

COVID-19 Vaccine, mRNA

(Moderna) (Systemic)

Nucleoside-modified mRNA vaccine used to stimulate active immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Class: 80:12 • Vaccines (AHFS primary)

Brands*:

*also available generically

Special Alerts:

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Uses

Prevention of Coronavirus Disease 2019 (COVID-19)

- Being investigated and used for prevention of COVID-19† caused by SARS-CoV-2. One of various COVID-19 vaccines being evaluated for prevention of COVID-19.
- Although efficacy and safety not definitely established, COVID-19 vaccine (Moderna) is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals ≥18 years of age.
- On December 18, 2020, FDA issued an EUA that permits use of the Moderna COVID-19 vaccine in individuals ≥18 years of age. The EUA requires that the vaccine be administered by vaccination providers using a 2-dose vaccination series as described in the EUA (See Dosage under Dosage and Administration.) and that vaccination providers participate and comply with terms and training required by CDC's COVID-19 vaccination program, including monitoring and complying with CDC and/or emergency response stakeholder vaccine management requirements concerning obtaining, tracking, and handling the vaccine and reporting vaccine administration data to CDC and state/local jurisdiction's Immunization Information System (IIS) or other designated systems. FDA reissued the EUA on February 25, 2021 to incorporate changes related to several safety reporting requirements.
- FDA issued the EUA for the Moderna COVID-19 vaccine after concluding that emergency use of the vaccine for prevention of COVID-19 met the criteria for issuance of an EUA for the following reasons: SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness; based on the totality of scientific evidence available to FDA, it is reasonable to believe that the vaccine may be effective in preventing COVID-19 and, when used under the conditions described in the authorization, known and potential benefits outweigh known and potential risks; and there are no adequate, approved, and available alternatives to emergency use of the vaccine to prevent COVID-19.
- Issuance of the EUA for the Moderna COVID-19 vaccine was based on FDA review of safety and efficacy data from an ongoing phase 3 clinical trial in adults indicating that a 2-dose regimen of the vaccine was 94.1% effective in preventing COVID-19 occurring ≥14 days after the second dose.

- The EUA for the Moderna COVID-19 vaccine authorizes that distribution of the vaccine will be controlled by the US government for use consistent with the terms and conditions of the EUA. (See Restricted Distribution under Preparations.)
- To mitigate risks of this unapproved vaccine, the EUA includes certain mandatory requirements (e.g., providing the recipient or caregiver with information consistent with the EUA fact sheet for recipients and caregivers, ensuring that all vaccination administration errors and all serious adverse events potentially attributable to the vaccine are reported as specified in the EUA fact sheet for healthcare providers). (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)
- Consult the Moderna COVID-19 vaccine EUA letter of authorization, EUA fact sheet for healthcare providers, and EUA fact sheet for recipients and caregivers for additional information.
- CDC's Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for use of the Moderna COVID-19 vaccine for prevention of COVID-19 in individuals ≥18 years of age. ACIP also issued interim recommendations regarding allocation of supplies of COVID-19 vaccines and interim considerations for phased implementation of COVID-19 vaccination and sub-prioritization among recommended populations in the US (available at CDC website at <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html> and <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>).
- There currently are 3 different COVID-19 vaccines available for use in the US under FDA EUAs, including 2 mRNA vaccines (Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine) and a viral-vectored vaccine (Janssen COVID-19 vaccine). ACIP does not state a preference for any specific COVID-19 vaccine when the vaccines are used within the scope of their respective EUAs and states that individuals should be encouraged to receive the earliest vaccine available to them. However, currently available COVID-19 vaccines are *not* interchangeable with each other. (See Dosage under Dosage and Administration.)

Dosage and Administration

General

- *Must* have appropriate medications and supplies immediately available to assess and manage immediate allergic reactions in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines, including COVID-19 vaccine (Moderna). Healthcare personnel trained and qualified to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination locations at all times. Vaccination locations that anticipate vaccinating large numbers of people (e.g., mass vaccination clinics) should plan adequate staffing and supplies (including epinephrine) for assessment and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)
- Prior to administration of each dose of the Moderna COVID-19 vaccine, screen all individuals for contraindications and precautions to vaccination. Do not give the vaccine to those with a contraindication. (See Contraindications and see Warnings/Precautions under Cautions.)
- *Monitor all vaccine recipients for immediate adverse reactions according to CDC (ACIP) guidelines.* When administered to individuals with no contraindications to vaccination with an mRNA COVID-19 vaccine, ACIP states observe those who have a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy and those who have a history of anaphylaxis due to any cause not considered a contraindication for 30 minutes, and observe all other individuals for 15 minutes. A longer period of observation may be indicated in some individuals based on clinical concern (e.g., pruritus and swelling confined to the injection site develops during observation period). Instruct vaccine recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site. (See Hypersensitivity Reactions under Cautions.)
- Syncope (vasovagal or vasodepressor reaction; fainting) may occur following administration of parenteral vaccines; such reactions usually occur within 15 minutes following vaccine administration and are reported most frequently in adolescents and young adults. Take appropriate measures to decrease risk of injury if a patient becomes weak or dizzy or loses consciousness (e.g., vaccinees should sit or lie down during and for 15 minutes after vaccination). If syncope occurs, observe patient until symptoms resolve.
- The Moderna COVID-19 vaccine is administered in a series of 2 doses given 1 month (28 days apart). (See Dosage under Dosage and Administration.) At the time that the first dose is administered, give vaccine recipient or their caregiver a vaccination record card that provides the date when the recipient needs to return for the second dose; counsel about the importance of completing the 2-dose vaccination series to optimize protection against COVID-19.
- Provide vaccine recipient or their caregiver with information on, and encourage participation in, CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in COVID-19 vaccine recipients. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

- Prior to vaccination, counsel vaccine recipient or their caregiver about local and systemic adverse effects that may occur following vaccination. (See Cautions and see Advice to Patients.) Unless a contraindication to vaccination exists, ACIP recommends encouraging vaccinees to complete the 2-dose vaccination series even if they develop local or systemic adverse effects following the first dose since this optimizes protection.
- Antipyretics or analgesics (e.g., acetaminophen, NSAIDs) may be taken to treat postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in vaccinees is not currently recommended since information not available regarding possible impact on antibody response to COVID-19 vaccines. Premedication with antihistamines prior to vaccination to prevent allergic reactions is *not* recommended; antihistamines do not prevent anaphylaxis and may mask cutaneous symptoms, which could delay diagnosis and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)
- Counsel individuals who receive the Moderna COVID-19 vaccine to continue following all current guidance to protect themselves and others. This includes wearing a mask, staying ≥6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands frequently, following CDC travel guidance, and following any applicable workplace or school guidance. This recommendation is based on the currently limited information on the extent to which vaccination may reduce viral transmission in the general population, unknown duration of vaccine-induced protection, and unknown extent of protection against emerging SARS-CoV-2 variants. (See Limitations of Vaccine Effectiveness under Cautions.)

