

FDA Approves and Authorizes Updated COVID-19 Vaccines

New versions of Moderna, Pfizer and Novavax vaccines are expected to better protect against currently circulating coronavirus variants.

August 30, 2024 By Food and Drug Administration (FDA)

Update: On August 30, the FDA also [authorized the updated COVID-19 vaccine from Novavax](#).

Today [August 22], the U.S. Food and Drug Administration approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2.

The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death.

Today's actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc.

In early June, the FDA advised manufacturers of licensed and authorized COVID-19 vaccines that the COVID-19 vaccines (2024-2025 formula) should be monovalent JN.1 vaccines. Based on the further evolution of SARS-CoV-2 and a rise in cases of COVID-19, the agency subsequently determined and advised manufacturers that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 formula) is the KP.2 strain, if feasible.

"Vaccination continues to be the cornerstone of COVID-19 prevention," said Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research. "These updated vaccines meet the agency's rigorous, scientific standards for safety, effectiveness, and manufacturing quality. Given waning immunity of the population from previous exposure to the virus and from prior vaccination, we strongly encourage those who are eligible to consider receiving an updated COVID-19 vaccine to provide better protection against currently circulating variants."

The updated mRNA COVID-19 vaccines include Comirnaty and Spikevax, both of which are approved for individuals 12 years of age and older, and the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine, both of which are authorized for emergency use for individuals 6

months through 11 years of age.

What You Need to Know

- 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.
- 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 the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- Individuals 5 years through 11 years of age regardless of previous vaccination are eligible to receive a single dose of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines; if previously vaccinated, the dose is administered at least 2 months after the last dose of any COVID-19 vaccine.
- Individuals 12 years of age and older are eligible to receive a single dose of the updated, approved Comirnaty or the updated, approved Spikevax; if previously vaccinated, the dose is administered at least 2 months since the last dose of any 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.

Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines and as described in the respective prescribing information or fact sheets. The updated vaccines are expected to provide protection against COVID-19 caused by the currently circulating variants. Barring the emergence of a markedly more infectious variant of SARS-CoV-2, the FDA anticipates that the composition of COVID-19 vaccines will need to be assessed annually, as occurs for seasonal influenza vaccines.

For today's approvals and authorizations of the mRNA COVID-19 vaccines, the FDA assessed manufacturing and nonclinical data to support the change to include the 2024-2025 formula in the mRNA COVID-19 vaccines. The updated mRNA vaccines are manufactured using a similar process as previous formulas of these vaccines. The mRNA COVID-19 vaccines have been administered to hundreds of millions of people in the U.S., and the benefits of these vaccines continue to outweigh

their risks.

On an ongoing basis, the FDA will review any additional COVID-19 vaccine applications submitted to the agency and take appropriate regulatory action.

The approval of Comirnaty (COVID-19 Vaccine, mRNA) (2024-2025 Formula) was granted to BioNTech Manufacturing GmbH. The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) was issued to Pfizer Inc.

The approval of Spikevax (COVID-19 Vaccine, mRNA) (2024-2025 Formula) was granted to ModernaTX Inc. and the EUA amendment for the Moderna COVID-19 Vaccine (2024-2025 Formula) was issued to ModernaTX Inc.

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