



Administrative Policy Statement KENTUCKY MARKETPLACE

Policy Name	Policy Number	Date Effective
COVID-19 Vaccination	PAD-0077-KY-MPP	11/1/2022
Policy Type		
Medical	ADMINISTRATIVE	



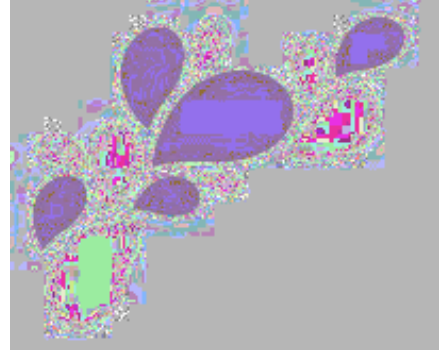
A. Subject

COVID-19 Vaccination

B. Background

The 2019 novel coronavirus, also known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes the disease known as coronavirus disease 2019 (COVID-19). The Food and Drug Administration (FDA) has issued full authorization for the Pfizer-BioNTech vaccine for prevention of COVID-19 for individuals 12 years and older and Moderna vaccine for prevention of COVID-19 for individuals 18 years and older. The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EAU) for the following vaccines for the prevention of COVID-19: Pfizer-BioNTech for individuals 6 months and older, Moderna for individuals 6 months and older, Janssen for individuals 18 years and older for whom other COVID-19 vaccines are inaccessible or clinically inappropriate, and Novavax for individuals 12 years and older as of October 2022. The CDC recommends that the J&J COVID-19 vaccine only be considered in certain situations, due to safety concerns. The Pfizer





- On October 12, 2022, the FDA amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent vaccines to authorize their use as a single booster dose in younger age groups. The Pfizer-BioNTech COVID-19 bivalent vaccine Bn(c)-1.7 (toc

- On August 12, 2021, the FDA expanded the EUA to allow for an additional dose to be given to certain immunocompromised individuals. On October 20, 2021, the FDA amended the Moderna COVID-19 Vaccine EUA to allow for a single booster dose, for all adults age 18 and older.
 - The FDA has since updated bivalent booster recommendation to being administered at least 2 months after initial series or initial booster in individuals 6 years of age and older.
- On June 17, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) amendments for the mRNA-1273 (Moderna) COVID-19 vaccine for use in children aged 6 months–5 years, administered as 2 doses (25



Janssen COVID-19 vaccine as the first single-shot COVID-19 vaccine in individuals 18 years of age or older for the prevention of COVID-19. The use of the Janssen COVID-19 vaccine under the EUA should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines. The interim recommendations and clinical considerations are based on use of the Janssen COVID-19 vaccine under an EUA and might change as more evidence becomes available.

- On October 20, 2021, the FDA expanded the EUA to include a single booster dose of the Janssen (Johnson and Johnson) COVID-19 Vaccination booster dose for adults age 18 and older. The single booster must be administered at least 2 months after completion of the primary vaccine dose. The single booster dose is the same dosage as the initial vaccine (0.5mL).
- Janssen COVID-19 vaccine should be considered for individuals 18 years and older for whom other COVID-19 vaccines are inaccessible or clinically inappropriate. The CDC recommends that the J&J COVID-19 vaccine only be considered in certain situations, due to safety concerns such as TTS.
- Before vaccination, the EUA Fact Sheet should be provided to the recipient and caregivers. Providers should counsel Janssen COVID-19 vaccine recipients about any expected systemic and local reactogenicity.
- Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant. Immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov.
- Novavax COVID -19 Vaccine: Vaccination with the Novavax COVID-19 vaccine consists of 2 doses (0.5 mL each) administered intramuscularly, 3 weeks apart for age 12 years and older. The vaccine is authorized for emergency use as a two-dose primary series.
 - On July 19th, 2022, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the Novavax COVID-19 vaccine in persons aged 18 and older as a primary 2-dose series for vaccination in the prevention of COVID-19. Use of all COVID-19 vaccines authorized under an EUA, including the Novavax COVID-19 vaccine, should be implemented in conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines. The interim recommendations and clinical considerations are based on use of the Novavax COVID-19 vaccine under an EUA and might change as more evidence becomes available.
 - FDA since updated recommendations to include individuals aged 12 years of age and older.
 - Before vaccination, the EUA Fact Sheet should be provided to recipients and caregivers. Providers should counsel Novavax COVID-

19 vaccine recipients about expected systemic and local reactogenicity.

- Additional clinical considerations, including details of administration and use in special populations (e.g., persons who are pregnant, immunocompromised or who have a history of severe allergic reactions) are available at www.cdc.gov

Guidance for COVID -19 Vaccination Boosters

- Individuals age 5 years and older (or 6 years and older for Moderna) may get the updated (bivalent) booster. Individuals should no longer receive an original (monovalent) Pfizer-BioNTech or Moderna booster.
- For individuals with prior COVID-19 infection, experts have recommended that individuals get a booster dose at least 3 months after symptoms began, or if asymptomatic, after the first positive test.
- Children under 5 years of age are not yet eligible to receive any booster.
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COVID-19 Vaccination
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	09/01/2021	Policy revised to update age for Pfizer vaccine, and update vaccine schedule for Pfizer and Moderna vaccine.
	11/30/2021	Policy revised to update age for Pfizer vaccine, Pfizer vaccination approval, vaccine schedules for all booster shots.
	12/09/2021	Policy revised to update for Pfizer vaccine booster age
	3/4/2022	Policy revised to update for new booster dose length
	10/20/2022	Policy revised to update for newly authorized Novavax primary series, bivalent Pfizer and Moderna booster shots and updated age recommendations for primary and booster series.
Date Effective	11/1/2022	



