

October 6, 2021



Dear Team Members and Families;

We are excited to announce that the CDC's Advisory Committee for Immunization Practices (ACIP) has finalized recommendations for COVID-19 **Booster Vaccines**. At this time, it is limited to **only the Pfizer COVID-19 vaccine**. St. Paul's Personal Care facilities in collaboration with Walberg Pharmacy can now provide booster doses of the Pfizer COVID-19 Vaccine for Heritage and Ridgewood residents, staff and Colony residents **if you have received both doses of the Pfizer vaccine at least 6 months ago**.

Our plan is to begin offering the booster vaccine to Heritage & Ridgewood residents on **Wednesday, October 20th**. The times will be announced later.

Attached, please find an Informed Consent for the COVID-19 Vaccination Additional Dose/Booster form. IF you have an interest in receiving the booster vaccine, we ask that you **complete and return this consent form by NOON Friday October 15th if you wish to be included in the October 20th clinic**.

We will also need a copy of (1) your vaccination card(s) and (2) your insurance cards, if you have insurance. There is NO COST for the booster vaccine.

This information can be returned in 1 of 4 ways:

- Email to djones@sp1867.org for Heritage residents and staff.
- Email to mchapman@sp1867.org for Ridgewood residents and staff.
- Drop the completed form off at the Heritage receptionist's desk, Attention: Dianna Jones.
- Drop the completed form off at The Ridgewood receptionist's desk, Attention: Mickie Chapman.

Please also refer to the attached **Pfizer Fact Sheet**. The CDC also has information available on its website regarding the Covid-19 Vaccine Booster Shot at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs>.

Individuals may have some side effects, which are normal signs that their bodies are building protection. The most common side effects are pain at the injection site, fever, and chills. These side effects tend to be mild to moderate and go away on their own within 1–2 days.

As a reminder, the best defense against COVID-19 is ensuring that all individuals receive their primary vaccine series. Boosters as well as the primary vaccine series can all be administered. If you have not yet been vaccinated and wish to begin the series, please call to obtain the appropriate consent form.

Please feel free to call with any questions, Dianna Jones @ Heritage 724-589-4601, or Mickie Chapman @ Ridgewood 724-588-9184

**VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS
ABOUT COMIRNATY (COVID-19 VACCINE, mRNA)
AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)**

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).

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.^[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 two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
 - **65 years of age and older**
 - **18 through 64 years of age at high risk of severe COVID-19**
 - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

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

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
 - **65 years of age and older**

^[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- **18 through 64 years of age at high risk of severe COVID-19**
 - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**
-

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 have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.¹

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

¹ The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- 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 vaccine 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 dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

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 VACCINE?

The vaccine includes 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), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, 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 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020.

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 one 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. 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 PFIZER-BIONTECH 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 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, 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
<p data-bbox="323 1398 630 1430">www.cvdvaccine.com</p> 	<p data-bbox="956 1444 1227 1514">1-877-829-2619 (1-877-VAX-CO19)</p>

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 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.



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-9.3

Revised: 22 September 2021



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

Barcode Date: 08/2021



WALBERG FAMILY PHARMACIES VACCINE ADMINISTRATION REPORT

NAME: _____ DOB: _____
 ADDRESS: _____ SEX: _____
 CITY: _____ STATE: _____ ZIP: _____
 PHONE: _____
 EMAIL: _____
 ALLERGIES: _____ PCP: _____

Screening Checklist for COVID-19 Vaccine

PATIENT QUESTIONS-ANSWER THE DAY OF THE VACCINATION

Are you sick today	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Have you ever received a dose of COVID-19 vaccine? If yes, what product?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Have you ever had a severe allergic reaction (e.g. anaphylaxis) in the past? Have you ever used an Epi-Pen due to an allergic reaction?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Was the severe allergic reaction after receiving another vaccine or injectable medication, Polyethylene glycol, polysorbate or a product containing PEG or polysorbate?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Have you received a vaccine in the past 14 days?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Have you received monoclonal antibodies or convalescent plasma as part of a COVID-19 treatment in the past 90 days?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Do you have a bleeding disorder or are you taking a blood thinner?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
For women, are you currently pregnant or breastfeeding?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

If patient is under 18 years of age, parent or legal guardian must be present. Patient must follow up with his/her primary care physician for annual well visit.

Insurance Information:

Rx BIN _____
 ID _____
 Group _____
 PCN _____
 MEDICARE ID OR SSN _____

SIGNATURE/LEGAL GUARDIAN: _____ DATE: _____

NAME (PRINT): _____ PHARMACIST'S SIGNATURE _____

Consent for Services, Medical Records, and HIPAA Privacy Information I have read, or have had read to me, the written information regarding the vaccine(s) being administered. I have had the opportunity to ask questions that were answered to my satisfaction. I understand the benefits and risks of the vaccine(s) being administered and have received a copy of a current Vaccine Information Sheet. I voluntarily assume full responsibility for any reactions that may result. I, on behalf of myself, my heirs, executors, personal representatives, agents, successors, and assigns hereby agree to release, indemnify, and hold harmless Walberg Family Pharmacies its subsidiaries, divisions, affiliates, agents, officers, directors, contractors, and employees from any and all claims arising out of, in connection with, or in any way related to the administration of the vaccine(s). I certify that I am at least 18 years old and hereby give my consent to the pharmacists of this Walberg Family Pharmacies to administer the vaccine(s). If under 18 years old signature by parent or guardian is required. I agree to wait near the vaccination location for approximately 15 minutes for observation by the pharmacist.

VACCINE ADMINISTRATION INFORMATION (Immunizer/Pharmacist Use Only)

Vaccine	Manufacturer	Lot	EXP DATE	Dose & Route	Site	Date of VIS/EUA	Person receiving VIS	Date VIS received	DOSE # (1,2, OR 3)
COVID-19 VACCINE					LD RD				