

October 6, 2023

## FDA Authorizes Updated Novavax COVID-19 Vaccine Formulated to Better Protect Against Circulating Variants

On October 3, 2023, the U.S. Food and Drug Administration amended the emergency use authorization (EUA) of the Novavax COVID-19 Vaccine, Adjuvanted for use in individuals 12 years of age and older to include the 2023-2024 formula. Individuals 12 years of age and older previously vaccinated with a COVID-19 vaccine (and who have not already been vaccinated with a recently updated mRNA COVID-19 vaccine) are eligible to receive one dose and unvaccinated individuals receive two doses.

The updated vaccine addresses currently circulating variants to provide better protection against serious consequences of COVID-19, including hospitalization and death. Consistent with the [totality of the evidence](#) and input from the FDA's expert advisors, the Novavax COVID-19 Vaccine, Adjuvanted, 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). *Notably, the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States.*

This authorization follows the FDA's [recent approvals and authorizations](#) of updated mRNA COVID-19 vaccines for 2023-2024 manufactured by ModernaTX Inc. and Pfizer Inc.

### Safety and Effectiveness:<sup>1</sup>

The FDA evaluated manufacturing data to support the change to the 2023-2024 formula of the Novavax COVID-19 Vaccine, Adjuvanted. Additionally, the FDA evaluated non-clinical immune response data suggesting that the vaccine provides protection against the currently circulating COVID-19 variants. The agency also relied on its evaluation of safety and effectiveness data from clinical trials of Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) and investigational monovalent and bivalent Novavax COVID-19 adjuvanted vaccines, as well as post-marketing data. The data accrued with these Novavax COVID-19 vaccines are relevant to Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) as the vaccines are manufactured using a similar process.

### Additional Details:<sup>2</sup>

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older as follows:

- **Individuals previously vaccinated with any COVID-19 vaccine:** one dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is administered at least 2 months after receipt of the last previous dose of an original monovalent (Original) or bivalent (Original and Omicron BA.4/BA.5) COVID-19 vaccine.
- **Individuals not previously vaccinated with any COVID-19 vaccine:** two doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) are administered three weeks apart.
- **Immunocompromised individuals:** an additional dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula). Additional doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.

**Availability: (For questions regarding availability, please contact [CAPT Weston Thompson, NSSC](#))**

The approved Pfizer and Moderna vaccinations are available to order in McKesson Connect and the recently approved Novavax vaccine will be available very soon, as well. NSSC will communicate details to the field once release dates are confirmed from McKesson. If you use McKesson Connect to procure your medications, you will use the same process to procure the updated COVID-19 vaccines when they are available in McKesson.

**Clinician Resources:<sup>1</sup>**

- FACT SHEET: [Healthcare Providers Administering Vaccine](#) (October 3, 2023)
- FACT SHEET: [Recipients and Caregivers](#) (October 3, 2023)
- [FDA Resources for the Fall Respiratory Illness Season](#)

**References:**

1. U.S. Food and Drug Administration. [FDA Authorizes Updated Novavax COVID-19 Vaccine Formulated to Better Protect Against Circulating Variants](#). Published online October 3, 2023.
2. U.S Food and Drug Administration. [Novavax COVID-19 Vaccine, Adjuvanted](#). Published October 3, 2023.