LOUISIANA DEPARTMENT OF HEALTH Public Health	**Louisiana Health Alert Message 23-18: FDA authorizes updated Novavax COVID-19 vaccine providing another option for protection this fall/winter**
Origination Date: October 9, 2023	**Revision Dates (List All Revision Dates):**

Louisiana Health Alert Message 23-18 FDA authorizes updated Novavax COVID-19 vaccine providing another option for protection this fall/winter

Recommendations

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the use of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula). This vaccine is for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

The Centers for Disease Control and Prevention (CDC) included the updated Novavax vaccine in the same recommendation it issued last month for updated COVID-19 vaccines from Pfizer and Moderna. This newly updated Novavax COVID-19 vaccine provides patients the choice of a protein-based non-mRNA vaccine and is expected to become available soon.

This Novavax COVID-19 vaccine, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula). The vaccine is authorized for use in individuals 12 years of age and older as follows:

Dosage and Administration of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)

- Individuals 12 Years of Age and Older Previously Vaccinated with Any COVID-19 Vaccine:
  The updated Novavax COVID-19 Vaccine is administered intramuscularly as a single 0.5 mL dose at least 2 months after receipt of the last previous dose of COVID-19 vaccine.
- Individuals 12 Years of Age and Older Not Previously Vaccinated with Any COVID-19 Vaccine:
  The updated Novavax COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 3 weeks apart.
- Individuals 12 Years of Age and Older with Certain Kinds of Immunocompromise:
  For individuals with certain kinds of immunocompromise (have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise), an additional 0.5 mL dose may be administered intramuscularly at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula). Additional doses may be administered intramuscularly as a 0.5 mL dose at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

The original Novavax COVID-19 Vaccine, Adjuvanted is no longer authorized for use in the United States and should not be administered. Providers with existing stock should dispose of the 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 ordered through the Louisiana COVID-19 Vaccine Program.

Commercialization and Patient Access to Novavax COVID-19 Vaccine

Despite the recent commercialization of updated COVID-19 vaccines, most Louisiana residents can still receive a COVID-19 vaccine for free. Most health insurance plans cover COVID-19 vaccine at no cost. Individuals with insurance can identify vaccination sites, including many retail pharmacies, which offer updated COVID-19 vaccines by visiting www.Vaccines.gov.

As part of the federal Bridge Access Program, select providers offer 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, offer free updated COVID-19 vaccinations to uninsured and underinsured adults. Eligible individuals can visit www.Vaccines.gov. After entering your zip code and selecting vaccine option, 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 visiting www.Vaccines.gov.

Contraindications

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted or to individuals who have had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Novavax COVID-19 Vaccine, Adjuvanted.

Interim Clinical Guidance

CDC interim clinical guidance is expected to be updated to include the Novavax, Adjuvanted (2023-2024 formula) 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

- Novavax, Adjuvanted (2023-2024 formula) – Fact Sheet for Healthcare Providers Administering Vaccine
- Novavax, Adjuvanted (2023-2024 formula) – Fact Sheet for Recipients and Caregivers