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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

CDC and FDA Authorize COVID Vaccines for Children Ages 6 months -5 years old

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Background:

The FDA authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine in children down to 6 months of age on June 17, 2022.

The Advisory Committee on Immunization Practices (ACIP) voted on June 18, 2022 to recommend the Pfizer-BioNTech COVID-19 Vaccine for children ages 6 months – 4 years and the Moderna COVID-19 Vaccine for children ages 6 months - 5 years. The CDC endorsed the ACIP recommendations shortly after the meeting.

While the FDA has also authorized emergency use of the Moderna Vaccine for children ages 6 years – 17 years, the ACIP is scheduled to discuss and provide recommendations on June 23, 2022.

While both vaccines were found to be safe and effective, no studies compare the two vaccines to each other. For each vaccine, the effectiveness data to support the EUAs is based on findings that children's response to the pediatric vaccine series was comparable to that of adults (control group) to the adult dose of vaccine. In addition, an analysis of Moderna data during the Omicron period found the vaccine to be 50.6% effective in preventing COVID-19 for children 6 – 23 months and 36.8% effective in preventing COVID-19. There is no comparable data for Pfizer.

COVID-19 Vaccine Recommendations for Children under 5:

- Children 6 months through 4 years of age can now be vaccinated with Pfizer-BioNTech (three dose primary series) vaccine.
- Children 6 months through 5 years of age can now be vaccinated with Moderna (two dose primary series) vaccine.
- COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series.
- Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight. In general, if a child moves from a younger age group to an older age group during the primary series, they should receive the vaccine dosage for the older age group for all subsequent doses.
- COVID-19 vaccines may be administered without regard to timing of other vaccines.
- Preterm infants, regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants.
- Infants of mothers who were vaccinated and/or had COVID-19 infection before or during pregnancy should be vaccinated according to the recommended schedule.

- All children, including children who have already had COVID-19, should get vaccinated.

Moderna COVID-19 Vaccine for ages 6 months – 5 years:

- The Moderna vaccine is administered as a primary series of two doses given 4 weeks apart. CDC allows that up to an 8-week interval between doses may be optimal for people ages 6 months – 64 years (and especially males 12 – 39 years) who are not immune compromised.
- This formulation is in a vial with a **dark blue cap** and **label with a magenta border**.
- The dosage for this formulation is 25 µg (contained in 0.25mL) for both doses.
- For children ages 6 months – 5 years who are moderately to severely immune compromised, a **third primary series dose** (25 µg, 0.25 mL) should be provided one month after the second dose.
- Individuals who will turn from 5 years to 6 years of age between doses in the primary series may receive, for any dose in the primary series, either:
 1. Moderna COVID-19 Vaccine for individuals 6 months through 5 years of age (0.25 mL dose; 25 µg) in vials with dark blue caps and labels with a magenta border; OR
 2. Either of the Moderna vaccine products for children ages 6 – 11 years (50 µg contained in 0.5ml) which have been FDA authorized and are expected to be endorsed by the CDC by the end of the week.
- No booster dose is authorized for this age group.

Pfizer-BioNTech COVID-19 Vaccine for ages 6 months – 4 years:

- The Pfizer-BioNTech Vaccine is administered as a three dose primary series.
- The initial two doses are administered three weeks apart followed by a third dose administered at least eight weeks after the second dose. CDC allows that up to an 8-week interval between doses may be optimal for people ages 6 months – 64 years (and especially males 12 – 39 years) who are not immune compromised.
- This formulation is in a vial with a **maroon cap** and must be diluted with 2.2 mL sterile 0.9% sodium chloride (provided) prior to use.
- The dosage of this formulation is 3 µg (contained in 0.2 ml) for all three doses.
- Individuals who will turn from 4 years to 5 years old between **any doses** in the primary series may receive **either**:
 1. A 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine for individuals 5- 11 years of age **OR**
 2. A 3-dose primary series **initiated** with the Pfizer-BioNTech COVID-19 Vaccine for individuals 6 months through 4 years of age. Doses 2 and 3 may be with either the orange cap formulation for ages 5 – 11 years OR the maroon cap formulation for ages 6 months – 4years old.
- No booster dose is authorized for this age group and there is no additional dose for immune compromised children in this age group.
- An important note about Pfizer labeling: the vial and carton labels may state “for age 2y to < 5y,” but the maroon cap vials can be used for individuals 6 months through 4 years of age.

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Safety Considerations:

- The FDA determined that the known and potential benefits of the Moderna and Pfizer-BioNTech COVID-19 vaccines outweigh the known and potential risks.
- Children may experience fewer side effects than adolescents or young adults. Local side effects noted in the vaccine trials included pain, swelling, and redness at the injection site, and axillary or inguinal lymphadenopathy. Systemic side effects included fever, fatigue, headache, chills, myalgia, arthralgia, irritability, crying, sleepiness, and loss of appetite.
- Based on epidemiology of myocarditis and safety monitoring in children ages 5-11, myocarditis after mRNA COVID vaccination in young children is anticipated to be rare. There were no known cases in clinical trials for this age group.

Additional Considerations:

1. COVID-19 vaccines continue to undergo the most intensive safety monitoring in U.S. history. Parents and caregivers can help monitor the safety of these vaccines by reporting their children's symptoms with the CDC's confidential monitoring system called v-safe: [V-safe After Vaccination Health Checker | CDC](#)
2. The CDC encourages a shift in thinking from "don't waste a dose" to "don't waste an opportunity to vaccinate a child."

Access to Vaccine for children under five in New Mexico:

- New Mexico COVID-19 vaccine providers can immediately implement the above recommendations.
- Providers can order vaccine in NMSIS today and can expect delivery on June 27, 2022.
- The statewide registration app has been updated to allow scheduling for children 6 months and older. Parents and caregivers can schedule at: [Get Vaccinated New Mexico | NMDOH \(vaccinenm.org\)](#) or directly with their medical and pharmacy providers.
- Many pharmacies plan to vaccinate children ages 3 and older.
- Vaccine appointments can also be found on the CDC Vaccine Finder website: [Vaccines.gov - Find COVID-19 vaccine locations near you.](#)
- All providers are encouraged to provide office-based COVID-19 vaccines.

Additional Resources:

1. Pfizer EUA for Providers: [Pfizer HCP FS 6m-4y Maroon 06172022 \(fda.gov\)](#)
2. Pfizer EUA for Vaccine Recipients: [Pfizer Recipient FS 6m-4y Maroon 06172022 \(fda.gov\)](#)
3. Moderna EUA for Providers: [6m-5y-facts-HCP.pdf \(modernatx.com\)](#)
4. Moderna EUA for Vaccine Recipients: [6m-5y-facts-recipient.pdf \(modernatx.com\)](#)
5. Clinical recommendations from CDC are updated here: [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)

6. For clinicians wishing to administer COVID-19 vaccine, please contact the NM DOH Immunization Team at covid.vaccines@state.nm.us or find more information at: [Immunization Education & Tools for Healthcare Providers \(nmhealth.org\)](https://www.nmhealth.org/immunization)to

New Mexico Health Alert Network: To register for the New Mexico Health Alert Network, click the following link to go directly to the HAN registration page <https://nm.readyop.com/fs/4cjZ/10b2> Please provide all information requested to begin receiving important health alerts and advisories.

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