Persons who have received HCT or CAR-T-cell therapy † 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).

ncov/vaccines/safety/myocarditis.html

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-

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. Vaccine effectiveness may also be increased with an interval longer than 3 weeks.

Additional clinical considerations
- Persons who have received HCT or CAR-T-cell therapy

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Diluent</th>
<th>Dosage (amount)/ Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 years of age and older (gray cap)</td>
<td>Do NOT dilute.</td>
<td>0.3 mL/IM injection</td>
</tr>
</tbody>
</table>

**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.

**Do NOT dilute.**
- 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
- 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

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† 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).
Revaccinate persons who received doses of COVID-19 vaccine prior to receiving HCT or CAR-T-cell therapy with a primary series 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/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

- Do NOT dilute.
- 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 administration data to the relevant system (e.g., immunization

**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).**

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<table>
<thead>
<tr>
<th>Sex and Weight of Patient</th>
<th>Needle Gauge</th>
<th>Needle Length</th>
<th>Injection Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female or male fewer than 130 lbs</td>
<td>22–25</td>
<td>⅜”–1”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female or male 130–152 lbs</td>
<td>22–25</td>
<td>1”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 152–200 lbs</td>
<td>22–25</td>
<td>1–1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 152–260 lbs</td>
<td>22–25</td>
<td>1–1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 200+ lbs</td>
<td>22–25</td>
<td>1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 260+ lbs</td>
<td>22–25</td>
<td>1½”</td>
<td>Deltoid muscle of arm</td>
</tr>
</tbody>
</table>

- 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.

- 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

**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).**

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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.
12 Years of Age and Older (Gray Cap)
Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine

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.
  - 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.
  - 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:
  - 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)
    - 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