VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 12 YEARS OF AGE AND OLDER

FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine authorized for Emergency Use Authorization (EUA) for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.[1]

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- **a 2-dose primary series to individuals 12 through 15 years of age;**
- **a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise;**
- **a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA);**
- **a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series;**
- **a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and**

[1] When prepared according to their respective instructions for use, the FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older can be used interchangeably without presenting any safety or effectiveness concerns.

- **a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.**

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- **a 2-dose primary series to individuals 12 years of age and older;**
- **a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise;**
- **a first booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA);**
- **a first booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The booster schedule is based on the labeling information of the vaccine used for the primary series;**
- **a second booster dose to individuals 50 years of age and older who have received a first booster dose of any authorized or approved COVID-19 vaccine; and**
- **a second booster dose to individuals 12 years of age and older with certain kinds of immunocompromise and who have received a first booster dose of any authorized or approved COVID-19 vaccine.**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

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 had a wide range of symptoms reported, ranging from mild 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.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, when prepared according to their respective instructions for use, can be used interchangeably.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?

Tell the vaccination provider about 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 received another COVID-19 vaccine
- have ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals with certain kinds of immunocompromise.

Booster Dose:

- A first booster dose of the vaccine may be administered at least 5 months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA) to individuals 12 years of age and older.

- A first booster dose of the vaccine may be administered to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. Please check with your healthcare provider regarding timing of the booster dose.
- A second booster dose of the vaccine may be administered to individuals 50 years of age and older at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine.
- A second booster dose of the vaccine may be administered at least 4 months after receipt of a first booster dose of any authorized or approved COVID-19 vaccine to individuals 12 years of age and older with certain kinds of immunocompromise.

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?
You should not get the vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINES?
COMIRNATY (COVID-19 Vaccine, mRNA) and the authorized formulations of the vaccine include the following ingredients:
- mRNA and lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol).

Pfizer-BioNTech COVID-19 vaccines for individuals 12 years of age and older contain 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:
- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR
- tromethamine, tromethamine hydrochloride, and sucrose

COMIRNATY (COVID-19 Vaccine, mRNA) contains 1 of the following sets of additional ingredients; ask the vaccination provider which version is being administered:
- potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

OR
- tromethamine, tromethamine hydrochloride, and sucrose

HAS THE VACCINE BEEN USED BEFORE?
Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccines and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020. The vaccine that is

authorized for use in individuals 12 years of age and older includes two formulations; one that was studied in clinical trials and used under EUA, and one with the same mRNA and lipids but different inactive ingredients. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be administered without dilution.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine, more commonly in males under 40 years of age than among females and older males. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Another choice for preventing COVID-19 is SPIKEVAX, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third primary series dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, after you received a first booster dose, you may receive a second booster dose of the vaccine if you are 12 years of age or older. Your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

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.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

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.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Pfizer

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LAB-1451-17.3d

Revised: 29 March 2022

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.

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000332

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, including but 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.

If you are 12 years and older, you may receive the second dose of the COVID-19 vaccine by Pfizer-BioNTech 3–8 weeks after the first dose. If you are 12 years and older and received primary vaccination with **certain** COVID-19 vaccines **not authorized or approved** by the FDA, you may be eligible for the COVID-19 vaccine by Pfizer-BioNTech as a primary dose, additional dose, and/or a booster dose. For example, if you were vaccinated outside the United States or from clinical trial participation (and received vaccines that have not received FDA approval or authorization such as the AstraZeneca COVID-19 vaccine, the Novavax COVID-19 vaccine, or the Sinopharm COVID-19 vaccine), you may be eligible to receive a primary dose, additional dose, and/or a booster dose. If you are 18 years and older with an immunocompromising condition and you received the Janssen COVID-19 Vaccine as your first dose, you may also be eligible to receive an additional dose of the COVID-19 vaccine by Pfizer-BioNTech. If you are 12 years and older with a moderately or severely immunocompromising condition and received certain therapies (hematopoietic cell transplant (HCT) or CAR-T-cell therapy) and received dose(s) of COVID-19 vaccine prior to or during treatment, you may be eligible to be revaccinated with the COVID-19 vaccine by Pfizer-BioNTech.

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.

See below for more information under "Who can receive a primary, additional, and/or booster dose(s) of the COVID-19 vaccine by Pfizer-BioNTech under the EUI".

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. 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. The uses of the COVID-19 vaccine by Pfizer-BioNTech permitted under EUI are:

- In persons ages 12 years and older as a second primary dose 3–8 weeks after the first primary dose, especially those at higher risk of myocarditis associated with mRNA COVID-19 vaccines.

- In persons ages 12 years and older as an additional (third) primary dose in those with certain immunocompromising conditions, a primary dose in those with incomplete primary dose series, and/or a booster dose after receiving certain **non-FDA authorized or approved** COVID-19 vaccines (for example, certain vaccines available outside of the United States or vaccines used in clinical trials).
- In persons 18–49 years of age without certain immunocompromising conditions as a second booster dose after receiving both a primary dose and first booster dose with the Janssen COVID-19 Vaccine.
- In persons ages 18 years and older with certain immunocompromising conditions as an additional dose after receiving primary vaccination with the Janssen COVID-19 Vaccine.
- In persons ages 12 years and older with a moderately or severely immunocompromising condition who received dose(s) of COVID-19 vaccine prior to or during treatment with certain therapies (HCT or CAR-T-cell therapy) as revaccination dose(s) with the COVID-19 vaccine by Pfizer-BioNTech, regardless of which vaccine was received initially.

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, 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, 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 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 may 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 (HCT or CAR-T-cell therapy) should be revaccinated with the COVID-19 vaccine by Pfizer-BioNTech, regardless of which vaccine was received initially, 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 dose for immunocompromised 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 immunocompromised individuals who received the Janssen vaccine for primary vaccination, an additional 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?
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. 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.

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/ 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.

Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you or your dependent feel after getting a COVID-19 vaccine. It takes just a few minutes to enroll and your participation in **v-safe** helps us monitor the safety of COVID-19 vaccines for everyone.

v-safe℠
after vaccination health checker

V-safe features:

- **Enroll your dependents** and complete check-ins on their behalf
- **Enter** and report how you feel after **first, second, additional, and booster doses**

How can I enroll and how does it work?

You can enroll in **v-safe** after any dose of COVID-19 vaccine by using your smartphone and going to vsafe.cdc.gov.

During the first week after each vaccination, **v-safe** will send you a text message each day to ask how you are feeling. After that, you will receive occasional check-ins, which you can opt out of at any time. Depending on your answers, someone from CDC may call to get more information. Your personal information in **v-safe** is protected so it's safe and private*.

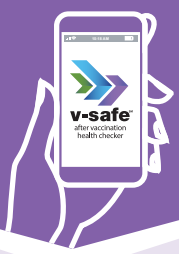
How can I enroll my dependent?

You can enroll any family member (or friend) who is eligible to be vaccinated in **v-safe.** Children under 16 years old must be enrolled using a parent or guardian's **v-safe** account. You can add a dependent to your existing account or create a new account if you don't have one yet. Creating an account to enroll a dependent does not require that you enter your own vaccination information or complete health check-ins for yourself.

Need step-by-step instructions? Go to: www.cdc.gov/vsafe

Sign up with your smartphone's browser at vsafe.cdc.gov

Share with your friends and CDC that you are using v-safe! Post a selfie and use the hashtag #BeSafeVSafe



Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

*__v-safe__ uses existing information systems managed by CDC, FDA, and other federal agencies. These systems use strict security measures to keep information confidential. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

CS324195-A 12/22/2021