



To our Incredible Patients and Residents, their Families and Loved Ones, and our Dedicated Team Members,

We've all been encouraged by news of the development, successful testing, and approval of the first effective vaccines against COVID-19. We are pleased that our state has placed a top priority on distributing and administering the vaccine to skilled nursing centers.

We are very excited of this opportunity, as the health, safety, and wellness of our residents, patients, and staff is our top priority. In an effort of full transparency, we are doing everything we can to help facilitate the vaccination process.

We are grateful for our partnership with **CVS Pharmacy**, as this vaccination process will be both convenient and efficient for our residents, patients, and team members. An immunization clinic will be on-site at our community, where a team of pharmacy representatives will help us manage the immunization process. As always, we will continue to maintain our COVID-19 precautionary measures throughout this process.

Our incredible clinical team and frontline heroes continue to go above and beyond to ensure the safety and well-being of those that we care for and serve each and every day.

By receiving the COVID-19 vaccination, we will be protecting not only our own health and safety, but also the health, safety, and wellness of our loved ones, those who we serve, and our fellow neighbors in our local community.

As shared by the CDC (Centers for Disease Control and Prevention), here are several key facts regarding the COVID-19 vaccination:

- Getting vaccinated can help prevent you and others from getting sick with COVID-19. If you get sick, you may spread the disease to friends, family, and others around you while you're sick, but a COVID-19 vaccination helps protect you by creating an antibody response without having to experience sickness.
- COVID-19 vaccines will not give you COVID-19.
- COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests.
- People who have gotten sick with COVID-19 may still benefit from getting vaccinated- experts aren't sure how long someone who has recovered from COVID-19 is protected from getting sick again.

Preliminary Vaccination Clinic Date: January 7, 2021 and January 28, 2021 (Subject to change)

We've all been in this together since the pandemic erupted in March, and it has forced us to consistently consider how to best protect ourselves and each other. This long-awaited COVID-19 vaccine provides us all with a great chance to move forward and stop the spread of the virus. Let's come together again and continue to look out for one another by getting vaccinated as soon as possible.

Sincerely,
Administration



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 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 with questions or reach out to CovidVaccineClinicsLTCF@CVSHealth.com. You will also be receiving numerous communications and other material throughout the process that should help answer most questions.

Consent Requirements & Process

COVID-19 Vaccination Clinics

Versions of Consent Forms:

- **COVID-19 Vaccine Consent Form: *PREFERRED*** Physical, triplicate form shipped to facilities (*alone or with RP cover sheet*)
- Electronic, editable PDF (two options)
 1. **COVID-19 Vaccine Full Intake Consent Form**
 2. **COVID-19 Vaccine Consent Responsible Party Form** (*abridged*)

Is verbal consent allowed?

- Yes, verbal consent from responsible party is allowed for patients who **do not have physical or cognitive ability to consent** (or minors). If patients or their responsible party are able to provide written consent, that process should be used.
- If consent is collected verbally by the facility, a facility representative signature is required to indicate that verbal consent to treat by patient's representative has been documented in the medical record. Further, the facility is authorizing CVS to bill on behalf of the individual.
- In such instances, the facility must complete and sign the consent form.

Requirements for CVS Clinics:

- Three (3) copies of **signed, completed** consent form (whether it's gathered electronically or in paper form).
- If a responsible party completes the electronic cover sheet, we need three (3) copies printed, to attach to each copy of the **COVID-19 Vaccine Consent Form**.
- Two (2) completed sets of consent forms will be required for each individual participating in the vaccination clinic – One set for the first dosing/clinic and a second set for the second dosing/clinic.

How LTCF will obtain/access consent forms:

- ***PREFERRED*** - Completion of the physical, triplicate **COVID-19 Vaccine Consent Form** shipped directly to the facility.
- Completion of the electronic, editable PDF (**COVID-19 Vaccine Full Intake Consent Form**) and/or **Responsible Party** (*abridged*) form via webpage or email.
 - Both will be posted to webpage for download and easy access.
 - Omnicare team (CovidVaccineClinicsLTCF@CVSHealth.com) OR client-engagement teams can send/attach via email.

