

## Louisiana Health Alert Message 22-35: Updated (Bivalent) COVID-19 Vaccines Authorized for Children Down to 6 Months of Age

12/12/2022 02:00:09 PM

Message Urgency: **HIGH**

This message is being sent via the Louisiana Department of Health Emergency Operations Center's (LDH EOC) Louisiana Health Alert Network (LA HAN) for all LA HAN recipients. This message is from LDH regarding **Updated (Bivalent) COVID-19 Vaccines Authorized for Children Down to 6 Months of Age**. Please see the message below to share and distribute with relevant stakeholders and partners through your own distribution channels.

Moderna and Pfizer-BioNTech bivalent COVID-19 vaccine boosters are now authorized for administration to children down to 6 months of age. On December 9, 2022, the U.S. Food and Drug Administration (FDA) authorized, and the US Centers for Disease Control and Prevention (CDC) recommended the expanded use of updated (bivalent) COVID-19 vaccines for children ages 6 months through 5 years. The Louisiana Department of Health (LDH) is now recommending these updated vaccines for these age groups.

- Moderna: Children ages 6 months through 5 years who previously completed a Moderna primary series are eligible to receive a Moderna bivalent booster 2 months after their final primary series dose.
- Pfizer-BioNTech: Children ages 6 months through 4 years who are currently in the process of completing a Pfizer primary series will receive a Pfizer bivalent vaccine as their third primary dose. **No booster is currently recommended for those children who have completed the 3-dose Pfizer series.** [See this link for details](#) .

The Moderna and Pfizer-BioNTech bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.

Individuals who receive the updated (bivalent) vaccines may experience similar side effects reported by individuals who received previous doses of the original (monovalent) mRNA COVID-19 vaccines.

The fact sheets for both bivalent COVID-19 vaccines for recipients and caregivers and for healthcare providers include information about the potential side effects, as well as the risks of myocarditis and pericarditis.

- [Pfizer-BioNTech COVID-19 Vaccines | FDA Fact Sheets](#)
- [Moderna COVID-19 Vaccines | FDA Fact Sheets](#)

Parents can visit [vaccines.gov](https://www.vaccines.gov) to find a vaccine provider close to them. For a person younger than age 18, parental/caregiver consent is needed to get the shot. LDH has developed a consent form that can be found on its website at [ldh.la.gov/Covid-19K-12](https://ldh.la.gov/Covid-19K-12).

### **Vaccine Safety**

The safety of a single booster dose of the Moderna COVID-19 bivalent vaccine for children 6 months through 5 years of age is supported by safety data from:

- A clinical study which evaluated a booster dose of Moderna’s investigational bivalent COVID-19 vaccine (original and omicron BA.1),
- Safety data from clinical trials which evaluated primary and booster vaccination with the monovalent Moderna COVID-19 vaccine, and
- Postmarketing safety data with the monovalent Moderna COVID-19 vaccine and Moderna COVID-19 bivalent vaccine.

The safety of the Pfizer-BioNTech COVID-19 bivalent vaccine as the third dose of a three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 vaccine in children 6 months through 4 years of age is based on safety data from:

- A clinical study which evaluated a booster dose of Pfizer-BioNTech’s investigational bivalent COVID-19 vaccine (original and omicron BA.1) in individuals greater than 55 years of age,
- Safety data from clinical trials which evaluated primary vaccination in individuals 6 months of age and older with the monovalent Pfizer-BioNTech COVID-19 vaccine,
- Safety data from clinical trials which evaluated booster vaccination in individuals 5 years of age and older with the monovalent Pfizer-BioNTech COVID-19 vaccine, and
- Postmarketing safety data with the monovalent Pfizer-BioNTech COVID-19 vaccine and the Pfizer-BioNTech COVID-19 bivalent vaccine.

### **Ordering Information**

Doses of bivalent Pfizer-BioNTech vaccine for children aged 6 months through 4 years and bivalent Moderna vaccine for children aged 6 months through 5 years will be made available to order in LINKS beginning the week of December 12 through 16.

Pfizer-BioNTech once diluted is a 10 dose vial. Moderna is a 2 dose vial. Letters will be sent to emphasize vaccine administration of pediatric bivalent vaccine.

**Please note vial and label coloring may be similar among the various Pfizer and Moderna products. Providers should pay close attention to label text to ensure proper product and dosing are used.**

### **Clinical Considerations**

- [Interim Clinical Considerations for Use of COVID-19 Vaccines](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines: Appendices, References, and Previous Updates](#)
- [FAQs for the Interim Clinical Considerations for COVID-19 Vaccination](#)

### **Related Information**

- [COVID-19 Bivalent Vaccine Boosters](#)
- [COVID-19 Vaccines](#)
- [Emergency Use Authorization for Vaccines Explained](#)



### **Reporting Adverse Events**

LDH reminds providers to report possible vaccine-related adverse events to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967.

Any possible severe adverse events (those resulting in hospitalization, death, or persistent disability) should be immediately reported to the LDH Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.

If you have vaccine-related questions, please contact [Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues, can call the Louisiana COVID-19 Community Hotline at 855-453-0774.](#)