



## **SILVERADO BELMONT HILLS COVID-19 UPDATE**

*DECEMBER 24, 2020*

Dear Family and Friends,

We continue to wait for an update on the two dates for the vaccine to be given to our associates and residents. Silverado home office has been informed by CVS who we are currently contracted with to provide the COVID-19 Vaccination Clinic Program, that our dates have been pushed into January 2021. COVID-19 is a fluid situation, but I have spoken to San Mateo County Public Health this week and they are still vaccinating at the hospital level and have not started Skilled Nursing Facilities (SNF) yet. Assisted Living/Memory Care communities are immediately after, so we believe we have a little more time. The urgency around the letter sent on 12/17/20 was due to us being advised we would have a vaccine clinic before the end of the year. This now looks unlikely and gives us all more time to gather facts and prepare.

Silverado's home office will be sending out information to all responsible parties to include updated information on the vaccine. I joined a zoom call with representatives from the Family Council this past Monday. They shared some questions which I did not have all the answers to. I forwarded those questions to Kim Butrum, MS, RN, and GNP, who is the Senior Vice President of Clinical Services for Silverado. I believe many responsible parties of residents throughout Silverado Memory Care Communities have similar questions. Many should be answered soon via a letter from our home office. I am adding additional information I have received from Silverado. There is also a link to the CVS website for additional information – see below.

<https://www.omnicare.com/covid-19-vaccine-resource>

The questions surrounding allergies and consent from your physician should be answered soon by the correspondence from our Silverado home office.

Please note the following:

- When I receive the dates of the two vaccine clinics, I will provide this information to all responsible parties.
- We will confirm which vaccine we are given as soon as we know. We believe it will be the Pfizer vaccine, but we cannot confirm at this time.

I will contact any responsible party of a resident who I have not received an email from for a verbal consent yes or no.



You can help me, please if you have not received an email back from me, please send me another one. I don't want any resident to miss our vaccine clinic if you would like them vaccinated. Thank you – I have so many emails...

The vaccine is strictly voluntary. At this time it is not a condition of employment for our associates and is not mandatory for our residents. I honestly do not know about the future and what may be required, but for now there is no requirement.

We continue to test residents and associates for COVID-19. We have not received all test results back. We will notify the responsible party of any resident who receives a negative COVID-19 result. We remain in contact with the Department of Social Services and San Mateo County Public Health Department and are continuing to follow their protocols. Any associate with a positive result would be sent home and quarantined for fourteen days, as well as any resident would be placed in our observation area and monitored for fourteen days.

Many thanks to all the families who have been so generous this holiday season. We have been enjoying lots of wonderful cookies, candies and treats. We thank the families who donated to our Associate Holiday Fund and we will be sending thank you notes specifically to those families from our associates.

We are so fortunate to have such a wonderful group of residents and families. Wishing everyone a very Merry Christmas.

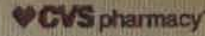
As always, if you have any questions, please feel free to contact me directly.

With Love and Gratitude,

Joan Newman  
Administrator

Email – [joan.newman@silverado.com](mailto:joan.newman@silverado.com)

# COVID Vaccine Intake Consent Form



### Clinic Information

Clinic ID	Clinic Name	Telephone	Store Number
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Address	City	State	Zip
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### Patient Information

Last Name	First Name	Date of Birth	Gender
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Address	City	State	Zip
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Primary Care Provider (PCP) Name	PCP Phone Number	PCP Fax Number
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PCP Address	City	State	Zip
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If you are part of a Senior Facility clinic, are you a **resident**  or an **employee/staff** ?  
 Is this the patient's **first**  or **second**  dose of the COVID-19 vaccination?

**Insurance Information** (If or onsite clinic, please ensure a copy of the patient insurance card(s) was collected)  
**Prescription Insurance:**  Yes  No  
 Why is this Primary Care Provider?  No, include the Primary Care Provider's DOB

Prescription Brand (If Any Name)	Controlled Subst	Rx Group ID	Unit	PCN
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**Medicare Fields**  
 Yes  No  
 Is the Patient age 65 or older or Medicare eligible? Medicare Part A/B/D Number (MID)  
Note: MID is required for all patients age 65 and older, or Medicare eligible. Refer to your Medicare card, W-2, and this card.

