FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 6 MONTHS THROUGH 4 YEARS OF AGE

FOR 6 MONTHS THROUGH 4 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine[1] or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent[2] to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

The Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide a 3-dose primary series to individuals 6 months through 4 years of age as follows:[3,4]

Dose 1: Pfizer-BioNTech COVID-19 Vaccine
Dose 2: Pfizer-BioNTech COVID-19 Vaccine
Dose 3: Pfizer-BioNTech COVID-19 Vaccine, Bivalent

This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's 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 YOUR CHILD GETS ANY OF THESE VACCINES

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

[1] The Pfizer-BioNTech COVID-19 Vaccine, a monovalent vaccine, encodes the spike protein of only the Original SARS-CoV-2.
[2] The Pfizer-BioNTech COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.
[3] If your child will turn 5 years of age in the next 11 weeks and has not started their primary series, your child may receive either: (1) a 3-dose primary series as described in this Fact Sheet; or (2) a 2-dose primary series with the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 years through 11 years of age. Please discuss the options with your provider.
[4] You may receive this Fact Sheet if your child is 5 years old and previously received a dose of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 6 months through 4 years of age. Your child may complete the 3-dose primary series as described in this Fact Sheet.

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.

HOW ARE THE PFIZER-BIONTECH COVID-19 VACCINE AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT RELATED?
The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine but it also contains an Omicron component to help prevent COVID-19 caused by the Omicron variant of SARS-CoV-2.

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 CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS ANY OF THESE VACCINES?
Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW ARE THESE VACCINES GIVEN?
The Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, will be given to your child as an injection into the muscle.

The complete primary series consists of 3 doses administered over at least 11 weeks:

- The Pfizer-BioNTech COVID-19 Vaccine is given for the initial 2 doses, which are administered 3 weeks apart.
- The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is given as the third dose, which is administered at least 8 weeks after the second dose.

The vaccine may not protect everyone.

WHO SHOULD <u>NOT</u> GET THE PFIZER-BIONTECH COVID-19 VACCINE OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Your child should not get any of these vaccines if your child:

- had a severe allergic reaction after a previous dose of the Pfizer-BioNTech COVID-19 Vaccine
- had a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THESE VACCINES?

The Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent include the following ingredients: mRNA, 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), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAVE THESE VACCINES BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA. In a clinical trial, approximately 1,200 individuals 6 months through 23 months of age, approximately 1,800 individuals 2 through 4 years of age, and approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In another clinical trial, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

Millions of individuals 5 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent under EUA. In a clinical trial, approximately 300 individuals greater than 55 years of age received 1 dose of a bivalent vaccine that differs from the Pfizer-BioNTech COVID-19 Vaccine, Bivalent in that it contains a different Omicron component.

WHAT ARE THE BENEFITS OF THESE VACCINES?

The Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19. FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide better protection against COVID-19 caused by the Omicron variant of SARS-CoV-2.

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

WHAT ARE THE RISKS OF THESE VACCINES?

There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the 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 Pfizer-BioNTech COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. In most of these people, symptoms began within a few days following

vaccination. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, particularly during the 2 weeks after your child receives a dose of either vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart
- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported with these vaccines 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/tenderness
- 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
- Dizziness
- Irritability

These may not be all the possible side effects of these vaccines. Serious and unexpected side effects may occur. The possible side effects of these vaccines are still being studied.

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

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 "Pfizer-BioNTech COVID-19 Vaccine EUA" or "Pfizer-BioNTech COVID-19 Vaccine, Bivalent EUA" 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 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 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Under the EUA, there is an option to accept or refuse receiving any of these vaccines. Should you decide for your child not to receive any of these vaccines, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Other vaccines to prevent COVID-19 may be available under EUA.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent at the same time with other vaccines. If you are considering having your child receive the Pfizer-BioNTech COVID-19 Vaccine or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent with other vaccines, discuss the options with your child's healthcare provider.

WILL THESE VACCINES GIVE MY CHILD COVID-19?
No. These vaccines do not contain SARS-CoV-2 and cannot give your child COVID-19.

KEEP YOUR CHILD'S VACCINATION CARD
When your child gets the first COVID-19 vaccine, you will get a vaccination card. Remember to bring the card when your child returns.

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 CHILD'S VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. 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 THESE COVID-19 VACCINES?
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 these vaccines. 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 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. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the 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 during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

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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.

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