

Governor

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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine: Individuals 12 Years of Age or Older Updated: November 18, 2022

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?

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.

- 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, notify them that they should defer future doses of EvusheldTM 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.
- 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) 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 known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines
- 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)
- People who develop Guillain-Barré syndrome (GBS) within 6 weeks after receipt of Janssen COVID-19 vaccine should not receive another dose of Janssen COVID-19 vaccine
- 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

<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 (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).
- For Janssen COVID-19 vaccine, a history of GBS
- 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 health care provider experienced in the management of severe allergic reactions.
 - Note: These individuals should not be administered COVID-19 vaccine at Stateoperated vaccination sites.
- For mRNA (Pfizer or Moderna) and protein subunit (Novavax) COVID-19 vaccines, for history of myocarditis or pericarditis after a dose of an mRNA (Pfizer or Moderna) or protein subunit (Novavax) COVID-19 vaccine, a subsequent dose of COVID-19 vaccine should generally be avoided. (See question 9 for further information regarding this precaution.)
- For patients who are determined eligible for COVID-19 vaccination after an assessment of allergy history, a 15-minute post-vaccination observation period should be considered for the following:
 - Patients with a history of any allergy not listed as a contraindication or precaution.
 - Any other recipients, particularly adolescents, to monitor for syncope. If syncope develops, patients should be observed until syncope resolves.
- For patients who are determined eligible for COVID-19 vaccination after an assessment of allergy history, a 30-minute post-vaccination observation period should be considered for the following:

- Non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
- 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)

More information regarding observation times can be found in the CDC's interim clinical considerations.

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 medical evaluation if they choose not 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 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 (Pfizer, Moderna or protein subunit (Novavax) COVID-19 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 an mRNA (Pfizer or Moderna) or protein subunit (Novavax) 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.

- Until additional safety data are available, experts advise that people who develop myocarditis or pericarditis after a dose of an mRNA (Pfizer or Moderna) or protein subunit (Novavax) 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 (Pfizer or Moderna) or protein subunit (Novavax) COVID-19 vaccines. These people should be made aware of the risks of TTS after receipt of Janssen (Johnson & Johnson) 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 an mRNA (Pfizer or Moderna) or protein subunit (Novavax) 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).
 - o Level of COVID-19 community transmission and personal risk of infection.
 - o Timing of immunomodulatory therapeutics; ACIP's <u>general best practice guidelines</u> for immunization can be consulted for more information.
- The CDC advises that an increased interval of 8 weeks between the 2 doses of the primary series may decrease the risk of myocarditis. However, the 3 week interval should be used for the following people:
 - o Immunocompromised people
 - o High risk for severe disease
 - Household members with high risk for severe disease
 - o High COVID-19 community levels
- 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</u> <u>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 Vaccines for more information on booster dosing and considerations for clinicians regarding the different vaccine products.

10. Have you had Guillain-Barré Syndrome (GBS) after receipt of the Janssen vaccine?

People who develop GBS within 6 weeks after receipt of Janssen COVID-19 vaccine should not receive another dose of Janssen COVID-19 vaccine. An mRNA COVID-19 vaccine should be used for any subsequent (i.e., booster) doses. Providers should also strongly consider using an mRNA COVID-19 vaccine for subsequent doses in people who had GBS onset beyond 6 weeks after receipt of Janssen COVID-19 vaccine.

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

<u>For children and adolescents with a history of MIS-C</u> 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 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

COVID-19 vaccination may also be considered for children and adolescents who had MIS-C and do not meet both 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.

<u>For adults with a history of MIS-A</u> 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-us.html#covid19-vaccination-misc-misa.

12. Are you 12 years of age or older and have you received a complete COVID-19 vaccine primary series (e.g., 2 doses of Moderna, Pfizer, or Novavax vaccine, or 1 dose of Janssen vaccine) or any booster dose at least 2 months ago?

• Individuals 12 years and older should receive a bivalent booster 2 months after completion of a monovalent primary series or a previous monovalent booster. They can receive either the Pfizer bivalent vaccine or the Moderna bivalent vaccine for this booster dose.

NOTE: this screening and consent form is meant for immunocompetent persons 12 years of age and older. Please see screening and consent form for children 6-11 years or for immunocompromised for those population specific questions. There are also accompanying screening checklists for those forms.

*There is no FDA authorized monovalent booster for individuals 12 and older, monovalent Pfizer and Moderna are only to be used as a primary series, or as a booster in those under 12 years of age.

13. Are you 18 years of age or older and have you received a complete COVID-19 vaccine primary series (e.g., 2 doses of Moderna, Pfizer, or Novavax vaccine, or 1 dose of Janssen vaccine) at least 6 months ago?

Novavax monovalent vaccine can be used as a booster dose in limited situations.
 Individuals ages 18 years and older who completed primary vaccination using any COVID-19 vaccine and have not received any previous booster dose(s) may receive a monovalent Novavax booster dose at least 6 months after completion of the primary series if they are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

14. 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 bivalent booster dose instead of an additional Janssen vaccine.

- 15. 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, Nuvaxovid, or CanSino Biologics Convidecia)?
 If yes, identify if the patient has received a complete or partial series of WHO Emergency Use Listing (EUL) vaccine.
 - 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 monovalent booster dose of the Pfizer-BioNTech vaccine for individuals who are at least 5 through 11 years old, a bivalent booster dose of the Pfizer BioNTech vaccine for individuals 12 years and older, or a bivalent booster of the Moderna vaccine for those 18 years and older and whose primary vaccine series was at least 2 months ago. Booster doses of Janssen COVID-19 vaccines should only be used in limited situations. Booster doses of Novavax vaccine are not permitted at this time.
 - If a patient received a partial series of a WHO-EUL COVID-19 vaccine they should complete
 the primary series with Moderna, Novavax, or Pfizer-BioNTech vaccine dose(s) as close to
 the recommended time as possible. The dose should be spaced from the last WHO-EUL
 vaccine by at least 28 days.
 - If a patient 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 them 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')."

^{*} 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).