**Protocol for Administration of Hepatitis A (HepA) Vaccine**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Indications (Pre-exposure) \***

ACIP recommends HepA vaccination for pre-exposure protection from hepatitis A virus (HAV) infection for the following previously unvaccinated persons:

* **Routine vaccination**: All children aged 12 through 23 months
* **Catch-up vaccination** of unvaccinated children aged two through 18 years
* All persons aged 19 years and older seeking protection from hepatitis A virus (HAV) infection.
* **Persons in special populations** at increased risk for HAV infection, including:
	+ Persons traveling to or working in countries that have high or intermediate endemicity of infection \*;
	+ Men having sex with men;
	+ Persons who use injection and non-injection illicit drugs;
	+ Persons with clotting-factor disorders;
	+ Persons with chronic liver disease; and
	+ Persons working with HAV-infected primates or with HAV in a research laboratory;
	+ Persons who anticipate close personal contact (e.g., household contact or regular babysitting) with an international adoptee from a country of high or intermediate endemicity during the first 60 days following arrival of the adoptee in the United States.
	+ Food service workers who work in areas where community-wide hepatitis A outbreaks are occurring and where state and local health authorities or private employers determine that such vaccination is cost-effective

\* **Countries outside the US other than Canada, Australia, New Zealand, Japan, and Western Europe should be considered to have high or intermediate endemicity for hepatitis A virus.**

**Recommended Schedule for Single-Antigen Hepatitis A Vaccine Formulations**

* All children should receive hepatitis A vaccine (HepA) at **one year of age**
(i.e., 12 through 23 months of age). The two doses in the series should be administered at least six to 18 months apart.
* Children who have received one dose of HepA vaccine before age 24 months should receive a second dose six to 18 months after the first dose.
* Children aged 24 months through 18 years should receive a primary dose with one booster dose six to 18 months later.
* Adults aged 19 years and older should receive a primary dose with one booster dose
six to 18 months later
* Close contacts of an international adoptee should receive the first dose of the 2-dose HAV series as soon as adoption is planned, ideally two or more weeks before the arrival of the adoptee in the United States.

**Dosage and Route**

* 0.5-mL, intramuscular (IM) - Infants and children (Pediatric / Adolescent formulation - 12 months through 18 years of age)
* 1-mL intramuscular (IM) – Adults, 19 years of age and older (Adult formulation)

**HAVRIX®** (HepA vaccine manufactured by GlaxoSmithKline) is available in two formulations, which differ according to the person’s age:

* Persons aged 12 months through18 years, should receive 720 EL.U. per dose
(0.5-mL) in a 2-dose schedule
* Persons aged 19 years and older should receive 1,440 EL.U. per dose (1-mL) in a
2-dose schedule.

**VAQTA®** (HepA vaccine manufactured by Merck & Co., Inc) is licensed in two formulations, which differ according to the person’s age:

* Persons aged 12 months through 18 years should receive 25 U per dose (0.5-mL) in a
2-dose schedule;
* Persons aged 19 years and older should receive 50 U per dose (1-mL) in a
2-dose schedule.

The pediatric formulations of either **HAVRIX®** or **VAQTA®** are not FDA approved for administration to adults, aged 19 years and older.

**Anatomical Site**

* In children and adolescents (i.e., persons aged 12 months through 18 years), the deltoid muscle can be used if the muscle mass is adequate
* The needle size for children and adolescents can range from 22 to 25 gauge and from
7/8 to 1 ¼ inches, on the basis of the size of the muscle
* For toddlers, the anterolateral thigh can be used, but the needle is usually 1 inch. For adults (i.e., persons aged 19 years and older) the deltoid muscle is recommended for routine intramuscular vaccinations. The anterolateral thigh can be used. The suggested needle size is 1-1½ inches and 22-25 gauge.
* In adults (i.e., persons aged 19 years and older), the deltoid muscle can be used if the muscle mass is adequate

**Precautions**

* **Pregnancy:** *The safety of HepA vaccination during pregnancy has not been determined; however, because HepA vaccine is produced from inactivated hepatitis A virus (HAV), the theoretical risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to HAV*
* Prior to administering the vaccine, obtain a vaccination history to determine any reactions to any vaccine including HepA vaccine.

**See precautions in package insert** for administration to individuals with a history of bleeding disorders such as hemophilia or thrombocytopenia or to individuals on anticoagulant therapy.

