



# **Janssen COVID-19 Vaccine (Johnson & Johnson)**

March 11, 2021

# Housekeeping

- **How to Ask Questions**

- Click on the  icon found at the bottom part of your screen
- A box will open where you can type in questions, comments, indicate sound problems, etc.
- Use this throughout the webinar to ask questions

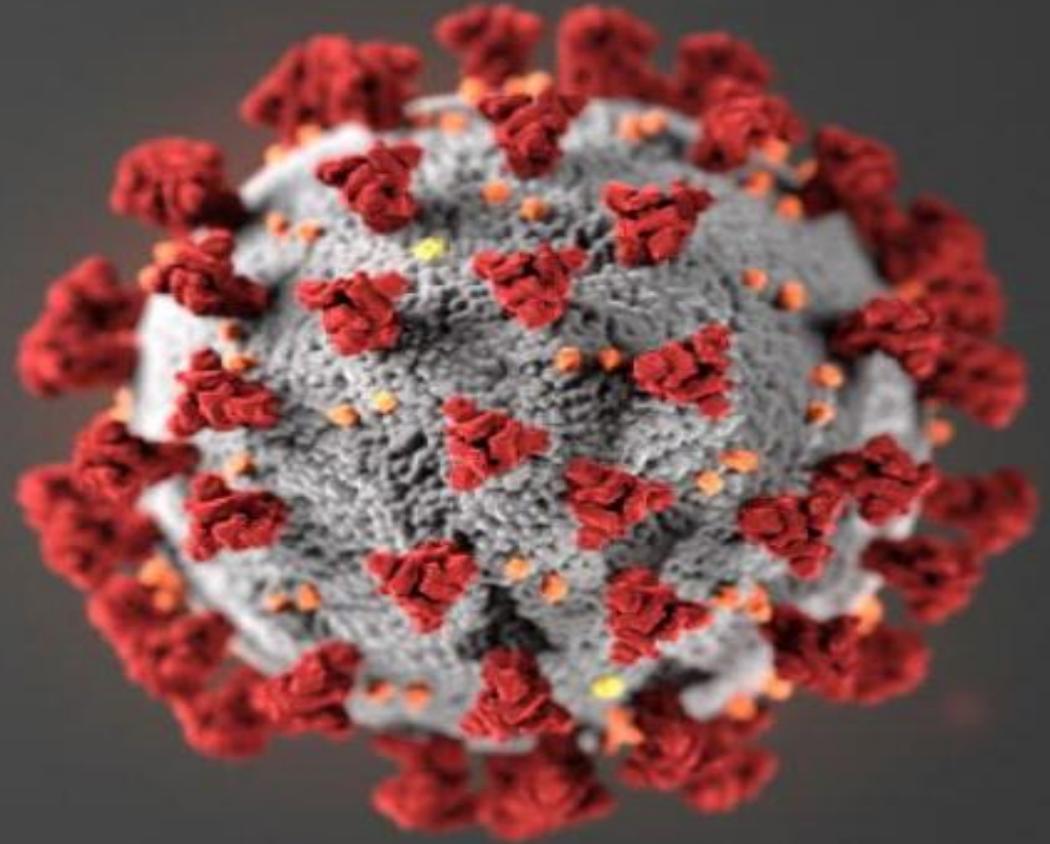
- **Slides & Recording**

- This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: [www.michigan.gov/COVIDvaccine](http://www.michigan.gov/COVIDvaccine) → Provider Guidance and Education

# Topics Covered

- Quick update on prioritization guidance
- Janssen COVID-19 Vaccine (Johnson and Johnson) Background
- Screening Assessment Tool/Contraindications and Precautions
- Administration Resources
- Storage and Handling Resources
- Q & A
- Additional Resources

# Michigan's Prioritization Guidance Updated



HOW TO GET A VACCINE

ACCESS THE STATE'S  
VACCINE DATA

GET YOUR QUESTIONS  
ANSWERED 

ATTEND AN UPCOMING  
TOWN HALL

## RESOURCES

FOOD PROCESSING &  
AGRICULTURAL WORKERS  


COMMUNITY OUTREACH  
PILOT PROGRAM 

PROTECT MICHIGAN  
COMMISSION

INTERIM COVID-19  
VACCINATION STRATEGY 

SOCIAL VULNERABILITY  
AND COVID-19 

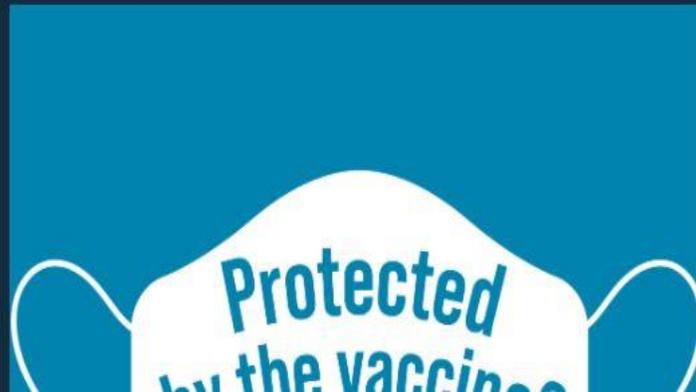
VACCINE ALLOCATION  
PLANNING 

VACCINE TESTIMONIALS

COVID-19 VACCINE  
PRIORITIZATION  
GUIDANCE 

COVID-19 VACCINE  
COMMUNICATION  
MATERIALS

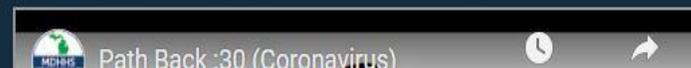
[www.michigan.gov/covidvaccine](https://www.michigan.gov/covidvaccine)



### PROTECTED BY THE VACCINE?

We must remain vigilant and continue to use the prevention strategies that have helped us slow the spread of COVID-19 pre-vaccine. Even if you've already been vaccinated, continue to help protect your community and mask up, Michigan. Wearing a mask, social distancing, and washing your hands, even after receiving the vaccine, will offer the most protection for yourself and those around you as we work towards community immunity.

 Have questions?  
Chat with Robin



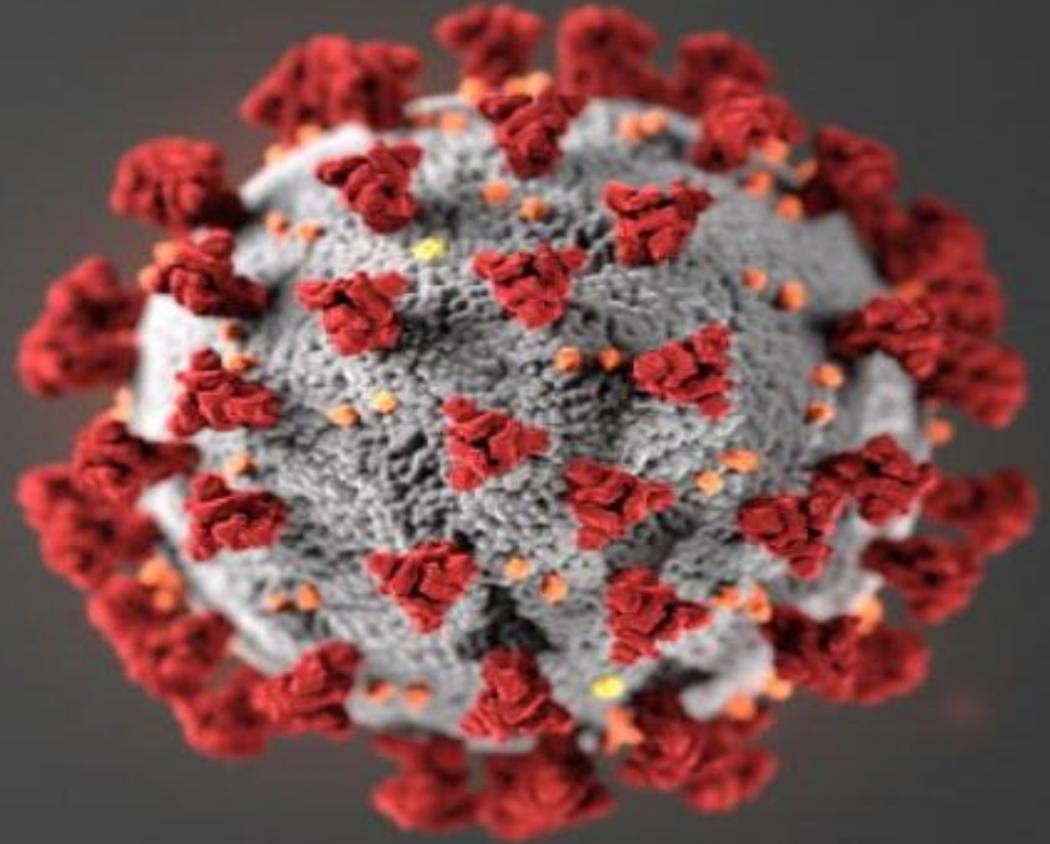
# Prioritization Groups Added for COVID-19 Vaccine Eligibility

- **March 1, 2021**, all areas of the state may, as vaccine supplies are available, also implement vaccination of people who are frontline essential workers in the food processing and agricultural industries.
- **By March 8, 2021**, all areas of the state may, as vaccine supplies are available, also implement vaccination of people who are aged 50 and up with medical conditions and disabilities, as well as caregiver family members and guardians age 16 and older of children who have special health care needs (**part of** Phase 1C Groups B and C). This includes individuals in Phase 1B Group B who live in congregate settings (i.e., homeless shelters, jails, prisons).
- **By March 22, 2021**, all areas of the state may, as vaccine supplies are available, also implement vaccination of people who are aged 50 and up (**part of** Phase 2). This includes people who live in congregate settings (i.e., homeless shelters, jails, prisons).

Estimated schedule for first doses administered

| Phase | People covered  | Dec         | Jan         | Feb | March      | April       | May         | June | July | Aug | Sept | Oct | Nov | Dec |  |  |
|-------|---|-------------|-------------|-----|------------|-------------|-------------|------|------|-----|------|-----|-----|-----|--|--|
| 1A    | Healthcare workers                                    | [Green bar] |             |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | Long term care residents and staff                    |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
| 1B    | 75 years+ not covered above                           |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | Prioritized frontline responders                      |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | School and child care staff                           |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | Corrections staff                                     |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | Agriculture/food processing workers                   |             |             |     | March 1st  | [Green bar] |             |      |      |     |      |     |     |     |  |  |
|       | Other essential frontline workers                     |             |             |     |            |             | [Green bar] |      |      |     |      |     |     |     |  |  |
| 1C    | 65-74 years old                                       |             | [Green bar] |     |            |             |             |      |      |     |      |     |     |     |  |  |
|       | 50-64 with disabilities/pre-existing conditions       |             |             |     | March 8th  | [Green bar] |             |      |      |     |      |     |     |     |  |  |
|       | Caregivers of children with special health care needs |             |             |     | March 8th  | [Green bar] |             |      |      |     |      |     |     |     |  |  |
|       | 16-49 with disabilities/pre-existing conditions       |             |             |     |            | [Green bar] |             |      |      |     |      |     |     |     |  |  |
|       | Remaining essential workers                           |             |             |     |            |             | [Green bar] |      |      |     |      |     |     |     |  |  |
| 2     | 50 to 64 years not covered above                      |             |             |     | March 22nd | [Green bar] |             |      |      |     |      |     |     |     |  |  |
|       | 16 to 49 years not covered above                      |             |             |     |            | [Green bar] |             |      |      |     |      |     |     |     |  |  |

# Janssen COVID-19 Vaccine (Johnson & Johnson)



# Janssen COVID-19 Vaccine (Johnson and Johnson)

- Authorized for use in persons **18 years of age and older**
- The clinical trial demonstrated an overall efficacy of **66.3%** against symptomatic, laboratory-confirmed COVID-19
  - **72%** in the United States
- Efficacy estimates for severe outcomes **assessed  $\geq 28$  days** post vaccination were higher: **83.5%** for severe disease, complete protection for hospitalization
- Similar vaccine efficacy demonstrated by age, comorbidities, sex, race, and ethnicity
- Results of the Janssen phase III clinical trials not comparable with mRNA vaccines
  - Different calendar time
  - Different geography
- ACIP states no preference for any of the three authorized COVID-19 vaccines

# Explaining Viral Vector COVID-19 Vaccines

- Viral vector vaccines use a modified version of a **different virus as a vector** to deliver instructions, in the form of genetic material (a gene), to a cell
  - These **do not contain live virus** and cannot cause infection with either COVID-19 or the virus that is used as the vector
  - Like all vaccines, viral vector vaccines for COVID-19 have been **rigorously tested** for safety before being authorized for use in the United States
  - Vaccines of this type have been **well-studied in clinical trials**, and viral vector vaccines have been **used to respond to recent Ebola outbreaks**
  - The genetic material delivered by the viral vector **does not integrate into a person's DNA**

# Janssen COVID-19 Vaccine

- We now have 3 COVID-19 vaccines to help in the fight against SARS-CoV-2
- Our focus for this presentation is for the Janssen COVID-19 vaccine but some clinical considerations are similar for all 3 of the COVID-19 vaccines
  - Differences come with vaccine platform, age indication, dosing schedule, and storage and handling

**This website was updated on March 5<sup>th</sup> to include the Janssen COVID-19 vaccine**

<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

## Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States



Interim considerations: [preparing for the potential management of anaphylaxis after COVID-19 vaccination](#)

Summary of recent changes (last updated March 5, 2021):

- Public health recommendations for vaccinated people have been moved to: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>

### Key points

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of [Pfizer-BioNTech](#), [Moderna](#), and [Janssen \(Johnson & Johnson\)](#) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

### Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of [Pfizer-BioNTech](#), [Moderna](#), and [Janssen \(Johnson & Johnson\)](#) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The Janssen vaccine is a recombinant replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2. None of the currently authorized COVID-19 vaccines are live virus vaccines.

### On This Page

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[Vaccine Administration](#)

[Interchangeability of COVID-19 vaccine products](#)

[Coadministration with other vaccines](#)

[Booster doses](#)

[COVID-19 vaccination and SARS-CoV-2 infection](#)

[Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks](#)

[Considerations for vaccination of people with certain underlying medical conditions](#)

[Vaccination of pregnant or lactating people](#)

[Vaccination of children and](#)

Sign up at the bottom of this page to receive email updates when clinical considerations are updated!

# COVID-19 Vaccination

## Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handling, reporting, and patient education for each specific vaccine

Product Information by US Vaccine



## CDC's Web Page for COVID-19 Vaccination Education

- Links to several CDC pages such as the storage and handling toolkit, vaccine administration, ACIP recommendations, and more
- Links to the COVID-19 product information by US vaccine
- There is a “Vaccination Resource Toolkits” tab that reviews the Communication Toolkit
- For further information: <https://www.cdc.gov/vaccines/covid-19/index.html>

# CDC's Janssen COVID-19 Vaccine Webpage

## Janssen COVID-19 Vaccine (Johnson & Johnson)



### Dosing information:

Multidose vial: 5 doses per vial  
Dosage: 0.5mL  
Do NOT mix with a diluent.  
Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

### Schedule:

Single dose

### Administration:

Intramuscular (IM) injection in the deltoid muscle

### Age Indications:

18 years of age and older



EUA



Interim Clinical Considerations

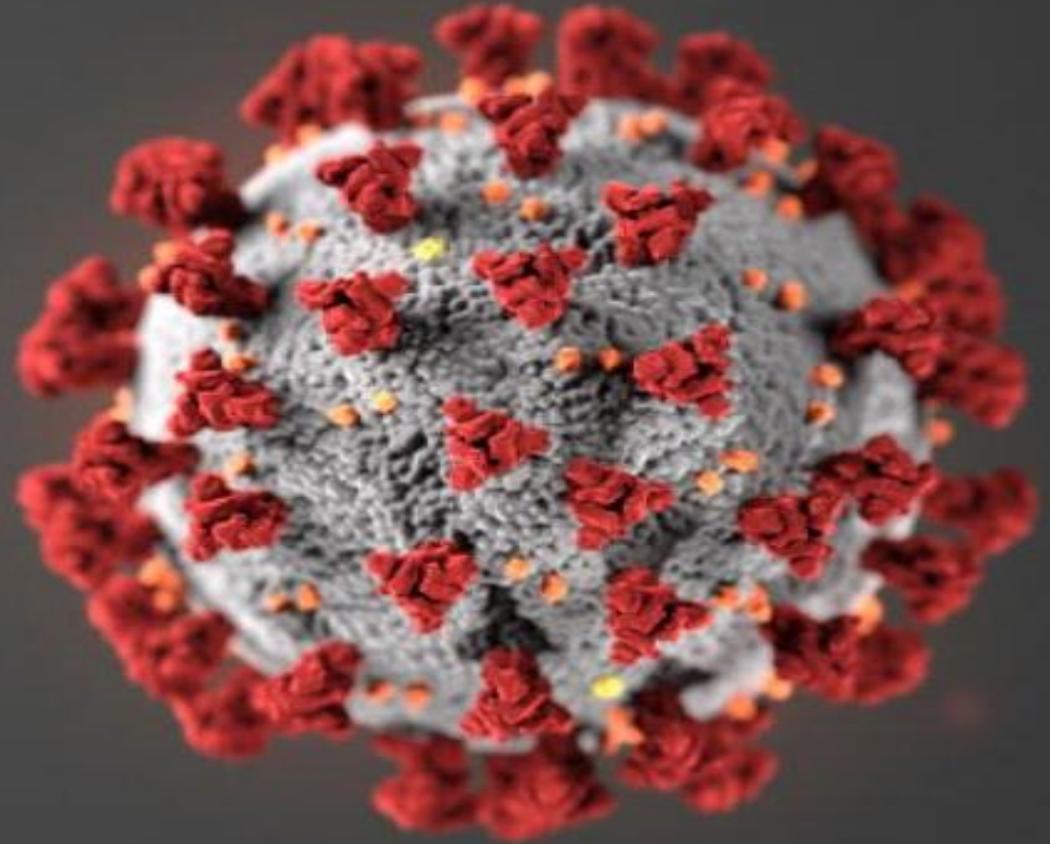


Janssen Covid-19 Vaccine FAQs



ACIP Recommendations

# Screening Tool and Contraindications and Precautions



# Tools to Identify Persons with Contraindications and Precautions

- Screen patients prior to receipt of each vaccine dose to identify if there is a contraindication or precaution
- CDC Prevaccination Questionnaire to assist with screening  
<https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>
- Persons with a contraindication should not be vaccinated

## Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients:

Patient Name \_\_\_\_\_

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today.

Age \_\_\_\_\_

**If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

|  | Yes | No | Don't know |
|--|-----|----|------------|
| 1. Are you feeling sick today?   |     |    |            |
| 2. Have you ever received a dose of COVID-19 vaccine?  |     |    |            |
| • If yes, which vaccine product did you receive?<br><input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Janssen (Johnson & Johnson) <input type="checkbox"/> Another product _____   |     |    |            |
| 3. Have you ever had an allergic reaction to:  |     |    |            |
| <small>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small> |     |    |            |
| • A component of a COVID-19 vaccine including either of the following:   |     |    |            |
| <input type="radio"/> Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures   |     |    |            |
| <input type="radio"/> Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids.   |     |    |            |
| • A previous dose of COVID-19 vaccine.   |     |    |            |
| • A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is not known which component elicited the immediate reaction.  |     |    |            |
| 4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication?  |     |    |            |
| <small>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small> |     |    |            |
| 5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.  |     |    |            |
| 6. Have you received any vaccine in the last 14 days?  |     |    |            |
| 7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?   |     |    |            |
| 8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?   |     |    |            |
| 9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?   |     |    |            |
| 10. Do you have a bleeding disorder or are you taking a blood thinner?   |     |    |            |
| 11. Are you pregnant or breastfeeding?   |     |    |            |
| 12. Do you have dermal fillers?  |     |    |            |

Form reviewed by \_\_\_\_\_

Date \_\_\_\_\_

| CONTRAINDICATION TO VACCINATION  | PRECAUTION TO VACCINATION  | MAY PROCEED WITH VACCINATION  |
|--|--|---|
| <p><b>History of the following:</b></p> <ul style="list-style-type: none"> <li>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†</li> <li>• Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†</li> </ul> | <p><b>Among people without a contraindication, a history of:</b></p> <ul style="list-style-type: none"> <li>• Any immediate allergic reaction* to other vaccines or injectable therapies‡</li> </ul> <p>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#</p> | <p><b>Among people without a contraindication or precaution, a history of:</b></p> <ul style="list-style-type: none"> <li>• Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>• History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>• Family history of allergies</li> </ul> |
| <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Do not vaccinate.</li> <li>• Consider referral to allergist-immunologist.</li> <li>• Consider other vaccine alternative.†</li> </ul>   | <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• Risk assessment</li> <li>• Consider referral to allergist-immunologist</li> <li>• 30-minute observation period if vaccinated</li> </ul>  | <p><b>Actions:</b></p> <ul style="list-style-type: none"> <li>• 30-minute observation period: people with history of anaphylaxis (due to any cause)</li> <li>• 15-minute observation period: all other people</li> </ul>  |

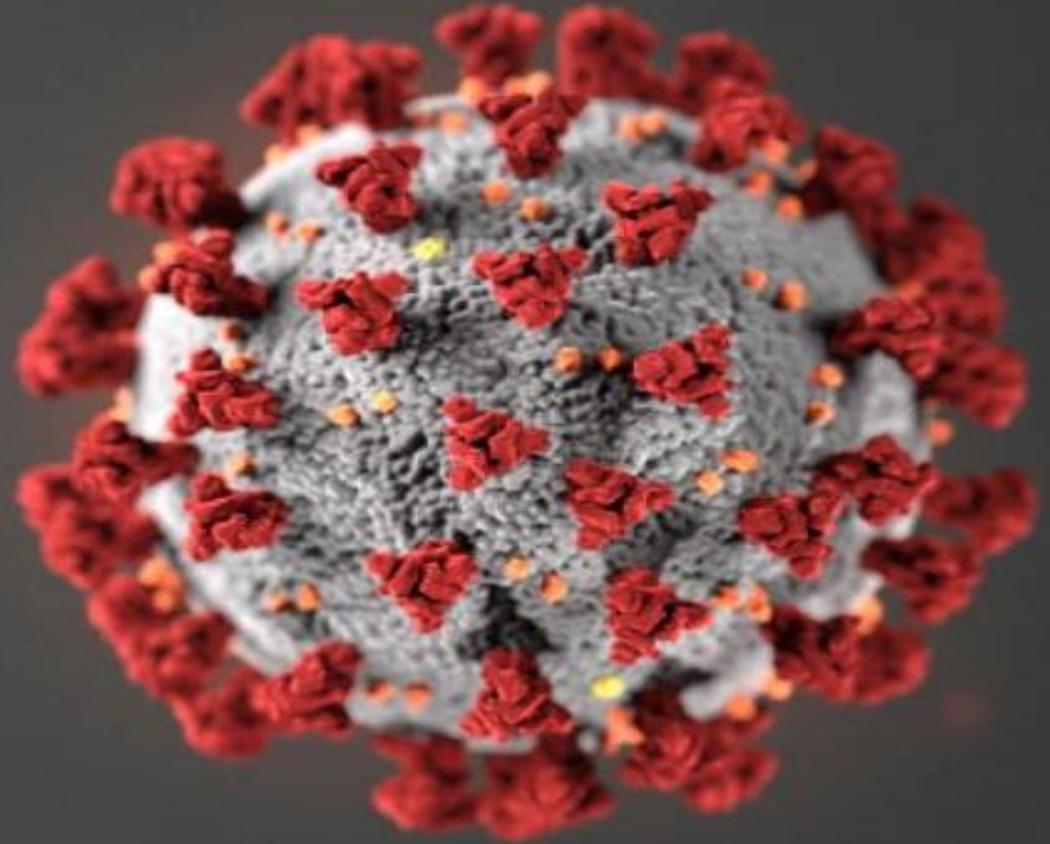
† See [Appendix C](#) for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

\* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

‡ Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction.

# Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these

# Janssen COVID-19 Vaccine Administration Resources

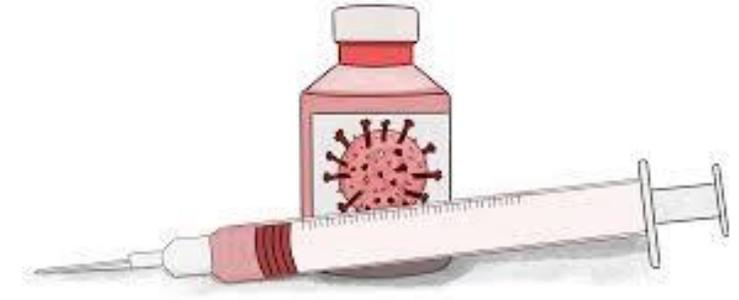


# Janssen COVID-19 Vaccine (Johnson & Johnson)

Vaccine Preparation and Administration

# Janssen COVID-19 Vaccine (Johnson & Johnson)

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



## General Information

Vaccine: Janssen COVID-19 Vaccine (Johnson & Johnson)

Multidose vial: 5 doses per vial

Dosage: 0.5 mL

**Do NOT mix with a diluent. Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.**

## Expiration Date

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to [www.vaxcheck.jnj](http://www.vaxcheck.jnj).

