

IMMUNIZATION COVID-19 Update

June 24, 2022 | Issue 65



Question of the Week

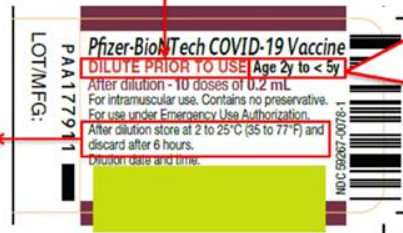
The label on the vials I received for the Pfizer-BioNTech vaccine say it is for “2 years to <5 years.” Is this the vaccine for kids down to age 6 months and above?

Yes. Some of the vials for this age group were mislabeled by the manufacturer. As shown below, vials with labels that read 2 years to <5 years AND that read 6 months through 4 years of age can be used for the new young age group

Initial shipments of Maroon Cap vials and cartons will have the following label characteristics:

Maroon Cap vaccine requires dilution prior to use

*Maroon Cap vial labels and cartons may state that a vial should be discarded **6 hours** after the first dilution. Results from recent stability studies will supersede the current vial label and support discarding the vaccine after **12 hours** from the time of dilution



IMPORTANT INFORMATION

- The vial and carton labels may state **2 years to <5 years** of age or **6 months through 4 years of age**.
- Vials with labels that state for use in individuals **2 years to <5 years of age** can be used for individuals **6 months through 4 years of age**.

LDH supports CDC/FDA recommendations for COVID-19 vaccines for children 6 months and above

Earlier this month, the CDC accepted the recommendation of its Advisory Committee on Immunization Practices to recommend the Moderna and Pfizer-BioNTech COVID-19 vaccines for children as young as 6 months of age. Prior to this, FDA granted emergency use authorization (EUA) to both manufacturers.

After closely reviewing the data and guidance, the Louisiana Department of Health recommends that all eligible children 6 months old and above receive the COVID-19 vaccine to protect themselves and minimize harmful effects of COVID-19.

COVID-19 vaccines are free and available in your community right now.

- For a list of locations, visit LDH's vaccine directory at <http://ldh.la.gov/kidsvax> or visit vaccines.gov, maintained by the federal government.
- To obtain a list of nearby vaccine locations, individuals can text their ZIP code to GETVAX (438829) in English, or VACUNA (822862) in Spanish.
- For questions or assistance scheduling an appointment, individuals can call 211 or Louisiana's COVID-19 Support Hotline at 1-855-453-0774.

The amended EUAs for the Moderna COVID-19 vaccine now make the vaccine available to children 6 months through 5 years and 6 years through 17 years of age. Previously, the vaccine was authorized only for use in adults 18 years of age and older.









The amended EUA for the Pfizer-BioNTech COVID-19 vaccine makes the vaccine available to children 6 months through 4 years of age. Previously, the vaccine was authorized for use in individuals 5 years of age and older.

Additional ordering information for these new vaccines, especially for the Moderna vaccine for 6 years through 11 years, will be provided by the Immunization Program as it becomes available.

Moderna: Labeling & packaging for pediatric vaccine

Vials of Moderna vaccine will have a blue colored cap and a magenta labeled border for ages 6 months through 5 years. Vials will have a blue cap and purple border for ages 6 through 11 years. Vials will have a red cap and light blue border for ages 12 and up. Please see the FDA provider fact sheet for full preparation and administration instructions.




The Pfizer-BioNTech COVID-19 vaccine is administered as a primary series of three doses, in which the initial two doses are administered three weeks apart, followed by a third dose, administered at least eight weeks after the second dose, in individuals 6 months through 4 years of age.

Age Group	6 months through 5 years (Primary Series)	6 years through 11 years (Primary Series) Currently unavailable (Use the vial with dark blue cap and a label with a purple border)	6 years through 11 years (Primary Series) 18 years and older (Booster Dose)	12 years and older (Primary Series) 18 years and older (Booster Dose)
Vial Cap Color	Dark Blue	Dark Blue	Dark Blue	Red
Vial Label Border Color	MAGENTA	TEAL	PURPLE	LIGHT BLUE
Vial Image				
Primary Dose Volume	0.25 mL	0.5 mL	0.5 mL	0.5 mL
Booster Dose Volume	None	None	0.5 mL	0.25 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua	 www.modernatx.com/covid19vaccine-eua

Pfizer: Labeling & packaging for pediatric vaccine

Vials of Pfizer vaccine will have a maroon cap for ages 6 months through 4 years. The vial and carton labels may state *2 years to <5 years of age* or *6 months through 4 years of age*, as some product labels were printed in advance prior to this current authorization. Despite this labeling error, either of these two labeled vials may be used in ages 6 months through 4 years. For Pfizer product, orange-colored tops are to be used in ages 5 through 11 years, and purple or grey colored tops are to be used in ages 12 and up. Please see the FDA provider fact sheet for full preparation and administration instructions.

Pfizer-BioNTech COVID-19 Vaccine Presentations

Age Group	6 months through 4 years	5 through 11 years	12 years and older	12 years and older
Vial Cap Color and Label Border Color	MAROON 	ORANGE 	PURPLE** 	GRAY** 
Is Dilution Needed?	Dilute Before Use	Dilute Before Use	Dilute Before Use	Do Not Dilute
Amount of Diluent* Needed per Vial	2.2 mL	1.3 mL	1.8 mL	NO DILUTION
Dose Volume	0.2 mL	0.2 mL	0.3 mL	0.3 mL
For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code.	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com	 www.cvdvaccine-us.com

*Diluent: sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

** The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

Pediatric vaccine safety

FDA evaluation and analysis of the safety, effectiveness and manufacturing data of these vaccines was rigorous and comprehensive, supporting the EUAs. The agency determined 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 use for each vaccine.

