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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine for Moderately to Severely Immunocompromised People

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Note: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

For information about primary COVID-19 Vaccine Series in the General Population, please refer to Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine at: <https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers>

1. Will you be under the age of 6 months, on the day of your appointment?

If yes, do not administer the vaccine until the person has reached the specified age.

2. Are you feeling sick today?

If yes, refer to the vaccination site health care provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the patient to return when symptoms improve.

3. In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?

- If yes, advise patient to return to isolation or quarantine and reschedule for after isolation/quarantine ends.
- If the patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 72 hours or more, patient may be vaccinated.
- If the patient has had a test in the last 10 days, ask for the result. If positive, send them home. If negative, they can proceed to vaccination. If the result is unsure or unknown, advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.
- Persons with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A) should consider delaying vaccination until they have recovered from their illness and for 90 days after the diagnosis of MIS-C or MIS-A. However, patients can choose to be vaccinated. For further information on counselling a patient with a history of MIS-C or MIS-A regarding COVID-19 vaccines, please see the CDC's section on MIS-C and MIS-A in their "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States" available at: <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#CoV-19-vaccination>.

4. Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose?

If yes, notify them that they should defer further doses of Evusheld™ for at least 2 weeks after vaccination. However, COVID-19 vaccination need not be delayed due to previous antibody therapy nor receipt of convalescent plasma.

- 5. Have you ever had an immediate allergic reaction, such as hives, facial swelling, difficulty breathing, anaphylaxis to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?**

If yes, then refer to the vaccination site health care provider for assessment of allergic reaction. Review the ingredient lists at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-C>.

Contraindications to COVID-19 vaccine:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine
- People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA COVID-19 vaccines (Pfizer or Moderna)
- TTS following receipt of a previous Janssen COVID-19 Vaccine (or other COVID-19 vaccines not currently authorized in the United States that are based on adenovirus vectors, e.g., AstraZeneca) is a contraindication to further doses of the Janssen COVID-19 vaccine.

Precautions to COVID-19 vaccine: (Refer to your organization's protocol to see whether individuals with a precaution to vaccination warrant further evaluation.)

- Immediate (onset within 4 hours after vaccination), but non-severe, allergic reaction after a previous dose of COVID-19 vaccine
- Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies)
- Individuals with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector)
 - Consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination, and vaccination of these individuals should only be undertaken in an appropriate clinical setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.
 - Note: These individuals should not be administered COVID-19 vaccine at State-operated vaccination sites.
- **For mRNA COVID-19 vaccines,** for history of myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine, a subsequent dose of COVID-19 vaccine should generally be avoided (there is a separate question on the screening and consent form regarding myocarditis and pericarditis – question #9).

For patients who are determined eligible for COVID-19 vaccination after assessment of allergy history, a 30-minute post-vaccination observation period is needed for the following:

- Patients with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy
- Patients with a contraindication to a different type of COVID-19 vaccine (e.g., mRNA vs. Janssen viral vector)
- Patients with a history of anaphylaxis due to any cause

- 6. Are you pregnant or considering becoming pregnant?**

If yes, ask the patient if they would like to have a discussion with a healthcare provider at site for counseling on the risks and benefits of COVID-19 vaccine during pregnancy. Patient may be

vaccinated if they choose and does not need to go to medical evaluation if they choose.

7. Are you moderately or severely immunocompromised due to one or more of the medical conditions or receipt of immunosuppressive medications or treatments listed below?

- 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
 - If yes, then administer the mRNA COVID-19 vaccine if the person is age appropriate and without contraindications. If possible, the additional dose should be with the same mRNA vaccine product (Pfizer or Moderna) used for the initial 2 dose primary series. If the same vaccine product is not available, then the other product may be administered after counseling about the unknown risks of a mixed dose series. At this time, there is no recommendation for additional doses for those who received the Janssen (Johnson & Johnson) COVID-19 vaccine.
 - If no, inform the person that they are not eligible at this time to receive a third dose. The FDA and the CDC are reviewing the data in relation to this topic and will provide updates as more information becomes available.

8. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner?

If yes, refer to health care provider to assess the patient's bleeding risk and thrombosis history. Persons with a history of Thrombosis with Thrombocytopenia Syndrome (TTS) following receipt of Janssen COVID-19 vaccine or of any other immune-mediated thrombosis and thrombocytopenia, such as Heparin-Induced Thrombocytopenia (HIT) within the past 90 days should be offered an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna vaccine) instead of Janssen (Johnson & Johnson) vaccine. If a person with a bleeding disorder or taking a blood thinner is cleared for vaccination, then administer vaccine using a 23-gauge or smaller caliber needle and apply firm pressure on the site of vaccination, without rubbing, for at least 2 minutes after vaccination. TTS after a dose of Janssen COVID-19 vaccine is a contraindication to further doses of Janssen COVID-19 vaccine.

9. Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart?)

If yes:

- Evaluate if this history was in relation to a dose of mRNA vaccine. If it was not, then the patient can receive any FDA authorized COVID-19 vaccine after complete resolution of a myocarditis or pericarditis episode.
- Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine generally **should not** receive a subsequent dose of any COVID-19 vaccine. If after a risk assessment, the decision is made to receive a subsequent COVID-19 vaccine dose, the person should wait until at

least after their episode of myocarditis or pericarditis has resolved (i.e., resolution of symptoms, no evidence of ongoing heart inflammation or sequelae as determined by patient's clinical team). For men ages 18 years and older who choose to receive a subsequent COVID-19 vaccine following recovery from post-vaccine myocarditis, some experts advise the use of Janssen COVID-19 vaccine be considered instead of mRNA COVID-19 vaccines. These people should be made aware of the risk of TTS after receipt of Janssen COVID-19 vaccine. Decisions to proceed with vaccination should include conversations with the patient, parent/legal representative, and the clinical team, including a cardiologist.

Considerations for vaccination may include:

- The myocarditis or pericarditis was considered unrelated to mRNA COVID-19 vaccination (e.g., due to SARS-CoV-2 or other viruses), especially if the myocarditis or pericarditis diagnosis occurred more than 3 weeks after the most recent COVID-19 vaccine.
- Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions)
- Level of COVID-19 community transmission and personal risk of infection.
- Timing of immunomodulatory therapeutics; ACIPs [general best practice guidelines for immunization](#) can be consulted for more information.
- For the full CDC interim clinical considerations regarding a history of myocarditis and/or pericarditis, please see the CDC's [COVID-19 Vaccines Currently Authorized in the United States](#) and ["Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults."](#)

10. Have you had Guillain-Barre Syndrome after receipt of the Janssen vaccine?

If yes, this is a precaution to further doses of Janssen COVID-19 vaccine. Subsequent doses of mRNA COVID-19 vaccine may be administered.

11. Do you have a history of MIS-C or MIS-A (multisystem inflammatory syndrome in children or multisystem inflammatory syndrome in adults)?

For children and adolescents with a history of MIS-C experts consider the benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C (i.e., a reduced risk of severe disease including potential recurrence of MIS-C after reinfection) to outweigh a theoretical risk of an MIS-like illness or the risk of myocarditis following COVID-19 vaccination for those who meet the following three criteria:

- Clinical recovery has been achieved, including return to normal cardiac function;
- It has been at least 90 days after the diagnosis of MIS-C; and
- The patient resides in an area where the COVID-19 community level is high or is otherwise at increased risk for exposure to SARS-CoV-2 (e.g., through occupation, travel, large gatherings)

COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet all three criteria, at the discretion of their clinical care team (see Consultation for decisions about COVID-19 vaccination). Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as the risk of severe COVID-19 due to certain medical conditions, may also be considered.

For adults with a history of MIS-A COVID-19 vaccination may be considered for adults who had MIS-A at the discretion of their clinical care team. Experts view clinical recovery, including return to normal cardiac function, as an important factor when considering COVID-19 vaccination. Additional factors, such as risk of severe COVID-19 due to age or certain medical conditions, may also be considered.

For the complete consideration for vaccination of children and adults with a history of MIS-C or MIS-A, and those who develop MIS-C or MIS-A after COVID-19 vaccination, please refer to the CDC's clinical considerations available at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#covid19-vaccination-misc-misa>.

12. Have you received two previous doses of the Pfizer, or Moderna COVID-19 vaccines, and was your last dose at least 28 days ago?

If yes, administer the additional dose with the same mRNA COVID-19 vaccine product used for the initial 2 dose primary series and dosage appropriate for the age of the patient on the day of vaccination. If the original mRNA COVID-19 vaccine product is not available, the other vaccine product of an age-appropriate dose on the day of vaccination can be used for the 3rd dose. If it has not been at least 28 days since the second dose, do not administer the vaccine until this interval has been reached.

Of note, children 6 months to 4 years of age who received 3 doses of the Pfizer vaccine as their primary series, an additional dose (4th dose) is not recommended for immunocompromised children at this time. Children 6 months to 5 years old who received the 2 dose Moderna primary series should receive an additional dose (3rd dose) at least 28 days after the second dose.

13. Have you received a previous dose of the Janssen (Johnson & Johnson) COVID-19 vaccine at least 28 days ago?

If yes, verify if this is a 2nd dose or a booster dose. If this is a 2nd dose, verify that the first dose was given at least 28 days ago. Administer an additional dose of an mRNA COVID-19 vaccine product (Pfizer or Moderna).

