

# Prevaccination Checklist for COVID-19 Vaccines



## 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. If a question is not clear, please ask your healthcare provider to explain it.

Name \_\_\_\_\_

Age \_\_\_\_\_

	Yes	No	Don't know
<b>1.</b> Are you feeling sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2.</b> Have you ever received a dose of COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> <li>If yes, which vaccine product did you receive?                              <input type="checkbox"/> Pfizer-BioNTech    <input type="checkbox"/> Moderna    <input type="checkbox"/> Janssen (Johnson &amp; Johnson)    <input type="checkbox"/> Another Product _____                         </li> <li>Have you received a complete COVID-19 vaccine series (i.e., 1 dose Janssen or 2 doses of an mRNA vaccine [Pfizer-BioNTech, Moderna])?                              <input type="checkbox"/> Yes    <input type="checkbox"/> No                         </li> <li>Did you bring your vaccination record card or other documentation?                              <input type="checkbox"/> Yes    <input type="checkbox"/> No                         </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>3.</b> Have you ever had an allergic reaction to:			
<i>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)</i>			
<ul style="list-style-type: none"> <li>A component of a COVID-19 vaccine, including either of the following:                             <ul style="list-style-type: none"> <li>Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures                                      <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Don't know                                 </li> <li>Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids                                      <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Don't know                                 </li> </ul> </li> <li>A previous dose of COVID-19 vaccine                              <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Don't know                         </li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4.</b> Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5.</b> Check all that apply to you:			
<input type="checkbox"/> Am a female between ages 18 and 49 years old			
<input type="checkbox"/> Am a male between ages 12 and 29 years old			
<input type="checkbox"/> Have a history of myocarditis or pericarditis			
<input type="checkbox"/> Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies			
<input type="checkbox"/> Had COVID-19 and was treated with monoclonal antibodies or convalescent serum			
<input type="checkbox"/> Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection			
<input type="checkbox"/> Have a bleeding disorder			
<input type="checkbox"/> Take a blood thinner			
<input type="checkbox"/> Have a weakened immune system (i.e., HIV infection, cancer) or take immunosuppressive drugs or therapies			
<input type="checkbox"/> Have a history of heparin-induced thrombocytopenia (HIT)			
<input type="checkbox"/> Am currently pregnant or breastfeeding			
<input type="checkbox"/> Have received dermal fillers			
<input type="checkbox"/> History of Guillain-Barré Syndrome (GBS)			

Form reviewed by \_\_\_\_\_

Date \_\_\_\_\_

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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 Advisory Committee on Immunization Practices *General Best Practice Guidelines for Immunization*, see <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

COVID-19 vaccines are authorized for different age groups and are given intramuscularly as a two-dose series\* or single dose.

VACCINE PRODUCT	AUTHORIZED AGE GROUPS	SERIES	INTERVAL
Pfizer-BioNTech COVID-19 Vaccine	12 years of age and older	2 doses*	21 days
Moderna COVID-19 Vaccine	18 years of age and older	2 doses*	28 days
Janssen COVID-19 Vaccine (Johnson & Johnson)	18 years of age and older	1 dose	N/A

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

## Postvaccination Observation Times for People without Contraindications to COVID-19 Vaccination

### ■ 30 minutes:

- History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA vaccines who receive a Janssen (Johnson & Johnson COVID-19 Vaccine)
- History of anaphylaxis due to any cause

### ■ 15 minutes:

- All other people

## Co-administration of COVID-19 vaccines and other vaccines

COVID-19 vaccines and other vaccines **may be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines during the same visit. Other vaccines can also be administered anytime before or after COVID-19 vaccination.

## 1. Are you feeling sick today?

While there is no evidence acute illness reduces vaccine efficacy or increases adverse reactions, as a precaution, **delay vaccinating patients with moderate or severe illness** until the illness has improved.

**Defer vaccination of people with current SARS-CoV-2 infection until the person has recovered from acute illness and discontinued isolation.** This recommendation applies

regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses, for a two-dose vaccine. Viral or serological testing to assess for current or prior infection solely for the purpose of vaccine-decision making is not recommended.

**People with mild illnesses can be vaccinated.** Do not withhold vaccination if a person is taking antibiotics.

\*People with moderate to severe immune compromise can receive an additional dose after an initial 2-dose primary mRNA COVID-19 vaccine series. See clinical considerations on page 9 for more information.

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

COVID-19 vaccines are not interchangeable.

For two-dose products, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. If the vaccine product for the first dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses

by at least 28 days). If two doses of different mRNA COVID-19 vaccine are inadvertently administered, no additional doses of either product are recommended.

People who received a trial vaccine should consult with the trial sponsors to determine if it is possible to receive additional doses.

For people who received a COVID-19 vaccine outside the United States:

- People who received all recommended doses of an FDA-authorized COVID-19 vaccine do not need any additional doses. People who received the first dose of an FDA-authorized COVID-19 vaccine that requires two doses **do not need** to restart the vaccine series in the United States but should receive the second dose as close to the recommended time as possible.
- People who have received all recommended doses of a COVID-19 vaccine listed for emergency use by WHO **do not need** any additional doses with an FDA-authorized COVID-19 vaccine. See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>) for a list of WHO vaccines for emergency use.
- People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by WHO may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.
- People who received all or some of the recommended doses of a COVID-19 vaccine not listed for emergency use by WHO and not authorized by FDA may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.

## 3. Have you ever had an allergic reaction to:

- A 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, which is found in some vaccines, film-coated tablets, and intravenous steroids
- A previous dose of COVID-19 vaccine

People with an immediate allergic reaction\* to a previous COVID-19 vaccine dose or a known (diagnosed) allergy to a component of the vaccine have a contraindication to vaccination.

People with a contraindication to an mRNA COVID-19 vaccine should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). People with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG<sup>†</sup>) have a precaution to Janssen COVID-19 Vaccine.

People with a contraindication to Janssen COVID-19 Vaccine (including due to a known [diagnosed] allergy to polysorbate\*) have a precaution to mRNA COVID-19 vaccines.

People with a history of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one

or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine, even if it is unknown which component elicited the allergic reaction.

\*When vaccine recipients report a history of 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 of an mRNA COVID-19 vaccine dose).

<sup>†</sup>Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 Vaccine. Because PEG and polysorbate are structurally related, cross-reactive hypersensitivity between these compounds may occur.

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## COVID-19 Vaccine Components\*

Description	Pfizer-BioNTech mRNA COVID-19 Vaccine	Moderna mRNA COVID-19 Vaccine	Janssen COVID-19 Vaccine
<b>Active ingredients</b>	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	Viral Vector; Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
<b>Inactive ingredients</b>	2[(polyethylene glycol {PEG}-2000)-N, N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin (HBCD)
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
Sucrose	Sucrose		

\*None of the vaccines contain eggs, gelatin, latex, or preservatives.

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

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the 2nd dose of an mRNA COVID-19 vaccine). 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 appropriate management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	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 the day after vaccination)

### SIGNS AND SYMPTOMS

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
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 in same 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

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Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
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

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	Vaccine side effects (local and systemic)
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA vaccine dose?	No	Yes	Yes

Healthcare providers or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>) for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance about an individual patient residing in the United States.

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.

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>

Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions. All people are recommended to be observed following COVID-19 vaccination for at least 15 minutes. Patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

## 4. 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 (within 4 hours) to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of COVID-19 vaccines) 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 should 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 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.**

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## 5. Clinical Considerations:

Response	Consideration
<p><b>Female between 18 and 49 years of age</b></p>	<p>Women 18 through 49 years of age can receive any FDA-authorized COVID-19 vaccine. However, they should be informed of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen COVID-19 Vaccine <a href="http://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine">www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine</a> and the availability of other FDA- authorized COVID-19 vaccines.</p> <p>TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin.</p> <p>Additional recipient education materials can be found at <a href="http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html">www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html</a>.</p>
<p><b>Male between 12 and 29 years of age</b></p>	<p>Males 12 through 29 years of age can receive any FDA-authorized vaccine. However, people receiving an mRNA COVID-19 vaccine, especially males in this age group and their parents/legal representative (when relevant), should be informed of the risk of developing myocarditis (an inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart) after receipt of an mRNA vaccine. Cases of myocarditis or pericarditis have occurred predominantly in males aged 12–29 years within a few days after receiving the second dose of an mRNA COVID-19 vaccine. The risk of developing either myocarditis or pericarditis is low.</p> <p>Additional recipient education materials can be found at <a href="http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html">www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html</a>.</p>
<p><b>History of myocarditis or pericarditis</b></p>	<p><b><i>Myocarditis or pericarditis after receipt of the first dose of an mRNA COVID-19 vaccine series but before administration of the second dose</i></b></p> <p>Experts recommend that people who develop myocarditis or pericarditis after a first dose of an mRNA COVID-19 vaccine defer receiving the second dose, until additional safety data are available.</p> <p>Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Decisions about proceeding with the second dose should include a conversation between the patient, their parent/legal representative (when relevant), and their clinical team, which may include a cardiologist.</p> <p>Considerations for vaccination can be found at: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions</a>. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at <a href="http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html">www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html</a>.</p> <p><b><i>History of myocarditis or pericarditis prior to COVID-19 vaccination</i></b></p> <p>People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.</p>
<p><b>Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies</b></p>	<p>Allergic reactions, including severe allergic reactions, <b>NOT</b> related to vaccines, injectable therapies, or components of COVID-19 vaccines, are <b>NOT</b> contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. However, individuals who have had severe allergic reactions to anything, regardless of cause, <b>should be observed for 30 minutes after vaccination.</b></p>

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Response	Consideration
<p><b>Had COVID-19 and was treated with monoclonal antibodies or convalescent serum</b></p>	<p>Vaccination should be offered to people regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. There is no recommended minimal interval between infection and vaccination.</p> <p>However, vaccination should be deferred for at least 90 days if a patient received monoclonal antibodies or convalescent serum as treatment for COVID-19. This is a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.</p>
<p><b>Had multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)</b></p>	<p>It is unknown if people with a history of MIS-C or MIS-A are at risk for a dysregulated immune response to COVID-19 vaccination.</p> <p>People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include:</p> <ul style="list-style-type: none"> <li>▪ Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function</li> <li>▪ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)</li> <li>▪ Level of COVID-19 community transmission and personal risk of reinfection</li> <li>▪ Lack of safety data of COVID-19 vaccines following these illnesses</li> <li>▪ Timing of any immunomodulatory therapies (general best practice guidelines for immunization can be consulted for more information <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</a>)</li> </ul> <p>Because current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from their infection and for 90 days after the date of diagnosis of MIS-C or MIS-A.</p> <p>A conversation between the patient, their guardian(s), and their clinical team or a specialist may assist with COVID-19 vaccination decisions. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment Project at <a href="http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html">www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html</a>.</p>
<p><b>Have a bleeding disorder</b></p> <p><b>Take a blood thinner</b></p>	<p>As with all vaccines, any COVID-19 vaccine product 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.</p> <p>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.</p> <p>People who regularly take aspirin or anticoagulants as part of their routine medications do not need to stop these medications prior to receipt of any COVID-19 vaccine.</p>