**Medical Insurance:**  Yes  No  
 Medical Insurance Carrier:  Yes  No  
 Control Number:  Yes  No  
 Group ID:  Yes  No  
 Plan ID:  Yes  No  
 Are you the Primary Care Provider?  Yes  No  
 If No, include the Primary Care Provider's DOB

If uninsured, you must check the box below to affirm that the following information is true and accurate:  
 I do not have any form of other insurance but not limited to Medicare, Medicaid or any other private or government-funded health benefit plan.

In order to have your vaccine administration fee paid for by the United States Health Resources & Services Administration's COVID-19 Program for Uninsured Patients, please provide either (a) a valid Social Security number, (b) state identification number and state of issuance, OR (c) a driver's license number and the state of issuance.

Social Security Number	or State Identification Number	or State	or Driver's License Number	or State
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### COVID-19 Screening Questions

- In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19? YES NO DON'T KNOW
- In the past two weeks, have you had contact with anyone who tested positive for COVID-19? YES NO DON'T KNOW
- Have you had the new onset of fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting, or diarrhea? YES NO DON'T KNOW

To be filled out by the Immunizer: Patient Temperature: \_\_\_\_\_ Date: \_\_\_\_\_  
 If patient presents with any of these symptoms or patient's rectal temperature is 100°F or greater, please inform them that they should not receive the vaccine at this time, instead they should see their primary care provider for next steps and that the facility conditions will be notified.

### Immunization Screening Questions

- Are you sick today? (For example: a cold, fever or acute illness) YES NO DON'T KNOW
- Do you have allergies or reactions to any foods, medications, vaccines or latex? (For example: eggs, gelatin, neomycin, chimerical, etc.) YES NO DON'T KNOW
- Have you ever had a serious reaction after receiving a vaccination? Do you have a history of fainting, particularly with vaccines? Has any physician or other healthcare professional ever cautioned or warned you about receiving certain vaccines or receiving vaccines outside of a medical setting? YES NO DON'T KNOW



## COVID-19 Vaccination Frequently Asked Questions

### Keep informed about the COVID-19 Vaccination Clinic Program.

Please note: due to the fluidity of the situation, we are continuously updating these FAQs. Please visit [www.omnicare.com/covid-19-vaccine-resource](http://www.omnicare.com/covid-19-vaccine-resource) routinely, to access and download the latest version of this FAQ document.

CVS Health® is actively monitoring the global COVID-19 pandemic, including guidance from trusted sources of clinical information such as the Centers for Disease Control (CDC) and World Health Organization (WHO). Below is information about policies and procedures that CVS Health has implemented that focus on the health and safety of our colleagues, customers, members, and patients. For more information about the virus, please visit the [CDC](https://www.cdc.gov) and/or [WHO](https://www.who.int) websites dedicated to this issue.



CVS Health® is an enterprise comprised of many business units that are coming together to support this vaccination effort. It is possible that you may receive outreach from Omnicare®, our long-term care pharmacy team, as well as our retail CVS Pharmacy® and MinuteClinic® teams. Know that we are connected and are all part of the CVS Health enterprise. Our shared mission is to help you and your patients on the path to better health.

***What is COVID-19?***

COVID-19 is an infectious disease caused by a novel respiratory coronavirus. COVID-19 poses a serious public health risk and is highly contagious. For more information about the virus, please visit the [CDC](#) and/or [WHO websites](#) dedicated to this issue. Visit the [CDC Traveler's Health website](#) for travel notices and precautions.

***How does COVID-19 spread?***

Human coronaviruses are usually spread from an infected person to others through the air by coughing and sneezing and through close personal contact, such as touching or shaking hands. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose or possibly their eyes, but this is not thought to be the main way the virus spreads.

For more information about the transmission of COVID-19, please see the CDC website.

***How would a COVID-19 vaccine work?***

As with any vaccine, the goal of a COVID-19 vaccine is to expose the body to an antigen that won't cause disease but will provoke an immune response that can block or kill the virus if a person becomes infected. Vaccines contain either the whole virus or a component. After receiving a vaccine, a person develops immunity to that disease without having to get the disease. The immunity varies based on the type of vaccine you receive. Some vaccines last a year (like the flu vaccine) and others last longer (like the polio vaccine). Current science suggests that the COVID-19 vaccine will be more like the flu vaccine requiring annual dosing, but research will be required to fully answer this question.