Administration

IM Administration

Administer *only* by IM injection into the deltoid.

The Moderna COVID-19 vaccine is supplied as a frozen suspension in multiple-dose vials that *must* be shipped and stored (long-term) at a temperature between -50 to -15°C. For short-term storage, may store unopened multiple-dose vials of the vaccine in a refrigerator (2–8°C) for up to 30 days prior to first use. (See Storage under Stability.)

Prior to use, remove the appropriate number of vials of the frozen Moderna COVID-19 vaccine from the freezer and thaw either in a refrigerator (2–8°C) or at room temperature (15–25°C). If thawed under refrigeration, allow vials to stand at room temperature for 15 minutes before use. (See Thawing under Dosage and Administration.)

Do not dilute the Moderna COVID-19 vaccine.

Swirl vials of vaccine gently after thawing and between withdrawal of each dose; do *not* shake.

To administer a dose, withdraw 0.5 mL of thawed Moderna COVID-19 vaccine from the vial using aseptic technique and an appropriate syringe and needle and administer immediately.

Moderna COVID-19 vaccine is supplied in 2 different multiple-dose vial presentations. There are multiple-dose vials containing a maximum of eleven 0.5-mL doses (range: 10–11 doses) and multiple-dose vials containing a maximum of fifteen 0.5-mL doses (range: 13–15 doses). Depending on type of syringes and needles used to withdraw doses from the multiple-dose vials, it may not be possible to extract more than 10 or more than 13 doses, respectively, from these vials. Each dose *must* contain 0.5 mL of the vaccine.

Because the vaccine does not contain preservatives, it is critical that any vaccine remaining in the vial that does not constitute a full 0.5-mL dose should be discarded and *not* be pooled with vaccine from other vials to create a dose.

Data not available regarding concomitant administration with other vaccines. ACIP recommends that the Moderna COVID-19 vaccine *not* be administered simultaneously with or within 14 days of any other vaccine. (See Vaccines under Interactions.)

Thawing

Thawing in a refrigerator (2–8°C): Thaw multiple-dose vials containing 11 or 15 doses for 2.5 or 3 hours, respectively, in a refrigerator. May store unopened vials in the refrigerator for up to 30 days prior to first use.

Thawing at room temperature (15–25°C): Allow multiple-dose vials containing 11 or 15 doses to sit at room temperature for 1 or 1.5 hours, respectively, to thaw. May store unopened vials for up to 24 hours at 8–25°C.

Thawed Moderna COVID-19 vaccine should appear as a white to off-white suspension and may contain white or translucent product-related particles; do *not* use if it is discolored or contains other particles.

Thawed vaccine *must* not be refrozen.

Dosage

Administer the Moderna COVID-19 vaccine in a series of two 0.5-mL doses given 1 month (28 days) apart. Each 0.5-mL dose contains 100 mcg of mRNA.

The 2-dose regimen of the Moderna COVID-19 vaccine is considered a complete, valid vaccination series. Individuals should *not* receive more than one single, valid vaccination series for active immunization against COVID-19 (i.e., 2-dose regimen of an mRNA vaccine [Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine] or single dose of Janssen COVID-19 vaccine).

Ensure that individuals who receive the first dose of the Moderna COVID-19 vaccine receive a second dose of the same vaccine at the recommended interval to complete the vaccination series.

FDA EUA that permits use of the Moderna COVID-19 vaccine specifies an interval of 1 month (28 days) between first and second vaccine doses. ACIP states do not schedule individuals to receive the second vaccine dose earlier than 1 month after the first dose; however, a second dose of the vaccine administered within a grace period of 4 days earlier than the recommended date is still considered valid. If adherence to the recommended interval not feasible and a delay is unavoidable, ACIP states may administer second dose up to 6 weeks (42 days) after first dose; only limited data available regarding efficacy if second dose of an mRNA COVID-19 vaccine is administered >6 weeks after first dose.

The Moderna COVID-19 vaccine is *not* interchangeable with the Pfizer-BioNTech COVID-19 vaccine or any other COVID-19 vaccine.

Safety and efficacy of a mixed vaccination series of mRNA COVID-19 vaccines not evaluated; individuals who receive a dose of the Moderna COVID-19 vaccine should complete the series using the same vaccine. Make every effort to determine which mRNA COVID-19 vaccine was used for first dose to ensure completion of the vaccination series using the same vaccine. ACIP states that in *exceptional* situations when the mRNA COVID-19 vaccine used for first dose cannot be determined or is no longer available, may administer any available mRNA COVID-19 vaccine using a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. In situations where the same mRNA vaccine is temporarily unavailable, ACIP states it is preferable to delay the second dose (up to 6 weeks) to allow completion of the vaccination series using the same mRNA COVID-19 vaccine rather than administering a mixed vaccination series composed of 2 different mRNA COVID-19 vaccines. If 2 doses of *different* mRNA COVID-19 vaccines are administered in such situations (or inadvertently), ACIP states that no additional doses of either vaccine are recommended at this time.

Safety and efficacy regarding use of the viral-vectored vaccine (Janssen COVID-19 vaccine) after a dose of an mRNA COVID-19 vaccine *not* established. However, ACIP states that, in limited, *exceptional* situations when an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the vaccination series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), may consider giving a single dose of the Janssen COVID-19 vaccine at least 28 days after the dose of mRNA COVID-19 vaccine. (See Hypersensitivity Reactions under Cautions.) In such exceptional circumstances, consider the individual to have received valid, single-dose vaccination with Janssen COVID-19 vaccine, not a mixed vaccination series.

Report all vaccine administration errors and deviations from currently recommended dosage and vaccination schedule to the vaccinee and the Vaccine Adverse Event Reporting System (VAERS). (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.) Information on preventing and reporting COVID-19 vaccine administration errors and recommendations for specific actions to take if an administration error or deviation from recommended vaccination schedule occurs are available at CDC website at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

Adults

Prevention of COVID-19

IM: FDA EUA that permits use for prevention of COVID-19† (see Prevention of Coronavirus Disease 2019 [COVID-19] under Uses) states that adults ≥18 years of age should receive two 0.5-mL doses of the vaccine administered 1 month (28 days) apart.

Cautions

Contraindications

- Known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. (See Actions.)
ACIP considers the following to be contraindications to vaccination with *both* mRNA vaccines (Moderna COVID-19 vaccine and Pfizer-BioNTech COVID-19 vaccine):
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or severe allergic reaction to a component of the vaccine (e.g., polyethylene glycol [PEG]).
- Immediate allergic reaction of any severity after a previous dose of an mRNA COVID-19 vaccine or known (diagnosed) allergy to a component of the vaccine (e.g., PEG).

Warnings/Precautions

Sensitivity Reactions

Hypersensitivity Reactions

Hypersensitivity reactions reported in 1.5% of vaccine recipients and 1.1% of placebo recipients in the ongoing phase 3 trial evaluating the Moderna COVID-19 vaccine; hypersensitivity events reported in the vaccine group and likely related to vaccination included injection site rash and injection site urticaria.

Although immediate allergic reactions not reported to date in clinical trials evaluating the Moderna COVID-19 vaccine, severe allergic reactions, including anaphylaxis, reported rarely following administration of mRNA COVID-19 vaccines during mass vaccination campaigns outside of clinical trials.

Following issuance of the FDA EUA for the **Pfizer-BioNTech COVID-19 vaccine**, safety monitoring data identified 21 cases of anaphylaxis among 1,893,360 individuals in the US who received the first dose of the vaccine (11.1 cases per million vaccine doses administered); this included 17 cases in individuals with documented history of allergies or allergic reactions to drugs or medical products, foods, or insect stings (7 of these had a history of anaphylaxis, including one after receipt of a dose of rabies vaccine and another after receipt of influenza vaccine). Median interval from receipt of vaccine to onset of anaphylaxis symptoms was 13 minutes (range: 2–150 minutes); 71% had onset of symptoms within 15 minutes after the dose and 90% were treated with epinephrine. No fatalities from anaphylaxis were reported; 17 individuals were treated in an emergency department and the other 4 were hospitalized (including 3 in an intensive care unit).

Following issuance of the FDA EUA for the **Moderna COVID-19 vaccine**, safety monitoring data identified 10 cases of anaphylaxis among 4,041,396 individuals in the US who received the first dose of the vaccine (2.5 cases per million vaccine doses administered); this included 9 cases in individuals with documented history of allergies or allergic reactions to drugs, contrast media, or food (5 of these had a history of anaphylaxis). Median interval from receipt of vaccine to onset of anaphylaxis symptoms was 7.5 minutes (range: 1–45 minutes); 9 of the 10 individuals had onset within 15 minutes and one had onset after 30 minutes; all 10 were treated with epinephrine. No fatalities from anaphylaxis were reported; 4 individuals were treated in an emergency department and the other 6 were hospitalized (including 5 in an intensive care unit).

From December 21, 2020 to January 10, 2021, safety monitoring data identified 43 cases of nonanaphylactic allergic reactions in individuals who received the first dose of the Moderna COVID-19 vaccine; 26 of these (60%) were classified as nonserious. Commonly reported symptoms included pruritus, rash, itchy sensations in the mouth and throat, sensations of throat closure, and respiratory symptoms. The median interval from receipt of vaccine to onset of symptoms was 15 minutes (range: <1 minute to 24 hours); 73% had symptom onset within 30 minutes.

Delayed-onset local reactions (e.g., erythema, induration, pruritus, tenderness) around the injection site area reported in some vaccine recipients, including some clinical trial participants, after first dose of an mRNA COVID-19 vaccine, including the Moderna COVID-19 vaccine. These local reactions may begin from a few days through the second week after the first dose and may be quite large. In some reported cases, such delayed-onset local reaction after first vaccine dose resolved in a median of 6 days (range: 2–11 days), and some individuals had similar (but less severe) local reactions after the second vaccine dose. ACIP states that delayed-onset local reaction after the first dose of an mRNA COVID-19 vaccine is *not* a contraindication or precaution to administration of the second vaccine dose. Therefore, individuals with such injection site reactions after the first dose of an mRNA COVID-19 vaccine should receive the second dose of the same vaccine at the recommended interval, preferably in the opposite arm.

If a hypersensitivity reaction, including anaphylaxis, occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Because anaphylactic reactions reported rarely following administration of COVID-19 vaccines, ACIP issued interim guidance with contraindications and precautions for use of COVID-19 vaccines pending further investigation. For purposes of this interim guidance, ACIP states that an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis occurring within 4 hours following administration. If reactions occur following vaccination with an mRNA COVID-19 vaccine, the vaccination provider should attempt to determine whether the reactions are consistent with allergic reactions that would contraindicate additional doses of the mRNA COVID-19 vaccine (see Hypersensitivity Reactions under Cautions) or are reactions commonly observed following vaccination (e.g., vasovagal reactions, postvaccination adverse effects) not considered contraindications to the second dose of the 2-dose vaccination series.

History of severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components (e.g., PEG): ACIP considers this a **contraindication** to vaccination with both the Moderna and the Pfizer-BioNTech COVID-19 vaccines. ACIP states may consider using an alternative COVID-19 vaccine (Janssen COVID-19 vaccine) in such individuals. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA COVID-19 vaccines and the Janssen COVID-19 vaccine (including PEG and polysorbate 80, respectively), consider consultation with an allergist-immunologist to help determine if the individual can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments can also request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>) when making such decisions. Although safety and efficacy of administering the Janssen COVID-19 vaccine after an mRNA COVID-19 vaccine not established, ACIP states that, in those *exceptional* situations when an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), may

consider giving a single dose of the Janssen COVID-19 vaccine at a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. (See Dosage under Dosage and Administration.)

History of immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or known (diagnosed) allergy to a component of the vaccine (e.g., PEG): ACIP considers this a **contraindication** to vaccination with both the Moderna and the Pfizer-BioNTech COVID-19 vaccines. ACIP states may consider using an alternative COVID-19 vaccine (Janssen COVID-19 vaccine) in such individuals. However, because of potential cross-reactive hypersensitivity between ingredients in mRNA COVID-19 vaccines and the Janssen COVID-19 vaccine (including PEG and polysorbate 80, respectively), consider consultation with an allergist-immunologist to help determine if the individual can safely receive the Janssen COVID-19 vaccine. Healthcare providers and health departments can also request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>) when making such decisions. Although safety and efficacy of administering the Janssen COVID-19 vaccine after an mRNA COVID-19 vaccine not established, ACIP states that, in those *exceptional* situations when an individual received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to a contraindication), may consider giving a single dose of the Janssen COVID-19 vaccine at a minimum interval of 28 days after the mRNA COVID-19 vaccine dose. (See Dosage under Dosage and Administration.)

History of polysorbate allergy: ACIP considers this a **precaution** to vaccination with both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine. ACIP states polysorbate allergy is a contraindication to vaccination with the Janssen COVID-19 vaccine; may consider using an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) in such individuals. However, polysorbates are structurally related to PEG and there is potential for cross-reactive hypersensitivity. Consider consultation with an allergist-immunologist to help determine if the individual with polysorbate allergy can safely receive an mRNA COVID-19 vaccine. Healthcare providers and health departments can also request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>) when making such decisions. If a decision is made to administer an mRNA COVID-19 vaccine to an individual with a contraindication to the Janssen COVID-19 vaccine (e.g., polysorbate allergy), administer the vaccine *only* in an appropriate setting under supervision of a healthcare provider experienced in management of severe allergic reactions.

History of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, or sub-Q vaccines or therapies): ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination. ACIP states that history of allergic reaction to sub-Q immunotherapy for allergies (i.e., allergy shots) is **not** a contraindication or precaution to COVID-19 vaccination.

History of immediate allergic reaction to a vaccine or injectable therapy that contains multiple components (one of which is a vaccine component), but it is not known which component elicited the reaction: ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination.

History of allergic reactions (including severe allergic reactions) not related to COVID-19 vaccines, other vaccines, or injectable therapies: ACIP states that food, pet, insect, venom, or environmental allergies and allergic reactions to oral medications (including the oral equivalents of injectable medications) are **not** a contraindication or precaution to COVID-19 vaccination. Latex allergy is **not** a contraindication or precaution since vial stoppers of COVID-19 vaccines are not made with natural rubber latex. Allergies to eggs or gelatin are **not** a contraindication or precaution since COVID-19 vaccines do not contain eggs or gelatin. In addition, a family history of allergies is **not** a contraindication or precaution to COVID-19 vaccination.

History of delayed-onset local reactions (e.g., erythema, induration, pruritus) around the injection site area after first dose of an mRNA COVID-19 vaccine: ACIP states that these local reactions are **not** a contraindication or precaution for administration of second dose of mRNA COVID-19 vaccine. Such individuals should receive second dose using the same mRNA COVID-19 vaccine used for first dose at the recommended interval, preferably in the opposite arm.

If a **precaution** for COVID-19 vaccination is identified, ACIP recommends performing a risk assessment to help decide whether the individual should be vaccinated. The risk assessment should consider risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation), risk of severe disease or death due to COVID-19 (e.g., because of age or underlying medical conditions), unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in individuals with a history of immediate allergic reactions to other vaccines or injectable therapies, and ability to be vaccinated in a setting where appropriate medical care is immediately available to treat anaphylaxis if it occurs.

When a COVID-19 vaccine, including the Moderna COVID-19 vaccine, is administered to individuals without a contraindication to such vaccines, ACIP states observe those with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy and those with a history of anaphylaxis due to any cause not considered a contraindication for 30 minutes after the vaccine dose and observe all other individuals for 15 minutes. Instruct vaccine

recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site.

Appropriate medications and supplies to assess and manage immediate allergic reactions (e.g. sufficient quantities of epinephrine in prefilled syringes or autoinjectors) *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. Early recognition of clinical signs and symptoms of anaphylaxis is important since such reactions require immediate treatment. Immediately treat individuals with suspected anaphylaxis with IM epinephrine.

ACIP interim guidance regarding early recognition of clinical signs and symptoms of anaphylaxis and guidance regarding preparation for and management of anaphylaxis at COVID-19 vaccination sites, including recommendations for medications and supplies to have immediately available and specific recommendations regarding therapeutic management of anaphylaxis, are available at the CDC website at <https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/managing-anaphylaxis.html> and <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

When confronted with a complex COVID-19 vaccine safety question concerning an individual patient that is not readily addressed by ACIP guidance, US healthcare personnel or health departments can request a clinical consultation from the Clinical Immunization Safety Assessment COVIDvax project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>).

Concomitant Illness

Base decision to administer or delay vaccination in an individual with a current or recent febrile illness on the severity of symptoms and etiology of the illness.

ACIP states that a moderate or severe acute illness is a precaution for administration of vaccines and recommends that a risk assessment be performed with potential deferral of vaccination. Deferring vaccination until an individual has recovered avoids superimposing adverse effects of the vaccine on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccination.

Individuals with Prior SARS-CoV-2 Infection

Available data suggest that COVID-19 vaccines can be given safely to individuals with evidence of *prior* SARS-CoV-2 infection. ACIP states COVID-19 vaccination should be offered to individuals regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

Data not available to date regarding safety and efficacy of administering COVID-19 vaccines to individuals who have received passive antibody therapy with investigational SARS-CoV-2-specific monoclonal antibodies or investigational COVID-19 convalescent plasma as part of treatment of COVID-19. (See Specific Drugs under Drug Interactions.)

Individuals with Current SARS-CoV-2 Infection

ACIP recommends deferring COVID-19 vaccination in individuals with known *current* SARS-CoV-2 infection until they have recovered from the acute illness (if symptomatic) and until criteria for discontinuance of isolation have been met. This recommendation applies to individuals who experience SARS-CoV-2 infection before receiving any doses of COVID-19 vaccine and those who experience SARS-CoV-2 infection after receiving the first dose of an mRNA COVID-19 vaccine but before receiving the second dose of the vaccine. There is no recommended minimum interval between SARS-CoV-2 infection and COVID-19 vaccination, but evidence to date suggests that risk of reinfection is low in the months after initial infection, but may increase with time due to waning immunity. If vaccine supply is limited, ACIP states that individuals with recent documented acute SARS-CoV-2 infection may choose to temporarily delay COVID-19 vaccination, if desired, recognizing that risk of reinfection and need for vaccination may increase with time following the initial infection.

ACIP states that viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purpose of COVID-19 vaccination decision-making *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Recent Exposure to SARS-CoV-2 Infection

ACIP states that COVID-19 vaccines not currently recommended for outbreak management or for postexposure prophylaxis in individuals with a specific known exposure to SARS-CoV-2; postexposure vaccination is unlikely to be effective in preventing disease following such exposures. (See Limitations of Vaccine Effectiveness under Cautions.)

Individuals in the community or outpatient setting with a known COVID-19 exposure:

ACIP states that such individuals should not seek COVID-19 vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other individuals to SARS-CoV-2 during the vaccination visit. This recommendation also applies to individuals with a known COVID-19 exposure after receiving the first dose of an mRNA COVID-19 vaccine but before receiving the second dose of the vaccine.

Individuals residing in congregate healthcare settings (e.g., long-term care facilities) or congregate non-healthcare settings (e.g., correctional and detention facilities, homeless shelters) with a known COVID-19 exposure: ACIP states that such individuals may receive COVID-19 vaccination since exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time in these settings and healthcare personnel and other staff are already in close contact with residents in these settings. Individuals providing vaccination services should employ appropriate infection prevention and control procedures.

Residents in congregate settings (healthcare and non-healthcare) with a known COVID-19 exposure waiting for results of SARS-CoV-2 testing: ACIP states that such individuals may receive COVID-19 vaccination if they do not have symptoms consistent with COVID-19. Individuals providing vaccination services should employ appropriate infection prevention and control procedures. Viral testing to assess for acute SARS-CoV-2 infection solely for the purpose of COVID-19 vaccination decision-making *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Underlying Medical Conditions

ACIP states that individuals with altered immunocompetence or certain underlying medical conditions may receive any authorized COVID-19 vaccine unless they have a contraindication to the vaccine. ACIP does not state a preference for any specific COVID-19 vaccine in such individuals. Clinical trials of COVID-19 vaccines demonstrated that safety and efficacy profiles in individuals with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, are similar to safety and efficacy profiles in those without comorbidities.

Individuals with Altered Immunocompetence

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy (see Specific Drugs under Interactions), may have diminished immune responses to vaccines, including the Moderna COVID-19 vaccine.

Although some individuals with altered immunocompetence (e.g., stable HIV infection) were included in the ongoing phase 3 trial evaluating the Moderna COVID-19 vaccine, the number of such individuals was insufficient to evaluate safety of the vaccine in such populations.

ACIP states that individuals with HIV infection or other immunocompromising conditions and individuals receiving immunosuppressive therapies may be at increased risk for severe COVID-19 and, although data are not currently available to establish safety and efficacy in such individuals, they may receive any authorized COVID-19 vaccine, unless they have a contraindication to the vaccine. However, counsel such individuals about the unknown safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses and need to continue following all current guidelines to protect themselves from COVID-19.

Antibody testing to assess for immunity to COVID-19 following COVID-19 vaccination in individuals with altered immunocompetence *not* recommended. (See Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals under Cautions.)

Individuals with Autoimmune Conditions

ACIP states that individuals with autoimmune conditions may receive any authorized COVID-19 vaccine, unless they have a contraindication to the vaccine. Although data not currently available regarding safety and efficacy of COVID-19 vaccines in individuals with autoimmune conditions, such individuals were not excluded from clinical trials evaluating mRNA COVID-19 vaccines and these trials showed no imbalances in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in trial participants who received a COVID-19 vaccine compared with those who received placebo.

Individuals with Liver Disease

American Association for the Study of Liver Diseases (AASLD) released a consensus statement regarding use of COVID-19 vaccines in individuals with chronic liver disease or a liver transplant.

Although safety and efficacy data regarding use of COVID-19 vaccines in individuals with chronic liver disease are limited and additional studies needed, safety and efficacy of the vaccines in such individuals expected to be similar to the general population. AASLD states that individuals with chronic liver disease receiving antiviral treatment for HBV or HCV infection and those receiving medical therapy for primary biliary cholangitis or autoimmune hepatitis should not discontinue such therapy when receiving COVID-19 vaccination. In addition, consider COVID-19 vaccination for patients with hepatocellular carcinoma undergoing locoregional or systemic therapy without interruption of treatment.

Although solid organ transplant recipients, including liver transplant recipients, not included in clinical trials of COVID-19 vaccines and efficacy and safety in such individuals not known, AASLD states that liver transplant candidates should receive COVID-19 vaccination prior to transplantation, whenever possible, to help ensure an adequate immune response. The best time for COVID-19 vaccination in previously unvaccinated liver transplant recipients is likely to be ≥ 3 months after transplant; however, vaccination may be given as early as 6 weeks after transplant if indicated based on ongoing community spread of SARS-CoV-2, especially in those at highest risk with other comorbid factors associated with severe COVID-19.

Consult AASLD consensus statement for additional guidance on use of COVID-19 vaccines in individuals with chronic liver disease.

Individuals with a History of Guillain-Barré Syndrome (GBS)

To date, GBS not reported in clinical trials evaluating mRNA COVID-19 vaccines.

ACIP states that individuals with a history of GBS may receive COVID-19 vaccination, unless they have a contraindication to the vaccine. A history of GBS is not usually considered a contraindication or precaution to vaccination with most vaccines.

If GBS occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Individuals with a History of Bell's Palsy

Although a causal relationship not established, several cases of Bell's palsy reported in clinical trials in individuals who received the Moderna or the Pfizer-BioNTech COVID-19 vaccines.

Data from the ongoing phase 3 trial evaluating the Moderna COVID-19 vaccine identified 3 cases Bell's palsy (facial paralysis) in the vaccine group (one was a serious adverse event) and one case of Bell's palsy in the placebo group. Onset of Bell's palsy was 22, 28, or 32 days after the vaccine dose and 17 days after the placebo dose. FDA stated that available data are insufficient to determine a causal relationship with the vaccine.

ACIP states that, in the absence of a causal relationship between COVID-19 vaccines and Bell's palsy, individuals with a history of Bell's palsy may receive COVID-19 vaccination, unless they have a contraindication to the vaccine.

If Bell's palsy occurs following COVID-19 vaccination, report the case to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Individuals with Increased Bleeding Risk

Advise individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their caregiver about the risk of hematoma from IM injections.

ACIP states that IM vaccines may be given to individuals who have bleeding disorders if a clinician familiar with the patient's bleeding risk determines that the preparation can be administered IM with reasonable safety. In these cases, use a fine needle (23 gauge or smaller) to administer the vaccine and apply firm pressure to the injection site (without rubbing) for ≥2 minutes. In individuals receiving therapy for hemophilia, schedule IM vaccines for administration shortly after a dose of such therapy.

Individuals receiving anticoagulation therapy presumably have the same bleeding risk as those with clotting factor disorders and should follow the same guidelines for IM administration. If possible, schedule IM vaccines prior to use of an anticoagulant so that the patient's risk of bleeding is not increased by the drug's therapeutic action.

History of Dermal Filler Use

Administration of an mRNA COVID-19 vaccine to individuals who have received injectable dermal fillers (e.g., hyaluronic acid dermal fillers) has infrequently resulted in swelling at or near the site of dermal filler injection (usually face or lips) starting 1–2 days after vaccination. This effect reported when the vaccine was given 2 weeks to 6 months or longer after last dermal filler injection; appears to be temporary and resolves with medical treatment, including corticosteroid therapy.

ACIP states that individuals who have received injectable dermal fillers may receive COVID-19 vaccination, unless they have a contraindication to the vaccine. However, advise such individuals to contact their healthcare provider for evaluation if they develop swelling at or near site of dermal filler injection following vaccination.

Lymphadenopathy

Lymphadenopathy, lymphadenitis, lymph node pain, injection-site lymphadenopathy, axillary swelling/tenderness, and axillary mass reported in clinical trials evaluating COVID-19 vaccine (Moderna). Data from the ongoing phase 3 trial evaluating the Moderna COVID-19 vaccine identified lymphadenopathy (axillary swelling and tenderness on the vaccination arm) in 21.4% of vaccine recipients <65 years of age and 12.4% of vaccine recipients ≥65 years of age compared with 7.5 and 5.8% of placebo recipients in those age groups, respectively. Reported more frequently after second dose than first dose.

Unilateral axillary adenopathy, including palpable axillary mass, identified through self-detection or incidentally on breast imaging in individuals who received an mRNA COVID-19 vaccine outside of clinical trials. In some reported cases, axillary adenopathy on same side as the vaccination site was seen on breast ultrasound performed 5–13 days after receipt of an mRNA COVID-19 vaccine. Consider vaccine-induced hyperplastic axillary adenopathy in differential diagnosis if unilateral axillary adenopathy identified on breast imaging in individuals who recently received an mRNA COVID-19 vaccine.

Limitations of Vaccine Effectiveness

May not protect all vaccine recipients against COVID-19.

The Moderna COVID-19 vaccine is administered in a series of 2 doses given 1 month (28 days) apart (see Dosage under Dosage and Administration). Limited data from the ongoing phase 3 trial evaluating the vaccine indicate that estimated vaccine efficacy is 80.2% following the first dose compared with 94.1% following the second dose. Counsel vaccine recipients on the importance of completing the 2-dose vaccination series to optimize protection against COVID-19.

Use of COVID-19 vaccines for outbreak management or for postexposure prophylaxis to prevent SARS-CoV-2 infection in individuals with a specific known exposure to the virus is unlikely to be effective and is not currently recommended. ACIP states that, because the median incubation period of SARS-CoV-2 infection is 4–5 days, it is unlikely that a dose of COVID-19

vaccine would provide an adequate immune response within the incubation period for effective postexposure prophylaxis.

FDA states that data are too limited to date to assess the effect of the Moderna COVID-19 vaccine for prevention of asymptomatic SARS-CoV-2 infection (as measured by detection of the virus and/or detection of antibodies against non-vaccine antigens that would indicate infection rather than an immune response induced by the vaccine); additional evaluations are needed, including data from clinical trials and from use of the vaccine after issuance of the EUA.

FDA states that data are too limited to date to assess effect of the Moderna COVID-19 vaccine against transmission of SARS-CoV-2 from individuals who become infected despite vaccination. Demonstrated high efficacy against symptomatic COVID-19 may translate to overall prevention of transmission in populations with high enough vaccine uptake; however, it is possible that if efficacy against asymptomatic infection were lower than efficacy against symptomatic infection, asymptomatic cases in combination with reduced mask-wearing and social distancing could result in significant continued transmission of the virus. Additional evaluations are needed, including data from clinical trials and from use of the vaccine after issuance of the EUA, to assess the effect of the vaccine in preventing virus shedding and transmission, particularly in individuals with asymptomatic infection.

Based on currently limited information on the extent to which vaccination may reduce viral transmission in the general population, unknown duration of vaccine-induced protection, and unknown efficacy against emerging SARS-CoV-2 variants, counsel individuals who receive COVID-19 vaccination to continue to follow current guidance to protect themselves and others. This includes wearing a mask, staying ≥6 feet away from others, avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, washing hands frequently, following CDC travel guidance, and following any applicable workplace or school guidance.

CDC issued interim public health recommendations for individuals who are fully vaccinated against COVID-19 (defined as at least 2 weeks after completion of a 2-dose vaccination series of the Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine or at least 2 weeks after a single dose of the Janssen COVID-19 vaccine). Consult these recommendations (available at the CDC website at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>) for information on precautionary measures that fully vaccinated individuals should take in various social situations and/or following exposure to someone with suspected or confirmed COVID-19.

Withholding COVID-19 vaccination due to concerns about efficacy against current or future SARS-CoV-2 viral variants not recommended.

If an individual is fully vaccinated against COVID-19 and tests positive for SARS-CoV-2, healthcare providers and local health departments are encouraged to request that the specimen be held and the case reported to the state health department. CDC will work with the state health department to collect information about the case. In addition, report information about such cases to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Duration of Immunity

Duration of protection against SARS-CoV-2 infection following completion of the 2-dose vaccination series of COVID-19 vaccine (Moderna) not fully evaluated.

Because available trial data have a limited length of follow-up to date, it is not possible at this time to assess sustained efficacy over a period longer than 2 months.

ACIP states that the need for and timing of booster doses of COVID-19 vaccines not established. Additional vaccine doses beyond those recommended for a complete, valid vaccination series (see Dosage under Dosage and Administration) *not* recommended at this time. Recommendations on revaccination or additional doses of COVID-19 vaccines may be updated when additional information available.

Improper Storage and Handling

Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccinees. Inspect all vaccines on delivery and monitor during storage to ensure that recommended storage temperatures are maintained.

The Moderna COVID-19 vaccine must be shipped, stored, and handled under specific conditions at all times, including maintaining cold chain conditions and chain of custody, according to specifications in the EUA fact sheet for healthcare providers and guidance from the manufacturer and CDC. Do not administer vaccine that has been mishandled or has not been stored at the recommended temperatures. (See Storage under Stability.)

Contact the manufacturer at 866-663-3762 for guidance if there are concerns about mishandling or defective or damaged vaccine.

EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting

Safety and efficacy not established. The FDA issued an EUA that permits use of the Moderna COVID-19 vaccine for prevention of COVID-19† in individuals ≥18 years of age when administered according to the 2-dose vaccination series specified in the EUA. (see Prevention of Coronavirus Disease 2019 [COVID-19] under Uses)

Some data available regarding adverse effects associated with use of the vaccine. (See Common Adverse Effects under Cautions.) Additional adverse effects, some of which may be serious, may become apparent with more widespread use.

Monitor all vaccine recipients for immediate adverse reactions according to CDC (ACIP) guidelines. (See General under Dosage and Administration.)

Provide vaccine recipients or their caregivers with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects. Reports to v-safe that indicate a medically important health impact are followed up by the CDC v-safe call center to collect additional information to complete a VAERS report. Information on v-safe is available at <https://www.cdc.gov/vsafe>.

It is mandatory that vaccination providers administering the Moderna COVID-19 vaccine report all vaccine administration errors (even if not associated with an adverse event) and serious adverse events (irrespective of attribution to vaccination) that occur following vaccination and also report all cases of multisystem inflammatory syndrome (MIS) and COVID-19 that result in hospitalization or death in vaccine recipients to VAERS. Can complete and submit VAERS reports online at <https://vaers.hhs.gov/reportevent.html> or by faxing to 877-721-0366; include the words "Moderna COVID-19 Vaccine EUA" in description section of the report. Obtain information on submitting a VAERS report by calling 800-822-7967 or emailing info@vaers.org. To the extent feasible, also provide a copy of the VAERS form to the manufacturer (Moderna) at ModernaPV@modernatx.com (email), 866-599-1342 (fax), or 866-663-3762 (phone).

Consult FDA fact sheet for healthcare providers for the Moderna COVID-19 vaccine available at the FDA website and at <http://www.modernatx.com/covid19vaccine-eua> for requirements and instructions regarding reporting of adverse reactions and vaccination errors.

Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals

Results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests) not affected by prior COVID-19 vaccination.

Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins (spike or nucleocapsid). Because COVID-19 vaccines, including the Moderna COVID-19 vaccine, encode the spike protein of the virus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination. Use a test that specifically evaluates IgM/IgG to the nucleocapsid protein to assess for evidence of prior infection in an individual who has received COVID-19 vaccination.

Antibody testing *not* currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. Antibody tests currently authorized for use under EUAs have variable sensitivity and specificity, as well as positive and negative predictive values, and are not authorized for assessment of immune response in individuals who have received COVID-19 vaccination. In addition, serologic correlates of protection against SARS-CoV-2 not established, and antibody testing does not evaluate cellular immune response, which may also play a role in vaccine-mediated protection. If antibody testing is performed following COVID-19 vaccination, do *not* administer additional doses of the same or different COVID-19 vaccine beyond those recommended based on results of antibody testing.

Interpretation of Tuberculosis Tests in Vaccinated Individuals

ACIP states do *not* delay COVID-19 vaccination in situations when an immune-based method of tuberculosis testing (i.e., intradermal tuberculin skin test [TST] or serum interferon gamma release assay [IGRA]) is required or indicated.

If TST or IGRA required according to administrative policies (e.g., healthcare employment, admission to long-term care facilities), perform such testing before or during same visit that COVID-19 vaccine is administered. If such testing cannot be done prior to or at the same time as COVID-19 vaccination, ACIP recommends delaying testing until ≥ 4 weeks after completion of vaccination. If a tuberculosis testing requirement or policy cannot be modified to accept a delay in TST or IGRA testing during the COVID-19 pandemic, it should be understood that a false-negative TST or IGRA cannot be excluded; in such situations, consider repeating a negative TST or IGRA test ≥ 4 weeks after completion of COVID-19 vaccination. In addition, if TST was performed as the initial test, consider the possibility that boosting could be a factor if results of a repeat TST are positive.

ACIP states COVID-19 vaccines can be given to individuals who have active tuberculosis disease or an illness being evaluated as active tuberculosis disease; however, consider that a moderate or severe acute illness usually is a precaution for vaccination (see Concomitant Illness under Cautions). If TST or IGRA is being considered for medical diagnosis of latent tuberculosis infection (e.g., during contact investigation after exposure to contagious tuberculosis disease), a decision to delay such testing until ≥ 4 weeks after completion of COVID-19 vaccination is at the discretion of the responsible medical provider and local tuberculosis program overseeing the contact investigation. If a decision is made to not delay TST or IGRA testing (e.g., in individuals at high risk for progression to tuberculosis disease) and test results are negative, ACIP states consider retesting ≥ 4 weeks after completion of COVID-19 vaccination.

Specific Populations

Pregnancy

Data insufficient to date regarding use of the Moderna COVID-19 vaccine in pregnant women to inform vaccine-associated risks during pregnancy.

A developmental toxicity study in female rats did not reveal evidence of vaccine-related adverse effects on female fertility, fetal development, or postnatal development.

Observational data suggest that, while the absolute risk is low, pregnant women with COVID-19 are at increased risk of severe illness, including illness resulting in admission to

an intensive care unit (ICU), mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death. Additionally, such women might be at an increased risk of adverse pregnancy outcomes, such as preterm birth.

FDA states that pregnancy is not a contraindication to use of the Moderna COVID-19 vaccine; pregnant women should discuss their options with their healthcare providers.

ACIP states that, based on current knowledge, COVID-19 vaccines are unlikely to pose a risk to pregnant women or the fetus; therefore, pregnant women may choose to be vaccinated. ACIP states that any authorized COVID-19 vaccine can be administered to pregnant women; ACIP does not state a preference for any specific COVID-19 vaccine in such women.

ACOG recommends that COVID-19 vaccines not be withheld from pregnant women. In the interest of patient autonomy, these experts recommend that pregnant women be free to make their own decision regarding COVID-19 vaccination.

ACIP and ACOG state that a conversation between the pregnant woman and her clinical team may assist with decisions regarding use of COVID-19 vaccines available under an EUA; however, such a conversation is not required prior to vaccination. When making a decision, pregnant women and their healthcare providers should consider the level of COVID-19 transmission in the community, the individual's personal risk of contracting COVID-19, risks of COVID-19 to the individual and potential risks to the fetus, efficacy of the vaccine, adverse effects of the vaccine, and lack of data about use of the vaccine during pregnancy.

Adverse effects similar to those reported in non-pregnant individuals can occur following COVID-19 vaccination in pregnant women. Advise pregnant women who experience fever following COVID-19 vaccination to take acetaminophen; may also offer acetaminophen as an option for pregnant women experiencing other postvaccination symptoms.

ACOG recommends that women who become pregnant after receiving the first dose of an mRNA COVID-19 vaccination series should receive the second dose according to the usual schedule, unless contraindicated.

Defer administration of other vaccines (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP], influenza vaccine) in pregnant women for 14 days after COVID-19 vaccination. (See Vaccines under Interactions.) ACOG states do not withhold Rh₀(D) immune globulin when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Specific Drugs under Interactions.)

Pregnancy exposure registry established to monitor pregnancy outcomes in women exposed to the Moderna COVID-19 vaccine during pregnancy. Encourage women who are vaccinated with the Moderna COVID-19 vaccine during pregnancy to enroll in the registry by calling 866-663-3762.

Encourage women who receive a COVID-19 vaccine during pregnancy and those who become pregnant within 30 days after receiving a COVID-19 vaccine to participate in CDC's v-safe program. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Females and Males of Reproductive Capacity

Routine pregnancy testing *not* recommended before receiving a COVID-19 vaccine.

ACIP states that women trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination.

ACOG recommends vaccination for all eligible individuals, including those who may consider future pregnancy.

There is no evidence that any of the authorized COVID-19 vaccines affect future fertility.

Lactation

Not known whether Moderna COVID-19 vaccine administered to a woman who is breast-feeding has any effects on the breast-fed infant or milk production.

FDA states that breast-feeding is not a contraindication to use of the Moderna COVID-19 vaccine; breast-feeding women should discuss their options with their healthcare providers.

ACIP states that COVID-19 vaccines are not thought to be a risk for breast-feeding women or their infants; therefore, breast-feeding women may choose to be vaccinated. ACIP states that any authorized COVID-19 vaccine can be administered to breast-feeding women; ACIP does not state a preference for any specific COVID-19 vaccine in such women.

ACOG states offer COVID-19 vaccines to lactating women, similar to other individuals. ACOG also states that theoretical concerns regarding safety of vaccinating lactating women do not outweigh potential benefits of the vaccine; there is no need for individuals who receive a COVID-19 vaccine to avoid initiating breast-feeding or to discontinue breast-feeding.

Pediatric Use

Safety and efficacy of the Moderna COVID-19 vaccine not assessed in individuals <18 years of age.

FDA EUA permits use of the Moderna COVID-19 vaccine *only* in individuals ≥ 18 years of age.

