Technical Bulletin

Date: April 13, 2021
Topic: Pause in Administration of Johnson & Johnson (Janssen) COVID-19 Vaccine
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To: All Health Care Providers and Facilities, Local Health Authorities, and Pharmacists

Pause in Administration of the Johnson & Johnson (Janssen) COVID-19 Vaccine

As of April 12, 2021, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the United States. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are reviewing data involving six reported cases of a rare and severe type of blood clot in individuals after receiving the Janssen vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia).

All six cases occurred among women between the ages of 18 and 48 years and symptoms occurred 6 to 13 days after vaccination. **Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.**

CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday, April 14th, to further review these cases and assess their potential significance. FDA will review the ACIP analysis as it also investigates these cases.

Until that process is complete, **the Nevada State Immunization Program is recommending a pause in the use of this vaccine out of an abundance of caution.** This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

Pending further notice, the following operational guidance should be implemented by vaccinating providers:

1. Approximately 220,000 Janssen doses will be delivered nationwide today, Tuesday, April 13, as scheduled. Please receive, inspect, and store these deliveries.
2. Existing Janssen inventory at enrolled provider sites should be held between 2°C and 8°C (36°F and 46°F) and labeled "Do not use. Awaiting guidance."
3. Follow proper vaccine storage and handling practices and continue to monitor and document storage unit temperatures.
4. Unfilled orders for Janssen vaccine submitted to CDC prior to this guidance will be held until further notice.
5. No new orders for Janssen vaccine will be accepted at this time by the Nevada State Immunization Program nor the CDC.
6. **No Janssen vaccine doses should be administered at this time.**

Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government and all reports of health problems following COVID-19 vaccination are taken seriously. People who have received the Janssen vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.

Thank you in advance for your cooperation. Further guidance will be made available after CDC's ACIP meets on Wednesday, April 14.

Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at https://vaers.hhs.gov/reportevent.html.

For instructions regarding testing and treating patients for this suspected adverse event, healthcare providers are encouraged to review the latest CDC Health Alert Network publication at https://emergency.cdc.gov/han/2021/han00442.asp

Additional resources:

- Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine
- Joint Media Call: FDA & CDC to Discuss Janssen COVID-19 Vaccine
- Virtual emergency ACIP meeting will be held on April 14, 2021, 1:30 p.m. to 4:30 p.m. (ET)
    - Webcast: Advisory Committee on Immunization Practices- ACIP (ustream.tv)
- Latest News from CDC's Health Alert Network
- Nevada Health Response issues statement on federal "pause" regarding use of Janssen vaccine

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