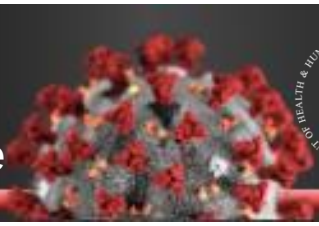
Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update



July 20, 2022

FDA Issues EUA for Novavax COVID-19 Vaccine

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.

The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three weeks apart. 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 that is native to Chile.

Efficacy Data

The vaccine was assessed in an ongoing randomized, blinded, placebo-controlled study conducted in the United States and Mexico. The effectiveness of the vaccine was assessed in clinical trial participants 18 years of age and older who did not have evidence of SARS-CoV-2 infection through 6 days after receiving the second vaccine dose. Among these participants, approximately 17,200 received the vaccine and approximately 8,300 received saline placebo. Overall, the vaccine was 90.4% effective in preventing mild, moderate or severe COVID-19, with 17 cases of COVID-19 occurring in the vaccine group and 79 cases in the placebo group. No cases of moderate or severe COVID-19 were reported in participants who received the vaccine, compared with 9 cases of moderate COVID-19 and 4 cases of severe COVID-19 reported in placebo recipients. In the subset of participants 65 years of age and older, the vaccine was 78.6% effective. The clinical trial was conducted prior to the emergence of delta and omicron variants.

Safety Data

The safety of the vaccine was assessed in approximately 26,000 clinical trial participants who received the vaccine and approximately 25,000 who received placebo. The most commonly reported side effects by vaccine recipients included pain/tenderness, redness and swelling at the injection site, fatigue, muscle pain, headache, joint pain, nausea/vomiting and fever. Approximately 21,000 vaccine recipients had at least two months of safety follow-up after their second dose.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) 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 for the Novavax COVID-19 Vaccine are accessible below:

- Healthcare Providers
- 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 18 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 of the following to the 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 (MIS) in adults, and
  - cases of 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 MIS 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 form.***

References:

1. 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.