

## Hepatitis A Vaccine (HAV)

**Revision Date: June 30, 2016**

**Rationale for Policy Update:** NACI Update on recommended use of Hepatitis A vaccine for infants 6 months of age and older.

Please consult the Product Monograph <sup>1</sup> for further information about the vaccine.		
	<b>HAVRIX® 720 Junior and HAVRIX® 1440</b>	<b>VAQTA®, Pediatric and Adult</b>
<b>Manufacturer</b>	GlaxoSmithKline Inc.	Merck Canada Inc
<b>Licensed Use</b>	<ul style="list-style-type: none"> <li>HAVRIX® 720 Junior - individuals one year up to and including 18 years of age.</li> <li>HAVRIX® 1440 – Individuals 19 years of age and older.</li> </ul>	<ul style="list-style-type: none"> <li>Pediatric Presentation - individuals one year up to and including 17 years of age.</li> <li>Adult Presentation – Individuals 18 years of age and older.</li> </ul>
<b>Off-license Use</b>	<ul style="list-style-type: none"> <li>HAVRIX 720 Junior - infant candidates and recipients of solid organ transplantation (SOT) 6 – 11 months of age at high risk for hepatitis A. See <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 months</a></li> <li>HAVRIX 720 Junior – infants 6 months of age and older who meet eligibility criteria (see indications)<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>Pediatric Presentation - infant candidates and recipients of solid organ transplantation (SOT) 6 – 11 months of age at high risk for hepatitis A. See <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 months</a></li> <li>Pediatric Presentation – infants 6 months of age and older who meet eligibility criteria (see indications)<sup>2</sup></li> </ul>
<b>Indications for use of provincially funded vaccine</b>	<p><b>Pre-exposure:</b></p> <ul style="list-style-type: none"> <li>Individuals with chronic liver disease including hepatitis B carriers or anti-HCV positive persons.</li> <li>Individuals who will undergo or have had liver transplantation and individuals who have developed liver chronic graft versus host disease following hematopoietic stem cell transplantation. See:                             <ul style="list-style-type: none"> <li><a href="#">Immunization for Child Hematopoietic Stem Cell Transplant Recipients</a></li> <li><a href="#">Immunization for Adult Hematopoietic Stem Cell Transplant Recipients</a></li> <li><a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 months</a></li> <li><a href="#">Immunization for Child Solid Organ Transplant After 18 Months of Age</a></li> <li><a href="#">Immunization for Adult Solid Organ Transplant Candidates and Recipients.</a></li> </ul> </li> <li>Individuals receiving repeated replacement of plasma-derived clotting factors.<sup>2</sup></li> <li>Individuals with lifestyle risks of infection, including people engaging in illicit drug use (injectable and non-injectable)<sup>3</sup> and men having sex with men.</li> <li>Household or close contacts of children adopted from hepatitis A endemic countries.<sup>3</sup></li> <li>Residents of communities with high rates of hepatitis A infection, including inmates of provincial correctional facilities.</li> <li>Residents and staff of institutions for the developmentally challenged in which there is evidence of sustained hepatitis A transmission.</li> <li>Workers involved in hepatitis A virus research or production of hepatitis A vaccine who may be exposed to hepatitis A virus.<sup>3</sup></li> <li>Zoo-keepers, veterinarians and researchers who handle non-human primates.<sup>3</sup></li> </ul>	

