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Technical Bulletin

Date: July 27, 2022
Topic: Novavax COVID-19 Vaccine, Adjuvanted Authorized for Emergency Use Authorization
Contact: Jessica Lamb, RN, Nevada State Immunization Program
To: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

Background:

On July 13, 2022, the [U.S. Food and Drug Administration \(FDA\)](#) issued an [Emergency Use Authorization \(EUA\)](#) for the [Novavax COVID-19 Vaccine, Adjuvanted](#) in individuals 18 years of age and older for the prevention of COVID-19 caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).

The FDA has determined that the Novavax COVID-19 Vaccine, Adjuvanted has met the statutory criteria to be issued an EUA. By authorizing an additional COVID-19 vaccine, adults in the United States who have not yet received a COVID-19 vaccine now have more available options. This vaccine contains the SARS-CoV-2 spike protein and [Matrix-M adjuvant](#). [Adjuvants](#) are ingredients used in some vaccines that help to create a stronger immune response for the vaccinated individual.

On July 19, 2022, with the [evidence](#) presented at the [Advisory Committee on Immunization Practices \(ACIP\)](#) meeting, the committee voted unanimously to recommend a two-dose Novavax COVID-19, Adjuvanted vaccine series for persons 18 years and older, under the EUA issued by FDA.

This technical bulletin summarizes the recent Novavax COVID-19 Vaccine, Adjuvanted eligibility recommended for individuals ages 18 years of age and older. **At this time**, Novavax is not authorized to be used as a booster dose and individuals receiving a Novavax primary series are not eligible for a booster dose of any COVID-19 vaccines.

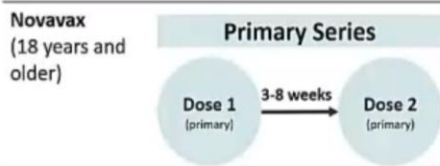
Those adults eligible to receive the recommended two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series include:

- **Any individual 18 years of age or older who is *not* moderately or severely immunocompromised**
 - *Dose interval: first dose administered on day 0, second dose administered 3-8 weeks after the first dose to complete the primary series ***
 - *Dose amount: 0.5mL each dose (containing 5mcg SARS-CoV-2rS and 50mcg Matrix-M adjuvant), to be administered intramuscularly*

- **Any individual 18 years of age or older who *is* moderately or severely immunocompromised**
 - *Dose interval: first dose administered on day 0, second dose administered 3 weeks after the first dose to complete the primary series ***
 - *Dose amount: 0.5mL each dose (containing 5mcg SARS-CoV-2rS and 50mcg Matrix-M adjuvant), to be administered intramuscularly*

Novavax COVID-19 Vaccination Schedule

People who are **NOT** moderately or severely immunocompromised



People who **ARE** moderately or severely immunocompromised

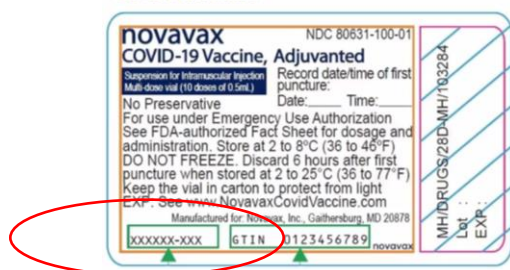


** According to the CDC, an 8-week interval between the first and second primary series doses of Moderna, Novavax and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months to 64 years (especially for males ages 12–39 years) as it may reduce the small risk of myocarditis/pericarditis associated with these vaccines. A shorter interval (3 weeks for Novavax and Pfizer-BioNTech; 4 weeks for Moderna) between the first and second doses remains the recommended interval for people who are moderately or severely immunocompromised; adults aged 65 years and older; and in situations where there is increased concern about COVID-19 community levels or an individual's higher risk of severe disease.

It is important to note the storage and handling requirements of this vaccine. The Novavax COVID-19 Vaccine, Adjuvanted **may not** be kept frozen and **does not** use diluent. Unpunctured, multi-dose vials must be stored in a refrigerator between 2 degrees to 8 degrees Celsius (36 degrees to 46 degrees Fahrenheit). After the first needle puncture, hold the vial between 2 degrees to 25 degrees Celsius (36 degrees to 77 degrees Fahrenheit) for up to 6 hours. Discard the vial 6 hours after the first puncture.

Please note that there is no expiration date printed on any Novavax COVID-19, Adjuvanted vials and/or cartons. To find the expiration date, access www.NovavaxCovidVaccine.com, navigate to the "United States Healthcare Professional" section of the website and enter the lot number printed on the carton or vial into the "Expiry Date Checker" tool. Providers must track the expiration date of each vial and should use [CDC's COVID-19 Vaccine Expiration Date Tracking Tool](#) for tracking this information.

Novavax Label²



The Lot number can be found on the product vial, as shown, and is alphanumeric.



The FDA evaluated and analyzed the effectiveness and safety data for the Novavax COVID-19 Vaccine, Adjuvanted through a rigorous and comprehensive evaluation process. This evaluation was used to support the issuance of an EUA. Effectiveness and safety data were generated in an ongoing, randomized, blinded, placebo-controlled study in the United States and Mexico which enrolled participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through six days after receiving the second vaccine dose. To ensure ongoing safety monitoring, the FDA and

the [Centers for Disease Control and Prevention \(CDC\)](#) have several systems in place to continually monitor COVID-19 vaccine safety and allow for the timely detection and investigation of potential safety concerns.

The FDA has released [Novavax's COVID-19 Vaccine, Adjuvanted](#) Information Fact Sheets as well as information and resources for any [Recipients and/or Caregivers](#) and [Healthcare Providers](#) for those individuals 18 years of age and older.

It is important to note the primary goal of the COVID-19 vaccine response should continue to be COVID-19 vaccine administration to the unvaccinated. The Nevada Department of Health and Human Services is encouraging individuals to speak with a health care provider about vaccination and COVID-19 vaccines. Individuals may be referred to [NVCOVIDFighter.org](#) or 1-800-401-0946 for more information on vaccine access and other COVID-19 resources.

Questions:

For updated guidance, review the [DPBH Technical Bulletin web page](#) and [Nevada Health Response website](#) regularly. Email dpbh-covid19vax@health.nv.gov for other questions regarding the Novavax COVID-19 vaccine.



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