

# Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine  
to Persons 16 Years of Age and Older



## » Clinical Materials Update

On April 13, 2021, **CDC and FDA recommended a pause in the use of Janssen COVID-19 Vaccine (Johnson & Johnson)** out of an abundance of caution while they review data involving a small number of reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in individuals after receiving Janssen COVID-19 Vaccine (<https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>). The Advisory Committee on Immunization Practices (ACIP, <https://www.cdc.gov/vaccines/acip/index.html>) met on April 14. After hearing additional data on these reports, ACIP agreed that more information is needed before policy recommendations can be made regarding continued use of the Janssen COVID-19 vaccine. CDC will collect more information and convene another ACIP meeting on April 23 to review any additional scientific evidence.

**At this time, the recommended pause supersedes any other recommendations for use of Janssen COVID-19 Vaccine.**

Recommendations for clinicians related to the detection, evaluation, proper management, and reporting of cases of CVST with thrombocytopenia after receipt of Janssen COVID-19 Vaccine are outlined in Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>. These can also be found in CDC's Health Alert (<https://emergency.cdc.gov/han/2021/han00442.asp>), issued April 13.

### **If you are a COVID-19 vaccination provider with Janssen COVID-19 Vaccine:**

1. Mark any Janssen COVID-19 Vaccine in your inventory "Do not use. Awaiting guidance."
2. Continue to store the vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
3. Continue to monitor and document storage unit temperatures and follow recommended vaccine storage practices.

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**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 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been administered or a single dose of Janssen vaccine has been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days (but preferably before 42 days).\*
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- Do not administer Pfizer-BioNTech COVID-19 Vaccine at the same time as other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine by 14 days before or after the administration of other vaccines.†
- Defer vaccination with Pfizer-BioNTech 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.
- If the recipient has a history of dermal filler use, advise them to contact their healthcare provider for evaluation if they develop swelling at or near the dermal filler site following vaccination.
- Screen for contraindications and precautions.
  - Contraindications:
    - » Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - » Immediate allergic reaction<sup>‡</sup> of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see Table 1 in this document for a list of vaccine components)
  - Note:** Persons who have a contraindication to the mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).#
  - Precautions:
    - » History of an immediate allergic reaction<sup>‡</sup> 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 polyethylene glycol (PEG) or another vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction.
    - » People with a contraindication to Janssen COVID-19 Vaccine have a precaution to both mRNA vaccines (see footnote)#
    - » Moderate to severe acute illness
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.

\*Administer the second dose as close as possible to the recommended interval (21 days). If the second dose is not administered within 42 days of the first dose, the series does not need to be restarted. Second doses inadvertently administered less than 21 days apart do not need to be repeated.

†However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus-toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in mRNA COVID-19 vaccination.

‡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.

#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](#). 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.

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Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site <sup>†</sup>
Female or male fewer than 130 lbs	22–25	5/8 <sup>§</sup> –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

<sup>†</sup>Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

<sup>§</sup>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).

- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 16 through 18 years of age: 1-inch needle is recommended.
  - 19 years of age and older: See chart above.
  - 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 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](http://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:
    - » **30 minutes:** Persons with a:
      - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
      - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech Vaccine
      - History of anaphylaxis due to any cause
    - » **15 minutes:** All other persons
  - 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>

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- 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 you 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.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
<b>Active ingredient</b>	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
<b>Inactive ingredients</b>	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
Sucrose	Sucrose		

\*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.