County of Fresno DEPARTMENT OF PUBLIC HEALTH

Health Update

April 28, 2021

Approval to Resume Use of Johnson & Johnson Vaccine

The Fresno County Department of Public Health (FCDPH) is informing providers that the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC), have lifted the recommended pause on the use of the Johnson & Johnson (Janssen) COVID-19 vaccine after conducting a thorough safety review.

According to the <u>Johnson & Johnson COVID-19 Vaccine Update</u> from April 26, 2021, the California Department of Public Health (CDPH) and the Western States Scientific Safety Review Workgroup support the recommendation from the FDA and the CDC to lift the pause on the Janssen vaccine. Clinics in California may begin administering the Janssen vaccine immediately as long as they provide appropriate educational materials to inform patients of the vaccine's low risk of associated health effects and other available vaccine options.

Background:

The pause was recommended 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 FDA and CDC have determined the following:

- Use of the Janssen COVID-19 Vaccine should be resumed in the United States
- The Janssen vaccine is safe and effective in preventing COVID-19
- The available data show that the vaccine's known and potential benefits outweigh its known and potential risks in individuals 18 years of age and older
- At this time, the available data suggest that the chance of Thrombosis with Thrombocytopenia Syndrome (TTS) occurring is very low, but the FDA and CDC will remain vigilant in continuing to investigate this risk

Categories of Health Alert Messages:

Health Alert: Conveys the highest level of importance; warrants immediate action or attention **Health Advisory:** Provides important information for a specific incident or situation; may not require immediate action **Health Update:** Provides updated information regarding an incident or situation; unlikely to require immediate action **Health Information:** Provides general health information which is not considered to be of emergent nature

Promotion, preservation and protection of the community's health

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 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 the Fact Sheet for Recipients and Caregivers, which have been revised to include information about the risk of TTS which has occurred in a very small number of people who have received the Janssen COVID-19 Vaccine

Resources

Factsheet for Healthcare Providers (FDA):

English- https://www.fda.gov/media/146304/download

Factsheet for recipients and caregivers (FDA):

English- https://www.fda.gov/media/146305/download Spanish- https://www.fda.gov/media/146305/download

Other- https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-

19/janssen-covid-19-vaccine#translated

Factsheet: Johnson & Johnson COVID-19 Vaccine Benefits and Risks (CDPH):

English- https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/JnJ factsheet.pdf

Spanish- https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/JnJ factsheet es.pdf

Information on the Janssen COVID-19 vaccine and rare side effects (CDC):

https://www.cdc.gov/media/releases/2021/fda-cdc-lift-vaccine-use.html.

Vaccine Comparison Flyer (FCDPH):

English- https://www.co.fresno.ca.us/Home/ShowDocument?id=53187
Spanish- https://www.co.fresno.ca.us/Home/ShowDocument?id=53267