May 7, 2023

StandingOrder for **Moderna** SARS-CoV-2 Vaccine Administration for

# Individuals Age 12 Years and Older

**Purpose**

To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 12 years and older in the state of Missouri who meet the criteria established by the 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**

1. Assess adults in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
   1. Must be 12 years and older
   2. Any minor authorized to receive this vaccine under this order, shall only receive such with the consent of a parent or guardian, or in compliance with Sections 431.056, 431.058, or 431.061, RSMo
   3. Moderna COVID-19 vaccine may be administered with any other vaccines. Use a different arm for other vaccine administration. It is unknown whether reactogenicity is increased with co-administration, including with other vaccines known to be reactogenic such as adjuvanted vaccines. When deciding to co-administer with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines and the reactogencity profile of the vaccines.
   4. **For individuals WHO ARE NOT moderately to severely immunocompromised**, refer to administration schedule and instructions in table 6A below
   5. **For individuals WHO ARE moderately to severely IMMUNOCOMPROMISED**, refer to administration schedule and instructions table 6B below.
2. Screen all individuals for contraindication and precautions for the SARS-CoV-2 vaccine
   1. Contraindications
      1. Under 12 years of age
      2. Do not give the SARS-CoV-2 vaccine to an individual who has experienced a serious reaction\* (e.g., anaphylaxis) to a prior dose of SARS-CoV-2 vaccine or to any of its components. For more information on vaccine components, refer to the manufactures’ package insert <https://www.fda.gov/media/144637/download>
      3. Do not give the SARS-CoV-2 vaccine to an individual who has had an immediate allergic reaction of any severity to a previous dose of any mRNA COVID-19 vaccine or any of its components (including polyethylene glycol (PEG)\*\*

\*Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticarial, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration of vaccine or Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States at [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)

\*\*These individuals should not receive mRNA SARS-CoV-2 vaccine at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

* 1. Precautions
     1. Moderate or severe acute illness with or without a fever
     2. Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine\*\*\* (not including Moderna Vaccine)

Action

Assess the risk of vaccination

Observe patient for 30 minutes following vaccination

* + 1. Polysorbate allergy is a precaution to Moderna COVID-19 vaccine (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
    2. Severe allergic reaction (e.g. Anaphylaxis) to a medication\*\*\* that is injectable

Action

Assess the risk of vaccination

Observe patient for 30 minutes following vaccination

* + 1. Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-2 exposure until quarantine period has ended, unless individual resides in congregate healthcare setting or resident of other congregate settings (e.g., correctional facilities, homeless shelter)
    2. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
    3. People who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally should not receive a subsequent dose of any COVID-19 vaccine ([https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)). If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, considerations for subsequent vaccination may include:
* The myocarditis or pericarditis was considered unrelated to the mRNA Covid-19 vaccination, especially if the myocarditis or pericarditis occurred more than 3 weeks after the most recent doses of COVID-19 vaccine
* Increased personal risk of severe acute COVID-19 disease
* Increased level of COVID-19 community transmission and personal risk of infection

If an additional dose is indicated then

* Ensure the episode of myocarditis or pericarditis is resolved
* For men ages 18 years and older consider using of Janssen COVID-19 vaccine instead of mRNA COVID-19 vaccines. A dose of Janssen’s COVID-19 could be considered as long as the patient is made aware of the risk of Thrombosis with thrombocytopenia syndrome (TTS) [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-Janssen](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)
  + 1. People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses) may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved. This includes resolution of symptoms attributed to myocarditis or pericarditis, as well as no evidence of ongoing heart inflammation or sequelae as determined by the person’s clinical team.
    2. Delay vaccination if the individual has history of MIS-C or MIS-A until 90 days have passed from the MIS-C or MIS-A diagnosis

\*\*\*Providers may consider deferring vaccination with the mRNA SARS-CoV-2 vaccine at this time until individual has been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available) depending on risk of exposure to SARS-CoV-2 or risk of severe disease or death due to COVID-19 for further guidance visit [https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)

1. Moderna COVID-19 Bivalent vaccine is recommended for patients who are pregnant, breastfeeding, trying to get pregnant now, or those who might become pregnant in the future. Routine testing for pregnancy or antibody testing is not recommended prior to vaccination.
2. Provide
   1. Provide the Emergency Use Authorization (EUA) Fact Sheet

Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the Emergency Authorization Fact Sheet. Provide non-English language if one is available and desired; these can be found at: <https://eua.modernatx.com/covid19vaccine-eua/bivalent-dose-recipient.pdf>

* 1. Provide the Vaccine Information Statement (VIS)

Provide all patients (or in the case of minors or incapacitated adults their legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language if one is available and desired; these can be found at [www.immunize.org](http://www.immunize.org/)

1. Prepare
   1. The Moderna COVID-19 Vaccine, Bivalent is supplied in a multiple-dose vial presentation (Blue Cap vial with a gray bordered label)
   2. Choose the correct needle length and gauge for an intramuscular injection

|  |  |  |  |
| --- | --- | --- | --- |
| Gender and Weight of patient | Needle Gauge | Needle Length | Injection Site |
| Female or Male less than 130 pounds | 22-25 | 5/8” – 1” | Intramuscular Deltoid |
| Female or Male 130 - 152 pounds | 22-25 | 1” | Intramuscular Deltoid |
| Female 153 - 200 pounds | 22-25 | 1 – 1 ½” | Intramuscular Deltoid |
| Male 153 - 260 pounds | 22-25 | 1” – 1 ½” | Intramuscular Deltoid |
| Female 200 + pounds | 22-25 | 1 ½” | Intramuscular Deltoid |
| Male 260 + pounds | 22-25 | 1 ½” | Intramuscular Deltoid |
| Females and Males | 22-25 | 1” to 1 ½” | Intramuscular Vastus Lateralis |

