

## COVID-19 Vaccine Information Brief

August 23, 2021

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

### U.S. FDA Fully Approves Pfizer's COVID-19 Vaccine for Those 16 Years and Older

On Monday, August 23, 2021, [FDA approved COMIRNATY \(COVID-19 Vaccine, mRNA\) for use as a two-dose series \(provide link\) for individuals 16 years of age and older](#). It can also be used under the EUA 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.

**CDC COVID-19 Vaccination Program Provider Agreements:** Providers are responsible for adhering to all requirements outlined in the agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#) of CDC, the [Advisory Committee on Immunization Practices](#), and the U.S Food and Drug Administration ([FDA](#)). This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as “off-label use”) is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

**Interchangeability of FDA authorized and FDA approved COVID-19 Products:** The FDA-approved Pfizer-BioNTech product COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under the EUA to administer the vaccination series for those seeking the approved vaccine. The Fact Sheet for Recipients provides additional information about both the approved and authorized vaccine. Providers should continue to use the vaccines on their shelves.

### Pfizer-BioNTech Vaccine Expiration Extension

The FDA has approved an amendment to the EUA for Pfizer-BioNTech extending the expiration dates of COVID-19 Vaccine from six to nine months.

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as authorized storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Please note: the ultra cold temperature range has been broadened to include -90° C (-130°F). **Frozen vials stored at -25°C to -15°C and refrigerated vials (2°C to 8°C) are NOT eligible for extension.**

Updated expiry dates for vaccine maintained in ultra-cold storage are shown below.

<u>Printed Expiry Date</u>	<u>Updated Expiry Date</u>
August 2021	November 2021
September 2021	December 2021
October 2021	January 2022
November 2021	February 2022
December 2021	March 2022
January 2022	April 2022
February 2022	May 2022

The extended expiration date is effective immediately for all currently available batches that have not yet expired. **NOTE:** Expiration dates extension does NOT apply to vials dated July 2021 and earlier.

No changes have been made to the vaccine itself to enable extension of expiry dating. This change is based on stability data generated on batches manufactured over approximately the past nine months of COVID-19 vaccine development, from the batches that supplied early clinical trials through the commercial scale batches currently in production. Currently available vaccine will not have an updated Nation Drug Code (NDC). Please refer to the current [EUA Fact Sheet for information.](#)

**It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.**

Additional information on Pfizer storage and handling may be found at: [Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC](#)