

Johnson and Johnson COVID-19 Vaccine

Updated: April 27, 2021

Background

On April 14, the Advisory Committee on Immunization Practices (ACIP) held its first emergency meeting to review the safety profile of the Johnson and Johnson (J&J) COVID-19 vaccine due to reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia after vaccination, which compelled CDC and FDA to issue a joint recommendation on April 13 to pause the use of the subject vaccine. Current data suggest that the risk of thrombosis with thrombocytopenia syndrome (TTS) following vaccination is rare; however, the observed cases appear to exceed expected cases among women aged 20-50 years (three-fold or greater). ACIP determined there was not enough information to alter current recommendations for the authorized use of the vaccine, and decided not to vote, but to maintain the pause to conduct more robust risk benefit analyses.

Update

On April 23, 10 days after the pause recommendation was issued, ACIP reconvened to review additional data from the [Vaccine Adverse Event Reporting System \(VAERS\)](#), medical literature, as well as [risk benefit assessments](#). After a thorough safety review, ACIP recommended lifting the pause on the J&J vaccine. FDA also determined available data for the J&J vaccine showed the known and potential benefits outweighed the known potential risks, and updated the J&J emergency use authorization to reflect a [warning](#) about TTS in women under the age of 50. CDC and FDA remain committed to closely monitoring the safety of COVID-19 vaccines. On the evening of April 23, CDC and the FDA jointly determined to lift the recommended pause and the use of the vaccine should resume.

Guidance to Jurisdictions

- FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- Ordering for J&J COVID-19 vaccine will resume as usual this week. There is no information on size of allocations at this time.
- Jurisdictions should encourage healthcare providers to review the [Janssen COVID-19 Vaccine Factsheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and [Factsheet for Recipients and Caregivers](#). These documents were updated to include information about the risk of TTS occurring in a small percentage of individuals who received the J&J COVID-19 vaccine.
- Jurisdictions should encourage providers to report adverse events to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Key Messages

General Messages:

- COVID-19 vaccine safety is a top priority, and all reports of health problems following COVID-19 vaccination are taken very seriously.

For Individuals Receiving J&J Vaccine:

- For people who got the vaccine more than a month ago, the risk is very low at this time.
- People who received the vaccine within the last few weeks should pay close attention to any symptoms.

- If you have received the vaccine and develop severe headache, abdominal pain, leg pain, or shortness of breath, you should contact your healthcare provider and seek medical treatment.

For Clinicians:

- [Treatment](#) for TTS that occurs after receipt of the Janssen COVID-19 vaccine is different from the treatment that might typically be administered. The anticoagulant drug heparin is normally used to treat blood clots. In the six reported CVST with thrombocytopenia cases, [administration](#) of heparin may be dangerous, and alternative treatments should be given.
- The [Janssen COVID-19 Vaccine Factsheet for Healthcare Providers Administering Vaccine](#) has been updated to include a warning about TTS.
- The American Society of Hematology has released [clinical guidance](#) on diagnosis and treatment, and are available to provide consultation services.
- Healthcare providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at <https://vaers.hhs.gov/reportevent.html>.

Additional Information

- ACIP
 - [Slides](#) from April 23, 2021 ACIP meeting
 - [Slides](#) from April 14, 2021 ACIP meeting
- CDC:
 - [Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021 \(April 27, 2021\)](#)
 - [CDC Recommends Use of Johnson & Johnson’s Janssen COVID-19 Vaccine Resume \(April 25, 2021\)](#)
 - [Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine](#)
 - [HAN ALERT: Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](#)
- FDA:
 - [FDA and CDC Lift Recommended Pause on Johnson & Johnson \(Janssen\) COVID-19 Vaccine Use Following Thorough Safety Review \(April 23, 2021\)](#)
 - [Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine \(April 13, 2021\)](#)
- Johnson and Johnson:
 - [Press statement \(April 23, 2021\)](#)
 - [Press statement \(April 14, 2021\)](#)
- White House:
 - [Press Briefing by White House COVID-19 Response Team and Public Health Officials \(April 23, 2021\)](#)
 - [Statement from Jeff Zients, White House COVID-19 Response Coordinator on Johnson & Johnson Vaccine](#)