

September 14, 2023

## FDA Takes Action on Updated mRNA COVID-19 Vaccines To Better Protect Against Currently Circulating Variants

On September 11, 2023, the U.S. Food and Drug Administration took action approving and authorizing for emergency use updated COVID-19 vaccines formulated to more closely target currently circulating variants and to provide better protection against serious consequences of COVID-19, including hospitalization and death. These actions relate to updated mRNA vaccines for 2023-2024 manufactured by Moderna and Pfizer-BioNTech. Consistent with the [totality of the evidence](#) and input from the FDA's expert advisors, these vaccines have been updated to include a monovalent (single) component that corresponds to the Omicron variant XBB.1.5.

The updated mRNA vaccines are each approved for individuals 12 years of age and older and are authorized under emergency use for individuals 6 months through 11 years of age. **As part of this action, the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.**

### What You Need to Know:

- **Individuals 5 years of age and older 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.
- The FDA is confident in the safety and effectiveness of these updated vaccines and the agency's benefit-risk assessment demonstrates that the benefits of these vaccines for individuals 6 months of age and older outweigh their risks.
- 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 as described in the respective prescribing information or 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.
- The U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices will meet tomorrow (Sept. 12), to discuss clinical recommendations on who should receive an updated vaccine, as well as further considerations for specific populations such as immunocompromised and older individuals.
- Manufacturers have publicly announced that the updated vaccines would be ready this fall, and the FDA anticipates that the updated vaccines will be available in the near future.

### **Safety and Efficacy Data:**

The mRNA COVID-19 vaccines now approved and authorized are supported by the FDA's evaluation of manufacturing data to support the change to the 2023-2024 formula and non-clinical immune response data on the updated formulations including the XBB.1.5 component.

- The updated mRNA vaccines are manufactured using a similar process as previous formulations. In studies that have been recently conducted, the extent of neutralization observed by the updated vaccines against currently circulating viral variants causing COVID-19, including EG.5 and BA.2.86, appears to be of a similar magnitude to the extent of neutralization observed with prior versions of the vaccines against corresponding prior variants against which they had been developed to provide protection. This suggests that the vaccines are a good match for protecting against the currently circulating COVID-19 variants.
- The benefit-risk profile of previously authorized and approved mRNA COVID-19 vaccines is well understood as these vaccines have been administered to hundreds of millions of people in the U.S.

Based on an evaluation of the totality of the evidence, the benefit-risk profile is favorable for individuals 6 months of age and older to receive an updated COVID-19 mRNA vaccine. Although serious outcomes from COVID-19 are less common in younger individuals, they do occur, and it has been demonstrated that recently receiving a COVID-19 vaccine reduces the risk of such serious outcomes.

### Additional Details:

Specifically, these actions include:

- Approval of Comirnaty (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, and a change to a single dose for individuals 12 years of age and older. Comirnaty was previously approved as a two-dose series for individuals 12 years of age and older.
- Approval of Spikevax (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, a change to a single dose for individuals 18 years of age and older, and approval of a single dose for individuals 12 through 17 years of age. Spikevax was previously approved as a two-dose series for individuals 18 years of age and older.
- Authorization of Moderna COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula and lower the age eligibility for receipt of a single dose from 6 years to 5 years of age. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.
- Authorization of Pfizer-BioNTech COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.

### Availability: *(For questions regarding availability, please contact [CAPT Weston Thompson, NSSC](#))*

The recently approved Pfizer and Moderna vaccinations will be available to order through McKesson Connect. If you use McKesson Connect to procure your medications, you will use the same process to procure the updated COVID-19 vaccines when they are available in McKesson. Additionally, if/when the Novavax vaccine is approved by the FDA, it will also be available to procure through McKesson Connect.

McKesson is reporting that the orders have been placed, the shipments have not arrived but the products are expected to be available in McKesson Connect in 1-2 weeks. This update was received on 9.13.2023.

These are commercial products now so there will be a direct cost associated with their procurement. Final pricing is uncertain for either vaccine, but indications are in the range of **\$80-95/dose**.

### Clinician Resources:

- [Comirnaty Resource Page](#)
- [Spikevax Resource Page](#)
- [Moderna COVID-19 Resource Page](#)
- [FDA Resources for the Fall Respiratory Illness Season](#)

### References:

1. U.S. Food and Drug Administration, [FDA Takes Action on Updated mRNA COVID-19 Vaccines to Better Protect Against Circulating Variants](#). Published online August 11, 2023