

Cherokee Nation Health Services

Registration and Consent for COVID-19 Vaccine and/or Influenza Vaccine

Please fill out completely and print clearly

Name: Last _____ First _____ M.I. _____ Other Names Used: _____

Sex: M F Date of Birth: _____ Marital Status: (Circle One): Single Married Divorced Widowed

Social Security Number: _____ Tribe of Membership: _____ Tribal #: _____

Mother's Maiden Name _____ Father's Name _____

Home Phone: _____ Alternate Phone: _____

Currently Mailing Address: _____ City: _____ State: _____ Zip: _____

If child is not a member of a federally recognized tribe, is child living in home with step parent, foster parent, adoptive parent, or guardian who is a member of a federally recognized tribe? Y or N

Medicaid/SoonerCare #: _____ Medicare #: _____

Name of Insurance Carrier: _____

Address of Insurance Company: _____ Insurance Phone #: _____

Policy # _____ Group #: _____ Effective/Beginning Date of Policy: _____

Policyholder Name: _____ Policyholder Date of Birth: ____/____/____

Policyholder's Address: _____ City: _____ State: _____ Zip: _____

Employer Name and Address: _____

Patient Portal Registration: All Patients may have access to their medical records online through the Patient Portal. Patients Age 0-12 require use of parents' email address. Patients Age 13-17 may sign-up for the Patient Portal using minor's own email address. For Age 13-17: Patient Portal Proxy Form must be completed if granting Parent/Guardianship Access.

Patient Portal Preferred Email Address: _____

Consent and Acknowledgement

I understand that the information given by me or collected is necessary for Cherokee Nation Health Services (CNHS) to provide for my health wellbeing. I understand CNHS will seek payment from any medical program that I might be eligible to participate in or from any liable third party and I assign to CNHS all benefits for services rendered by CNHS. I understand that CNHS may verify the information necessary to process the claim.

_____ I consent to receive the Influenza vaccination for myself or as the parent/legal guardian of the above patient.

_____ I consent to receive the COVID-19 vaccination for myself or as the parent/legal guardian of the above patient and have been provided the Emergency Use Authorization (EUA) Fact Sheet or Vaccine Information Statement (VIS). I have had the opportunity to read, discuss the information, and to ask questions regarding COVID-19, the COVID-19 vaccine, and the associated risks and benefits.

I am directing CNHS to disclose my/my child's COVID-19 vaccine administration information to the Centers for Disease Control and Prevention (CDC) through the Indian Health Service National Data Warehouse to the CDC IZ clearinghouse for mandatory COVID-19 vaccine reporting purposes.

I agree for myself or my child to be monitored for 15-30 minutes after COVID-19 vaccination. I understand the risks associated with not being monitored which include, but are not limited to, severe allergic reaction, fainting or loss of consciousness, motor vehicle crash, and death.

For vaccination of minors, please select one:

_____ My child's COVID-19 and/or Influenza immunization can be done **WITHOUT MY PRESENCE**.

_____ My child's COVID-19 and/or Influenza immunization can **ONLY** be done **WITH MY PRESENCE**.

Patient/Guardian's Signature: _____ Date _____ Time _____

CNH-NUR-123-DC (10/2021)

CNHS COVID-19 Vaccination Pre-Screening and Administration Tool

Comment

Patient Name:		Age:	
Have you ever received a dose of COVID-19 vaccine?		Yes	No
If yes, which vaccine product did you receive? <input type="checkbox"/> Pfizer <input type="checkbox"/> Janssen <input type="checkbox"/> Novavax <input type="checkbox"/> Moderna <input type="checkbox"/> Another product _____		Last Dose Received: <input type="checkbox"/> 1st Dose <input type="checkbox"/> 3rd Dose <input type="checkbox"/> 2nd Dose <input type="checkbox"/> Booster Dose	
Are you feeling sick today?		Yes	No
Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised? <i>(Includes, but not 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)</i>		Yes	No
Have you received COVID-19 vaccine before or during hematopoietic cell transplant (HCT) or CAR-T-cell therapies?		Yes	No
Do any of the following apply to you: <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> History of myocarditis or pericarditis <small>(optimal interval 8 weeks for 2nd dose)</small> <input type="checkbox"/> History of Multisystem Inflammatory Syndrome (MIS-C or MIS-A) <input type="checkbox"/> History of an immune-mediated syndrome defined by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT) </div> <div> <input type="checkbox"/> History of thrombosis with thrombocytopenia syndrome (TTS) <input type="checkbox"/> History of Guillain-Barré Syndrome (GBS) <input type="checkbox"/> History of COVID-19 disease within the past 3 months </div> </div>			
Have you ever had an allergic reaction to: <i>(Includes severe allergic reaction [e.g. anaphylaxis]; required treatment with epinephrine or EpiPen; or caused you to go to the hospital. Also includes allergic reaction that caused hives, swelling, respiratory distress or wheezing.)</i> <input type="checkbox"/> A component of the COVID-19 vaccine <input type="checkbox"/> A previous dose of COVID-19 vaccine <input type="checkbox"/> Another vaccine (other than COVID-19) or an injectable medication			

Complete for Booster COVID-19 Dose ONLY

☐ Patient educated; unable to receive Booster Dose

*For Booster COVID-19 Dose: Patient must be ≥ 18 years for Moderna OR ≥ 5 years for Pfizer monovalent booster; OR ≥ 12 years for a Pfizer bivalent booster	
For 5 to 11 years - Patient meets the below criteria for a monovalent mRNA Booster Dose: <input type="checkbox"/> For Immunocompromised - ≥ 3 months after 3rd dose of Pfizer primary series <input type="checkbox"/> ≥ 5 months after 2nd primary dose of Pfizer	For 12 and older - Patient meets the below criteria for a bivalent mRNA Booster Dose: <input type="checkbox"/> ≥ 2 months after completion of any primary series dose

For Immunocompromised- Complete for 3rd Primary or Additional mRNA Dose after Janssen Primary COVID-19 Dose ONLY

*3rd Primary Dose/Additional Dose of COVID-19 Dose: ≥ 6 months for Pfizer or Moderna			
PFIZER: Has it been: for 6 months– 4 yrs ≥ 8 wks after 2nd dose OR for 5 yrs and older ≥ 4 wks after 2nd dose?		Yes	No
MODERNA: Has it been: for 6 months and older ≥ 4 weeks after 2nd dose? OR may receive Pfizer/ Moderna ≥ 4 weeks after receiving a Janssen dose (18 yrs & older)?		Yes	No
If NO: <input type="checkbox"/> Patient educated; unable to receive 3rd Primary Dose		If YES: <input type="checkbox"/> Patient educated; able to receive 3rd Primary Dose	
Reason for 3rd Primary COVID-19 dose: <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Cancer treatment for tumors or cancer of the blood <input type="checkbox"/> Received an organ transplant and are taking medicine to suppress the immune system <input type="checkbox"/> Received a stem cell transplant within the last 2 years <input type="checkbox"/> Moderate or severe primary immunodeficiency </div> <div> <input type="checkbox"/> HIV Infection <input type="checkbox"/> Active treatment with high-dose corticosteroids or other drugs that may suppress immune system <input type="checkbox"/> Patient request; educated re: intended purpose of 3rd Primary Dose </div> </div>			

CNHS COVID-19 Vaccination Pre-Screening and Administration Tool

Name:	NKDA / Allergies:
Date of Birth:	
MRN:	CNHS Employee: YES / NO Location: _____

COVID-19 Vaccination Order (Circle dose to be given):

Pfizer 12 years & older:

- ☐ Pfizer 1st Dose (30mcg/0.3mL)
- ☐ Pfizer 2nd Dose (30mcg/0.3mL)
- ☐ Pfizer 3rd Primary (30mcg/0.3mL)
(Immunocompromised)
- ☐ Pfizer Bivalent Booster (30mcg/0.3mL)

Pfizer 5-11 years:

- ☐ Pfizer 1st Dose (10mcg/0.2mL)
- ☐ Pfizer 2nd Dose (10mcg/0.2mL)
- ☐ Pfizer 3rd Primary (10 mcg/0.2mL)
(Immunocompromised)
- ☐ Pfizer Monovalent Booster (10mcg/0.2mL)

Pfizer 6 months-4 years (3 Primary Required):

- ☐ Pfizer 1st Dose (3 mcg/0.2mL)
- ☐ Pfizer 2nd Dose (3 mcg/0.2mL)
- ☐ Pfizer 3rd Primary (3 mcg/0.2mL)

Moderna 18 years & older:

- ☐ Moderna 1st Dose (100mcg/0.5mL)
- ☐ Moderna 2nd Dose (100mcg/0.5mL)
- ☐ Moderna 3rd Primary (100mcg/0.5mL)
(Immunocompromised)
- ☐ Moderna Bivalent Booster (50mcg/0.5mL)

Moderna 12-17 years:

- ☐ Moderna 1st Dose (100mcg/0.5mL)
- ☐ Moderna 2nd Dose (100mcg/0.5mL)
- ☐ Moderna 3rd Primary (100mcg/0.5mL)
(Immunocompromised)

Moderna 6-11 years:

- ☐ Moderna 1st Dose (50mcg/0.5mL)
- ☐ Moderna 2nd Dose (50mcg/0.5mL)
- ☐ Moderna 3rd Primary (50mcg/0.5mL)
(Immunocompromised)

Moderna 6 months-5 years:

- ☐ Moderna 1st Dose (25mcg/0.25mL)
- ☐ Moderna 2nd Dose (25mcg/0.25mL)
- ☐ Moderna 3rd Primary (25mcg/0.25mL)

Janssen 18 years & older:

- ☐ Janssen 1st Dose

Novavax 12 years & older:

- ☐ Novavax 1st Dose
- ☐ Novavax 2nd Dose

Date of Injection:	Given by:
Time of Injection: _____	
Lot #:	Injection Site:
Manufacturer:	LEFT Deltoid / RIGHT Deltoid
<u>Pfizer-BioNTech</u> / Moderna / Janssen (J&J) / Novavax	Alternate Site:
Expiration:	LEFT Thigh (VL) / RIGHT Thigh (VL)
	*VL= Vastus Lateralis

Non-CN Dose Historical Documentation:

Date(s) of Non-CN Dose(s):	Source of Historical Information:
Location(s) of Non-CN Dose(s):	Immunization Record / Medical Record
	Other:
Manufacturer:	Lot Number(s):
Pfizer-BioNTech / Moderna / Janssen (J&J) / Novavax	

CNHS Influenza Vaccination Pre-Screening and Administration Tool

Comment

Is the person to be vaccinated sick today?	Yes	No	
Does the person to be vaccinated have an allergy to an ingredient of the vaccine?	Yes	No	
Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?	Yes	No	
Has the person to be vaccinated ever had Guillain-Barré syndrome?	Yes	No	

Vaccinator Use Only:

Name: Date of Birth: MRN:	NKDA / Allergies:
CNHS Employee: YES / NO Location: _____	Date of Injection: _____ Time of Injection: _____
Given by:	6-35 months / 36+ months / 65+ years Lot #: Expiration:
Manufacturer:	Injection Site: LEFT Deltoid / RIGHT Deltoid

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza vaccine can prevent influenza (flu).

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant people, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

Influenza vaccine may be given at the same time as other vaccines.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

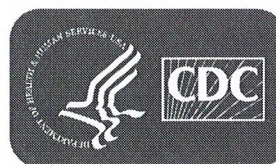
- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. People who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting influenza vaccine.

Your health care provider can give you more information.



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at www.vaers.hhs.gov or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at www.hrsa.gov/vaccinecompensation or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at www.fda.gov/vaccines-blood-biologics/vaccines.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/flu.



**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA), 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 12 YEARS OF AGE AND
OLDER**

FOR 12 YEARS OF AGE AND OLDER

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, 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 the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, and also includes information about the U.S. Food and Drug Administration (FDA)-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 12 years of age and older¹.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine authorized under 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.²

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 12 years of age and older. It is also authorized under EUA to provide:

- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.**

¹ You may receive this Vaccine Information Fact Sheet even if your child is 11 years old. Children who will turn from 11 years to 12 years of age between doses in the primary regimen may receive, for any dose in the primary regimen, either: (1) the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older.

² 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.

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; and
- a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

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

- a single booster dose to individuals 12 years of age and older at least 2 months after completion of primary vaccination with any authorized or approved monovalent³ COVID-19 vaccine; or
- a single booster dose to individuals 12 years of age and older at least 2 months after receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent, 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 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 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 COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, AND THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT RELATED?

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. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is made in the same way as COMIRNATY and Pfizer-BioNTech COVID-19 Vaccine but it also

³ Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

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 VACCINATION PROVIDER BEFORE YOU GET ANY OF THESE VACCINES?

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 ARE THESE VACCINES GIVEN?

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

Primary Series: The Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 Vaccine, mRNA) are given for the 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: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered as a single booster dose at least 2 months after:

- completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

The vaccine may not protect everyone.

WHO SHOULD NOT GET COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

You should not get any of these vaccines if you:

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

WHAT ARE THE INGREDIENTS IN THESE VACCINES?

COMIRNATY (COVID-19 Vaccine, mRNA), Pfizer-BioNTech COVID-19 Vaccine, and Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 Vaccine for individuals 12 years of age and older 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

Pfizer-BioNTech COVID-19 Vaccine, Bivalent for individuals 12 years of age and older contains the following additional ingredients:

- 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

HAVE THESE VACCINES BEEN USED BEFORE?

In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. Millions of individuals have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020.

In a clinical trial, approximately 300 individuals greater than 55 years of age received one 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?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have been shown to prevent COVID-19. FDA has authorized 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 1 hour after getting a dose. 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 COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 Vaccine, 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 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 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
- 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 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 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)”, “Pfizer-BioNTech COVID-19 Vaccine EUA”, or “Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 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), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

Under the EUA, it is your choice to receive or not receive any of these vaccines. Should you decide not to receive any of these vaccines, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA), THE PFIZER-BIONTECH COVID-19 VACCINE, OR THE PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT?

For primary vaccination, another choice for preventing COVID-19 is SPIKEVAX (COVID-19 Vaccine, mRNA), an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2.

CAN I RECEIVE COMIRNATY (COVID-19 VACCINE, mRNA), 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 COMIRNATY (COVID-19 Vaccine, mRNA), 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 receiving COMIRNATY (COVID-19 Vaccine, mRNA), the Pfizer-BioNTech COVID-19 Vaccine, or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent 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 Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 Vaccine, mRNA). Individuals 12 years of age and older may receive a booster dose with Pfizer-BioNTech COVID-19 Vaccine, Bivalent. Vaccinations may 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. 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 THESE VACCINES GIVE ME COVID-19?

No. These vaccines do not contain SARS-CoV-2 and cannot give you COVID-19.


KEEP YOUR VACCINATION CARD

When you get your first COVID-19 vaccine, you will get a vaccination card. 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 of the primary series. 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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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

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