

Pfizer-BioNTech COVID-19 Vaccine

XXXX Standing Orders for Administering Vaccine (Bivalent)

Vaccine	Diluent	Dosage/Injection Amount	Route
Bivalent: Orange capped vial with orange-bordered label	1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	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*†

- If the recipient has never received a COVID-19 vaccine administer 1 dose of bivalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 or more previous doses of:
 - Monovalent Pfizer-BioNTech or Moderna COVID-19 Vaccine, administer 1 dose Bivalent Pfizer-BioNTech COVID-19 vaccine at least 8 weeks after previous dose.

Persons who ARE moderately or severely immunocompromised*#†

- If the recipient has never received a COVID-19 vaccine administer 1 dose of bivalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 dose of Pfizer-BioNTech COVID-19 vaccine, administer 1 dose Bivalent Pfizer-BioNTech COVID-19 vaccine at least 3 weeks after previous dose.
- If the recipient has received 2 doses of Pfizer-BioNTech COVID-19 vaccine, administer 1 dose of Bivalent Pfizer-BioNTech COVID-19 vaccine at least 4 weeks after the previous dose.
- If the recipient has received 3 doses of mRNA COVID-19 vaccine, they may received one additional dose of Pfizer-BioNTech Bivalent COVID-19 vaccine at least 8 weeks after their previous dose of mRNA Bivalent COVID-19 vaccine
- Parents should consult with child's health care team for further additional dose recommendations if indicated.

* 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.](#)

#People in this age group who previously received a dose(s) of Pfizer-BioNTech vaccine are authorized to receive only Pfizer-BioNTech vaccine. Recipients who previously received Moderna vaccine are authorized to receive either bivalent mRNA vaccine.

† 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).

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.
 - If myocarditis or pericarditis occurred after a previous 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:
 - Revaccination of persons who received doses of COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy should be managed by their medical team in compliance with CDC recommendations and are not authorized through these orders.
- 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 (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](#)

Do not administer the Pfizer-BioNTech COVID-19 vaccine if contraindications or precautions are identified through screening. Refer to primary care provider.

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Bivalent)

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"])
- 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**[§]
- 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](#).
- Obtain consent in accordance with Washington law.
- 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[¶]
- Administer Pfizer-BioNTech COVID-19 Vaccine (monovalent or bivalent) by intramuscular (IM) injection
 - **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 Washington State Immunization Information System (IIS) 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.
 - Report the vaccination to the IIS.

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.

[§] 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.

[¶] 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.

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Statewide Standing Orders for Administering Vaccine (Bivalent)

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 in the XXXX effective XX until rescinded on XXXXXX nd supersedes any previous Pfizer-BioNTech COVID-19 Vaccine Statewide Standing Order for Administering Vaccine to Persons 5 through 11 Years of Age.

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Signature

Printed Name

License Number Date

Adapted with appreciation from the Centers for Disease Control and Prevention (CDC) standing orders