FAQ on Resumption of J&J COVID-19 Vaccine

Why was use of the J&J vaccine paused?

On April 13, 2021, after six cases of extremely rare but severe cases of blood clots associated with low platelet count were reported in women who had received the Johnson & Johnson/Janssen vaccine, the U.S. CDC and U.S. FDA paused use of the vaccine. This pause allowed the U.S. CDC's Advisory Committee on Immunization Practices to investigate the case reports and assess the safety of the vaccine.

Maine halted use of the J&J vaccine in the state of Maine on April 13, 2021, while the scientific review process took place.

What did the U.S. CDC and FDA decide after their scientific review?

After an 11-day pause on the use of the Johnson & Johnson/Janssen vaccine to review scientific and case data related to extremely rare cases of severe blood clots, the U.S. CDC and FDA authorized providers to resume use of the J&J vaccine on April 23, 2021.

The pause was instituted after reports of six cases of a rare and severe type of blood clot in individuals following administration of the Janssen COVID-19 Vaccine. During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

Following their scientific review, U.S. CDC and FDA determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States.
- The FDA and CDC have confidence that this vaccine is safe and effective in preventing COVID-19.
- The FDA has determined that the available data show that the vaccine's known and potential benefits outweigh its known and potential risks.
- At this time, the available data suggest that the chance of TTS occurring is very low, and the FDA and CDC will remain vigilant in continuing to investigate this risk.
- Health care providers administering the vaccine and vaccine recipients or caregivers should review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare

Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of this syndrome, which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine.

Can I get the J&J vaccine now?

The Maine Department of Health and Human Services (DHHS) and Maine Center for Disease Control and Prevention (Maine CDC) recommend that vaccine providers who have Johnson & Johnson vaccine on hand resume administering doses, effective immediately, to individuals age 18 and older, per the emergency use authorization.

If I am a provider and have Johnson & Johnson/Janssen vaccine on hand from allotment prior to the pause, can it be used now?

Yes, so long as your supply of J&J vaccine has been properly stored and vials were not punctured, you may resume use of the vaccine allotment you had on hand.

Are there restrictions on using the J&J vaccine in certain patient populations?

No, ACIP did not recommend any restrictions on the use of the J&J vaccine in specific patient populations.

Will the State of Maine be ordering more J&J vaccine?

Yes, as soon as the U.S. CDC makes J&J vaccine available for ordering, the State will place additional orders for the vaccine.

Will patients need to sign a consent form before the J&J vaccine can be administered?

The consent form for the J&J vaccine has not changed.