Centers for Disease Control and Prevention
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Janssen COVID-19 Vaccine (Johnson & Johnson) Questions

Janssen COVID-19 Vaccine (Johnson & Johnson): Effective April 23, 2021, CDC and FDA recommend that use of the Janssen COVID-19 Vaccine resume in the United States. However, women younger than 50 years old especially should be made aware of a rare risk of blood clots with low platelets following vaccination and the availability of other COVID-19 vaccines where this risk has not been observed. Read the **CDC/FDA statement**.

Learn more: Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March–April 2021 and Anxiety-Related Adverse Event Clusters After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021

Vaccine Supply and Distribution

What is the minimum order size for Janssen COVID-19 Vaccine? –

The minimum order size and increment for Janssen COVID-19 Vaccine is 100 doses (2 cartons of 10 multidose vials, 5 doses per vial) per order.

Vaccination Schedule and Use

Who can receive Janssen COVID-19 Vaccine?

Janssen COVID-19 Vaccine is authorized and recommended for persons 18 years of age and older.

The recommendation for Janssen COVID-19 Vaccine should be implemented in conjunction with the Advisory Committee on Immunization Practices' (ACIP) interim recommendations for allocation of COVID-19 vaccine.

How many doses of Janssen COVID-19 Vaccine do patients need?

All people for whom vaccination is indicated should receive 1 dose of Janssen COVID-19 Vaccine.

My patient received an mRNA COVID-19 vaccine for their first dose but would now like Janssen COVID-19 Vaccine. What should I do?

COVID-19 vaccines are **not** interchangeable. The safety and efficacy of a mixed-product series have not been evaluated. In most cases, if patients begin a series with an mRNA COVID-19 vaccine, they should complete the series with the same product. In limited, exceptional situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), you may consider a single dose of Janssen COVID-19 Vaccine, with a minimum interval of 28 days between doses. See the Contraindications and Precautions section of CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information on use of Janssen COVID-19 Vaccine and additional precautions for people with a contraindication to mRNA COVID-19 vaccines.

Is there a minimum interval between routine vaccines and Janssen COVID-19 Vaccine?

Yes. You should routinely administer Janssen COVID-19 Vaccine alone, with a minimum interval of 14 days before or after administration of any other vaccine.

However, you may administer Janssen COVID-19 Vaccine and other vaccines within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (such as tetanus-toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers to or delays in COVID-19 vaccination (for example, in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to or upon admission or onboarding). If Janssen COVID-19 Vaccine is administered within 14 days of another vaccine, do not repeat doses of either vaccine. This deviation from CDC guidance does not require reporting to the Vaccine Adverse Event Reporting System (VAERS).

Learn more about coadministration with other vaccines.

Vaccine Indications

Can I vaccinate patients with underlying medical conditions?

Yes, you may administer any currently authorized COVID-19 vaccine to people with underlying medical conditions; the Advisory Committee on Immunization Practices (ACIP) does not state a product preference. This includes people with:

- Immunocompromising conditions or people who take immunosuppressive medication or therapies
- Autoimmune conditions
- A history of Guillain-Barré syndrome
- A history of Bell's palsy
- A history of dermal filler use

Learn more about vaccinating patients with underlying medical conditions.

Are there special considerations for vaccinating immunocompromised patients or timing immunosuppressive therapy?

Immunocompromised patients can receive any currently authorized COVID-19 vaccine; however, you should consider counseling them and timing immunosuppressive therapies.

Counsel immunocompromised patients about the:

- Unknown vaccine safety profile and effectiveness in immunocompromised populations
- Potential for reduced immune responses
- Need to continue to follow current guidance to protect themselves against COVID-19

Data are currently insufficient to inform optimal timing of COVID-19 vaccination and receipt of immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised people, ideally **COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies**. When it is not possible to administer a complete COVID-19 vaccine series (i.e., 2 doses of an mRNA vaccine or a single dose of Janssen COVID-19 Vaccine) in advance, you may still vaccinate patients on immunosuppressive therapy. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the patient's risks related to their underlying condition.

At this time, revaccination is not recommended after patients regain immune competence. Recommendations on revaccination or additional doses of COVID-19 vaccines may be updated when more information is available.

Learn more about vaccinating patients with underlying medical conditions.

Can pregnant or lactating people be vaccinated? –

Yes. Pregnant or lactating people can receive any of the currently authorized COVID-19 vaccines; the Advisory Committee on Immunization Practices (ACIP) does not state a product preference.

When making a decision about vaccination, you and your pregnant patient should consider the:

- Level of COVID-19 community transmission
- Patient's personal risk of contracting COVID-19
- Risks of COVID-19 to the patient and potential risks to the fetus
- Efficacy of the vaccine
- Side effects of the vaccine
- Limited data about the vaccine during pregnancy

Encourage pregnant people who choose to be vaccinated to enroll in v-safe, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. A v-safe pregnancy registry has been established to follow outcomes among pregnant people who are vaccinated.

Learn more about vaccination of pregnant or lactating people.

Can people with a prior or current SARS-CoV-2 infection or COVID-19 disease be vaccinated? What if they received passive antibody therapy for COVID-19 treatment?

Recommendations for vaccination depend on when a person has or had SARS-CoV-2 infection and when they received treatment.

People with a history of infection: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

While there is no recommended minimum interval between infection and vaccination, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. **While vaccine supply remains limited**, people with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired. However, they should recognize that the risk of reinfection and, therefore, the need for vaccination, can increase with time following initial infection.

People with a current infection: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation. This recommendation applies to any vaccine, including the first and second doses of COVID-19 vaccine.

People who previously received passive antibody therapy as part of COVID-19 treatment: Defer vaccination for at least 90 days after receipt of passive antibody therapy (monoclonal antibodies or convalescent plasma). This recommendation applies to people who receive passive antibody therapy before receiving any COVID-19 vaccine dose and to those who receive passive antibody therapy after the first dose of an mRNA COVID-19 vaccine but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

Learn more about COVID-19 vaccination and SARS-CoV-2 infection.

My patient is receiving intravenous immunoglobulin. Do they have to wait 90 days before receiving COVID-19 vaccine?

No, your patient may be vaccinated. Although people who have received passive antibody therapy as treatment for COVID-19 should wait 90 days before vaccination, there is **no minimum interval** between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

My patient has shingles. Can they receive Janssen COVID-19 Vaccine?

As with other vaccines, a moderate or severe illness is a precaution to receiving any currently authorized COVID-19 vaccine. It is not considered a contraindication. Generally, vaccination should be delayed until the acute illness has improved. However, if you and your patient feel the potential benefits of vaccination outweigh the potential risks, they may receive COVID-19 vaccine.

The following considerations can be used to help the provider conduct a risk assessment for COVID-19 vaccination:

- Risk of exposure to SARS-CoV-2 (e.g., living in a congregate setting, such as a long-term care facility; or occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age or underlying medical conditions)
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
    - Note: Vaccination is recommended for people with a history of COVID-19. However, because the risk of reinfection is low in the months after initial infection, people with a precaution to vaccination and recent COVID-19 may choose to delay vaccination.

Contraindications and Precautions

What are contraindications to Janssen COVID-19 Vaccine?

Contraindications to vaccination with Janssen COVID-19 Vaccine include:

- Severe allergic reaction (e.g., anaphylaxis) to a component of Janssen COVID-19 Vaccine
- Immediate allergic reaction of any severity or known (diagnosed) allergy to a component of the vaccine (see Appendix C for a list of vaccine components)

Do not vaccinate people with a contraindication. Consider referral to an allergist-immunologist or other vaccine alternative. You may consider mRNA COVID-19 vaccination for people with a contraindication to Janssen COVID-19 Vaccine (including a contraindication due to a known polysorbate allergy). People with a contraindication to Janssen COVID-19 Vaccine have a precaution to mRNA vaccines. In these cases, 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 people should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

Learn more about COVID-19 vaccine contraindications and precautions.

What are precautions for Janssen COVID-19 Vaccine?

Precautions for Janssen COVID-19 Vaccine include:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
- Contraindication to an mRNA COVID-19 vaccine
- Moderate or severe acute illness

The following considerations can be used to help the provider conduct a risk assessment for vaccination of patients with a precaution to vaccination:

- Risk of exposure to SARS-CoV-2
- Risk of severe disease or death due to COVID-19
- Unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. For people with a contraindication to another type of COVID-19 vaccine (e.g., mRNA vaccines), vaccination with another type (e.g., Janssen viral vector vaccine) should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

Learn more about COVID-19 vaccine contraindications and precautions.

Can a patient with a contraindication to mRNA COVID-19 vaccines receive Janssen COVID-19 Vaccine?

People with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 Vaccine at least 28 days after the mRNA vaccine, but it is considered a precaution. In these cases, consider consulting 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 people should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

See more information on:

- Contraindication and precautions
- Potential characteristics of allergic reactions

Vaccine Storage and Handling

How should I store Janssen COVID-19 Vaccine? +

Store Janssen COVID-19 Vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F) until the expiration or beyond-use date (BUD). Do NOT store vaccine in the freezer. Refer to the Janssen COVID-19 Vaccine product information or Janssen COVID-19 Vaccine Storage and Handling Summary for more information.

Does Janssen COVID-19 Vaccine have a beyond-use date (BUD)? +

After first puncturing the vial, the vial should be held between 2°C and 8°C (36°F and 46°F) for up to 6 hours **OR** at room temperature (up to 25°C [77°F]) for up to 2 hours.

See Janssen COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

What type of temperature monitoring device (TMD) should be used to monitor storage unit temperatures? –

CDC requires vaccination providers participating in the COVID-19 Vaccination Program to use a specific type of TMD called a "digital data logger" (DDL) to monitor vaccine temperatures. A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). DDLs using a buffered temperature probe provide the most accurate way to measure actual vaccine temperatures. Always use DDLs with a current and valid Certificate of Calibration Testing.

For more storage and handling information, see:

- CDC's *Vaccine Storage and Handling Toolkit*
- Janssen COVID-19 Vaccine Storage and Handling Summary

After first puncturing the vial, can the vaccine be held at room temperature for 2 hours, then in the refrigerator for an additional 6 hours, for a total of 8 hours?

No. After the vial is first punctured, the vaccine vial may be held:

- For up to 2 hours at room temperature; discard any vaccine not used within 2 hours
  —-OR—-
- For up to 6 hours refrigerated between 2°C and 8°C; discard any vaccine not used within 6 hours

You should not add these time limits together (i.e., you may not hold the vaccine at room temperature for 2 hours and **then** hold it refrigerated for another 6 hours).

If you **do not reach the 2-hour time limit at room temperature**, you may transfer the punctured vial to a refrigerated storage unit between 2°C and 8°C for the remaining time, up to 2 hours. For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (between 2°C and 8°C) for no more than 1 hour before using or discarding. If the 2-hour time limit at room temperature has been reached, the vaccine must be discarded and cannot be transferred to the refrigerator.

See Janssen COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

Can punctured vials be moved between refrigerator and room temperature storage?

The allowed storage time after first vial puncture or dose withdrawal is either a maximum of 6 hours refrigerated or 2 hours at room temperature. These maximum hold times and temperatures are not cumulative. You should discard the punctured vial once it exceeds either of these conditions, even if there are doses remaining. If stored in the refrigerator after the first puncture, the vaccine can be moved to room temperature for brief periods of time for administration. This does not affect the maximum 6-hour hold period for vaccine stored in the refrigerator.

See Janssen COVID-19 Vaccine Storage and Handling Summary for more storage and handling information.

Whom can I contact about a problem with COVID-19 vaccine (e.g., temperature excursion, damaged vaccine)?

If the vaccine experienced problems during shipment (for example, damage or temperature excursion), contact:

- Directly distributed vaccine (Pfizer): Contact Pfizer at 800-666-7248 (option 8) or CVGovernment@Pfizer.com.
- Centrally distributed vaccine (for example, Moderna): Contact McKesson Specialty Customer Service at (833) 343-2703, Monday–Friday, 8 AM–8 PM Eastern Time.

If the vaccine experienced problems after it was received and placed into storage, contact the vaccine manufacturer for guidance on improper storage and handling.

For temperature excursions (out-of-range temperatures), take immediate action:

- Label the vaccine "Do Not Use" and store at the recommended temperature range until you receive manufacturer guidance.
- Document the date and length of time of the excursion, storage unit temperature, room temperature, and inventory affected.
- Record any other relevant information.
- Contact the manufacturer for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination.
- Document the event and action taken for record-keeping requirements.

Vaccine Administration

Does Janssen COVID-19 Vaccine require reconstitution?

No. Janssen COVID-19 Vaccine comes in a multidose vial and does not require reconstitution.

See Janssen COVID-19 Vaccine Preparation and Administration Summary for more information.

How many doses are in a multidose vial of Janssen COVID-19 Vaccine?

Each multidose vial of Janssen COVID-19 Vaccine contains **five** 0.5 mL doses.

Can I draw extra doses of vaccine?

CDC recommends healthcare providers follow the dosing guidance from the manufacturer as outlined in the Emergency Use Authorization (EUA). CDC will update its guidance if the EUA and ancillary supply kits support obtaining additional doses per vial in the future.

We don't want to waste vaccine and can get more doses if we combine vaccine from multiple vials. Is it acceptable to combine or "pool" vaccine from more than one vial?

No. CDC recommends following these practices:

- **Never** combine or "pool" partial doses from two or more vials to obtain a full dose of vaccine.
- Withdraw only the number of doses authorized for the specific vaccine.
- Discard vaccine vial and remaining vaccine if the amount of vaccine left in the vial is not a full dose.

Although no one wants to waste vaccine, it is crucial for infection control and patient safety to administer vaccine properly. Combining vaccine doses from multiple vials can result in cross-contamination, potentially causing bacterial infection in patients.

We are using low dead-volume syringes and needles. How much vaccine should we withdraw into the syringe? Do we need to adjust the dosage (volume) for these syringes?

No, the dosage should NOT be adjusted regardless of the type of needles and syringes used. ALWAYS withdraw the amount of vaccine indicated by the manufacturer. For Janssen COVID-19 Vaccine, withdraw 0.5 mL into the syringe.

How should I administer Janssen COVID-19 Vaccine?

The route of administration for this vaccine is an intramuscular injection. Refer to the following CDC resources:

- Janssen COVID-19 Vaccine (Johnson & Johnson) Preparation and Administration Summary
- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older
- Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age
- Resource Library includes demonstration videos for intramuscular injections

Janssen COVID-19 Vaccine was mistakenly administered to a 16-year-old patient. What should we do?

If Janssen COVID-19 Vaccine is inadvertently administered to a patient age 16 through 17 years, do not repeat the dose with Pfizer-BioNTech COVID-19 Vaccine.

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Janssen COVID-19 Vaccine was administered to a patient subcutaneously. What should we do?

If any of the currently authorized COVID-19 vaccines are administered subcutaneously, do **not** repeat the dose. The series is complete, and no additional doses are needed.

Inform the recipient of the potential for local and systemic adverse events.

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Review resources on vaccine administration:

- Vaccine Administration: Intramuscular (IM) Injection Adults 19 years of age and older
- You Call the Shots: Vaccine Administration

While vaccinating a patient, the needle and syringe were not tightly secured together, and vaccine leaked from the syringe. What should we do?

If a lower-than-authorized dose volume is administered for any of the currently authorized vaccines, adhere to the following interim recommendation:

- **If more than half of the dose was administered, do not repeat the dose**. The series is complete, and no additional doses are needed.
- **If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately in the opposite arm**.

This is considered a vaccine administration error. Determine how the error occurred and implement strategies to prevent it from happening again. Report this error to VAERS.

Is there general guidance for what we should do when vaccine administration errors occur?

Interim recommendations for COVID-19 vaccine administration errors differ from ACIP's general best practice guidelines. Review vaccine administration errors and deviations for COVID-19 vaccines to learn about the interim recommendation for each type of error.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS) unless otherwise indicated in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

How do I dispose of COVID-19 vaccine vials and packaging?

To reduce the risk of fake or counterfeit vaccines, dispose of vials and packaging as medical waste by placing vials in a sharps container and packaging in a red medical waste bag. If medical waste containers are in short supply, deface or safely crush packaging materials so they cannot be reintroduced or reproduced. After the products are sufficiently defaced or destroyed, dispose with regular waste.

The disposal process for unused COVID-19 vaccine and diluent may be different. For guidance, contact your jurisdiction's immunization program.

Do I need to observe patients after vaccination?

Yes. CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes for people with:
  - A history of an immediate allergic reaction of any severity to another vaccine or injectable therapy
  - A contraindication to an mRNA COVID-19 vaccine who receive Janssen COVID-19 Vaccine
  - History of anaphylaxis due to any cause
- 15 minutes for all other people

Vaccine Safety and Efficacy

What side effects might occur following vaccination?

Common side effects include:

Local reactions:

- Pain
- Redness
- Swelling

Systemic reactions:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

How effective is the Janssen COVID-19 Vaccine?

Clinical trial data demonstrated vaccine efficacy was 66.3% at least 14 days after vaccination against symptomatic, laboratory-confirmed COVID-19 in persons without evidence of previous SARS-CoV-2 infection; 93.1% for the prevention of COVID-19-associated hospitalization; and 75% against all-cause death.

Learn more about Janssen COVID-19 Vaccine's efficacy.

Off-Site Clinics

Can I predraw vaccine?

CDC does not recommend predrawing vaccine. If vaccine must be predrawn:

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event.
- Each person administering vaccines should draw up no more than one multidose vial or 10 doses* at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when ready for administration.
- If predrawn vaccine is not used within 30 minutes of being reconstituted, follow manufacturer guidance for storage conditions and time limits.

*You may withdraw a total of 12 doses (2 multidose vials) of Pfizer-BioNTech COVID-19 Vaccine. This applies only to Pfizer-BioNTech COVID-19 Vaccine.

See CDC's *Vaccine Storage and Handling Toolkit* for more information.

Can I transport vaccine in a syringe?

CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

Need more Information?

Get your Questions answered about other specific COVID-19 vaccines, including:

Moderna | **Pfizer-BioNTech** | **General Information**

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