# 2024-2025 Pfizer-BioNTech COVID-19 Vaccine for Age 12 Years and Older

vaccine protocol for Persons Age 12 Years and Older

**Document reviewed and updated: November 5, 2024**

## 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 2024-2025 Pfizer-BioNTech COVID-19 Vaccine product for people 12 years and older.

## Condition-specific criteria and prescribed actions

[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. **Delete this paragraph before signing protocol**.]

Indications

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person is currently healthy and age 12 years or older. | Proceed to vaccinate if meets remaining criteria. |
| Person has not received a primary series of COVID-19 vaccine. | Proceed to vaccinate. |
| Person is less than age 12 years. | Do not vaccinate with this vaccine product.  Refer to protocol for *2024-2025 Pfizer-BioNTech COVID-19 Vaccine for 5 through 11 Years.* |
| Person is currently healthy but has a chronic medical condition. | Proceed to vaccinate. |
| Person 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 potential for reduced immune responses.  2) The need to continue to follow [current guidance](https://www.cdc.gov/coronavirus/2019-ncov/index.html) to protect themselves. |
| Person who falls into one of following categories of moderate to severe immunocompromise:   * 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] |
| Person is pregnant. | Proceed to vaccinate. |
| Person is lactating. | Proceed to vaccinate. |

Contraindications

|  |  |
| --- | --- |
| Criteria: Allergies | Prescribed action |
| Person 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 |
| Person 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} |
| Person 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. | The person may be vaccinated but should seek counsel from an allergist-immunologist to discuss risks and benefits of vaccination.  People who choose vaccination should be observed for 30 minutes in a vaccination site that has equipment and personnel that is familiar with managing anaphylaxis. |
| 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 has a history of myocarditis or pericarditis after a previous dose of mRNA vaccine. | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person had a delayed allergic reaction at the injection site (e.g., erythema, induration, pruritis at the injection site). | Proceed to vaccinate. Give vaccine in the opposite arm from where the first dose was given. |
| Person has received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. | Proceed to vaccinate once recovered from acute illness and isolation period is complete. |
| Person received monoclonal antibodies or convalescent plasma as post-exposure prophylaxis. | Proceed to vaccinate when quarantine period is complete. |
| Person was previously ill with COVID-19 and had Multisystem Inflammatory Syndrome. | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |

## Prescription

### Primary vaccination:

Give 2024-2025 Pfizer-BioNTech COVID-19 vaccine, 30 micrograms, 0.3 mL, intramuscular (IM):

* One 2024-2025 vaccine dose for those who were never vaccinated.
* Give one dose 2024-2025 vaccine at least 2 months following any previous COVID-19 vaccine dose.

### Individuals 65 years of age and older previously vaccinated with the 2024-2025 COVID-19 vaccine:

Give one additional dose of 2024-2025 Pfizer-BioNTech COVID-19 Vaccine, 30 micrograms, 0.3 mL, intramuscular (IM) 6 months following any previous 2024-2025 COVID-19 dose (minimum interval 2 months).

### For persons with immunocompromising conditions:

Give 2024-2025 Pfizer-BioNTech COVID-19 Vaccine; 30 micrograms, 0.3 mL, intramuscular (IM), 3 dose series for those who were never vaccinated:

* Give the second dose 3 weeks following the first dose.
* Give the third dose at least 4 weeks following the second dose.
* If started series with previous COVID-19 vaccine, complete series with 2024-2025 vaccine at the recommended intervals.

### For this who have previously completed an initial series:

* Give two doses of 2024-2025 COVID-19 vaccine spaced 6 months apart (minimum interval 2 months from any previous COVID-19 dose).
* May give one or more additional 2024-2025 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 until rescinded.**

Name of prescriber (please print):

Prescriber signature:

Date:

## Ingredient listing for 2024-2025 Pfizer-BioNTech COVID-19 vaccine for age 12 years and older

Each 0.3 mL dose of the 2024-2025 Pfizer-BioNTech COVID-19 vaccine is formulated to contain 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant lineage KP.2.

Each 0.3 mL dose also includes the following ingredients:

* Lipids (0.43 mg) (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol).
* 0.06 mg tromethamine.
* 0.4 mg tromethamine hydrochloride.
* 31 mg sucrose.

**More information**:

* The 2024-2025 Pfizer-BioNTech COVID-19 Vaccine does not contain preservative.
* The vial stoppers are not made with natural rubber latex.

Taken from the [Package Insert and FDA Approved Patient Labeling - COMIRNATY (www.fda.gov/media/151707/download?attachment)](https://www.fda.gov/media/151707/download?attachment).