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COVID-19 UPDATE

FDA Narrows EUA for the Johnson & Johnson Vaccine

The FDA has restricted its Emergency Use Authorization for the adenovirus-based COVID-19 vaccine manufactured by Johnson & Johnson (Janssen) to adults who are unable or unwilling to receive another COVID-19 vaccine. The mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)* are preferred for all persons without a contraindication.[1,2]

The EUA was revised because of the risk of thrombosis with thrombocytopenia syndrome (TTS) associated with the Johnson & Johnson vaccine. In an analysis of submissions to its Vaccine Adverse Event Reporting System (VAERS), the FDA identified 60 confirmed cases of TTS following administration of the vaccine (3.23 cases per million doses), 9 of which were fatal (0.48 deaths per million doses). Cases were reported most frequently in females 30-49 years old (~8 cases per million doses).[1,3]

According to CDC guidelines, **immunocompetent persons** who already received a primary dose of the Johnson & Johnson vaccine should generally receive a booster dose of an mRNA vaccine (Pfizer 30 mcg or Moderna 50 mcg) ≥2 months later; a second mRNA vaccine booster given ≥4 months after the first can be considered in patients ≥50 years old. Those who received both a primary and a booster dose of the Johnson & Johnson vaccine may receive a booster dose of an mRNA vaccine ≥4 months after their second Johnson & Johnson vaccine dose.[2]

Moderately or severely immunocompromised persons who have received 1 or 2 doses of the Johnson & Johnson vaccine should continue their vaccination series with an mRNA vaccine until they have received 3 total vaccine doses. An mRNA vaccine should be given ≥4 weeks after an initial Johnson & Johnson vaccine dose and/or ≥2 months after a second dose of any COVID-19 vaccine. If the completed series will include only one mRNA vaccine dose, it should be with the dose used for a primary dose (Pfizer 30 mcg or Moderna 100 mcg). If the completed series will include 2 mRNA vaccine doses, one should be a primary dose and the other a booster dose. In either case, an additional mRNA booster dose given ≥4 months after the third vaccine dose can also be considered.[2] ■

1. FDA News Release. Coronavirus (COVID-19) update: FDA limits use of Janssen COVID-19 vaccine to certain individuals. May 5, 2022. Available at: https://bit.ly/37TG5Qh. Accessed May 23, 2022.
2. CDC. Interim clinical considerations. Use of COVID-19 vaccines in the United States. April 21, 2022. Available at: https://bit.ly/38i7CIH. Accessed May 23, 2022.
3. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). May 5, 2022. Available at: https://bit.ly/3e6KEaD. Accessed May 23, 2022.

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