



CLINICAL POLICY

Standing Order for SARS-CoV-2 (COVID) Vaccine

A. EFFECTIVE DATE :

May 28, 2021

B. PURPOSE :

The purpose of this standing order is to reduce the morbidity and mortality of the SARS-CoV-2 virus by vaccinating adults and adolescents 12 years and older, as permitted by the Pfizer/BioNTech Food and Drug Administration (FDA) Emergency Use Authorization (EUA) or 18 years and older, as permitted with the Moderna/Janssen FDA EUA, in accordance with recommendations by the Center for Disease Control and Prevention's (CDC) Vaccination Program and the criteria established by the Advisory Committee on Immunization Practices (ACIP).

C. POLICY :

This standing order authorizes any healthcare provider licensed to administer immunizations in the State of Connecticut and/or meets the qualifications under the Connecticut Governor's Executive Order Expanding Authorized Professions to Administer Vaccines (dated 12/7/2020), to administer COVID vaccines available to persons 12 years old and older under the Pfizer/BioNTech FDA EUA, or 18 years and older, as permitted with the Moderna/Janssen FDA EUA.

All credentials of personnel vaccinating must be active and in good standing in the State of Connecticut.

Vaccine administration prioritization should align with the COVID Vaccine Phases of Eligibility established by the State of Connecticut.

All personnel described in this section should administer the vaccine as outlined in the procedure below.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event of an acute anaphylactic reaction following administration of the vaccine. Emergency medications may be administered under the scope of practice of the individual healthcare provider's license as outlined in this procedure, or in the case of epinephrine, under the Connecticut Governor's Executive Order Expanding Authorized Professions to Administer Vaccines (dated 12/7/20).

D. SCOPE :

This policy applies to vaccine administered by licensed UConn Health personnel or qualified affiliates not authorized to independently prescribe vaccine.

E. DEFINITIONS :

Standing order- order initiated by appropriate licensed personnel per designated procedures, without a patient specific order, if the patient meets certain criteria

F. MATERIAL(S) NEEDED :

COVID vaccine, diluent (if applicable), syringes and needles for administration, medication labels, personal protective equipment (PPE), cleaning supplies, hand sanitizer, vaccine documentation cards, sharps containers, hardware with access to the integrated electronic medical record for appointments and documentation, access to COVID-Vaccine EUA Fact Sheets for Recipients and Caregivers, emergency medications, and cold compress.

G. PROCEDURE :

1. Criteria for COVID-19 vaccine

a. Pfizer-BioNTech COVID-19 vaccine

i. Assess persons 12 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:

1. History of complete two-dose mRNA COVID-19 vaccination, regardless of brand, or complete single-dose adenovirus COVID-19 vaccination. If two doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended. If one dose of a single-dose adenovirus COVID-19 vaccination has been administered, no additional doses are recommended.
2. If the recipient has received one previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
3. The Pfizer-BioNTech COVID-19 Vaccine vaccine is administered in a two-dose series. Separate doses by at least 21 days (4 day leeway).

b. Moderna COVID-19 vaccine

i. Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

1. History of complete two-dose mRNA COVID-19 vaccination, regardless of brand, or complete single-dose adenovirus COVID-19 vaccination. If two doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended. If one dose of a single-dose adenovirus COVID-19 vaccination has been administered, no additional doses are recommended.
2. If the recipient has received one previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
3. This vaccine is administered in a two-dose series. Separate doses by at least 28 days.

c. Janssen COVID-19 Vaccine

- i. Assess persons 18 years of age and older for vaccination with Janssen COVID-19 Vaccine based on the following criteria:
 1. History of complete two-dose mRNA COVID-19 vaccination, regardless of brand, or complete single-dose adenovirus COVID-19 vaccination. If two doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended. If one dose of a single-dose adenovirus COVID-19 vaccination has been administered, no additional doses are recommended.
 2. This vaccine is administered as a single-dose, with no additional doses required.

2. Screen for Contraindications and Precautions for COVID-19 Vaccine

- a. Contraindications for Pfizer-BioNTech and Moderna COVID-19 vaccine:
 - i. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine.
 - ii. Immediate allergic reaction with any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]).
 - iii. Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG).
- b. Contraindications for Janssen COVID-19 vaccine:
 - i. Known history of a severe allergic reaction to any component of the vaccine, consisting of recombinant adenovirus type vector and the following inactive ingredients: citric acid monohydrate, trisodium citrate, ethanol, HBCD, and polysorbate-80.
- c. Precautions all COVID-19 vaccines:
 - i. History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
 - ii. Moderate to severe acute illness
- d. Confirm patients have reviewed and understand the current Federal EUA Fact Sheet for Recipients and Caregivers.
- e. Confirm all patients have consented to the risk and benefits of receiving the vaccine as outlined in the EUA.

3. Dosage Forms and Storage

- a. Pfizer-BioNTech COVID-19 vaccine
 - i. Multiple dose vial containing 0.45mL off-white frozen suspension that contains no preservative and should be thawed prior to administration.
 - ii. Vial should be stored in an ultra-low temperature freezer (-80°C to -60°C).
 - iii. Vials can be thawed in refrigerator or at room temperature
 1. Allow vials to thaw in the refrigerator (2°C to 8°C). May take up to three hours to thaw. Thawed vials can be stored in the refrigerator for up to 31 days.
 - a) Undiluted vials that require distribution to offsite clinics with a refrigerator on-site will be transported in an insulated tote with ice packs and a Temperature Monitoring Device (TMD), which is

not to exceed 8°C (46°F) for up to 12 hours. Any hours used to transport these vials will count against the 31 days. A Beyond Use Date (BUD) sticker will be placed on the vials upon removal from the freezer that reflect this 31 day limit, or the manufacturer's expiration date, whichever is earlier.

2. Allow vials to thaw at room temperature. May take up to 30 minutes.
 - a. Vials at room temperature should be mixed within two hours.
- iv. Vaccine drawn in syringes may be used for six hours at room temperature (47°F to 77°F).
- v. Do not refreeze thawed vaccine
- b. Moderna COVID-19 vaccine
 - i. Multiple dose vial containing 5mL white to off-white frozen suspension that contains no preservative and should be thawed prior to administration
 - ii. Vial should be stored in a freezer (-25°C to -15°C).
 - iii. Vials can be thawed in refrigerator or at room temperature
 1. To thaw in refrigerator: place vaccine in refrigerator between 2°C to 8°C for two hours and 30 minutes
 2. To thaw at room temperature: place vaccine in room between 15°C to 25°C for one hour
 - iv. Thawed vials that have not been punctured may be kept between 8°C to 25°C for up to 24 hours
 1. Once vial is punctured, vial is good for 12 hours
 - v. Do not refreeze thawed vaccine
 - vi. Vaccine drawn in syringes may be used for 12 hours at room temperature.
- c. Janssen COVID-19 Vaccine
 - i. Multiple dose vial containing five 0.5ml doses of colorless to slightly yellow, clear to opalescent suspension that contains no preservative.
 - ii. Store intact vials under refrigeration (2°C to 8°C) and do not store frozen.
 - iii. Vaccine is initially stored by the manufacturer frozen; if received frozen, thaw prior to use in refrigerator. If thawing at room temperature, may take 1-2 hours to thaw.
 - iv. Do not refreeze thawed vaccine.
 - v. Intact vials may be stored at room temperature (9°C to 25°C) for up to 12 hours.
 - vi. After the vial is punctured, the vial can be stored under refrigeration (2°C to 8°C) up to six hours or room temperature (9°C to 25°C) up to two hours.
 - vii. Vaccine drawn in syringes may be stored under refrigeration (2°C to 8°C) up to six hours or room temperature (9°C to 25°C) up to two hours.

4. Prepare

- a. Prepare the Pfizer-BioNTech COVID-19 vaccine
 - i. Thaw the vaccine vial if frozen for 30 minutes at room temperature or for 3 hours in a refrigerator.
 - ii. Before dilution process, invert vial ten times but do not shake vial.
 - iii. Inspect liquid prior to dilution for any discoloration or if particles are observed.
 - iv. Using 0.9% Sodium Chloride (NS), withdraw 1.8mL of NS using aseptic technique (21-gauge or narrower needle). Diluent should be stored at room temperature.

