



NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Ashwin Vasani, MD, PhD
Commissioner

July 29, 2022

Dear Colleague,

On July 19, 2022, the Centers for Disease Control and Prevention (CDC) recommended that the Novavax COVID-19 vaccine be used as a COVID-19 primary series option for adults ages 18 years and older (two 0.5 mL doses administered intramuscularly and spaced 3-8 weeks apart). This recommendation follows an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA). Novavax COVID-19 vaccine is the first COVID-19 protein subunit vaccine recommended for use in the U.S. Protein subunits are a well-understood vaccine platform that has been used for many other vaccines, including influenza, hepatitis, human papillomavirus (HPV), meningococcal B and shingles.

New York City is receiving a very small allocation of 20,700 doses of Novavax COVID-19 vaccine from the federal government. This allocation includes first and second doses. The vaccine is available in 10-dose vials. Unpunctured vials should be refrigerated at 36–46°F. Expiration dates are available at [NovavaxCovidVaccine.com](https://www.novavax.com/covid-19); expiration dates are not printed on the vial or carton. Vials must be used or discarded within 6 hours after the first needle puncture. The vaccine does not require reconstitution or dilution. Detailed information is available in the FDA's [Novavax fact sheets](#) and CDC's [Interim Clinical Considerations](#).

Given the limited quantity of Novavax COVID-19 vaccine, providers should continue to rely primarily on mRNA COVID-19 vaccines (Pfizer and Moderna). However, Novavax may be the most appropriate option for some individuals in limited circumstances. This includes people with a contraindication to an mRNA vaccine and people who otherwise would not get vaccinated against COVID-19. At this time, Novavax is only authorized for use as a two-dose primary series, but the EUA may be expanded in the future to include booster doses and/or additional doses for people who are immunocompromised.

Providers who are interested in ordering Novavax vaccine should email covidvax@health.nyc.gov. Ordering for Novavax will not be available on the Online Registry.

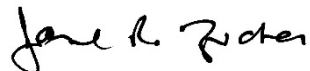
The Novavax recommendation was based on safety and efficacy data, including an ongoing randomized controlled trial, demonstrating that [the benefits of the vaccine outweigh its risks](#). As of September 27, 2021, data from 17,272 vaccine recipients and 8,385 placebo recipients in the randomized trial found overall vaccine efficacy against PCR-confirmed mild, moderate or severe COVID-19 was 90.4% (95% CI 83.8, 94.3). Participants had a median of 2.5 months of follow-up post-dose 2. The clinical data was conducted during a period of alpha variant predominance. Data about the effectiveness of the Novavax vaccine against currently

circulating SARS-CoV-2 variants (i.e., Omicron sub-variants) are not available. Data on duration of protection are unknown at this time.

Most adverse events in the trial were mild to moderate and resolved in 1 to 2 days. In the total clinical safety database of approximately 40,000 Novavax vaccine recipients, 6 people reported myocarditis and/or pericarditis, including 5 events within 20-days post-vaccination. A warning is included in the Novavax EUA fact sheets that the clinical trials provide evidence for increased risks of myocarditis and pericarditis. There will be additional post-authorization monitoring for both vaccine effectiveness and safety.

Thank you for continuing to promote and protect the health of New Yorkers through vaccination.

Sincerely,

A handwritten signature in black ink that reads "Jane R. Zucker". The signature is written in a cursive, flowing style.

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunization