



May 6, 2022

## FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals

On May 5, 2022, the U.S. Food and Drug Administration (FDA) limited the authorized use of the Janssen COVID-19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to 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.

### Key Points:

- After conducting an updated analysis, evaluation and investigation of reported cases, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine.
- The FDA has determined that the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for 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.
- The [Fact Sheet for Healthcare Providers Administering Vaccine](#) now reflects the revision of the authorized use of the Janssen COVID-19 Vaccine and includes a warning statement at the beginning of the fact sheet for prominence which summarizes information on the risk for TTS. Additionally, information on the revision to the authorized use of the vaccine and this risk of blood clots with low levels of blood platelets has been added to the [Fact Sheet for Recipients and Caregivers](#).

### Background

The Janssen COVID-19 Vaccine was authorized for emergency use on Feb. 27, 2021. On April 13, 2021, the FDA and the Centers for Disease Control and Prevention (CDC), [announced a recommended 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, including two meetings of the CDC's Advisory Committee on Immunization Practices (ACIP), the 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 (VAERS), including the original six reported cases, out of approximately 8 million doses administered.

These data, plus the deliberations and recommendations by the ACIP, helped with FDA's assessment that the known and potential benefits of Janssen COVID-19 Vaccine outweighed its known and potential risks in individuals 18 years of age and older. The available data suggested the chance of TTS occurring was remote, but investigation into the level of potential excess risk due to vaccination and specific risk factors continued. At that time the Fact Sheet (Healthcare Providers) was revised to include a warning pertaining to the risk of TTS and the Fact Sheet for Recipients and Caregivers was also revised to include information about blood clots in combination with low blood platelets after receiving the Janssen COVID-19 Vaccine.

In December 2021, after reviewing updated vaccine effectiveness and safety data, the ACIP made a preferential recommendation for the use of mRNA COVID-19 vaccines over the Janssen COVID-19 Vaccine in all persons 18 years of age and older in the United States. The ACIP recommended and CDC endorsed that the Janssen COVID-19 Vaccine may be considered in some situations: when a person has a contraindication to receipt of mRNA COVID-19 vaccines, when a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines, and when a person wants to receive the Janssen COVID-19 Vaccine despite the safety concerns identified.

### **Current Status**

The FDA and CDC have continuously monitored for and investigated all suspected cases of TTS reported to VAERS. In an updated analysis of TTS cases following administration of the Janssen COVID-19 Vaccine that were reported to VAERS through March 18, 2022, the FDA and CDC have identified 60 confirmed cases, 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. In making the determination to limit the authorized use of the Janssen COVID-19 Vaccine, the agency considered that reporting rates of TTS and TTS deaths following administration of the Janssen COVID-19 Vaccine are not appreciably lower than previously reported. Furthermore, the factors that put an individual at risk for TTS following administration of Janssen COVID-19 Vaccine remain unknown. The FDA also considered that individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, that TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. The agency also considered the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS.

### **Examples of individuals who may still receive the Janssen COVID-19 Vaccine include:**

- individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine,
- individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine
- individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines.

### **Ongoing Safety Monitoring**

The FDA has a robust safety surveillance system in place to monitor the safety of COVID-19 vaccines approved and authorized for emergency use. The FDA is monitoring COVID-19 vaccine safety through both passive and active safety surveillance systems in collaboration with the CDC, the Centers for Medicare and Medicaid Services, the Department of Veterans Affairs and other academic and large non-government healthcare data systems.

### **References:**

U.S. Food and Drug Administration. [Coronavirus \(COVID-19\) Update: FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals](#). Published May 5, 2022.