

COVID-19 vaccines: Pfizer-BioNTech

Pfizer-BioNTech COVID-19 vaccine

On Aug. 23, 2021, the Food and Drug Administration (FDA) granted full approval to the Pfizer-BioNTech COVID-19 vaccine for use in individuals 16 years of age and older. This is the first COVID-19 vaccine and first mRNA to receive full approval and is being marketed as Comirnaty.

Pfizer-BioNTech's mRNA vaccine became the first COVID-19 vaccine to receive FDA's Emergency Use Authorization (EUA) on Dec. 11, 2020. The vaccine is currently authorized for emergency use in children ages 5-15.

Pfizer-BioNTech has also received an EUA for administration of a single COVID-19 vaccine booster dose for all individuals 12 years of age and older. The FDA has authorized the use of a single booster dose five months after completion of the primary vaccination series of the Pfizer-BioNTech COVID-19 vaccine. The Pfizer-BioNTech vaccine is also available to those who completed the Moderna primary series six months ago or those who completed the J&J primary vaccine two months ago.

The other authorized mRNA COVID-19 vaccine and booster dose available is produced by Moderna. Johnson & Johnson-owned Janssen Pharmaceuticals offers an authorized SARS-CoV-2 viral vector vaccine and booster dose, however, mRNA COVID-19 vaccines are **preferred** for the primary series and booster dose, over the J&J COVID-19 vaccine for the prevention of COVID-19 for those 18 years of age and older due to the risk of rare adverse events such as thrombosis with thrombocytopenia (TTS).

Clinical information

Find clinical vaccine guidance from the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and other health organizations.

FDA

- The FDA has issued an Emergency Use Authorization (EUA) to permit the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older.
- Fact Sheet for Healthcare Providers Administering the Pfizer-BioNTech COVID-19 Vaccine for individuals 5-11 years of age and individuals 12 years of age or older.

Learn more about FDA information on COVID-19 vaccines and the FDA's Vaccines and Related Biological Products Advisory Committee.

CDC

- Administration Overview for Pfizer-BioNTech COVID-19 Vaccine
- CDC Morbidity and Mortality Weekly Report:
 - The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years—United States, November 2021.
 - The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years—United States, May 2021.
 - The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States, December 2020.
- What Clinicians Need to Know About the Pfizer-BioNTech COVID-19 Vaccine.
- Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination
- Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Learn more about the CDC's Advisory Committee on Immunization Practices. The CDC offers a guide on preparing for COVID-19 vaccination for health care professionals and a COVID-19 vaccination communications tool kit for medical centers, clinics and clinicians.

Featured AMA news and media

Explore featured AMA news and media about the Pfizer-BioNTech COVID-19 vaccine, including the AMA COVID-19 Video Update.

AMA COVID-19 Video Update

- Gerald Harmon, MD, on FDA's full approval of Pfizer vaccine

- Andrea Garcia, JD, MPH, discusses FDA's full approval of Pfizer vaccine
- AMA experts discuss how to counsel patients about Pfizer vaccine allocation
- What physicians need to know about Pfizer vaccine use and allocation
- Mira Irons, MD, talks COVID-19 numbers and trending topics including Pfizer vaccine

News highlights

- 4 keys for doctors to know on Pfizer COVID-19 vaccine booster
- Pfizer COVID-19 vaccine booster: Who can get it, who could benefit
- 8 things physicians and patients need to know about the Pfizer vaccine
- Full FDA approval of Pfizer vaccine is milestone in pandemic fight
- What FDA's full approval of Pfizer-BioNTech COVID-19 vaccine means
- Pfizer's COVID-19 vaccine OK'd for ages 12-15: What doctors must know
- Pfizer's COVID-19 vaccine earns FDA nod. Here's what comes next.

Media coverage

- Statement on ACIP guidelines for Pfizer COVID-19 vaccine in children
- Statement on ACIP recommendation for Pfizer COVID-19 vaccine booster
- AMA, AHA, ANA applaud FDA full approval of Pfizer COVID-19 vaccine
- AMA on ACIP recommendation for use of Pfizer COVID-19 vaccine in teens