

California COVID-19 Vaccination Program Update

Preparing for COVID-19 Vaccine for 6 months-to-4-year-olds

To help local health jurisdictions (LHJs) and providers prepare for vaccination of 6 months-to-4 years olds with COVID-19 vaccine, we want to inform you of some key information shared by the CDC this week. Additional information will be released as it becomes available.

Note: An Emergency Use Authorization (EUA) request for the Pfizer-BioNTech vaccine for children 6 months to 4 years old is anticipated to receive approval the week of February 14, 2022. Therefore, the information below includes details about the anticipated Pfizer product based on current facts and assumptions and may be updated bases on FDA review.

When is Authorization Expected?

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Tuesday, February 15. The CDC's Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on Thursday, February 17. (These dates are subject to change.) Providers enrolled in the COVID-19 Vaccination Program, particularly those most likely to vaccinate or already vaccinating pediatric populations as part of routine pediatric care, should be ready to vaccinate children 6 months to 4 years old shortly thereafter, pending FDA authorization, CDC recommendations, and review by the [Western States Scientific and Safety Review Workgroup](#) (WSSSRW).

Will the Pfizer vaccine for children 6 months-4 years old differ from the current product for adolescents and adults?

The Pfizer COVID-19 vaccine for 6 month-to-4-year-olds is a new formulation with a different dosage, different dilution volume and new National Drug Code (NDC). The

pediatric (5-11 years, orange cap). Shipping, storage, and handling considerations are identical to the Pfizer pediatric (5-11 years, orange cap). **Current products for adults and adolescents cannot be used in children under 5 years of age.**

How Will Vaccine Be Rolled Out?

CDC will allocate product to ensure equitable distribution across states. For the initial roll out, CDC will provide states with an initial allocation of Pfizer pediatric (5-11 years, orange cap) product for pre-ordering in 2 phases extending from this week, through the week of February 25. Shipment for pediatric vaccines can begin once the FDA issues the EUA, and vaccine administration in California can begin once the CDC Director and the WSSSRW issue their independent recommendations.

Smaller orders may be available later in the rollout once myCAVax configurations for Small Ordering are made in the system and the State's Third-party Redistributor (TPR, AmerisourceBergen) is able to ship the new formulation.

Vaccine Ordering

Based on currently available information, the new Pfizer-BioNTech COVID-19 pediatric (6 months – 4 years, maroon cap) vaccine is currently being configured in myCAVax, to allow for vaccine allocation, ordering, and transmission of orders to CDC.

Pre-orders for the first phase will be available for LHJs/MCEs on today, February 9. Orders placed as part of this phase have an anticipated delivery date of Monday, February 21. Therefore all LHDs/MCEs orders (including those placed on behalf of provider locations) **MUST** be able to receive deliveries on the President's day holiday.

Providers will be able to directly submit Standard pre-orders (100 dose minimum) for this product during the second phase, expected to be available in myCAVax on Monday, February 14. Orders placed as part of this phase have an anticipated delivery date of February 22, 2022.

Smaller orders (less than 100 doses) may be available later in the rollout (anticipated Monday, February 21), once myCAVax configurations for Small Ordering are made in the system and the State's Third-party Redistributor (TPR, AmerisourceBergen) is able to ship the new formulation.

Providers should be prepared to increase vaccination capacity of 6 months-to-4 year olds based on parent and community demand. This includes:

- **Prepare communications:** Enhance capacity for call center or clinic phone lines. Update phone system and website with relevant vaccination efforts and vaccine availability. Prepare patient notifications.
- **Prepare systems:** Make system changes to clinic's EMR and appointment and reporting systems to ensure preparedness to [report](#) and track vaccine administration for 6 months-to-4 year olds.
- **Prepare staff:** Prepare processes and train staff on vaccine management and administration guidance for new product, as they become available.
- **Prepare to order and administer:** Determine initial vaccine order need. Prepare to [co-administer](#) COVID-19, influenza, and other childhood vaccines, when appropriate (pending ACIP approval).

Clinical Considerations and Product Information

Additional information on clinical information, and more detailed product information will be forthcoming upon EUA approval, ACIP vote, and CDC recommendation. The packaging configuration for vaccine product for children ages 6m–4 years is expected to be 10-dose vials in cartons of 10 vials each. The diluent will be provided with ancillary supplies to support 100 doses per kit. Note: Opting out of kits for this product, as all other Pfizer products, is not possible.

The Pfizer-BioNTech vaccine for 6mo–4-year-olds will ship at -80°C, like all current Pfizer COVID-19 vaccines, and may be stored at ULT temperatures until the expiry date, or stored at refrigerated temperatures (2°C to 8°C) for up to 10 weeks.

Training Opportunities

There will be additional resources and trainings offered to prepare providers to administer vaccine to younger children. Information on these will be forthcoming.

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