

HOWARD A. ZUCKER, M.D., J.D. Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine: Individuals 12 years of age or older Updated: November 21, 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.

1. Are you feeling sick today?

Governor

If yes, refer to the vaccination site healthcare 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.

- 2. 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 healthcare 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 counseling a patient with a history of MIS-C or MIS-A regarding COVID-19 vaccines, please see the Centers for Disease Control and Prevention's (CDC) 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/clinical-considerations/covid-19-vaccines-us.html.
- 3. 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, clarify if the antibody therapy or convalescent plasma was received as treatment for COVID-19 or postexposure prophylaxis.

- Passive antibody product used for post-exposure prophylaxis: defer COVID-19 vaccination for 30 days
- Passive antibody product used for COVID-19 treatment: defer COVID-19 vaccination for 90 days

4. 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 healthcare provider for assessment of allergic reaction. Review the ingredient lists at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

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).

<u>Precautions to COVID-19 vaccine</u>: (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.
 - <u>Note</u>: These individuals should not be administered COVID-19 vaccine at Stateoperated 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

5. 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.

6. Do you have cancer, leukemia, HIV/AIDS, or any other condition that weakens the immune system?

If yes, ask the patient if they would like to have a discussion with the vaccination site healthcare provider about what is known and not yet known about COVID-19 vaccine for immunocompromised people. You can tell the patient that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose not to.

- 7. Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?
 If yes, ask the patient if they would like to have a discussion with the vaccination site healthcare provider about what is known and not yet known about COVID-19 vaccine for immunosuppressed people. You can tell the patient that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if they choose and does not need to go to
- 8. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner? If yes, refer to healthcare 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:

medical evaluation if they choose not to.

- Evaluate if this history was in relation to a dose of mRNA vaccine. If it was not, then the patient can receive any U.S. Food and Drug Administration (FDA) authorized COVID-19 vaccine after complete resolution of a myocarditis or pericarditis episode.
- If the patient developed myocarditis or pericarditis after the first dose of an mRNA vaccine, experts recommend deferral of the second dose 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:
 - o Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions).
 - o 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; ACIP's general best practice guidelines for immunization can be consulted for more information.
- For the full CDC interim clinical considerations regarding a history of myocarditisand/or pericarditis, please see the CDC's <u>COVID-19 Vaccines Currently Authorized in the United States</u> and <u>Clinical Considerations</u>: <u>Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults</u>.

Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. Please see CDC's Interim Clinical Considerations for Use of COVID-19

<u>Vaccines</u> for more information on booster dosing and considerations for clinicians regarding the different vaccine products.

10. Are you 18 years old or older, and have you received 2 doses of the Pfizer vaccine, the second dose being at least 6 months ago?

If yes, verify if this is a second dose or third dose. If this is a second dose of mRNA COVID-19 vaccine, be sure it is from the same manufacturer as the previous dose and that the second dose is being administered within the correct timeframe (21 days from first dose for Pfizer). If the patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received. The second dose of an mRNA COVID-19 vaccine should be administered as close to the recommended interval as possible.

If this is a third dose, verify if this is a booster dose of the Pfizer COVID-19 vaccine, or an additional third dose for a person who is moderately to severely immunocompromised. If this is a booster dose, verify that the person received Pfizer COVID-19 vaccine for their primary series, that it has been at least 6 months since the second dose. Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. 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.

If this dose is an additional third dose of the Pfizer COVID-19 vaccine for a person who is moderately to severely immunocompromised, there is a separate screening and consent form and a separate instruction document available for providers and these patients. These forms are available at https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers.

If this is a fourth dose of the Pfizer COVID-19 vaccine for a person who is moderately to severely immunocompromised, be sure this fourth dose is at least 6 months after the third dose was received.

11. Have you received 2 doses of the Moderna vaccine, the second dose being at least 6 months ago? If yes, verify if this is a second dose or third dose. If this is a second dose of mRNA COVID-19 vaccine, be sure it is from the same manufacturer as the previous dose and that the second dose is being administered within the correct timeframe (28 days from first dose for Moderna). If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received. The second dose of an mRNA COVID-19 vaccine should be administered as close to the recommended interval as possible.

