Janssen COVID-19 Vaccine – Revised emergency use authorization (EUA)

- On May 5, 2022, the FDA limited the authorized use of the Janssen coronavirus disease 2019 (COVID-19) vaccine to individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 vaccine because they would otherwise not receive a COVID-19 vaccine.

- After conducting an updated safety assessment, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 vaccine, warrants limiting the authorized use of the vaccine.

- As of March 18, 2022, 60 confirmed cases of TTS, including nine fatal cases have been reported to the Vaccine Adverse Event Reporting System (VAERS).

    - The factors that put an individual at risk for TTS following administration of Janssen COVID-19 vaccine remain unknown.
    - Individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment. TTS can lead to long-term and debilitating health consequences and TTS has a high death rate.

- A warning for the risk of TTS has been added to the fact sheet for healthcare providers and updated information about the TTS risk and revised authorization has been added to the fact sheet for recipients and caregivers.

- Examples of individuals who may still receive the Janssen COVID-19 vaccine include: individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine, individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine, and individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines.