



Missouri Department of Health and Senior Services

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Standing Orders for Pfizer-BioNTech's COVID-19 Vaccine Administration to Persons 12 Years of Age 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

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.

Procedure

Primary Series Vaccination

1. Assess adults and Adolescents in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria
 - a. Must be 12 years and older
 - b. If the recipient has received a previous dose of Pfizer-BioNTech COVID-19 vaccine, the second dose of the same brand should be administered.
 - c. The vaccine is administered in a 2-dose series separated by at least 21 days however if dose was given as early as 17 days after the first dose, then do not repeat.
 - d. PfizerBioNTech 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.
 - e. A third dose of Pfizer-BioNTech COVID-19 vaccine may be administered for certain individuals 12 years and older with moderate to a severe immune

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compromise due to a medical condition or recipe of immunosuppressive medication or treatments including but not limited to

- i. Immune compromised due to undergone solid organ transplantation and taking immune suppressing medications
- ii. Immune compromised active treatment for solid tumor and hematologic malignancies
- iii. Immune compromised receipt of CAR-T cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- iv. Moderate to severe primary immunodeficiency (eg., DiGeorge, Wiskott-Aldrich Syndromes)
- v. Immune compromised due to Advanced or untreated HIV infection
- vi. Immune compromised due to “Active treatment with high-dose corticosteroids or other drugs that may suppress immune response: high-dose corticosteroids (ie., ≥ 20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blocker or other biologic agents that are immunosuppressive or immunomodulatory”

Booster Vaccination

- f. **A single dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is FDA-authorized for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:**
 - i. **Completion of a primary vaccination with any authorized or approved monovalent* COVID-19 vaccine or**
 - ii. **Receipt of the most recent booster dose with any authorized and approved monovalent COVID-19 vaccine**

***Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the original SARS-CoV-2 virus**

2. Screen all adults and adolescents for contraindication and precautions for the SARS-CoV-2 vaccine
 - a. Contraindications
 - i. Under 12 years of age
 - ii. 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/144413/download>
 - iii. 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>

**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)

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 vaccine (not including Pfizer-BioNTech COVID-19 Vaccine)
 - Action
 - a. Assess the risk of vaccination
 - b. Observe patient for 30 minutes following vaccination
- iii. Polysorbate allergy is a precaution to Pfizer-BIONTech COVID-19 vaccine (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
- iv. Severe allergic reaction ** (e.g. Anaphylaxis) to a medication that is injectable
 - Action
 - a. Assess the risk of vaccination
 - b. Observe patient for 30 minutes following vaccination
- v. 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)
- vi. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
- vii. 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>). 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>

- viii. 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.
- ix. 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>

3. Special Populations for which special counseling 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:
 - Unknown vaccine safety and efficacy profiles in immunocompromised persons
 - Need to continue to follow all current guidance to protect themselves against COVID-19
 - Have individuals seeking a 3rd dose of the mRNA PfizerBioNTech COVID-19 vaccine complete the additional mRNA COVID-19 Vaccine Dose Attestation statement

4. Routine testing for pregnancy or antibody testing is not recommended prior to vaccination

5. Provide

- a. Provide the Emergency Use Authorization (EUA) Fact Sheet
 - i. 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/144413/download>
- b. 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 1/2"	Intramuscular Deltoid
Male 153 - 260 pounds	22-25	1"-1 1/2"	Intramuscular Deltoid
Female 200 + pounds	22-25	1 1/2"	Intramuscular Deltoid
Male 260 + pounds	22-25	1 1/2"	Intramuscular Deltoid

b. Prepare the PfizerBioNTech COVID-19 vaccine

i. **Identify which PfizerBioNTech vaccine you are using**

Pfizer-BioNTech (purple cap) COVID-19 Vaccine	Pfizer-BioNTech-Tris COVID-19 Vaccine (Gray cap) – <u>DO NOT DILUTE</u>
Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator	Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator
Once thawed remove the cap of the Pfizer vaccine and inject 1.8 ml of 0.9% sodium chloride that comes in the ancillary kit of the vaccine	Gently invert the vaccine vial 10 times.
Gently invert the vaccine vial 10 times	Clean top of Pfizer vaccine vial with alcohol prep pad and with draw 0.3ml of vaccine
Document date and time the vaccine was diluted on the Pfizer vaccine vial	Document date and time the vaccine vial was punctured on the Pfizer vaccine vial
Clean top of Pfizer vaccine vial with alcoholprep pad and with draw 0.3ml of vaccine	Discard open vial after 12 hours or after all doses have been removed (Whichever comes first)
Discard open vial after 6 hours or after all doses have been removed (Whichever comes first)	

ii. Due to production at the factory a 6th dose may be removed. However any remaining vaccine that does not equal a full 0.3ml dose should not be pooled with other remaining vaccine to obtain a full 0.3ml dose

7. Administer

Type of vaccine	Age group	Dose	Route	Instruction	Dose schedule
Pfizer *2 dose Primary eries	Individuals 12 years and older	0.3ml	Intramuscular	Administer vaccine in the Deltoid muscleor the Vastus Lateralis	Give dose #1 and 2 3-8 weeks apart
Pfizer **3 dose Primary series	Moderately to severely immune compromised individuals 12 years and older	0.3ml	Intramuscular	Administer vaccine in the Deltoid muscleor the Vastus Lateralis	Give dose #1 and #2 at least 21 days apart #2 and #3 at least 28 days apart
<u>Pfizer- BioNTech COVID- 19 Vaccine, Bivalent (Original and Omicron BA.4/BA. 5)</u>	Individuals 12 years and older	0.3mL	Intramuscular	Administer vaccine in the Deltoid muscle or the Vastus Lateralis	Give 1 bivalent booster dose at least 2 months after the last dose in the primary series or last ***monovalent booster dose

*An 8-week interval may be optimal for people ages 12 years through 64 years, and especially for males ages 12 through 39 years, who are not moderately or severely immunocompromised. A shorter interval (3 weeks for Pfizer-BioNTech) between the first and second dose remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and others who need early protection due to increased concern about community transmission or risk of severe disease. COVID-19 mRNA vaccine doses administered after the recommended time frame are valid and do not need to be repeated.

**If the same vaccine that the person received previously is not available, a mixed series of mRNA COVID-19 or a dose of Janssen COVID-19 vaccine 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>.

*****Monovalent refers to any authorized and approved COVID-19 vaccine that contains or encodes the spike protein of only the original SARS-CoV-2 virus**

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

8. Document

- a. 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.

- b. Immunization Record Card: Record the date of vaccination, and the name/location of the administering clinic and supply to recipient at time of vaccination.
- c. 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.

Age group	Range of weight	Epinephrine dose (<i>dose is dependent on whether an ampule or auto-injector is utilized</i>)	
		1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine auto injector or prefilled syringe 0.3 mg)
12 years of age	77 - 99 lbs. or 35 - 45 kg.	0.35-0.4ml or	0.3mg/dose
13 years of age or older	100+lbs. or 46+ kg.	0.5ml or 0.5mg	

*If weight known, then dose by weight is preferred, if unknown then dose by age is appropriate. May use Diphenhydramine (Benadryl) as a second line treatment

Age group	Range of weight	Diphenhydramine (<i>Benadryl</i>) dose <i>50mg/ml intramuscularly</i>
12 years of age	77 lbs. or 35-45 kg.	25 - 50 mg/ dose
13 years of age and older	100+ lbs. or 46+ kg.	50 mg/dose (up to 50mg or 100mg single dose) **

*If weight known then dose by weight is preferred, if unknown then dose by age is appropriate.

**AAP. Red Book: 2018–2021, 31st ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40mg, for children age 12 years and older, 100mg.

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

- iii. 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.
- iv. Notify the patient's primary care physician.

This order and procedure shall be effective on September 2, 2022 and shall remain in effect until rescinded or until December 31, 2022.



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VACCINE ADMINISTRATION RESOURCE LINKS

Pfizer Products

<https://www.fda.gov/media/144413/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>