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Response	Consideration
<p><b>Have a weakened immune system (HIV infection, cancer)</b></p> <p><b>Take immunosuppressive drugs or therapies</b></p>	<p>COVID-19 vaccines may be administered to people with underlying medical conditions, such as HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, who have no contraindications to vaccination.</p> <p>Consider an additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:</p> <ul style="list-style-type: none"> <li>▪ Active treatment for solid tumor and hematologic malignancies</li> <li>▪ Receipt of solid-organ transplant and taking immunosuppressive therapy</li> <li>▪ Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)</li> <li>▪ Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)</li> <li>▪ Advanced or untreated HIV infection</li> <li>▪ Active treatment with high-dose corticosteroids (i.e., <math>\geq 20</math>mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory</li> </ul> <p>Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.</p> <p>Whenever possible, administer the same additional mRNA COVID-19 vaccine product as the initial 2-dose mRNA COVID-19 primary vaccine series (Pfizer-BioNTech or Moderna). If the mRNA COVID-19 vaccine product given for the first two doses is not available, the other mRNA COVID-19 vaccine product may be administered. A person should not receive more than three valid mRNA COVID-19 vaccine doses.</p> <p>Until additional data are available, the additional dose of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 vaccine series, based on expert opinion. Whenever possible, complete mRNA COVID-19 vaccination doses (including the primary series and an additional dose) at least two weeks before initiation or resumption of immunosuppressive therapies. Timing of COVID-19 vaccination should take into consideration current or planned immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine.</p> <p>A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.</p> <p>Additional information can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</a></p> <p>People who are immunocompromised should be counseled about the potential for a reduced immune response to COVID-19 vaccines and the need to continue to follow current prevention measures to protect themselves against COVID-19 until advised otherwise by their healthcare professional.</p>

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Response	Consideration
<p><b>History of heparin-induced thrombocytopenia (HIT)</b></p>	<p>Although the cause of thrombosis with thrombocytopenia syndrome (TTS) associated with the Janssen COVID-19 Vaccine is unclear, it appears to be similar to another rare immune-mediated syndrome, heparin-induced thrombocytopenia (HIT). Until more information becomes available, experts advise that people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered another COVID-19 vaccine (i.e., mRNA vaccine) if it has been 90 days or less since their illness resolved. After 90 days, patients may be vaccinated with any FDA-authorized COVID-19 vaccine.</p> <p>Experts believe that the following factors do not make people more susceptible to TTS after receipt of the Janssen COVID-19 Vaccine. People with these conditions can be vaccinated with any FDA-authorized COVID-19 vaccine, including the Janssen COVID-19 Vaccine:</p> <ul style="list-style-type: none"> <li>■ A prior history of venous thromboembolism</li> <li>■ Risk factors for venous thromboembolism (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S or antithrombin deficiency)</li> <li>■ A prior history of other types of thromboses not associated with thrombocytopenia</li> <li>■ Pregnancy, post-partum, or receipt of hormonal contraceptives (e.g., combined oral contraceptives, patch, ring)</li> </ul> <p>Additional recipient education materials can be found at <a href="http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html">www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html</a>.</p>
<p><b>Currently pregnant or breastfeeding</b></p>	<p>Vaccination is recommended for all people aged 12 years and older, including people that are:</p> <ul style="list-style-type: none"> <li>■ Pregnant</li> <li>■ Breastfeeding</li> <li>■ Trying to get pregnant now or who might become pregnant in the future</li> </ul> <p>A growing body of evidence on the safety and effectiveness of COVID-19 vaccination – in both animal and human studies – indicates that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. If a person becomes pregnant following the first dose of a COVID-19 vaccine that requires two doses (i.e., Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine), the second dose should be administered as indicated for the person to have maximum protection.</p> <p>Pregnant, breastfeeding, and post-partum people 18 through 49 years of age should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 Vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines).</p>
<p><b>Have dermal fillers</b></p>	<p>FDA-authorized COVID-19 vaccines can be administered to people who have received injectable dermal fillers who have no contraindications or precautions for vaccination.</p> <p>Infrequently, these people might experience temporary swelling at or near the site of filler injection (usually the face or lips) following administration of a dose of an COVID-19 vaccine. These people should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.</p>
<p><b>History of Guillain-Barré Syndrome</b></p>	<p>People with a history of GBS can receive any FDA-authorized COVID-19 vaccine. However, given the possible association between the Janssen COVID-19 Vaccine and an increased risk of GBS, a patient with a history of GBS and their clinical team should discuss the availability of mRNA vaccines to offer protection against COVID-19.</p>