

Louisiana Health Alert Message 23-17: CDC recommends updated COVID-19 vaccines designed to bolster protections for the fall/winter respiratory virus season

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Louisiana Health Alert Message 23-17: CDC recommends updated COVID-19 vaccines designed to bolster protections for the fall/winter respiratory virus season

Following action by the US Food and Drug Administration (FDA) and review by the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC) is recommending everyone ages 6 months and older receive an updated COVID-19 vaccine.

The updated monovalent mRNA vaccines (2023-2024 formula) from Pfizer and Moderna target the XBB.1.5 Omicron subvariant of the COVID-19 virus. Updated vaccines from Pfizer-BioNTech and Moderna are expected to begin arriving in provider offices and retail pharmacies in the coming days.

The updated vaccines are expected to provide increased protection against severe disease and death from currently circulating COVID-19 variants. The FDA anticipates that the composition of COVID-19 vaccines may need to be updated annually, as is done for the seasonal influenza vaccine.

- **Individuals age 12 and older:** Pfizer and Moderna updated mRNA vaccines (2023-2024 formula) are approved by the FDA for individuals 12 years of age and older.
- Individuals age 6 months through 11 years: Pfizer and Moderna updated mRNA vaccines (2023-2024 formula) are authorized for emergency use (EUA) by the FDA for individuals 6 months through 11 years of age.
- Older bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized or approved for use in the United States and should not be administered going forward.
 - Providers should dispose of the bivalent COVID-19 vaccine in accordance with local regulations and processes currently in place to dispose of regulated medical waste.
 - Disposed vaccines must be recorded as wasted doses in LINKS if the vaccines was ordered through the Louisiana COVID-19 Vaccine Program.

Who Should Receive the Vaccines?

- Individuals 5 years of age and older regardless of previous vaccination are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months following the last dose of any COVID-19 vaccine.
- Individuals 6 months through 4 years of age who have previously received at least one dose of COVID-19 vaccine are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine. The timing and number of doses to administer depends on the previous COVID-19 vaccine received. Please see chart at the bottom of this HAN.
- Unvaccinated individuals 6 months through 4 years of age are eligible to receive three doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated authorized Moderna COVID-19 Vaccine. Please see dosage chart at the bottom of this HAN.

Commercialization and Patient Access to Updated mRNA Vaccines

Despite the updated COVID-19 vaccines now being commercialized, most Louisiana residents can still receive a COVID-19 vaccine for free. Most health insurance plans will cover COVID-19 vaccine at no cost. Individuals with insurance can identify vaccination sites (including many retail pharmacies) offering updated COVID-19 vaccines by accessing www.Vaccines.gov.

As part of the federal Bridge Access Program, local Parish Health Units (PHUs) and participating Federally Qualified Health Centers (FQHCs) will be offering free COVID-19 vaccines to individuals without health insurance or with health plans that do not cover the vaccine. Many retail pharmacies throughout the state, including national Bridge Access Program partners CVS and Walgreens, will also be offering free updated COVID-19 vaccinations to uninsured and underinsured adults.

• Eligible individuals can go to Vaccines.gov. After entering your zip code, see "Participating in Bridge Access Program."

Children eligible for the Vaccines for Children (VFC) program may also receive the vaccine at no cost from a provider enrolled in the VFC program. VFC sites offering the updated COVID-19 vaccines can also be identified by accessing <u>www.Vaccines.gov</u>.

Additional Vaccine Details

- With the Comirnaty (Pfizer) 2023-2024 formula approval, comes a change to a single dose for individuals 12 years of age and older. Comirnaty was previously approved as a two-dose series for individuals 12 years of age and older.
- Pfizer-BioNTech COVID-19 Vaccine (2023-2024 formula) is authorized for emergency use in individual's ages 6 months through 11 years. Additional doses are also authorized for certain immunocompromised individual's ages 6 months through 11 years according to clinical discretion.
- With the Spikevax (Moderna) 2023-2024 formula, comes a change to a single dose for individuals 18 years of age and older, and approval of a single dose for individuals 12 through 17 years of age. Spikevax was previously approved as a two-dose series for individuals 18 years of age and older.
- The Moderna COVID-19 Vaccine 2023-2024 formula is authorized for emergency use in individuals 6 months through 11 years of age and lowers the age eligibility for receipt of a single dose from 6 years to 5 years of age. Additional doses are also authorized for certain immunocompromised individual's ages 6 months through 11 years according to clinical discretion.

Side Effects

Individuals who receive an updated mRNA COVID-19 vaccine may experience similar side effects as those reported by individuals who previously received mRNA COVID-19 vaccines.

Clinical Guidance

CDC interim clinical guidance is expected to be updated later this week and can be accessed by visiting https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Reporting Adverse Reactions

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.

More Information

- <u>Comirnaty package insert (COVID-19 Vaccine, mRNA) (2023-2024 Formula)</u>
- <u>Spikevax package insert (COVID-19 Vaccine, mRNA) (2023-2024 Formula)</u>
- <u>Moderna COVID-19 Vaccine recipient and caregiver fact sheet (2023-2024 Formula)</u>
- Moderna COVID-19 Vaccine healthcare provider fact sheet (2023-2024 Formula)
- Pfizer-BioNTech COVID-19 Vaccine recipient and caregiver fact Sheet (2023-2024 Formula)
- Pfizer-BioNTech COVID-19 Vaccine provider fact Sheet (2023-2024 Formula)

Number of Previous Doses of Pfizer- BioNTech COVID-19 vaccine(s) ^a	Pfizer-BioNTech COVID-19 Vaccine, (2023- 2024 Formula) Vial Cap and Label Border Color	Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Dosing Regimen, Dose and Schedule ^b
0°	Yellow	3 doses ^d , 0.3 mL each Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥8 weeks after Dose 2
1	Yellow	2 doses ^d , 0.3 mL each Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine ^a Dose 2: ≥8 weeks after Dose 1
2 to 4	Yellow	Single dose, 0.3 mL ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine ^a

Pfizer dosage chart for individuals 6 months through 4 years of age

a. Previous doses of Pfizer-BioNTech COVID-19 vaccine(s) refers to doses with Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United Stat

b. For individuals with certain kinds of immunocompromise previously vaccinated

with Pfizer-BioNTech COVID-19 vaccines, see text below tables for dosing

information.

c. Not previously vaccinated with any COVID-19 vaccine.

d. For individuals turning from 4 to 5 years of age during the vaccination series,

administer all doses with Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) supplied in vials with yellow caps and labels with yellow borders.

Moderna dosage chart for individuals 6 months through 4 years of age

Number of Previous Doses of Moderna COVID-19	Moderna COVID-19 Vaccine (2023-2024 Formula)
Vaccine(s)ª	Dosing Regimen, Dose and Schedule ^b
0°	2 doses, ^d 0.25 mL each Dose 1: month 0 Dose 2: month 1

1	Single Dose, 0.25 mL One month after receipt of a previous dose of Moderna COVID-19 vaccine ^a
≥2	Single dose, 0.25 mL ≥2 months after receipt of the last previous dose of Moderna COVID-19 vaccineª

^a Previous dose(s) of Moderna COVID-19 vaccine(s) refers to Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.

^b For individuals with certain kinds of immunocompromise previously vaccinated with a Moderna COVID-19 vaccine, see text following the tables for dosing information.

^c Not previously vaccinated with any COVID-19 vaccine.

^d Individuals turning from 4 years to 5 years of age during the vaccination series should receive both doses with Moderna COVID-19 Vaccine (2023- 2024 Formula).