6 Years of Age and Older

Bivalent Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine

Bivalent Vaccine	Dose/Injection Amount	Route
Blue capped vial with gray-bordered label	**Ages 6–11 years:** 25 *µg*/ 0.25 mL **Ages 12 years and older:** 50 *µg*/ 0.50 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

NOTE: Monovalent Moderna COVID-19 Vaccine is no longer recommended and should not be used.

Assess persons 6 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

Persons who ARE NOT moderately or severely immunocompromised*†

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of bivalent Moderna COVID-19 Vaccine.
  - If ages 6 through 64, additional doses are not currently recommended.
  - If ages 65 or older, 1 additional dose of bivalent Moderna COVID-19 vaccine may be given at least 4 months after first bivalent mRNA vaccine dose.
- If the recipient has received 1 or more previous dose(s) of any monovalent COVID-19 vaccine, administer 1 dose of bivalent Moderna COVID-19 Vaccine at least 8 weeks after the previous dose.
  - If ages 6 through 64, additional doses are not currently recommended.
  - If ages 65 or older, 1 additional bivalent mRNA vaccine dose may be given at least 4 months after the first dose of a bivalent mRNA vaccine.

Persons who ARE moderately or severely immunocompromised*

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of bivalent Moderna COVID-19 Vaccine (Dose 1).
- If the recipient has received 1 previous dose of:
  - **Monovalent** or **bivalent** Moderna COVID-19 Vaccine, administer bivalent Moderna COVID-19 Vaccine (Dose 2) at least 4 weeks (28 days) after the Dose 1.
  - **Monovalent** or **bivalent** Pfizer-BioNTech, Novavax, or Janssen COVID-19 vaccines, then bivalent Moderna COVID-19 Vaccine (Dose 2) may be administered.‡
  - If the Dose 1 product cannot be determined, is no longer available, or contraindicated, administer bivalent Moderna COVID-19 Vaccine at least 4 weeks (28 days) after the first dose.‡
- If the recipient has received 2 doses of:
  - **Monovalent** or **bivalent** Moderna vaccine, administer bivalent Moderna COVID-19 Vaccine (Dose 3) at least 28 days (4 weeks) after Dose 2.§
  - **Monovalent** or **bivalent** Pfizer-BioNTech, Novavax, or Janssen COVID-19 vaccines, then bivalent Moderna COVID-19 Vaccine (Dose 3) may be administered.‡§
  - If the previous vaccine products cannot be determined, are no longer available, or contraindicated, administer bivalent Moderna COVID-19 Vaccine (Dose 3) at least 4 weeks after the second dose.‡§

* Inform recipients, especially males 12–39 years of age and their parents/legal representative (when relevant) of the rare risk 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 vaccination by 3 months from symptom onset or positive test (if infection was asymptomatic).

‡ See Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for schedule details, including intervals and interchangeability of products..

§ People 6 years of age and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances, at least 2 months after the last COVID-19 vaccine dose.

- If the recipient has received 3 doses of:
  - Monovalent Moderna COVID-19 Vaccine, administer bivalent Moderna COVID-19 Vaccine (Dose 4) at least 8 weeks (2 months) after Dose 3.*
- An additional dose of a Moderna bivalent vaccine may be administered at least 2 months following the last recommended bivalent Moderna COVID-19 vaccine dose.*

Additional Clinical Considerations

- See Interim Clinical Considerations for the USe of COVID-19 Vaccines| CDC specific guidance when children turn from 5 to 6 years of age during the Moderna vaccination series.
- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may receive Moderna vaccine after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after a dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine. 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 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 in the United States
  - See clinical guidance in Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices
- Moderna COVID-19 vaccine may be coadministered with other routinely recommended vaccines without regard to timing, including simultaneous administration.
  - If mpox vaccine is indicated, see Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for guidance.
- 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 Vaccination | CDC

Screen for Contraindications and Precautions

Contraindications:

History of a:

- 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 COVID-19 vaccine. Use of COVID-19 Vaccines in the U.S.: Appendices | 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 type 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

* People 6 years of age and older who are moderately or severely immunocompromised have the option to receive 1 additional dose of a bivalent mRNA vaccine at least 2 months following the last recommended bivalent mRNA COVID-19 vaccine dose. Further additional bivalent dose(s) may be administered, informed by the clinical judgement of a healthcare provider and personal preference and circumstances. Any further additional doses should be administered at least 2 months after the last COVID-19 vaccine dose.

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Administration

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male less than 130 lbs	22–25	⅝†–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

† Some experts recommend a 5/8-inch needle for men and women who weigh less than 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine following the manufacturer's guidance. Choose the correct needle gauge, needle length, and injection site for persons:
  - **12 through 18 years of age:**
    - Needle gauge/length: 22–25 gauge, 1-inch
    - Site: Deltoid muscle of arm
  - **19 years of age and older:** See chart
- Administer Moderna COVID-19 Vaccine by intramuscular (IM) injection:
  - **Ages 6 through 11 years:** 0.25 mL/25 *ug*
  - **Ages 12 years and older:** 0.5 mL/50 *ug*
- See Moderna COVID-19 Vaccine: Bivalent Vaccine Vial Infographic for more information.

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
  - **Recipient's vaccination record card:** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional.
  - **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Be prepared to manage medical emergencies

- Vaccination providers should consider observing patients after vaccination to monitor for allergic reactions and syncope:
  - **30 minutes for persons with:**
    - 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 particularly 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 myocarditis
  - Cases of pericarditis
  - Cases of COVID-19 that result in hospitalization or death
  - 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"
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults 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 5/25/2023 (date) until rescinded or until 5/24/2024 (date).

Medical Director Joan Duwve, M.D. (print name) / [signature] (signature) 5/25/2023 (date)

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