May 4, 2023

# Standing Orders for Pfizer-BioNTech 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

# Vaccination

1. Assess adults and adolescents in need of vaccination against the SARS-CoV-2 vaccine based on the following criteria

**For individuals WHO ARE NOT moderately to severely immunocompromised:**

1. Must be 12 years and older
2. Individuals who have never received a dose of any SARS-Co-V-2 vaccine, administer one dose of the PFIZER-BioNTech SARS-Co-V-2 Bivalent vaccine
3. Individuals who have completed a monovalent SARS-Co-V-2 vaccine series (either Moderna or Pfizer-BioNTech) and have not received a Bivalent booster dose of an mRNA vaccine (either Moderna or Pfizer-BioNTech), administer one (1) dose of the Pfizer-BioNTech SARS-Co-V-2 Bivalent vaccine at least 8 weeks after the last dose in the primary series.
4. Individuals who have received a previous dose of a monovalent SARS-Co-V-2 vaccine (J&J/ Janssen) may receive a dose of the Pfizer-BioNTech SARS-Co-V-2 bivalent vaccine spaced at least 8 weeks from the previous dose of monovalent SARS-Co-V-2 vaccine.
5. Individuals 65 years or older and if they have already received one (1) booster dose of an authorized mRNA bivalent vaccine may receive an additional dose of the Pfizer-BioNTech SARS-Co-V-2 Bivalent vaccine Pfizer-BioNTech bivalent mRNA vaccine spaced at least 16 weeks (4 months) from the last bivalent dose.
6. Individuals who have received 2 doses of the Novavax SARS-Co-V-2 vaccine may receive a dose of the Pfizer-BioNTech SARS-Co-V-2 bivalent vaccine spaced at least 8 weeks from the last dose of Novavax.
7. PfizerBioNTech COVID-19 Bivalent 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 vaccine.

**For individuals WHO ARE moderately to severely immunocompromised:**

* Unvaccinated individuals should receive three (3) doses of the PfizerBioNTech vaccine, Bivalent. Dose 1 and 2 should be spaced at least 3 weeks apart and dose 2 and 3 should be spaced at least 4 weeks apart
* Individuals who have already received one (1) dose of a monovalent SARS-CoV-2 vaccine should receive two (2) doses of the PfizerBioNTech Bivalent vaccine. Space bivalent dose 1 at least 3 weeks from the last monovalent dose. Space bivalent dose 2 at least 4 weeks after bivalent dose 1.
* Individuals who have already received two (2) doses of a monovalent SARS-CoV-2 vaccine should receive one (1) dose of the PfizerBioNTech Bivalent vaccine. Space bivalent dose at least 4 weeks after the last monovalent dose.
* Individuals who have already received three (3) doses of a monovalent SARS-Co-V-2 vaccine should receive one (1) dose of the PfizerBioNTech Bivalent vaccine, spaced at least 8 weeks after the last monovalent dose.
* Individuals who have already received 3 doses of a monovalent SARS-CoV-2 vaccine and one dose of a SARS-Co-V-2 mRNA Bivalent vaccine, Bivalent may receive one (1) additional dose of the PfizerBioNTech Bivalent vaccine spaced at least 8 weeks from the last bivalent dose.

1. Screen all adults and adolescents for contraindication and precautions for the SARS-CoV-2 vaccine
   1. Contraindications
2. Under 12 years of age
3. Known diagnosed allergy to a component of the COVID-19
4. 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/167211/download>
5. 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-](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications) [considerations.html#Contraindications](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)

* 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 Pfizer-BioNTech COVID-19 Vaccine)
   * Action
3. Assess the risk of vaccination
4. Observe patient for 30 minutes following vaccination
5. Polysorbate allergy is a precaution to Pfizer-BioNTech COVID-19 vaccine (due to potential cross-reactivity hypersensitivity with the vaccine ingredient PEG)
6. Severe allergic reaction \*\*\*(e.g. anaphylaxis) to a medication that is injectable
   * Action
7. Assess the risk of vaccination
8. Observe patient for 30 minutes following vaccination
9. 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)
10. Defer vaccination for both symptomatic and asymptomatic COVID-19 patients until they have met criteria to discontinue isolation
11. 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>

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
3. Persons who have received HCT or CAR-T-cell therapy who have received doses of the COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy with a primary series of any authorized SARS-Co-V-2 vaccine may, receive 2 doses of the PfizerBioNTech SARS-Co-V-2 bivalent vaccine. These individuals are advised to speak to their healthcare provider

\*\*\*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

1. Special Populations for which special counseling is recommended.
   1. PfizerBioNTech 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. Immunocompromised
2. Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies
3. Data is limited to establish safety and efficacy of vaccine in these groups
4. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
5. Individuals should be counseled about:
   * Limited vaccine safety and efficacy profiles in immunocompromised persons
   * Need to continue to follow all current guidance to protect themselves against COVID-19
6. Provide
   1. Provide the Emergency Use Authorization (EUA) Fact Sheet
7. 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/167211/download
   1. Provide the Vaccine Information Statement (VIS)
8. 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)
9. Prepare
   1. Choose the correct needle length and gauge for an intramuscular injection

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| **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 PfizerBioNTech COVID-19 vaccine

# Identify which PfizerBioNTech vaccine you are using

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| **Pfizer-BioNTech-Tris COVID-19 Vaccine (Gray cap) – DO NOT DILUTE** |
| Thaw the vaccine vial if frozen for 30  minutes at room temperature or for 3 hours in a refrigerator |
| 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 vial was  punctured on the Pfizer vaccine vial |
| Discard open vial after 12 hours or after all doses have been removed (Whichever comes first) |
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# 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

# Administer

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| **Individuals who ARE NOT moderately to Severely immunocompromised** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction/ route** | **Vaccination History /Dose schedule** |
| Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)  Vial has a Gray cap | 12- 64 years of age | 0.3mL | Administer intramuscularly vaccine in the Deltoid muscle or the Vastus lateralis | Administer 1 Bivalent dose to unvaccinated individuals  Individuals who have received one or more doses of a monovalent vaccine should receive   * 1 dose spaced 8 weeks from the last dose of the monovalent |
| 65 years and older |  |  | Individuals who have received one mRNA bivalent dose may receive an additional dose   * Dose 1 and 2 are 4 months apart |

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| --- | --- | --- | --- | --- |
| **Individuals who ARE moderately to severely immunocompromised** | | | | |
| **Type of vaccine** | **Age group** | **Dose** | **Instruction/ route** | **Vaccination History /Dose schedule** |
| Pfizer-BioNTech COVID-19 Vaccine Bivalent (Original and Omicron BA.4/BA.5)  Vial has Gray cap | 12 years and older | 0.3mL | Administer vaccine intramuscularly | Unvaccinated individuals should receive 3 doses   * Dose 1 and 2 are 3 weeks apart * Dose 2 and 3 are 4 weeks apart   Individuals with 1 previous dose of a mRNA monovalent vaccine should receive 2 doses   * Dose 1 at least 3 weeks from the last monovalent dose * Dose 1 and 2 are 4 weeks apart   Individuals with 2 previous dose of monovalent mRNA vaccines should receive 1 dose spaced at least 4 weeks after the last monovalent dose  Individuals with 3 previous doses of monovalent mRNA should receive 1 dose spaced at least 8 weeks after the last monovalent dose  *Individuals with 3 previous doses of monovalent vaccine and 1 dose of bivalent mRNA vaccine may receive an additional dose of bivalent vaccine spaced at least 8 weeks from the last dose* |

\*\*If the same vaccine that the person received previously is not available, a mixed series of mRNA 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](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.

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| **Age group** | **Range of weight** | **Epinephrine dose *(dose is dependent on whether an ampule or auto-injector is utilized)*** | |
| 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

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| **Age group** | **Range of weight** | **Diphenhydramine *(Benadryl)* dose**  *50mg/ml intramuscularly* |
| 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.

1. Monitor the patient closely until EMS arrives. Monitor blood pressure and pulse every 5 minutes.
2. 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.
3. 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.
4. 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

Pfizer Products

<https://www.fda.gov/media/167211/download>

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>