6 Months Through 4 Years of Age

2024–2025 Formula Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine

2024–25 Formula Vaccine Presentation	Dose/Injection Amount	Route
Manufacturer-filled syringe	0.25 mL/25 *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 2024–25 Moderna COVID-19 Vaccine based on the following criteria:

Children who are NOT moderately or severely immunocompromised*

COVID-19 vaccination history is:	Administer:†
Unvaccinated	Give a 2-dose initial series. Administer:‡ ▪ Dose 1 now ▪ Dose 2 at least 4–8 weeks after Dose 1§
1 previous dose of any Moderna COVID-19 Vaccine (Dose 1)	Complete the series. Administer:‡ ▪ Dose 2 at least 4-8 weeks after Dose 1§
2 or more doses Moderna COVID-19 Vaccine, **NOT** including at least 1 dose of 2024–25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the previous dose.‡
2 or more doses Moderna COVID-19 Vaccine, **INCLUDING** at least 1 dose of 2024–25 COVID-19 vaccine	No further doses are indicated.

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

† Children 6 months through 4 years of age should receive the vaccine from the same manufacturer for all doses.

‡ In the following circumstances, a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication.

- Children who received Dose 1 from one manufacturer but will receive subsequent dose(s) from a different manufacturer, administer:
  - Dose 2 at least 4–8 weeks after Dose 1.
  - Dose 3 at least 8 weeks after Dose 2.
- Children who have received 2 doses of vaccine from different manufacturers, administer Dose 3 at least 8 weeks after Dose 2.

§ An 8-week interval between the first and second doses of Moderna COVID-19 Vaccine might be optimal for some people as it might reduce the rare risk of myocarditis and pericarditis associated with these vaccines.

Children who ARE moderately or severely immunocompromised

COVID-19 vaccination history is:	Administer:*
Unvaccinated	Give a 3-dose initial series. Administer:† ▪ Dose 1 now ▪ Dose 2 at least 4 weeks after Dose 1 ▪ Dose 3 at least 4 weeks after Dose 2
1 previous dose of any Moderna COVID-19 Vaccine (Dose 1)	Complete series. Administer:† ▪ Dose 2 at least 4 weeks after Dose 1 ▪ Dose 3 at least 4 weeks after Dose 2
2 doses of any Moderna COVID-19 Vaccine (Doses 1 and 2)	Complete series. Administer:† ▪ Dose 3 at least 4 weeks after Dose 2
3 or more doses of Moderna COVID-19 Vaccine, **NOT** including at least 1 dose of 2024–25 COVID-19 vaccine	Give 1 dose at least 8 weeks after the previous dose.†
3 or more doses of Moderna COVID-19 Vaccine, **INCLUDING** at least 1 dose of 2024–25 COVID-19 vaccine	▪ People who are moderately or severely immunocompromised may receive 1 additional dose at least 8 weeks 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 after the last COVID-19 vaccine dose.

* Children 6 months through 4 years of age should receive the vaccine from the same manufacturer for all doses.

† In the following circumstances, a different age-appropriate COVID-19 vaccine product may be administered: the same vaccine is not available at the time of the clinic visit, the previous dose is unknown, the person would otherwise not receive a recommended dose, or the person starts but is unable to complete a vaccination series with the same vaccine due to a contraindication. If mRNA vaccine is administered from different manufacturers, a 3-dose initial series should be followed:

- Children who received Dose 1 from one manufacturer but will receive subsequent dose(s) from a different manufacturer, administer:
  - Dose 2 at least 4 weeks after Dose 1.
  - Dose 3 at least 8 weeks after Dose 2.
- Children who received 2 doses of vaccine from different manufacturers, administer Dose 3 at least 8 weeks after Dose 2.

Additional Clinical Considerations

2024–25 Moderna 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 start at least 12 weeks after 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:
  - EUA fact sheet for children 6 months through 11 years of age
- Choose the correct needle gauge, needle length, and injection site:
- Needle gauge and length: Use a 22–25 gauge, 1-inch*
- Injection site for children:
  - **6 months through 2 years:** Vastus lateralis muscle in the anterolateral thigh†
  - **2 through 4 years:** Deltoid muscle in the upper arm‡
- Administer **0.25 mL /25 *µg*** of Moderna COVID-19 Vaccine by intramuscular (IM) injection.

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

* 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.

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 COVID-19 vaccines given under an Emergency Use Authorization (EUA), vaccination providers are required to report to VAERS:

- 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 is available at Vaccine Adverse Event Reporting System (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.