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FDA Dramatically Narrows Use of Johnson & Johnson COVID-19 Vaccine

The single-shot Covid-19 vaccine will now only be available for adults who cannot or will not receive an mRNA vaccine.

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The Food and Drug Administration has restricted the use of the Johnson & Johnson Covid-19 vaccine to adults who are unable or unwilling to get the Pfizer-BioNTech or Moderna mRNA shots.

The decision comes after the agency completed an updated risk analysis of developing thrombosis with thrombocytopenia syndrome, or TTS, a rare and possibly fatal combination of blood clots and low platelet counts one to two weeks after receiving the vaccine, the agency said Thursday.

Given the severity and urgency of the syndrome, and the availability of other Covid-19 vaccines, FDA decided that the benefits of Covid-19 protection from the Johnson & Johnson vaccine outweigh the risk of TTS only for those who cannot or will not receive other forms of vaccination.

> "Our action reflects our updated analysis of the risk of [thrombosis with thrombocytopenia syndrome] following administration of this vaccine and limits the use of the vaccine to certain individuals," Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in a statement. "We recognize that the Janssen COVID-19 Vaccine still has a role in the current pandemic response in the United States and across the global community … The agency will continue to monitor the safety of the Janssen COVID-19 Vaccine and all other vaccines."

Johnson & Johnson said in a statement it will continue to work with regulators worldwide to ensure consumers "are warned and fully informed about reports of TTS."

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