6 Months Through 4 Years of Age

Bivalent Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage/Injection Amount	Route
Ages: 6 months through 4 years **Bivalent:** Maroon capped vial with maroon-bordered label	2.2 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	3 *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

Note: Monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer recommended and should not be used .

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*†

- If the recipient has never received a COVID-19 vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 1).
- If the recipient has received 1 dose of:
  - **Monovalent** or **bivalent** Pfizer-BioNTech COVID-19 Vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 2) at least 3 through 8 weeks‡ after Dose 1.
  - If the vaccine product administered for Dose 1 cannot be determined, is no longer available, or contraindicated, administer bivalent Pfizer-BioNTech COVID-19 Vaccine at least 4 through 8 weeks‡ after Dose 1.§
- If the recipient has received 2 doses of:
  - **Monovalent** or **bivalent** Pfizer-BioNTech COVID-19 Vaccine administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 3) at least 8 weeks (2 months) after Dose 2.
  - If the previous vaccine products cannot be determined, is no longer available, or contraindicated, administer bivalent Moderna COVID-19 Vaccine at least 8 weeks (2 months) after Dose 2.§
- If the recipient has received 3 doses of:
  - **Monovalent** Pfizer- BioNTech COVID-19 Vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the Dose 3.

Children who ARE moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 1).
- If the recipient has received 1 dose of:
  - **Monovalent** or **bivalent** Pfizer-BioNTech COVID-19 Vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 2) at least 3 weeks after Dose 1.
  - If the Dose 1 product cannot be determined, is no longer available, or contraindicated, administer bivalent Pfizer-BioNTech COVID-19 Vaccine at least 4 weeks after the Dose 1.§

* Inform recipients, especially males 12–39 years of age and their parents/legal representative (when relevant) of the of the rare risk of myocarditis or pericarditis following receipt of any COVID-19 vaccine 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 dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ An 8-week interval between the first and second doses of 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. The authorized interval (3 weeks for Pfizer-BioNTech COVID-19 Vaccine) 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 an individual's higher risk of severe disease.

§ If the previously administered products are unknown, not available, contraindicated or a mixed manufacturer-product series (Moderna and Pfizer-BioNTech vaccines), follow a 3-dose schedule. A third dose of either a bivalent Moderna vaccine or a bivalent Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.

- If the recipient has received 2 doses of:
  - **Monovalent** or **bivalent** Pfizer-BioNTech COVID-19 Vaccine administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 3) at least (8 weeks) (2 months) after Dose 2.*
  - If the previous vaccine products cannot be determined, is no longer available, or contraindicated, administer bivalent Moderna COVID-19 Vaccine at least 8 weeks (2 months) after Dose 2.*†
- If the recipient has received 3 doses of:
  - **Monovalent** Pfizer- BioNTech COVID-19 Vaccine, administer bivalent Pfizer-BioNTech COVID-19 Vaccine (Dose 4) at least 8 weeks (2 months) after Dose 3.*
- An additional dose of a bivalent Pfizer-BioNTech vaccine may be administered at least 2 months following the last recommended bivalent Pfizer-BioNTech COVID-19 Vaccine dose.*

Additional clinical considerations

- See Interim Clinical Considerations for the Use of COVID-19 Vaccines| CDC for specific guidance when children turn from 4 to 5 years of age during the Pfizer-BioNTech vaccination series.
- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may receive Pfizer-BioNTech vaccine product after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after a dose of any COVID-19 vaccine, experts advise no additional doses of any COVID-19 vaccine, including Pfizer-BioNTech COVID-19 vaccine. Consult Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC if a subsequent dose is being considered.
- 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 following the current COVID-19 vaccination schedule. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- For persons who received a COVID-19 vaccine:
  - Outside of the United States
  - Not currently authorized in the United States
  - See clinical guidance at Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC
- Pfizer-BioNTech COVID-19 Vaccine may be coadministered with other routinely recommended vaccines without regard to timing, including simultaneous administration.
  - If mpox vaccine is indicated, see Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for guidance.
- 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

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. Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices,

Precautions:

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 type of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever

* Children 6 months through 4 years of age who are moderately or severely immunocompromised have the option to receive 1 additional dose of a homologous bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional homologous bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances at least 2 months after the last COVID-19 vaccine dose.

† If the previously administered products are unknown, not available, contraindicated or a mixed manufacturer-product series (Moderna and Pfizer-BioNTech vaccines), follow a 3-dose schedule. A third dose of either a bivalent Moderna vaccine or a bivalent Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose to complete the primary series.

- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of any 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 2.2 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent
  - **Punctured vial:** Use within 12 hours of mixing
  - 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 Pfizer-BioNTech COVID-19 Vaccine (maroon capped vial 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 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.
- Additional preparation and administration information is available on the manufacturer's website.

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:
    - 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. Immediate allergic reaction of any severity to a non-COVID-19 vaccine 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 COVID-19 that result in hospitalization or death
  - Cases of myocarditis
  - Cases of pericarditis

* 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 if the muscle mass is adequate.

‡ Vastus lateralis muscle in the anterolateral thigh may be used.

- 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"
- Medical Management of Vaccine Reactions in Children and Teens 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 _____

effective_____ until rescinded or until _____ .

Medical director (or other authorized practitioner)

_____ / _____ /_____.

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