

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine



Vaccine	Diluent	Dosage (amount)/ Route
Formulation: 5 through 11 years of age	1.3 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

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

- Primary-series vaccination
 - 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 an interval of least 21 days.*
 - If 2 doses of an mRNA vaccine have been administered, the child is considered fully vaccinated after completing the primary vaccination series.
- Children with a history of myocarditis or pericarditis:
 - If history is prior to COVID-19 vaccination, may receive Pfizer-BioNTech formulation 5 thorough 11 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, 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 <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-pfizer-biontech-moderna>

- Educational materials on myocarditis/pericarditis are available at <http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>, www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- Additional primary dose for persons who are moderately or severely immunocompromised
 - Administer an additional primary dose of Pfizer-BioNTech vaccine (orange cap) at least 28 days after the initial 2-dose Pfizer-BioNTech primary 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>

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

Precaution:

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- 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"])

* If the second dose is administered less than 17 days after the first dose (4-day grace period), the dose should be repeated. The repeat dose should be spaced at least 21 days after the improperly administered Pfizer-BioNTech dose.

† 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.



- This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness
- Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct formulation, injection site, needle gauge and length.
 - Prepare the vaccine following the manufacturer's directions using **1.3 mL** of 0.9% sodium chloride (normal saline, preservative-free) diluent
 - Use the 5 through 11 years of age formulation (multidose vial with orange cap and orange bordered label).
 - 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 0.2 mL of Pfizer-BioNTech COVID-19 Vaccine formulation: 5 through 11 years of age (orange cap and orange 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 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.
- 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:

[‡] 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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- » 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 of the _____
effective _____ until rescinded or until _____.

Medical director (or other authorized practitioner)

_____/_____/_____

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