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**Sent:** Wednesday, July 20, 2022 1:09 PM

**Subject:** Pfizer BLA, Novavax EUA, Fall Booster Updates July 20, 2022



DEPARTMENT OF PUBLIC HEALTH

## **Subject: Pfizer BLA, Novavax EUA, Fall Booster Updates**

**July 20, 2022**

*This communication is being sent to all key contacts at provider organizations administering COVID-19 vaccine— please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our [web site](#).*

Dear Connecticut COVID-19 Vaccine Providers,

### **Comirnaty Expansion**

On July 8, 2022, the US Food and Drug Administration ([FDA](#)) [approved Pfizer-BioNTech's supplemental Biologics License Application \(BLA\) for their COVID-19 vaccine](#), known as COMIRNATY®, to include individuals 12 through 15 years of age. The vaccine was previously made available to this age group in the under an emergency use authorization (EUA).

Providers may now use either the Comirnaty or EUA authorized Pfizer-BioTech gray cap products when administering vaccine to individuals 12 years of age and older for either a primary series or booster dose.

### **Novavax EUA**

Last week the FDA issued an EUA and yesterday [CDC endorsed](#) the Advisory Committee on Immunization Practices' (ACIP) recommendation for the Novavax COVID-19 Vaccine for individuals 18 years of age and older. The Novavax COVID-19 vaccine is the first COVID-19 protein subunit vaccine recommended for use in the United States. Having multiple types of vaccines offers more options and flexibility for people receiving COVID-19 vaccines. This vaccine is recommended as a two-dose primary series, administered 3-8 weeks apart.

Ordering for the Novavax should begin shortly, within the next couple of weeks. Expect a communication when it becomes available. The product is a 10-dose multi-dose vial that does not require any diluent and is stored at refrigerator temperatures 2° to 8°C (36° to 46°F).

See the attached document for key messages and the [FDA news release](#) and [ACIP presentation materials](#) for additional effectiveness and safety data.

Below is a list of resources and upcoming informational activities related to the recommendations:

- Updated [Interim Clinical Considerations](#)
- Updated web pages for the public including:
  - [Novavax COVID-19 Vaccine Overview and Safety | CDC](#)
  - [Understanding Protein Subunit COVID-19 Vaccines](#)
  - [Stay Up to Date with Your COVID-19 Vaccines | CDC](#)
  - [COVID-19 Vaccines for People who are Moderately or Severely Immunocompromised | CDC](#)
- Updated CDC [COVID-19 booster tool](#)
- COCA call – [Thursday, July 28, 2022, at 2-3 PM ET](#)
- MMWR – August 4, 2022

## Fall Boosters

Last month, [FDA's VRPBAC met to discuss COVID-19 strain selection/future boosters](#). They voted in favor of including a SARS-CoV-2 omicron component in COVID-19 vaccines that would be used for boosters in the U.S. FDA has advised manufacturers seeking to update their COVID-19 vaccines to develop modified vaccines that add an omicron BA.4/5 spike protein component to the current vaccine composition to create a two component (bivalent) booster vaccine, so that the modified vaccines can potentially be used starting fall 2022.

When the new booster dose formulation first becomes available, it is unlikely that it will be authorized for all ages; initially it may only be authorized for adults and possibly adolescents. **Please help us to share this message with parents who may be waiting to vaccinate their children until the new formulation is available. Don't wait--it is critical to ensure that everyone is [up-to date on their COVID-19 vaccines](#) because it provides a base of protection against serious outcomes COVID-19 caused by circulating strains of SARS-CoV-2.** This is especially true for children, as they soon prepare for a new school year.

**CDC recommends everyone ages 6 months and older get vaccinated against COVID-19.** Everyone 5 years and older should also get a COVID-19 booster, if eligible. To learn if and when you can get boosters to stay up to date with your COVID-19 vaccines, use [CDC's COVID-19 booster tool](#).

**Thank you for all your ongoing work and support of our COVID-19 vaccine roll-out in Connecticut.**

For the CT DPH Immunization Program, visit: [Contact Us](#)

For the COVID-19 webpage, visit: [COVID-19 Vaccine Program](#)

*If you would like to unsubscribe from these communications, please send an email to [Dph.immunizations@ct.gov](mailto:Dph.immunizations@ct.gov) with the subject line "Unsubscribe from COVID-19 Program communications".*

## KEY MESSAGES

- Today, the Centers for Disease Control and Prevention (CDC) [endorsed](#) the Advisory Committee on Immunization Practices (ACIP)'s recommendation of the Novavax COVID-19 vaccine for primary series vaccination in adults ages 18 and older.
- Novavax is the first COVID-19 protein subunit vaccine that the CDC has recommended for use in the United States.
  - Protein subunit vaccines contain harmless pieces (proteins) of the COVID-19 virus alongside another ingredient called an adjuvant that helps the immune system respond to the virus in the future if exposed.
  - Vaccines using protein subunits have been used for more than 30 years in the United States, beginning with the first licensed hepatitis B vaccine. Other protein subunit vaccines used in the United States today include those to protect against influenza and acellular pertussis (whooping cough).
- ACIP's vote—which follows the U.S. Food and Drug Administration (FDA)'s [emergency use authorization](#)—is for the use of the Novavax COVID-19 vaccine for adults ages 18 and older as a two-dose primary series. This recommendation is for all adults, including those who are moderately or severely immunocompromised.
- COVID-19 vaccines have undergone the most intense safety monitoring in U.S. history. Clinical research has demonstrated the safety and effectiveness of the Novavax COVID-19 vaccine.
- COVID-19 vaccines used in the U.S. continue to be highly effective in reducing the risk of severe disease, hospitalization, and death, including against the still-circulating Omicron variant and subvariants.
  - CDC recommends everyone ages 6 months and older get vaccinated against COVID-19, and that everyone ages 5 years and older get a COVID-19 booster, if eligible.
  - To learn if and when you or your child can get COVID-19 boosters, use [CDC's COVID-19 booster tool](#).