



November 22, 2021

****Emergency Use Authorization (Expanded Use)****

FDA Expands Eligibility for Moderna and Pfizer-BioNTech COVID-19 Vaccine Boosters

Background & Current Status¹:

- On December 11, 2020, the U.S Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 Vaccine for prevention for COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.
- On May 10, 2021, the FDA reissued and expanded the Pfizer-BioNTech COVID-19 Vaccine EUA to include individuals aged 12 to 15 years.
- On August 23, 2021, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, now known as Comirnaty®, for the prevention of COVID-19 in individuals aged 16 years and older.
- On October 29, 2021, the FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age.
- **On November 19, 2021, the FDA [amended the EUA](#) for both Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. This action expands the use of booster doses of both vaccines to include all individuals 18 years of age and older at least six months after completion of the primary vaccination series of Moderna or Pfizer-BioNTech COVID-19 Vaccines or at least two months after completion of primary vaccination with the Janssen COVID-19 Vaccine.**

Vaccine Efficacy¹:

The EUA for a single booster dose for individuals 18 years of age and older for the Moderna (administered as half of the dose of a primary series dose) and Pfizer-BioNTech COVID-19 vaccines is based on the FDA's analysis of immune response data that supported use in the previously authorized populations for boosters.

For the Moderna COVID-19 Vaccine booster dose, the FDA analyzed the immune response data from 149 participants 18 years of age and older from the original clinical studies who received a booster dose at least six months after their second dose and compared it to the immune responses of 1,055 study participants after completing their two-dose series. The antibody response against the virus 29 days after a booster dose of the vaccine demonstrated a booster response.

For the Pfizer-BioNTech COVID-19 Vaccine booster dose, the FDA analyzed the immune response data from approximately 200 participants 18 through 55 years of age who received a single booster dose about six months after their second dose. The antibody response against the virus one month after a booster dose of the vaccine when compared to the response one month after the two-dose primary series in the same individuals demonstrated a booster response.

Vaccine Safety¹:

Since Moderna and Pfizer-BioNTech initially submitted safety and effectiveness data on a single booster dose following primary vaccination to the FDA, additional real-world data have become available on the recently increasing number of cases of COVID-19 in the U.S. and on the risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the outer lining of the heart) following vaccination with these vaccines.

These additional data enabled the FDA to reassess the benefits and risks of the use of these vaccines in the general adult population. The FDA has determined that the benefits of a single booster dose of either the Moderna or Pfizer-BioNTech COVID-19 vaccines outweigh the risks of myocarditis and pericarditis in individuals age 18 years of age and older when used following completion of primary vaccination to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.

The Fact Sheets for both vaccines for recipients and caregivers and for healthcare providers contain information about the potential side effects, including the risk of myocarditis and pericarditis. The most commonly reported side effects by individuals who received a booster dose of the vaccines were pain, redness and swelling at the injection site, as well as fatigue, headache, muscle or joint pain and chills. Of note, swollen lymph nodes in the underarm were observed more frequently following the booster dose than after the primary two-dose series.

Ongoing Safety Monitoring¹:

Both Pfizer and Moderna are conducting post-authorization/post-marketing studies to assess known serious risks of myocarditis and pericarditis. In addition, the FDA and the CDC have several systems in place to continually monitor COVID-19 vaccine safety and allow for the rapid detection and investigation of potential safety concerns.

CDC Interim Clinical Considerations²:

Summary of recent changes (last updated November 19, 2021):

- [Updated guidance for COVID-19 booster doses in recipients of mRNA COVID-19 vaccines](#)

Key points

- COVID-19 vaccination is recommended for everyone aged 5 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- COVID-19 vaccines currently approved or authorized by FDA [are effective](#) in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.

Current EUA Fact Sheets³⁻⁶:

As a convenience, Fact Sheets for the **Pfizer-BioNTech COVID-19 Vaccine** (Boosters, ≥ 18 years) are accessible below:

- ❖ [Healthcare Providers](#)
- ❖ [Recipients and Caregivers](#)

As a convenience, Fact Sheets for the **Moderna COVID-19 Vaccine** (Boosters, ≥ 18 years) are accessible below:

- ❖ [Healthcare Providers](#)
- ❖ [Recipients and Caregivers](#)

Mandatory Requirements under the EUA^{3,5}:

- Use Pfizer-BioNTech or Moderna COVID Vaccine only in authorized patients described in the respective Fact Sheets.
- Communicate to recipients or caregivers, as age appropriate, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to receiving Pfizer-BioNTech or Moderna COVID-19 Vaccine.
- Include vaccination information in the local jurisdiction’s Immunization Information System or other system.
- Mandatory reporting of the following to the [Vaccine Adverse Event Reporting System \(VAERS\)](#):
 - Vaccine administration errors whether or not associated with an adverse event,
 - Serious adverse events (irrespective of attribution to vaccination),
 - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
 - Cases of COVID-19 that result in hospitalization or death.
- Respond to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer BioNTech or Moderna COVID-19 Vaccines to recipients.
- *Federal, Tribal, and Urban programs are all encouraged to put “IHS” into field #26 of the form.*

References:

1. Food and Drug Administration. FDA News Release. [Coronavirus \(COVID-19\) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters](#). Published online on November 19, 2021.
2. Centers for Disease Control and Prevention. [ACIP Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#). Updated November 19, 2021.
3. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine: [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: 19 November 2021.
4. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine: [FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#). Revised: 19 November 2021.
5. Food and Drug Administration. Moderna COVID-19 Vaccine: [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE](#). Revised: 19 November 2021.
6. Food and Drug Administration. Moderna COVID-19 Vaccine: [FACT SHEET FOR RECIPIENTS AND CAREGIVERS](#). Revised: 19 November 2021.