

COMIRNATY COVID-19 Vaccine

Receives Full U.S. FDA Approval For Individuals 16 Years and Older

Updated August 23, 2021

On August 23, 2021, the **U.S. Food and Drug Administration** (FDA) approved **COMIRNATY** (COVID-19 Vaccine, mRNA) to prevent COVID-19 in individuals 16 years of age and older. COMIRNATY is the first COVID-19 vaccine to be granted FDA approval.

Indication & Authorized Use

COMIRNATY 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 Emergency Use Authorization (EUA) to be administered for emergency use to:
 - prevent COVID-19 in individuals **12 through 15 years**, and
 - provide a third dose to individuals **12 years of age and older** who have been determined to have certain kinds of immunocompromise

FDA authorized the **Pfizer-BioNTech COVID-19 Vaccine**, which has the same formulation as **COMIRNATY**, in the U.S under Emergency Use Authorization (EUA) since December 11, 2020, and is still currently under EUA to:

- prevent COVID-19 in individuals **12 years of age and older**, and
- provide a third dose to individuals **12 years of age and older** who have been determined to have certain kinds of immunocompromise

An individual may be offered either COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.



For more information, please visit:

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-covid-19-vaccine-comirnatyr-receives-full>

