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US FDA limits use of Janssen COVID-19 vaccine to certain individuals

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FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS) warrants limiting the authorized use of the vaccine



The US Food and Drug Administration (FDA) has 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.

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 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.