Consent Requirements & Process

COVID-19 Vaccination Clinics

How will LTCF know exactly what is needed of them:

- Options for consent collection are offered below. LTC facilities are requested to follow the prioritized options as follows:
 1. ***PREFERRED*** - Completion of physical, triplicate **COVID-19 Vaccine Consent Form**, completed and signed by participant.
 2. LTCF emails Responsible Party cover sheet (**Responsible Party Form (abridged)**)
 - Applicable where patient is unable to complete form or is a minor.
 - Abridged consent form Responsible Party (RP) is returned to LTCF to print three (3) copies, attach one to each copy of triplicate COVID-19 Vaccine Consent Form.
 - Facility staff responsible for completion of remainder of triplicate COVID-19 Vaccine Consent Form intake form. Signature by staff member to indicate alignment to RP authority.
 - CVS immunizer completes bottom section on physical form once, carbon copies to other 2 for documentation, cover sheet attached to each.
 3. Consent is gathered by email confirmation by the LTCF
 - Applicable where patient is unable to complete form (or is a minor) and where the Responsible Party was unable to complete the **Responsible Party Form (abridged)**
 - Email consent from Responsible Party (RP) is returned. LTCF to print three (3) copies, attach one to each copy of triplicate COVID-19 Vaccine Consent Form.
 - Facility staff responsible for completion of remainder of triplicate COVID-19 Vaccine Consent Form intake form. Signature by staff member to indicate alignment to RP authority.
 - CVS immunizer completes bottom section on physical form once, carbon copies to other 2 for documentation, cover sheet attached to each.

Consent Requirements & Process

COVID-19 Vaccination Clinics

4. Consent is collected verbally by the facility
 - Applicable where patient is unable to complete form.
 - Facility representative signature is required to document that patient's responsible party provided verbal consent to treat and such consent to treat has been documented in the medical record. Further, the facility is authorizing CVS to bill on behalf of the beneficiary.
 - In such instances, the facility should complete and sign the consent form.
5. LTC facility emails editable **COVID-19 Vaccine Full Intake Consent Form** to responsible party for completion
 - Applicable where patient is unable to complete form.
 - Electronic signature needs to be present on all three copies.
 - Signed forms should be returned to LTC facility. LTC facility prints three (3) copies.
 - Facility must confirm health status prior to clinic. Facility is responsible for completing all incomplete fields not populated by the responsible party.
 - CVS immunizer completes bottom sections.

COVID Vaccine Intake Consent Form



Clinic Information

Clinic ID	Clinic Name	Telephone	Store Number
Address		City	State Zip

Patient Information

Last Name	First Name	Date of Birth	Gender
Address		City	State Zip SSN* (or driver's license)
Primary Care Provider (PCP) Name		PCP Phone Number	PCP Fax Number
PCP Address		City	State Zip

SSN and state of residence, or state identification/driver's license is needed to verify patient eligibility. If a SSN and state of residence, or state identification/driver's license is not submitted, you will need to attest that you attempted to capture this information before submitting a claim and the patient did not have this information at the time of service, or that you did not have direct contact with the patient and thus did not have an opportunity to attempt to capture this information. Claims submitted without a SSN and state of residence, or state identification/driver's license may take longer to verify for patient eligibility.

If you are part of a Senior Facility clinic, are you a **resident or an **employee/staff** ?**

If someone else manages health decisions on behalf of the resident, please provide the following:

Caregiver or Financially Responsible Party Name	Relationship	Phone Number
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Insurance Information: Fill in all that apply

Prescription Insurance:

Patient is primary card holder (check box if yes)

Pharmacy Insurance Provider	ID #	GRP ID	BIN	PCN
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Medicare Fields: (Note: COVID Vaccine will be billed at Part B through your Medicare provider)

Yes No

Is the patient age 65 or older or is the patient Medicare Eligible?	Medicare Part A/B ID Number (MBI)
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Medical Insurance:

Yes No

Medical Insurance Provider	ID #	GRP ID	Is the patient the Primary Cardholder?
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If you are uninsured, please read the below statement and check the box for acknowledgement:

I do not have medical insurance, Medicare, Medicaid or any commercial or government-funded health benefit plan I acknowledge that I must answer this question truthfully in order to have the cost of my test covered by the U.S. Department of Health and Human Services (HHS) Uninsured Program. If I have active insurance that I fail to provide, I may be charged in full for the vaccine.

