Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Pfizer-BioNTech COVID-19 vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States

You may be eligible for COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose (if aged ≥12 years) or a single booster dose (if aged ≥18 years) after completing a primary series vaccination with a **certain** COVID-19 vaccine **not authorized or approved** by the Food and Drug Administration (FDA). For example, people who were vaccinated outside the United States or from clinical trial participation (such as the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine) may be eligible to receive an additional primary dose and/or a booster dose.

The additional primary and booster doses of COVID-19 vaccine by Pfizer-BioNTech are described in these Emergency Use Instructions (EUI), which are issued by the Centers for Disease Control and Prevention (CDC) and are further explained in this Fact Sheet.

What are Emergency Use Instructions (EUI)?
EUI are issued by CDC to provide information about emergency use of FDA-approved medical products that may not be included in or differ in some way from the information provided in the FDA-approved labeling (package insert). EUI consist of fact sheets for healthcare providers and recipients.

Why is CDC issuing EUI for the COVID-19 vaccine by Pfizer-BioNTech?
The COVID-19 vaccine by Pfizer-BioNTech is an FDA-approved COVID-19 vaccine (brand name Comirnaty, mRNA) to prevent COVID-19 in persons 16 years of age and older. CDC is issuing EUI to provide information about use of this vaccine as an additional primary dose in certain immunocompromised persons (12 years of age and older) and a booster dose in certain adults (18 years of age and older) who received certain **non-FDA authorized or approved COVID-19 vaccine** (e.g., certain vaccines available outside of the United States or from clinical trial participation).

What is COVID-19?
COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from no symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills, cough, shortness of breath, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, diarrhea.

Who can receive an additional primary dose or a single booster dose of the COVID-19 vaccine by Pfizer-BioNTech under this EUI?

- Certain moderately and severely immunocompromised persons aged 12 years of age and older who received a primary series of certain **non-FDA authorized or approved COVID-19 vaccines**.
- Certain adults aged 18 years and older who completed primary vaccination with certain **non-FDA-authorized or approved COVID-19 vaccine**.

Talk to your healthcare provider about if and when you should receive an additional primary dose or a single booster dose. See CDC's Interim Clinical Considerations for additional information on moderately and severely immunocompromised persons recommended for an additional primary dose and populations eligible for a booster dose.

Who should <u>NOT</u> get the COVID-19 vaccine by Pfizer-BioNTech?
You should not get the vaccine if you:

- had a severe allergic reaction after a previous dose of the COVID-19 vaccine by Pfizer-BioNTech
- had a severe allergic reaction to any ingredient of the COVID-19 vaccine by Pfizer-BioNTech

What should I mention to the vaccination provider before getting the COVID-19 vaccine by Pfizer-BioNTech?
Tell your vaccination provider the name, number of doses, and date(s) of COVID-19 vaccine(s) you received previously. Also, mention all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have ever fainted in association with an injection

How is the COVID-19 vaccine by Pfizer-BioNTech given?
The additional primary or booster dose of the COVID-19 vaccine by Pfizer-BioNTech is given as a single injection into the muscle.

Has the COVID-19 vaccine by Pfizer-BioNTech been used before?
Yes. Millions of people have received this vaccine in the United States when since it became available starting in mid -December 2020. Also, in clinical trials, approximately 23,000 people 12 years of age and older have received at least 1 dose of the vaccine. There have been some studies in people who received the COVID-19 vaccine by Pfizer-BioNTech after completing a primary vaccination with a non-FDA authorized or approved COVID-19 vaccine.

What are the risks of the COVID-19 vaccine by Pfizer-BioNTech?
Limited data are available on use of the COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose or a booster dose in people who completed their primary vaccination with a non-FDA authorized or approved COVID-19 vaccine. Side effects of the COVID-19 vaccine by Pfizer-BioNTech include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, swollen lymph nodes (lymphadenopathy), decreased appetite, rash, pain in extremity, diarrhea, and vomiting. Common side effects reported were mostly mild, but some people had side effects that affected their ability to do daily activities. Cases of myocarditis and pericarditis in adolescents and young adults have been reported after mRNA COVID-19 vaccines; however, these reports are rare.

Additional information on the common and serious side effects of the COVID-19 vaccine by Pfizer-BioNTech can be found in the package insert for Comirnaty and in the EUA Fact Sheet for Recipients and Caregivers.

What are the benefits of the COVID-19 vaccine by Pfizer-BioNTech?
The COVID-19 vaccine by Pfizer-BioNTech has been shown in clinical studies to be effective in preventing COVID-19. An additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech may help to increase immune response in people who completed their primary vaccination with a non-FDA authorized or approved COVID-19 vaccine, which could improve protection against COVID-19. The COVID-19 vaccine by Pfizer-BioNTech may not protect everyone.

What are the Risks and Benefits of the COVID-19 vaccine by Pfizer-BioNTech?
The FDA approved COVID-19 vaccine by Pfizer-BioNTech to prevent COVID-19 based on safety and efficacy data available from clinical trials. Additionally, the FDA issued an Emergency Use Authorization of the

COVID-19 vaccine by Pfizer-BioNTech as an additional dose or booster dose, determining, among other things, that the known and potential benefits of vaccination outweigh the known and potential risks of the vaccine. Based on available information, the use of the COVID-19 vaccine by Pfizer-BioNTech as described in this Fact Sheet could help improve or restore protection that may not have been sufficient or may have decreased over time after the primary vaccination.

What alternative choices are available for an additional primary or booster dose other than the COVID-19 vaccine by Pfizer-BioNTech?
The COVID-19 vaccine you initially received for primary vaccination is not authorized, approved, or available in the United States. Currently, the COVID-19 vaccine by Pfizer-BioNTech is the only FDA-approved COVID-19 vaccine for which EUI provide information about an additional primary dose or booster dose following the COVID-19 vaccine that you received.

It is your choice to receive or not receive the COVID-19 vaccine by Pfizer-BioNTech as an additional primary dose or booster dose. Should you decide not to receive it, it will not change your standard medical care.

Will I get a vaccination card?
When you are administered the additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech, you will get a vaccination card to document when you received the shot. You should keep your vaccination card.

What is the Countermeasures Injury Compensation Program?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

How can I learn more?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

Questions and Answers about Emergency Use Instructions (EUI)
Below are answers to frequently asked questions about Emergency Use Instructions (EUI). Refer to the EUI Fact Sheet for Healthcare Providers and Fact Sheet for Recipients and Caregivers for detailed information regarding the EUI for Pfizer-BioNTech's COVID-19 Vaccine for Additional Primary and Booster Doses in Certain Persons Who Completed Primary Vaccination with Vaccines Not Approved/Authorized in the United States.

What are Emergency Use Instructions (EUI)?
Emergency Use Instructions (EUI) allow CDC to inform healthcare providers and recipients about certain uses of medical products approved (licensed) by the U.S. Food and Drug Administration (FDA) that are needed during public health emergencies without the FDA needing to issue an Emergency Use Authorization (EUA). The CDC Director has legal authority to create, issue, and disseminate EUI before or during an emergency for FDA-approved medical products with instructions to inform healthcare providers and recipients about such products' approved, licensed, or cleared conditions of use under circumstances that go beyond the scope of the approved labeling (package insert). EUI consist of fact sheets for healthcare providers and recipients that provide information regarding the emergency use of an FDA-approved medical product.

What EUI did CDC issue and why?
On November 17, 2021, CDC issued EUI to allow additional primary and booster doses of the COVID-19 vaccine by Pfizer-BioNTech in certain individuals. CDC issued the EUI and updated its interim clinical considerations to ensure that certain people who were vaccinated outside of the United States, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. While this only impacts a small number of people, the EUI and CDC's guidance help to ensure these individuals can get an additional primary dose or booster dose of COVID19 vaccine by Pfizer-BioNTech so they can be better protected against COVID-19. This is important with cases of COVID-19 still high across the United States and globally.

Because the EUI can only be issued for an FDA-approved medical product, only Pfizer-BioNTech's COVID-19 vaccine can be used at this time under CDC-issued EUI for an additional primary or booster dose in certain persons who were vaccinated with certain non-FDA authorized or approved COVID-19 vaccines.

The COVID-19 vaccine by Pfizer-BioNTech (brand name Comirnaty) was approved by FDA in August 2021 as a 2-dose primary series for active immunization to prevent COVID-19 in persons ages 16 and older. Because the FDA-approved use does not include additional primary or booster doses, FDA also amended the EUA for the Pfizer-BioNTech COVID-19 vaccine to authorize an additional primary dose in certain immunocompromised persons ages 12 years and older and a booster dose in adults ages 18 and older following primary vaccination with the COVID-19 vaccine by Pfizer-BioNTech or a different FDA-authorized COVID-19 vaccine. CDC issued EUI to allow use of the COVID-19 vaccine by Pfizer-BioNTech for additional primary or booster doses in certain individuals who completed primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines.

Who is eligible for an additional primary dose or booster dose under the EUI?
Certain people who were vaccinated outside of the United States, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in a clinical trial, can get an additional primary dose or booster dose of the COVID-19 vaccine by Pfizer-BioNTech. The recommendations are similar to those for people who received an FDA-authorized COVID-19 vaccine primary series:

- A single additional primary dose of Pfizer-BioNTech may be given to certain moderately and severely immunocompromised individuals ages 12 years and older who completed a primary series of a COVID-19 vaccine that is not FDA authorized or approved but is listed for emergency use by the World Health Organization (WHO).

- A single booster dose of Pfizer-BioNTech may be given to certain adults ages 18 years and older who have completed a primary series of a COVID-19 vaccine that is not FDA authorized or approved but is listed for emergency use by WHO.

More information can be found on CDC's Interim Clinical Considerations webpage and on the EUI Fact Sheet for Healthcare Providers and EUI Fact Sheet for Recipients and Caregivers.

What is the recommended dose and interval of an additional primary dose of Pfizer-BioNTech under EUI? What about the booster dose recommendation?

Under EUI, a single additional primary dose of Pfizer-BioNTech may be given to certain individuals ages 12 years and older who are moderately or severely immunocompromised at least 28 days after completion of primary vaccination with a non-FDA authorized or approved COVID-19 vaccine.

Under EUI, a single booster dose of Pfizer-BioNTech may be administered in certain adults ages 18 years and older at least six months after completion of primary vaccination with a non-FDA authorized or approved COVID-19 vaccine. Refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.

What are the risks and benefits of mix-and-match uses of non-FDA authorized/approved vaccines with the COVID-19 vaccine by Pfizer-BioNTech?

Available data on the safety or efficacy of an additional primary or booster dose of Pfizer-BioNTech's COVID-19 vaccine after receipt of a non-FDA authorized or approved COVID-19 vaccine are limited. However, based on available information, the known and potential risks of an additional primary or booster dose of Pfizer-BioNTech's COVID-19 vaccine might be outweighed by its likely benefit to enhance or restore protection by the primary vaccination, which might have waned over time. Refer to the Interim Clinical Considerations for Use of COVID-19 Vaccines for additional information.