

Pre-vaccination Assessment and Consent: COVID-19 Vaccine

Individuals should be given the EUA Fact Sheet for Recipients and Caregivers before vaccination | ***Under the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) individuals 12 years of age and older (Pfizer BioNTech) and 18 years and older (Moderna, Janssen/Johnson & Johnson) may receive this vaccination.**

Last Name, First Name (PRINT)	Date: / / HP <input type="checkbox"/> NP <input type="checkbox"/>
	Medical Record Number (MRN):
Date of Birth: / / _____	Please state the ethnicity/race you MOST identify with: Examples: African American, Caucasian, Chinese, Filipino, Japanese, etc.

Please answer the following questions prior to receiving the COVID-19 vaccine (circle YES or NO)		
1. Have you had anaphylaxis or an immediate reaction to a previous dose of any COVID-19 vaccine?	Yes	No
2. Do you have a history of anaphylaxis or immediate allergy to polyethylene glycol (PEG) or polysorbate ? **	Yes	No
3. Do you have a history of anaphylaxis or immediate allergy to a vaccine, any component of a vaccine, or to any injectable medication (intramuscular, intravenous or subcutaneous)?	Yes	No
4. Do you have a fever ($\geq 100.4^{\circ}\text{F}$) or feel ill today?	Yes	No
5. Have you had any other vaccine(s) in the last 14 days ? (For office use only: If vaccine given, document in comments: "#5: risk/benefit reviewed")	Yes	No
6. Are you currently experiencing a COVID-19 infection, and are you under quarantine for an actual or potential COVID-19 exposure?	Yes	No
7. Have you received monoclonal antibody or convalescent plasma treatment for COVID-19 infection within the last 90 days?	Yes	No
8. Are you currently pregnant or breastfeeding? (For office use only: If vaccine given, document in comments: "#8: pregnancy/breastfeeding handout given")	Yes	No
9. Do you have a history of anaphylaxis to oral/topical medications, IV contrast, food, or insect stings?	Yes	No
10. Do you have a history of any of the following cancers: breast, head/neck, melanoma of upper body?	Yes	No
11. Do you have any screening tests scheduled in the near future like a mammogram, chest CT, or breast MRI?	Yes	No
Have you received a first dose of the COVID-19 vaccine?	Yes	No
If yes: Where: _____	Manufacturer: _____	Date: _____

If you have any additional questions, please talk with your physician or healthcare provider before receiving the COVID-19 vaccine.

I consent to health evaluations, administration and monitoring necessary for immunization for COVID-19 as ordered or provided by doctors, nurses, assistants, or other staff employed or contracted by Kaiser Permanente Health Plan Inc, Kaiser Foundation Hospital or Hawaii Permanente Medical Group. I also consent to any necessary treatment, whether diagnostic or therapeutic, should I have an adverse reaction to the vaccine. I acknowledge receipt of the Emergency Use Authorization Fact Sheet and my questions, if any, have been answered.

Signature _____ **(circle one) SELF / PARENT / GUARDIAN**

FOR CLINIC USE ONLY

<input type="checkbox"/> Cleared: assessment done and no valid contraindications	<input type="checkbox"/> Not cleared: patient referred to provider
X _____ Staff Name: <input type="checkbox"/> RN <input type="checkbox"/> Practitioner	Date: _____ / _____ / _____ MM DD YY

Vaccine Administration Documentation

Name/Title (PRINT): _____ **Time:** _____ AM/PM | **Deltoid Site:** Right or Left

** “PEG Polyethylene glycol (PEG) is a common, water-soluble ingredient in a wide variety of commercial products including some vaccines and medications. It is the primary ingredient in many colonoscopy preparations (Golytely) and constipation treatment (Miralax) along with IV medications such as PEGylated medications. It is also in ultrasound gel and injectable steroid injections such as methylprednisolone acetate. Reactions to polyethylene glycol are rare but anaphylaxis has been reported.”

Definition of Anaphylaxis:

Anaphylaxis (say "ann-uh-fuh-LAK-suss") is a severe allergic reaction that affects the entire body (systemic). It can occur within a few seconds or minutes after a person is exposed to a substance (allergen or antigen).

