

# Updated (2023–2024 Formula) Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine



2023–24 Formula Vaccine Presentation	Age	Diluent	Dose/Injection Amount	Route
Single-dose vial with blue cap and blue label	5 through 11 years	None	0.3 mL/10 µg	Intramuscular (IM) injection
Single-dose vial with gray cap and gray label	12 years and older	None	0.3 mL/30 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 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 health care 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 years of age and older for vaccination with the 2023–24 Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

### People who are NOT moderately or severely immunocompromised\*

COVID-19 vaccination history <sup>†</sup> (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Pfizer-BioNTech COVID-19 Vaccine
Unvaccinated	Give 1 dose now.
Any number of previous doses of COVID-19 vaccine, <b>NOT</b> including at least 1 dose of 2023–24 COVID-19 vaccine	Give 1 dose at least 8 weeks (2 months) after the previous dose.
Any number of previous doses COVID-19 vaccine, <b>INCLUDING</b> at least 1 dose of 2023–24 COVID-19 vaccine	<p><b>People 5 through 64 years of age:</b> No further doses are indicated.</p> <p><b>People 65 years of age and older:</b> Administer 1 additional dose at least 4 months following the previous dose of 2023-24 COVID-19 vaccine.</p>

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

† COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent (ancestral) mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

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## People who ARE moderately or severely immunocompromised

COVID-19 vaccination history* (regardless of COVID-19 vaccine formula)	Schedule for administration of 2023-24 Pfizer-BioNTech COVID-19 Vaccine
Unvaccinated	Give a 3-dose initial series. Administer: <ul style="list-style-type: none"> <li>▪ Dose 1 now</li> <li>▪ Dose 2 at least 3 weeks after Dose 1</li> <li>▪ Dose 3 at least 4 weeks after Dose 2</li> </ul>
1 previous dose of any Pfizer-BioNTech COVID-19 Vaccine (Dose 1) <sup>†</sup>	Complete series. Administer: <ul style="list-style-type: none"> <li>▪ Dose 2 at least 3 weeks after Dose 1</li> <li>▪ Dose 3 at least 4 weeks after Dose 2</li> </ul>
2 doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2) <sup>†</sup>	Complete series. Administer: <ul style="list-style-type: none"> <li>▪ Dose 3 at least 4 weeks after Dose 2</li> </ul>
3 or more doses of Pfizer-BioNTech COVID-19 Vaccine, <b>NOT</b> including at least 1 dose of 2023–24 COVID-19 vaccine <sup>†</sup>	Give 1 dose at least 8 weeks (2 months) after the previous dose.
3 or more doses of Pfizer-BioNTech COVID-19 Vaccine, <b>INCLUDING</b> at least 1 dose of 2023–24 COVID-19 vaccine <sup>†</sup>	<ul style="list-style-type: none"> <li>▪ <b>People 5 through 64 years of age:</b> May receive 1 additional dose at least 8 weeks (2 months) following the previous dose of 2023-24 COVID-19 vaccine.</li> <li>▪ Further additional dose(s) may be administered, informed by the clinical judgement of a health care provider and personal preference and circumstances.</li> <li>▪ Administer any further additional doses at least 8 weeks (2 months) after the last 2023-24 COVID-19 vaccine dose.</li> </ul>
	<ul style="list-style-type: none"> <li>▪ <b>People 65 years of age and older:</b> Administer 1 additional dose at least 8 weeks (2 months) following the previous dose of 2023-24 COVID-19 vaccine.</li> <li>▪ Further additional dose(s) may be administered, informed by the clinical judgement of a health care provider and personal preference and circumstances.</li> <li>▪ Administer any further additional doses at least 8 weeks (2 months) after the last 2023-24 COVID-19 vaccine dose.</li> </ul>

\* COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent (ancestral) mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified; for people ages 12 years and older, Original monovalent Novavax COVID-19 Vaccine doses, alone or in combination with any mRNA vaccine doses; and for people ages 18 years and older, Janssen COVID-19 Vaccine doses, alone or in combination with any mRNA or Original monovalent Novavax vaccine doses.

† People who are recommended to receive a multidose mRNA series for initial vaccination (i.e., children ages 6 months–4 years and people who are moderately or severely immunocompromised) should receive all doses from the same manufacturer. However, in the following exceptional situations a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available, the person would otherwise not complete the vaccination series, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication.



## Additional Clinical Considerations

- 2023–24 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.
- 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 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 information 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:** There is currently no VIS. Once a VIS is available it should be used; but providers should not delay use of a vaccine because of the absence of a VIS. See more information on [alternative information materials](#) that can be provided.
- Prepare to administer the vaccine following the manufacturer's guidance (ages [5–11](#) and [12 and older](#)). Choose the correct [needle gauge, needle length](#), and injection site for persons:
  - 5 through 18 years of age:**
    - Needle gauge/length: 22–25 gauge, 5/8\*–1-inch
    - Site: Deltoid muscle of arm<sup>†</sup>
  - 19 years of age and older:** See chart below.
- Administer Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection:
  - 5 through 11 years:** 0.3 mL/10 µg
  - 12 years and older:** 0.3 mL/30 µg

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site <sup>†</sup>
Female or male less than 130 lbs	22–25	5/8 <sup>‡</sup> –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

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

<sup>†</sup> 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.

<sup>‡</sup> Some experts recommend a 5/8-inch needle for men and women who weigh less than 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

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### 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 persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes** for persons 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 persons

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)

**For licensed Pfizer-BioNTech COVID-19 vaccines** (for people ages 12 years and older), healthcare providers are **strongly encouraged** to report to [VAERS](https://vaers.hhs.gov):

- 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

**For Pfizer-BioNTech COVID-19 vaccines given under an EUA** (for people 11 years of age and younger) vaccination providers are **required** to report to [VAERS](https://vaers.hhs.gov):

- 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 to VAERS is available at <https://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 Practice Guidelines for Immunization, "Preventing and Managing Adverse Reactions,"](#)
- [Medical Management of Vaccine Reactions in Children and Teens in a Community Setting](#)
- [Medical Management of Vaccine Reactions in Adults in a Community Setting](#)

5 Years of Age and Older

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**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 immunize.org standing orders.