# 2024-2025 Moderna COVID-19 Vaccine for Age 6 Months to 11 Years

vaccine protocol for children Age 6 months to 11 years

**Document reviewed and updated:** **August 28, 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 Moderna COVID-19 vaccine product for people 6 months through 11 years.

## 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 11 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 2024-2025 vaccine dose.  |
| Child has not started or has not completed a primary series of COVID-19 vaccine.   | Proceed to vaccinate.  |
| Child who completed their primary series of previous COVID-19 vaccine at least 2 months ago. | Proceed to give one 2024-2025 vaccine dose. |
| Child has not started or has not completed a primary series of COVID-19 vaccine. | Proceed to vaccinate. |
| Child is 12 years of age or older. | Do not vaccinate with this product. Refer to protocol for *Moderna (2024-2025) COVID-19 Vaccine for Age 12 Years and Older.* |
| Child is currently healthy but has a chronic medical condition. | Proceed to vaccinate. |
| Child with HIV infection, other immunocompromising conditions, or who takes immunosuppressive medications or therapies. | Proceed to vaccinate. Counsel the individual 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. |
| Child 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 2 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., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, 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 children with immunocompromising conditions.[Refer to primary care provider if additional doses may be indicated.]  |

Contraindications

|  |  |
| --- | --- |
| Criteria | 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 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. |
| Child received monoclonal antibodies or convalescent plasma as post-exposure prophylaxis. | Proceed to vaccinate when quarantine period is complete. |
| Child was previous 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. |
| 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. | The child may be vaccinated but should seek 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. |
| History of severe allergic reaction (e.g., anaphylaxis) to any 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.  |
| Child 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. |
| Child had a delayed local allergic reaction (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. |

## Prescription

### Primary vaccination

* **For children 6 months through 4 years**: 2 doses, 2024-2025 Moderna COVID-19 Vaccine 25 micrograms, 0.25 mL, intramuscular (IM), given 4 – 8 weeks apart.
	+ If first dose was previous COVID-19 vaccine, complete the series with 2024-2025 vaccine.
	+ If primary series was complete with previous COVID-19 vaccine give one 2024-2025 vaccine dose, at least 2 months after completion of a primary series.
* **For children 5 years through 11 years**: 1 dose, 2024-2025 Moderna COVID-19 Vaccine 25 micrograms, 0.25 mL, intramuscular (IM).
	+ Give one dose 2024-2025 vaccine at least 2 months following any previous COVID-19 vaccine dose.

### For children with immunocompromising conditions:

**For 6 months of age through 11 years**: 3 dose series, 2024-2025 Moderna COVID-19 Vaccine, 25 micrograms, 0.25 mL, intramuscular (IM) for those who were never vaccinated.

* Give second dose 4 weeks following the first dose.
* Give third dose at least 4 weeks following the second dose.
* Give one 2024-2025 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 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 Moderna COVID-19 Vaccine for Age 6 months through 11 years

Each 0.25 mL dose of the 2024-2025 Moderna COVID-19 Vaccine includes the following ingredients:

* 25 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Omicron variant lineage KP.2.
* 0.5 mg lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) SM-102 (Proprietary to Moderna).
* 0.13 mg Tromethamine.
* 0.62 mg Tromethamine hydrochloride.
* 0.011 mg Acetic acid.
* 0.049 mg Sodium acetate trihydrate.
* 21.8 mg Sucrose.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION MODERNA COVID-19 VACCINE*found in [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE: EMERGENCY USE AUTHORIZATION OF MODERNA COVID-19 VACCINE (2024-2025 FORMULA), FOR INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE (www.fda.gov/media/167208/download?attachment)](https://www.fda.gov/media/167208/download?attachment).