## Prepare and Administer the Vaccine

|  |  |
|--|--|
| <p>Assess recipient status:</p> <ul style="list-style-type: none"> <li>Screen for contraindications and precautions.</li> <li>Review vaccination history.</li> <li>Review medical considerations.</li> </ul>     |  |
| <p>Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*</p>   |  |
| <p><b>Unpunctured vials:</b> Check the expiration date. Never use expired vaccine.<br/><b>Punctured vials:</b> Check the beyond-use time. Never use vaccine after the beyond-use time.</p>                       |  |
| <p>With the vial upright, gently swirl the vaccine for <b>10 seconds. Do NOT shake.</b> If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.</p> |  |
| <p>Examine the vaccine. It should be a colorless to slightly yellow, clear to very opalescent suspension. Do not use if liquid contains particulate matter or if it is discolored.</p>                           |  |
| <p>Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.</p>   |  |
| <p>Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.</p>  |  |

## Age Indications

18 years of age and older

## Schedule

1 dose

Do not use the remainder of any dose

## Administration

Intramuscular

**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:

- Has not received a COVID-19 vaccine, regardless of the type of vaccine.
- The Janssen COVID-19 Vaccine is the only COVID-19 vaccine given.
- If the recipient has received a COVID-19 vaccine, the second dose of the Janssen COVID-19 Vaccine should be given.
- In situations where a COVID-19 vaccine is given, the Janssen COVID-19 Vaccine should be given as a minimum.
- In situations where a COVID-19 vaccine is given, the Janssen COVID-19 Vaccine should be given as a minimum.
- Janssen COVID-19 Vaccine should be given at the same time as any other COVID-19 vaccine.
- Defer vaccination for 90 days for persons who have received a COVID-19 vaccine (monoclonal antibody or mRNA COVID-19 vaccine).

Screen for contraindications and precautions.

## How to Prepare and Administer the Janssen Vaccine

### How to Prepare the Vaccine

+

### How to Administer the Vaccine

+

### Scheduling

+

## Janssen COVID-19 Vaccine Administration Resources

Janssen COVID-19 Vaccine Standing Orders

Prevaccination Screening Form

Preparation and Administration Summary

Vaccine administration training and clinical materials

\*Consultation with an allergist or immunologist is recommended for persons with a history of severe allergic reaction to any component of the vaccine or to any other vaccine.

†People with a contraindication to any component of the vaccine should not receive the 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.

\*How to use the vaccine.

†For the use of the vaccine.

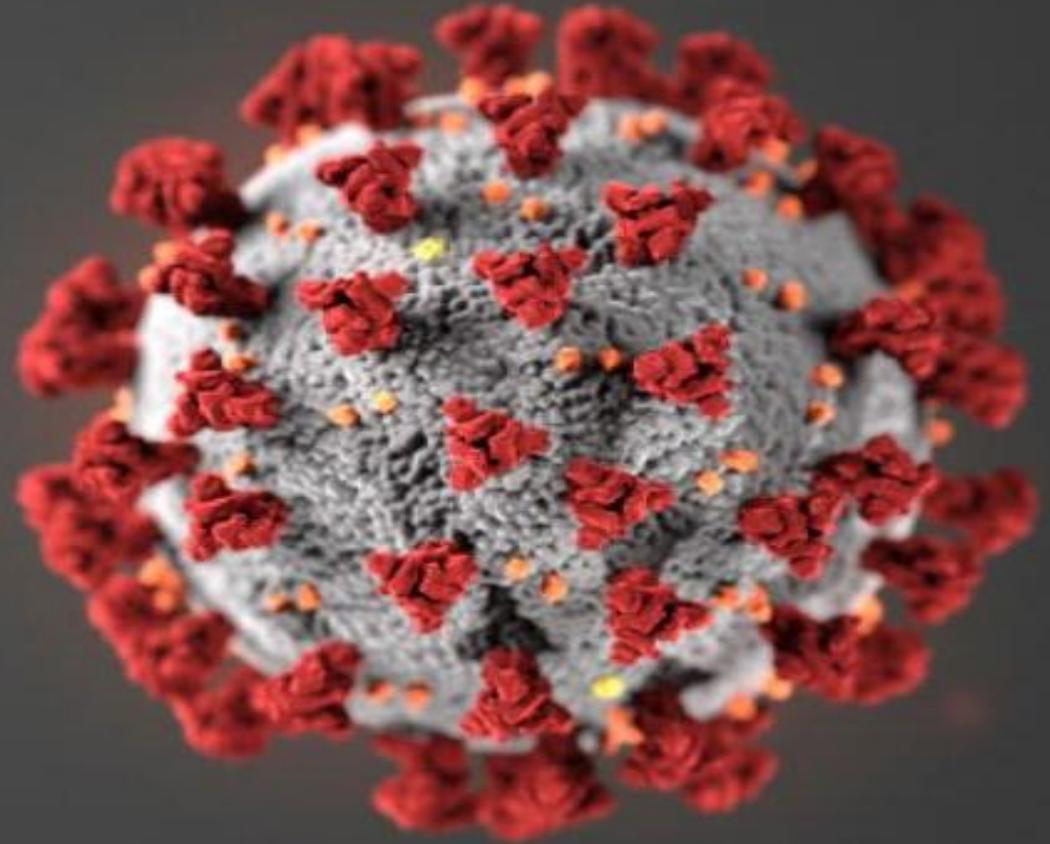
<https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>

# Recap of Administration of COVID-19 Vaccines

- COVID-19 vaccines are administered intramuscularly as either a two-dose or one-dose series

| Vaccine         | Age Group          | Dose Volume | Number Doses/Series | Interval Between Doses |
|-----------------|--------------------|-------------|---------------------|------------------------|
| Pfizer-BioNTech | 16 years and older | 0.3 mL      | 2                   | 3 weeks (21 days)      |
| Moderna         | 18 years and older | 0.5 mL      | 2                   | 1 month (28 days)      |
| Janssen         | 18 years and older | 0.5 mL      | 1                   | N/A                    |

# Janssen COVID-19 Vaccine Storage and Handling



**NEW Information:** <https://www.janssencovid19vaccine.com/hcp.html>

CDC Site: <https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>

## Overview of Janssen COVID-19 Vaccine (Johnson & Johnson)

|  |  |
|--|--|
| Doses Per Shipment                         | 100 doses minimum  |
| Storage Temperature                        | Store at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) until the expiration date before vials are punctured  |
| If Arrive Frozen By Manufacturer—Thaw Time | If frozen upon receipt thaw at refrigerated temperatures<br>If need immediately, thaw at room temperature (max 25°C/77°F)  |
| Unpunctured Vials                          | Unpunctured vials should be stored at refrigerated temperatures until the expiration date<br>Unpunctured vials may be stored at room temperatures between 9°C and 25°C (47°F and 77°F) for up to 12 hours                      |
| Punctured Vials                            | After the first dose has been withdrawn, vial should be held between 2°C and 8°C (36°F and 46°F) for up to 6 hours OR at room temperature (max 25°C/77°F) for up to 2 hours<br>Discard the vial if not used within these times |
| Refreeze Vaccine?                          | <b>NO</b>  |

For further information on Janssen COVID-19 vaccine storage and handling requirements go to:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>

# Janssen COVID-19 V (Johnson & Johnson)

Transporting Vaccine for Vaccination Held at Satellite, Temporary, or Off-Site Locations

# Janssen COVID-19 Vaccine (Johnson & Johnson)

Storage and Handling Summary



## » Procedure

Follow storage and handling best practices outlined in CDC's *Vaccine Storage and Handling Toolkit* to maintain the cold chain when packing vaccine.

Transport Janssen COVID-19 Vaccine in a portable refrigerator packout qualified to maintain temperature between 2°C and 8°C. To monitor vaccine temperatures, use a digital data logger with temperature probe that displays current, minimum, and maximum. A DDL with an external temperature display is preferred to monitor transport container.

Upon arrival at clinic, place vaccine in an on-site storage unit to maintain recommended temperatures, if available. If there is no storage unit, place the vaccine in the transport container, maintaining recommended temperatures. Temperature monitoring: Record time and min/max temperature.

- At the start of transport
- Whenever the transport container is opened
- When transport concludes



## » General Information

- Vaccine vials may be transported more than once.
- Both punctured and unpunctured vials may be transported.

### Refrigerated transport: Between 2°C and 8°C (36°F)

- Unpunctured vials:** Vaccine may be transported at refrigerated temperatures until the expiration date.
  - CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 6 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
- Punctured vials:** Punctured vials may be transported at refrigerated temperatures.
  - Once punctured, store the vaccine at refrigerated temperatures. Vaccine must be used within 6 hours.
  - Time used for transport counts as part of the 6-hour time limit.

## » Basics

- Store vaccine in a refrigerator. See guidance below for further details.
- Each carton contains 10 multidose vials (50 doses).
  - A carton is approximately 3.7 in x 3.7 in x 2.1 in.
  - Each multidose vial contains 5 doses.
- Check and record storage unit temperatures each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

## » Deliveries

### Vaccine

- The vaccine is stored at 2°C and 8°C.
- Examine the vaccine upon receipt.
- Each shipment includes:
  - The Vaccine Storage and Handling Summary
  - The Freezer Storage Temperature Log (Celsius)
  - The Freezer Storage Temperature Log (Fahrenheit)
- Remove the vaccine from the transport container immediately upon receipt.
- The expiration date is determined by the lot number.

- Scan the QR code on the Vaccine Storage and Handling Summary.
- Call 1-800-232-0223 for more information.
- Visit [www.cdc.gov/vaccines/imz/downloads/ts/handling](https://www.cdc.gov/vaccines/imz/downloads/ts/handling).

### Ancillary Supplies

- An ancillary kit is included in the vaccine kit.
- Administrative forms are included in the vaccine kit.
- The kit is designed for use in a single location and quantity.

## How to Store the Janssen COVID-19 Vaccine

### Storing in a Refrigerator

+

### Monitoring Temperature

+

### Temperature Excursions

+

## Storage and Handling Resources

[Storage and Handling Summary](#)

[Refrigerator Storage Temperature Log \(Celsius\)](#)

[Storage and Handling Labels](#)

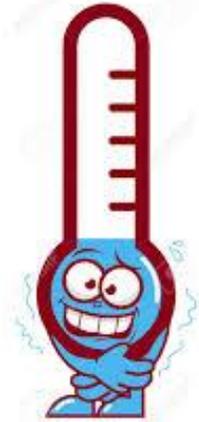
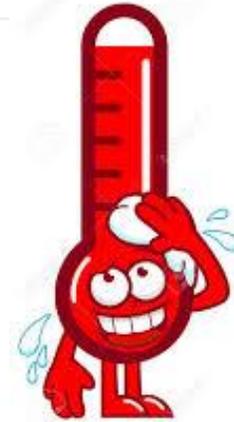
[Refrigerator Storage Temperature Log \(Fahrenheit\)](#)

[Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations](#)

[Vaccine Storage Troubleshooting Record for temperature excursions](#)

[Transport Temperature Log](#)

[Vaccine Expiration Date Tracking Tool](#)



# Unpunctured Multi-dose Vials of Janssen COVID-19 Vaccine

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- Storage prior to first puncture:
  - Unpunctured multi-dose vials of the Janssen COVID-19 Vaccine should be stored between 2°C and 8°C (36°F and 46°F)
    - Until the expiration date
- Protect Janssen COVID-19 vaccine from light
- **Do not store frozen**

# Punctured Multi-dose Vials of Janssen COVID-19 Vaccine

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- Storage after first dose has been withdrawn:
  - Hold the vial between 2°C and 8°C (36°F and 46°F) for up to 6 hours
  - OR**
  - May also be stored at room temperature (maximally 25°C/77°F) for up to 2 hours
  - Note the date and time the vial was punctured
  - Discard the vial if vaccine is not used within these times

# Janssen COVID-19 Vaccine MDV Expiration Date

- The expiration date is NOT printed on the vaccine vial or carton
- To determine expiration date:
  - Scan the QR code on the outer carton, or
  - Call 1-800-565-4008, or
  - Visit [www.vaxcheck.jnj](http://www.vaxcheck.jnj)
- As the expiration date approaches, check the expiration date again
  - Repeat above steps

**COVID-19 Vaccine Expiration Date Tracking Tool** 

Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction..

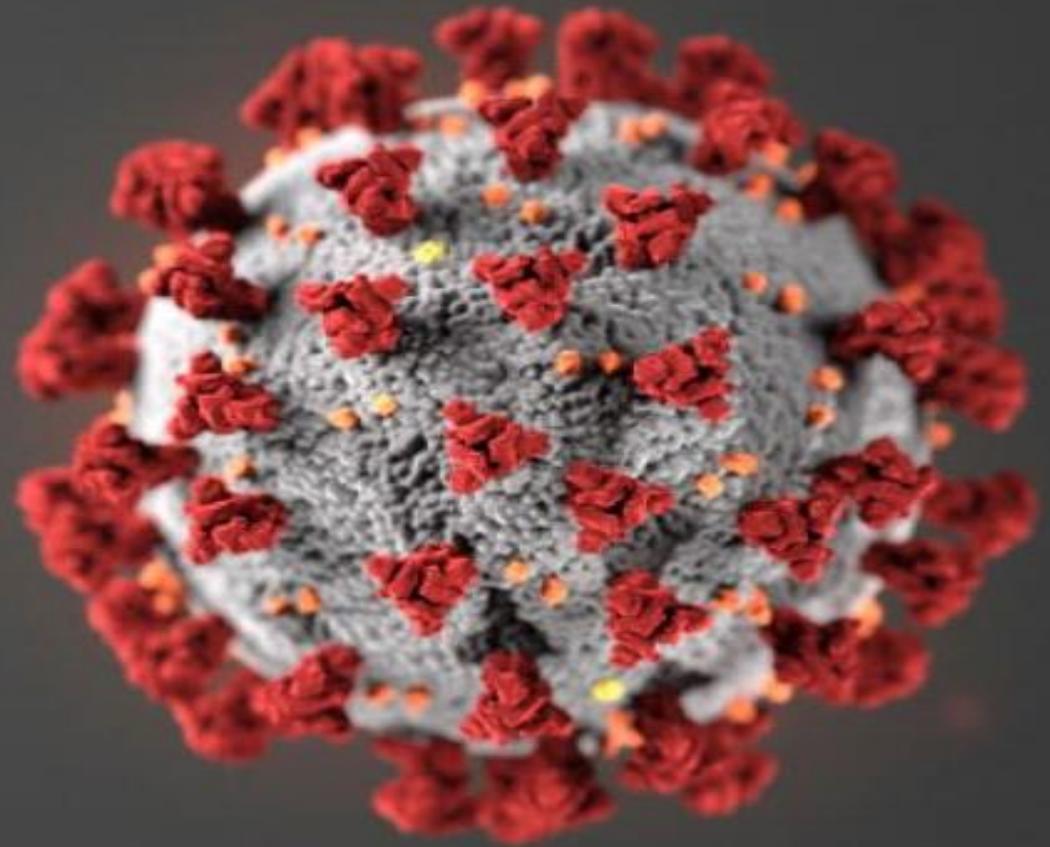
Product name: \_\_\_\_\_ Manufacturer: \_\_\_\_\_ Original Expiration Date: \_\_\_\_\_

Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)

| Date                          | Lot Number   | Updated Expiration Date | Info Source  | Name           |
|-------------------------------|--------------|-------------------------|--|----------------|
| <i>Example:</i><br>09/01/2020 | ABC123DEF456 | 06/30/2021              | <input checked="" type="checkbox"/> Website <input type="checkbox"/> Barcode | Susie Smith RN |
|                               |              |                         |  |                |
|                               |              |                         |  |                |

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf>

**Questions and Answers  
from Our Janssen  
COVID-19 Vaccine  
Webinar on March 3<sup>rd</sup>**



When is someone considered protected after receiving COVID-19 vaccine?

- **Pfizer COVID-19 Vaccine**
  - Approximately 14 days after the second dose
- **Moderna COVID-19 Vaccine**
  - Approximately 14 days after the second dose
- **Janssen COVID-19 Vaccine**
  - Approximately 14 days after the dose

- **Per Johnson & Johnson (news as of 3/11/21):**
  - After the first dose has been withdrawn, hold the FILLED SYRINGE(s) between 2°C and 8°C (36°F and 46°F) for up to **6 hours** or at room temperature (maximally 25°C/77°F) for up to **2 hours**
  - The FILLED SYRINGE(s) should be **discarded** after 6 hours at refrigerated temperatures or 2 hours at room temperature after first vial puncture
    - Even if all doses have not been used

How long is the Janssen COVID-19 vaccine good for once drawn up into the syringe?

## Is there a consent form for the Janssen COVID-19 Vaccine?

- Written informed consent is not required under EUA
- As indicated in the Provider Agreement, providers must provide a COVID-19 vaccination record card, EUA fact sheet, and V-safe flyer to each vaccine recipient/parent/legal guardian
- EUA translations anticipated to be available
  - Burmese, German, and Russian available now
- Vaccine administration sites can create their own consent form if they would like
- Vaccine administration must be documented in the Michigan Care Improvement Registry (MCIR) within **24 hours** of vaccination

- There is no specific time frame, however, you would want to make sure that the screening is current so at least the day of administration since individuals health status could change day to day

If this will be given to inpatients, what is the timeframe allowed from screening to vaccine administration?

## If patient is on a blood thinner, can they receive this vaccine?

- Receiving blood thinners is not a contraindication to receiving COVID-19 vaccine
- With intramuscular vaccines there is a risk for hematoma if the individual has a bleeding disorder or is receiving anticoagulation therapy
- If a physician familiar with the patient's bleeding risk determines that the vaccine can be administered by this route with reasonable safety, a fine-gauge needle (23-gauge or smaller caliber) should be used for vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes
- The patient or family should be given information on the risk for hematoma from the injection
- If possible, vaccination could be scheduled prior to the use of these medications, so that the patients' risk of bleeding is not increased by their therapeutic action

- The ACIP recommended that the Janssen vaccine be used and recommended for all persons 18 and older in the US based on the allocation and prioritization
- There may be populations particularly interested in this vaccine (e.g., individuals who don't want to come back for a second dose, want protection quickly, have difficulties returning for a second dose, etc.)
- MDHHS is having conversations about this at this time

Who will qualify  
to receive the  
Janssen Vaccine?

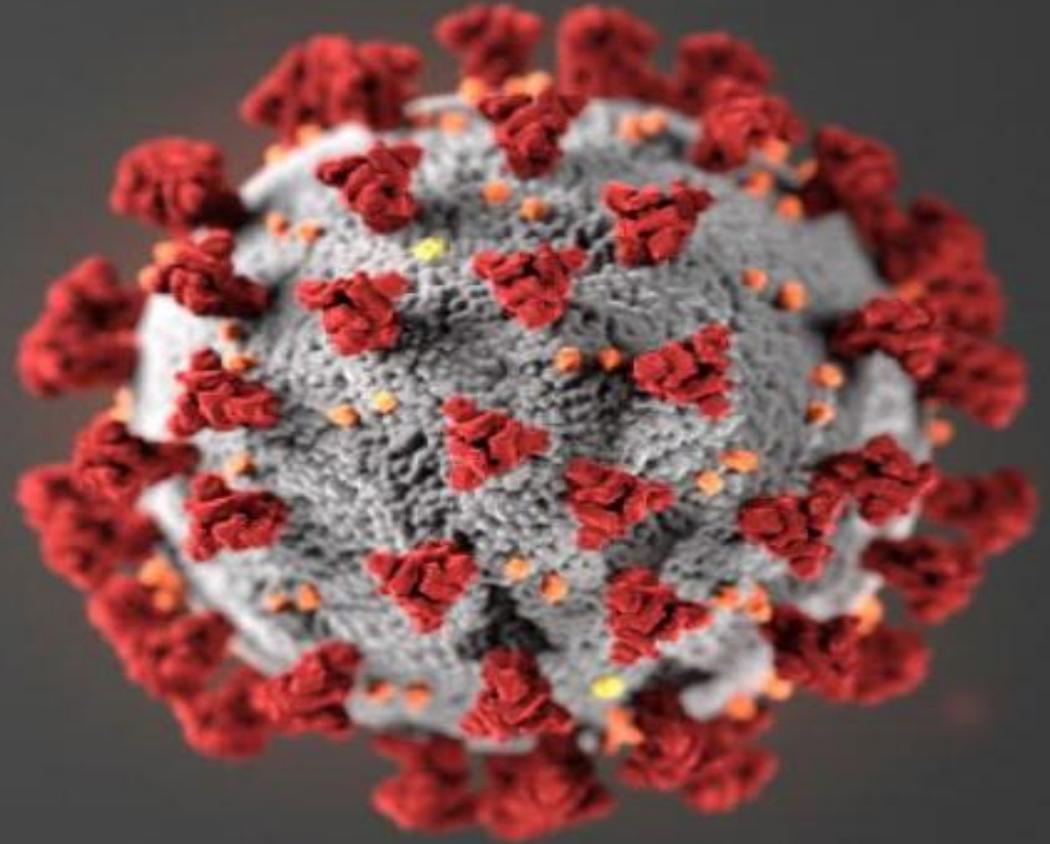
If a patient had hives after the first dose of mRNA vaccine, can they receive Janssen vaccine?