	<p><b>Note:</b> Infants 6 – 11 months of age who are candidates or recipients of SOT and meet the above eligibility criteria for hepatitis A vaccine should receive the vaccine. See <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 months</a>.</p> <p><b>Pre-immunization serology for anti-HAV (IgG) is recommended for:</b></p> <ul style="list-style-type: none"> <li>• Individuals born prior to 1945<sup>4,5</sup></li> <li>• Individuals from an endemic country. All countries/areas of the world except those with very low risk for hepatitis A are to be considered endemic. Countries/areas with very low risk<sup>5,6,7</sup> include:          Andorra, Australia, Austria, Belgium, Canada, Denmark (including Faeroe Islands), Greenland, Finland (including Aland Islands), France, Germany, Greece, Iceland, Ireland, Italy, Japan, Liechtenstein, Luxembourg, Monaco, Netherlands, Norway, New Zealand, Portugal, San Marino, Spain, Sweden, Switzerland, United Kingdom and the United States.</li> <li>• Individuals with a history of hepatitis or jaundice that may have been caused by hepatitis A.<sup>3</sup></li> <li>• Adults who are diagnosed with hepatitis C.</li> <li>• Adults who are diagnosed with hepatitis B.</li> </ul> <p><b>Post-exposure:</b></p> <p>Post-exposure prophylaxis should be administered to susceptible contacts as soon as possible within 14 days of the last exposure to the case (when the exposure occurred while the case was in the infectious period) and may include hepatitis A vaccine, immune globulin or both. See specific recommendations below.</p> <ul style="list-style-type: none"> <li>• Contacts at risk of developing severe complications (i.e. those with chronic liver disease; hepatitis B carriers; individuals who are anti-HCV positive; candidates and recipients of liver transplant) and individuals who are immune compromised<sup>3</sup> (congenital and acquired immunodeficiency; immunosuppressive therapy and HIV infection) should receive both hepatitis A vaccine (two-dose series) and immune globulin. Both doses of hepatitis A vaccine will be provincially funded.</li> <li>• Contacts younger than 6 months of age<sup>2</sup> and individuals in whom hepatitis A vaccine is contraindicated should receive immune globulin only.<sup>2</sup> See <a href="#">Biologicals - Immune Globulin</a>.</li> <li>• All other contacts should receive hepatitis A vaccine.<sup>2,3</sup> One dose of hepatitis A vaccine will be provincially funded but individuals should be encouraged to receive the 2<sup>nd</sup> dose for long term protection. Both doses of vaccine will be provincially funded for individuals eligible to receive hepatitis A vaccine as outlined in pre-exposure indications.</li> </ul> <p><b>Note:</b> Hepatitis A vaccine may be considered if more than 14 days have elapsed since the last exposure, as there is no data on the outer limit of efficacy.<sup>3</sup> This would be at the discretion of the Medical Officer of Health, on a case-by-case basis.</p> <p>For disease information, contact assessment and reporting guidelines refer to <i>Public Health Notifiable Disease Management Guidelines –Hepatitis A</i>.<sup>8</sup></p>	
<p><b>Dose</b></p>	<p><b>HAVRIX® 720 Junior</b> (individuals 6 months up to and including 18 years of age):</p> <ul style="list-style-type: none"> <li>❖ 0.5 mL</li> </ul> <p><b>HAVRIX® 1440</b> (Individuals 19 years of age and older)</p> <ul style="list-style-type: none"> <li>❖ 1.0 mL</li> </ul>	<p><b>Pediatric/Adolescent Presentation</b> (children/adolescents 6 months up to and including 17 years of age):</p> <ul style="list-style-type: none"> <li>❖ 0.5 mL</li> </ul> <p><b>Adult Presentation</b> (adults 18 years of age and older):</p> <ul style="list-style-type: none"> <li>❖ 1.0 mL</li> </ul>

<b>Route</b>	Intramuscular injection
<b>Schedule</b>	<ul style="list-style-type: none"> <li>❖ Dose 1: day 0</li> <li>❖ Dose 2: 6 to 12 months after dose 1</li> </ul> <p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>• If the second dose in the hepatitis A vaccine series is missed, it can be administered at a later time without repeating the first dose.</li> <li>• Infant candidates or recipients of SOT. See <a href="#">Immunization for Children Expecting Solid Organ Transplant before 18 months</a>.</li> </ul> <p><b>Combined hepatitis A and B vaccine TWINRIX® eligibility:</b>          TWINRIX® should be considered for individuals who are eligible for both pre-exposure hepatitis A and hepatitis B vaccines and who do not require double-strength hepatitis B vaccine. See Biological Product - TWINRIX®</p>
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of hepatitis A vaccine or its packaging.</li> <li>• Anaphylactic or other allergic reactions to a previous dose of vaccine containing hepatitis A antigen.</li> </ul>
<b>Precautions</b>	It is possible that subjects may be in the incubation period of a hepatitis A infection at the time of immunization. It is not known whether or not hepatitis A vaccine will prevent hepatitis A in such cases. <sup>1</sup>
<b>Possible reactions</b>	<p><b>Local reactions:</b></p> <ul style="list-style-type: none"> <li>• Pain, redness, swelling and induration at the injection site.<sup>1</sup></li> <li>• Local side effects in children appear to be less frequent than in adults.<sup>3</sup></li> </ul> <p><b>Systemic reactions:</b></p> <ul style="list-style-type: none"> <li>• Headache, irritability, appetite loss, drowsiness, malaise, fatigue, fever, dizziness, rhinitis, rash, myalgia, and gastrointestinal symptoms.<sup>1</sup></li> <li>• Rarely hypoaesthesia, paraesthesia, pruritus and chills were reported.<sup>1</sup></li> <li>• Most side effects reported are generally mild and transient.<sup>3</sup></li> </ul> <p><u>For Havrix® only:</u></p> <ul style="list-style-type: none"> <li>• The following adverse events have been reported from post-marketing surveillance: anaphylaxis, allergic reactions, convulsions, vasculitis, arthralgia, angioneurotic edema, urticaria, and erythema multiforme.<sup>1</sup></li> </ul> <p><u>For Vaqta® only:</u></p> <ul style="list-style-type: none"> <li>• The following adverse events have been reported from post-marketing surveillance: very rarely Guillain-Barré Syndrome (GBS), cerebellar ataxia, encephalitis and thrombocytopenia.<sup>1</sup></li> </ul> <p>Refer to: <i>Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.</i><sup>9</sup></p>
<b>Pregnancy</b>	Hepatitis A vaccine may be administered to pregnant women when indicated. <sup>3</sup> The safety of hepatitis A vaccine administered during pregnancy has not been studied in clinical trials. Since the vaccine is prepared from inactivated viruses, any risk to the developing fetus is theoretical only. <sup>3</sup>
<b>Lactation</b>	Breastfeeding women should receive hepatitis A vaccine when indicated. <sup>3</sup>

### References

- <sup>1</sup> GlaxoSmithKline Inc. (2016, March 21). HAVRIX®: Hepatitis A vaccine, inactivated. *Product Monograph*. Merck Canada Inc. (2013, March 28). VAQTA®: Hepatitis A vaccine, purified inactivated. *Product Monograph*.
- <sup>2</sup> National Advisory Committee on Immunization. (2016, April). Update on the recommended use of Hepatitis A vaccine.
- <sup>3</sup> National Advisory Committee on Immunization. (2015). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. [www.canada.ca/en/public-health/services/canadian-immunization-guide.html](http://www.canada.ca/en/public-health/services/canadian-immunization-guide.html)
- <sup>4</sup> National Advisory Committee on Immunization. (2008, July). Statement on hepatitis A vaccines for travelers. *Canada Communicable Disease Report*, 34(ACS-2).
- <sup>5</sup> Grabenstein, JD. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013*. St. Louis, MO: Wolters Kluwer Health.
- <sup>6</sup> American Academy of Pediatrics. (2015). *Red Book: 2015 Report of the Committee on Infectious Diseases* (30<sup>th</sup> ed.). Elk Grove Village, IL: Author
- <sup>7</sup> World Health Organization. (2012). Hepatitis A Countries or Areas at Risk. Retrieved May 13, 2016 from [gamapserver.who.int/mapLibrary/Files/Maps/Global\\_HepA\\_ITHRiskMap.png](http://gamapserver.who.int/mapLibrary/Files/Maps/Global_HepA_ITHRiskMap.png)
- <sup>8</sup> Alberta Health. *Public Health Notifiable Disease Management Guidelines – Hepatitis A*. [www.health.alberta.ca/professionals/notifiable-diseases-guide.html](http://www.health.alberta.ca/professionals/notifiable-diseases-guide.html)
- <sup>9</sup> Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*. [www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf](http://www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf)