

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Jennifer S. Read, MD, FIDSA; Medical Epidemiologist

Recommendations for the Use of the Janssen COVID-19 Vaccine

On February 27, 2021, the U.S. Food and Drug Administration (FDA) has issued an [Emergency Use Authorization EUA for the use of the Janssen COVID-19 vaccine](#). The vaccine is for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in people 18 years of age or older. The vaccine contains a recombinant, replication-incompetent human adenovirus serotype 26 (Ad26) vector, encoding the SARS-CoV-2 viral spike (S) glycoprotein, stabilized in its pre-fusion form. The dosing regimen is a single dose of 0.5 mL administered intramuscularly.

On February 28, 2021, the Advisory Committee on Immunization Practices (ACIP) issued an **interim recommendation for the use of the Janssen COVID-19 vaccine** in people aged 18 years or older for the prevention of COVID-19.

Safety and efficacy data reviewed by the FDA and the ACIP were from an ongoing phase 3 trial which had enrolled 43,783 participants randomized 1:1 to receive this vaccine or a placebo. Participants were 18 years of age or older.

1. **Safety:** Vaccine recipients frequently experienced reactogenicity symptoms, defined as solicited local injection site or systemic adverse reactions during the 7 days after vaccination. But the symptoms were mostly mild to moderate and resolved 1–2 days after vaccination. Symptoms were more frequent among people aged 18–59 years than among those aged ≥ 60 years. Severe local or systemic reactogenicity symptoms (grade ≥ 3) were more common in vaccine recipients than in placebo recipients (2.2% versus 0.7%). The frequency of reported serious adverse events was low (0.4%) both in vaccine and placebo recipients. Three serious adverse events were determined by FDA to be related to vaccination (injection site pain, hypersensitivity, and systemic reactogenicity). After a median duration of 8 weeks after receiving the vaccine or placebo, no specific safety concerns were identified in subgroup analyses by age, race, ethnicity, underlying medical conditions, or previous SARS-CoV-2 infection.
2. **Efficacy:** The vaccine was 66.9% effective (95% confidence interval (CI): 59.0, 73.4) and 66.1% effective (95% CI: 55.0, 74.8) in preventing **moderate to severe/critical COVID-19** occurring at least 14 days and at least 28 days after vaccination, respectively. Vaccine efficacy for the prevention of **COVID-19–associated hospitalization** ≥ 14 days after vaccination was 93.1%; 95% CI = 71.1%–98.4% and ≥ 28 days after vaccination was 100%; 95% CI = 74.3%–100.0%. Vaccine efficacy against **all-cause death** was 75.0% (95% CI = 33.4%–90.6%). Preliminary data suggest that the Janssen COVID-19 vaccine also

may provide **protection against asymptomatic SARS-CoV-2 infection**, as measured by seroconversion to a non-spike protein. Among a subset of participants with SARS-CoV-2 serology results 71 days after vaccination, 0.7% of vaccine recipients had no symptoms of COVID-19 but had documented seroconversion to a non-spike protein, compared with 2.8% of placebo recipients (estimated efficacy = 74.2%; 95% CI = 47.1%–88.6%).

The Janssen COVID-19 vaccine is feasible to implement, requiring only a single dose and refrigerator temperatures (36°F–46°F [2°C–8°C]) for transportation and storage. These characteristics will allow for expanded availability of the Janssen COVID-19 vaccine in most community settings and mobile sites when this vaccine becomes more widely available. In addition, people who want to complete their vaccination schedule quickly or who might have difficulty returning for a second dose might prefer a single-dose vaccine.

Additional considerations:

- The Janssen COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products.
- Providers should counsel Janssen COVID-19 vaccine recipients about expected systemic and local reactogenicity.
- People may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them.
- Additional clinical considerations are available from [CDC](#).
- Additional considerations for implementation are available from [CDC](#).

REQUESTED ACTION:

Be familiar with current recommendations regarding the Janssen COVID-19 vaccine:

- The vaccine is for people 18 years of age or older.
- The dosing regimen is a single dose of 0.5 mL administered intramuscularly.
- Vaccine recipients frequently experienced mild to moderate reactogenicity symptoms which resolved 1–2 days after vaccination. Severe local or systemic reactogenicity symptoms occurred in approximately 2% of vaccine recipients. Severe adverse events occurred in 0.4% of both in vaccine and placebo recipients.
- The vaccine was efficacious in preventing moderate to severe/critical COVID-19, COVID-19-associated hospitalization, and death.
- The vaccine requires refrigerator temperatures (36°F–46°F [2°C–8°C]) for transportation and storage.
- The Janssen COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthand@vermont.gov.

HAN Message Type Definitions

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.