LOUISIANA DEPARTMENT OF HEALTH Public Health	**Health Alert Network Message 22-25: CDC and FDA Authorize Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted**
Origination Date: *July 26, 2022*	**Revision Dates (List All Revision Dates):**

CDC and FDA Authorize Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted

On July 19, the Centers for Disease Control and Prevention (CDC) affirmed the Food & Drug Administration's emergency use authorization (EUA) for the Novavax COVID-19 vaccine, Adjuvanted. CDC's Advisory Committee on Immunization Practices (ACIP) said their recommendation offers the public another choice for COVID-19 vaccination with no major safety or efficacy concerns.

The Novavax vaccine prevents severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years and older.

Unlike the mRNA vaccines developed by Pfizer-BioNTech and Moderna, the Novavax vaccine is a protein-based shot. Protein-based vaccines have been used for decades to combat diseases including Hepatitis B and influenza.

The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual. The spike protein in this vaccine is produced in insect cells; the Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree which is native to Chile.

Although the U.S. government has secured 3.2 million Novavax vaccine doses, the manufacturer is still conducting quality testing before the vaccine is released to providers in the U.S. According to Novavax, testing should be complete in the next few weeks.

Ordering Novavax
Providers can now make orders in LINKS using the normal ordering pages starting this week. This new product can be ordered in as little as 10 doses and will come refrigerated with ancillary supplies from M&D or 100 doses for direct shipment from McKesson.

For general questions regarding the Novavax vaccine, visit the Novavax website at www.NovavaxCovidVaccine.com or call 1-855-239-9174.

The CDC will hold an informational office hour to discuss their recommendations this Thursday, July 28. Novavax will hold informational office hours throughout the month of August.

Administration and Storage

- Age: 18 years and older primary series
- Interval: 2 dose primary series, 21 days apart
- Dose: 5 mcg SARS-CoV-2rS/50 mcg Matrix-M™ adjuvant
- Injection volume: 0.5 mL
- Preparation: Do not dilute
- Doses per vial: 10 doses
- Injection route/site: Intramuscular/deltoid
- Storage: Refrigerator 2° to 8°C (36°to 46°F) DO NOT FREEZE
- Beyond use time: 6 hours after first puncture
- Expiration: No expiration date is printed on the vial or carton. To confirm expiration dates, providers should enter the lot number in the "Expiry Date Checker" tool found at https://www.novavaxcovidvaccine.com/

Safety and Effectiveness

FDA has conducted analysis and evaluation regarding Novavax's safety and effectiveness. The agency determined that the known and potential benefits of the vaccine outweigh its known and potential risks for those eligible to receive the vaccine.

- In clinical trials, the most reported side effects of Novavax included pain/tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting and fever.
- The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) includes a warning that clinical trial data provide evidence for increased risks of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of tissue surrounding the heart) following administration of Novavax COVID-19 Vaccine.
- The Fact Sheet for Recipients and Caregivers informs that in most people who have had myocarditis or pericarditis after receiving the vaccine, symptoms began within 10 days following vaccination and that vaccine recipients should seek medical attention right away if they experience any of the following symptoms after vaccination: chest pain, shortness of breath, feelings of having a fast-beating, fluttering or pounding heart.

Updated Clinical Considerations: COVID Vaccines + Monkeypox

The guidance for primary series vaccination using Novavax COVID-19 Vaccine in adults ages 18 years and older is now updated in CDC Interim Clinical Considerations.

Reporting Adverse Events

LDH reminds providers to report possible vaccine-related adverse events and vaccination administration errors 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.

If you have 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 855-453-0774.

Related Information

- Novavax COVID-19 Vaccine, Adjuvanted
- COVID-19 Vaccines
- Emergency Use Authorization for Vaccines Explained
- Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry
- Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry