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.

Patient Name _____

Age _____

	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 ☐ Moderna ☐ Janssen *(Johnson & Johnson)* ☐ Another Product _____			
• How many doses of COVID-19 vaccine have you received? _____			
• Did you bring your vaccination record card or other documentation? *(yes/no)*	☐	☐	

3. Check all that apply:

☐ I live in a long-term care setting.

☐ I have been diagnosed with a medical condition(s). Please list: _____

_____

☐ I am a first responder.

☐ I work in a long-term care facility, correctional facility, hospital, restaurant, retail setting, school, or other setting with high exposure to the public.

4. Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised? (This would include treatment for cancer or HIV, receipt of organ transplant, immunosuppressive therapy or high-dose corticosteroids, CAR-T-cell therapy, hematocrit therapy [HCT], DiGeorge syndrome or Wiskott-Aldrich syndrome)	☐	☐	☐
5. Have you received hematopoietic cell transplant (HCT) or CAR-T-cell therapies since receiving COVID-19 vaccine?	☐	☐	☐
6. Have you ever had an allergic reaction to: *(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.)*			
• A component of a COVID-19 vaccine, including either of the following:			
○ 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	☐	☐	☐

Prevaccination Checklist for COVID-19 Vaccines

	Yes	No	Don't know
7. Have you ever had an allergic reaction to another vaccine *(other than COVID-19 vaccine)* or an injectable medication? *(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.)*	☐	☐	☐

8. Check all that apply to you:

- ☐ Am a female between ages 18 and 49 years old
- ☐ Am a male between 12 and 29 years old
- ☐ Have a history of myocarditis or pericarditis
- ☐ Have been treated with monoclonal antibodies or convalescent serum to prevent or treat COVID-19
- ☐ Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection
- ☐ Have a bleeding disorder
- ☐ Take a blood thinner
- ☐ Have a history of heparin-induced thrombocytopenia (HIT)
- ☐ Am currently pregnant or breastfeeding
- ☐ Have received dermal fillers
- ☐ History of Guillain-Barré Syndrome (GBS)

Form reviewed by _____ **Date** _____

Prevaccination Checklist for COVID-19 Vaccines

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 in connection 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 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

☐ **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

_____

Date

Prevaccination Checklist for COVID-19 Vaccines

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 and approved for different age groups and are given intramuscularly.

VACCINE PRODUCT	AUTHORIZED AGE GROUPS	SERIES	INTERVAL
Pfizer-BioNTech COVID-19 Vaccine (Orange cap and orange border on the label)	5 through 11 years of age	**Primary:** 2 doses	21 days
		Additional primary dose: N/A*	N/A
		Booster dose: N/A*	N/A
Pfizer-BioNTech COVID-19 Vaccine (Purple cap and may have a purple border on the label)	12 years of age and older	**Primary series:** 2 doses	21 days
		Additional primary dose: 1 dose*	At least 28 days after last primary series dose
		Booster dose: 1 dose*	At least 6 months after last primary series dose or additional primary dose
Moderna COVID-19 Vaccine	18 years of age and older	**Primary series:** 2 doses	28 days
		Additional primary series: 1 dose*	At least 28 days after primary series dose
		Booster dose: 1 dose*	At least 6 months after last primary series dose or additional primary dose
Janssen COVID-19 Vaccine (Johnson & Johnson)	18 years of age and older	**Primary series:** 1 dose	N/A
		Additional primary series: N/A*	N/A
		Booster dose: 1 dose*	At least 2 months (8 weeks) after primary dose

*Booster doses can be a different COVID-19 vaccine product. See questions 2, 3, and 4 below for additional information regarding who is recommended for an additional primary dose or booster dose.

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

30 minutes:

- People with a history of:
  - A contraindication to another type of COVID-19 vaccine product (i.e., mRNA or viral vector COVID-19 vaccines)
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapies
  - Anaphylaxis due to any cause
  - Immediate allergic reaction of any severity to a non-COVID-19 vaccine

15 minutes:

- All other people

Prevaccination Checklist for COVID-19 Vaccines

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 administrationof 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** untilthe illness has improved.

Defer vaccination of people with current SARS-CoV-2 infection until the person has recovered from acute illness and has discontinued isolation. This recommendation applies regardless of whether the SARS-CoV-2 infection occurred before the recipient received an initial dose or between doses. 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.

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

VACCINE PRODUCT	Primary Series Dosage (Amount)
Pfizer-BioNTech COVID-19 Vaccine *(Orange Cap)* 5 through 11 years of age	0.2 mL
Pfizer-BioNTech COVID-19 Vaccine *(Purple Cap)* 12 years of age and older	0.3 mL
Moderna COVID-19 Vaccine	0.5 mL
Janssen COVID-19 Vaccine (Johnson & Johnson)	0.5 mL

All COVID-19 primary series doses and additional primary doses should be the same vaccine product. Booster doses may be a different product than the COVID-19 vaccine product used in the primary series (e.g., mix and match may be used for boosters.

To determine previously administered COVID-19 doses, check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. If the vaccine product for a primary mRNA dose cannot be determined or is no longer available, any available mRNA vaccine may be administered (separate doses by at least 28 days). If a different mRNA COVID-19 vaccine is inadvertently administered for the primary series or additional primary dose, the dose is considered valid, and 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.

People 5 years of age and older **should** receive a primary series of COVID-19 vaccine.

Ages 5 through 11 years of age:
Pfizer-BioNTech (orange cap), 2 doses

Ages 12 through 17 years of age:
Pfizer-BioNTech (purple cap), 2 doses

Ages 18 and older:
Pfizer-BioNTech (purple cap), 2 doses
Moderna, 2 doses
Janssen (Johnson & Johnson), 1 dose

See answers to questions 3 (to determine if a booster dose is needed) and to question 4 (to determine if an additional primary dose is 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 or-approved COVID-19 vaccine or a WHO-EUL† COVID-19 vaccine do not need any subsequent primary series doses.
- People who received the first dose of an FDA-authorized or-approved 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 completed a mix-product regimen of FDA-authorized, FDA-approved, or WHO-EUL† COVID-19 vaccines are considered fully vaccinated and do not need to restart a COVID-19 primary series.
- People who received only the first dose of a 2-dose WHO-EUL† COVID-19 vaccine primary series or who received all or some of a COVID-19 vaccine primary series doses not on the WHO-EUL list may be offered a complete FDA-approved or -authorized COVID-19 primary series. Wait at least 28 days after the last dose of the previous product before administering vaccine.
- People who completed a primary vaccination series of an FDA- approved or -authorized vaccine mRNA vaccine (including a mixed mRNA product primary series) may receive an additional primary mRNA dose at least 28 days after the second mRNA vaccine if they are moderately or severely immunocompromised.
- People who have completed a primary vaccination series of an FDA-approved or -authorized COVID-19 vaccine may receive or a booster dose if they are eligible.
- Additional guidance for people who received COVID-19 vaccine outside the United States, guidance can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#people-vaccinated-outside-us

†See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.htmll) for a list of WHO vaccines for emergency use.

3. Check all that apply.

VACCINE PRODUCT	Booster Dosage (Amount)
Pfizer-BioNTech COVID-19 Vaccine *(Orange Cap)* 5 through 11 years of age	N/A
Pfizer-BioNTech COVID-19 Vaccine *(Purple Cap)* 12 years of age and older	0.3 mL
Moderna COVID-19 Vaccine	0.25 mL
Janssen COVID-19 Vaccine (Johnson & Johnson)	0.5 mL

People identified as at high risk of complications of COVID-19 or high risk of exposure and transmission of SARS-CoV-2 should or may receive a booster dose of COVID-19 vaccine. Based on response to this question, consider providing a booster dose to these individuals based on the following criteria:

People who received Pfizer-BioNTech or Moderna as their primary series:

- A booster dose, at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose, or the additional primary dose for moderately or severely immunocompromised persons), **should** be given to:
  - Persons aged 50 years and older
  - Residents of long-term care settings aged 18 years and older
- A booster dose, at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., after the 2nd dose, or the additional primary dose for moderately or severely immunocompromised persons), **may** be given to all other persons aged 18 years and older based on their individual benefits and risks.
- For moderately or severely immunocompromised persons, the booster dose may be given after an additional (3rd) primary series dose (for a total of 4 doses). For additional information, see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-immunocopromised
- The booster may be a different vaccine product than the primary series.

People who received Janssen (Johnson & Johnson) as their primary dose:

A single booster dose at least 2 months (8 weeks) after the primary dose should be given to all people 18 years and older.

Moderately or severely immunocompromised person who received a primary Janssen COVID-19 vaccine should not receive more than 1 booster dose (total of 2 doses).

A different COVID-19 product than the primary series may be used for any booster dose.

4. Do you have a health condition or are you undergoing treatment that makes you moderately or severely immunocompromised?

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.

VACCINE PRODUCT	Additional Primary Series Dosage (Amount)
Pfizer-BioNTech COVID-19 Vaccine *(Orange Cap)* 5 through 11 years of age	N/A
Pfizer-BioNTech COVID-19 Vaccine *(Purple Cap)* 12 years of age and older	0.3 mL
Moderna COVID-19 Vaccine	0.5 mL
Janssen COVID-19 Vaccine (Johnson & Johnson)	0.5 mL

Moderately or severely immunocompromised persons 12 years of age and older (Pfizer-BioNTech recipients) or 18 years and older (Moderna recipients) should receive an additional primary dose of the same mRNA COVID-19 vaccine administered for the primary series at least 28 days after completion of the initial 2-dose series. An additional primary dose is NOT recommended for Janssen vaccine recipients (see #3 for additional information for people who received a primary dose of Janssen.)

These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg 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

Moderately and severely immunocompromised people 18 years and older should follow the booster recommendations for the general population (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-covid19-vax-booster), based on their age and high-risk underlying condition.

A patient's clinical team is best positioned to determine the degree of immune compromise and appropriate timing of vaccination.

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 (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html) to protect themselves against COVID-19 until advised otherwise by their healthcare professional.

Additional information can be found in the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

5. Have you received a hematopoietic cell transplant (HCT) or CAR-T-cell therapy since receiving COVID-19 vaccine?

HCT and CAR-T-cell recipients who received doses of COVID-19 vaccine prior to receiving an HCT or CAR-T-cell therapy should be revaccinated with a primary vaccine series at least 3 months (12 weeks) after transplant or CAR-T-cell therapy.

6. 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 a severe 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 who had an immediate (< 4 hours), but non-severe allergic reaction to a previous dose of COVID-19 vaccine, have a precaution to receiving the same type of COVID-19 vaccine product. Although they can receive the same product, a different COVID-19 vaccine product can also be administered.

People with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) should not receive any doses of that type of vaccine and have a precaution to the other type of vaccine (e.g., Janssen viral vector). 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.

‡ 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.

§ 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).

COVID-19 Vaccine Components*

Description	Pfizer-BioNTech mRNA COVID-19 Vaccine		Moderna mRNA COVID-19 Vaccine	Janssen COVID-19 Vaccine
	For 5-11 years formulation (Orange Cap)	For 12 years and older formulation (Purple Cap)		
Active ingredients	Nucleoside-modified mRNA encoding the viralspike (S) glycoprotein of SARS-CoV-2		Nucleoside-modified mRNA encoding theviral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	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
	Cholesterol		Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(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
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

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

Prevaccination Checklist for COVID-19 Vaccines

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 whethera person can receive additional doses of the 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
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 might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
VACCINE RECOMMENDATIONS AND CLINICAL MANAGEMENT			
Characteristic	**Immediate allergic reactions (including anaphylaxis)**	**Vasovagal reactions**	**Vaccine side effects (local and systemic)**
Can receive a subsequent dose of COVID-19 vaccine	No, contraindicated if: ▪ Severe allergic reaction (e.g., anaphylaxis) ▪ Known (diagnosed) allergy to a component of a COVID-19 vaccine Yes, with precaution if: ▪ Any immediate (onset <4 hours after exposure) allergic reaction to other vaccines (non-COVID-19) or injectable therapies ▪ Non-severe, immediate allergic reaction after a previous dose ofCOVID-19 vaccine. People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine and vice versa.	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 severe 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 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 for vaccination and during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve.

7. 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 (onset <4 hours of exposure) 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 FDA-authorized or -approved COVID-19 vaccines. This also applies if the non-COVID-19 vaccine or therapy has multiple components, one or more of which is a component of a COVID-19 vaccine, and it is unknown which component elicited the allergic reaction. 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**

8. Clinical Considerations:

Response	Consideration
Female between 18 and 49 years of age	Women 18 through 49 years of age can receive any FDA-authorized or -approved 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 and the availability of other FDA-authorized and -approved COVID-19 vaccines. People who had TTS after a first dose of Janssen vaccine should not receive a subsequent dose of Janssen product. (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine) Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html.

