July 19, 2022

CDC Novavax COVID-19 Vaccination Operational Planning Guide

Overview

On July 13, 2022, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Novavax COVID-19 vaccine for use among people ages 18 years and older for primary series vaccination. On July 19, 2022, CDC's Advisory Committee on Immunization Practices (ACIP) recommended use of the Novavax COVID-19 vaccine in this population.

The Novavax COVID-19 vaccine is administered as a two-dose primary series, with the doses given 3 weeks apart. A limited number of doses of Novavax COVID-19 vaccine will be distributed and **not all providers are expected to carry Novavax COVID-19 vaccine.** This operational planning guide includes details about the anticipated Novavax product.

BACKGROUND INFORMATION

Novavax COVID-19 vaccine is an adjuvanted protein subunit vaccine. Protein subunit vaccines are a well-established type of vaccine traditionally used in shingles, certain types of flu, and other vaccines. The Novavax COVID-19 vaccine contains nanoparticles carrying the viral spike protein, which teach the immune system to make antibodies specific to the spike proteins found on the surface of SARS-CoV-2.

The vaccine is stable at standard vaccine refrigeration temperatures (2°C to 8°C). The packaging configuration of the vaccine is expected to be 10-dose vials in cartons of 10 vials each (100 doses total), with a minimum order quantity of 100 doses. **Once opened, each vial must be used within 6 hours.** Ancillary supplies will be provided, including a variety of 1-inch & 1.5-inch needles and syringes to support 100 doses of vaccine. Novavax COVID-19 vaccine does not require a diluent.

PROJECTED LAUNCH PLAN

Pre-ordering will not be available for Novavax COVID-19 vaccine. This means open ordering will begin only after the vaccine is both authorized by FDA and recommended by CDC. There will be a one-time threshold of vaccine for all channels. Awardees will control second dose management.

There will be a **limited supply** of Novavax COVID-19 vaccine of approximately 3 million doses, which should be directed to providers with expected demand among unvaccinated patients (which may include people who are unable to receive mRNA COVID-19 vaccines or choose not to).

Due to the minimum order quantity and limited supply of this vaccine, jurisdictions should consider internal distribution and hub & spoke operations to avoid wasting vaccine. Dashboards will be developed within Tiberius that will enable jurisdictions to view their order thresholds and optimally prioritize providers to receive initial shipments.

The public will be directed to Vaccines.gov to find providers offering Novavax COVID-19 vaccine. After receiving their initial vaccine orders, providers are asked to report their inventory to Vaccines.gov as soon as possible.

The following summary table provides estimated dates. Additional details regarding the timing of ordering or delivery of vaccine shipments will be updated based on available information.

Estimated Date (all subject to change)	Action
7/19	ACIP meeting, CDC recommendations
7/20	All-awardee call
Tentatively the week of July 25th	Ordering opens
To be determined (pending when ordering opens)	First deliveries of vaccine arrive

CONSIDERATIONS FOR JURISDICTIONS

To enhance readiness to launch the Novavax program and begin administering vaccine, jurisdictions should identify providers who will receive the initial doses. Jurisdictions will need to balance making vaccine accessible to those who would like to receive it while avoiding distributing inventory across too many sites and seeking to minimize vaccine loss. While jurisdictions and providers are encouraged to adopt strategies to minimize unnecessary wastage, **they should not miss any opportunities to vaccinate every eligible person** who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

Novavax COVID-19 vaccine will be made available to jurisdictions through a one-time pro rata threshold. A limited quantity of doses will be held and distributed based on need. Jurisdictions should create a distribution plan in coordination with local health departments and other partners and determine which sites will receive vaccine product, incorporating the considerations listed below. It should be reiterated that the primary series for the Novavax COVID-19 vaccine consists of two doses 3 weeks apart. Jurisdictions should be aware of this and plan for a second dose for these individuals.

Considerations for selecting sites to receive the initial doses include:

- Location and access to key populations interested in receiving this vaccine (e.g., people who are hesitant to receive mRNA COVID-19 vaccines but open to protein subunit vaccines) and ensuring that distribution to these groups is equitable to the extent possible.
- Ability to handle 100-dose product configurations, depending on whether the jurisdiction has plans in place for redistribution.
- Ability to efficiently vaccinate within 6 hours once a vial is opened. Sites should consider vial size and the expected demand when planning and scheduling individuals for vaccination.
- Ability to manage inventory to ensure availability of subsequent doses in their supply chain. Jurisdictions will be responsible for managing the vaccines made available to them in their thresholds to cover second doses.
- Overall readiness (e.g., staffing, training, scheduling capabilities).

READINESS CHECKLIST

Main Theme	Key Activities for Readiness and Response
Supply and Ordering Readiness	❑ Determine which provider locations will receive initial vaccine supply, balancing equitable access with vaccination capacity and consideration of initial demand. ❑ Finalize a list of providers and sequence of provider activation for the first week of vaccine deliveries. Jurisdictions will submit orders for providers to facilitate delivery of initial orders. ❑ Review CDC and manufacturer materials regarding product configuration, shipping, storage, dosing, dosing intervals, and adverse event profiles as they become available.

	❑ Optimize vaccine use by ordering supply to minimize unnecessary accumulation of inventory and wastage while also ensuring no vaccination opportunity is missed. ❑ Plan for internal redistribution to reduce wastage and improve access. ❑ Manage and accurately report on-hand product inventory to inform tracking near-expiry and redistribution.
Provider Readiness	❑ Ensure providers are enrolled to reach the key populations; identify providers who are not yet COVID-19 vaccination providers and facilitate their enrollment, especially providers who can fill a geographic gap in access and providers who care for the key target populations. ❑ Ensure providers or other on-location staff are equipped and trained to respond to possible severe allergic reactions, like anaphylaxis. ❑ Encourage providers to consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., family members, community members). ❑ Reinforce how providers are required to report certain adverse events following COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) and support providers in encouraging enrollment in v-safe. ❑ Encourage providers who are not able to offer COVID-19 vaccination to refer their patients to nearby vaccination providers.
Information Technology Systems, Reporting and Monitoring	❑ Ensure electronic systems, including immunization information systems (IISs), are prepared to report and track vaccine administration. ❑ Remember that the Special Project Provider (COVID-19 Providers) label is required for COVID-19 vaccine ordering. Inclusion of this flag on the provider record indicates that the jurisdiction has signed the agreement with the provider to receive COVID-19 vaccines. ❑ Once the vaccination program begins, continue to leverage Tiberius dashboards to monitor the program.
Communications	❑ Create a communication plan that outlines strategies, audiences, and products that will be used to promote COVID-19 vaccination of unvaccinated key populations. ❑ Understand existing data, attitudes, and perceptions regarding COVID-19 vaccination (including co-administration with influenza vaccine) in terms of demand, provider types, and locations where vaccination would be preferred. Share these data with local jurisdictions and partners to help shape messages. ❑ Develop communications products for providers, pharmacies, and the public that align with federal messaging and ensure communication materials are culturally and linguistically appropriate. ❑ Leverage partnerships to help mobilize providers and promote vaccination messaging. ❑ Engage and educate partners and trusted messengers (e.g., healthcare professionals, community leaders, faith leaders and faith-based organizations) as soon as possible.