***What are the different technologies being used to develop a COVID-19 vaccine?***

Manufacturers are taking different approaches toward developing a COVID-19 vaccine including using portions of the virus, genetic material or other vectors.

Traditional technology

A traditional vaccine technology is to use protein sub-units that can be injected into cells to stimulate a response. Such vaccines usually need adjuvants—or immune-stimulating molecules—delivered in conjunction with the vaccine and may also require multiple doses. Some of the candidates in development using this technique are from Novavax and Sanofi/GSK.

Novel technologies

Viral vector vaccines use another virus that has been engineered to express the S protein to generate an immune response. Some of the candidates in development using this category are from AstraZeneca/Oxford, Johnson & Johnson, Merck and Vaxart.

Nucleic acid vaccines deliver genetic material into the cell which is then translated into a protein – usually the S protein. However, this method – and the way the genetic material (RNA or DNA) is delivered into the cell – requires that these vaccines be stored and transported at ultracold temperatures of -20 to -70 degrees Celsius. Some candidates in development in this category are from BioNTech/Pfizer, Inovio and Moderna.



***What is the FDA's Emergency Use Authorization and how does the process work?***

In order to help make a vaccine available as soon as possible, the Food and Drug Administration (FDA) would need to authorize its distribution under an Emergency Use Authorization (EUA). The agency has issued guidance for the criteria that will be used to evaluate any EUA application.

The FDA evaluates the following criteria when determining whether to issue an EUA:

- **Safety:** Whether the chemical, biological, radiological or nuclear (CBRN) agent can cause a serious or life-threatening disease or condition. The known and potential benefits of the product, when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- **Efficacy:** If the product is determined to be effective in preventing SARS-CoV-2.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Under the EUA, any investigational vaccines developed to prevent COVID-19 will be assessed on a case-by-case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product and the totality of the available scientific evidence relevant to the product. The final guidance specific to EUA for vaccines to prevent COVID-19 can be found [here](#).

***What are some of the clinical considerations or uncertainties concerning a potential vaccine?***

Given each vaccine will have different clinical profiles, there are a number of important criteria to evaluate as part of overall planning efforts. Understanding these criteria will help the clinical community plan for safe and effective administration of the vaccine. Some of these considerations include:

- Efficacy, safety, age of vaccine recipient, duration of immunity and route of administration (e.g., intramuscular, intradermal injection, oral, other)
- Dosing frequency and tracking (e.g., single dose vs. multiple doses, time between doses)
- Shipping/storage requirements (e.g., room temperature, refrigerated, frozen, deep-frozen)
- Compounding requirements (e.g., reconstitution, ready-to-use)

Most COVID-19 vaccines under development are likely to require a second booster shot a month or so after the initial dose. Providers will need to ensure that individuals who got the first shot receive a second shot of the right vaccine at the right time. Educating the population about the importance of receiving the booster shot will be critical.

***Is it safe to receive the vaccine?***

CVS Health's COVID-19 vaccination services will be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. CVS Health will only be administering vaccines that have been approved for emergency use by the FDA.

***How is CVS Health working with the CDC to make the COVID-19 vaccine available?***

As announced by the HHS and Department of Defense, CVS Health has entered into a contract with the CDC to be one of the official COVID-19 Vaccination Program Providers in the Pharmacy Partnership for Long-Term Care Program. As a result, once a COVID-19 vaccine is approved and available, the U.S. government will make a supply of the publicly funded vaccine available to CVS Health to provide on-site vaccination clinic services to residents and staff of long-term care facilities.

***Who is eligible to receive the COVID-19 vaccination under this contract?***

Under this contract, CVS Health will receive a supply of the publicly funded COVID-19 vaccine and necessary supplies for administration once the vaccine is authorized and available. This supply of vaccine will be used to provide vaccinations to patients and staff of long-term care facilities.

***When will CVS Pharmacy begin offering the COVID-19 vaccine?***

Once a COVID-19 vaccine (or vaccines) is available, CVS Health will work rapidly to make vaccinations available to staff and residents of long-term care facilities, consistent with governmental priorities.

***How will CVS Health identify/select the long-term care facilities that it will support through this vaccination program?***

CVS Health will not select facilities. Rather, facilities will select their preferred pharmacy partner through the CDC's survey process. CDC will then provide a list of facilities to CVS Health where onsite clinics will be scheduled and conducted.

***Will patients be charged for the vaccine?***

No. Section 3203 of the CARES Act generally requires issuers offering non-grandfathered group or individual health insurance coverage to cover any qualifying coronavirus preventive service, including a COVID-19 vaccine, without imposing any cost sharing requirements, such as a copay, coinsurance or deductible.

No patient will be charged for the vaccine or its administration. The federal government will provide the vaccine itself, and CVS Health will be reimbursed by the patient's insurance or, in the case of uninsured patients, the Health Resources and Services Administration (HRSA) program for uninsured patients, for the administration of the vaccine. The Centers for Medicare & Medicaid Services (CMS) has established the reimbursement rates for administration of the vaccine for patients covered by Medicare as well as those covered by the program for the uninsured.

***How many doses of vaccine will be made available to CVS Health?***

The volume to be made available to CVS Health will be determined by the federal government's allocation methodology.

***Which vaccines will be offered? Will there be more than one type?***

The type of vaccine made available to CVS Health will be determined by the federal government's allocation methodology.

***In how many states will CVS Pharmacy be able to offer these clinics?***

CVS Health is prepared to provide vaccination clinics for long term care facilities in all 50 states.

***Where will the vaccinations take place? Will they take place at CVS Pharmacy locations or on-site at the selected long-term care facilities?***

For this specific program, CVS Health will coordinate and schedule a series of vaccination clinics on-site at the identified long-term care facilities.

***Will you be vaccinating both residents and staff members at these long-term care facilities?***

Yes, through this program we will be vaccinating both residents and staff members at identified long-term care facilities.

***Is CVS Health ready to provide appropriate temperature-controlled storage of the vaccine, even if the approved vaccine requires extreme cold storage and cold-chain standards?***

Yes. CVS Health will be able to appropriately store vaccines at the manufacturer's required temperature range.

***Who administers the vaccines at on-site clinics?***

Appropriate trained personnel under applicable state and federal laws and guidance will administer vaccines to facility patients and employees at the on-site clinics. CVS Health immunizers are trained and certified according to company and state specific regulations. These immunizers may include pharmacists, pharmacy interns, and trained pharmacy technicians, as well as other qualified healthcare professionals. All CVS Health immunizers are trained in the administration of immunizations and hold an active CPR certification.

***Will CVS Health be able to use the COVID-19 vaccine provide through this program for other populations outside of long-term care facility settings?***

Under the Pharmacy Partnership for Long-Term Care Program, the federal government will supply vaccine for use only to vaccinate residents and staff of long-term care facilities. Under the separate agreement CVS Health has entered into with HHS, CVS Pharmacies will receive vaccine supply to administer vaccines in our retail locations in accordance with the government's prioritization guidelines.

***How do I schedule an on-site COVID-19 vaccine clinic?***

To accommodate all interested facilities and to streamline operations for a positive experience, COVID-19 vaccine clinics will be automatically scheduled for pre-selected clinic dates and times, based on location, staffing and vaccine availability into specific geographies.

Three clinics will be scheduled for each facility, to accommodate both vaccine doses and potential new admissions and/or new hires.

Please note that facilities will not have the ability to request a reschedule, nor adjust their pre-selected clinic dates and times.

***If my facility did not complete the CDC survey for enrollment in this program, am I able to still register and sign up for a clinic?***

No. If a response was not provided on the CDC survey during the allotted window to enroll in this program, you will need to work directly with you state and/or local jurisdictions to determine a plan for receiving COVID-19 vaccine.

***What will the CVS pharmacy team bring to the clinic?***

The pharmacist will bring all requested vaccine product and other supplies necessary (including all appropriate Personal Protective Equipment, PPE) for administration, according to vaccination protocol.

***PPE & Cleaning Procedures***

CVS Health will follow CDC guidance to ensure vaccines are administered as safely as possible. We will abide by any state specific requirements regarding COVID-19 protocols, as well as CMS guidance.



