: GlaxoSmithKline** | |
| **INDICATIONS ❶❷❸❹** | **INITIAL SERIES** |
| **(1) Persons ≥ 24 weeks and ≤18 years of age.**<br><br>**See Hepatitis A Vaccine: Indications & Hepatitis B Vaccine: Indications for usage recommendations.** | **(1) Three dose schedule:**<br>Give **0.5 ml IM at**: 0, 4 weeks and 24 weeks.<br><br>• **Alternate rapid dosing schedule (3 +1 reinforcement):**<br>Give 0.5 ml IM at: 0, 7 and 21 days (+reinforcement one year after dose 1). |
| **REINFORCEMENTS** | (1) None for 3 dose series complete.<br><br>• **For alternate rapid dosing schedule only: Give 0.5mL IM 12 months after dose 1.** |
| **CONTRAINDICATIONS** | History of anaphylactic reaction to a previous dose of any hepatitis A or hepatitis B-containing vaccine or to any component of Twinrix Junior® vaccine, or to latex. |
| **VACCINE COMPONENTS** | Neomycin sulfate, formaldehyde, aluminum hydroxide, aluminum phosphate, 2-phenoxyethanol, polysorbate 20 and traces of yeast. |
| **ADVERSE EVENTS** | **Local:** rarely, redness, swelling and pain.<br>**Systemic:** fever (≤ 37.7° C), headache, malaise, fatigue, nausea |

❶ Each 0.5 ml dose contains Havrix®360 ELU and Engerix®-B 10 mcg.

❷ If a client is to be given monovalent hepatitis A vaccine in place of a dose (or doses) of Twinrix®, the following vaccines may be used: HAVRIX®, VAQTA®, AVAXIM™, or AVAXIM™ Pediatric, administering the age-specific dosage for the particular product. If a client is to be given monovalent hepatitis B vaccine in place of a dose (or doses) of Twinrix®, the following vaccines may be used: Engerix®-B or RecombivaxHB®, administering the age-specific dosage and the number of doses for the particular product.

❸ The preferred injection site for children and adults is the deltoid muscle. For those < 12 months of age, the preferred site is the vastus lateralis. The vaccine should not be administered in the gluteal region.

❹ Twinrix Junior® is licensed for persons ≥1 year of age. However, numerous studies have demonstrated the immunogenicity and safety of hepatitis A vaccine for infants at 6 months of age. Immune response may be blunted in some children less than 6 months of age due to interference with maternally derived antibody. As maternal hepatitis A antibody status is usually not known, give Ig to all infants < 6 months of age who are at risk for hepatitis A. Consult Immunization Manager to discuss giving Ig to infants < 6 months of age who are at risk for hepatitis A.