Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

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).

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

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) 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 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
  - If the vaccine product previously given cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days, preferably within 6 weeks.*
- Moderna COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Moderna COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Moderna COVID-19 Vaccine.¶
- Moderna COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- If the recipient has a history of dermal filler use, advise them to contact their healthcare provider for evaluation if they develop swelling at or near the dermal filler site following vaccination.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine.
    - Immediate allergic reaction± of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG]). See Table 1 of vaccine components on page 3.
    - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG).
  - Precautions:
    - History of an immediate allergic reaction to any other vaccine or therapies [excluding subcutaneous immunotherapy of allergies, i.e. "allergy shots"] not related to a component of mRNA COVID-19 vaccines or polysorbate).
    - Moderate to severe acute illness.
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.

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 153–260 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

*Administer the second dose as close to the recommended interval (28 days) as possible. If the second dose is not administered within 6 weeks of the first dose, the series does not need to be restarted. Doses inadvertently administered less than 28 days apart do not need to be repeated.

¶However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination.

±For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

†Alternatively, the anterolateral thigh also can be used.

§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**).

- Choose the correct needle gauge, needle length, and injection site for persons:
  - 18 years of age: 1-inch needle is recommended.
  - 19 years of age and older: See table above.
- Follow the manufacturer's guidance for storing/handling punctured vaccine vials.
- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection.

- 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 relevant system (e.g., Immunization Information System) for the jurisdiction 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
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at https://www.modernatx.com/.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - **30 minutes:** 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
    - **15 minutes:** All other persons
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.
  - 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**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), 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 or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's 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

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ effective _____ until rescinded or until _____.

Medical director (or other authorized practitioner)
_____/_____/_____.

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders

Table 1: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

*Neither vaccine contains eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity can occur between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database (https://dailymed.nlm.nih.gov/dailymed/index.cfm) may also be used as a resource. As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in CDC's Vaccine Excipient Summary [https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf]). Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized. *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533–1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf