

5 Years of Age and Older 2024–2025 Formula Pfizer-BioNTech COVID-19 Vaccine



Standing Orders for Administering Vaccine

2024-25 Vaccine	Age	Diluent	Dose/Injection Amount	Route
Single-dose vial with blue cap	5 through 11 years	None	0.3 mL/10 μg	Intramuscular (IM) injection
Manufacturer-filled syringe	12 years and older	None	0.3 mL/30 μg	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 people 5 years of age and older for vaccination with the 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:	
People 5 through 64 years of age $^+$		
Unvaccinated (0 doses)	Give 1 dose now.	
Any number of previous doses of any COVID-19 vaccine, NOT including 1 dose of any 2024–25 COVID-19 vaccine [‡]	Give 1 dose at least 8 weeks after the last dose.	
Any number of previous doses of any COVID-19 vaccine, INCLUDING 1 dose of any 2024–25 COVID-19 vaccine [‡]	No further doses indicated.	
People 65 years of age and older		
Unvaccinated (0 doses)	Give 1 dose now, followed by 1 dose 6 months later. [§]	
Any number of previous doses of any COVID-19 vaccine, NOT including 1 dose of any 2024–25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the last dose, followed by 1 dose 6 months later.§	
Any number of previous doses of any COVID-19 vaccine, INCLUDING ONLY 1 dose of any 2024–25 COVID-19 vaccine [‡]	Give 1 dose 6 months after the last dose of the 2024–25 COVID-19 vaccine. [§]	
Any number of previous doses of any COVID-19 vaccine, INCLUDING 2 doses of any 2024–25 COVID-19 vaccine [‡]	No further doses 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).

⁺ CDC recommends that people receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination. For children who turn 5 years of age during the initial series, administer 1 dose of the age-appropriate vaccine (0.3 mL/10 µg). If the 10 µg dose is:

[•] Dose 2: Administer 3–8 weeks after Dose 1. No further doses of 2024–25 COVID-19 vaccine are indicated.

Dose 3: Administer at least 8 weeks after Dose 2. No further doses of 2024–25 COVID-19 vaccine are indicated.

⁺ If the vaccination history includes only 1 dose of Novavax COVID-19 Vaccine, see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for detailed guidance.

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

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People who ARE moderately or severely immunocompromised

COVID-19 vaccination history is:	Administer:*	
People 5 years of age and older ⁺		
Unvaccinated (0 doses)	 Give a 3-dose initial series. Dose 1 now. Dose 2 at least 3 weeks after Dose 1. Dose 3 at least 4 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. Dose 2 at least 3 weeks after Dose 1. Dose 3 at least 4 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. Dose 3 at least 4 weeks after Dose 2. Dose 4: Give 6 months after Dose 3.[‡] 	
3 or more previous doses of any mRNA COVID-19 vaccine, NOT including 1 dose of any 2024–25 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 mRNA COVID-19 vaccine, INCLUDING ONLY 1 dose of any 2024–25 COVID-19 vaccine	Give 1 dose 6 months after the last dose of 2024–25 COVID-19 vaccine. [‡]	
4 or more previous doses of any mRNA COVID-19 vaccine, INCLUDING at least 2 doses of any 2024–25 COVID-19 vaccine	Additional dose(s) may be administered using shared clinical decision-making at least 8 weeks after last dose of any 2024–25 COVID-19 vaccine.	
2 doses of 2024–25 Novavax COVID-19 Vaccine (Doses 1 and 2) $^{\$}$	Give 1 dose 6 months after the last dose of 2024–25 COVID-19 vaccine. [‡]	
2 or more previous doses of any Novavax COVID-19 Vaccine, NOT including 1 dose of any 2024–25 COVID-19 vaccine [§]	Give 1 dose at least 8 weeks after the last dose, followed by 1 dose 6 months later. [‡]	
2 or more previous doses of any Novavax COVID-19 Vaccine, INCLUDING ONLY 1 dose of any 2024–25 COVID-19 vaccine [§]	Give 1 dose 6 months after the last dose of 2024–25 COVID-19 vaccine. [‡]	
3 or more previous doses of any Novavax COVID-19 Vaccine, INCLUDING at least 2 doses of any 2024–25 COVID-19 vaccine [§]	Additional dose(s) may be administered using shared clinical decision-making at least 8 weeks after last dose any 2024–25 COVID-19 vaccine.	

^{*} People who are moderately or severely immunocompromised should receive the same vaccine product to complete the initial series. For Pfizer-BioNTech COVID-19 Vaccine, it is a 3-dose initial series. 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 people 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 4 weeks after Dose 2.

§ Novavax COVID-19 Vaccine is authorized for people 12 years of age and older. If administered to someone 11 years of age and younger, this is a vaccine administration error. See Appendix B Vaccine Administration Errors and Deviations at <u>Interim Clinical Considerations for Use of COVID-19 Vaccines</u>: <u>Appendices</u>, <u>References</u>, <u>and Previous Updates</u> for guidance.

⁺ People should receive the age-appropriate vaccine product and dosage based on their age on the day of vaccination. Children who turn:

^{• 5} years of age during the 3-dose initial series should complete the series with the age-appropriate dosage **0.3 mL /10 µg**.

^{• 12} years of age during the 3-dose initial series should complete the series with the age-appropriate dosage 0.3 mL/30 µg.

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



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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 <u>orthopoxvirus</u> vaccine and COVID-19 vaccine.
 - People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines.
 - However, if a patient's risk for mpox or severe disease due to COVID-19 is increased, administration of mpox and COVID-19 vaccines should not be delayed.
- People who have received hematopoetic 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 3 months (12 weeks) 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 appropriate informational material:

- For 5 through 11 years of age: Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- For 12 years of age and older: Provide all recipients and/or parents/legal guardians with a copy of the current <u>COVID-19 Vaccine Information Statement</u>.
- Prepare to administer the vaccine following the manufacturer's guidance.
 - EUA fact sheet for children 5-11 years of age
 - o Comirnaty package insert
- Choose the correct <u>needle gauge, needle length</u>, and injection site for people:
 - 5 through 18 years of age:
 - » Needle gauge/length: 22–25 gauge, 5/8^{*} to 1-inch
 - » Site: Deltoid muscle of arm[†]
 - o 19 years of age and older: See chart below.
- Administer Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection. Dosage based on age, administer:
 - o 5 through 11 years: 0.3 mL/10 µg
 - 12 years and older: 0.3 mL/30 μg

^{*} A 5/8-inch needle can be used if the skin is stretched tightly, and subcutaneous tissues are not bunched.

⁺ Alternately, the anterolateral thigh can be used. A 1- or 1.5-inch needle may be used if administering vaccine in this site, depending on the age of the patient.

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Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site [*]
Female or male less than 130 lbs	22–25	5/8†–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1.5"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1.5"	Deltoid muscle of arm
Female 200+ lbs	22–25	1.5"	Deltoid muscle of arm
Male 260+ lbs	22–25	1.5"	Deltoid muscle of arm

* Alternately, the anterolateral thigh can be used. A 1- or 1.5-inch needle may be used if administering vaccine in this site, depending on the age of the patient.

+ Some experts recommend a 5/8-inch needle for persons who weigh less than 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

Document Vaccination

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 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.

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)

Children 5–11 years of age

For COVID-19 vaccines given under an Emergency Use Authorization (EUA), vaccination providers are **required** to report to <u>VAERS</u>:

- 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:
 - o 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.



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- 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.

People 12 years of age and older

For licensed COVID-19 vaccines, healthcare providers are strongly encouraged to report to <u>VAERS</u>:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event.
- Vaccine administration errors, whether or not associated with an adverse event.

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 to is available at <u>Vaccine Adverse Event Reporting</u> <u>System (VAERS) (hhs.gov)</u> 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"
- <u>Medical Management of Vaccine Reactions in Children</u> and Teens in a Community Setting
- <u>Medical Management of Vaccine Reactions in Adults in a</u> <u>Community Setting</u>

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)		
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Adapted with appreciation from Immunize.org standing orders.