6 Months Through 4 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Statewide Standing Orders for Administering Vaccine for Persons 6 Months Through 4 Years of Age (Maroon Cap)

Vaccine	Diluent	Dosage (amount)/ Route
Formulation: 6 months through 4 years of age	2.2 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.2 mL/IM injection

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

- This standing order enables health care professionals authorized by law to administer COVID-19 vaccines in the State of Washington 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 children 6 months through 4 years of age for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Children who ARE NOT moderately or severely immunocompromised*†
  - Primary Series
    - » If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.
    - » If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3–8 weeks after Dose 1.
    - » If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer the third dose at least 8 weeks after Dose 2.
- Children who ARE moderately or severely immunocompromised†
  - Primary Series
    - » If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.
    - » If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at least 3 weeks after Dose 1.
    - » If the recipient has received 2 previous doses of Pfizer-BioNTech Vaccine, administer the third dose at least 8 weeks after Dose 2.
- Children with a history of myocarditis or pericarditis
  - If history is prior to COVID-19 vaccination, may receive Pfizer-BioNTech formulation 6 months through 4 years of age after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine. If, after a risk assessment. a decision is made to administer a subsequent dose of COVID-19 vaccine, vaccine should not be administered until the myocarditis or pericarditis has resolved. Clinical considerations can be found at www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna
- COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series. In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the primary series cannot be determined or is not available, either age-appropriate available mRNA COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 primary vaccination series. Children ages 6 months-4 years who receive different mRNA products for the first 2 doses should receive a third doses of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose series.
- Additional clinical considerations
  - For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
  - Pfizer-BioNTech COVID-19 Vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.
  - For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

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

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 (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

* 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).

† Inform parents/legal representative (when relevant) of the possibility 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. Educational materials are available at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

Precautions:

History of:

- Immediate allergic reaction‡ to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness
- History of MIS-C or MIS-A
- Myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Vaccine Administration

- Provide all parents/legal guardians of recipeint with a copy of the current Fact Sheet for Recipients and Caregivers.
- Obtain Consent in accordance with Washington law.
- Prepare to administer vaccine (maroon and maroon-bordered label) by IM injection.
  - Needle gauge and length: Use a 22–25 gauge, 1 inch§
  - For children:
    - 6 months through 2 years: Vastus lateralis muscle in the anterolateral thigh¶
    - 2 through 4 years: Deltoid muscle in the upper arm**
- Administer 0.2 mL of Pfizer-BioNTech COVID-19 Vaccine for children 6 months through 4 years of age (maroon vial cap with maroon-bordered label).
- 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 or their parent/guardian.
    - Report the vaccination to the IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes;** Persons with a history of:
      - A contraindication to another type of COVID-19 vaccine product.
      - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
      - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
      - Anaphylaxis due to any cause.
    - **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, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - 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.

‡ An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.
§ 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.
¶ The deltoid muscle in the upper arm may be used of the muscle mass is adequate.
** Vastus lateralis muscle in the anterolateral thigh may be used.

- For more information, please see:
  - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
  - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
  - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), 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 (https://www.cdc.gov/mis-c/mis-a.html) or children (https://www.cdc.gov/mis-c/index.html)
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gov/):
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

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 State of Washington effective June 21, 2022, until rescinded or superseded .

Mao Sheng Kwan-Gett, MD MPH - MD00031968 / June 21, 2022

Signature | Printed Name | License Number | Date

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