



To: CAHAN San Diego Participants

Date: July 14, 2021

From: Public Health Services

Health Advisory Update #54: Coronavirus Disease 2019 (COVID-19) Vaccine Update: Vaccine Eligibility Down to Six Months of Age

Key Messages

- The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have authorized the Pfizer-BioNTech COVID-19 primary series (3 doses) for children 6 months to 4 years of age and Moderna primary series (2 doses) for children 6 months to 17 years of age.
- An additional dose of the Moderna primary series formulations is authorized for children with moderate to severe immunocompromise at least one month after the second primary series dose for children 6 months to 17 years of age with the Moderna vaccine and 6 years to 11 years of age.
- The Centers for Disease Control and Prevention (CDC) has updated their interim clinical considerations page and a Clinical Outreach and Communications Activity (COCA) recorded [presentation on the new indications is available](#).
- COVID vaccines can be co-administered with routine child and adolescent vaccines.

Situation

Following a thorough evaluation and analysis of the safety and effectiveness data, federal agencies granted both Pfizer-BioNTech (Pfizer) and Moderna COVID-19 vaccines Emergency Use Authorization (EUA) and recommendations for primary series for children down to 6 months of age.

Approval Process

Federal

On June 17, 2022, the Food and Drug Administration (FDA) [expanded the eligibility for the Pfizer COVID-19 vaccine](#) to include a 3-dose primary series for children 6 months to 4 years of age. The FDA also [expanded the eligibility of the Moderna-BioNTech COVID-19 vaccine](#) to include a 2-dose primary series for children 6 months to 17 years of age. The FDA determined that the known and potential benefits of the Moderna and Pfizer-BioNTech COVID-19 vaccines outweigh the known and potential risks in the pediatric populations authorized for the use of each vaccine.

On June 18, following a meeting of the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC) updated its COVID-19 vaccine recommendations to include the Pfizer primary series for 6-month- to 4-year-olds and the Moderna vaccine for 6 month- to 5-year-olds ([presentations are available](#)). ACIP then met on June 23 and unanimously agreed to recommend the Moderna vaccine formulation for 6- to 17-year-olds. A Clinical Outreach Communication Activity held on June 22 discussed the 6-month through 5-year data, and recommendations were recorded and are available [here](#).

The Western States and California

The Western States Scientific Safety Review Workgroup also met on June 18 and 28, 2022. The Workgroup then issued two [joint statements with the California Department of Public Health](#) (CDPH) strongly supporting CDC's recommendations for extension of age indications for these two vaccines.

Vaccine Administration

Pfizer Vaccine

- The Pfizer primary series formulation for 6-month to 4-year-olds contains 3 mcg mRNA (0.2 mL, maroon cap).
 - Doses 1 and 2 should be separated by at least 3 weeks.
 - Doses 2 and 3 should be separated by at least 8 weeks.
- Individuals who will turn from 4 years to 5 years of age between any doses in the primary series may receive:
 - a 2-dose primary series with the Pfizer vaccine authorized for 5- through 11-year-olds (each 0.2 mL dose containing 10 mcg mRNA, orange caps) OR
 - a 3-dose primary series initiated with the Pfizer vaccine authorized for 6-month through 4-year-olds (each 0.2 mL dose containing 3 mcg mRNA, maroon cap). Each of Doses 2 and 3 may be with:
 - Pfizer vaccine formulation for 6-month through 4-year-olds (maroon cap), or
 - Pfizer vaccine formulation for 5- through 11-year-olds (orange cap).

Moderna Vaccine

- The Moderna primary series formulations are as follows.
 - For 6-months- to 5-year-olds: 25 mcg mRNA (0.25 mL, dark blue cap) to be given at least one month apart.
 - For 6- to 11-year-olds: 50 mcg mRNA (0.5 mL, dark blue cap) to be given at least one month apart.
 - For 12- to 17-year-olds: 100 mcg mRNA (0.5 mL, red cap) to be given at least one month apart.
 - This is the same formulation for booster doses for persons >18 years of age.
- An additional third dose is authorized for children with [moderate to severe immune compromising conditions](#) aged 6 months and older.

The American Academy of Pediatrics (AAP) [supports the expanded age indication for Pfizer and Moderna vaccines and the co-administration of COVID-19](#) vaccine with routine childhood and adolescent immunizations to catch children up on any missed vaccine.

Scheduling

MyTurn.ca.gov is currently being updated to reflect the expanded eligibility. Parents and guardians are encouraged to check with their child's health care provider to schedule their vaccine appointments.

Actions Requested

1. If not already enrolled, providers can listen to the recorded webinar on [how to enroll in the California COVID-19 vaccination program](#) and participate in COVID-19 vaccination.
2. Remain up-to-date on COVID-19 vaccine [clinical considerations, including contraindications and precautions](#).
3. Providers supplied with Pfizer vaccine should consider co-administration of routine childhood and adolescent vaccines with COVID-19 vaccine to catch children up on any missed vaccines.
4. Report vaccine-related adverse events and deaths, as well as vaccine administration errors to the [Vaccine Adverse Event Reporting System \(VAERS\)](#), and to the County Immunization Program at IZINFO.HHSA@sdcounty.ca.gov or Fax: (619) 692-5677.

Resources

- [Fact Sheet for Recipients and Caregivers, Pfizer COVID-19 Vaccine, 6-months- to 4-year-olds | FDA](#)
- [Fact Sheet for Healthcare Providers, Pfizer COVID-19 Vaccine, 6-months- to 4-year-olds | FDA](#)
- [Fact Sheet for Recipients and Caregivers, Moderna COVID-19 Vaccine, 6-months- to 5-year-olds | FDA](#)
- [Fact Sheet for Healthcare Providers, Moderna COVID-19 Vaccine, 6-months- to 5-year-olds | FDA](#)
- [Fact Sheet for Recipients and Caregivers, Moderna COVID-19 Vaccine, 6- to 11-year-old | FDA](#)

- [Fact Sheet for Healthcare Providers, Moderna COVID-19 Vaccine, 6- to 11-year-olds | FDA](#)
- [Fact Sheet for Recipients and Caregivers, Moderna COVID-19 Vaccine, 12- to 17-year-old | FDA](#)
- [Fact Sheet for Healthcare Providers, Moderna COVID-19 Vaccine, 12- to 17-year-old | FDA](#)
- [Guidance for COVID-19 Vaccination for People Who Are Moderately or Severely immunocompromised | CDC](#)
- [Safety of COVID-19 Vaccines | CDC](#)
- [Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit | CDC](#)
- [Vaccine Resources and Guidance \(SanDiegoCounty.gov\)](#)

Thank you for your participation.

CAHAN San Diego

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