If this is a third dose, verify if this is a booster dose of the Moderna COVID-19 vaccine or an additional third dose for a person who is moderately to severely immunocompromised. If this is a booster dose, verify that the person received Moderna COVID-19 vaccine for their primary series, that it has been at least 6 months since the second dose. Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. 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.

If this dose is an additional third dose of the Moderna COVID-19 vaccine for a person who is moderately to severely immunocompromised, there is a separate screening and consent form and a separate instruction document available for providers and these patients. These forms are available at https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers.

If this is a fourth dose of the Moderna COVID-19 vaccine for a person who is moderately to severely immunocompromised, be sure this fourth dose is at least 6 months after the third dose was received.

12. Have you received a previous dose of the Janssen vaccine, at least 2 months ago?

(Individuals aged 18 years old or older who received a single dose Janssen primary series <u>SHOULD</u> receive a single COVID-19 booster dose (Pfizer-BioNTech, Moderna or Janssen) at least 2 months (8 weeks) after completing their Janssen primary series.)

If yes, verify if this is a booster dose. If this is a booster dose of Janssen COVID-19 vaccine, be sure that the dose is being administered at least 2 months from the first Janssen vaccine dose. If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received.

Individuals recommended to receive a booster should speak with their healthcare provider about which vaccine is best for their booster dose. If they choose a different vaccine booster, according to FDA and CDC guidelines, they can select from any FDA-approved or authorized COVID-10 vaccine for which they are eligible. 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.

13. If you had a previous dose of Janssen, did you develop thrombosis with thrombocytopenia syndrome (TTS)?

If yes, do not administer a Janssen booster dose. TTS is a rare condition diagnosed by a health care provider in which people have blood clots and low platelet counts. Persons with a history of TTS following the Janssen vaccine should be offered an mRNA COVID-19 booster dose instead of an additional Janssen vaccine.

14. Have you received a previous dose of a non-FDA authorized or approved COVID-19 vaccine)¹ (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm/BIBP, COVAXIN)?

- If yes, identify if the patient has received a complete or partial series of WHO Emergency Use Listing (EUL) vaccine.
 - o If the patient received a complete series (e.g., 2 doses) of a WHO-EUL COVID-19 vaccine, CDC considers them to be fully vaccinated and no additional doses are needed. If this patient is seeking a booster dose, CDC's EUI has authorized a booster dose of the Pfizer-BioNTech vaccine ONLY for individuals who are at least 18 years old or older, and whose primary vaccine series was at least 6 months ago. Booster doses of either Moderna or Janssen COVID-19 vaccines are not permitted at this time.
 - If a patient received a partial series of a WHO-EUL COVID-19 vaccine or received all
 or some of the recommended doses of a COVID-19 vaccine primary series that is not
 listed for emergency use by the WHO, the CDC does NOT consider these persons to

be fully vaccinated. If at least 28 days has passed since the vaccine dose was administered, a complete age-appropriate series of an FDA authorized COVID-19 vaccine can be offered to the patient.

• If the patient received either a partial series or complete series of a COVID-19 vaccine that is not authorized for use by either the WHO or the FDA, the CDC does NOT consider these persons to be fully vaccinated. If at least 28 days has passed since the last vaccine dose was administered, a complete age-appropriate series of an FDA authorized COVID-19 vaccine can be offered to the patient.

If this dose is an additional third dose of the COVID-19 vaccine for a person who is moderately to severely immunocompromised, there is a separate screening and consent form and a separate instruction document available for providers and these patients. These forms are available at https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers.

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')."

<u>At State-operated vaccination sites</u>: If a person presents for a Janssen COVID-19 vaccine after previously having received one dose of the Pfizer or Moderna COVID-19 primary vaccine series due to allergic reaction or other adverse event, 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 healthcare 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).