Moderna <6:

Based on the totality of scientific evidence available, the benefits of the Moderna COVID-19 vaccine when administered as a 2-dose series (25 ug each dose) outweigh its risks for use in infants and children 6 months through 5 years of age. For this age group, 2 doses of the vaccine demonstrated comparable immunogenicity and efficacy as 2 doses of Moderna for adults.

Safety: Pain at the injection site and fatigue were the most common adverse reactions.



Pfizer-BioNTech <5:

Based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 vaccine when administered as a 3-dose series (3 ug each dose) outweigh its risks for use in infants and children 6 months through 4 years of age. Efficacy and immunogenicity against Omicron were comparable with adults who received 3 doses of Pfizer-BioNTech.

Safety. For the 2 to <5 age group, local and systemic reactions were mild to moderate, with the most common reactions being pain at the injection site, fatigue, and fever.

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 Office Public Health (OPH) Infectious Disease/Epidemiology Hotline at 1-800-256-2748.
- For vaccine-related questions, please contact la.immunization@la.gov.
- Any member of the public with questions on COVID-19 testing, therapeutics, vaccines, or other related issues, can call the Louisiana COVID Community Hotline at 1-855-453-0774.

Pediatric vaccine toolkit for providers

Providers can now access tools to educate parents, patients, and the public about the pediatric COVID-19 vaccines. LDH's Bring Back Louisiana campaign has a variety of resources at your disposal.

View the BBL [6 months and up EUA Resource Toolkit for Partners](#) from LDH's Bring Back Louisiana campaign specifically focused on this Under 5 EUA announcement. This toolkit and other resources are also linked [here](#) on a fully revamped webpage highlighting this announcement.

Training materials for administering vaccine to children

CDC has a suite of online training materials for administering vaccine to young children. All training materials can be accessed at the following webpage: [Vaccine Administration Resource Library](#) .

Training Guidelines:

- [Training and Education for COVID-19 Vaccination](#)
- [COVID-19 Vaccine: Vaccine Administration Competencies Assessment Form-February 2021](#)
- [Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)

Videos:

- [Comfort and Restraint Techniques](#): This training demonstrates comfort and restraint techniques. Determine the best position for the patient based on comfort, age, activity level, administration site, and safety. Instruct the parent on how to help the infant or child stay still so you can administer the vaccine(s) safely.

- [Intramuscular \(IM\) Injection: Supplies \(Children Birth through 18 Years of Age\)](#): This training addresses how to select the equipment needed to prepare an intramuscular (IM) injection for children from birth through 18 years of age.
- [Intramuscular \(IM\) Injection: Sites](#): This training helps providers identify intramuscular (IM) injection sites.

Pediatric COVID-19 Resources:

- [Summary Document for Interim Clinical Considerations](#)
- [Interim Clinical Considerations for COVID-19 Vaccination](#)
 - Summary of recent changes (last updated June 19, 2022):
 - New guidance for use of Pfizer-BioNTech COVID-19 vaccine in children ages 6 months–4 years
 - New guidance for use of Moderna COVID-19 vaccine in children ages 6 months–5 years
 - Reorganization of sections on COVID-19 vaccination recommendations and schedules
 - Addition of new section in Special populations for infants and young children
- [Interim COVID-19 Immunization Schedule](#)
- [At-A-Glance COVID-19 Vaccination Schedule](#) (NEW 6/19/2022)
- [Administration Error Revaccination Guidance](#)
- [Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#) (FDA fact sheet for providers and other documents)
- [Moderna COVID-19 Vaccine](#) (FDA fact sheet for providers and other documents)
- [COVID-19 Vaccines](#)
- [Emergency Use Authorization for Vaccines Explained](#)
- [Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry](#)

COVID-19 Resources

- [COVID-19 Vaccine: Quick Reference Guide for Healthcare Professionals](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines](#)
- [COVID-19 Vaccine Lot Number and Expiration Dates](#)
- [Pfizer-BioNTech COVID-19 Vaccines](#)
- [Administration Overview for Moderna COVID-19 Vaccine](#)
- [Administration Overview for Johnson & Johnson's Janssen COVID-19 Vaccine](#)
- [CDC COVID Data Tracker: Vaccinations in the US](#)
- [COVID-19 Vaccine Handling Toolkit](#)

Good Reads

- [Moderna CEO: COVID Variant Vaccine to Be Ready for Shipping in August](#)
- [Omicron-Specific COVID Vaccines on the Horizon, Pfizer Chief Says](#)
- [Study Finds Wearable Health Trackers Can Detect COVID Before Symptoms Appear](#)
- [NHS warns of scam Covid-test texts](#)
- [Lots of COVID in Louisiana; little of it severe](#)

- [Louisiana opens COVID vaccine appointments for children under 5](#)
- [Louisiana Department of Health supports COVID-19 vaccines for young kids](#)

GET THE FACTS

COVID-19 SUPPORT HOTLINE
855-453-0774

MONDAY - FRIDAY
8:00 AM - 8:00 PM

SUNDAY
12:00 PM - 8:00 PM

BRING BACK
LOUISIANA

Submit a Question of the Week

Do you have a frequently asked question that you would like to submit or have answered in the QOW?

SUBMIT HERE

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