

6 Months Through 4 Years of Age

2024–2025 Formula

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine



| 2024–25 Vaccine | Diluent | Dose/Injection Amount | Route |
|--------------------------------|---|-----------------------|------------------------------|
| Multidose vial with yellow cap | 1.1 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent | 0.3 mL/3 μ g | Intramuscular (IM) injection |

Purpose

To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating people 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 health care professionals (e.g., pharmacists) to assess and vaccinate people 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 age-appropriate 2024–25 Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

People who are NOT moderately or severely immunocompromised*

| COVID-19 vaccination history is: | Administer:† |
|---|--|
| Unvaccinated (0 doses) | Give a 3-dose initial series. <ul style="list-style-type: none">■ Dose 1 now.■ Dose 2 at least 3–8 weeks after Dose 1.‡■ Dose 3 at least 8 weeks after Dose 2. |
| 1 previous dose of any Pfizer-BioNTech COVID-19 Vaccine (Dose 1) | Complete the series. <ul style="list-style-type: none">■ Dose 2 at least 3–8 weeks after Dose 1.‡■ Dose 3 at least 8 weeks after Dose 2. |
| 2 previous doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2) | Complete the series. <ul style="list-style-type: none">■ Dose 3 at least 8 weeks after Dose 2. |
| 3 or more previous doses of any Pfizer-BioNTech COVID-19 Vaccine, NOT including 1 dose of any 2024–25 Pfizer-BioNTech COVID-19 Vaccine§ | Give 1 dose at least 8 weeks after the last dose. |
| 3 or more previous doses of any Pfizer-BioNTech COVID-19 Vaccine, INCLUDING at least 1 dose of any 2024–25 Pfizer-BioNTech COVID-19 vaccine§ | No further doses are indicated. |

* People with a recent SARS-CoV-2 infection may consider delaying vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).

† Children 6 months through 4 years of age should receive the vaccine from the same manufacturer for all doses. In the following circumstances, a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication. For children who received Dose 1 from one manufacturer but will receive subsequent dose(s) from a different manufacturer, administer:

- **Dose 2** at least 4–8 weeks after Dose 1.
- **Dose 3** at least 8 weeks after Dose 2.

‡ An 8-week interval between the first and second doses of Pfizer-BioNTech COVID-19 Vaccine might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

§ If the vaccination history includes 1 dose of 2024–25 Moderna COVID-19 Vaccine, the dose can be counted, and no further doses are indicated.

**People who ARE moderately or severely immunocompromised**

| COVID-19 vaccination history is: | Administer:* |
|--|--|
| Unvaccinated (0 doses) | Give a 3-dose initial series. <ul style="list-style-type: none"> ■ Dose 1 now. ■ Dose 2 at least 3 weeks after Dose 1. ■ Dose 3 at least 8 weeks after Dose 2. Dose 4: Give 6 months after Dose 3. [†] |
| 1 previous dose of any Pfizer-BioNTech COVID-19 Vaccine (Dose 1) | Complete the series. <ul style="list-style-type: none"> ■ Dose 2 at least 3 weeks after Dose 1. ■ Dose 3 at least 8 weeks after Dose 2. Dose 4: Give 6 months after Dose 3. [†] |
| 2 previous doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2) | Complete the series. <ul style="list-style-type: none"> ■ Dose 3 at least 8 weeks after Dose 2. Dose 4: Give 6 months after Dose 3. [†] |
| 3 or more previous doses of any Pfizer-BioNTech COVID-19 Vaccine, NOT including 1 dose of any 2024–25 Pfizer-BioNTech COVID-19 vaccine [‡] | Give 1 dose at least 8 weeks after the last dose, followed by 1 dose 6 months later. [†] |
| 3 or more previous doses of any Pfizer-BioNTech COVID-19 Vaccine, INCLUDING ONLY 1 dose of any 2024–25 Pfizer-BioNTech COVID-19 vaccine [‡] | Give 1 dose 6 months after the last dose of 2024–25 mRNA COVID-19 vaccine. [†] |
| 4 or more previous doses of any Pfizer-BioNTech COVID-19 Vaccine, INCLUDING at least 2 doses of any 2024–25 Pfizer-BioNTech COVID-19 vaccine [‡] | Additional dose(s) may be administered using shared clinical decision-making at least 8 weeks after last dose of 2024–25 mRNA COVID-19 vaccine. |

* Children 6 months through 4 years of age who are moderately to severely immunocompromised should receive the vaccine from the same manufacturer for all doses. In the following circumstances, a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication. If mRNA vaccines are administered from different manufacturers, a 3-dose initial series should be followed:

- Children who received Dose 1 from one manufacturer but will receive subsequent dose(s) from a different manufacturer, administer:
 - **Dose 2** at least 4 weeks after Dose 1.
 - **Dose 3** at least 8 weeks after Dose 2.
- Children who received 2 doses of vaccine from different manufacturers, administer Dose 3 at least 8 weeks after Dose 2.

[†] May be administered as soon as 8 weeks after the last dose of 2024–25 COVID-19 vaccine.

[‡] If the vaccination history includes a dose(s) of 2024–25 Moderna COVID-19 Vaccine, the dose(s) can be counted.

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Additional Clinical Considerations

- 2024–25 Pfizer-BioNTech COVID-19 Vaccine may be simultaneously administered with other routinely recommended vaccines. There are additional considerations for simultaneous administration of an [orthopoxvirus](#) vaccine and COVID-19 vaccine.
- People who have received hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy:
 - Revaccinate people 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 12 weeks after after transplant or CAR-T-cell therapy.
- For additional details and all clinical considerations, see [Interim Clinical Considerations for Use of COVID-19 Vaccines](#).

Contraindications:

History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine.

Precautions:

History of:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine.
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type.
- Moderate to severe acute illness, with or without fever.
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A).
- Myocarditis or pericarditis within 3 weeks 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 using manufacturer-supplied diluent following the manufacturer's guidance.
 - [EUA fact sheet for children 6 months through 4 years of age](#)

- Choose the correct needle gauge, needle length, and injection site:
 - [Needle gauge and length](#): Use a 22–25 gauge, 1-inch*
 - Injection site 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 **0.3 mL/3 µg** of Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.

Document Vaccination

Document each recipient's vaccine administration information on the:

- **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 for recipient**: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional.
- **Immunization information system (IIS)**: Report the vaccination to the appropriate state/local IIS.

Be Prepared to Manage Medical Emergencies

Consider observing people after vaccination to monitor for allergic reactions and syncope:

- **30 minutes** for people with:
 - A history of a non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type
 - A history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine, if receiving the same vaccine type

- **15 minutes**: All other people

Syncope may occur in association with injectable vaccines. Procedures should be in place to avoid falling injuries and manage syncopal reactions.

Have a written protocol to manage medical emergencies following vaccination.

* 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 for children ages 1–4 years.

† The deltoid muscle in the upper arm may be used if the muscle mass is adequate for ages 1 through 2 years.

‡ The vastus lateralis muscle in the anterolateral thigh may be used as an alternate site.

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Health care 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)

For COVID-19 vaccines given under an Emergency Use Authorization (EUA), vaccination providers are required to report to [VAERS](#):

- Vaccine administration errors, whether or not associated with an adverse event.
- Serious adverse events regardless of causality. Serious adverse events per FDA are defined as:
 - Death
 - A life-threatening adverse event
 - Inpatient hospitalization or prolongation of existing hospitalization
 - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
 - A congenital anomaly/birth defect

- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report is available at [Vaccine Adverse Event Reporting System \(VAERS\) \(hhs.gov\)](#) or by calling 1-800-822-7967.

For More Information, Please See:

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

Note: For 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 another authorized practitioner)

_____ / _____ / _____.

Adapted with appreciation from Immunize.org standing orders.