

6 Months Through 4 Years of Age

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

Standing Orders for Administering Vaccine



2023–24 Formula Vaccine Presentation	Diluent	Dose/Injection Amount	Route
Multidose vial with yellow cap and yellow label	1.1 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.3 mL/3 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 6 months through 4 years of age 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 [†] (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">■ 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 series. Administer: <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 doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2) ^{§¶}	Complete series. Administer: <ul style="list-style-type: none">■ Dose 3 at least 8 weeks after Dose 2
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, NOT including at least 1 dose of 2023–24 COVID-19 vaccine [§]	Give 1 dose at least 8 weeks (2 months) after the previous dose.
3 or more doses Pfizer-BioNTech COVID-19 Vaccine, INCLUDING at least 1 dose of 2023–24 COVID-19 vaccine [§]	No further doses are indicated.

* 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 mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

‡ An 8-week interval between the first and second COVID-19 vaccine (Moderna, Novavax, and Pfizer-BioNTech) doses might be optimal for some people as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

§ 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.

¶ For children who have received 1 Moderna and 1 Pfizer-BioNTech vaccines of any formulation, follow a 3-dose schedule. A third dose of either Moderna vaccine or Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.

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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">▪ Dose 1 now▪ Dose 2 at least 3 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 series. Administer: <ul style="list-style-type: none">▪ Dose 2 at least 3 weeks after Dose 1▪ Dose 3 at least 8 weeks after Dose 2
2 doses of any Pfizer-BioNTech COVID-19 Vaccine (Doses 1 and 2) ^{†‡}	Complete series. Administer: <ul style="list-style-type: none">▪ Dose 3 at least 8 weeks after Dose 2
3 or more doses of Pfizer-BioNTech COVID-19 Vaccine, NOT including at least 1 dose of 2023–24 COVID-19 vaccine [†]	Give 1 dose at least 8 weeks (2 months) after the previous dose.
3 or more doses of Pfizer-BioNTech COVID-19 Vaccine, INCLUDING at least 1 dose of 2023–24 COVID-19 vaccine [†]	<ul style="list-style-type: none">▪ People who are moderately or severely immunocompromised have the option to receive 1 additional dose at least 8 weeks (2 months) following the last recommended dose.▪ Further additional dose(s) may be administered, informed by the clinical judgement of a health care provider and personal preference and circumstances.▪ Any further additional doses should be administered at least 8 weeks (2 months) after the last COVID-19 vaccine dose.

* COVID-19 vaccination history refers to previous receipt of dose(s) of Original monovalent mRNA, bivalent mRNA vaccine, Updated (2023–2024 Formula), or a combination of the three, unless otherwise specified.

† 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.

‡ For children who have received 1 Moderna and 1 Pfizer-BioNTech vaccines of any formulation, follow a 3-dose schedule. A third dose of either Moderna vaccine or Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose.

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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 all recipients and/or parents/legal guardians with a copy of the current [Fact Sheet for Recipients and Caregivers](#).
- Prepare to administer the vaccine following the [manufacturer's guidance](#).
- Prepare to administer vaccine by IM injection.
 - [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[‡]

* 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.

- Administer Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection using the vial with yellow cap and yellow label. Administer 0.3 mL/3 μ g.

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)

Adverse events that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:

- Vaccine administration errors, whether or not associated with an adverse event
- Serious adverse events, irrespective of attribution to vaccination

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- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- 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](#)

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.