Indian Health Service
National Pharmacy and Therapeutics Committee

COVID-19 Emerging Treatments Update

December 10, 2021

**Emergency Use Authorization (Expanded Use) **

FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year Olds

Background & Current Status[1,2,3]:

- 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 emergency use authorization (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, the FDA authorized the use of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for administration to all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.
- ***On December 9, 2021, the FDA amended the EUA for the Pfizer-BioNTech COVID-19 Vaccine, authorizing the use of a single booster dose for administration to individuals 16 and 17 years of age at least six months after completion of primary vaccination with the Pfizer-BioNTech COVID-19 Vaccine.***

Vaccine Efficacy[1,2]:

The EUA for a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 and 17 years of age is based on the FDA's previous analysis of immune response data that supported use of a booster dose in individuals 18 years of age and older. The FDA had analyzed the immune response data from approximately 200 participants, 18 through 55 years of age, who received a single booster dose approximately six months after their second dose. The antibody response against the SARS-CoV-2 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. The FDA's assessment of the effectiveness of a booster dose for individuals 16 and 17 years of age is based on these data. Based on the available data for individuals 18 and older regarding effectiveness, the FDA has concluded that these data support extending the eligible booster age population to 16- and 17-year-olds.

Vaccine Safety[1,2]:

In the time since Pfizer initially submitted safety and effectiveness data on a single booster dose following the two-dose primary series to the FDA, additional real-world data have become available on the 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 the Pfizer-BioNTech COVID-19 Vaccine. These additional data enabled the FDA to reassess the benefits and risks of the use of the vaccine in a wider population. The FDA has determined that the benefits of a single booster dose of the Pfizer-BioNTech COVID-19 Vaccine or Comirnaty outweigh the risks of myocarditis and pericarditis in individuals 16 and 17 years of age to provide continued protection against COVID-19 and the associated serious consequences that can occur including hospitalization and death.

Ongoing Safety Monitoring[1]:

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

COVID-19 Vaccine Booster Shots[4] (per CDC website; updated Dec. 9, 2021)

Everyone Ages 16 and Older Can Get a Booster Shot

IF YOU RECEIVED	Who can get a booster: / Who should get a booster:	When to get a booster:	Which booster can you get:
Pfizer-BioNTech	Who can get a booster: • Teens 16-17 years old Who should get a booster: • Adults 18 years and older	At least 6 months after completing your primary COVID-19 vaccination series	• Teens 16–17 years old can get a Pfizer-BioNTech COVID-19 vaccine booster • Adults 18 years and older can get any of the COVID-19 vaccines authorized in the United States
Moderna	Who should get a booster: Adults 18 years and older	At least 6 months after completing your primary COVID-19 vaccination series	Any of the COVID-19 vaccines authorized in the United States
Johnson & Johnson's Janssen	Who should get a booster: Adults 18 years and older	At least 2 months after completing your primary COVID-19 vaccination	Any of the COVID-19 vaccines authorized in the United States

Current EUA Fact Sheets[3,5]:

As a convenience, Fact Sheets for the Pfizer-BioNTech COVID-19 Vaccine (16-17 years) are accessible below:

- Fact Sheet for Healthcare Providers
- Fact Sheet for Recipients and Caregivers

Mandatory Requirements under the EUA[3]:

- Use Pfizer-BioNTech 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 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 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 Pfizer-BioNTech COVID-19 Booster Dose to 16- and 17-Year-Olds. Published online on December 9, 2021.
2. Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization. Issued December 9, 2021.
3. Food and Drug Administration. FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE. Revised: 9 December 2021.
4. Centers for Disease Control and Prevention. COVID-19 Vaccine Booster Shots. Updated December 9, 2021.
5. Food and Drug Administration. FACT SHEET FOR RECIPIENTS & CAREGIVERS. Revised: 9 December 2021.