

Steve Sisolak
Governor



Richard Whitley, MS
Director

DEPARTMENT OF
HEALTH AND HUMAN SERVICES
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Lisa Sherych
Administrator

Ihsan Azzam,
Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date: September 27, 2022
Topic: Novavax COVID-19 Vaccine, Adjuvanted, Now Recommended by CDC for 12+ Years
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 has met the statutory criteria to be issued an Emergency Use Authorization (EUA). By authorizing an additional COVID-19 vaccine, adults in the United States who have not yet received a COVID-19 vaccine now have expansion in available vaccine 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.

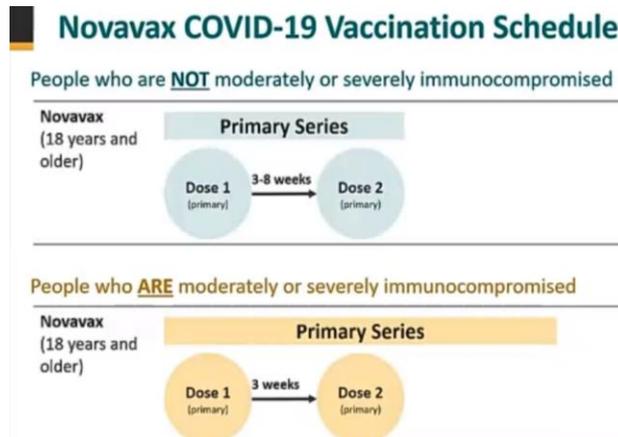
On August 19, 2022, the [U.S. Food and Drug Administration](#) extended and reissued [Emergency Use Authorization \(EUA\)](#) for the Novavax COVID-19 vaccine to individuals 12 through 17 years of age. On August 22, 2022, the [Centers for Disease and Prevention](#) signed a decision memo that Novavax COVID-19 vaccine, Adjuvanted, be used as another primary series option for adolescents ages 12 through 17.

This technical bulletin summarizes the recent Novavax COVID-19 vaccine eligibility recommended for individuals ages 12 years of age and older. **At this time**, the Novavax COVID-19 vaccine is only authorized to be administered as a primary series and is not authorized to be administered as a booster dose. Upon completion of a Novavax primary series, individuals 12 years of age and older will be eligible to receive a COVID-19 bivalent booster dose (administered 2 months or more after the last primary series dose). To determine bivalent booster dose eligibility and primary series dose completion, please use [CDC's Interim COVID-19 Vaccination Schedule](#).

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

- **Any individual 12 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: 0.5 mL each dose (containing 5 mcg SARS-CoV-2rS and 50 mcg Matrix-M adjuvant) to be administered intramuscularly.*

- Any individual 12 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: 0.5 mL each dose (containing 5 mcg SARS-CoV-2rS and 50 mcg Matrix-M adjuvant) to be administered intramuscularly.

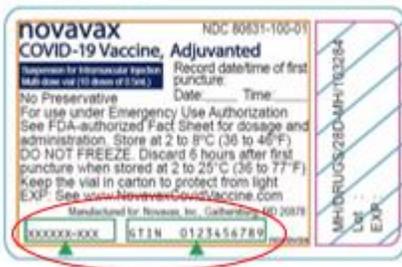


According to the CDC, an **8-week interval between the first and second primary series doses of Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines may be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it may reduce the small risk of myocarditis/pericarditis 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 ages 65 years and older; and in situations in which 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 **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.

Note that there is no expiration date printed on any Novavax COVID-19 vaccine vials and/or cartons. To find the expiration date, access [the Novavax COVID-19 Vaccine website](#), 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 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.

[Novavax's COVID-19 Vaccine, Adjuvanted](#) Information Fact Sheets have now been **updated to reflect the new adolescent authorization**. Below you will find additional information and resources for:

- Any [Recipients and/or Caregivers](#) and [Healthcare Providers](#) for those individuals 12 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 the [Nevada Health Response website](#) regularly. Email questions to dpbhcovid19vax@health.nv.gov.



Lisa Sherych, Administrator
Division of Public and Behavioral Health



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Chief Medical Officer