12 Years of Age and Older (Purple Cap)

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage (amount)/ Route
12 years of age and older (purple cap)	**1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) diluent	**0.3 mL**/IM injection

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

Assess persons 12 years of age and older for vaccination with Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Pfizer- BioNTech COVID-19 Vaccine, administer the second dose at least 3 to 8 weeks after the first dose
  - If the first-dose vaccine product cannot be determined or is no longer available, administer Pfizer-BioNTech COVID-19 Vaccine at least 3 to 8 weeks after the first dose.
  - While a 3-week interval remains optimal for moderately to severely immunocompromised persons, adults ages 65 years and older, and others who need rapid protection because of community transmission or risk of disease, an 8-week interval may be optimal for some people, including males 12-39 years of age because of the small risk of myocarditis associated with mRNA COVID-19 vaccines. Vaccine effectiveness may also be increased with an interval longer than 3 weeks.
- If the recipient has received 2 previous doses of Pfizer- BioNTech COVID-19 Vaccine, administer a booster dose at least 5 months after dose 2
- If the recipient has received 3 previous doses of Pfizer-BioNTech COVID-19 Vaccine (2 primary series doses and a booster), administer a second booster dose to persons 50 years of age or older at least 4 months after the most recent dose. (4 total doses)
- If the recipient has received 1 dose of Janssen COVID-19 Vaccine, administer a booster dose (mRNA vaccine preferred) at least 2 months (8 weeks) after the single primary series dose.
- If the recipient has received 2 doses of Janssen COVID-19 Vaccine and is:
  - 18 – 49 years of age, a booster dose of mRNA vaccine may be given at least 4 months after the previous dose (3 total doses)
  - 50 years of age and older, a booster dose of mRNA vaccine should be given at least 4 months after the previous dose (3 total doses)
- If the recipient has received 2 doses of COVID-19 vaccine (1 dose of Janssen and 1 dose mRNA vaccine) and are 50 years of age and older administer a second mRNA booster dose at least 4 months after the most recent dose. (3 total doses)

Persons who **ARE** moderately or severely immunocompromised*†

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Pfizer- BioNTech COVID-19 Vaccine, administer the second dose at least 21 days (3 weeks) after the first dose.
  - If the first-dose vaccine product cannot be determined or is no longer available, administer Pfizer-BioNTech COVID-19 Vaccine at least 21 days (3 weeks) after the first dose.
- If the recipient has received:
  - 2 doses of Pfizer-BioNTech Vaccine, administer a third dose at least 28 days (4 weeks) after dose 2
  - 1 dose of Janssen COVID-19 Vaccine, administer Pfizer-BioNTech COVID-19 Vaccine at least 28 days (4 weeks) after Janssen COVID-19 Vaccine.
- If the recipient has received:
  - 3 previous doses of Pfizer- BioNTech COVID-19 Vaccine, administer a booster dose at least 3 months after the dose 3 in the mRNA primary series.
  - 1 dose of Janssen and an additional dose of mRNA vaccine (any product), administer a booster dose at least 2 months (8 weeks) after the additional dose of mRNA vaccine.
- If the recipient has received:
  - 4 previous doses of Pfizer-BioNTech COVID-19 Vaccine (3 primary series doses and a booster), administer a second booster dose at least 4 months after the most recent dose. (5 total doses)
  - 1 dose of Janssen, an additional dose of mRNA vaccine, and 1 booster dose, a second mRNA booster should be administered at least 4 months after the first booster. (4 total doses)
- Additional clinical considerations
  - Persons who have received HCT or CAR-T-cell therapy:
    - » Revaccinate persons who received doses of COVID-19 vaccine prior to receiving or during HCT or CAR-T-cell therapy with a primary series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.

* Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of mycarditis or pericarditis develop after vaccination. Educational materials are available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

- For persons who received a COVID-19 vaccine:
  - Outside of the United States
  - Not currently authorized/approved in the United States

  See clinical guidance, including booster dose recommendations, at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us
- Pfizer-BioNTech COVID-19 Vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection guidance, including after receiving passive antibody products, can be found at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination

- 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 vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)
  - Precautions:
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - Immediate allergic reaction‡ to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
      - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
    - Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
    - Contraindication to one type of COVID-19 vaccine (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)§
    - Moderate to severe acute illness, with or without fever
    - History of MIS-C or MIS-A
    - History of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site¶
Female or male fewer 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

- Provide all recipients and/or parents/legal guardians with a copy of the current Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. 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.
  - Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- 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

‡ An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

§ Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

¶ 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 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

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

- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope:
    - **30 minutes:** persons with a history of:
      - A contraindication to another type of COVID-19 vaccine product.
      - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine.
      - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
      - Anaphylaxis due to any cause.
    - **15 minutes:** All other persons
  - Syncope may occur in association with injectable vaccines, in particular 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, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
  - 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.
  - For more information, please see:
    - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/p□zer/anaphylaxis-management.html**
    - **CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html**
    - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA) (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), 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 (https://www.cdc.gov/mis-c/mis-a.html) or children (https://www.cdc.gov/mis-c/index.html)
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS (https://vaers.hhs.gov/):
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

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 _____

effective_____ until rescinded or until _____ .

Medical director (or other authorized practitioner)

_____ / _____ /_____.

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