6 Months Through 5 Years of Age

Moderna COVID-19 Vaccine

(Monovalent and Bivalent)

Standing Orders for Administering Vaccine

Vaccine	Dose/Injection Amount	Route
Monovalent: Blue capped vial with magenta-bordered label	**Primary dose:** 25 *µg*/ 0.25 mL	Intramuscular (IM) injection
Bivalent: Dark pink capped vial with yellow-bordered label	**Booster dose:**10 *µg*/0.2 mL	Intramuscular (IM) injection

NOTE: Use these standing orders in conjunction with Interim COVID-19 Immunization Schedule for Persons 6 Months and Older

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 healthcare 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 5 years of age for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

Children who ARE NOT moderately or severely immunocompromised[*†]

- If the recipient has never received a COVID-19 vaccine, administer the first primary series dose of monovalent Moderna COVID-19 Vaccine.
- If the recipient has received 1 previous dose:
  - Monovalent Moderna COVID-19 Vaccine, administer the second primary series dose of monovalent Moderna COVID-19 Vaccine at least 4 through 8 weeks[‡] after Dose 1. (Primary series completed)
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 through 8 weeks[‡] after Dose 1. (Primary series completed)
- If the recipient has received 2 previous doses[§] of monovalent Moderna COVID-19 vaccine, administer 1 booster dose of **bivalent Moderna COVID-19 vaccine** at 8 weeks (2 months) after the previous dose.

Children who ARE moderately or severely immunocompromised[*†]

- If the recipient has never received a COVID-19 vaccine, administer the first primary series dose of monovalent Moderna COVID-19 Vaccine.
- If the recipient has received 1 previous dose:
  - Monovalent Moderna COVID-19 Vaccine, administer the second primary series dose of monovalent Moderna COVID-19 Vaccine at least 28 days (4 weeks)[‡] after Dose 1.
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 28 days (4 weeks)[‡] after the first dose.
- If the recipient has received 2 previous doses:
  - Monovalent Moderna COVID-19 Vaccine, administer a 3rd dose of monovalent Moderna COVID-19 Vaccine at least 28 days (4 weeks) after Dose 2. (Primary series completed)
  - If the vaccine products previously administered cannot be determined, are no longer available, or contraindicated, administer monovalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the Dose 2. (Primary series completed)
- If the recipient has received 3 previous doses[§] of monovalent Moderna COVID-19 vaccine, administer 1 booster dose of **bivalent Moderna COVID-19 vaccine** at 8 weeks (2 months) after the previous dose.

Additional clinical considerations

- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may receive Moderna vaccine product (monovalent or bivalent) after the episode of myocarditis or pericarditis has completely resolved.

* Inform recipients, especially males 12–39 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Myocarditis and Pericarditis educational materials

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. The authorized interval (4 weeks for Moderna COVID-19 Vaccine) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

§ If the previously administered products are unknown, not available, contraindicated or a mixed manufacturer-product series (Pfizer-BioNTech and Moderna vaccines), follow a 3-dose schedule. A third dose of either a monovalent Moderna vaccine or a bivalent Pfizer-BioNTech vaccine should be administered at least 8 weeks after the second dose to complete the primary series. These children cannot receive any booster dose.

- If myocarditis or pericarditis occurred after a dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Moderna COVID-19 vaccine (monovalent or bivalent). Administration of a subsequent dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at Clinical Considerations: Myocarditis after mRNA COVID-19 Vaccines | CDC

- 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 with a primary series following the current COVID-19 vaccination schedule. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.
- For persons who received a COVID-19 vaccine:
  - Outside of the United States
  - Not currently authorized/approved in the United States
  - See clinical guidance, including booster dose recommendations, at Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC
- Moderna COVID-19 Vaccine (monovalent or bivalent) may be coadministered with other vaccines without regard to timing, including simultaneous administration.

See clinical guidance for COVID-19 vaccination and SARS CoV-2 infection, including recommendations after receiving passive antibody products, at Clinical Guidance for COVID-19

Screen for contraindications and precautions

Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine. See, Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates | CDC

Precautions:

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the **same type of COVID-19 vaccine**
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the **other types of COVID-19 vaccines**[¶]
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax 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 vaccine (monovalent or bivalent) 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[‡‡]
- Administer Moderna COVID-19 Vaccine (monvalent or bivalent) by intramuscular (IM) injection:
  - **Primary Series Doses 1 and 2:** 0.25 mL of monovalent vaccine (blue capped vial with magenta-bordered label)
  - **Booster Dose 3:** 0.2 mL of bivalent vaccine (dark pink vial capped vial with yellow-bordered label)

Document vaccination.

- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
- 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 card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.

¶ An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.
** 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.
†† The deltoid muscle in the upper arm may be used if the muscle mass is adequate.
‡‡ The vastus lateralis muscle in the anterolateral thigh may also be used.

- Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.

- Additional preparation and administration information is available on the manufacturer's website.

Be prepared to manage medical emergencies.

- Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
  - **30 minutes:** Persons with a history of:
    - An allergy-related contraindication to a different type of COVID-19 vaccine
    - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
    - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies.
  - **15 minutes:** All other persons.
- Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
- Have a written protocol to manage medical emergencies following vaccination. Recommendations, including equipment and medications can be found in Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination
- Healthcare 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).

- While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
  - Vaccine administration errors (whether associated with an adverse event [AE] or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS) in adults or children
  - Cases of COVID-19 that result in hospitalization or death
  - Cases of myocarditis (for mRNA vaccines)
  - Cases of pericarditis (for mRNA vaccines)
  - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS:
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

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 andTeens 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 Kansas Local Health Departments effective 12/9/2022 (date) until rescinded or until 12/9/2023 (date).

Medical Director Joan Duwve, M.D. (print name) / Joan Duwve MD, MPH (signature) 12/9/2022 (date)

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders.