



Vaccine	Diluent	Dosage/Injection Amount	Route
<b>Monovalent:</b> Orange capped vial with orange-bordered label	1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	<b>Primary:</b> 10 µg/0.2 mL	Intramuscular (IM) injection
<b>Bivalent:</b> Orange capped vial with orange-bordered label		<b>Booster:</b> 10 µg/0.2 mL	Intramuscular (IM) injection

**NOTE:** Use these standing orders in conjunction with [Interim COVID-19 Immunization Schedule for Persons 6 Months and Older](#)

### Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

### Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

### Procedure

Assess persons 5 through 11 years of age for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

#### Persons who ARE NOT moderately or severely immunocompromised<sup>†</sup>

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Monovalent Pfizer-BioNTech COVID-19 Vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 to 8 weeks<sup>‡</sup> after the first dose. (Primary series completed)
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 to 8 weeks<sup>‡</sup> after the first dose. (Primary series completed)
- If the recipient has received 2 or more doses of a monovalent COVID-19 vaccine (Pfizer-BioNTech or Moderna), administer 1 booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the previous dose.

#### Persons who ARE moderately or severely immunocompromised<sup>†</sup>

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Monovalent Pfizer-BioNTech COVID-19 Vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 weeks (21 days) after the first dose.
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 weeks (21 days) after the first dose.
- If the recipient has received 2 doses of:
  - Monovalent Pfizer-BioNTech COVID-19 Vaccine, administer a third dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 28 days (4 weeks) after Dose 2. (Primary series completed)
  - If the vaccine product previously administered cannot be determined, are no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 weeks (21 days) after the first dose. (Primary series completed)
- If the recipient has received 3 or more doses of a monovalent COVID-19 vaccine, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the previous dose.

#### Additional clinical considerations

- Children with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may be vaccinated after the episode of myocarditis or pericarditis has completely resolved.

\* Inform recipients, especially males 12–39 years of age and their parents/legal representative (when relevant) of the rare risk of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. [Myocarditis and Pericarditis educational materials](#).

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ An 8-week interval between the first and second primary series dose of an mRNA vaccine (ie., Moderna or Pfizer-BioNTech COVID-19 vaccines) may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A shorter interval (3 weeks for Pfizer) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.



- If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Pfizer-BioNTech formulation for children 5 through 11 years of age. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at [Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC](#)
- Persons who have received HCT or CAR-T-cell therapy:
  - Revaccinate persons who received doses of COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy with a primary series using monovalent COVID-19 vaccine and 1 booster dose of bivalent COVID-19 vaccine. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- For children who received a COVID-19 vaccine:
  - Outside of the United States
  - Not currently authorized/approved in the United States
  - See clinical guidance, including booster dose recommendations, at [Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC](#)
- Pfizer-BioNTech COVID-19 Vaccine (monovalent or bivalent) may be coadministered with other vaccines without regard to timing, including simultaneous administration.
- See clinical guidance for COVID-19 vaccination and SARS CoV-2 infection, including recommendations after receiving passive antibody products, at [Clinical Guidance for COVID-19 Vaccination | CDC](#)
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the **same type of COVID-19 vaccine**
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the **other types of COVID-19 vaccines**<sup>§</sup>
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

### Administration

- Provide all recipients and/or parents/legal guardians with a copy of the current [Fact Sheet for Recipients and Caregivers](#).
- Prepare the vaccine following the [manufacturer's guidance](#):
  - **Unpunctured vial:** Mix using 1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent
  - **Punctured vial:** Use with 12 hours of mixing.
  - Deltoid muscle is preferred. Vastus lateralis muscle in the anterolateral thigh can also be used.
  - Needle gauge and length: Use a 22-25 gauge, 1 inch<sup>¶</sup>
- Administer Pfizer-BioNTech COVID-19 Vaccine (monovalent or bivalent) by intramuscular (IM) injection
  - **Primary Series:** 0.2 mL of monovalent vaccine
  - **Booster Dose:** 0.2 mL of bivalent vaccine

### Document vaccination

- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- Document each recipient's vaccine administration information:
  - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
  - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
  - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

### Screen for contraindications and precautions

#### Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine. [Use of COVID-19 Vaccines in the U.S.: Appendices | CDC](#)

#### Precaution:

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])

<sup>§</sup> People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines.

<sup>¶</sup> A 5/8 inch needle may be used if administering the vaccine in the deltoid muscle AND the skin is stretched tightly and the subcutaneous tissue is not bunched.



### Be prepared to manage medical emergencies

- Vaccination providers should consider observing patients after vaccination to monitor for allergic reactions and syncope:
  - **30 minutes for persons with:**
    - » An allergy-related contraindication to a different type of COVID-19 vaccine
    - » A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
    - » A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
  - **15 minutes:** All other persons
- Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
- Have a written protocol to manage medical emergencies following vaccination. Recommendations, including equipment and medications can be found in [Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

### Report adverse events to the Vaccine Adverse Event Reporting System (VAERS)

- While this vaccine is under [Emergency Use Authorization \(EUA\)](#), healthcare professionals are required to report to [VAERS](#):
  - Vaccine administration errors (whether associated with an adverse event [AE] or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS) in [adults](#) or [children](#)
  - Cases of myocarditis (for mRNA vaccines)
  - Cases of pericarditis (for mRNA vaccines)
  - Cases of COVID-19 that result in hospitalization or death
  - Any additional AEs and revised safety requirements per the [Food and Drug Administration's](#) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to [VAERS](#):
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

### For more information, please see:


- [Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)
- [CDC's General Best Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions"](#)
- [Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting"](#)

**Note:** For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

### Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Kansas Local Health Departments effective 10/13/2022 until rescinded or until 10/13/2023.

date date

Medical Director Joan Duwve, M.D. /  10/13/2022

print name signature date

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders