Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Additional Doses of the Updated COVID-19 Vaccine, 2023-2024 Formula, by Pfizer-BioNTech

This Fact Sheet describes Emergency Use Instructions (EUI) that have been issued by the Centers for Disease Control and Prevention (CDC) to provide information about additional doses of the Updated COVID-19 vaccine, 2023-2024 Formula (monovalent, XBB containing), by Pfizer-BioNTech (Comirnaty) that go beyond its FDA-approved labeling. These uses under EUI are for doses for people ages 12 years and older who are moderately or severely immunocompromised. See below for more information on the uses of the updated COVID-19 vaccine by Pfizer-BioNTech under EUI.

If you are 12 years and older and you are receiving vaccination for uses provided under EUI, you have a choice of receiving the updated COVID-19 vaccine by either Pfizer-BioNTech or Moderna (see the Moderna EUI Fact Sheet for Recipients and Caregivers).

What are Emergency Use Instructions (EUI)?
EUI are issued by CDC to provide information about emergency use of FDA-approved (licensed) 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 updated COVID-19 vaccine by Pfizer-BioNTech?
The updated COVID-19 vaccine by Pfizer-BioNTech is an FDA-approved COVID-19 vaccine (brand name Comirnaty, mRNA) to prevent COVID-19 in persons ages 12 years and older. CDC is issuing EUI to provide information about this vaccine for the below uses that extend beyond its FDA-approved labeling (see "Who can receive additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech under the EUI?"). The updated COVID-19 vaccine by Moderna can also be used under EUI for similar uses as an alternative mRNA COVID-19 vaccine (see the Moderna EUI Fact Sheet for Recipients), and the same or similar recommendations in this EUI also apply to the use of the updated COVID-19 vaccine by Moderna under EUI.

What is COVID-19?
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a coronavirus called SARS-CoV-2. It is predominantly a respiratory illness that can affect other organs. People with SARS-CoV-2 infection have reported a wide range of symptoms, 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, and diarrhea.

Who can receive additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech under the EUI?
People who can receive the updated COVID-19 vaccine by Pfizer-BioNTech under EUI are described below.

- People ages 12 years and older who are moderately or severely immunocompromised

The updated COVID-19 vaccine by Moderna can also be used under EUI for similar uses in persons ages 12 years and older as an alternative updated mRNA COVID-19 vaccine (see the Moderna EUI Fact Sheet for Recipients).

Talk to your healthcare provider about if and when you should receive additional vaccine doses. See CDC's Interim Clinical Considerations for additional information on people who are moderately and severely immunocompromised recommended for an additional doses

Who should NOT get the updated 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 updated 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
- Have ever fainted in association with an injection
- Are pregnant
- Are breastfeeding

How is the updated COVID-19 vaccine by Pfizer-BioNTech given?

COVID-19 vaccine by Pfizer-BioNTech is given as an injection into the muscle.

Has the COVID-19 vaccine by Pfizer-BioNTech been used before?

Millions of people have received a Pfizer-BioNTech COVID-19 vaccine in the United States since it became available starting in mid-December 2020. Also, in clinical trials, approximately 23,000 people ages 12 years and older received at least 1 dose of a Pfizer-BioNTech COVID-19 vaccine (original monovalent).

The updated Pfizer-BioNTech COVID-19 Vaccine is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine (original monovalent) and Pfizer-BioNTech COVID-19 vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

What are the risks of the COVID-19 vaccine by Pfizer-BioNTech?

Side effects that have been reported following administration of a Pfizer-BioNTech COVID-19 vaccine include injection site pain, fatigue, headache, chills, muscle pain joint pain, fever, injection site swelling, and injection site redness. 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 have rarely been reported in some people. Cases have occurred predominantly in adolescents and young adult males within the first week following vaccination. Anaphylaxis (severe allergic reaction to the vaccine) has been rarely observed following COVID-19 vaccines. These types of allergic reactions can rarely occur with any kind of vaccine or medical product.

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.

What are the benefits of the COVID-19 vaccine by Pfizer-BioNTech?

The COVID-19 vaccine by Pfizer-BioNTech has been shown in multiple studies to be effective in preventing severe illness and death from COVID-19. Additional doses of the updated COVID-19 vaccine by Pfizer-BioNTech as described under EUI may help to increase immune response in people who are moderately or severely immunocompromised, which could improve protection against COVID-19. The updated COVID-19 vaccine by Pfizer-BioNTech may not protect everyone.

What are the Risks and Benefits of the updated COVID-19 vaccine by Pfizer-BioNTech?
The FDA approved Pfizer-BioNTech COVID-19 vaccines to prevent COVID-19 based on safety and efficacy data available from clinical trials. Based on available information, the use of the updated 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 vaccination, and as such the known and potential benefits of vaccination outweigh the known and potential risks of the vaccine.

What alternative choices are available for additional doses other than the COVID-19 vaccine by Pfizer-BioNTech?
Currently, the updated Pfizer-BioNTech COVID-19 vaccine (Comirnaty) and updated Moderna COVID-19 vaccine (Spikevax) are the only FDA-approved COVID-19 vaccines for which EUI provide information about additional doses for people who are moderately or severely immunocompromised.

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

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.