COVID-19 Screening Questions

	YES	NO	DON'T KNOW
1. In the past two weeks, have you tested positive for COVID-19 or are you currently being monitored for COVID-19?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. In the past two weeks, have you had contact with anyone who tested positive for COVID-19?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Do you currently or have you in the past 14 days, had a 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?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

To be filled out by the immunizer: Patient Temperature:

Date:

If patient answers yes to any of these questions or patient's bodily temperature is 100°F or greater, please inform them that they should not receive the vaccine at this time, instruct them to contact their primary care provider for next steps and that the facility coordinator will be notified.

Immunization Screening Questions

	YES	NO	DON'T KNOW
1. Are you sick today? (For example: a cold, fever or acute illness)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Do you have allergies or reactions to any foods, medications, vaccines or latex? (For example: eggs, gelatin, neomycin, thimerosal, etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. 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?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Last Name	First Name	Date of Birth
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Immunization Screening Questions (continued)

	YES	NO	DON'T KNOW
4. Have you had a seizure or a brain or other nervous system problem or Guillain Barre?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Do you take anticoagulation medication? For example: warfarin, Coumadin or other blood thinner.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Do you have a long-term health problem such as heart disease, lung disease, liver disease, asthma, kidney disease, metabolic disease (e.g., diabetes), anemia or other blood disorder?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Do you have cancer, leukemia, HIV/AIDS, rheumatoid arthritis, ankylosing spondylitis, Crohn's disease or any other immune system problem?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Do you have a weakened immune system or in past 3 months, taken medications that weaken it such as cortisone, prednisone, other steroids, anticancer drugs, or radiation treatments?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. For women, are you pregnant or is there a chance you could become pregnant during the next month?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Have you received any vaccinations or TB skin test in the past 4 weeks?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

CONSENT FOR SERVICES: I have been provided with the Vaccine Information Sheet(s) corresponding to the vaccine(s) that I am receiving. I have read the information provided about the vaccine I am to receive. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand that I should remain in the vaccine administration area for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand if I experience side effects that I should do the following: call pharmacy, contact doctor, call 911. I request that the vaccine be given to me or to the person named above for whom I am authorized to make this request. State of Georgia only: I verify a pharmacist asked for my health history and whether I have had a physical exam within the past year. Health care providers did not identify condition(s) that would mean I should not receive vaccine(s).

AUTHORIZATION TO REQUEST PAYMENT: I do hereby authorize CVS Pharmacy® ("CVS") to release information and request payment. I certify

that the information given by me in applying for payment under Medicare or Medicaid is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

DISCLOSURE OF RECORDS: I understand that CVS® may be required to or may voluntarily disclose my health information to the physician responsible for this protocol of specific health information of people vaccinated at CVS (if applicable), my Primary Care Physician (if I have one), my insurance plan, health systems and hospitals, and/or state or federal registries, for purposes of treatment, payment or other health care operations (such as administration or quality assurance). I also understand that CVS will use and disclose my health information as set forth in the CVS Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy). State of California only: I agree to have CAIR share my immunization data with Health Care Providers, agencies or schools. Vaccine Clinics: If I am receiving a vaccine through a vaccine clinic, I understand that my name, vaccine appointment date and time will be provided to the clinic coordinator.

X

Signature of patient to receive vaccine or person authorized to make the request	Date
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Vaccine Administration Information for Immunizer/Pharmacist use only

			<input type="radio"/> L	<input type="radio"/> R
Administration Date	Vaccine	VIS Date	Manufacturer	
Lot #	Exp. Date	Route	Site	Volume (mL)
Administering Immunizer Name & Title			Administering Immunizer Signature	

To be filled out by immunizer, as required for state immunization registry reporting. Only for states listed.

MS: Check all fields for patients 18 years of age and younger

OK: Check Race and Ethnicity for all patients. Select Next of Kin for patients 18 years of age and younger.

Race: 1 - American Indian or Alaska Native 2 - Asian 3 - Native Hawaiian/Other Pacific Islander
 4 - Black or African American 5 - White 6 - Other Race

Ethnicity: 1 - Hispanic 2 - Not Hispanic or Latino 3 - Unknown

Next of Kin (18 or younger)

Name	Phone Number	Relationship
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Address

State of NJ only

Prescriber Name	Prescriber Address
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For CA, MA, MT, NJ, NM, NY, TX (For CA, this indicator means the registry will not share with Universities, Schools or other agencies)

Registry Sharing Indicator: Yes No

COVID-19 Responsible Party Consent Form



Resident or Patient Information

Last Name	First Name	Date of Birth	Gender	
Address	City	State	Zip	SSN* (or driver's license)
Primary Care Provider (PCP) Name	PCP Phone Number	PCP Fax Number		
PCP Address	City	State	Zip	

SSN and state of residence, or state identification/driver's license is needed to verify patient eligibility. If a SSN and state of residence, or state identification/driver's license is not submitted, the patient will need to attest that you attempted to capture this information before submitting a claim and the patient did not have this information at the time of service, or that you did not have direct contact with the patient and thus did not have an opportunity to attempt to capture this information. Claims submitted without a SSN and state of residence, or state identification/driver's license may take longer to verify for patient eligibility.

CONSENT FOR SERVICES: I have been provided or can request the Vaccine Information Sheet(s) corresponding to the vaccine(s) that the individual listed above will receive. I have read the information provided about the vaccine they are about to receive. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand the individual stated above should remain in the vaccine administration area for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand if they experience side effects that I should do the following: call pharmacy, contact doctor, call 911. I request that the vaccine be given to the individual named above for whom I am authorized to make this request. State of Georgia only: I verify a pharmacist can ask the individual stated above for their health history and whether they have had a physical exam within the past year. Health care providers did not identify condition(s) that would mean they should not receive vaccine(s).

AUTHORIZATION TO REQUEST PAYMENT: I do hereby authorize CVS Pharmacy® ("CVS®") to release information and request payment. I certify that the information given by me in applying for payment under Medicare or Medicaid is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

DISCLOSURE OF RECORDS: I understand that CVS® may be required to or may voluntarily disclose health information to the physician responsible for this protocol of specific health information of people vaccinated at CVS (if applicable), a Primary Care Physician (if they have one), insurance plan, health systems and hospitals, and/or state or federal registries, for purposes of treatment, payment or other health care operations (such as administration or quality assurance). I also understand that CVS will use and disclose this health information as set forth in the CVS Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy). State of California only: I agree on behalf of the party I am responsible for to have CAIR share my immunization data with Health Care Providers, agencies or schools.

Vaccine Clinics: If receiving a vaccine through a vaccine clinic, I understand that their name, vaccine appointment date and time will be provided to the clinic coordinator.

If you are legally responsible for the resident listed above, please provide the following:

Name of Responsible Party or Power of Attorney	Relationship	Date
Signature of Responsible Party or Power of Attorney	Phone Number	

Vaccines & Immunizations

Answering Patients' Questions

Some patients won't have questions about coronavirus disease 2019 (COVID-19) vaccination when you give your strong recommendation and use language that assumes patients will get vaccinated when doses are widely available. If a patient questions your recommendation about COVID-19 vaccination, this does not necessarily mean they will not accept a COVID-19 vaccine. This is a new vaccine, and some questions are to be expected. Your patients consider you their most trusted source of information when it comes to vaccines, and sometimes they simply want *your* answers to their questions.

This page outlines some topics patients ask about most vaccines and tips for how to answer their questions.



Questions about Vaccine Safety and the Speed of Vaccine Development

The federal government, under the umbrella of [Operation Warp Speed](#), has been working since the start of the pandemic to make a COVID-19 vaccine available as soon as possible. This accelerated timeline is unprecedented and has raised concerns for some people that safety may be sacrificed in favor of speed. However, as with all vaccines, safety is a top priority.

Patients may ask: How do we really know if COVID-19 vaccines are safe? To respond, you can explain how:

- The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
- The Advisory Committee on Immunization Practices (ACIP) reviews all safety data before recommending any COVID-19 vaccine for use. [Learn how ACIP makes vaccine recommendations.](#)
- FDA and CDC will continue to monitor the safety of COVID-19 vaccines, to make sure even very rare side effects are identified.

Example:

COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.



Questions about Whether It Is Better to Get Natural Immunity Rather than Immunity from Vaccines

Because some people with COVID-19 can have very mild symptoms, some may see natural infection as preferable to receiving a new vaccine. Others may be concerned that getting a COVID-19 vaccine could make a later illness worse. Help your patients understand the risks and benefits so they can be confident choosing to get vaccinated.

Patients may ask: Is the vaccine that helpful? I heard getting COVID-19 gives you better and longer immunity than the protection a vaccine can give. Can it actually make my illness worse if I do end up getting COVID-19? **To respond, you can:**

- Explain the potential serious risk COVID-19 infection poses to them and their loved ones if they get the illness or spread it to others. Remind them of the potential for long-term health issues after recovery from COVID-19 disease.
- Explain that scientists are still learning more about the virus that causes COVID-19. And it is not known whether getting COVID-19 disease will protect everyone against getting it again, or if it does, how long

whether getting COVID-19 disease will protect everyone against getting it again, or, if it does, how long that protection might last.

- Describe how the vaccine was tested in large clinical trials and what is currently known about its safety and effectiveness.

Be transparent that the vaccine is not a perfect fix. Patients will still need to practice other precautions like wearing a mask, social distancing, handwashing and other hygiene measures until public health officials say otherwise.

Example:

“Both this disease and the vaccine are new. We don’t know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice.”



Questions about Known Side Effects

Some COVID-19 vaccines may be more reactogenic than vaccines that people are familiar with. Information about specific side effects of the COVID-19 vaccine will be available when it is approved. It is important to set this expectation with your patient, in case they experience a strong reaction.

Patients may ask: How much will the shot hurt? Can it cause you to get very sick? **To respond, you can:**

- Explain what the most common side effects from vaccination are and how severe they may be.
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving Shingrix for older adults who have received it).
- Make sure patients know that a fever is a potential side effect and when they should seek medical care.
- Let them know that symptoms typically go away on their own within a week. Also let them know when they should seek medical care if their symptoms don’t go away.
- Explain that the vaccine cannot give someone COVID-19.
- Explain that side effects are a sign that the immune system is working.

Example:

“Most people do not have serious problems after being vaccinated. We will understand more about mild side effects of the COVID-19 vaccine before we start to use it. However, your arm may be sore, red, or warm to the touch. These symptoms usually go away on their own within a week. Some people report getting a headache or fever when getting a vaccine. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.”



Questions about Unknown, Serious, Long-term Side Effects

Due to the relative speed with which these vaccines were developed, patients’ concerns about long-term side effects are reasonable and to be expected.

Patients may ask: How do we know that these vaccines are safe when they are so new? Couldn’t they cause problems that we don’t know about yet? What about long-term problems? **To respond, you can:**

- Explain how FDA and CDC are continuing to monitor safety, to make sure even long-term side effects are identified.

- Reassure patients that COVID-19 vaccines will be continuously monitored for safety after authorization, and ACIP will take action to address any safety problems detected.
- Compare the potential serious risk of COVID-19 infection to what is currently known about the safety of COVID-19 vaccines.

Example:

COVID-19 vaccines are being tested in large clinical trials to assess their safety. However, it does take time, and more people getting vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as it comes in and provides regular safety updates. If a safety issue is detected, immediate action will take place to determine if the issue is related to the COVID-19 vaccine and determine the best course of action.



How Many Doses Are Needed and Why?

All but one of the COVID-19 vaccines currently in phase 3 clinical trials use two shots. The same vaccine brand must be used for both shots.

Patients may ask: How many shots am I going to need? To respond, you can:

- Explain that two shots are generally needed to provide the best protection against COVID-19 and that the shots are given several weeks apart. The first shot primes the immune system, helping it recognize the virus, and the second shot strengthens the immune response.
- When applicable, explain the dosing options available in your office and advise the patient that they can set up an appointment before they leave to come back for a second dose.

Example:

Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer.

