COVID-19 Vaccine Information Brief

September 24, 2021

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

NEW Information Includes:

- **ACIP Recommends Pfizer COVID-19 Vaccine Booster Dose for Adults 65+ and Specific At-Risk Groups**
- **These recommendations are ONLY for individuals who originally received the two-dose (primary) series of Pfizer's COVID-19 vaccine.**

CDC's Advisory Committee Recommends Pfizer Booster Dose for Adults 65+ and Specific At-Risk Groups

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted yesterday September 23, 2021 to recommend a booster dose of Pfizer's mRNA COVID-19 vaccine in certain populations. Individuals may self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered.

Effective immediately, CDC recommends:

- People 65 years and older and residents in long-term care settings should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.
- People aged 50–64 years with underlying medical conditions should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.
- People aged 18–49 years with underlying medical conditions may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.
- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

These recommendations are ONLY for those who originally received two-dose series of Pfizer's COVID vaccine in the primary series. Booster doses might be recommended in the future for those who received COVID vaccines manufactured by Moderna or Janssen (Johnson & Johnson), or those who received a different mRNA vaccine for each dose in the primary series, but ACIP did not address these situations. **CDC will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or people who got the Moderna or Johnson & Johnson vaccines.**

Many of the people who are now eligible to receive a booster shot received their initial vaccine early in the vaccination program and will benefit from additional protection. With the Delta variant's dominance as the circulating strain and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations who are at high-risk for exposure to COVID-19 or the complications from severe disease.

As a reminder, providers are responsible for adhering to all requirements outlined in the COVID-19 Vaccination Program Provider 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.

Booster Dose Resources

Below is a list of upcoming informational activities related to the recommendation, as well as resource pages that are in the process of being revised and will be available in the days ahead:

- COCA Call (Tuesday, Sept. 28, 2021, 2-3 PM ET)
- Updated booster page
- Updated interim clinical considerations
- Pfizer EUA Fact Sheet for Vaccine Recipients and Caregivers
- Pfizer EUA Fact Sheet for Healthcare Providers

Thank you for everything that you have done and are continuing to do to ensure everyone has access to COVID-19 vaccines.