# Pfizer-BioNTech (2023-2024) COVID-19 Vaccine for Age 6 Months to 4 Years

vaccine protocol for Persons Age 6 months to 4 Years

**Document reviewed and updated: September 14, 2023**

## Condition for protocol

To reduce incidence of morbidity and mortality of COVID-19 disease.

## Policy of protocol

The nurse will implement this protocol for COVID-19 vaccination using the 2023-2024 Pfizer-BioNTech COVID-19 Vaccine for 6 months through 4 years of age.

## Condition-specific criteria and prescribed actions

**Delete this entire paragraph before printing/signing protocol.**

[Instructions for persons adopting these protocols: The table below lists indication, contraindication, and precaution criteria and suggested prescribed actions that are necessary to implement the vaccine protocol. The prescribed actions include examples shown in brackets but may not suit your institution’s clinical situation and may not include all possible actions. A licensed prescriber must review the criteria and actions and determine the appropriate prescribing action.]

Indications

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Child is currently healthy and age 6 months through 4 years. | Proceed to vaccinate if meets remaining criteria. |
| Child is under 6 months of age. | Do not vaccinate, have child return when older than 6 months. |
| Child who completed their primary series of previous COVID-19 vaccine at least 2 months ago. | Proceed to give one 2023-2024 vaccine dose. |
| Child has not started or has not completed a primary series of COVID-19 vaccine. | Proceed to vaccinate. |
| Child is 5 years of age or older. | Do not vaccinate with this product. Refer to protocol for *Pfizer-BioNTech (2023-2024) COVID-19 Vaccine for 5 to 11 Years.* |
| Child is currently healthy but has a chronic medical condition. | Proceed to vaccinate. |
| Child with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies. | Proceed to vaccinate. Counsel the individual and/or parent/guardian about: 1) The unknown vaccine safety profile and effectiveness in Immunocompromised populations.  2) The potential for reduced immune responses.  3) The need to continue to follow [current guidance](https://www.cdc.gov/coronavirus/2019-ncov/index.html) to protect themselves. |
| Child seeking primary vaccination and who falls into one of following categories of moderate to severe immunocompromise and is 6 months to 4 years:   * Active treatment for solid tumor and hematologic malignancies. * Receipt of solid-organ transplant and taking immunosuppressive therapy. * Receipt of CAR-T-cell or hematopoietic stem cell transplant (within two years of transplantation or taking immunosuppression therapy). * Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). * Advanced or untreated HIV infection. * Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory. | Proceed to vaccinate using schedule for people with immunocompromising conditions.  [Refer to primary care provider if additional doses may be indicated] |

Contraindications

|  |  |
| --- | --- |
| Criteria: Allergies | Prescribed action |
| Child had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of mRNA COVID-19 vaccine or any of its components. | Do not vaccinate. |

Precautions

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Child has a moderate to severe illness defined as temperature \_\_\_\_°F/°C or higher with symptoms such as: {to be determined by medical prescriber} | Defer vaccination and {to be determined by medical prescriber} |
| Child had a non-severe immediate (within 4 hours) allergic reaction to a previous dose of COVID-19 vaccine or a reaction of any severity to a product that contains polysorbates. | May be vaccinated.  Consider seeking counsel from an allergist-immunologist to discuss risks and benefits of vaccination.  Persons who choose vaccination should be observed for 30 minutes in a vaccination site that has equipment and personnel that is familiar with managing anaphylaxis. |
| Child has a history of Multisystem Inflammatory Syndrome in Children (MIS-C). | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous).  *This precaution does not include allergies not related to vaccines or injectable therapies (e.g., food, pet, environmental, or latex allergies; oral medications – including the oral equivalents of injectable medications).* | May be vaccinated.  Provide counseling on the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of COVID-19 vaccination.  Observe them for 30 minutes after vaccination. |
| Person had a delayed allergic reaction at the injection site. | Proceed to vaccinate. Give vaccine in the opposite arm from where the first dose was given. |
| Child had a delayed allergic reaction at the injection site. | Proceed to vaccinate when recovered from acute illness and isolation period is complete. |
| Child was previously ill with COVID-19 and received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. | Proceed to vaccinate when recovered from acute illness and isolation period is complete. |
| Child received monoclonal antibodies or convalescent plasma as post-exposure prophylaxis. | Proceed to vaccinate when quarantine period is complete. |

## Prescription

### Primary vaccination:

* Give 2023-2024 Pfizer-BioNTech COVID-19 Vaccine (in multiple dose vials with yellow caps and labels with yellow borders) for 6 months through 4 years; 3 micrograms, **0.3 mL**, intramuscular (IM).
* Give the second dose 3 to 8 weeks following the first dose.
* Give the third dose at least 8 weeks following the second dose.
* If started series with previous vaccine complete series with 2023-2024 vaccine:
  + If child had one dose of previous vaccine, give 2023-2024 vaccine second dose 3-8 weeks after first dose and 2023-2024 vaccine third dose at least 8 weeks later.
  + If child had two doses of previous vaccine, give 2023-2024 vaccine third dose at least 8 weeks after second dose.
  + If all three primary doses were previous COVID-19 vaccine give one 2023-2024 vaccine dose, at least 2 months after completion of a Pfizer primary 3 dose series.

### For persons with immunocompromising conditions:

* Give Pfizer-BioNTech 2023-2024 COVID-19 Vaccine for 6 months through 4 years; 3 micrograms, **0.3 mL**, intramuscular (IM), 3 dose series.
* Give the second dose 3 weeks following the first dose.
* Give the third dose at least 8 weeks following the second dose.
* If started series with previous COVID-19 vaccine complete series with 2023-2024 vaccine at the recommended intervals.
* Give one 2023-2024 vaccine dose if all three primary doses were previous COVID-19 vaccine at least 2 months after completion of primary series.

May give one or more additional 2023-2024 vaccine doses at least 2 months following the last dose based on clinical condition.

## Medical emergency or anaphylaxis

Follow pre-established agency protocol for anaphylaxis.

## Question or concerns

**Insert overseeing medical consultant’s information below and delete this sentence before printing/signing.**

In the event of questions or concerns call (insert name) at (insert phone number).

**This protocol shall remain in effect for all Minnesota residents until rescinded.**

Name of prescriber (please print):

Prescriber signature:

Date:

## Ingredient listing for 2023-2024 Pfizer-BioNTech COVID-19 vaccine for 6 months through 4 years (in multiple dose vials with yellow caps and labels with yellow borders)

After dilution, each 0.3 mL dose is formulated to contain 3 mcg of nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

Each 0.3 mL dose also includes the following ingredients:

* Lipids (0.04 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol).
* 9.4 mg sucrose.
* 0.02 mg tromethamine.
* 0.12 mg tromethamine hydrochloride.

**More information:**

* Diluent: 0.9% Sodium Chloride Injection, USP.
* The 2023-2024 Pfizer-BioNTech COVID-19 vaccine does not contain preservative.
* The vial stoppers are not made with natural rubber latex.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION PFIZER-BIONTECH COVID-19 VACCINE* found in [FDA: Pfizer HCP FS 04182023 (www.fda.gov/media/167211/download)](https://www.fda.gov/media/167211/download).