

# COVID-19 Vaccine Information Brief

June 10, 2022

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Changes to the document from the previous version are highlighted in yellow.

## **IMPORTANT/NEW COVID-19 Vaccine Information**

- Pfizer Adult/Adolescent COVID-19 - Comirnaty Vaccine Orders
- Pfizer COVID-19 Adult Vaccine – Comirnaty
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Key Summary and Actions Items

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### **Pfizer Adult/Adolescent COVID-19 - Comirnaty Vaccine Orders**

It is anticipated the Pfizer COVID-19 vaccine for adults (the Biologics License Application [BLA] labeled product known as Comirnaty will be used to fill a portion of all Pfizer adult vaccine orders beginning the week of June 13, 2022.

- The Department will receive a portion of the Pfizer adult/adolescent COVID-19 threshold as Comirnaty vaccine.
- The minimum order quantity of Comirnaty vaccine will be 300 doses, consistent with the minimum order size of the EUA labeled product (Tris).
- The availability and amount of Comirnaty vaccine will be limited.

The Department will send local public health agencies (LPHAs) the Vaccine Allocation Survey on Monday, June 13, 2022. The Department will fulfill as much of the requested Pfizer adult/adolescent vaccine with Comirnaty as possible. Vaccine requests above the established CDC threshold for Comirnaty will be fulfilled with the EUA labeled product (Tris). LPHAs will receive the allocation in IRIS on Wednesday, June 15, 2022 and need to complete the allocation by 12:00 PM Thursday, June 16th.

***The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Tris - Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to respective instructions for use, can be used interchangeably.***

## **Pfizer COVID-19 Adult Vaccine – Comirnaty**

The licensed Pfizer COVID-19 vaccine for adults (the [Biologics License Application \[BLA\]](#) labeled product known as Comirnaty) will soon be available to Iowa healthcare providers during a limited release. Comirnaty is the first COVID-19 vaccine to receive [full FDA approval](#) as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

***The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the Tris - Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to respective instructions for use, can be used interchangeably.***

Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- a 2-dose primary series to individuals 12 through 15 years of age;
- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise;
- a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA);
- a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series;
- a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and
- a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.

The EUA labeled product will remain available during and after the use of the BLA-labeled product (Comirnaty).

- The EUA and BLA products both have a GRAY Cap.
  - **The EUA and BLA products have different labels and NDCs; however, the vaccines are identical and interchangeable, as determined by the FDA.**
  - **The storage and handling guidelines are the same for both products.** See the [COVID-19 Vaccine Quick Reference Guide](#) for details.
  - The EUA and BLA are identical and interchangeable for both primary and booster vaccinations. Support and education will be provided by Pfizer to help stakeholders understand the labeling differences to ensure all vaccines are administered correctly. See training links below.
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## **Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training**

Pfizer has expanded its training sessions to address questions about currently recommended COVID-19 vaccine products as well as vaccines for children that are anticipated to be approved through an EUA. The COVID-19 vaccine medical updates and site training webinars aim to educate providers and immunization staff on the proper use of the Pfizer-BioNTech COVID-19 Vaccines. Daily training (Monday through Friday) will begin Monday, June 20, 2022, and continue through July 8, 2022 (with no training on July 4<sup>th</sup>). For details, see [dates and links for upcoming training sessions](#).

### **Resources**

- [Fact Sheet for Healthcare Providers](#) - 12 years and older
  - [Fact Sheet for Recipients and Caregivers](#) - 12 years and older
  - [Pfizer-BioNTech COVID-19 Vaccine | CDC](#)
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### **Key Summary and Actions Items**

- It is anticipated Comirnaty will be used to fill a portion of all Pfizer adult vaccine orders beginning the week of June 13, 2022.
- The vaccine survey will ask LPHAs to request how many doses of adult/adolescent Pfizer COVID-19 vaccine are needed for the weeks of June 13 and June 20.
- IDPH will then determine each county's allocation of Comirnaty. County requests for Comirnaty may be reduced and or substituted with Pfizer Tris based upon product availability.
- LPHAs will receive the allocation in IRIS on Wednesday, June 15, 2022 and need to complete the allocation by 12:00 PM Thursday, June 16th.
  - LPHAs will determine COVID-19 vaccination providers to receive Comirnaty and Tris vaccine as allocated.
- The EUA (Pfizer Tris) and BLA (Comirnaty) products have different labels and NDCs; however, the vaccines are identical and interchangeable, as determined by the FDA. The storage and handling guidelines are the same for both products. The EUA and BLA products both have a GRAY cap.