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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine

Additional Dose for Moderately to Severely Immunocompromised

Updated: August 19, 2021

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 the July 12, 2021

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https://coronavirus.health.ny.gov/system/files/documents/2021/07/revised_information_for_health_care_providers_covid-19_screening_checklist_updated_7_12_21.pdf

1. Will you be under the age of 12 years old for the Pfizer vaccine, or under 18 years old for the Moderna vaccine, 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, reschedule at least 90 days after last dose of antibody therapy.

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) or immediate allergic reaction of any severity after a previous dose or 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)

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

- 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 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 health care 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?

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

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.
 - If the patient developed myocarditis or pericarditis after the first or second dose of an mRNA vaccine, experts recommend deferral of additional doses until additional safety data are available. However, the second dose can be considered after

complete resolution of a myocarditis or pericarditis episode. 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:

- Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions)
 - Level of COVID-19 community transmission and personal risk of infection.
 - Additional data on the risk of myocarditis or pericarditis following an occurrence of either condition after the first dose of an mRNA COVID-19 vaccine.
 - Additional data on the long-term outcomes of myocarditis or pericarditis that occurred after receipt of an mRNA COVID-19 vaccine.
 - 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 the ["Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults"](#).

10. Have you received two previous doses of the Pfizer, or Moderna, COVID-19 vaccine, 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. If the original mRNA COVID-19 vaccine product is not available, the other vaccine product 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. There is currently no recommendation for additional doses for persons who received the Janssen/Johnson & Johnson COVID-19 vaccine.

11. Have you received a previous dose of the Janssen/Johnson & Johnson COVID-19 vaccine?

If yes, do not administer an additional dose. There is currently no recommendation for additional doses for persons who received the Janssen/Johnson & Johnson COVID-19 vaccine.

12. Have you received a previous dose of a COVID-19 vaccine authorized by the WHO but not by the FDA (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm)?

If yes, do not administer an additional dose. Due to insufficient data, CDC does not support the use of an additional mRNA COVID-19 vaccine dose after a WHO but NOT FDA approved vaccination.

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 health care provider could explain it further).**