12 Years of Age and Older

Moderna COVID-19 Vaccine

(Bivalent)

XXXX Standing Orders for Administering Vaccine

Vaccine product	Dose/Injection Amount	Route
Bivalent: Blue capped vial with gray-bordered label	Booster dose: **50 µg/ 0.5 mL**	IM

Note: Use these standing orders in conjunction with Interim COVID-19 Immunization Schedule for Persons 6 Months and Older at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- This standing order enables health care professionals authorized by law to administer COVID-19 vaccines in the State of Washington to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

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

Persons who ARE NOT moderately or severely immunocompromised[*†]

- If the recipient has never received a COVID-19 vaccine: A single dose of Moderna COVID-19 Vaccine, Bivalent is administered.
- If the recipient has received 1 or more doses of a monovalent# COVID-19 vaccine: A single dose of Moderna COVID-19 Vaccine, Bivalent is administered at least 2 months after the last dose of any monovalent COVID-19 Vaccines.
- Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine: A dose of Moderna COVID-19 vaccine, Bivalent may be administered at least 4 months after the dose of bivalent COVID-19 vaccine.
- Inform recipients, especially males 12–39 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination. Educational materials are available at https://www.cdc.gov/coronavirus/2019- ncov/vaccines/safety/myocarditis.html

Persons who ARE moderately or severely immunocompromised[*†]

- If the recipient has never received a COVID-19 vaccine: Administer a dose of Moderna COVID-19 Vaccine, Bivalent .
- If the recipient has received 1 dose of a Moderna COVID-19 vaccine: Administer a dose of Moderna Bivalent COVID-19 Vaccine at least 4 weeks after their previous dose.
- If the recipient has received 2 doses of Moderna COVID-19 vaccine: Administer a dose of Moderna Bivalent COVID-19 Vaccine at least 4 weeks after their last dose of Moderna COVID-19 vaccine
- If the recipient received 3 doses of Monovalent Moderna COVID-19 vaccine, administer 1 doses of Moderna Bivalent COVID-19 vaccine at least 8 weeks after their last monovalent dose.
- If the Recipient has received 1 booster dose of a Bivalent COVID-19 vaccine and it has been at least 2 months, they may receive an additional booster dose.

Additional Clinical Considerations

- Persons with a history of myocarditis or pericarditis:
  - If history is prior to COVID-19 vaccination, may receive Moderna vaccine product (monovalent or bivalent) after the episode of myocarditis or pericarditis has completely resolved.
  - If myocarditis or pericarditis occurred after a previous dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Moderna COVID-19 vaccine (monovalent or bivalent). Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis
- Persons who have received HCT or CAR-T-cell therapy
  - Re-vaccination of persons who received doses of COVID-19 vaccine prior to or during HCT or CAR-T-cell therapy should be managed by their medical team in compliance with CDC recommendations and are not authorized through these orders.
- For persons who received a COVID-19 vaccine:
  - Outside of the United States
  - Not currently authorized/approved in the United States
  - See clinical guidance, including booster dose recommendations, at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-b

† Persons with a recent SARS-CoV-2 infection may consider delaying a primary series or booster dose by 3 months from symptom onset or positive test (if infection was asymptomatic).
# Monovalent pertains to the monovalent formulations of Pfizer-BioNTech/Moderna, Janssen and Novavax COVID-19 vaccines.

- Moderna COVID-19 vaccine may be coadministered with most vaccines without regard to timing, including simultaneous administration. In the individual has received JYNNEOS vaccine in the last 28 days, please review guidance at: https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html.
- See clinical guidance for COVID-19 vaccination and SARS CoV-2 infection, including recommendations after receiving passive antibody products, at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.

Do Not administer the Moderna COVID-19 Vaccine if Contraindications or Precautions are identified through screening, refer to primary care provider for further evaluation. Contraindications:

History of a:

- 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 (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-c for a list of vaccine components)

Precautions:

History of :

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the **same type of COVID-19 vaccine**
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the **other types of COVID-19 vaccines**¶
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Obtain consent in accordance with Washington law.
- Prepare to administer the vaccine. Choose the correct needle gauge, needle length, and injection site for persons:
  - 12-18 years of age:
    - Needle gauge/length: 22-25 gauge, 1-inch
    - Site: Deltoid muscle of arm
  - 19 years of age and older: See chart
- Administer Moderna COVID-19 Vaccine by intramuscular (IM) injection:
  - **Dose:** 0.5 mL of bivalent vaccine (Blue capped vial with gray-bordered label)

Document vaccination

- COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the Washington State Immunization Information System (IIS) n as soon as practicable and no later than 72 hours after administration.
- Document each recipient's vaccine administration information:
  - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
  - Recipient's vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Indicate if the vaccine dose is a monovalent or bivalent product, if possible.
  - Report the vaccination to the IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.modernatx.com

Be prepared to manage medical emergencies

- Vaccination providers should consider observing patients after vaccination to monitor for allergic reactions and syncope:
  - **30 minutes for persons with:**
  - An allergy-related contraindication to a different type of COVID-19 vaccine
  - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
  - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies

¶ People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types. Consider consultation with an allergist/immunologist to help determine if a patient with a contraindication to the Novavax vaccine can safely receive another COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/ monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

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Administration

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site**
Female or male fewer than 130 lbs	22–25	⅝†† –1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 152–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

- **15 minutes:** All other persons

- Syncope may occur in association with injectable vaccines, in particularly among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.
- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

Report adverse events to the Vaccine Adverse Event Reporting System (VAERS)

- While this vaccine is under Emergency Use Authorization (EUA)(https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization), healthcare professionals are required to report to VAERS:
  - Vaccine administration errors (whether associated with an adverse event [AE] or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem inflammatory syndrome (MIS) in adults (https://www.cdc.gov/mis-c/mis-a.html) or children (https://www.cdc.gov/mis-c/index.html)
  - Cases of myocarditis (for mRNA vaccines)
  - Cases of pericarditis (for mRNA vaccines)
  - ~~Cases of COVID-19 that res~~ult in hospitalization or death
  - Any additional AEs and revised safety requirements per the Food and Drug Administration's (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to VAERS:
  - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

For more information, please see:

- Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html
- CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html
- Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients in the XXXXX effective XXXXXXX until rescinded on XXXXX and supersedes any previous Moderna COVID-19 Vaccine XXXXXXX Standing Order for Administering Vaccine to Persons 18 Years of Age and Older.

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Signature Printed Name License Number Date

Adapted with appreciation from the Centers for Disease Control and Prevention (CDC) standing orders

** Alternately, the anterolateral thigh can be used. A 1.5-inch needle may be used if administering vaccine in this site.

†† Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).