Symptoms and signs of a severe allergic reaction may include:

- Itching.
- Raised, red bumps on the skin (hives or wheals).
- Wheezing or difficulty breathing.
- Rapid swelling, either in one area or over the entire body. Swelling is most serious when it involves the lips, tongue, mouth, or throat and interferes with breathing.
- Belly pain or cramps.
- Nausea or vomiting.
- Low blood pressure, shock, and unconsciousness.

The sooner symptoms occur after exposure to the substance, the more severe the anaphylactic reaction is likely to be. An anaphylactic reaction may occur with the first exposure to an allergen, with every exposure, or after several exposures. An anaphylactic reaction can be life-threatening and is a medical emergency. Emergency care is always needed for an anaphylactic reaction.

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COVID-19 Vaccination Resources



Wear a mask



Wash your hands often



Avoid crowds



Stay at least 6 feet apart

Kaiser Permanente thanks you for taking a big step to help end the pandemic! By getting vaccinated, you not only protect yourself, but also those around you, especially those at increased risk. Continue to wear a mask, stay at least 6 feet apart, avoid crowds, and wash your hands often. Stopping a pandemic requires use of all the tools available.

How to use online resources

To reduce paperwork, Kaiser Permanente is providing online resources to learn about the vaccination you are receiving. The QR codes provided on this information sheet will take you directly to the fact sheets and other resources on the COVID-19 vaccination.

How to use QR codes:

1. Using your smart phone, open your camera app.
2. Hover over the QR code and the information sheet will launch.

Emergency Use Authorization (EUA)

Please review your vaccine card to see which vaccine you received. Using your smart phone, hover over the appropriate QR code below to review the fact sheet for the vaccination you received.

Moderna

This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. The Moderna 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 Moderna COVID-19 Vaccine.



Pfizer-BioNTech

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.





COMMON QUESTIONS AND ANSWERS

Will I have side effects after the 2nd dose?

- Most people will experience some side effects from the vaccine, especially after the 2nd dose.
- Common side effects include fatigue, headache, fever, chills, muscle aches, and pain or redness at the injection site. These side effects appear less common and intense in those who are older.
- While side effects can be uncomfortable, they are a sign that the vaccine is working and won't last long (generally a day or two).
- As with any vaccine, if you have a bad reaction or a severe allergic response, which are uncommon, it's important to call your doctor and file a report (see information under Adverse Events).

Can the vaccine keep you from getting sick with COVID-19?

- In research studies, those who got the vaccine were less likely to get COVID-19 than those who did not get the vaccine.
- Research also found that people who were exposed to COVID-19 after being vaccinated had milder cases of COVID-19. While the vaccine is one way to protect yourself, you should continue to wear a mask, stay at least 6 feet apart, avoid crowds, and wash your hands often.

Does the vaccine provide long-term protection?

- At this time, more long-term data is needed to see if the vaccine provides long-term protection.
- Researches continue to follow study participants to see if protection continues long-term. As researchers learn more, they will be able to provide more guidance.



QUESTIONS OR CONCERNS:

If you have any issues or concerns after you get your vaccine, contact your primary care doctor. For more information, visit kp.org/coronavirus.



ADVERSE EVENTS

If you or a family member has a bad reaction after getting the vaccine, it's important to report the reaction so that collectively we can understand these new vaccines better.

- After seeking care, work with your physician to report any issues via the Vaccine Adverse Event Reporting System (VAERS, vaers.hhs.gov/esub/index.jsp).
- This is a national program co-managed by the Food and Drug Administration and the Centers for Disease Control to monitor vaccine safety.

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code



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 12 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 12 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
- have ever fainted in association with an injection

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

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 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 23,000 individuals 12 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?

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. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

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

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

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

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET 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. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

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
<p>www.cvdvaccine.com</p> 	<p>1-877-829-2619 (1-877-VAX-CO19)</p>

HOW CAN I LEARN MORE?

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

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

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

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or <https://TIPS.HHS.GOV>.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

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
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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: 05/2021