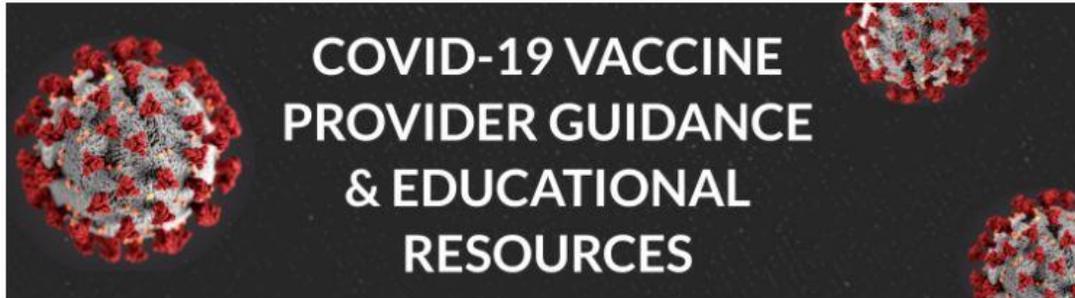
- Immediate allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine is a contraindication to COVID-19 vaccine
- Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with **urticaria**, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration
- People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa
- For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](#) project

- CDC's recommendation is to only draw up the number of doses listed within the EUA which is 5 doses (0.5mL each dose)
- The ancillary kits support 5 doses

Was there any discussion yet on the option to get an extra dose out of the Janssen COVID-19 Vials?

# Janssen COVID-19 Vaccine Additional Resources





This webpage will house materials to support COVID-19 Vaccine Providers in successful implementation of the COVID-19 Vaccination Program. Be sure to "bookmark" this page and check back frequently for updates!

## GENERAL COVID-19 VACCINE RESOURCES

- [MDHHS COVID-19 Vaccination Interim Prioritization Guidance](#)
- [CDC COVID-19 Vaccine Resources for Healthcare Professionals](#)
  - Vaccine administration, storage and handling, reporting, and patient education for each specific vaccine
- [COVID-19 Vaccine Training Module](#)
  - Self-paced module with certificate of completion (no CE)
  - MDHHS strongly recommends that all COVID-19 Vaccine Providers complete this training.
- [CDC HCP Vaccine Administration Resource Library](#)

## CONTENT-SPECIFIC COVID-19 RESOURCES

- [Webinars](#)
  - **Upcoming Noontime Knowledge: Thursday March 11, 2021: Janssen COVID-19 Vaccine (Johnson and Johnson)**
- [Enrollment & Redistribution](#)
- [Vaccine Billing and Vaccine Code Sets](#)
- [Product-Specific Information & EUAs](#)
  - [Pfizer](#)
  - [Moderna](#)
  - [Janssen \(Johnson & Johnson\)](#)
    - **Standing orders now available!**
- [VaccineFinder](#)
- [MCIR Documentation & Inventory](#)
- [Order & Shipment Tip Sheets](#)
  - [COVID-19 Vaccine Product Information Guide - Updated 3/2/21](#)
    - This guide provides specifications for COVID-19 vaccine and associated products. This is NOT a

# MDHHS COVID-19 Vaccine Provider Web Page

COVID-19 vaccine webpage

[www.michigan.gov/COVIDvaccine](http://www.michigan.gov/COVIDvaccine), then selecting "Provider Guidance and Education"

# Janssen COVID-19 Vaccine Website

## \*\*NEW—Website from Janssen COVID-19 Vaccine:

- Important Safety Information
- EUA
- Storage and Administration
- Adverse Reactions
- Reporting Adverse Events and Vaccine Administration Errors



The screenshot shows the top portion of the Janssen COVID-19 Vaccine website. At the top, there is a dark blue navigation bar with links for 'FDA EUA Letter', 'EUA Fact Sheet for HCPs', 'EUA Fact Sheet for Recipients & Caregivers', 'Adverse Event Reporting', and 'Go to Recipient & Caregiver Site'. Below this is the Janssen logo and the text 'PHARMACEUTICAL COMPANIE OF Johnson & Johnson'. To the right of the logo are links for 'Important Safety Information', 'Janssen.com', and 'Medical Inquiries'. A secondary navigation bar contains icons and text for 'Home', 'About the Vaccine', 'Storage, Dosage & Administration', 'Check Expiration', and 'Resources & FAQs'. The main content area features a large image of a healthcare professional and a patient, both wearing masks. Overlaid on this image is a blue banner with the text: 'The U.S. FDA Has Granted the Janssen COVID-19 Vaccine an Emergency Use Authorization (EUA)'. Below the banner is a section titled 'IMPORTANT SAFETY INFORMATION' with a plus sign icon. Underneath, the heading 'CONTRAINDICATIONS' is followed by the text: 'Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine.'

**Website:** <https://www.janssencovid19vaccine.com/hcp.html>

# Thank You!

Next “Noontime  
Knowledge” Update: March  
25, 2021 at 12:00p.m.

Topic: TBD

Please watch your email for  
an updated link and topic!

[www.michigan.gov/COVIDvaccine](http://www.michigan.gov/COVIDvaccine) → Provider Guidance and Education

