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).

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 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- Women aged 18–49 years: Inform women of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group and about the availability of other authorized vaccines (i.e., mRNA vaccines).†
- Offer another FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) to persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia (e.g., heparin-induced thrombocytopenia) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.‡

Note: Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

- People with a history of Guillain-Barré Syndrome (GBS) can receive any FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, discuss with these patients the availability of mRNA COVID-19 vaccines to offer protection against COVID-19.
- Has not completed a COVID-19 vaccination series, regardless of brand.
  - The Janssen COVID-19 Vaccine requires 1 dose. No additional doses are needed.
  - If the recipient has received 1 previous dose of an mRNA vaccine, the same brand should be administered for the second dose.
  - In situations where the first dose of an mRNA COVID-19 vaccine was received but the patient is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. However, vaccination should be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions. Consider referral to an allergist-immunologist. See footnote for further information on administering Janssen COVID-19 Vaccine to persons with a contraindication to mRNA COVID-19 vaccines.§

Note: For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines

- Janssen COVID-19 Vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.¶
- Defer vaccination with Janssen COVID-19 Vaccine for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications
    - Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
    - Immediate allergic reaction† of any severity to a component of the vaccine (see Table 1 in this document for a list of ingredients in COVID-19 vaccines)
  - Precautions
    - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
    - History of an immediate allergic reaction† of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
      - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is polysorbate or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - People with a contraindication to an mRNA COVID-19 vaccine have a precaution to the Janssen COVID-19 Vaccine (see footnote).¶
      - Moderate to severe acute illness

†Educational materials are available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
‡When deciding whether to coadminister COVID-19 vaccine and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines. They should also consider the patient’s risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.
§For the purpose of this guidance, 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.
¶Consultation with an allergist-immunologist should be considered 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. 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.
Janssen COVID-19 Vaccine
(Johnson & Johnson)
Standing Orders for Administering Vaccine
to Persons 18 Years of Age and Older

<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>5/8” – 1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female or male 130–152 lbs</td>
<td>22–25</td>
<td>1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 152–200 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 152–260 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 200+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 260+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
</tbody>
</table>

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

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 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 on page 2.
  - Follow the manufacturer’s guidance for storing/handling punctured vaccine vials.
  - Administer 0.5 mL Janssen 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 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.janssencovid19vaccine.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 an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to mRNA COVID-19 vaccines who receive Janssen vaccine
      - History of 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:
    - 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), 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 or children
  - Cases of COVID-19 that result in hospitalization or death
  - Any additional AEs and revised safety requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if they are not sure whether the vaccine caused the adverse event

### 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

### Table 1: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines reported in the prescribing information for each vaccine.

<table>
<thead>
<tr>
<th>Description</th>
<th>Pfizer-BioNTech (mRNA)</th>
<th>Moderna (mRNA)</th>
<th>Janssen (viral vector)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active ingredient</strong></td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</td>
</tr>
<tr>
<td>Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2</td>
<td>PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
<td>Polysorbate-80</td>
<td></td>
</tr>
<tr>
<td>PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>2-hydroxypropyl-β-cyclodextrin</td>
<td></td>
</tr>
<tr>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>Cholesterol</td>
<td>Citric acid monohydrate</td>
<td></td>
</tr>
<tr>
<td>Cholesterol</td>
<td>(4-hydroxybutyl)azanediyldibis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
<td></td>
</tr>
<tr>
<td>(4-hydroxybutyl)azanediyldibis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>Sodium chloride</td>
<td>Trisodium citrate dihydrate</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Tromethamine</td>
<td>Sodium chloride</td>
<td></td>
</tr>
<tr>
<td>Tromethamine</td>
<td>Monobasic potassium phosphate</td>
<td>Ethanol</td>
<td></td>
</tr>
<tr>
<td>Monobasic potassium phosphate</td>
<td>Potassium chloride</td>
<td>Acetic acid</td>
<td></td>
</tr>
<tr>
<td>Potassium chloride</td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
<td></td>
</tr>
<tr>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sucrose</td>
<td>Sucrose</td>
<td></td>
</tr>
</tbody>
</table>

* None of the vaccines contain eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called “pegylation” to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients in vaccines and medications can be found in the package insert. CDC’s vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as resources.