

## California COVID-19 Vaccination Program Update

# Preparing for COVID-19 Vaccine for Children 6 Months and Older

To help local health jurisdictions (LHJs/MCEs) and providers prepare for vaccination of 6 months-to-5 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 and Moderna vaccines for children 6 months-to-5 years old is anticipated to receive approval after June 15, 2022. Therefore, the information below includes details about the anticipated 6 months-to-5 years old product based on current facts and assumptions and may be updated based on FDA review.*

### **When is Authorization Expected?**

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Tuesday, June 14 through Wednesday, June 15. The CDC's Advisory Committee on Immunization Practices (ACIP) is scheduled to meet on Friday, June 17 through Saturday, June 18 (these 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-5 years old shortly thereafter, pending FDA authorization, CDC recommendations, and review by the [Western States Scientific and Safety Review Workgroup \(WSSSRW\)](#).

### **Will the vaccines for children 6 months and older differ from the current formulations for adolescents and adults?**

The Pfizer COVID-19 vaccine for 6 months-to-4-year-olds is a new formulation with a different dosage, different dilution volume and new National Drug Code (NDC). The vaccine will have a maroon cap but otherwise, the packaging is similar to the Pfizer 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.

CDPH is still awaiting more information about the specifics of the Moderna COVID-19 vaccine for 6 months-to-5 years.

### **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 (6 months-to-4 years) and Moderna pediatric (6 months-to-5 years) products for pre-ordering in 2 waves, with wave 1 pre-orders starting Friday, June 3 through Monday, June 6, and wave 2 pre-orders from Tuesday, June 7 through Friday, June 10 at 5pm. 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. Wave 1 pre-orders will be delivered on Monday, June 20, while wave 2 pre-orders will be delivered from Tuesday, June 21 through Friday, June 24.

Smaller orders will 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 for the new Pediatric vaccines in myCAvax**

Based on currently available information, the new Pfizer-BioNTech COVID-19 pediatric (6 months – 4 years, maroon cap) and Moderna COVID-19 pediatric (6 months–5 years) vaccines have been configured in myCAvax to allow for vaccine allocation, ordering, and transmission of orders to CDC.

**Pre-orders for the first wave were made available for all providers on Friday, June 3 through Monday, June 6 at 5pm. Any orders submitted after 5pm on June 6 will be included with wave 2.**

- All pre-orders submitted and approved as part of wave 1 will be delivered on Monday, June 20.
  - **Pre-orders for wave 2 will be available for ordering from Tuesday, June 7 through Friday, June 10 at 5pm.** Orders placed as part of this wave have anticipated delivery dates of Tuesday, June 21 through Friday, June 24, 2022.

Routine ordering for both products is anticipated to be available in myCAvax after EUA approval has been granted. **Small orders (less than 100 doses) will 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.

### **Provider Readiness**

Providers should be prepared accommodate immunization of young children based on local demand:

- **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 ages 6 months to 5 years.
- **Prepare staff:** Prepare processes and train staff on vaccine management and administration guidance for the new products.
- **Prepare to order and administer:** Determine your initial vaccine order. Prepare to **co-administer** COVID-19, influenza, and other childhood vaccines, when appropriate.

### **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 6 months-to-5 years is expected to be 10-dose vials in cartons of 10 vials each, with a minimum order quantity of 100 doses per product. Note: Diluent will be provided with ancillary supplies to support 100 doses per kit for the Pfizer vaccine, therefore opting out of the ancillary kit for the Pfizer 6 months-to-4 years product will not be allowable.

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.

The Moderna vaccine for 6mo–5-year-olds will ship at frozen temperatures, -50°C to -15°C, like all current Moderna 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 30 days.

### **Training Opportunities**

Stay tuned for additional resources and trainings to prepare providers to administer vaccine to younger children.

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## COVID19 Vaccination Program



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