***How are we ensuring discharged residents get booster administration?***

Close coordination between CVS Health and the Long-Term Care facility will be utilized to provide access to the next clinic dates for the discharged residents to complete their vaccination.

***What if a new admission comes in between the clinic dates?***

New admissions between clinics dates should be incorporated into the next available on-site clinic to begin the vaccination process if they choose to.

***What if a new admission comes from another setting that has received an alternative vaccine?***

CVS Health is not responsible for completing the booster dose for vaccinations of an alternative vaccine to what CVS Health was provided by the federal government and that patient should seek resolution with their care providers.

***If we get new admissions the day of the clinic can we add them to the clinic?***

In most instances the new admission will be able to receive the vaccine at that day's clinic as long as all paperwork is appropriately complete and vaccine is available. In some cases the patient will need to wait until the next on-site clinic to begin the vaccination process.

***Will there be consent forms available?***

Yes. Each individual planning to participate in the clinic and receive a COVID-19 vaccination (patient and facility staff) will need to complete a vaccine administration consent form. A packet of consent forms will be mail directly to your facility in advance of the clinic.

***What if a patient refuses consent?***

It is each patient's and/or responsible party's right to refuse the COVID 19 vaccination.

***Do participants need to provide their insurance cards?***

Yes, FRONT and BACK photocopies of each participant's current insurance cards will need to be obtained and attached to their consent form, to allow our teams access to unique claim billing details and avoid interruptions to your staff at point of care.

***Can patients receive other vaccines at the time of COVID-19 vaccine administration?***

Other vaccinations will not be offered at the time of COVID-19 vaccine administration and no patient should receive the COVID vaccine having received other vaccinations within 14 days

***Are the immunizers going to be vaccinated?***

CVS Health immunizer teams will be offered the opportunity to be vaccinated when available but are not required to be part of the vaccination effort

***How will CVS communicate with my facility?***

CVS plans on utilizing multiple communication channels but it will be important that they have the appropriate contact information, both email and phone, for the people responsible for the facilities clinics.

***How will the disposal of waste be handled at on-site clinics?***

CVS colleagues will bag waste from the clinics (trash bag provided by CVS) and dispose of the bagged waste in the facility's dumpster. Waste is defined as gloves, mask, gown, band-aids, used alcohol wipes, cotton balls., etc.

Please note that items such as empty vaccine vials, immunization supplies (needles, syringe), etc. would still be put into a Sharps container and transported back to CVS Pharmacy for disposal.

***How do I contact CVS if I have questions?***

Please reference [www.omnicare.com/covid-19-vaccine-resource](http://www.omnicare.com/covid-19-vaccine-resource) with questions or reach out to [CovidVaccineClinicsLTCF@CVSHealth.com](mailto:CovidVaccineClinicsLTCF@CVSHealth.com). You will also be receiving numerous communications and other material throughout the process that should help answer most questions.

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS**

**EMERGENCY USE AUTHORIZATION (EUA) OF  
THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS  
DISEASE 2019 (COVID-19)  
IN INDIVIDUALS 16 YEARS OF AGE AND OLDER**

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

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

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.cvdvaccine.com](http://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. This type of coronavirus has not been seen before. 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. 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?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

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 PFIZER-BIONTECH COVID-19 VACCINE?**

**Tell the vaccination provider about all of your medical conditions, including if you:**

- have any allergies
- 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

**WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

**WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

You should not get the Pfizer-BioNTech COVID-19 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 PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer BioNTech COVID-19 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.

**HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?**

The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

### **HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

### **WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

### **WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 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 Pfizer-BioNTech COVID-19 Vaccine. 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

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is 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 "Pfizer-BioNTech COVID-19 Vaccine 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
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

**WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 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 PFIZER-BIONTECH COVID-19 VACCINE?**

Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

**CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

**WHAT IF I AM PREGNANT OR BREASTFEEDING?**

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

**WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?**

No. The Pfizer-BioNTech COVID-19 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 second dose of Pfizer-BioNTech COVID-19 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
<a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a> 	1-877-829-2619 (1-877-VAX-CO19)

## HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Contact your local or state public health department.

## WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

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

## 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/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The 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 Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. 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.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).



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