



For vaccine recipients: The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. fa question is not clear, please ask your healthcare provider to explain it.	Patient Name	Yes	No	Don't know
1. Are you feeling sick today?				
2. Have you ever received a dose of COVID-19 vaccine?				
If yes, which vaccine product did you receive? Pfizer				
3. Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment we lt would also include an allergic reaction that occurred within 4 hours that caused hives, sw				ospital.
 A component of the COVID-19 vaccine, including polyethylene glycol some medications, such as laxatives and preparations for colonoscop 				
• Polysorbate				
A previous dose of COVID-19 vaccine				
4. Have you ever had an allergic reaction to another vaccine (other than CO injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment we caused you to go to the hospital. It would also include an allergic reaction that occurred we swelling, or respiratory distress, including wheezing.)	ith epinephrine or EpiPen® or that			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to someth component of COVID-19 vaccine, polysorbate, or any vaccine or injectable include food, pet, environmental, or oral medication allergies.				
6. Have you received any vaccine in the last 14 days?				
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you	u that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or contreatment for COVID-19?	onvalescent serum) as			
9. Do you have a weakened immune system caused by something such as H you take immunosuppressive drugs or therapies?	IV infection or cancer or do			
10. Do you have a bleeding disorder or are you taking a blood thinner?				
11. Are you pregnant or breastfeeding?				

Form reviewed by





I have read or had explained to me the 2020-2021 Vaccine Information Statement for the COVID-19 vaccine and understand the risks and benefits. Furthermore, I have also had an opportunity to ask questions about these immunizations. I believe the benefits outweigh the risks and I voluntarily assume full responsibility for any reactions that may result from either my receipt of the immunization(s) or the receipt of the immunizations(s) by the person named below for whom I am the legal guardian ("Ward"). My medical record may be shared with my physician or other healthcare provider and the medical record of my Ward may be shared with his/her physician or other healthcare provider. I am requesting that the immunization(s) be given to me or my Ward. I, for myself and on behalf of my Ward and each of our respective heirs, executors, personal representatives and assigns, hereby release the provisioning mass vaccination center, and its affiliates, subsidiaries, divisions, directors, contractors, agents and employees (collectively "Released Parties"), from any and all claims arising out of, in connection with or in any way related to my receipt and the receipt of my Ward of this or these immunization(s). Neither the provisioning mass vaccination center nor any of the Released Parties shall, at any time or to any extent whatsoever, be liable, responsible or any way accountable for any loss, injury, death or damage suffered or sustained by any person at any time inconnection with or as a result of this vaccine program or the administration of the vaccines described above. The provisioning vaccination center will use and disclose your personal and health information or the personal and health information of your Ward, to treat you or your Ward, to receive payment of the care we provide, and for other healthcare operations. Healthcare operations generally include those activities we perform to improve the quality of care. We have prepared a

Healthcare operations generally include those activities we perform to improve the quality of care. We have prepared a detailed NOTICE OF PRIVACY PRACTICES to help you better understand our policies in regard to you and your Ward's personal health information.

https://www.cdc.gov/other/privacy.html

\square I acknowledge that I have received a copy of the Notice of Privacy Practices		
Signature		
Print: Last Name, First Name (Middle Initial)		
State		
County		
Email Address		





Information for Healthcare Professionals

For additional information on COVID-19 vaccine clinical guidance, see: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

For additional information on ACIP general recommendations, see: https://www.cdc.gov/vaccines/hcp/ acip-recs/general-recs/index.html.

Two COVID-19 vaccines are currently authorized for use in the United States. These vaccines are authorized for use among different age groups.

PRODUCT	AUTHORIZED AGE GROUPS
Pfizer-BioNTech COVID-19 Vaccine	16 years of age and older
Moderna COVID-19 Vaccine	18 years of age and older

Anyone outside of the authorized age groups for a product should not receive the vaccine.

Postvaccination Observation	n Times for Persons without	Contraindications to	COVID-19 Vaccination
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30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy
or a history of anaphylaxis due to any cause

15 minutes: All other persons

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics.

Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are **NOT** interchangeable. Currently authorized COVID-19 vaccines require two doses. Both doses of the series should be completed with the same product. Product dosing schedules vary.

Check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses.

PRODUCT	DOSING SCHEDULE between doses 1 and 2
Pfizer-BioNTech COVID-19 Vaccine	21 days
Moderna COVID-19 Vaccine	28 days





Information for Healthcare Professionals

COVID-19 Vaccine Components

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	
	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	
Lipids	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	
Lipius	Cholesterol	Cholesterol	
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	
	Potassium chloride	Tromethamine	
Calla	Monobasic potassium phosphate	Tromethamine hydrochloride	
Salts, sugars,	Sodium chloride	Acetic acid	
buffers	Dibasic sodium phosphate dihydrate	Sodiumacetate	
	Sucrose	Sucrose	

Have you ever had an allergic reaction to:

Any component of a COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures?

Polysorbate

A previous COVID-19 vaccine

History of anaphylaxis or an immediate allergic reaction (of any severity) to any COVID-19 vaccine or any component of an mRNA COVID-19 vaccine is a contraindication to any current COVID-19 vaccine. Polyethylene glycol (PEG) is an ingredient in mRNA COVID-19 vaccines. Because of potential cross-reactive hypersensitivity with the COVID-19 vaccine ingredient PEG, a history of allergic reaction to polysorbate is also a contraindication to an mRNA COVID-19 vaccine.

Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.

See Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC for additional guidance.

Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) is a precaution to currently authorized COVID-19 vaccines. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered. Considerations for vaccination include risk of exposure to SARS-CoV-2, risk of severe disease or death due to COVID-19, previous infection with COVID-19, unknown risk of anaphylaxis following mRNA COVID-19 vaccination, and ability of recipient to receive care immediately for anaphylaxis if necessary. **These individuals should be observed for 30 minutes after vaccination.**

When vaccine recipients report an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving the second vaccine dose). See page 6 for additional information.

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Information for Healthcare Professionals

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.

Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. HOWEVER, individuals who have had severe allergic reactions to anything, regardless of cause, **should be observed for 30 minutes after vaccination.** All others, including those with immediate allergic reactions that were not severe, should be observed for 15 minutes.

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

Have you received another vaccine in the last 14 days?

The COVID-19 vaccine series should be administered alone, with a minimum interval of 14 days before or after administration of other vaccines. This recommendation is based on the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines.

Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?

Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired, because current evidence suggests reinfection is uncommon during this time. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purpose of vaccine decision-making is not recommended.

Have you received passive antibody therapy as treatment for COVID-19?

Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, might be at increased risk for severe COVID-19. mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19, including wearing a mask, social distancing, and washing hands frequently. Revaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs.

Do you have a bleeding disorder or are you taking a blood thinner?

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As with all vaccines, COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.





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Are you pregnant or breastfeeding?

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. For pregnant people seeking guidance in making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about use of the vaccine during pregnancy.

A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated. There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA COVID-19 vaccination

In patients who develop postvaccination symptoms, determining the etiology is important to decide whether a person can receive additional doses of mRNA COVID-19 vaccines. The following table of signs and symptoms is meant to serve as a resource but may not be exhaustive, and patients may not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and sympton	ms		
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site, lymphadenopathy insame arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Recommended to receive second dose of mRNA COVID-19 vaccine?	No	Yes	Yes

Healthcare professionals or health departments in the United States can request a consultation from the <u>Clinical Immunization</u>

<u>Safety Assessment COVIDvax project</u> for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance about an individual patient residing in the United States not readily addressed by CDC guidance.

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