- v. Add 1.8mL of NS into the vaccine vial.
 - vi. ****Equalize vial pressure before removing the needle from the vial by withdrawing 1.8mL of air into the empty syringe****
 - vii. Gently invert vial ten times to mix the vaccine
 - viii. Inspect liquid prior to dilution for any discoloration or if particles are observed.
 - ix. Record the date and time of dilution on a label and store between (2°C to 25°C).
 - x. Discard any unused vaccine 6 hours after dilution.
 - xi. Using aseptic technique, cleanse the vial stopper with an alcohol prep pad, and withdraw 0.3mL of the vaccine.
 - 1. Each vial allows for a minimum of six total doses. Overfill may be used for additional doses. However, any remaining vaccine that does not equal a full 0.3ml dose should not be pooled with other remaining vaccine to obtain a full 0.3ml dose.
 - xii. Vaccine drawn in syringes may be used for six hours from the time of dilution.
 - xiii. Vaccine drawn in syringes should be appropriately labeled with beyond use date and time.
- b. Prepare the Moderna COVID-19 vaccine
- i. Remove the required number of vial(s) from storage and thaw each before use.
 - ii. Thaw under refrigerated conditions and once thawed, let vial stand at room temperature for 15 minutes before use.
 - iii. Swirl vial gently after thawing and between each withdrawal.
 - iv. Do not shake vial or dilute the vaccine.
 - v. Using aseptic technique, cleanse the vial stopper with an alcohol prep pad, and withdraw 0.5mL of the vaccine.
 - vi. Each vial allows for a minimum of ten total doses (13-15 if it is the bigger vial size). Overfill may be used for additional doses. However, any remaining vaccine that does not equal a full 0.5 mL dose should not be pooled with other remaining vaccine to obtain a full 0.5 mL dose.
 - vii. Vaccine drawn in syringes may be used for 12 hours.
 - viii. Vaccine drawn in syringes should be appropriately labeled with beyond use date and time.
- c. Prepare the Janssen COVID-19 Vaccine
- i. Before withdrawing each dose, carefully mix the contents of the vial by swirling gently in the upright position for 10 seconds; do not shake.
 - ii. Each dose is 0.5ml and each vial contains five doses. Do not pool excess vaccine from multiple vials.
 - iii. Using aseptic technique, cleanse the vial stopper with an alcohol prep pad, and withdraw 0.5mL of the vaccine.
 - iv. Vaccine drawn in syringes may be used for six hours under refrigeration or two hours at room temperature.
 - v. Vaccine drawn in syringes should be appropriately labeled with beyond use date and time.

5. Administration

Ensure area is cleaned between recipients and don appropriate PPE.

- a. Administration of the Pfizer-BioNTech COVID-19 vaccine

- i. Age group: 12 years of age and older
 - ii. Dose: 0.3 mL
 - iii. Route: Intramuscular
 - iv. Instruction: Administer vaccine in deltoid muscle
 - v. Person should wait 21 days (+/- 4 days) to receive the second dose of the vaccination
 - 1. Patients who do not receive the 2nd vaccination dose at 21 days should still receive that 2nd dose as soon as possible thereafter.
 - vi. All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose
 - 1. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes.
- b. Administration of the Moderna COVID-19 Vaccine
- i. Age group: 18 years of age and older
 - ii. Dose: 0.5 mL
 - iii. Route: Intramuscular
 - iv. Instruction: Administer vaccine in the deltoid muscle
 - v. Person should wait 28 days (+/- 4) to receive the second dose of the vaccination.
 - 1. Patients who do not receive the 2nd vaccination dose at 28 days should still receive that 2nd dose as soon as possible thereafter.
 - vi. All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose
 - 1. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes.
- c. Administration of the Janssen COVID-19 Vaccine
- i. Age group: 18 years of age and older
 - ii. Dose: 0.5 mL
 - iii. Route: Intramuscular
 - iv. Instruction: Administer vaccine in the deltoid muscle
 - v. All vaccine recipients should be monitored for at least 15 minutes following each vaccination dose
 - 1. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes.

Discard syringes and needles in the appropriate sharps containers. Efforts should be made to avoid vaccine waste.

6. Emergency Protocols

All patients should be observed after receiving vaccine, as outlined in Section G.1.

Administration. Personnel observing vaccine recipients should have a current certification in basic cardiopulmonary resuscitation.

