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Janssen (Johnson & Johnson) COVID-19 Vaccine Pause

1 message

Ascension Wisconsin <noreply@communications.ascension.org> Tue, Apr 13, 2021 at 6:52 PM
Reply-To: noreply@communications.ascension.org
To: scott.jenquin@ascension.org

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To: Ascension Wisconsin Leaders, Clinicians and Associates

From: Vanessa Freitag, Vice President, Pharmacy and Lab, Ascension Wisconsin

Doug Culling, DO, MS, CPE, Clinical President, Ascension Medical Group Wisconsin

Cc: Bernie Sherry, Senior Vice President, Ascension and Ministry Market Executive, Ascension Wisconsin

Gregory Brusko, DO, MMM, FACOS, Chief Clinical Officer, Ascension Wisconsin

Heather Schimmers, Chief Nursing Officer, Ascension Wisconsin

Monica Hilt, Chief Operating Officer, Ascension Wisconsin

Date: April 13, 2021

Subject: Janssen (Johnson & Johnson) COVID-19 Vaccine Pause

This communication is being shared now with all Ascension Wisconsin leaders, clinicians and associates.

Good evening,

Today, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued a joint statement calling for an immediate pause in the use of the Janssen (Johnson & Johnson) COVID-19 vaccine at federal sites and urged states to do the same.

Please review this **Executive Memo** on Janssen (Johnson & Johnson) COVID-19 Vaccine Pause from Richard Fogel, MD, FACC, FHRs, Senior Vice President and Chief Clinical Officer, Clinical & Network Services, to Ascension Executive Leadership.

Thank you.

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To: Ascension Executive Leadership

cc: Joseph Cacchione, MD, FACC
Executive Vice President, Clinical & Network Services

Craig Cordola, MBA, MHA, FACHE
Executive Vice President and Chief Operating Officer

Nick Ragone, JD
Executive Vice President and Chief Marketing and Communications Officer

From: Richard Fogel, MD, FACC, FHRS Richard D Fogel MD
Senior Vice President and Chief Clinical Officer, Clinical & Network Services

Date: April 13, 2021

Subject: Janssen (Johnson & Johnson) COVID-19 Vaccine Pause

Today the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) called for an immediate pause in the administration of the Janssen (Johnson & Johnson) COVID-19 vaccine at federal sites and urged states to do the same. This came after six recipients of the vaccine in the United States were reported to have developed a "rare and severe" type of blood clot. All six cases were women between the ages of 18 and 48 who developed symptoms 6-13 days after receiving the Janssen (Johnson & Johnson) 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), according to the FDA and CDC statement. The FDA and CDC will use this pause as an opportunity to further study the six reported cases. As of April 12, more than 6.8 million doses of the Janssen (Johnson & Johnson) vaccine had been administered in the U.S., according to the FDA and CDC.

The FDA and CDC recommended the pause in the use of this particular vaccine "out of an abundance of caution," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, and Dr. Anne Schuchat, principal deputy director of the CDC, said in the joint statement. "Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously."

Therefore, we are pausing administration of the Janssen (Johnson & Johnson) COVID-19 vaccine at all Ascension sites of care.

Our teams are preparing key message points and FAQs to share with our clinicians and patients who have already received this vaccine or are scheduled to do so, or anyone who has questions. Market leaders are advised to:

- Share this communication directly with vaccine leaders in your market(s).
- Quarantine inventory of the Janssen (Johnson & Johnson) vaccine within refrigerators at required temperatures until further notice. Ensure procedures are in place to prevent vaccines from being inadvertently removed and administered.
- Remind all providers, including hospital-based providers, to report any suspected cases of CVST occurring after COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and in the internal Event Reporting System (ERS) system in accordance with Ascension's COVID-19 Vaccine Adverse Event Reporting Guidance.
- Expect more information following a meeting tomorrow of the CDC's Advisory Committee on Immunization Practices to further review these cases and assess their potential significance.

Please cascade this information as appropriate. Thank you.