IMMUNIZATIONS

STATEWIDE PROTOCOL

Iowa Board of Pharmacy

Table of Contents

| I. Purpose | 2 |
|---|----|
| II. Authority | 2 |
| III. Qualifications | 2 |
| IV. Authorization | 2 |
| V. Protocol, facility, and equipment | 2 |
| VI. Informed consent | 3 |
| VII. Record | 3 |
| VIII. Reporting | 3 |
| IX. Vaccination safety | 3 |
| X. Management of adverse events | 4 |
| XI. Vaccines | 4 |
| Appendix A: Required supplies and equipment | 5 |
| Appendix B: Screening questionnaire | 6 |
| Appendix C: Vaccine Administration Record | 7 |
| Appendix D: Management of Adverse Reactions | 8 |
| Appendix E: Adverse Reaction Log | 10 |
| Appendix F: Vaccine Information | 11 |

Pharmacists, according to and in compliance with Iowa Code section 155A.46, may order and administer immunizations as outlined in this protocol. For the purpose of this protocol, "pharmacist" shall mean a qualified pharmacist or pharmacist-intern pursuant to Iowa Administrative Code (IAC) rule 657—39.11(155A). This protocol acknowledges that the ACIP guidelines, law, and prescribing information may change or conflict with the terms of this protocol. In the case of conflict, ACIP guidelines, law, and prescribing information shall supersede this protocol. This protocol authorizes a pharmacist to exercise the pharmacist's professional judgment to administer a vaccine in accordance with the most current guidelines.

I. <u>Purpose</u>

Immunizations serve as a tool to reduce morbidity and mortality from preventable infectious diseases. This statewide protocol is intended to ensure that immunizations may be readily obtainable by any person who meets the criteria established by the United States Centers for Disease Control (CDC) and Prevention Advisory Committee on Immunization Practices (ACIP) for immunization administration.

II. <u>Authority</u>

This statewide protocol is issued pursuant to Iowa Code section 155A.46 which permits the ordering and administration of immunizations by a pharmacist in compliance with IAC rule 657—39.11(155A). For the purpose of this protocol, the pharmacist's order shall constitute a prescription.

III. <u>Qualifications</u>

A pharmacist administering vaccines pursuant to this protocol shall meet the requirements required in IAC rule 657—39.11(155A).

IV. <u>Authorization</u>

This protocol authorizes a pharmacist to order and administer the following immunizations in accordance with the parameters identified herein:

- A. To patients ages six months and older:
 - a. An immunization for influenza, and
 - b. Other immunizations in response to a public health emergency;
- B. To patients ages eleven years and older:
 - a. The final dose(s) in a course of vaccinations for human papillomavirus (HPV);
- C. To patients ages eighteen and older:
 - a. An immunization or vaccination recommended by the United States centers for disease control and prevention advisory committee on immunization practices in its approved vaccination schedule, and
 - b. An immunization or vaccination recommended by the United States Centers for Disease Control and Prevention for international travel.

V. <u>Protocol, Facility, and Equipment</u>

Pharmacists who administer vaccines under this protocol shall maintain a current copy of this protocol at each location at which a pharmacist administers a vaccine and an appropriately private area for administering vaccines with the supplies and equipment listed in Appendix A.

VI. <u>Informed Consent</u>

Before administering a vaccine, the pharmacist shall provide to the recipient or their legal representative information about the risks and benefits associated with the vaccination.

A. Vaccine Information Statements. The pharmacist shall provide to each recipient or the recipient's legal representative a copy of the most current Vaccine Information Statement (VIS) for the vaccine to be administered. The recipient or legal representative shall be given the opportunity to read the VIS prior to administration of the vaccine and the pharmacist shall provide answers to any questions raised. Non-English speaking persons shall be provided a copy of the VIS in their native language, if available.

B. Consent Form. Prior to vaccine administration, the pharmacist must document the informed consent of the recipient or the recipient's legal representative in writing. A sample consent form is provided in Appendix D. An equivalent consent form may be used.

VII. <u>Record</u>

A pharmacist administering a vaccine pursuant to this protocol must create a vaccination record for each recipient and must maintain this record in accordance with state and federal regulations. The record may include the Vaccine Administration Record in Appendix C or another record substantially equivalent. This vaccination record shall be readily retrievable and shall include the following:

(a) The name, address, date of birth, gender and telephone number of the recipient;

(b) A copy of the recipient's responses to eligibility questionnaires;

(c) The name, dose, manufacturer, expiration date, and lot number of the vaccine administered;

(d) The date of the administration of the vaccine and the injection site;

(e) A signed and dated consent form;

(f) A record of any adverse events or complications that arose following vaccination; and

(g) A copy of the notification letter sent to the recipient's designated primary health care provider of the vaccine administered.

VIII. <u>Reporting</u>

As soon as reasonably possible following administration of a vaccine, the pharmacist shall report the vaccine administration to the statewide immunization registry (<u>IRIS</u>) or health information network and to the patient's primary health care provider, if known.

Adverse Event Reporting – The pharmacist shall report any clinically significant event following vaccine administration to the Vaccine Adverse Event Reporting System (VAERS) and the recipient's primary health care provider within 24 hours, even if it is not certain that the event was caused by the vaccine. Clinically significant events include, but are not limited to: death, hypersensitivity reactions, and those events described in the manufacturer's package insert as contraindications to additional doses of vaccine.

IX. <u>Vaccination Safety</u>

A. *Infection Control and Sterile Technique*. Each pharmacist administering vaccines shall follow appropriate precautions to minimize risk for spread of disease. Hands shall be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water between each contact. Gloves shall be worn if the pharmacist administering the vaccine is likely to come into contact

with potentially infectious body fluids or has open lesions on his or her hands. Needles used for injections must be sterile and disposable to minimize the risk for contamination.

B. *Prevention of Needlestick Injuries*. To prevent inadvertent needle-stick injury or reuse, needles and syringes shall be discarded immediately after use in labeled, puncture-proof containers located in the same room where the vaccine is administered. Needles must not be recapped before being placed in the container. Safety needles or needle-free injection devices should be used to reduce the risk for injury.

X. <u>Management of Adverse Events</u>

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, recipients must be carefully screened for precautions and contraindications before the vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from inconvenient (e.g. soreness, itching) to severe and life threatening (e.g. anaphylaxis). If reactions occur, the pharmacist shall be prepared for their management. The procedures for managing adverse reactions are set forth in Appendix E.

XI. <u>Vaccines</u>

A pharmacist may order and administer US Food and Drug Administration (FDA) approved formulations of immunizations identified in section IV of this protocol, alone or in combination, provided they follow all requirements set forth in this protocol, assess patient eligibility according to indications, precautions, and contraindications recommended in current guidelines from the ACIP, and adhere to dosing and administration information provided by the manufacturer package inserts and ACIP recommended guidelines. A pharmacist should make a reasonable effort to ensure vaccination series initiated by the pharmacist are completed. Appendix F has additional information on dosing, injection route/site, directions for use, storage requirements, eligibility criteria, contraindications, precautions, and any additional applicable information.

APPENDIX A

REQUIRED SUPPLIES AND EQUIPMENT

The following items must be available in the area where vaccines are administered:

(1) A current copy of this Protocol.

(2) The most current federal VIS for vaccines being administered.

(3) Aqueous epinephrine USP (1:1000), in ampules, vials of solution, or prefilled devices (i.e. EpiPen and Epipen Jr). The amount of epinephrine stocked shall be sufficient to allow for the potential maximum number of doses prior to EMS arrival.

(4) Diphenhydramine (Benadryl) injectable solution (50 mg per mL) and/or oral 25 mg dosage form, to include tablets, capsules or liquid.

(5) Syringes: appropriate sized/type (e.g. filtered if using ampules) for emergency supplies and the vaccinations on hand.

(6) Alcohol swabs and bandages.

(7) Blood pressure monitoring device or stethoscope and sphygmomanometer (with appropriately sized cuffs).

(8) Appropriate sized pocket masks with one-way valve.

APPENDIX B

SCREENING QUESTIONNAIRE TO DETERMINE SAFETY OF ALL VACCINES

Prior to vaccine administration, the pharmacist shall assess the safety of the vaccine for a patient using a general screen questionnaire which is at least sufficiently comparable to the <u>Screening</u> <u>Checklist for Contraindications to Vaccines for Adults</u> provided by the CDC. Vaccine-specific screening questions must also be asked based on the vaccine's contraindications and precautions according to current ACIP guidelines and manufacturer's package inserts. The pharmacist shall document relevant responses and explanations provided in response to the screening questions.

PRECAUTION

Precaution must be taken before vaccine administration to a potential recipient with moderate or severe acute illness, with or without fever. Vaccination should be delayed until the illness has resolved.

REFERRAL

A potential recipient with any contraindications and/or complex medical issues including immunosuppression or history of Guillain-Barré syndrome should be referred to their primary health care provider.

LIVE VACCINES

Prior to the administration of a live vaccine, the pharmacist shall ask a patient the following general screening questions, in addition to the screening questionnaire used pursuant to Appendix B. Vaccine-specific screening questions shall also be asked based on the vaccine's contraindications and precautions according to ACIP guidelines and manufacturer package inserts.

1. Are you currently on home infusions or weekly injections (such as Remicade, Humira, Enbrel, Cimzia, Simponi, Simponi Aria, Xeljanz, Orencia, Arava, Actermra, Cytoxan, Rituxan, adalimumab, infliximab or etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?

2. Have you received any vaccinations or skin tests in the past four weeks?

3. Have you received a transfusion of blood, blood products or been given a medication called immune (gamma) globulin in the past year?

4. Are you currently taking high-dose steroid therapy (prednisone >20mg/day or equivalent) for longer than two weeks?

APPENDIX C

VACCINE ADMINISTRATION RECORD

This pharmacy is providing necessary vaccines to you in a safe and convenient setting in order to promote adherence to current immunization guidelines recommended by the CDC and ACIP. It does not take the place of an ongoing relationship with your primary care provider to address ongoing medical issues and other types of preventive care. We are providing your primary care provider with a copy of the vaccine(s) administered here so that your medical records may be complete, but be sure to take your personal record with you to your next appointment as well.

Please review the statement below confirming your consent for vaccination and provide the information requested above the dotted line.

I have read, or had explained to me, the Vaccine Information Statement for the [NAME OF] vaccine. I understand the risks and benefits, and have been provided an opportunity to ask questions, which have been answered to my satisfaction. I wish to receive the [NAME OF] vaccine and hereby give consent for the administration the vaccine(s) and communicate the administration of the vaccine(s) to my primary health care provider (HCP) listed below.

| Patient Name (printed) | Date of Birth |
|--|-----------------------------|
| Signature of patient or legal representative | Today's Date |
| Primary Health Care | |
| Vaccine Given: Dose: | VIS Date: |
| Method: IM / SQ Location: Right / Left Arm or Other Lot #: | |
| Manufacturer: | |
| Expiration Date: | |
| Identification of Administering Pharmacist or Pharma | acist-Intern |
| Pharmacy name and phone number for Administering | g or Supervising Pharmacist |
| Form sent to HCP (initials and date): | |
| Entered in IRIS (Initials and date): | |

APPENDIX D

MANAGEMENT OF ADVERSE REACTIONS TO VACCINE ADMINISTRATION

Prior to vaccine administration, if the patient exhibits **fright/agitation**, have the patient sit or lie down for the vaccine administration. Do not immunize a combative patient.

Following vaccine administration, the pharmacist shall observe the patient for immediate adverse reaction(s) to the vaccine(s). If no reaction is immediately evident, request that the patient remain for observation for a period of 10-15 minutes. If the patient displays any signs of any of the following reactions, the pharmacist shall execute the following procedures.

- If the patient experiences symptoms of a local reaction (e.g., **minor pain, redness, warmth, pruritus, swelling at injection site**):
 - O Apply ice to the injection site
 - O Consider administration of an analgesic
 - O Observe the patient closely for 30 minutes, watching for generalized symptoms
 - O Make sure the patient has the telephone number of a provider to contact in case condition deteriorates.
 - O If the patient does not progress to any other symptoms, send patient home and contact patient 4-6 hours later to assess recovery.
- If the patient becomes **pale** and/or **feels faint**, have the patient lie flat or sit in head down position for several minutes.
- If the patient **loses consciousness**, but has a steady pulse, normal blood pressure and respirations:
 - O Have the patient lie flat on their back with their feet elevated
 - O Have the patient rest in a quiet area for 30 minutes after regaining consciousness
 - O Notify the patient's primary care provider about the incident
 - O Continue to monitor vital signs. If the patient remains unconscious for more than 3 minutes, **CALL 911**.
- If the patient's vital signs are abnormal (decreased blood pressure, increased or irregular pulse, etc.):
 - O Place the patient flat on their back with their feet elevated
 - O CALL 911.
- If the patient experiences symptoms of an anaphylactic reaction (e.g., the sudden or gradual onset of **generalized itching**, **erythema (redness)**, or **urticaria (hives)**; **angioedema (swelling of lips, face, throat; bronchospasm (wheezing)**; **shortness of breath**; **shock**; **abdominal cramping**; or **cardiovascular collapse**:
 - O If symptoms are generalized, activate the emergency medical system (CALL 911) immediately (this should be done by a second person while the pharmacist assesses the level of consciousness, circulation, airway, and breathing of the patient)
 - O Place patient in a recumbent position and elevate the legs
 - O The first line therapy in anaphylaxis is epinephrine. There are no contraindications to epinephrine in the setting of anaphylaxis.
 - Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01ml/kg/dose (adult dose ranges from 0.3ml to 0.5ml, with maximum single dose of 0.5ml)
 - O If EMS has not arrived and symptoms are still present, the dose of epinephrine may be repeated every 5 to 15 minutes until emergency assistance arrives, depending on the patient's response

- O OPTIONAL TREATMENT: administer diphenhydramine (either orally or intramuscularly; the standard dose is 1-2mg/kg every 4-6 hours, up to 50mg maximum single dose). Do not attempt to give oral medications to a recipient who is not fully alert and able to swallow safely.
- O Monitor the patient closely and check vital signs (BP, pulse, respirations) every 2 to 5 minutes. Stay with patient until emergency assistance arrives.
- O If necessary, perform cardiopulmonary resuscitation (CPR) and maintain airway.
- O Keep patient in supine position unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
- O Record all vital signs, medications administered to the patient (including the time, dosage, response, and the name of the person who administered the vaccine), and other relevant clinical information concurrently in an adverse reaction medication log to be maintained by the pharmacy, a copy of which may be provided to EMS and/or the patient's primary care provider. An Adverse Reaction Log form is attached as Appendix E.
- O Notify the patient's primary health care provider as soon as reasonably possible. Each patient experiencing an anaphylactic reaction must be referred for evaluation, even if symptoms resolve completely. The pharmacist shall also report the adverse reaction to the VAERS within 24 hours.

APPENDIX E

ADVERSE REACTION LOG

Date and Time of Adverse Reaction(s):

Name and Date of Birth of Vaccine Recipient:

Name of Vaccine(s) Given:

Describe adverse reaction(s): (e.g., shortness of breath, angioedema, chest Pain, syncope, rash, etc.)

Describe interventions (include medications and dosage, CPR, etc.) for adverse reaction(s):

| Disposition: | (home, | EMS, | etc.) |
|--------------|--------|------|-------|
|--------------|--------|------|-------|

| Signature of Administering Pharmacist-Intern (if applicable) | Date: |
|--|-------|
| Signature of Administering or Supervising Pharmacist | Date: |
| Form sent to Primary HCP (Initials and date): | |
| Reported to VAERS (Initials and date): | |

Version 1.1 040520

APPENDIX F

VACCINE INFORMATION

The information contained within these tables is meant to serve as a quick resource for those following this protocol. It is not meant to be an all-inclusive source for information related to immunization guidelines. Please refer to US Centers for Disease Control & Prevention's Advisory Committee on Immunization Practices and applicable state and federal law for complete guidance.

<u>Influenza</u>

Flu vaccination contains many formulations with many factors impacting selection. Pharmacists should perform a thorough review of the ACIP's issued guidance each year prior to selection of formulations and eligible candidates for each formulation. Below are two tables taken from the Recommendations of the Advisory Committee on Immunization Practices— United States, 2019-20 Influenza Season¹ that can serve as quick references, but not as allinclusive documents to provide guidance.

TABLE 1. Influenza vaccines — United States, 2019–20 influenza season*

| Trade name (Manufacturer) | Presentation | Age indication | HA (IIVs and RIV4) or virus count (LAIV4) for each vaccine virus (per dose) | Route | Mercury (from thimerosal) (µg/0.5mL) |
|--|--|--|---|-------|--|
| IIV4—Standard Dose—Egg based [†] | | | | | |
| Afluria Quadrivalent (Seqirus) | 0.25-mL PFS [§] | 6 through 35 mos | 7.5 μg/0.25 mL [§] | IM¶ | _ |
| | 0.5-mL PFS [§] | ≥3 yrs | 15 μg/0.5 mL [§] | | _ |
| | 5.0-mL MDV [§] | ≥6 mos (needle/syringe) 18 through 64 yrs (jet injector) | | | 24.5 |
| Fluarix Quadrivalent (GlaxoSmithKline) | 0.5-mL PFS | ≥6 mos | 15 μg/0.5 mL | IM¶ | _ |
| FluLaval Quadrivalent (GlaxoSmithKline) | 0.5-mL PFS | ≥6 mos | $15 \mu g/0.5 m L$ | IM¶ | _ |
| | 5.0-mL MDV | ≥6 mos | | | <25 |
| Fluzone Quadrivalent (Sanofi Pasteur) | 0.25-mL PFS** | 6 through 35 mos | 7.5 μg/0.25 mL** | IM¶ | _ |
| | 0.5-mL PFS** | ≥6 mos | 15 μg/0.5 mL** | | _ |
| | 0.5-mL SDV** | ≥6 mos | | | _ |
| | 5.0-mL MDV** | ≥6 mos | | | 25 |
| IIV4—Standard Dose—Cell culture based | (ccIIV4) | | | | |
| Flucelvax Quadrivalent (Seqirus) | 0.5-mL PFS | ≥4 yrs | 15 μg/0.5 mL | IM¶ | _ |
| | 5.0-mL MDV | ≥4 yrs | | | 25 |
| IIV3—High Dose—Egg based [†] (HD-IIV3) | | | | | |
| Fluzone High-Dose (Sanofi Pasteur) | 0.5-mL PFS | ≥65 yrs | 60 µg/0.5 mL | IM¶ | _ |
| IIV3—Standard Dose—Egg based [†] with M | F59 adjuvant (allV3) | | | | |
| Fluad (Segirus) | 0.5-mL PFS | ≥65 yrs | 15 μg/0.5 mL | IM¶ | _ |
| RIV4—Recombinant HA | | | 13 | | |
| Flublok Quadrivalent (Sanofi Pasteur) | 0.5-mL PFS | ≥18 yrs | 45 μg/0.5 mL | IM¶ | _ |
| LAIV4—Egg based [†] | 0.5 112115 | 210,10 | 15 µg/ 0.5 mE | | |
| FluMist Ouadrivalent (AstraZeneca) | 0.2-mL | 2 through 40 yrs | 106.5-7.5 | NAS | |
| riumist Quadrivalent (Astrazeneca) | prefilled single-use intranasal sprayer | 2 through 49 yrs | fluorescent focus units/0.2 mL | INAS | — |

¹ Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2019-20 Influenza Season; Centers for Disease Control and Prevention MMWR, August 23, 2019

Abbreviations: ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; HA = hemagglutinin; IIV3 = inactivated influenza vaccine, trivalent; IIV4 = inactivated influenza vaccine, quadrivalent, IM = intramuscular; LAIV4 = live attenuated influenza vaccine, quadrivalent; MDV = multidose vial; NAS = intranasal; PFS = prefilled syringe; RIV4 = recombinant influenza vaccine, quadrivalent; SDV = single-dose vial.

- * Vaccination providers should consult FDA-approved prescribing information for 2019–20 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at https://www.fda. gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states. Availability of specific products and presentations might change and differ from what is described in this table and in the text of this report.
- ⁺ Persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.

- ⁵ The dose volume for Afluria Quadrivalent is 0.25 mL for children aged 6 through 35 months and 0.5 mL for persons aged ≥3 years.
 ⁹ Intramuscularly-administered influenza vaccines should be given by needle and syringe only, with the exception of the MDV presentation of Afluria Quadrivalent, which may alternatively be given by the PharmaJet Stratis jet injector for persons aged 18 through 64 years only. For adults and older children, the recommended site for IM influenza vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh. Additional guidance regarding site selection and needle length for intramuscular administration is available in the ACIP General Best Practice Guidelines for Immunization (https:// www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf).
- ** Fluzone Quadrivalent may be given to children aged 6 through 35 months as either 0.25 mL per dose or 0.5 mL per dose. No preference is expressed for one or the other dose volume for this age group. Persons aged ≥3 years should receive the 0.5-mL dose volume.

TABLE 2. Contraindications and precautions to the use of influenza vaccines — United States, 2019–20 influenza season*

| Vaccine type | Contraindications and conditions for which use is not recommended | Precautions |
|-----------------|--|---|
| IIV | History of severe allergic reaction to any component of the vaccine [†] or to a previous dose of any influenza vaccine | Moderate or severe acute illness with or without fever History of Guillain-Barré syndrome within 6 weeks after receipt of influenza vaccine |
| RIV4 | History of severe allergic reaction to any component of the vaccine | Moderate or severe acute illness with or without fever History of Guillain-Barré syndrome within 6 weeks after receipt of influenza vaccine |
| LAIV4 | History of severe allergic reaction to any component of the vaccine[†] or to a previous dose of any influenza vaccine Concomitant aspirin- or salicylate-containing therapy in children and adolescents Children aged 2 through 4 years who have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the past 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred within the past 12 months Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection) Close contacts and caregivers of severely immunosuppressed persons who require a protected environment Pregnancy Receipt of influenza antiviral medication within the past 48 hours | Moderate or severe acute illness with or without fever History of Guillain-Barré syndrome within 6 weeks after receipt of influenza vaccine Asthma in persons aged ≥5 years Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g., chronic pulmonary, cardiovascular [excluding isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus]) |

Abbreviations: ACIP = Advisory Committee on Immunization Practices; FDA = Food and Drug Administration; IIV = inactivated influenza vaccine; LAIV4 = live-attenuated influenza vaccine, quadrivalent; RIV4 = recombinant influenza vaccine, quadrivalent.

^{*} Vaccination providers should check FDA-approved prescribing information for 2019–20 influenza vaccines for the most complete and updated information, including (but not limited to) indications, contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at https://www.fda.gov/ vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.

⁺ History of severe allergic reaction (e.g., anaphylaxis) to egg is a labeled contraindication to the use of most IIVs and LAIV4. However, ACIP recommends that persons with a history of egg allergy may receive any licensed, recommended influenza vaccine that is otherwise appropriate for their age and health status. Those who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis) or who required epinephrine or another emergency medical intervention should be vaccinated in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions.

| Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | <u>Hepa</u> | <u>titis A</u> | |
|--|--|--|--|
| interval depends on vaccine brand Criteria for eligibility: Persons traveling to or working in countries with high or intermediate hepatitis A endemicity (i.e. all countries except the US, Canada, Japan, Australia, New Zealand, and Western Europe) Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infecter with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons nis settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)¹ Additional information: | Dosage: Adults: 1mL | Injection route and site: IM in deltoid | |
| Criteria for eligibility: Persons traveling to or working in countries with high or intermediate hepatitis A endemicity (i.e. all countries except the US, Canada, Japan, Australia, New Zealand, and Western Europe) Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! | | Storage: Refrigerate at 35-46°F (2-8°C) | |
| Persons traveling to or working in countries with high or intermediate hepatitis A endemicity (i.e. all countries except the US, Canada, Japan, Australia, New Zealand, and Western Europe) Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syring stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! | | | |
| endemicity (i.e. all countries except the US, Canada, Japan, Australia, New Zealand, and Western Europe) Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! | | | |
| Western Europe) Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! | | - | |
| Men who have sex with men (MSM) Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! | • | JS, Canada, Japan, Australia, New Zealand, and | |
| Injection or non-injection drug use Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever)! Additional information: | 1 | | |
| Work with hepatitis A virus in a research laboratory or with nonhuman primates infected with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | Men who have sex with men (MSM) | | |
| with hepatitis A virus Chronic liver disease Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | Injection or non-injection drug use | | |
| Close, personal contact with an international adoptee (e.g., household or regular babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | | laboratory or with nonhuman primates infected | |
| babysitting) during the first 60 days after arrival in the United States from a country with high or intermediate endemicity (administer the first dose as soon as the adoption is planned) Homelessness Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | Chronic liver disease | | |
| Healthy adults who have been exposed to hepatitis A virus in the prior 14 days and have not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | babysitting) during the first 60 days after high or intermediate endemicity (admini | r arrival in the United States from a country with | |
| not previously completed the 2-dose HepA series; adults older than age 40 years may receive immunoglobulin, if indicated Previously unvaccinated persons living with human immunodeficiency virus (HIV) infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | Homelessness | | |
| infection (regardless of CD4 count) Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ | not previously completed the 2-dose Hep receive immunoglobulin, if indicated | oA series; adults older than age 40 years may | |
| Persons who are not at risk but desire protection from hepatitis A Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | | | |
| Persons in settings for exposure, such as health care settings and care facilities Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | | otection from hepatitis A | |
| Contraindications: Immediate and/or severe allergic or hypersensitivity reaction to hepatitis A containing vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | | | |
| vaccines or any component of the formulation, including neomycin Precautions: Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | Contraindications: | | |
| Hypersensitivity to latex – some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | • • • • | | |
| syringe stoppers. Caution should be taken with immunization supplies when administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | Precautions: | | |
| administering immunizations to those with hypersensitivities to latex Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | • Hypersensitivity to latex – some brands | contain latex in the syringe tips, vial caps, and | |
| Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | syringe stoppers. Caution should be taken with immunization supplies when | | |
| Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹ Additional information: | administering immunizations to those with hypersensitivities to latex | | |
| fever); vaccination should not be delayed for patients with mild acute illness (with or without fever) ¹ Additional information: | • Defer administration in patients with mo | oderate or severe acute illness (with or without | |
| | fever); vaccination should not be delayed | | |
| | Additional information: | | |
| | | administration | |

| Нера | titis B |
|--|---|
| Dosage: Based on age and vaccine brand | Injection route and site: IM in deltoid |
| Directions for use: Inject 2 or 3 dose series | Storage: Refrigerate at 35-46°F (2-8°C) |
| at 0, 1, and 6 months. Number of doses is | |
| brand specific | |
| Criteria for eligibility: | |
| Chronic liver disease | |
| HIV infection | |
| HIV infection Percutaneous or mucosal risk of exposure to blood – this includes household contacts of HBsAg positive persons; adults younger than age 60 years with diabetes mellitus or aged 60 years or older with diabetes mellitus based on individual clinical decision; adults in predialysis care or receiving hemodialysis or peritoneal dialysis; recent or current injection drug users; health care and public safety workers at risk for exposure to blood or blood-contaminated body fluids Sexual exposure risk – this includes sex partners of HbsAG positive persons, sexually active persons not in a mutually monogamous relations, persons seeking evaluation for sexually transmitted infection Men who have sex with men (MSM) Those that receive care in a setting where a high proportion of adults have risks for hepatitis B infection, including facilities providing sexually transmitted disease treatment, drug abuse treatment and prevention services, hemodialysis and end-stage renal disease programs, institutions for developmentally disabled persons, health care settings targeting services to injection drug users or MSM, HIV testing and treatment facilities, and correctional facilities Travel to countries with high or intermediate hepatitis B endemicity Persons who are not at risk but desire protection from hepatitis B Pregnant persons who are at risk for infection or severe outcome from infection during | |
| pregnancy Contraindications: | |
| • Severe allergic or hypersensitivity reaction component of the formulation | on to yeast, hepatitis B vaccine, or any |
| Precautions: | |
| Defer administration in patients with more fever); vaccination should not be delayed without fever)¹ | oderate or severe acute illness (with or without for patients with mild acute illness (with or |
| • The ACIP recommends HBsAg testing for all pregnant females. Pregnancy itself is not a contraindication to vaccination; vaccination is recommended for those identified as being at risk for HBV infection ³ ; use of Heplisav-B is not recommended for pregnant women | |
| • Hypersensitivity to latex – some brands of syringe stoppers. Caution should be take administering immunizations to those with the second structure of the second structure o | |
| Additional information:Shake suspension prior to withdrawal or | administration |

| Hepatitis A/B | | |
|---|---|--|
| Dosage: 1mL | Injection route and site: IM in deltoid | |
| Directions for use: Inject at 0,1, and 6 months | Storage: Refrigerate at 35-46°F (2-8°C) | |
| ÷ 8 | neet criteria for eligibility in both the Hepatitis A individual sections for detailed eligibility criteria. | |
| Contraindications: Severe allergic or hypersensitivity reachepatitis A vaccine, or any component | ction to yeast, neomycin, hepatitis B vaccine, t of the formulation | |
| Precautions: | | |
| - | moderate or severe acute illness (with or without | |
| • | sk of hepatitis A or hepatitis B infection; | |
| vaccination should not be delayed for patients with mild acute illness (with or without fever) ¹ | | |
| , | ds contain latex in the syringe tips, vial caps, and | |
| syringe stoppers. Caution should be taken with immunization supplies when | | |
| administering immunizations to those with hypersensitivities to latex | | |
| • Animal reproduction studies have not been conducted with this combination. Inactivate | | |
| vaccines have not been shown to cause | e increased risks to the fetus ¹ | |
| Additional information: | | |
| Shake suspension prior to withdrawal | or administration | |

| Human Pap | <u>villomavirus</u> |
|--|---|
| Dosage: 0.5mL | Injection route and site: IM in deltoid |
| Directions for use: Inject final dose(s) in | Storage: Refrigerate at 35-46°F (2-8°C) |
| the series following initial vaccination; | protect from light |
| reference product insert for specific schedules | |
| Criteria for eligibility: | |
| Individuals aged 11-26 that have previou | sly received an initial HPV vaccination |
| (individuals aged 27-45 may be vaccinate | ed based on individual clinical decision) |
| The number of doses of HPV vaccine to b vaccination | be administered depends on age at initial HPV |
| Age ≥15 at initiation: Administer final tw months following initial dose (minimum | o doses in the series at 1–2 months and 6 intervals: 4 weeks between doses 1 and 2, 12 |
| 5 | ths between doses 1 and 3; repeat doses if given |
| Aged 11–14 years at HPV vaccine series is 5 months apart: Administer 1 dose | nitiation and received 1 dose or 2 doses less than |
| Aged 11–14 years at HPV vaccine series initiation and received 2 doses at least 5 months apart: No additional dose is needed | |

- Adults with immunocompromising conditions (including HIV infection) through age 26 years: Administer final two doses in the series at 1–2 months and 6 months following initial dose
- Men who have sex with men (including transgender persons) through age 26 years: Administer final dose(s) in the series depending on age at initial vaccination (see above)
- Pregnant women through age 26 years: HPV vaccination is not recommended during pregnancy, but there is no evidence that the vaccine is harmful and no intervention needed for women who inadvertently receive HPV vaccine while pregnant; delay remaining doses until after pregnancy; pregnancy testing is not needed before vaccination

• Severe allergic or hypersensitivity reaction to yeast, a previous dose of the vaccine, or any component of the formulation

Precautions:

• Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹

Additional information:

• Shake suspension prior to withdrawal or administration

| <u>Measles, Mumps, Rubella Vaccine (Live)</u> | | |
|---|--|--|
| Dosage: 0.5mL Injection route and site: SC in | | |
| | posterolateral fat of upper arm | |
| Directions for use: Inject at 0 and >4 weeks | Storage: Refrigerate at 35-46°F (2-8°C) | |
| | protect from light | |

Criteria for eligibility:

- Administer 1 dose of measles, mumps, and rubella vaccine (MMR) to adults with no evidence of immunity to measles, mumps, or rubella
- Evidence of immunity: documentation of adequate MMR vaccination, laboratory evidence of immunity or disease, or persons born before 1957 (except for health care personnel, see below)
- Documentation of a health care provider-diagnosed disease without laboratory confirmation is not considered evidence of immunity Special populations
- Pregnant women and non-pregnant women 18 years and older with no evidence of immunity to rubella: Administer 1 dose of MMR (if pregnant, administer MMR after pregnancy and before discharge from health care facility)
- HIV infection and CD4 cell count ≥200 cells/µL for at least 6 months and no evidence of immunity to measles, mumps, or rubella: Administer 2 doses of MMR at least 28 days apart
- Students in postsecondary educational institutions, international travelers, and household contacts of immunocompromised persons (at least 18 years of age): Administer 2 doses of MMR at least 28 days apart (or 1 dose of MMR if previously administered 1 dose of MMR)

- Health care personnel born in 1957 or later with no evidence of immunity (at least 18 years of age): Administer 2 doses of MMR at least 28 days apart for measles or mumps, or 1 dose of MMR for rubella (if born before 1957, consider 2 doses of MMR at least 28 days apart for measles or mumps or 1 dose for rubella)
- Adults who previously received 2 doses of mumps containing vaccine and are identified by public health authority to be at increased risk for mumps in an outbreak: Administer 1 dose of MMR

- Hypersensitivity to measles, mumps, and/or rubella vaccine or any component of the formulation, including neomycin
- Current febrile respiratory illness or other febrile infection
- Patients receiving immunosuppressive therapy (does not include corticosteroids as replacement therapy)
- Primary and acquired immunodeficiency states
- Individuals with blood dyscrasias, leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic systems
- Family history of congenital or hereditary immunodeficiency (until immune competence in the vaccine recipient is demonstrated)
- Pregnancy

Precautions:

- Defer administration in patients with moderate or severe acute illness (with or without fever). Although fever is a contraindication per the manufacturer, current guidelines allow for administration to patients with mild acute illness (without fever)^{1, 4}
- Blood (e.g., whole blood, packed red blood cells, and plasma) and other antibodycontaining blood products (e.g., immune globulin, hyperimmune globulin, and IGIV) can inhibit the immune response to measles and rubella vaccines for 3-11 months depending on indication and product received¹

Additional information:

• Documentation from provider of disease is not considered adequate evidence of immunity

| Meningococcal Conjugate Vaccine, Groups A, C, Y, and W-135 | | |
|--|---|--|
| Dosage: 0.5mL | Injection route and site: IM in deltoid | |
| Directions for use: 1 or 2 doses depending | Storage: Refrigerate at 35-46°F (2-8°C), | |
| on indication, then booster every 5 years if risk | protect from light | |
| remains | | |
| Criteria for eligibility: | | |
| Administer 2 doses of MenACWY at lease | t 8 weeks apart and revaccinate with 1 dose of | |
| MenACWY every 5 years, if the risk remains, to adults with the following indications: | | |
| Anatomical or functional asplenia (including sickle cell disease and other | | |
| hemoglobinopathies) | | |
| HIV infection | | |
| Persistent complement component deficiency | | |

• Eculizumab or ravulizumab use

- Administer 1 dose of MenACWY and revaccinate with 1 dose of MenACWY every 5 years, if the risk remains, to adults with the following indications:
 - Travel to or live in countries where meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or during the Hajj (Muslim pilgrimage to Mecca)
 - $\circ~$ At risk from a mening ococcal disease outbreak attributed to serogroup A, C, W, or Y
 - Microbiologists routinely exposed to Neisseria meningitides
 - Administer 1 dose of MenACWY to the following:
 - Military recruits
 - First-year college students who live in residential housing (if they did not receive MenACWY at age 16 years or older)

• Severe hypersensitivity (e.g., anaphylaxis) to other meningococcal-containing vaccines or any component of the formulation including diphtheria toxoid or CRM197 (a diphtheria toxin carrier protein)

Precautions:

- Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹
- Guillain-Barré syndrome (GBS): Risk of developing GBS may be increased following vaccination in persons previously diagnosed with GBS. Individuals with a previous history of GBS should only receive Menactra after an assessment of risks and benefits

| Meningococcal Group B | | |
|---|--|--|
| Dosage: 0.5mL | Injection route and site: IM in deltoid | |
| Directions for use: 2 or 3 doses depending | Storage: Refrigerate at 35-46°F (2-8°C) | |
| on vaccine | | |
| Criteria for eligibility: | | |

- May administer to adults aged 18 and, based on individual clinical decision, to adults aged 19–23 years who are not at increased risk 2-dose series of MenB-4C (Bexsero) at least 1 month apart or 2-dose series of MenB-FHbp (Trumenba) at least 6 months apart (MenB-4C and MenB-FHbp are not interchangeable)
- Administer 2-dose series of MenB-4C at least 1 month apart or 3-dose series of MenB-FHbp at 0, 1–2, and 6 months to adults with the following indications (if dose 2 administered at least 6 months after dose 1, dose 3 not needed; 1 dose MenB booster 1 yr after primary series and revaccinate every 2-3 years if risk remains):
 - Anatomical or functional asplenia (including sickle cell disease)
 - Persistent complement component deficiency
 - Eculizumab or ravulizumab use
 - At risk from a meningococcal disease outbreak attributed to serogroup B
 - Microbiologists routinely exposed to *Neisseria meningitidis*

Contraindications:

• Severe hypersensitivity to the meningococcal group B vaccine or any component of the formulation

Precautions:

- Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹
- Hypersensitivity to latex some brands contain latex in the syringe tips, vial caps, and syringe stoppers. Caution should be taken with immunization supplies when administering these immunizations to those with hypersensitivities to latex
- Delay vaccination until after pregnancy unless at increased risk and vaccination benefits outweigh potential risks

Additional information:

- Vaccine does not provide protection against all circulating meningococcal group B strains
- Current vaccines are FDA approved for ages 10-25

| Pneumococcal (PCV13 and PPSV23) | |
|---|---|
| Dosage: 0.5mL | Injection route and site: IM in deltoid; PPSV23 |
| | may be administered SC, however IM is preferred |
| Directions for use: See Criteria for | Storage: Refrigerate at 35-46°F (2-8°C) |
| eligibility | |
| Critaria for aligibility | |

Criteria for eligibility:

- Administer to immunocompetent adults aged 65 years or older 1 dose of 23-valent pneumococcal polysaccharide vaccine (PPSV23); if PPSV23 was administered prior to age 65, administer 1 dose PPSV23 at least 5 years after previous dose
- May administer, based on individual clinical decision, to immunocompetent adults aged 65 years or older 1 dose of 13-valent pneumococcal conjugate vaccine (PCV13), if not previously administered, followed by 1 dose of PPSV23 at least 1 year after PCV13; if PPSV23 was previously administered but not PCV13, administer PCV13 at least 1 year after PPSV23
- When both PCV13 and PPSV23 are indicated, administer PCV13 first (PCV13 and PPSV23 should not be administered during the same visit); additional information on vaccine timing is available at <u>Pneumococcal Vaccine Timing for Adults</u>
- Administer to adults aged 19 through 64 years with the following chronic conditions 1 dose of PPSV23 (at age 65 years or older, administer 1 dose of PCV13, if not previously received, and another dose of PPSV23 at least 1 year after PCV13 and at least 5 years after PPSV23):
 - Chronic heart disease (excluding hypertension)
 - Chronic lung disease
 - Chronic liver disease
 - o Alcoholism
 - Diabetes mellitus
 - Cigarette smoking

- Administer to adults aged 19 years or older with the following indications 1 dose of PCV13 followed by 1 dose of PPSV23 at least 8 weeks after PCV13, and a second dose of PPSV23 at least 5 years after the first dose of PPSV23 (if the most recent dose of PPSV23 was administered before age 65 years, at age 65 years or older, administer another dose of PPSV23 at least 5 years after the last dose of PPSV23):
 - Immunodeficiency disorders (including B- and T-lymphocyte deficiency, complement deficiencies, and phagocytic disorders)
 - HIV infection
 - Anatomical or functional asplenia (including sickle cell disease and other hemoglobinopathies)
 - Chronic renal failure and nephrotic syndrome
 - Leukemia, lymphoma, Hodgkin disease, generalized malignancy, iatrogenic immunosuppression (drug or radiation therapy), solid organ transplant, multiple myeloma
- Administer to adults aged 19 years or older with the following indications 1 dose of PCV13 followed by 1 dose of PPSV23 at least 8 weeks after PCV13 (if the dose of PPSV23 was administered before age 65 years, at age 65 years or older, administer another dose of PPSV23 at least 5 years after the last dose of PPSV23):
 - Cerebrospinal fluid leak
 - Cochlear implant

• Severe allergic reaction (e.g. anaphylactic/anaphylactoid reaction) to pneumococcal vaccine or any component of the formulation

Precautions:

• Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹

Additional information:

• PCV13 and PPSV23 should not be administered during the same office visit

| Tetanus and Diphtheria Toxoids (Td) | | |
|--|--|--|
| Dosage: 0.5mL | Injection route and site: IM in deltoid | |
| Directions for use: Vaccinated: Inject once | Storage: Refrigerate at 35-46°F (2-8°C) | |
| every 10 years | | |
| Unvaccinated: Inject at 0, 1, and 6-12 months | | |
| Critaria for aligibility | | |

Criteria for eligibility:

- Persons at least 18 years of age who have not received at least 3 doses of tetanus and diphtheria toxoid-containing vaccine (at least one of which should be Tdap)
- Persons at least 18 years of age who have not received a tetanus and diphtheria toxoidcontaining vaccine in the previous 10 years
- Persons at least 18 years of age with a recent deep, dirty wound with no evidence of a tetanus toxoid-containing vaccine in the previous 5 years (may administer Td or Tdap)

Contraindications:

• Hypersensitivity to diphtheria, tetanus toxoid, or any component of the formulation

Precautions:

- Defer administration in patients with moderate or severe acute illness (with or without fever); vaccination should not be delayed for patients with mild acute illness (with or without fever)¹
- Guillain-Barré syndrome: Use with caution if Guillain-Barré syndrome occurred within 6 weeks of prior tetanus toxoid-containing vaccine⁵
- Arthus-type hypersensitivity: Patients with a history of severe local reaction (Arthustype) following a previous diphtheria toxoid or tetanus toxoid-containing vaccine dose should not be given further routine or emergency doses of Td unless ≥10 years since most recent dose, even if using for wound management with wounds that are not clean or minor; these patients generally have high serum antitoxin levels⁵

Additional information:

- Those seeking tetanus prophylaxis as part of wound management may be referred to their PCP at the discretion of the pharmacist
- Shake suspension prior to withdrawal or administration
- For persons that have not received Tdap, substitute one dose of Tdap for Td preferably the first dose

| Tetanus toxoid, reduced diphtheria t | toxoid, and acellular pertussis (Tdap) |
|--|--|
| Dosage: 0.5mL | Injection route and site: IM in deltoid |
| Directions for use: Inject 1 time | Storage: Refrigerate at 35-46°F (2-8°C) |
| Criteria for eligibility: | |
| | not receive a dose of Tdap as an adult or child |
| (routinely recommended at age 11–12 years) 1 dose of Tdap, followed by a booster every | |
| 10 years_of a dose of either tetanus and diphtheria toxoids (Td) or Tdap | |
| • Pregnant women at least 18 years of age: Administer 1 dose of Tdap during each | |
| pregnancy, preferably in the early part of gestational weeks 27–36 | |
| • Persons at least 18 years of age with a recent deep, dirty wound with no evidence of a | |
| | previous 5 years (may administer Tdap or Td) |
| Contraindications: | |
| Hypersensitivity to diphtheria, tetanus toxoids, pertussis, or any component of the | |
| formulation | |
| • encephalopathy occurring within 7 days of administration and not attributable to | |
| another cause | |
| Precautions: | |
| Defer administration in patients with mo | oderate or severe acute illness (with or without |
| fever); vaccination should not be delayed | l for patients with mild acute illness (with or |
| without fever) ¹ | |
| • Guillain-Barré syndrome: Use with caution if Guillain-Barré syndrome occurred within 6 | |
| weeks of prior tetanus toxoid-containing | ů li do li d |
| 1 0 | ith a history of severe local reaction (Arthus- |
| | oid or tetanus toxoid-containing vaccine dose |
| | nergency doses of Td unless ≥ 10 years since |
| | action of a contract and the contract of the c |

most recent dose, even if using for wound management with wounds that are not clean or minor; these patients generally have high serum antitoxin levels⁵

Additional information:

- Shake suspension prior to withdrawal or administration
- After receipt of Tdap, either Tdap or Td may be used for booster immunizations

| <u>Varicella (Live)</u> | |
|--|--|
| Dosage: 0.5mL | Injection route and site: SC in posterolateral fat |
| | of upper arm |
| Directions for use: Inject at 0 and 1 | Storage: Power: freeze -58 to +5°F (-50 to -15°C) |
| month | Diluent: Room temperature 68-77°F or refrigerate at |
| | 35-46°F (2-8°C) |

Criteria for eligibility:

- Administer to adults without evidence of immunity to varicella
- Evidence of immunity to varicella is:
 - U.S.-born before 1980 (except for pregnant women and health care personnel, see below)
 - Documentation of receipt of 2 doses of varicella or varicella-containing vaccine at least 4 weeks apart
 - Diagnosis or verification of history of varicella or herpes zoster by a health care provider
 - Laboratory evidence of immunity or disease
- Administer 2 doses of VAR 4–8 weeks apart if previously received no varicellacontaining vaccine (if previously received 1 dose of varicella-containing vaccine, administer 1 dose of VAR at least 4 weeks after the first dose) to:
 - Pregnant women at least 18 years of age without evidence of immunity (Administer the first of the 2 doses or the second dose after pregnancy and before discharge from health care facility)
 - Health care personnel without evidence of immunity
 - Based on individual clinical decision, adults with HIV infection and CD4 cell count ≥200 cells/ μ L (2 doses, 3 months apart)

Contraindications:

- History of severe allergic reaction to any component of the vaccine (including neomycin and gelatin) or to a previous dose of varicella vaccine
- Primary or acquired immunodeficiency states
- Any febrile illness or active infection, including untreated tuberculosis
- Pregnancy

Precautions:

- Avoid contact with high-risk individuals susceptible to varicella because of possible transmission of varicella vaccine virus
- Defer vaccination for at least 5 months following blood or plasma transfusions, or administration of immune globulins

Additional information:

- Following reconstitution vaccine must be administered within 30 minutes; if times exceeds 30 minutes vaccine should be discarded
- Do not freeze reconstituted vaccine

| He | rpes Zoster |
|---|--|
| Dosage: 0.5mL (*Shingrix) *Preferred by ACIP 0.65mL (Zostavax) | Injection route and site: IM in deltoid (Shingrix) SC in posterolateral fat of upper arm (Zostavax) |
| Directions for use: Inject at 0 and 2-6 months (Shingrix); Inject once (Zostavax) | Storage: Refrigerate at 35-46°F (2-8°C) |
| Criteria for eligibility: Shingrix: Person 50 years or older w Zostavax or episode of herpes zoster Zostavax: Persons 60 years or older | |
| Contraindications: Shingrix: | |
| History of severe allergic rea gelatin and neomycin, of the Zostavax: | ction (e.g., anaphylaxis) to any component, including vaccine or after a previous dose of the vaccine phylactoid reaction to gelatin, neomycin, or any other |
| Immunosuppression or ImmPregnancy | nunodeficiency |
| (with or without fever); vaccination illness (with or without fever)¹ Zostavax: Hypersensitivity reactions including Transmission of vaccine virus may or | occur between vaccines and susceptible contacts ate illness (for example, in the presence of fever) or perculosis |
| Additional information: | |
| • Patients previously vaccinated with Shingrix | Zostavax should wait 8 weeks prior to receiving |

Vaccinations for International Travel

| Travel- related Diseases | Transmission | Prevention Modalities: Vaccination, Medication, Consultation |
|--------------------------------|---|--|
| <u>Hepatitis A</u> | Contaminated food and water | Vaccination (2-dose vaccination): Recommended for most travelers. Administer 2 doses, at least 6 months apart. At least 1 dose should be given before travel. Consultation: Advise patients to wash hands frequently and avoid unsafe food and water. |
| <u>Hepatitis B</u> | Sexual contact, contaminated needles and blood products, vertical transmission | Vaccination (3-dose vaccine): Recommended for all non-immune travelers, but especially those who are traveling to a country with <u>hepatitis-B prevalence ≥ 2%</u>. Administer doses at 0, 1, and 6 months. Accelerated schedule is available. Consultation: Advise patient to practice safe sex and avoid contaminated needles and blood products. |
| <u>Typhoid</u> | Contaminated food and water | Vaccination (with oral or injectable vaccines): Recommended for travelers going to a country that is endemic for typhoid. Administer injectable vaccine at least 2 weeks before travel. Complete 4 doses of oral vaccine (taken 2 days apart) at least 10 days before travel. Consultation: Advise patient to wash hands frequently and avoid unsafe food and water. |
| Rabies | Saliva of infected animals | Vaccination (3-dose vaccine): Consider offering vaccine to travelers to high-risk countries, who: Plan to spend a lot of time outdoors or in high-risk environments (such as adventure travelers or cavers). Will be handling animals (such as veterinarians, animal handlers, field biologists, or laboratory employees working with animal specimens). Are children who may be at higher risk because they are more likely to approach animals and less likely to report bites. Will be traveling to rural areas (because treatment might not be available). Begin vaccine series at least 21 days before travel. Administer doses at 0, 7, and 21 days or 28 days. Consultation: Advise patient to avoid contact with animals. The risk of rabies is extremely small for travelers who know the risk, have a plan for getting care if they are bitten, and have travel health insurance to pay for treatment (and, potentially, evacuation to an area where treatment is available). |
| Yellow fever | Mosquito bites | Vaccination (single-dose vaccine): Recommended for travelers |

| | | to certain parts of South America and Africa. Administer at least 10 days before planned arrival (this is an international country requirement). • <u>Find the nearest clinic for referrals.</u> Consultation : Advise patient to avoid mosquitos. Patient should also be advised to carry proof of vaccination (yellow card) when traveling to certain <u>destinations</u> that require yellow fever vaccination for entry. |
|---|---|---|
| <u>Japanese</u> <u>encephalitis</u> | Mosquito bites | Vaccination (2-dose vaccine): Recommended for certain travelers to Asia and the western Pacific, including long-term travelers (ie., trips lasting ≥ 1 month) to endemic areas during rainy season. Consider for the following groups: Short-term (<1 month) travelers to endemic areas during Japanese encephalitis virus transmission season if their itinerary or activities will increase their risk (e.g., spending substantial time outdoors in rural or agricultural areas, or staying in accommodations without air conditioning, screens, or bed nets). Travelers to an area with an ongoing outbreak of Japanese encephalitis. Travelers to endemic areas who are uncertain of specific activities or duration of travel. Administer doses at 0 and 28 days. An accelerated schedule of doses at 0 and 7 days has been approved. Ideally, complete vaccine series at least 1 week before travel. |
| <u>Cholera</u> | Contaminated food and water | Vaccination: Recommended for adults who are traveling to areas of active cholera transmission. Administer at least 10 days before travel. Consultation: Advise patient to wash hands frequently and avoid unsafe food and water. |
| <u>Meningococc</u> <u>al disease</u> | Person-to- person, oral and respiratory secretions | Vaccination: Recommended for travelers to areas in the <u>"meningitis belt" of sub-Saharan Africa</u>, particularly during the dry season (December through June), when the disease is more common. <i>Required</i> for travelers to Saudi Arabia for the Hajj. See <u>Saudi Arabia: Hajj/Umrah Pilgrimage</u> for more information. Administer at least 10 days before travel. Consultation: Advise patient to wash hands often and avoid touching face and activities with risk of saliva exchange. |
| <u>Malaria</u> | Mosquito bites | Vaccination : Consider malaria prophylaxis for travelers to areas with malaria transmission, which include parts of Africa, Latin America, parts of the Caribbean, South Asia, East Asia, the |

| | Middle East, Eastern Europe, and the South Pacific. Choosing a medication for prophylaxis must take into account the traveler's medical history and current medications, as well as malaria drug resistance in the area(s) of travel. Consultation: Advise patient to avoid mosquitos. Advise pregnant women to avoid travel to areas with malaria transmission if possible. |
|--|--|
|--|--|

References

- 1. Kroger AT, Duchin J, Vazquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP).
- Kim, D. K., Riley, L. E., & Hunter, P. (2018). Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018*. Annals of Internal Medicine, 168(3), 210. doi:10.7326/m17-3439
- 3. Schillie S, Vellozzi C, Reingold A, et al. Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep.* 2018;67(1):1-31. doi:10.15585/mmwr.rr6701a1.
- McLean HQ, Fiebelkorn AP, Temte JL, Wallace GS; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2013;62(RR-04):1-34.
- Liang JL, Tiwari T, Moro P, et al. Prevention of pertussis, tetanus, and diphtheria with vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2018;67(2):1-44. doi: 10.15585/mmwr.rr6702a1.
- 6. Zostavax (zoster vaccine live) [prescribing information]. Whitehouse Station, NJ: Merck & Co; August 2018.
- 7. Shingrix (zoster vaccine, recombinant) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; received September 2018.
- 8. Varivax (varicella virus vaccine) [prescribing information]. Whitehouse Station, NJ: Merck & Co; July 2018.
- 9. Adacel (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed) [prescribing information]. Swiftwater, PA: Sanofi Pasteur; March 2014.
- 10. Boostrix (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2016.
- 11. Prevnar 13 (pneumococcal conjugate vaccine [13-valent]) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals; August 2017.
- 12. Pneumovax 23 (pneumococcal vaccine polyvalent) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; May 2015.