

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

- On August 22, 2024, the [FDA approved Pfizer/BioNTech's Comirnaty \(KP.2\)](#) and [Moderna's Spikevax \(KP.2\) COVID-19 vaccine](#) 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 [Pfizer/BioNTech's COVID-19 vaccine \(2024-2025 formula\)](#) and [Moderna's COVID-19 vaccine \(2024-2025 formula\)](#) 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 [Centers for Disease Control and Prevention's \(CDC\) Director](#) 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.