

County of Fresno DEPARTMENT OF PUBLIC HEALTH

David Luchini, Director Dr. Rais Vohra, Interim Health Officer

Health Alert

August 27, 2024

FDA Authorizes Updated COVID-19 mRNA Vaccines

On Thursday August 22, 2024, the U.S. Food and Drug Administration (FDA) 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. Those actions relate to updated mRNA COVID-19 vaccines manufactured by ModernaTX Inc. and Pfizer Inc.

Per the FDA, the <u>2023 - 2024 Moderna or Pfizer-BioNTech COVID-19 vaccines are no longer authorized</u> <u>and should not be administered</u>. It will be considered an administration error if this vaccine is given now that the new COVID-19 vaccine has been approved for use.

Please ensure the following to minimize the risk of vaccine administration errors:

- Remove all 2023 2024 mRNA COVID-19 vaccines from storage units immediately, even if they are not expired.
- Cancel appointments scheduled where only the 2023-2024 Moderna or Pfizer-BioNTech COVID-19
 vaccines were to be administered.
- Return all unused 2023 2024 mRNA COVID vaccines to the Centers for Disease Control's (CDC) centralized distributor using the normal process for returning spoiled/expired vaccines. Note: VFC and BAP providers are to return expired/spoiled vaccines to McKesson. Guidance is available at https://eziz.org/vaccine-management/vaccine-returns/.
- Document any vaccine identified for disposal as 'wasted' in myCAvax/CAIR.
- If you administered any of the 2023-2034 COVID-19 vaccines after 8/22/2024, doses need to be reported in the <u>Vaccine Adverse Event Reporting System</u> (VAERS) and <u>Vaccine Error Reporting</u> (VERP). For additional information, see CDPH Job Aid for reporting.

Click here for more information on the FDA's approval of the 2024-2025 COVID-19 Vaccine.

The 2023–2024 Novavax COVID-19 vaccine remains authorized but is no longer available in the United States, as all doses have expired. Accordingly, at this time, the CDC recommendations for use of Novavax

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

1221 Fulton Street, Fresno CA 93721 u P.O. Box 11867, Fresno, CA 93775 (559) 600-3200 u FAX (559) 600-7687

The County of Fresno is an Equal Employment Opportunity Employer www.co.fresno.ca.us http://fcdph.org

Page 1 of 2



FDA Authorizes Updated COVID-19 mRNA Vaccines

COVID-19 vaccine have been removed. The CDC recommendations will be updated if the FDA approves or authorizes additional 2024–2025 COVID-19 vaccines.

COVID-19 Vaccine Accessibility:

- Most people will not have out-of-pocket expenses for COVID-19 vaccines.
- 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.
- Under Review: California Bridge Access Program (BAP) Extension
 - CDC has indicated additional 317 funds will be made available to continue to support COVID-19 vaccine ordering for uninsured and underinsured adults during the upcoming 2024 – 2025 respiratory season.
 - With the additional funds, CDPH will work on extending COVID-19 vaccine ordering within the same infrastructure in place for the California Bridge Access Program (BAP).
 - Additional details will be forthcoming, including if new provider participation agreements need to be signed, and potential slight name change.
- Children eligible for the <u>Vaccines for Children (VFC)</u> program may receive the vaccine from a provider enrolled in that program.
- The updated COVID-19 vaccines are expected to arrive in Fresno County in the coming weeks and will be available at the Fresno County Department of Public Health (FCDPH) Immunization Clinic, local pharmacies, and through many primary care providers.

The FCDPH will continue to provide updates as more information becomes available. Please continue to encourage all eligible patients to stay safe this fall and winter by making plans to get the updated COVID-19 vaccines, influenza, RSV, and all routine childhood, preteen, and adult vaccinations.

For information on vaccine storage and ordering, visit:

- Pfizer COVID-19 Vaccine Summary
- Moderna COVID-19 Vaccine Summary

For more information visit:

- Pfizer-BioNTech Updated COVID-19 Vaccines
- Moderna Updated COVID-19 Vaccines