PFIZER

Prevaccination Checklist for COVID-19 Vaccination

Please complete before seeing provider.

Name _____

For vaccine recipients (both children and adults):

The following questions will help us determine if there is any reason COVID-19 vaccine cannot be given today. **If you answer "yes" to any question, it does not necessarily mean the vaccine cannot be given.** It just means additional questions may be asked. If a question is not clear, please ask the healthcare provider to explain it.

	Yes	No	Don't know
1. How old is the person to be vaccinated? _____			
2. Is the person to be vaccinated sick today?	☐	☐	☐
3. Has the person to be vaccinated ever received a dose of COVID-19 vaccine?	☐	☐	☐
• If yes, which vaccine product was administered? ☐ Pfizer-BioNTech ☐ Janssen *(Johnson & Johnson)* ☐ Another Product ☐ Moderna ☐ Novavax _____			
• How many doses of COVID-19 vaccine were administered? _____			
• Did you bring the vaccination record card or other documentation?	☐	☐	
4. Does the person to be vaccinated have a health condition or is undergoing treatment that makes them moderately or severely immunocompromised? *This would include, but not be limited to, treatment for cancer, HIV, receipt of organ transplant, immunosuppressive therapy or high-dose corticosteroids, CAR-T-cell therapy, hematopoietic cell transplant [HCT], or moderate or severe primary immunodeficiency.*	☐	☐	☐
5. Has the person to be vaccinated received COVID-19 vaccine before or during hematopoietic cell transplant (HCT) or CAR-T-cell therapies?	☐	☐	☐
6. Has the person to be vaccinated ever had an allergic reaction to: *(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)*			
• A component of a COVID-19 vaccine	☐	☐	☐
• A previous dose of COVID-19 vaccine	☐	☐	☐
7. Has the person to be vaccinated ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? *(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)*	☐	☐	☐

8. Check all that apply to the person to be vaccinated:

- ☐ Have a history of myocarditis or pericarditis
- ☐ Have a history of Multisystem Inflammatory Syndrome (MIS-C or MIS-A)?
- ☐ History of an immune-mediated syndrome defined by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)
- ☐ Have a history of thrombosis with thrombocytopenia syndrome (TTS)
- ☐ Have a history of Guillain-Barré Syndrome (GBS)
- ☐ Have a history of COVID-19 disease within the past 3 months?
- ☐ Vaccinated with monkeypox vaccine in the last 4 weeks?

Form reviewed by _____ **Date** _____

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

You or your child is being offered the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to prevent coronavirus disease 2019 (COVID-19) which is caused by the virus SARS-CoV-2. This fact sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent which you or your child 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.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Pfizer-BioNTech COVID-19 Vaccine, Bivalent available during the COVID-19 pandemic (for more details about an EUA please see "**WHAT IS AN EMERGENCY USE AUTHORIZATION?**" at the end of this document). The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close 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 THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a vaccine for use in individuals 6 months of age and older to prevent COVID-19[1]. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent under an EUA.

The Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect everyone.

[1] 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.

WHAT SHOULD YOU MENTION TO THE VACCINATION PROVIDER BEFORE YOU OR YOUR CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

Tell the vaccination provider about all your or your child's medical conditions, including if you or your child:

- 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 or your child's 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, Bivalent is given as an injection into the muscle.

Individuals 6 months through 4 years of age:

- **Unvaccinated individuals[2]:** Three doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are administered over at least 11 weeks. The first two doses are administered three weeks apart. The third dose is administered at least 8 weeks after the second dose.
- **Individuals who have received one dose of the monovalent[3] Pfizer-BioNTech COVID-19 Vaccine:** Two doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are administered. The first dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is given three weeks after the monovalent Pfizer-BioNTech COVID-19 Vaccine and the second dose at least 8 weeks later.
- **Individuals who have received two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine:** A single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered at least 8 weeks after the monovalent Pfizer-BioNTech COVID-19 Vaccine.
- **Individuals who have received three doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine:** A single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered at least 2 months after the monovalent Pfizer-BioNTech COVID-19 Vaccine.

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[2] If your child will turn 5 years old in the next 11 weeks and has not started their vaccination series, please discuss the options with your provider.

[3] The Pfizer-BioNTech COVID-19 Vaccine, a monovalent vaccine, encodes the spike protein of only the Original SARS-CoV-2.

Individuals 5 years of age and older:

- **Unvaccinated individuals:** A single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- **Individuals who have received one or more doses of a monovalent COVID-19 vaccine[4]:** A single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered at least 2 months after any monovalent COVID-19 vaccine.
- **Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine:** A dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 4 months after the dose of the bivalent COVID-19 vaccine.
- **Immunocompromised individuals 5 years of age and older who have received one dose of a bivalent COVID-19 vaccine**: An additional dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the dose of the bivalent COVID-19 vaccine; additional doses may be administered at the discretion of the healthcare provider.

WHO SHOULD NOT GET PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

A person should not get Pfizer-BioNTech COVID-19 Vaccine, Bivalent if they had:

- a severe allergic reaction after a previous dose of Pfizer-BioNTech COVID-19 Vaccine, Pfizer-BioNTech COVID-19 Vaccine, Bivalent, or COMIRNATY (COVID-19 Vaccine, mRNA)[5]
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

Pfizer-BioNTech COVID-19 Vaccine, Bivalent contains the following ingredients: messenger ribonucleic acid (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, and sucrose. Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 6 months through 11 years of age also contains sodium chloride.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent under EUA. In clinical trials, 60 individuals 6 months through 4 years of age, 113 individuals 5 through 11 years of age, 107 individuals 12 through 17 years of age, 103 individuals 18 through 55 years of age, and 106 individuals greater than 55 years of age received a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

In addition, millions of individuals 6 months of age and older have received the monovalent Pfizer-BioNTech COVID-19 Vaccine under EUA. In a clinical trial,

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[4] Monovalent refers to a COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

[5] COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine. COMIRNATY encodes the spike protein of only the Original SARS-CoV-2.

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.

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.

WHAT ARE THE BENEFITS OF PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to provide protection against COVID-19.

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

WHAT ARE THE RISKS OF PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

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 one hour after getting a dose. For this reason, the vaccination provider may ask you or your child to stay at the place where you or 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, Bivalent, the Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA), more commonly in adolescent males and adult males under 40 years of age than among females and older males. 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 you or your child have any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after you or 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

Additional symptoms, particularly in children, may include:

- 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 Pfizer-BioNTech COVID-19 Vaccine, Bivalent, Pfizer-BioNTech COVID-19 Vaccine, or COMIRNATY (COVID-19 Vaccine, mRNA) 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. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you or your child experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your or your child's healthcare provider if you or your child have any side effects that bother you or 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, 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 GET OR NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for yourself or your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?
Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2. COMIRNATY and SPIKEVAX (COVID-19 Vaccine, mRNA) are FDA-approved monovalent COVID-19 vaccines.

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

WHAT IF I AM, OR MY CHILD IS, IMMUNOCOMPROMISED?
Immunocompromised individuals 5 years of age and older may receive one or more additional doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, you or your child should continue to maintain physical precautions to help prevent COVID-19. Your close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If you are, or your child is, pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THIS VACCINE GIVE ME OR MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give you or your child COVID-19.

KEEP THE VACCINATION CARD
When you, or your child, receive the first COVID-19 vaccine, you will get a vaccination card. Remember to bring the card if you or your child receive additional doses.

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 VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your or 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 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)?

The FDA has made Pfizer-BioNTech COVID-19 Vaccine, Bivalent available under an emergency access mechanism called an EUA. 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 under EUA during the COVID-19 pandemic.

The 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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