- a. **Localized Reactions** - If a patient experiences itching and swelling confined to the injection site where the vaccination was given, apply a cold compress to the injection site. Observe patient closely for the development of generalized symptoms until symptoms subside.
- b. **Generalized Reactions** -For generalized symptoms (generalized itching, redness, urticarial (hives); or including angioedema (swelling of the lips, face or throat); shortness of breath; shock; or abdominal cramping; **call 911 immediately**.
 - a. Healthcare professional should assesses the airway, breathing, circulation and level of consciousness of the patient. Vital signs (heart rate and respirations) monitored every five minutes.
 - b. Initiate basic cardiopulmonary resuscitation if necessary.
 - c. **For Generalized Hives or Itching:** administer diphenhydramine 25mg intramuscularly or intravenously. Diphenhydramine 25mg may be repeated once if symptoms persist beyond five minutes.
 - d. **For an anaphylactic reaction:** administer a dose of Epinephrine 0.3 mg/0.3 mL via the Epinephrine auto-injector (0.3ml) (Epi-pen®).
 - i. If EMS has not arrived and symptoms are still present, may repeat dose of epinephrine every 5-15 minutes for up to three doses depending on the patient's response. Additionally, administer methylprednisolone succinate 125mg intravenously or intramuscularly once (if given intramuscularly, avoid the deltoid muscle).
 - ii. For residual respiratory symptoms not responding to epinephrine, administer Albuterol (90mcg/actuation) two inhalations for symptom relief.
 - e. Monitor the patient closely until EMS arrives. Monitor vital signs (see above) every 5 minutes at a minimum.
- c. Record the patient's reaction to the vaccine (e.g., hives, anaphylaxis), all vital signs and medications administered to the patient, including time of administration, response and the name of the medical personnel who administered the medication and any other relevant clinical information in the electronic medical record.
- d. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or <https://vaers.hhs.gov/reportevent.html>.

H. ATTACHMENTS :

[State of Connecticut Governor's Order Expanding Authorized Professions to Administer Vaccines, dated December 7, 2020](#)

I. REFERENCES:

1. Pfizer COVID-19 Vaccine [prescribing information] New York,NY/Mainz, DE; Pfizer/BioNTech; 2020.
2. Moderna COVID-19 Vaccine [prescribing information] Cambridge, MA; Moderna; 2020.
3. Janssen COVID-19 Vaccine [prescribing information] Horsham, PA; Janssen/Johnson & Johnson; 2021.
4. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med.* 2020;383(27):2603-2615. doi:10.1056/NEJMoa2034577.

5. Baden LR, El Sahly HM, Essink B, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine [published online ahead of print, 2020 Dec 30]. *N Engl J Med*. 2020; NEJMoa2035389. doi:10.1056/NEJMoa2035389.
6. CDC Covid-19 Vaccine Website. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>. Published December 20, 2020. Accessed January 27, 2021.

J. SEARCH WORDS :

Emergency, COVID, SARS-CoV-2, Standing order, Vaccine, Moderna, Pfizer, Janssen

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS:

Pharmacy and Therapeutics – March 31, 2021

N. FINAL APPROVAL :

- | | |
|---|--|
| <p>1. <u>Andrew Agwunobi, MD (Signed)</u>
 Andrew Agwunobi, MD, MBA
 UConn Health Chief Executive Officer</p> | <p><u>06/02/2021</u>
 Date</p> |
| <p>2. <u>Anne Horbatuck (Signed)</u>
 Anne D. Horbatuck, RN, BSN, MBA
 Clinical Policy Committee Co-Chair</p> | <p><u>06/02/2021</u>
 Date</p> |
| <p>3. <u>Scott Allen, MD (Signed)</u>
 Scott Allen, MD
 Clinical Policy Committee Co-Chair</p> | <p><u>06/01/2021</u>
 Date</p> |
| <p>4. <u>Caryl Ryan (Signed)</u>
 Caryl Ryan, MS, BSN, RN
 VP Quality and Patient Services & Chief Nursing Officer</p> | <p><u>05/28/2021</u>
 Date</p> |

O. REVISION HISTORY :

Date Issued: 2/16/21

Date Reviewed: 3/31/2021

Date Revised: 3/9/21, 3/31/2021, 5/26/21