# Janssen Vaccine Update

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# Janssen (Johnson & Johnson) COVID-19 Vaccine

- Single dose adenovirus vector vaccine; vaccine shipment and storage at refrigerator temperatures
- FDA Emergency Use Authorization on 2/27/21
- ACIP voted to recommend; CDC Director signed off on 2/28/21
- ACIP meeting 2/28 and 3/1 to review evidence and agree on clinical recommendations
- Western States Scientific Review determination shortly!
- CDC COCA call 3/3/21; slides available here

  - https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
  - https://www.cdc.gov/mmwr/volumes/70/wr/mm7009e4.htm?s_cid=mm7009e4_w
  - https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html
  - https://emergency.cdc.gov/coca/ppt/2021/030221_slide.pdf

# Janssen Vaccine Characteristics

- Single-dose series
- Vaccine shipment and storage (3 months) at refrigerator temperatures (2-8 C)*
- Authorized for persons aged ≥18 years
- Intramuscular injection (0.5 ml)
- No diluent required

# Janssen vaccine is highly effective against severe COVID-19

- 100% vaccine efficacy against deaths due to COVID-19
- 93% vaccine efficacy against hospitalization
- 83.5% vaccine efficacy against severe disease
- 66.3% vaccine efficacy against symptomatic COVID-19

# Janssen COVID-19 Vaccine

- ACIP states no preference for any of the three authorized vaccines
- Results of Janssen Phase III trials not comparable with mRNA vaccines
  - Different calendar time
  - Different geography

} Different circulating variants
Higher background incidence

- Strong protection against severe COVID-19
  - 93% VE against hospitalizations (2 cases in vaccinated vs. 29 in placebo)
  - No COVID-associated deaths in vaccinated vs. 7 in placebo

# Janssen vaccine is safe

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.4% vs 0.4%)
- Local reactions within 7 days occurred in ~50% vaccine recipients
  - Pain at the injection site most common
- Systemic reactions within 7 days occurred in ~55% vaccine recipients
  - Headache, fatigue, and myalgia most common
- Most symptoms resolved after 1-2 days

# Clinical considerations for use of mRNA COVID-19 vaccines

- CDC clinical considerations for mRNA COVID-19 vaccines published previously:
  - https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- Clinical considerations are being updated to include Janssen COVID-19 vaccine
  - Viral vector COVID-19 vaccine

Interim Clinical Considerations for Use of mRNA 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 February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

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Sign up to receive email updates when clinical considerations are updated: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical -considerations.html

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# Interchangeability of COVID-19 vaccine products

- Any COVID-19 vaccine can be used when indicated; no product preference

- COVID-19 vaccines are **not** interchangeable
  - Safety and efficacy of a mixed series has not been evaluated

- If first dose of mRNA COVID-19 vaccine was received but patient unable to compete series with same or different mRNA vaccine (e.g., contraindication)
  - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose*
  - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series (mRNA/viral vector)

*Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

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https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/03-COVID-MacNeil.pdf

# Coadministration of COVID-19 vaccines with other vaccines

- Currently authorized COVID-19 vaccines are all inactivated vaccines
- COVID-19 vaccine should be administered alone with minimum interval of 14 days before or after administration of other vaccines
- A shorter interval may be used in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks (e.g., tetanus toxoid vaccine for wound management, etc.) or to avoid barriers or delays to vaccination

# COVID-19 vaccination of persons with underlying medical conditions

- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including:
  - Immunocompromised persons
  - People with autoimmune conditions
  - People with history of Guillain-Barré syndrome, Bell's palsy, dermal filler use

- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

# Contraindications and precautions for COVID-19 vaccines

| CONTRAINDICATION TO VACCINATION | PRECAUTION TO VACCINATION | MAY PROCEED WITH VACCINATION |
|---|---|---|
| History of the following:<br>• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†<br>• Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†<br><br>Actions:<br>• Do not vaccinate.<br>• Consider referral to allergist-immunologist.<br>• Consider other vaccine alternative.† | Among persons without a contraindication, a history of:<br>• Any immediate allergic reaction* to other vaccines or injectable therapies‡<br><br>Actions:<br>• Risk assessment<br>• Consider referral to allergist-immunologist<br>• 30-minute observation period if vaccinated | Among persons without a contraindication or precaution, a history of:<br>• Allergy to oral medications (including the oral equivalent of an injectable medication)<br>• History of food, pet, insect, venom, environmental, latex, etc., allergies<br>• Family history of allergies<br><br>Actions:<br>• 30-minute observation period: persons with history of anaphylaxis (due to any cause)<br>• 15-minute observation period: all other persons |

† See Appendix C for a list of ingredients. Persons 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 persons 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 compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

# Contraindications and Precautions: Updates

| mRNA COVID-19 vaccines | Janssen COVID-19 vaccine |
|---|---|
| • Persons with contraindication to one mRNA vaccine should not receive doses of either vaccine (Pfizer-BioNTech or Moderna)<br>• Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine.*<br>• In persons who received one mRNA COVID-19 dose but are contraindicated to receive the 2nd dose, consideration may be given to vaccination with Janssen COVID-19 vaccine (at least 28 days after mRNA dose).* | • Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines.* |

*In patients with these precautions, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.

Note: 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 compounds may occur.



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/03-COVID-MacNeil.pdf

# Summary

- There are now 3 COVID-19 vaccines with FDA Emergency Use Authorization, and all have high efficacy against severe COVID-19: Pfizer, Moderna, and Janssen
- Janssen 1-dose vaccine is safe and effective