* 1. Prepare the Moderna COVID-19 vaccine (Blue Cap vial with a gray bordered label)

Thaw the vaccine vial if frozen for 1 hour at room temperature or for 2 hours and 30 minutes in a refrigerator

Once thawed remove the cap of the Moderna vaccine

Let vial sit at room temperature for 15 minutes before administering

Document date and time the vaccine was opened on the Moderna vaccine vial

Clean top of Moderna vaccine vial with alcohol prep pad and withdraw:

0.5mL of Bivalent booster vaccine

Gently swirl the vial between each dose withdrawn

Discard open vial after 12 hours or after all doses have been removed (whichever comes first)

1. Administer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TABLE 6A: Individuals who ARE NOT moderately to Severely Immunocompromised** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction** | **Vaccination History /Dose schedule** |
| Moderna COVID-19 Vaccine **Bivalent** (Original and Omicron BA.4/BA.5)  Vial with Dark Blue Cap with Gray Label Border | 12- 64 years of age | 0.5mL | Administer vaccine in the Deltoid muscle or the Vastus lateralis Intramuscularly | **Unvaccinated individuals** should receive 1 bivalent dose.  **Individuals who have received one or more doses of a monovalent covid vaccine** should receive 1 bivalent dose   * At least 8 weeks after the last monovalent dose |
| 65 years and older | **Individuals 65 years and older who have received one mRNA bivalent dose** may receive 1 additional bivalent dose   * At least 4 months after their last bivalent dose |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TABLE 6B: Individuals who ARE moderately to Severely IMMUNOCOMPROMISED** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction** | **Vaccination History /Dose schedule** |
| Moderna COVID-19 Vaccine **Bivalent** (Original and Omicron BA.4/BA.5)  Vial with Dark Blue Cap with Gray Label Border | 12 years and older | 0.5mL | Administer vaccine in the Deltoid muscle or the Vastus lateralis Intramuscularly | **Unvaccinated individuals** should receive 3 doses   * Dose 1 and 2 are 4 weeks apart * Dose 2 and 3 are 4 weeks apart   **Individuals with 1 previous dose of a Moderna COVID-19 monovalent vaccine** should receive 2 doses   * Dose 1 is at least 4 weeks from the last monovalent dose * Dose 2 is 4 weeks after dose 1   **Individuals with 2 previous doses of a Moderna COVID-19 monovalent vaccine** should receive 1 dose   * Spaced at least 4 weeks after the last monovalent dose   **Individuals with 3 previous doses of Moderna COVID-19 monovalent** should receive 1 dose   * spaced at least 8 weeks after the last monovalent dose   **Individuals with 3 previous doses of Moderna COVID-19 monovalent vaccine and 1 dose of bivalent mRNA vaccine** mayreceive one additional dose of bivalent vaccine   * spaced at least 8 weeks from the last dose   (This dose is optional and dependent on personal preference and/or health circumstances). |

\*If the same vaccine that the person received previously is not available, a mixed series of mRNA COVID-19 may be administered spaced appropriately apart according to the most recent clinical guidelines that can be found here [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html HYPERLINK "https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html%20"](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html%20) .

All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose

1. Document
   1. Consent Form: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, the vaccine dosage, and the name and title of the person administering the vaccine. Document the VIS given, and VIS publication date.
   2. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic and supply to recipient at time of vaccination.
   3. Documentation of the vaccination in Missouri’s immunization information system- ShowMeVax within 24-48 hours following vaccination
2. Emergency Protocols
   1. If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.
   2. If symptoms are generalized (generalized itching, redness, urticaria (hives); or include angioedema (swelling of the lips, face, or throat); shortness of breath; shock; or abdominal cramping; call 911 and notify the patient’s physician. Notifications should be done by a second person while the primary healthcare professional assesses the airway, breathing, circulation and level of consciousness of the patient. Vital signs (heart rate, respirations and Blood Pressure, pulse ox) should be taken every 5 minutes.

First-line treatment of an anaphylactic reaction is to administer Epinephrine 1:1000 dilution intramuscularly adult dose 0.3ml to 0.5ml with maximum dose of 0.5ml; or

To administer Epinephrine auto-injector (0.3ml)

For hives or itching, you may also administer diphenhydramine (orally or intramuscular with a standard dose of 25-50mg.) or hydroxyzine (standard oral dose is 25mg - 100mg or 0.5 - 1.0 mg/kg.

Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.

If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5-15 minutes for up to 3 doses depending on patient’s response.

Record the patient’s reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs, and medications administered to the patient, including time dosage, response, and the name of the medical personnel who administered the medication and other relevant clinical information. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html> or call 1-800-822-7967.

Notify the patient’s primary care physician.

This order and procedure shall be effective on DATE and shall remain in effect until rescinded or until DATE.

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Chief Medical Officer

VACCINE ADMINISTRATION RESOURCE LINKS

Moderna Products

<https://www.fda.gov/media/159306/download>

At a Glance Schedule

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-vacc-schedule-at-a-glance-508.pdf>

Vaccine Needle Length and Gauge chart

<https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf>

Frequently Asked Questions by Health Care providers

<https://www.cdc.gov/vaccines/covid-19/hcp/faq.html>

Training Material

<https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>