Prevaccination Checklist for COVID-19 Vaccines

Response	Consideration
Male between 12 and 29 years of age	Males 5 through 17 years of age may receive the correct formulation of Pfizer-BioNTech COVID-19 vaccine. Males 18 and older can receive any FDA-authorized or -approved vaccine. However, people receiving an mRNA COVID-19 vaccine, especially males 12 through 29 years of age 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. The risk of developing either myocarditis or pericarditis after vaccination is low, and lower than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults. Vaccine recipients should be counseled about the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html.
History of myocarditis or pericarditis	***Myocarditis or pericarditis after receipt of the first dose of an mRNA COVID-19 vaccine series but before administration of the second dose*** Experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine not receive a subsequent dose of any COVID-19 vaccine, until additional safety data are available. Administration of a subsequent dose of COVID-19 vaccine before safety data are available can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Until additional data are available, some experts recommend a Janssen COVID-19 vaccine be considered instead of an mRNA COVID-19 vaccine. Decisions about proceeding with a subsequent dose should include a conversation between the patient, their parent/legal representative (when relevant), and their clinical team, which may include a cardiologist. Considerations for vaccination can be found at: https://www.cdc.gov/vaccines/covid-19/ clinical-considerations/covid-19-vaccines-us.html#underlying-conditions. Healthcare providersand health departments may also request a consultation from the Clinical Immunization SafetyAssessment Project at www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. ***History of myocarditis or pericarditis prior to COVID-19 vaccination*** People who have a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination may receive any FDA-authorized or -approved COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved.
Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies	Allergic reactions, including severe allergic reactions, **NOT** related to vaccines, injectable therapies, or components of COVID-19 vaccines, are **NOT** contraindications or precautions to vaccination with currently FDA-authorized or -approved COVID-19 vaccines. However, individuals who have had severe allergic reactions to anything, regardless of cause, **should be observed for 30 minutes after vaccination.**

Response	Consideration
Treated with monoclonal antibodies or convalescent serum	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. However, vaccination should be deferred if a patient received monoclonal antibodies or convalescent serum as treatment for COVID-19 or for post-exposure prophylaxis. This is a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses. Defer COVID-19 vaccination for 30 days when a passive antibody product was used for post-exposure prophylaxis. Defer COVID-19 vaccination for 90 days when a passive antibody product was used to treat COVID-19.
Had multisystem inflammatory syndrome; either MIS-C (children) or MIS-A (adults)	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. People with a history of MIS-C or MIS-A may choose to be vaccinated. Considerations for vaccination may include: ▪ Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function ▪ Personal risk of severe acute COVID-19 (e.g., age, underlying conditions) ▪ High or substantial community transmission of SARS-CoV-2 and personal increased risk of reinfection. ▪ Timing of any immunomodulatory therapies (general best practice guidelines for immunization can be consulted for more information https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html) ▪ It has been 90 days or more since their diagnosis of MIS-C ▪ Onset of MIS-C occurred before any COVID-19 vaccination 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 www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.
Have a bleeding disorder **Take a blood thinner**	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. 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. 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.

Response	Consideration
History of heparin-induced thrombocytopenia (HIT) or thrombosis with thrombocytopenia syndrome (TTS)	Although the etiology of 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). People with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, should be offered a currently FDA-approved or FDA-authorized mRNA COVID-19 vaccine if it has been ≤90 days since their TTS resolved. After 90 days, patients may be vaccinated with any currently FDA-approved or FDA-authorized COVID-19 vaccine, including Janssen COVID-19 Vaccine. However, people who developed TTS after their initial Janssen vaccine should not receive a Janssen booster dose. Experts believe 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 or - approved COVID-19 vaccine, including the Janssen COVID-19 Vaccine: ▪ A prior history of venous thromboembolism ▪ 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 ▪ A prior history of other types of thromboses not associated with thrombocytopenia ▪ Pregnancy, post-partum status, or receipt of hormonal contraceptives (e.g., combined oral contraceptives, patch, ring) Additional recipient education materials can be found at www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html.
Currently pregnant or breastfeeding	Vaccination is recommended for all people aged 12 years and older, including people that are: ▪ Pregnant ▪ Breastfeeding ▪ Trying to get pregnant now or who might become pregnant in the future 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 or -approved COVID-19 vaccines (i.e., mRNA vaccines). For purposes of decisions around administering both primary series vaccination and a booster dose, (https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html) pregnant and recently pregnant people (for at least 42 days following end of pregnancy) should be considered in the same group as people with underlying medical conditions (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html).

Response	Consideration
Have dermal fillers	FDA-authorized or -approved COVID-19 vaccines can be administered to people who have received injectable dermal fillers who have no contraindications for vaccination. 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 mRNA 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.
History of Guillain- Barré Syndrome (GBS)	People with a history of GBS can receive any FDA-authorized or -approved 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. The highest risk has been observed in men aged 50-64 years with symptoms of GBS beginning within 42 days after Janssen COVID-19 vaccination. People who had GBS after receiving Janssen vaccine should be made aware of the option toreceive an mRNA COVID-19 vaccine booster at least 2 months (8 weeks) after the Janssen dose. However, Janssen vaccine may be used as a booster, particularly if GBS occurred more than 42 days after vaccination or was related to a non-vaccine factor. Prior to booster vaccination, a conversation between the patient and their clinical team may assist with decisions about use ofa COVID-19 booster dose, including the timing of administration.