



Louisiana Health Alert Message 23-05: FDA and CDC updates and simplifies COVID-19 Vaccine schedule for all age groups

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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 **Simplified Uses for COVID-19 Vaccines**. Please see the message below to share and distribute with relevant stakeholders and partners through your own distribution channels. summarized below:

CDC has simplified COVID-19 vaccine recommendations for most people including additional doses for certain higher risk populations.

CDC actions follow an earlier recommendation by the U.S. Food and Drug Administration that amended the emergency use authorizations (EUAs) of the Moderna and Pfizer-BioNTech COVID-19 bivalent mRNA vaccines.

Summary of Recommendation Changes

- **Most individuals previously vaccinated with a primary monovalent series and who have not received a bivalent booster** may receive a single dose of a bivalent.
- **Most individuals who have received a single dose of a bivalent vaccine** are not currently eligible for another bivalent dose.
- **Individuals 65 years and older who have received a single dose of bivalent vaccine** may receive an additional dose at least four months after their initial bivalent dose.
- **Immunocompromised individuals who have received a bivalent vaccine** can receive an additional bivalent vaccine two months following a dose of bivalent vaccine; additional doses may be administered at the discretion of their healthcare provider.
 - However, for immunocompromised individuals 6 months through 4 years of age, eligibility for additional doses will depend on the vaccine previously received.
- **Most unvaccinated individuals may receive a single dose of a bivalent vaccine** rather than multiple doses of the original monovalent mRNA vaccines.
- **Children 6 months through 5 years of age who have not been vaccinated** can receive a two-dose series of Moderna bivalent (6mo – 5yr) or three-dose series Pfizer bivalent (6mo – 4yr).

- Children who are 5 years of age may receive two doses of the Moderna bivalent vaccine or a single dose of the Pfizer-BioNTech bivalent vaccine.
- **Children 6 months through 5 years of age who have received one, two or three doses** of a monovalent vaccine can receive one or more bivalent doses depending on how their initial series was completed.

Bivalent Doses Replace Monovalent Doses

- Bivalent Pfizer and Moderna COVID-19 vaccines are now authorized by the FDA for both primary series and booster doses. Monovalent doses are no longer authorized by the FDA.
 - Providers should immediately discontinue the use of mRNA monovalent vaccines for primary series. With the exception of the Novavax vaccine, all monovalent Moderna and Pfizer vaccine ordering has now been inactivated in LINKS, Louisiana's Immunization Information System.
 - If a provider has placed an order for mRNA monovalent vaccines prior to today and they have not been received, these orders will not be delivered.
 - Providers should reconcile their inventory in LINKS with the removal of the mRNA vaccines.
 - This does not include Novavax as it can still be utilized for the primary series.
 - Additional information will be provided on disposal of COVID-19 vaccines.

With the authorization, the fact sheets have been updated and consolidated for the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Each vaccine now has one fact sheet for healthcare providers and one fact sheet for recipients and caregivers, rather than different fact sheets for the various authorized age groups.

Dosing Recommendations

See the charts for different age groups for both Moderna and Pfizer vaccines at the end of this message.

- Moderna: pages 3-4
- Pfizer: pages 4-5

Clinical Considerations

CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States](#) are expected to be updated soon at this link.

Related Information

- [Pfizer-BioNTech COVID-19 Vaccines](#)
- [Moderna COVID-19 Vaccines](#)
- [COVID-19 Vaccines](#)
- [Emergency Use Authorization for Vaccines Explained](#)
- [Pfizer EUA Fact Sheet for Providers](#)
- [Moderna EUA Fact Sheet for Providers](#)

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.

Moderna Dosage and Administration

Individuals 6 Months of Age and Older Not Previously Vaccinated with a COVID-19 Vaccine (2.3)

Age	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose, and Schedule
6m-5y	Dark Blue Cap and a Label with Gray Border	2 doses, 0.25 mL each Dose 1: month 0 Dose 2: month 1
6-11y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.25 mL
12-64y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL
≥65y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL One additional dose, 0.5 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

Individuals 6 Months Through 5 Years of Age Previously Vaccinated with Moderna COVID-19 Vaccine¹ (2.3)

Age	Number of Previous Doses of Moderna COVID-19 Vaccine	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose and Schedule
6m-5y	1 previous dose	Dark Blue Cap and a Label with Gray Border	Single Dose, 0.25 mL One month after receipt of Moderna COVID-19 Vaccine
6m-5y ²	2 previous doses	Dark Pink Cap and a Label with a Yellow Box	Single dose, 0.2 mL ≥2 months after receipt of Moderna COVID-19 Vaccine

¹ The monovalent Moderna COVID-19 Vaccine is no longer authorized for use in the United States.

² For individuals with certain kinds of immunocompromise (as defined in footnote 4), see text below tables for dosing regimen, dose and schedule

Individuals 6 Years of Age and Older Previously Vaccinated with 1 or More Doses of Any Monovalent COVID-19 Vaccine³ (2.3)

Age	Moderna COVID-19 Vaccine, Bivalent Vial Cap and Label Color	Dosing Regimen, Dose and Schedule
6-11y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.25 mL ≥2 months after monovalent COVID-19 vaccine
12-64y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL ≥2 months after monovalent COVID-19 vaccine
≥65y	Dark Blue Cap and a Label with Gray Border	Single dose, 0.5 mL ≥2 months after monovalent COVID-19 vaccine One additional dose, 0.5 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

³ Monovalent refers to any COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

Pfizer Dosage and Administration

Individuals 6 months of age and older not previously vaccinated with a COVID-19 vaccine (2.3)

Age	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
6m-4y ¹	Maroon	3 doses, 0.2 mL each Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥ 8 weeks after Dose 2
5-11y	Orange	Single dose, 0.2 mL
12-64y	Gray	Single dose, 0.3 mL
≥65y	Gray	Single dose, 0.3 mL One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

¹ Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive all doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.

Individuals 6 months through 4 years of age previously vaccinated with the monovalent Pfizer-BioNTech COVID-19 Vaccine² (2.3)

Age	Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccine	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
6m-4y	1 previous dose	Maroon	2 doses ³ , 0.2 mL each Dose 1: 3 weeks after receipt of Pfizer-BioNTech COVID-19 Vaccine Dose 2: ≥8 weeks after Dose 1
6m-4y	2 previous doses	Maroon	Single dose, 0.2 mL ≥8 weeks after receipt of second dose of Pfizer-BioNTech COVID-19 Vaccine
6m-4y	3 previous doses	Maroon	Single dose, 0.2 mL ≥2 months after receipt of third dose of Pfizer-BioNTech COVID-19 Vaccine

² The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States.

³ Notwithstanding the age limitations for use of the vaccine, individuals turning from 4 to 5 years of age during the vaccination series should receive 2 doses with Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in vials with maroon caps and labels with maroon borders.

Individuals 5 years of age and older previously vaccinated with 1 or more doses of a monovalent COVID-19 vaccine⁴ (2.3)

Age	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
5-11y	Orange	Single dose, 0.2 mL ≥2 months after monovalent COVID-19 vaccine
12-64y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine
≥65y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

⁴ Monovalent refers to a COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.