

## Comirnaty<sup>®</sup> and Spikevax<sup>®</sup> (KP.2) 2024 – 2025 vaccines – FDA approval and Emergency Use Authorization

- On August 22, 2024, the <u>FDA approved Pfizer/BioNTech's Comirnaty (KP.2)</u> and <u>Moderna's Spikevax (KP.2) COVID-19 vaccine</u> in individuals 12 years of age and older as a single dose at least 2 months since the last dose of any COVID-19 vaccine.
- In addition, the FDA granted emergency use authorization (EUA) to <u>Pfizer/BioNTech's COVID-19</u> vaccine (2024-2025 formula) and <u>Moderna's COVID-19 vaccine (2024-2025 formula)</u> in individuals from 6 months to 11 years of age.
  - Individuals 5 years to 11 years of age regardless of previous vaccination are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months since the last dose of any COVID-19 vaccine.
  - Individuals 6 months through 4 years of age who have previously been vaccinated against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
  - Unvaccinated individuals 6 months through 4 years of age are eligible to receive three
    doses of the updated authorized Pfizer/BioNTech COVID-19 vaccine or two doses of the
    updated authorized Moderna COVID-19 vaccine.
  - Additional doses are authorized for certain immunocompromised individuals ages 6 months through 11 years of age as described in the Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine fact sheets.
- The updated vaccines are expected to provide good protection against COVID-19 from the
  currently circulating variants. Barring the emergence of a markedly more virulent variant, the FDA
  anticipates that the composition of COVID-19 vaccines may need to be updated annually, as is
  done for the seasonal influenza vaccine.

## What's Next?

- The <u>Centers for Disease Control and Prevention's (CDC) Director</u> already adopted the Advisory Committee on Immunization Practices (ACIP)'s recommendations for use of 2024 2025 COVID-19 vaccines when authorized or approved by the FDA in people ages 6 months and older.
- Pfizer/BioNTech and Moderna will begin shipping the updated 2024 2025 vaccines to pharmacies and other care settings in the coming days.



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