COVID-19 Emerging Treatments Update



January 10, 2022

** Emergency Use Authorization (Expanded Use) **

FDA Shortens Interval for Booster Dose of Moderna COVID-19 Vaccine to Five Months

Background & Current Status^{1,2,3}:

- On December 19, 2020, the U.S Food & Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals ≥18 years of age.
- On November 19, 2021, the FDA authorized the use of Moderna COVID-19 Vaccine as a single booster dose in individuals 18 years of age or older at least 6 months after completing the primary series.
- On January 7, 2022, the FDA amended the EUA for the Moderna COVID-19 Vaccine to shorten the time between the completion of primary vaccination of the Moderna COVID-19 Vaccine and a booster dose to at least five months. On January 7, 2022, the Centers for Disease Control and Prevention also adjusted their recommendations for when people can receive a Moderna COVID-19 booster shot, shortening the interval from 6 months to 5 months.

Vaccine Data¹:

Booster interval updated to five months for people 18 years of age and older.

The FDA is authorizing the use of a single booster dose with the Moderna COVID-19 vaccine five months after completion of the primary vaccination series. This follows the January 3, 2022 EUA update shortening the time between the completion of primary vaccination of the Pfizer-BioNTech COVID -19 Vaccine and a booster dose to at least five months in patients 12 years of age and older.

Table 1: Vaccine eligibility by vaccine manufacturer, age, and time since primary series completion.

Primary vaccine			
series:	Pfizer-BioNTech	Moderna	Janssen (J&J)
Booster may be given if:	It has been at least 5 months since completing a primary series and you are: Age 12+	It has been at least 5 months since completing a primary series and you are: Age 18+	It has been at least 2 months since completing a primary series and you are: Age 18+
If eligible, may give a booster of:	 Pfizer-BioNTech* Moderna Janssen (J&J) *Only Pfizer-BioNTech can be used as a booster in those aged 12-17 years 	Pfizer-BioNTechModernaJanssen (J&J)	Pfizer-BioNTechModernaJanssen (J&J)

**Current EUA Fact Sheets^{4,5}:

As a convenience, Fact Sheets for the Moderna COVID-19 Vaccine are accessible below:

- Healthcare Providers
- Recipients and Caregivers

References:

- Food and Drug Administration. FDA News Release. <u>Coronavirus (COVID-19) Update: FDA Shortens Interval for Booster Dose of Moderna COVID-19 Vaccine to Five Months</u>. Published online on January 7, 2022.
- 2. Food and Drug Administration. Moderna COVID-19 Vaccine EUA Letter of Authorization. Issued January 7, 2022.
- 3. Centers for Disease Control and Prevention. CDC Recommends Moderna Booster at 5 Months. Published online on January 7, 2022.
- 4. Food and Drug Administration. Moderna COVID-19 Vaccine: FACT SHEET FOR HEALTHCARE PROVIDERS. Revised: January 7, 2022.
- 5. Food and Drug Administration. Moderna COVID-19 Vaccine: FACT SHEET FOR RECIPIENTS AND CAREGIVERS. Revised: January 7, 2022.