Janssen COVID-19 Vaccine (Johnson & Johnson)

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Vaccine	Dosage (amount)/ Route
Janssen COVID-19 Vaccine (Johnson & Johnson)	**0.5 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 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:

- mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary series and booster vaccination. The remainder of this section details criteria if a person elects to receive Janssen.
- If the recipient has never received a COVID-19 vaccine*, administer 1 dose of Janssen COVID-19 Vaccine.
- If the recipient has received 1 dose of a Janssen COVID-19 Vaccine, no additional primary-series doses are needed. A booster dose is recommended 2 months (8 weeks) after the primary Janssen dose (mRNA vaccine preferred)*.
- If the recipient has received a 2-dose primary mRNA vaccine, administer a Janssen COVID-19 Vaccine at least 5 months after completion of the 2-dose primary mRNA series. However, mRNA vaccines are preferred.*
- If 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine has been administered, the person is considered fully vaccinated 2 weeks after completing the primary vaccination series.
- 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, (i.e., due to contraindication) consideration may be given to vaccination with the Janssen COVID-19 Vaccine at a minimum interval of 28 days after receipt of the first 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.†
- Thrombosis with thrombocytopenia syndrome:
  - Inform all persons receiving a Janssen vaccine of the risks and symptoms of TTS in the 2 weeks after vaccination as well as the need to seek immediate medical care should symptoms develop.
  - It is contraindicated to administer Janssen COVID-19 Vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 Vaccine or any other adenovirus vector-based COVID-19 vaccines. These people should receive a dose of an mRNA COVID-19 vaccine as a booster at least 2 months (8 weeks) following their dose of the Janssen COVID-19 Vaccine and after their clinical condition has stabilized.‡
  - People with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia, should receive an mRNA COVID-19 vaccine.
- Persons who have received HCT or CAR-T-cell therapy:
  - 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.
- Booster doses:
  - Administer a booster dose at least 2 months (8 weeks) after completion of the Janssen COVID-19 Vaccine primary dose to:
    - All persons who received the Janssen COVID-19 Vaccine, including those moderately and severely immunocompromised
  - Use of heterologous booster doses is allowed. Any FDA-approved or FDA-authorized COVID-19 vaccine product can be administered. An mRNA COVID-19 vaccine is preferred.

* Although mRNA vaccines are preferentially recommended in most situations over the Janssen COVID-19 Vaccine, Janssen COVID-19 Vaccine may be considered in some situations. See Interim Clinical Considerations (www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#primary-series) for more inforamtion.

† 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 (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.

‡ Prior to booster vaccination, a conversation between the patient and their clinical team, including hematologists or other specialists, may assist with decisions about using an mRNA COVID-19 vaccine as a booster and the timing of the booster vaccination.

- For additional information, see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#booster-dose

- Additional clinical considerations
  - 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
  - Janssen 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, see 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)
      - TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors)
  - 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

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 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.
  - 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:

§ 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.

¶ 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**).

- 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:
      - 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/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**
- 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 they 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