12 Years of Age and Older

Pfizer-BioNTech COVID-19 Vaccine

(Monovalent and Bivalent)

Standing Orders for Administering Vaccine

Vaccine	Diluent	Dosage/Injection Amount	Route
Monovalent: Gray capped vial with gray-bordered label	Do **NOT** dilute.	**Primary dose:** 30 *µg*/0.3 mL	Intramuscular (IM) injection
Bivalent: Gray capped vial with gray-bordered label	Do **NOT** dilute.	**Booster dose:** 30 *µg*/0.3 mL	Intramuscular (IM) injection

NOTE: Use these standing orders in conjunction with Interim COVID-19 Immunization Schedule for Persons 6 Months and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf

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 monovalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Monovalent Pfizer-BioNTech COVID-19 Vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 to 8 weeks[‡] after the first dose. (Primary series completed)
  - Monovalent Janssen COVID-19 Vaccine, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the first dose.
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 4 to 8 weeks[‡] after the first dose. (Primary series completed)
- If the recipient has received 2 primary series doses of:
  - Monovalent COVID-19 Vaccine (Moderna, Novavax or Pfizer-BioNTech), regardless of the number of monovalent booster doses, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the previous dose.[§]

Persons who ARE moderately or severely immunocompromised[*†]

- If the recipient has never received a COVID-19 vaccine, administer 1 dose of monovalent Pfizer-BioNTech COVID-19 Vaccine.
- If the recipient has received 1 previous dose of:
  - Monovalent Pfizer-BioNTech COVID-19 Vaccine, administer the second primary dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 weeks (21 days) after the first dose.
  - Monovalent Janssen COVID-19 Vaccine, administer an additional dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 4 weeks after the first dose.
  - If the first-dose vaccine product cannot be determined, is no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 3 weeks (21 days) after the first dose.
- If the recipient has received 2 doses of:
  - Monovalent Pfizer-BioNTech Vaccine, administer a third dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 28 days (4 weeks) after Dose 2. (Primary series completed)
  - Monovalent Janssen COVID-19 Vaccine, administer an additional dose of monovalent Pfizer-BioNTech COVID-19 Vaccine at least 28 days (4 weeks) after the second dose.
  - Monovalent Novavax COVID-19 Vaccine, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the previous dose.

* Inform recipients, especially males 12–39 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 myocarditis 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).

‡ An 8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis and pericarditis associated with these vaccines. A shorter interval (4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults ages 65 years and older; and in situations in which there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

§ For persons who have received 2 doses of monovalent Janssen COVID-19 Vaccine, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine.

- If the previous vaccine products cannot be determined, are no longer available, or contraindicated, administer monovalent Pfizer-BioNTech COVID-19 Vaccine at least 4 weeks (28 days) after the second dose. (Primary series completed)

- If the recipient has received 3 or more doses of any monovalent COVID-19 vaccine, administer a booster dose of bivalent Pfizer-BioNTech COVID-19 Vaccine at least 8 weeks (2 months) after the previous dose.
  - This includes 3 or more doses of the same monovalent product, or a mix of products, e.g., Janssen and mRNA vaccines.

Additional clinical considerations

- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may receive Pfizer-BioNTech vaccine product (monovalent or bivalent) after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Pfizer-BioNTech COVID-19 vaccine (monovalent or bivalent). Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis

- Persons who have received HCT or CAR-T-cell therapy
  - Revaccinate persons who received doses of COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy with a primary series using monovalent COVID-19 vaccine and up to 1 booster dose of bivalent COVID-19 vaccine. Revaccination should start at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.

- 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/interim-considerations-us-appendix.html#appendix-b

- Pfizer-BioNTech COVID-19 Vaccine (monovalent or bivalent) may be coadministered with other vaccines without regard to timing, including simultaneous administration.
- See clinical guidance for COVID-19 vaccination and SARS CoV-2 infection, including recommendations after receiving passive antibody products, at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#infection

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 COVID-19 vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c for a list of vaccine components)

Precautions:

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines¶
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

¶ People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types. Consider consultation with an allergist/immunologist to help determine if a patient with a contraindication to the Novavax vaccine can safely receive another COVID-19 vaccine. 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.

Administration

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
  - Do NOT dilute
- Administer Pfizer-BioNTech COVID-19 Vaccine (monovalent or bivalent) by intramuscular (IM) injection
  - **Primary Series:** 0.3 mL of monovalent vaccine
  - **Booster Dose:** 0.3 mL of bivalent vaccine

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 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
  - Recipient's vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Indicate if the vaccine dose is a monovalent or bivalent product, if possible.
  - 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 consider observing patients after vaccination to monitor for allergic reactions and syncope:
  - **30 minutes for persons with:**
    - An allergy-related contraindication to a different type of COVID-19 vaccine
    - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
    - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
  - **15 minutes:** All other persons
- Syncope may occur in association with injectable vaccines, particularly 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.

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)

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

- Cases of myocarditis (for mRNA vaccines)
- Cases of pericarditis (for mRNA vaccines)
- 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

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/pfizer/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

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