Other Questions Patients May Have about COVID-19 Vaccination

If you have additional questions from patients, reference [Frequently Asked Questions about COVID-19 Vaccination](#) for regularly updated answers to common questions.

Page last reviewed: November 2, 2020

COVID-19 (Coronavirus Disease)

[MENU >](#)

CASES ARE RISING.
ACT NOW!



WEAR A MASK



STAY 6 FEET APART



AVOID CROWDS

Importance of COVID-19 Vaccination for Residents of Long-term Care Facilities

Updated Dec. 13, 2020 [Print](#)

Based on [recommendations](#) from the [Advisory Committee on Immunization Practices \(ACIP\)](#), an independent panel of medical and public health experts, CDC recommends residents of long-term care facilities be included among those offered the first supply of COVID-19 vaccines.

Vaccinating LTCF residents will save lives

Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccines are available will help save the lives of those who are most at risk of dying from COVID-19. According to ACIP's recommendations, long-term care facility residents include adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. The communal nature of LTCFs and the population served (generally older adults often with underlying medical conditions) puts facility residents at increased risk of infection and severe illness from COVID-19. By November 6, 2020, [approximately 569,000–616,000 COVID-19 cases and 91,500 deaths](#) were reported among LTCF residents and staff members in the United States, accounting for 39% of deaths nationwide.

Benefits of vaccination believed to outweigh possible risks

All COVID-19 vaccines were tested in clinical trials involving tens of thousands of people to make sure they meet safety standards and protect adults of different races, ethnicities, and ages, including adults over the age of 65. There were no serious safety concerns. The most common side effects were pain at the injection site and signs and symptoms like fever and chills. After a review of all the available information, ACIP and CDC agreed the lifesaving benefits of COVID-19 vaccination for LTCF residents outweigh the risks of possible side effects.

The safety of COVID-19 vaccines is a top priority

To help make important unapproved medical products, including vaccines, available quickly during the [COVID-19](#) pandemic, the US Food and Drug Administration (FDA) can use what is known as an [Emergency Use Authorization \(EUA\)](#) [↗](#). Before any vaccine can be authorized for use under an EUA, FDA must determine that the vaccine's benefits outweigh possible risks.

Once people begin receiving COVID-19 vaccinations, CDC and FDA will monitor vaccine safety closely. The United States will use existing robust systems and data sources to conduct ongoing safety monitoring. An additional layer of safety monitoring has also been added that allows CDC and FDA to evaluate COVID-19 vaccine safety almost immediately. [Learn more about COVID-19 vaccine safety monitoring.](#)

For LTCFs in particular, CDC will work with pharmacies and other partners to report possible side effects (called adverse events) to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) [↗](#). Facility staff and residents' families are encouraged to also report any adverse events immediately.

CDC will work with pharmacies and other partners to provide communication materials to help LTCFs educate residents and their families about the vaccine, answer their questions about vaccine safety and other issues, and prepare them for vaccination clinics. For some COVID-19 vaccines, two shots are needed to provide the best protection, and the shots are given several weeks apart. Each recipient or caregiver will receive a vaccination record card to ensure they receive the correct vaccine for the second dose.

Risks and benefits will be explained to everyone offered a COVID-19 vaccination

Explaining the risks and benefits of any treatments to a patient in a way that they understand is the standard of care. In LTCFs, consent or assent for vaccination should be obtained from residents (or the person appointed to make medical decisions on their behalf) and documented in the resident's chart per standard practice.

For LTCFs participating in the [Federal Pharmacy Partnership for Long-term Care Program](#), pharmacies will work directly with LTCFs to ensure staff and residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and benefits of the COVID-19 vaccine they are receiving and what to expect. Each LTCF resident's medical chart must note that this information was provided to the resident. If a resident is unable to make medical decisions due to decreased mental capacity or illness, the EUA fact sheet will be provided to the person appointed to make medical decisions on their behalf (the medical proxy or power of attorney).

Last Updated Dec. 13, 2020

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.

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
www.pfizersafetyreporting.com	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
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. 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/ 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).



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
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55131 Mainz, Germany

LAB-1451-1.0

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

Barcode Date: 12/2020