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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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MDHHS shares FDA's updated guidelines for Janssen COVID-19 vaccine

LANSING, Mich.- The Michigan Department of Health and Human Services (MDHHS) is updating vaccine providers across the state about the U.S. Food and Drug Administration (FDA) limiting the authorized use on the administration of the Janssen (Johnson & Johnson) COVID-19 vaccine.

On May 5, FDA released a statement that it has revised its Emergency Use Authorization (EUA) and limited the authorized use of the Janssen COVID-19 vaccine. The updated EUA limits use to:

- Individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate; or
- Individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine.

Based on its investigation, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), warrants limiting the authorized use of the vaccine. TTS is a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets. TTS linked with the Janssen COVID-19 vaccine has most frequently presented within 10 days to two weeks following vaccine administration.

The FDA and Centers for Disease Control and Prevention (CDC) have identified 60 confirmed TTS cases following the administration of Janssen COVID-19 vaccine, including nine fatal cases. The FDA has determined that the reporting rate of TTS is 3.23 per million doses of vaccine administered and the reporting rate of TTS deaths is 0.48 per million doses of vaccine administered.

“Throughout the pandemic, our federal partners have been committed to ensuring that science and data guided their decisions,” said Dr. Natasha Bagdasarian, MDHHS chief medical executive. “These new guidelines further underscore the robust safety review process in place for these vaccines. We continue to urge all Michiganders ages 5 and older to get their safe and effective COVID-19 vaccine as soon as possible and to get boosted if eligible.”

For individuals who have received the Janssen COVID-19 vaccine as their primary dose, it is recommended they receive a COVID-19 vaccine booster dose. mRNA vaccines are preferred for the first booster dose. Additionally, if Janssen COVID-19 vaccine was used for both the primary and booster doses, individuals are eligible for an

additional dose of an mRNA vaccine. In both instances, vaccine protection has been shown to increase following administration of an mRNA vaccine.

Background & Safety Monitoring for Janssen (Johnson & Johnson) EUA

- On Feb. 27, 2021, Janssen COVID-19 vaccine was [authorized for emergency use](#). On April 13, 2021, FDA and CDC [recommended a pause in administration](#) of the vaccine to investigate six reported cases of TTS, and to help ensure that health care providers were made aware of the potential for TTS, and could plan for proper recognition and management due to the unique treatment required for TTS.
- On April 23, 2021, following a thorough safety evaluation, FDA and CDC [lifted the recommended pause](#) regarding the use of the Janssen COVID-19 vaccine. The agencies confirmed a total of 15 cases of TTS had been reported to the Vaccine Adverse Event Reporting System, including the original six reported cases, out of approximately 8 million doses administered.
- In December 2021, after reviewing updated vaccine effectiveness and safety data, the CDC's Advisory Committee on Immunization Practices made a recommendation for the use of mRNA COVID-19 vaccines over the Janssen COVID-19 vaccine.

To date, nearly 6.7 million Michiganders (67%) have received their first does of COVID-19 vaccine. More than 393,000 residents have received the Janssen COVID-19 vaccine.

Michigan residents seeking more information about the COVID-19 vaccine can visit [Michigan.gov/COVIDvaccine](https://www.michigan.gov/COVIDvaccine).

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[Fact Sheet for Healthcare Providers Administering Vaccine](#)

[Fact Sheet for Recipients and Caregivers](#)

[Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)