Indian Health Service
National Pharmacy and Therapeutics Committee
COVID-19 Emerging Treatments Update

August 23, 2022

FDA Expands Eligibility for Novavax COVID-19 Vaccine to Include Adolescents 12 through 17 Years of Age

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 for the prevention of COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

On August 19, 2022, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the July 13, 2022, letter in its entirety with revisions incorporated to authorize the use of Novavax COVID-19 Vaccine, Adjuvanted **for individuals 12 through 17 years of age.**

Efficacy & Safety Data

For individuals 12 years through 17 years of age, the FDA's analysis of available descriptive efficacy data from 1,799 participants 12 years through 17 years of age without evidence of SARS-CoV-2 infection through 6 days after the second dose and who had a median follow-up of 67 days after Dose 2 during the pre-crossover period shows that the vaccine was 78.29% effective in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 occurring at least 7 days after Dose 2. In this analysis, no cases of moderate or severe COVID-19 were reported in participants who had received the Novavax COVID-19 Vaccine, Adjuvanted or placebo. Based on these data, the FDA concluded that it is reasonable to believe that the Novavax COVID-19 Vaccine, Adjuvanted may be effective in individuals 12 through 17 years of age.

For individuals 12 years through 17 years of age, the safety of the vaccine was assessed in 1,487 clinical trial participants who received the vaccine and 745 who received placebo. The FDA's review considered the safety and effectiveness data as they relate to the request for EUA and did not identify specific safety concerns that would preclude issuance of an EUA.

The Fact Sheet for Healthcare Providers Administering Vaccine includes a warning that clinical trial data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted. 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.

Current EUA Fact Sheets

As a convenience, Fact Sheets are accessible here**:** (1) Healthcare Providers =AND= (2) Recipients and Caregivers

Mandatory Requirements under the Emergency Use Authorization *(all requirements must be met)*

- Use of Novavax COVID-19 Vaccine, Adjuvanted is authorized for use in individuals 12 years of age and older.
- The vaccination provider must communicate to the individual receiving the Novavax COVID-19 Vaccine, Adjuvanted or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Novavax COVID-19 Vaccine, Adjuvanted.
- The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
- The vaccination provider is responsible for mandatory reporting to Vaccine Adverse Event Reporting System (VAERS):
  - vaccine administration errors whether or not associated with an adverse event,
  - serious adverse events* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome in adults and COVID-19 that result in hospitalization or death.
- The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of Multisystem Inflammatory Syndrome in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Novavax COVID-19 Vaccine, Adjuvanted to recipients.

Federal, Tribal, and Urban programs are all encouraged to put "IHS" into field #26 of the VAERS form.

References:

1. U.S. Food and Drug Administration, Letter of Authorization**.** Published online on August 19, 2022.
2. U.S. Food and Drug Administration. FDA News Release. Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted**.** Published online on July 13, 2022.