



Missouri Department of Health and Senior Services

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December 29, 2022

Standing Order for Janssen COVID-19 Vaccine

Purpose

To reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating individuals 18 years and older in the state of Missouri who meet the criteria established by the Advisory Committee on Immunization Practices (ACIP).

Policy

This standing order establishes administration parameters for any individual authorized to administer a COVID-19 vaccine by declaration of the Secretary of the Department of Health and Human Services, issued pursuant to the Public Readiness and Emergency Preparedness Act. Any healthcare provider who is authorized to administer a COVID-19 vaccine in Missouri under the March 18, 2021 DHSS Standing Orders, that is not expressly authorized to vaccinate by the declaration of the Secretary of the Department of Health and Human Services, is still authorized to administer a COVID-19 vaccine, if such individual complies with the requirements enumerated in the applicable March 18, 2021 Standing Order. All other provisions of the March 18, 2021 Standing Orders relating to administration of a COVID-19 vaccine are hereby terminated and this Order shall control.

Either authorized mRNA COVID-19 vaccines are preferred over the Janssen COVID-19 vaccine for the prevention of COVID-19 in individuals 18 years and older due to the risk of thrombosis with thrombocytopenia or Guillain-Barré Syndrome (GBS) following vaccination.

Procedure

1. Assess adults in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
 - a. Must be 18 years and older
 - b. Individual is received only one dose of mRNA COVID-19 vaccine, and cannot finish the mRNA series may receive a dose of Janssen COVID-19 vaccine as long as 28 days have passed since receiving the mRNA vaccine
 - c. Janssen 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 reactogenicity profile of the vaccines
2. Screen all adults for contraindication and precautions for the SARS-CoV-2 vaccine¹
 - a. Contraindications
 - i. Under 18 years of age

¹ These precautions and contraindications are subject to change following the final release of the Advisory Committee on Immunization Practices and CDC recommendations to be published in the MMWR March 2021.

- ii. Do not give the vaccine to anyone who has had a severe allergic reaction to the Janssen Covid-19 vaccine or any ingredient of this vaccine (<https://www.fda.gov/media/146304/download>)
- iii. Do not give the SARS-CoV-2 vaccine to an individual who has had an immediate allergic reaction of any severity to polysorbate (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG**)
- iv. Do not administer the Janssen COVID-19 vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (e.g., AstraZeneca's COVID-19 vaccine which is not approved or licensed in the United States)

*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 Janssen COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications>

** These individuals should not receive Janssen COVID-19 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)

b. Precautions

- i. Moderate or severe acute illness with or without a fever
- ii. Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any mRNA vaccine including both Moderna and PfizerNBioTech SARS CoV-2 vaccines**
 - 1. Action
 - 1. Assess the risk of vaccination
 - 2. Observe patient for 30 minutes following vaccination
- iii. Severe allergic reaction (e.g. Anaphylaxis) to a medication** that is injectable
 - 1. Action
 - 1. Assess the risk of vaccination
 - 2. Observe patient for 30 minutes following vaccination
- iv. Delay vaccination in individuals in community or outpatient settings who have a known SARS-CoV-3 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)
- v. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
- vi. 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 Janssen COVID-19 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>

3. Special Populations for which special counseling and a 15 minute observation period is recommended.
 - a. Pregnant females are recommended for vaccine depending on
 - i. Level of COVID-19 community transmission (risk of acquisition)
 - ii. Personal risk of contraction COVID-19 to her and potential risks to the fetus
 - iii. The efficacy of the vaccine
 - iv. The known side effects of the vaccine
 - v. The lack of data about the vaccine during pregnancy
 - b. Lactating (Breastfeeding) is not a contraindication to vaccination
 - c. Immunocompromised
 - i. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
 - ii. Data not currently available to establish safety and efficacy of vaccine in these groups
 - iii. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
 - iv. Individuals should be counseled about:
 1. Unknown vaccine safety and efficacy profiles in immunocompromised persons
 2. Need to continue to follow all current guidance to protect themselves against COVID-19
 - d. Precaution to review with all individuals:
 - i. The rare possibility of developing a rare blood clotting disorder, especially in women under 50 years of age, called thrombosis with thrombocytopenia syndrome (TTS). The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia (<https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>).
 1. Persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (such as Heparin Induced Thrombocytopenia (HIT)) should be offered another FDA – authorized COVID-19 vaccine and defer vaccine for 90-180 days after resolution of illness
 2. If you experience any of the following symptoms seek medical attention right away:
 - Shortness of breath
 - Chest pain
 - Leg pain or swelling
 - Backache
 - Persistent abdominal pain
 - Severe and persistent headaches
 - Visual changes

- Easy bruising or tiny blood spots under the skin beyond the site of the injection
- e. Routine testing for pregnancy or Antibody testing is not recommended prior to vaccination
4. Provide the Emergency Use Authorization (EUA) Fact Sheet
1. 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://www.fda.gov/media/146305/download>
5. Provide the Vaccine Information Statement (VIS)
- i. 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
6. Prepare
- a. 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 |

- b. Prepare the Janssen COVID-19 vaccine
 - i. Remove the vaccine vial from the refrigerator
 - ii. Document date and time the vaccine was opened on the Janssen vaccine vial
 - iii. Clean top of Janssen vaccine vial with alcohol prep pad and with draw 0.5 ml of vaccine
 - iv. After the first dose has been withdrawn, hold the vial between 2°-8° C or 36°-46°F for up to 6 hours or at room temperature for up to 2 hours. Discard vaccine if not used within this time frame.
 - v. Gently swirl the vial between each dose withdrawn

- vi. Any remaining vaccine that does not equal a full 0.5 ml dose should not be pooled with other remaining vaccine to obtain a full 0.5 ml dose.

7. Administer

| Type of Vaccine | Age group | Dose | Route | Instruction |
|-----------------------------------|---|--------|--|---|
| Janssen COVID-19 | Adults 18 years and older | 0.5 ml | Intramuscular via Deltoid/ Vastus Lateralis | Administer 1 dose of the vaccine |
| *Janssen COVID-19 additional dose | All Adults 18 years and old who are moderately to severely immune compromised | 0.5ml | Intramuscular via Deltoid/ Vastus Lateralis | Administer an additional dose at least 28 days after 1 st dose |
| *Janssen COVID-19 booster | Adults 18 years and older | 0.5 ml | Intramuscular via Deltoid/ Vastus Lateralis | Administer a single booster dose at least 8 weeks after last dose |

**Individuals who received a dose of Janssen COVID-19 vaccine as the first dose may receive a dose of any mRNA approved COVID-19 vaccine. Any Booster dose administered should be at least 8 weeks apart from the 1st dose and for individuals that are moderately or severely immune compromised 8 weeks after the additional dose. More information on interim clinical guidelines of the Janssen vaccine can be found at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>*

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

8. Document

- 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.
- Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic and supply to recipient at time of vaccination.
- Documentation of the vaccination in Missouri's immunization information system- ShowMeVax within 24-48 hours following vaccination

9. Emergency Protocols

- a. 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.
- b. 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.
 - i. 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
 - ii. To administer Epinephrine auto-injector (0.3ml)
 - iii. 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.
 - iv. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
 - v. 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.
 - vi. 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.
 - vii. Notify the patient's primary care physician.

This order and procedure shall be effective on December 29, 2022 and shall remain in effect until rescinded or until March 31, 2023.



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