Moderna COVID-19 Vaccine

Vaccine Preparation and Administration Summary

General Information

Vaccine: Moderna COVID-19 Vaccine

Multidose vial: Maximum of 15 primary series doses or 20 booster doses per vial

Dosage:

- Primary series and additional primary dose: 0.5 mL
- Booster dose: 0.25 mL

Age Indications

18 years of age and older

Schedule for Primary Series and Boosters

- 2-dose series separated by 1 month (28 days)*.
- Moderately and severely immunocompromised people: Consider an additional dose at least 28 days after the initial 2-dose primary series.*
- A series started with Moderna COVID-19 Vaccine should be completed with this product.
- A booster dose at least 6 months after the primary series **should** be given for:
  - People 50 years of age and older
  - Residents 18 years of age and older in long-term care settings
- A booster dose at least 6 months after the primary series **may** be given for:
  - All other people 18 years of age and older based on their individual risks and benefits

Administration

Intramuscular (IM) injection in the deltoid muscle

Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
  - **Refrigerator:** Between 2°C and 8°C (36°F and 46°F). Unpunctured vials may be stored in the refrigerator for up to 30 days.
  - **Room temperature:** Between 8°C and 25°C (46°F and 77°F). Unpunctured vials may be held at room temperature for up to 24 hours.
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
  - » In the refrigerator: Up to 3 hours
  - » Room temperature: Up to 1 hour and 30 minutes
- **Do NOT** refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from the freezer.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.

Expiration Date

To determine the expiration date, scan the QR code located on the vial or carton. The QR code will bring up a website; then choose the lookup option, enter the lot number, and the expiration date will be displayed. Another option is to access the website directly: http://www.modernatx.com/covid19vaccine-eua. CDC's expiration date tracking tool (https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf) can facilitate documenting expiration dates.

Prepare and Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.†

Vaccine must be thawed before using. If removing the vial from the refrigerator, let it stand at room temperature for 15 minutes.

Unpunctured vials: Check the expiration date. Never use expired vaccine.

Punctured vials: Check the beyond-use time. Never use vaccine after the beyond-use time.

With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.

Examine the vaccine. It should be white to off-white in color and may contain white or translucent particles. Do not use if liquid contains other particulate matter or is discolored.

* For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

† Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

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Prepare and Administer the Vaccine (Continued)

Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

Withdraw 0.5 mL of vaccine into the syringe.*
Ensure the prepared syringe is not cold to the touch.

- Discard vial when there is not enough vaccine to obtain a complete dose.
- Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals. 0.5 mL.

Once you can no longer withdraw a complete dose from a vaccine vial, dispose of the vial (with any remaining vaccine) as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program (https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html) for guidance.

Note the date and time the vial was first punctured. **Keep the vaccine between 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.**

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.

Ensure staff has the correct PPE before administering vaccine and implement policies for the use of face coverings for vaccine recipients (if tolerated).

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.

Observe recipients after vaccination for an immediate adverse reaction:

- **30 minutes:** Persons with a history of:
  - A contraindication to another type of COVID-19 vaccine product
  - Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine
  - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
  - Anaphylaxis due to any cause
- **15 minutes:** All other persons

* It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated

Scheduling Doses

Vaccination History†‡	And	Then	Next Dose Due
0 doses		Give dose 1 today	Give dose 2 at least 28 days after dose 1§
1 dose (Moderna COVID-19 Vaccine)	It has been at least 28 days since dose 1	Give dose 2 today	Series complete; no additional doses needed¶
	It has not been at least 28 days since dose 1	No dose today	Give dose 2 at least 28 days after dose 1§
2 doses (Moderna COVID-19 Vaccine) at least 28 days apart§			Series complete; no additional doses needed¶
2 doses (1 product unknown) at least 28 days apart‡			Series complete; no additional doses needed¶

† COVID-19 vaccines may be coadministered with other vaccines, including simultaneous administration.

‡ Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the vaccine given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

§ **Administer the second dose as close as possible to the recommended interval (28 days). It is not necessary to restart the series if the dose is given after the recommended interval.** Primary series doses inadvertently administered before the 4-day grace period (i.e., less than 24 days apart) should be repeated.

¶ See the schedule section on page 1 of this document for information on:

- an addition primary series dose (3rd) for moderately and severely immunocompromised persons
- a booster dose for eligible persons

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Contraindications and Precautions

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

Precautions:

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- Immediate allergic reaction* to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
  - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Contradiction to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)†
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- 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.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.

Document the 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 (i.e., 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 in the:

- **Medical record**
  - Vaccine and the date it was administered
  - Manufacturer and lot number
  - Vaccination site and route
  - Name and title of the person administering the vaccine
- **Personal vaccination record card (shot card):**
  - Date of vaccination
  - Product name/manufacturer
  - Lot number
  - Name/location of the administering clinic or healthcare professional
  - Give to the vaccine recipient.
- **Immunization information system (IIS) or "registry":**
  - Report the vaccination to the appropriate state/local IIS.

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* 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.

† Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. 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.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 Vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (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 reporting requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at www.modernatx.com/covid19vaccine-eua/.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A.