

FDA Authorizes New Novavax COVID Vaccine

The protein-based vaccine works in a different way than the mRNA vaccines from Moderna and Pfizer-BioNTech.

October 3, 2023 By Liz Highlyman

On October 3, the Food and Drug Administration (FDA) authorized an updated version of the Novavax COVID-19 vaccine, following its [mid-September approval](#) of updated messenger RNA (mRNA) vaccines from Moderna and Pfizer-BioNTech. The three new vaccines are designed to provide better protection against recent SARS-CoV-2 coronavirus variants.

“The COVID-19 vaccines have saved countless lives and have prevented serious outcomes of COVID-19 caused by the SARS-CoV-2 virus,” Peter Marks, MD, PhD, director of the FDA’s Center for Biologics Evaluation and Research, [said in a news release](#). “Today’s authorization provides an additional COVID-19 vaccine option that meets the FDA’s standards for safety, effectiveness and manufacturing quality needed to support emergency use authorization. As we head into the fall season and transition into 2024, we strongly encourage those who are eligible to consider receiving an updated COVID-19 vaccine to provide better protection against currently circulating variants.”

Today, we amended the emergency use authorization (EUA) of an additional COVID-19 vaccine for use in individuals 12 years of age and older to transition to the 2023-2024 formula. <https://t.co/6PrnlSzFlq>

[pic.twitter.com/1g8kj4xF9s](https://t.co/6PrnlSzFlq)

— U.S. FDA (@US_FDA) [October 3, 2023](#)

[Last month](#), the Centers for Disease Control and Prevention (CDC) recommended that people of all

ages get the new vaccines—which are no longer being called “boosters”—though they are especially important for older individuals and others at higher risk for severe illness. The FDA authorized the new Novavax shot for people ages 12 years and older, while the Moderna and Pfizer-BioNTech vaccines are authorized for those ages 6 months and up. CDC advisors will not need to meet again to add the new Novavax vaccine to the recommendation.

The Novavax vaccine contains an engineered version of the SARS-CoV-2 spike protein produced in insect cells plus an adjuvant to induce a stronger immune response. This vaccine employs more traditional technology that is already used for influenza and hepatitis B vaccines. In contrast, the mRNA vaccines contain genetic code that instructs cells in the body to produce the spike protein. All the new vaccines are based on the XBB.1.5 viral variant.

Studies showed that the new Novavax vaccine is safe and active against the coronavirus. In clinical trials, the [original version of the vaccine](#), using the same technology, was highly effective at reducing the risk of severe illness and death, stimulating both antibody production and a strong T-cell response. Antibodies start to wane after a few months, but [memory B-cell and T-cell responses](#) provide longer-lasting protection. Some evidence suggests vaccines may also reduce the likelihood of developing [long COVID](#).

The Novavax vaccine is generally well tolerated. Typical side effects include pain or swelling at the injection site and flu-like symptoms, such as fatigue and headache. Serious adverse events, such as anaphylaxis (severe allergic reaction) and myocarditis (heart muscle inflammation), are rare. Clinical trials—and anecdotal reports from people who have received both vaccine types—suggest that the Novavax shot causes milder side effects than the mRNA vaccines.

The CDC previously said that the original Novavax vaccine was recommended only for people unable or unwilling to get one of the mRNA shots. Last year, only people who had not already received an mRNA booster were eligible for a Novavax booster. But now, those restrictions have been lifted, and all adolescents and adults can get the new Novavax shot, regardless of their previous vaccination history. In fact, some studies suggest that mixing vaccine types may lead to a broader immune response.

People ages 12 and older who previously received a COVID vaccine—but have not yet gotten the updated Moderna or Pfizer-BioNTech shots—are eligible to receive one Novavax dose, while unvaccinated individuals should receive two doses. Most people should wait at least two to three months after their last vaccine dose or COVID infection before getting another shot.

The new Novavax vaccine will be available at thousands of locations across the United States in the coming days, including physicians’ offices and major chain pharmacies, [according to the company](#). Although the federal government is no longer directly buying and distributing them, most people will still be able to get a free vaccine covered by their health insurance or [the CDC’s Bridge Access Program](#).

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