Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: 2024–2025 COVID-19 Vaccine 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 2024–2025 COVID-19 vaccine by Pfizer-BioNTech (Comirnaty) that go beyond its FDA-approved labeling. These uses under EUI are for doses for people ages 65 years and older and people ages 12 years and older who are moderately or severely immunocompromised. See below for more information on the uses of the 2024–2025 COVID-19 vaccine by Pfizer-BioNTech under EUI.

If you are 12 years and older, you have a choice of receiving the 2024–2025 COVID-19 Formula vaccine by Pfizer-BioNTech, Moderna (see the Moderna EUI Fact Sheet for Recipients and Caregivers), or Novavax (see the Interim Clinical Considerations or Novavax Emergency Use Authorization [EUA] Fact Sheet).

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 2024–2025 COVID-19 vaccine by Pfizer-BioNTech?
The 2024–2025 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 2024–2025 COVID-19 vaccine by Pfizer-BioNTech under the 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 also 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 2024–2025 COVID-19 vaccine by Pfizer-BioNTech under the EUI?
People who can receive additional doses of the 2024–2025 COVID-19 vaccine by Pfizer-BioNTech under EUI are described below.

- People ages 12 years and older who are moderately or severely immunocompromised should receive a second dose of 2024-2025 COVID-19 vaccine 6 months after their first dose (minimum interval 2 months). Additional doses can be considered in consultation with a healthcare provider. If previously unvaccinated or receiving initial vaccination series, at least two doses of 2024-2025 vaccine are recommended and depending on vaccination history more may be needed.
- People ages 65 years and older should receive a second dose of 2024-2025 COVID-19 vaccine 6 months after their first dose (minimum interval 2 months), except for adults ages 65 years and older who have never been vaccinated against COVID-19 and receive a 2024-2025 Novavax initial series. Those adults should receive a third dose of any age-appropriate 2024-2025 COVID-19 vaccine 6 months after their second dose of 2024-2025 Novavax vaccine (minimum interval 2 months).

The 2024–2025 COVID-19 vaccine by Moderna can also be used under EUI for the same uses in persons ages 12 years and older as an alternative 2024–2025 mRNA COVID-19 vaccine (see the Moderna EUI Fact

Sheet for Recipients). In addition, the 2024–2025 COVID-19 vaccine by Novavax is authorized under EUA for persons ages 12 years and older (see the Interim Clinical Considerations or the Novavax EUA Fact Sheet).

Talk to your healthcare provider about if and when you should receive additional COVID-19 vaccine doses. See CDC's Interim Clinical Considerations for additional information.

Who should NOT get the 2024–2025 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 or Moderna
- Had a severe allergic reaction to any ingredient of the COVID-19 vaccine by Pfizer-BioNTech or Moderna

What should I mention to the vaccination provider before getting the 2024–2025 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
- Are breastfeeding
- Have ever received another COVID-19 vaccine
- Have ever fainted in association with an injection

How is the 2024–2025 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 2024-2025 Pfizer-BioNTech COVID-19 Vaccine is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine (original monovalent), Pfizer-BioNTech COVID-19 vaccine (Bivalent), and Pfizer BioNTech COVID-19 vaccine (2023-2024 Formula), but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage KP.2 (Omicron KP.2).

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. Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. This risk has been observed most frequently in adolescent and young adult males. The chance of this occurring is low. Anaphylaxis (severe allergic reaction to the vaccine) has been rarely observed following COVID-19 vaccines. Allergic reactions can rarely occur with any kind of vaccine or medical

product. Fainting (syncope), which may be associated with injury, may occur in association with administration of injectable vaccines, including Pfizer-BioNTech COVID-19 vaccine.

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 2024–2025 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 2024–2025 COVID-19 vaccine by Pfizer-BioNTech may not protect everyone.

What are the risks and benefits of the 2024–2025 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 2024–2025 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 2024–2025 Pfizer-BioNTech COVID-19 vaccine (Comirnaty) and 2024–2025 Moderna COVID-19 vaccine (Spikevax) are the only FDA-approved COVID-19 vaccines for which EUI provide information about additional doses for people ages 65 years and older or who are moderately or severely immunocompromised. The 2024–2025 Novavax COVID-19 vaccine is also available under EUA for individuals 12 years of age and older (see the Novavax EUA Fact Sheet). See the Interim Clinical Considerations for recommendations regarding the use of Novavax COVID-19 vaccine for persons who are ages 65 years and older or moderately or severely immunocompromised.

It is your choice to receive or not receive the 2024–2025 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/covid/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.