



Health Advisory

September 15, 2023

FDA Authorizes Updated COVID-19 mRNA Vaccines

Earlier this week, the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention authorized the updated mRNA COVID-19 vaccines formulated to protect against currently circulating COVID-19 variants. The updated vaccines from Pfizer-BioNTech and Moderna include a monovalent (single) spike protein sequence from the Omicron variant XBB.1.5. A summary of the safety and efficacy data for the updated COVID-19 vaccines can be found [here](#).

Barring the emergence of a 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 updated mRNA vaccines are:

- Fully licensed for ages 12 years of age and older
- Authorized under emergency use for ages 6 months through 11 years of age

Important Updates:

- The bivalent Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines available over the last year are no longer authorized for use in the United States. **This is effective immediately.**
- **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).

Categories of Health Alert Messages:

Health Alert: Conveys the highest level of importance; warrants immediate action or attention

Health Advisory: Provides important information for a specific incident or situation; may not require immediate action

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action

Health Information: Provides general health information which is not considered to be of emergent nature

Promotion, preservation and protection of the community's health

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- **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.

Next Steps:

- The updated COVID-19 vaccines are expected to arrive in Fresno County in late September 2023.

COVID-19 Vaccine Accessibility After Commercialization:

- Most people will not have any out-of-pocket expenses for COVID-19 vaccines. See [COVID-19 Vaccine Access & Ordering](#) infographic and [CDC Press Release](#) for more information.
- Patients with health insurance will be able to get the COVID-19 vaccine at no cost to the patient from their insurance plan.
 - For those with private insurance plans, the CDC's Advisory Committee on Immunization Practices (ACIP) routinely recommended vaccines, including COVID-19 vaccines, will be fully covered without a co-pay when receiving the vaccine in network, per the Affordable Care Act. There may be fees for out-of-network care.
 - For Medicare Part B beneficiaries, COVID-19 vaccinations are covered without cost sharing, and this will continue.
 - Medi-Cal (Medicaid) will continue to cover all COVID-19 vaccinations without a co-pay or cost sharing.
- Patients without health insurance or with health plans that do not cover the cost of a COVID-19 vaccine can get a free vaccine from their local health centers; state, local, tribal, or territorial health department; and pharmacies participating in the [CDC's Bridge Access Program \(BAP\)](#).
 - If you are a provider that sees uninsured adults regularly, and would like more information about enrolling in BAP, please contact Josef Liang at jliang@fresnocountyca.gov
- Children eligible for the [Vaccines for Children](#) program also may receive the vaccine from a provider enrolled in that program.
- The FCDPH will continue to provide updates as more information becomes available. Please continue to encourage all eligible patients to stay safe this fall by making plans to get the updated COVID-19 vaccines, influenza, [RSV](#), and all routine childhood and adult vaccinations.

For more information visit:

- [Pfizer-BioNTech Updated COVID-19 Vaccines](#)
- [Moderna Updated COVID-19 Vaccines](#)