* Persons with immunodeficiency (may have a suboptimal response)
* Latex allergy – **See WARNINGS in package insert** for information about any latex components in the vial stopper and / or prefilled syringes for the particular brand of hepatitis A vaccine being used.

**Contraindications**

Individuals with:

* **Allergy to vaccine components**Anaphylactic reaction to the vaccine or a constituent of the vaccine
* **Acute, moderate or severe illness with or without fever**

**Adverse Events**

* See the product’s package insert
* See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

* Store in refrigerator at 36oF – 46oF (2oC – 8oC)
* DO NOT FREEZE; discard if product has been frozen.

**Other Important Notes** --If administered concomitantly with immune globulin (IG), use a separate syringe and different anatomical site, preferably a different limb, for the administration of HepA vaccine.

**ADDITIONAL INFORMATION**

Preventing the spread of Hepatitis A virus to others:

* Educate on careful hand washing techniques and good hygiene
* Vaccination with hepatitis A is recommended for persons at increased risk for HAV infection or its consequences

**Post Exposure Prophylaxis** (e.g. During Hepatitis A outbreaks or as part of a contact investigation):

Persons who have recently been exposed to HAV and who have not been previously vaccinated should receive post exposure prophylaxis (PEP) as soon as possible and within two weeks of HAV exposure.

Options for Hepatitis A PEP, updated in 2017, include:

* Single antigen HepA vaccine is preferred for healthy persons aged 12 months through 40 years
* Immune globulin (IG) (new dose of 0.1 mL/kg).
	+ IG (0.1 mL/kg) should be used for children less than 12 months of age, immunocompromised persons, persons who have chronic liver disease, and persons for whom HepA vaccine is contraindicated.
	+ IG is preferred for persons aged 41 years and older, however HepA vaccine can be used if IG is not available
	+ IG may be used for persons eligible to be vaccinated, who elect not to receive HepA vaccine
* Both single antigen HepA vaccine and IG: Persons administered IG for whom HepA vaccine is also recommended for other reasons should receive a dose of vaccine simultaneously with IG. For persons who receive HepA vaccine the second dose to complete the series should be administered according to the licensed schedule.

**Preexposure Prophylaxis for International Travel**

HepA vaccine at the age-appropriate dose is preferred to IG (see page 1) for many people.

Travelers who elect not to receive HepA vaccine, who are aged <12 months, or who are allergic to a component of HepA vaccine should receive a single dose of IG before travel

For travel that will begin in ≤2 weeks to countries with high or intermediate hepatitis A endemicity \*, older adults, immunocompromised persons, and persons with chronic liver disease or other chronic medical conditions may receive IG simultaneously with HepA vaccine at a separate anatomic injection site.

The following doses of IG (updated in 2017) are recommended for preexposure prophylaxis:

**Length of Stay Dose**

Up to 1 month 0.1 mL/kg

Up to 2 months 0.2 mL/kg

More than 2 months 0.2 mL/kg (repeat every 2 months)

\* **Countries outside the US other than Canada, Australia, New Zealand, Japan, and Western Europe should be considered to have high or intermediate endemicity for hepatitis A virus.**

**References:**

New Recommendations to Increase the Dose of GamaSTAN S/D (Immune Globulin [Human]) When Used for Prophylaxis for Hepatitis A,

[https://www.fda.gov/new-prescribing-recommendations-for-IG-in-hepatitis-A-PEP](http://www.immunize.org/catg.d/p3085.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Nelson NP. Updated Dosing Instructions for Immune Globulin (Human) GamaSTAN S/D for Hepatitis A Virus Prophylaxis. MMWR Morb Mortal Wkly Rep 2017;66:959–960. DOI:  [http://dx.doi.org/10.15585/mmwr.mm6636a5](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-06-15-mening.pdf)

MMWR: Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 Through 18 Years — United States, 2017,

[https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf](https://www.vaccineshoppe.com/image.cfm).

Recommended Adult Immunization Schedule,

[http://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html](http://www.cdc.gov/hepatitis/Partners/Perinatal/EducationalMaterials.htm)

Recommended Childhood Immunization Schedule,

<http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

Package Insert: **HAVRIX®** (manufactured by GlaxoSmithKline) (Dated 05/2016)

<https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Havrix/pdf/HAVRIX.PDF>

Package Insert: **VAQTA**® (manufactured by Merck & Co., Inc) (Dated 02/2014)

<http://www.merck.com/product/usa/pi_circulars/v/vaqta/vaqta_pi.pdf>

Updated January 31, 2010, August 1, 2012, July 1, 2014 and October 12, 2017