December 20, 2021

Medical Advisory: Preferential Recommendation for mRNA COVID-19 vaccines over Janssen COVID-19 vaccine

Dear Healthcare Providers:

The Centers for Disease Control and Prevention (CDC) has issued new recommendations regarding the COVID-19 vaccines. **Based on an updated risk-benefit analysis, use of mRNA COVID-19 vaccines (Pfizer-BioNTech or Moderna) are preferred over the Janssen COVID-19 vaccine for all vaccine eligible persons for primary and booster vaccination.**

- Vaccine providers should start the two-dose mRNA COVID-19 series even if there is uncertainty about how the patient will receive their second dose.
  - Setting alone should not be a reason to offer the Janssen COVID-19 vaccine.
  - Two-dose mRNA COVID-19 vaccines are feasible for use in most vaccine-eligible populations or settings.

- Use of an mRNA COVID-19 booster is preferred even for those who received Janssen COVID-19 vaccine for their single dose primary series.

Although the condition is rare, current evidence suggests a causal association of receipt of Janssen COVID-19 vaccine with Thrombosis with Thrombocytopenia Syndrome (TTS) that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. Cases of TTS following administration of the Janssen COVID-19 vaccine have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30 – 49 years; overall approximately 15% of TTS cases have been fatal.

Janssen COVID-19 vaccine may be offered in some situations as described below:

- When there is a contraindication to mRNA COVID-19 vaccines (e.g., severe allergic reaction after a previous dose or to a component of an mRNA COVID-19 vaccine)
- When a person would otherwise remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines
- When a person wants to receive the Janssen COVID-19 vaccine despite the safety concerns identified.

All persons who elect to receive a Janssen COVID-19 vaccine should be informed about the risk and symptoms of TTS that could occur after vaccination (typically within 2 weeks after receipt), the need to seek immediate medical care should such symptoms develop at any time, and the availability of mRNA COVID-19 vaccines instead of Janssen COVID-19 vaccine. **It is contraindicated to administer Janssen COVID-19 vaccine to persons with a history of TTS following receipt of the Janssen COVID-19 vaccine or any other adenovirus vector-based**
COVID-19 vaccine (e.g., AstraZeneca’s COVID-19 Vaccine, which is not authorized or approved in the United States). In addition, people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT), should receive a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine.

For further information, please refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. A recording of the December 17, 2021 COCA call on Updated Guidance for Clinicians on COVID-19 Vaccines, presenting the latest evidence on TTS after administration of the Janssen COVID-19 vaccine and updated vaccine recommendations is available for viewing on the COCA Call webpage.

Sincerely,

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On behalf of:
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