

## **Emergency Use Instructions (EUI) Fact Sheet for Recipients and Caregivers: Pfizer-BioNTech COVID-19 Vaccine for Primary, Additional, and/or Booster Doses**

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 the primary, additional, and booster doses of the COVID-19 vaccine by Pfizer-BioNTech that go beyond its FDA-approved labeling. These uses under EUI include, but are not limited to, longer interval between primary doses of the COVID-19 vaccine by Pfizer-BioNTech, use in certain individuals who received primary vaccination with certain COVID-19 vaccines not authorized or approved by the Food and Drug Administration (FDA) for such use and in immunocompromised individuals who received one primary dose of the Janssen COVID-19 Vaccine. See below for more information on the uses of the COVID-19 vaccine by Pfizer-BioNTech under EUI.

mRNA vaccines are preferred for persons with moderate or severe immune compromise. If you are 18 years and older and you are receiving vaccination for uses provided under EUI, you have a choice of receiving the COVID-19 vaccine by either Pfizer-BioNTech or Moderna (see the [Moderna EUI Fact Sheet for Recipients and Caregivers](#)). Persons 12–17 years of age should only receive the COVID-19 vaccine by Pfizer-BioNTech.

### **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 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 ages 16 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 primary, additional, and/or booster dose(s) of the COVID-19 vaccine by Pfizer-BioNTech under the EUI?”). The COVID-19 vaccine by Moderna can also be used under EUI for similar uses in persons ages 18 years and older 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 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 primary, additional, and/or booster dose(s) of the COVID-19 vaccine by Pfizer-BioNTech under the EUI?**

People who can receive the COVID-19 vaccine by Pfizer-BioNTech under EUI are described below.

- People ages 12 years and older, especially those at higher risk of myocarditis associated with mRNA COVID-19 vaccines, may receive the second primary dose of the COVID-19 vaccine by Pfizer-BioNTech 3–8 weeks after the first primary dose. The second dose should not be received earlier than 3 weeks after the first dose.

- People ages 12 years and older who recently had SARS-CoV-2 infection may receive a second primary dose after a deferral period of 3 months from symptom onset or positive test (if infection was asymptomatic)
- People ages 12 years and older who received an incomplete primary dose series (only the first dose of a 2-dose primary series) with certain non-FDA authorized or approved COVID-19 vaccines at least 28 days ago should receive a primary dose of the COVID-19 vaccine by Pfizer-BioNTech to complete the series.
- People ages 12 years and older who are not immunocompromised and completed their primary vaccination with mRNA COVID-19 vaccine or primary vaccination that included certain non-FDA authorized or approved COVID-19 vaccines should receive a booster dose of the COVID-19 vaccine by Pfizer-BioNTech at least 5 months after completion of primary vaccination.
- People ages 18–49 years who received a primary dose and booster dose of the Janssen COVID-19 Vaccine should receive a second booster dose of the COVID-19 vaccine by Pfizer-BioNTech at least 4 months after the previous booster dose. A second booster dose for people ages 50 years and older is authorized under EUA.
- For people who are moderately or severely immunocompromised:
  - People ages 12 years and older who are moderately or severely immunocompromised and completed their primary vaccination with mRNA COVID-19 vaccine or primary vaccination that included certain non-FDA authorized or approved COVID-19 vaccines should receive a booster dose of the COVID-19 vaccine by Pfizer-BioNTech at least 3 months after completion of primary vaccination.
  - People ages 12 years and older who are moderately or severely immunocompromised and received their primary vaccination with certain non-FDA authorized or approved COVID-19 vaccines at least 28 days ago should receive an additional (third) primary dose of the COVID-19 vaccine by Pfizer-BioNTech.
  - People ages 18 years and older with a moderately or severely immunocompromising condition who received a primary dose of the Janssen COVID-19 Vaccine should receive an additional dose with the COVID-19 vaccine by Pfizer-BioNTech at least 28 days after receiving the Janssen COVID-19 Vaccine primary dose. People who already received a booster dose with an authorized COVID-19 vaccine after receiving the Janssen COVID-19 Vaccine primary dose should receive an additional dose with the COVID-19 vaccine by Pfizer-BioNTech at least 2 months after the booster dose.
  - People ages 12 years and older with a moderately or severely immunocompromising condition who received dose(s) of COVID-19 vaccine prior to or during certain therapies (indicated below) should be revaccinated with the COVID-19 vaccine by Pfizer-BioNTech, regardless of which vaccine was received initially.
    - Received COVID-19 vaccine dose(s) during treatment with B-cell-depleting therapies over a limited period: the suggested interval to start revaccination is about 6 months after completion of the B-cell-depleting therapy
    - Received COVID-19 vaccine dose(s) prior to or during treatment with hematopoietic cell transplant (HCT) or chimeric antigen receptor (CAR)-T-cell therapy: revaccination at least 3 months after treatment

The COVID-19 vaccine by Moderna can also be used under EUI for similar uses in persons ages 18 years and older as an alternative mRNA COVID-19 vaccine (see the [Moderna EUI Fact Sheet for Recipients](#)).

Talk to your healthcare provider about if and when you should receive a primary, additional, and/or a 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 NOT 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
- have ever fainted in association with an injection

### **How is the 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?**

Yes. Millions of people have received this 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 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 or Janssen 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, or as an additional primary or second booster dose for individuals who received Janssen COVID-19 Vaccine for primary vaccination. 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, arm pain, 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 have rarely been reported in some people. Cases have occurred predominantly in adolescents and young adult males within the first week after the second dose of 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](#) 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. Receiving the second primary dose of the COVID-19 vaccine by Pfizer-BioNTech 3–8 weeks after the first dose may reduce the risk of myocarditis and result in greater immune response and better protection against COVID-19. Primary, additional, and/or booster doses of the COVID-19 vaccine by Pfizer-BioNTech as described under EUI may help to increase immune response in people, which could improve protection against COVID-19. Similarly, for individuals who received the Janssen vaccine for primary vaccination, an additional primary or second booster dose of the COVID-19 vaccine by Pfizer-BioNTech

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 the 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 primary or a 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 primary, additional, and/or booster doses other than the COVID-19 vaccine by Pfizer-BioNTech?**

Currently, the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine are the only FDA-approved COVID-19 vaccines for which EUI provide information about primary, additional, and/or booster doses following the COVID-19 vaccine that you received. If vaccinated outside of the United States or through a clinical trial and the COVID-19 vaccine you initially received for primary vaccination is not authorized or approved in the United States, then the vaccine you initially received may not be available to you.

It is your choice to receive or not receive the COVID-19 vaccine by Pfizer-BioNTech as a primary, additional, and/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 a primary, additional, or a 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/](http://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.

To allow medical care provider(s) accurate immunization status information, an immunization assessment, and a recommended schedule for future immunizations, information will be sent to the Michigan Care Improvement Registry. Individuals have the right to request that their medical care provider not forward immunization information to the Registry.

The mRNA vaccines (those by Pfizer and Moderna) did not use a fetal cell line to produce or manufacture the vaccine. However, a fetal cell line was used in a very early phase to confirm efficacy prior to production and manufacturing.