

Governor

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### Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine Administration of Pfizer-BioNTech COVID-19 Vaccine Administration for 5-11 years old

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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 <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html">www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html</a>.

#### 1. Are you between the ages of 5 and 11 years old?

If yes, proceed with screening question #3. If no, advise the parent or guardian that this patient is not currently eligible for the 5-11 years old pediatric Pfizer BioNTech Covid-19 formulation (10  $\mu$ g/ 0.2 mL). Instead, this patient may receive the Pfizer BioNTech Covid-19 adult formulation for children 12 years old or older (30  $\mu$ g/ 0.3 mL). There is no COVID-19 vaccine currently authorized for a child less than 5 years old.

If a child turns from 11 to 12 years of age in between their first and second dose in the primary regimen, they may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation for children aged 5–11 years (each 0.2 ml dose containing 10  $\mu$ g in an orange cap vial); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30  $\mu$ g in a purple cap vial). If they receive the 10  $\mu$ g dose for their second dose instead of the 30  $\mu$ g dose, this is not considered an error, VAERS reporting is not required, and the child is considered fully vaccinated. However, based on clinical judgment, a repeat dose of the 30  $\mu$ g adult formulation may be administered 21 days after the second pediatric formulation dose was administered.

#### 2. Are you 12 years old or older?

If the patient is 12 years old, or greater, they are eligible for the adult Pfizer vaccine formulation. "Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine" for individuals 12 years old or older can be found on the <a href="New York State COVID-19 Vaccine Information for Providers">New York State COVID-19 Vaccine Information for Providers</a> page.

#### 3. Are you feeling sick today?

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 parent or guardian to return with the patient when symptoms improve.

- 4. 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 σquarantine at home due to COVID-19 infection or exposure?
  - If yes, advise the parent or guardian that the patient must return to isolation or quarantine and reschedule for afterisolation/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 themhome. 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, the parent or guardian can choose to have the patient vaccinated. For further information on counseling a parent or guardian with a child who has 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: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</a>.
- 5. 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.
- 6. 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-19vaccine, 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: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Appendix-C.">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Appendix-C.</a>

#### 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 a dose of the Pfizer 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 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, or a component of a COVID-19 vaccine may have a precaution to the other.
  - 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 allergyhistory, 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 any type of COVID-19 vaccine (e.g., mRNA or Janssen viral vector).
- Patients with a history of anaphylaxis due to any cause.
- 7. Do you have cancer, leukemia, HIV/AIDS, or any other condition that weakens the immune system? If yes, ask the parent or guardian 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 parent or guardian that the patient may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if the parent or guardian chooses to, and they are not required to go to medical evaluation.
- 8. Do you take any medications that affect your immune system, such as cortisone, prednisone orother steroids, anticancer drugs, or have you had any radiation treatments?

  If yes, ask the parent or guardian 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 parent or guardian that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if the parent or guardian chooses to, and they are not required to go to medical evaluation.
- 9. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner? If yes, refer to parent or guardian to their 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 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.

## 10. 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 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 thatoccurred 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</u> <u>Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults.</u>

#### 11. Have you received a previous dose of the Pfizer, Moderna or Janssen COVID-19 vaccine?

If yes, verify if this the patient is still under the age of 12 years old. Children ages 5-11 who already received a first dose of a two-dose mRNA COVID-19 vaccine should be offered the age-appropriate second dose of an mRNA vaccine, which at this time is only the Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11 (10  $\mu$ g).

If the patient is 12 years old or older, please counsel the parent or guardian on current guidelines to provide a Pfizer COVID-19 vaccine adult formulation (30  $\mu$ g) to anyone in the age range. The Moderna and Janssen vaccines are only authorized for those 18 years or older.

# 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/BIBP)?

- 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), CDC considers them to be fully vaccinated and no additional doses are needed.
- If a patient received a partial series of a WHO authorized COVID-19 vaccine that is notcurrently authorized for use in the U.S. by the FDA, the CDC does NOT consider these persons to be fully vaccinated. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e. Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).
- 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. They should be offered a two-dose series of the age-appropriate COVID-19 vaccine (i.e. Pfizer-BioNTech COVID-19 Vaccine formulation for children ages 5-11).

<sup>\*</sup> 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).