14. Are you 5 years old or older and have received 3 doses of the Pfizer or Moderna COVID-19 vaccine, and was your last dose at least 3 months ago?

If yes, verify if that the 3rd dose was given at least 3 months ago. Persons with moderately to severely immunocompromising conditions are recommended to receive a 4th dose 3 months after the 3rd additional dose of an mRNA vaccine. mRNA vaccines (Pfizer or Moderna) are preferred as the 4th dose. Please see CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines for more information on booster dosing and considerations for clinicians regarding the different vaccine products. Booster doses are not authorized for children less than 5 years old at this time.

15. Have you received 2 doses of a Janssen (Johnson & Johnson) COVID-19 vaccine, or one dose of Janssen (Johnson & Johnson) followed by an mRNA vaccine (Pfizer or Moderna), and was your last dose at least 2 months ago?

If yes, verify if that the 2nd dose was given at least 2 months ago. Persons with moderately to severely immunocompromising conditions are recommended to receive a booster 2 months after the additional dose, for a total of 3 doses. mRNA vaccines (Pfizer or Moderna) are preferred as the booster dose. Some patients that initially received a Janssen (Johnson & Johnson) vaccine, may have already received a booster dose. Regardless of the type of vaccine or the timing, administer an additional dose of mRNA COVID-19 vaccine (Pfizer or Moderna) at least two months after the 2nd dose. The additional dose of Moderna COVID-19 vaccine for immunocompromised individuals should be 100 mcg (0.5 mL), regardless of whether it is given before or after the booster dose. Please see CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for more information on booster dosing and considerations for clinicians regarding the different vaccine products.

16. Are you 12 years old or older and have received 4 doses of the Pfizer or Moderna COVID-19 vaccine, and was your last dose at least 4 months ago?

If yes, verify if that the 4th dose was given at least 4 months ago. Persons with moderately to severely immunocompromising conditions are recommended to receive a 5th dose 4 months after the 4th dose (first booster dose) of an mRNA vaccine. Only mRNA vaccines (Pfizer or Moderna) are authorized for the 5th dose. Only Pfizer COVID-19 vaccine is authorized for those 12 years to 17 years of age. Both Pfizer and Moderna COVID-19 vaccine are authorized for those 18 years and older. Please see [CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for more information on booster dosing and considerations for clinicians regarding the different vaccine products. Booster doses are not authorized for children less than 5 years of age at this time.

17. Have you received any combination of Janssen (Johnson & Johnson) COVID-19 vaccine and mRNA vaccine (Pfizer or Moderna) totaling 3 doses, and was the last dose at least 4 months ago?

If yes, verify if that the 3rd dose was given at least 4 months ago. Persons with moderately to severely immunocompromising conditions are recommended to receive a booster 4 months after the 3rd (first booster) dose, for a total of 4 doses. Only mRNA vaccines (Pfizer or Moderna) are authorized for the 2nd booster dose. Please see CDC's [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) for more information on booster dosing and considerations for clinicians regarding the different vaccine products.

18. Have you received a previous dose of a non-FDA authorized or approved COVID-19 vaccine¹ (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm/BIBP, COVAXIN, Novavax – Covovax, Nuvaxovid, or CanSino Biologics - Convidecia)?

If yes, identify if the patient has received a complete or partial series of the vaccine. If the patient received a complete series (e.g., 2 doses) of a World Health Organization (WHO) Emergency Use Listed (EUL) COVID-19 vaccine, CDC considers them to be fully vaccinated but they may receive an additional dose of Pfizer if they are 6 months and older, or Moderna if they are 6 months to less than 5 years or at least 18 years and older, and at least 28 days have passed since the completion of their primary series if they are moderately or severely immunocompromised. If this patient is seeking a booster dose, CDC has authorized a booster dose of the Pfizer BioNTech if they are 12 years and older, or Moderna if they are at least 18 years and older, and whose primary vaccine series was at least 3 months prior. Booster doses of Janssen COVID-19 vaccines are not authorized at this time.

¹ As set forth in the CDC's EUI, a non-FDA authorized or approved COVID-19 vaccine includes such vaccines "listed for emergency use by the World Health Organization, or is included in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order, or that is a non-placebo part of a clinical trial within or outside the United States that is a WHO-EUL COVID-19 vaccine or a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy in the United States (hereinafter 'non-FDA authorized or approved COVID-19 vaccines')."

At State-operated vaccination sites: If a person presents for a Janssen COVID-19 vaccine after previously having received one dose of the Pfizer or Moderna COVID-19 vaccine, they should not be administered the Janssen COVID-19 vaccine at a state-operated site and should consult with their healthcare provider.

*Anyone answering "Unknown" to any screening question should be referred to the medical director or responsible health care provider at the POD or clinic to further assess their answer to that question (e.g., the person might not have understood the question and the healthcare provider could explain it further).