Geriatric Use

Individuals ≥ 65 years of age were included in clinical trials evaluating the Moderna COVID-19 vaccine and data from such individuals contribute to overall assessment of safety and efficacy of the vaccine.

At the time of FDA's safety and efficacy analysis of data from the ongoing phase 3 trial for the EUA, 24.8% of participants were ≥ 65 years of age and 4.6% were ≥ 75 years of age. Subgroup efficacy analysis based on age indicated that vaccine efficacy in those ≥ 65 years

of age was 86.4% compared with 95.6% in those 18 to <65 years of age. No overall notable differences in safety profiles between participants ≥65 years of age and younger adults.

Common Adverse Effects

Local adverse effects reported in clinical trials include injection site pain (92%), swelling (14.7%), erythema (10%).

Systemic adverse effects reported in clinical trials include fatigue (70%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23%), axillary swelling/tenderness (19.8%), fever (15.5%).

Local and systemic adverse effects were usually reported within the first 1–2 days after a vaccine dose, had a median duration of 2–3 days, and were reported more frequently after the second dose of the 2-dose vaccination series. Use of antipyretic or pain medication within 7 days after receiving the first or second vaccine dose reported in 23.3 or 57.3%, respectively, of those 18–64 years of age and in 17.9 or 41.9%, respectively, of those ≥65 years of age.

At the time of FDA's safety analysis of data from the ongoing phase 3 trial for the EUA, serious adverse events reported in 1% of vaccine recipients and 1% of placebo recipients. FDA considered 3 of the serious adverse events reported in the vaccine group to be possibly related to the vaccine (i.e., intractable nausea and vomiting in an individual 1 day after vaccination; facial swelling with onset 1–2 days after vaccination in 2 individuals with a history of injection of facial cosmetic dermal fillers).

Severe allergic reactions, including anaphylaxis, reported rarely when mRNA COVID-19 vaccines were administered outside of clinical trials. (See Hypersensitivity Reactions under Cautions.)

Interactions

Vaccines

Data not available to date to assess concomitant administration of COVID-19 vaccine (Moderna) with other vaccines.

ACIP recommends giving the 2-dose vaccination series of the Moderna COVID-19 vaccine alone, with a minimum interval of 14 days before or after administration of any other vaccine. However, COVID-19 vaccines and other vaccines may be administered within a shorter period if benefits of vaccination outweigh potential unknown risks of concomitant administration (e.g., tetanus toxoid-containing vaccination as part of wound management; rabies vaccination for postexposure prophylaxis; measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to or at time of admission or onboarding). If administered within 14 days of another vaccine, ACIP states there is no need to repeat doses of either vaccine.

Specific Drugs

Drug	Interaction	Comments
COVID-19 convalescent plasma	Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine	To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection; however, COVID-19 vaccination not contraindicated in those who received passive antibody therapy within the past 90 days and COVID-19 vaccine doses received <90 days after receipt of passive antibody therapy do not need to be repeated If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect

Immune globulin and antibody therapies not specific for SARS-CoV-2 (e.g., immune globulin IV [IGIV], Rh₀[D] immune globulin)

Immunosuppressive agents (e.g., cancer chemotherapy, corticosteroids, radiation)

SARS-CoV-2-specific monoclonal antibodies (bamlanivimab, bamlanivimab and etesevimab, casirivimab and imdevimab)

treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment

Possible decreased or suboptimal antibody responses to vaccines, including the Moderna COVID-19 vaccine

Data insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies

ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccination if they have no contraindications to the vaccine

Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥2 weeks before initiation of immunosuppressive therapies; consider individual's risks related to their underlying condition if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination

Revaccination after immune competence regained not recommended in individuals who received COVID-19 vaccine during chemotherapy or treatment with other immunosuppressive agents

If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of corticosteroids, or timing of such treatment

ACIP states there is no recommended minimum interval between receipt of antibody therapies not specific for SARS-CoV-2 and COVID-19 vaccination

ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccination if they have no contraindications to the vaccine

Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥2 weeks before initiation of immunosuppressive therapies; consider individual's risks related to their underlying condition if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination

Revaccination after immune competence regained not recommended in individuals who received COVID-19 vaccine during chemotherapy or treatment with other immunosuppressive agents

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ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccination if they have no contraindications to the vaccine

Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥2 weeks before initiation of immunosuppressive therapies; consider individual's risks related to their underlying condition if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination

Revaccination after immune competence regained not recommended in individuals who received COVID-19 vaccine during chemotherapy or treatment with other immunosuppressive agents

If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of corticosteroids, or timing of such treatment

Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine

To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy based

on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection; however, COVID-19 vaccination not contraindicated in those who received passive antibody therapy within the past 90 days and COVID-19 vaccine doses received <90 days after receipt of passive antibody therapy do not need to be repeated

If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment

- The mRNA contained in the Moderna COVID-19 vaccine encodes a full-length spike (S) glycoprotein of SARS-CoV-2 stabilized in a prefusion conformation with 2 proline substitutions (S-2P). Following IM injection, the LNPs in the vaccine enable delivery of the mRNA into host cells where it is released and translated to the encoded S antigen of SARS-CoV-2. The S antigen elicits an immune response to provide protection against SARS-CoV-2.
- Data from clinical trials in healthy adults indicate dose-dependent antibody responses to a 2-dose regimen of the Moderna COVID-19 vaccine, with antibody responses boosted after the second dose. The vaccine induces both binding and neutralizing antibodies at levels comparable to or higher than those reported in convalescent serum obtained from individuals who have recovered from COVID-19; antibody responses in adults ≥56 years of age are similar to those reported in adults 18–55 years of age. The vaccine also directly activates T-cells, which eliminate infected cells and support B-cell responses; the T-cell response is predominantly type 1 helper (Th1).
- COVID-19 vaccine (Moderna) available for use under the FDA EUA is provided as a frozen suspension in multiple-dose vials. Following thawing as directed by the manufacturer, each 0.5-mL dose of the Moderna COVID-19 vaccine contains 100 mcg of mRNA encoding the S glycoprotein of SARS-CoV-2. Each dose also contains 4 different lipids (SM-102, PEG 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.
- Does not contain preservatives; vial stoppers are not made with natural rubber latex.

Advice to Patients

- Prior to administration of COVID-19 vaccine (Moderna), the vaccine recipient or their caregiver must be provided with information consistent with the Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 Years of Age or Older and given a copy of the fact sheet or directed to the manufacturer's website at <https://www.modernatx.com/covid19vaccine-eua> to obtain the fact sheet.
- At the time that the first dose of the Moderna COVID-19 vaccine is administered, inform the vaccine recipient or their caregiver that the vaccine is administered in a series of 2 doses given 1 month (28 days) apart and advise them of the importance of receiving the second dose of the 2-dose vaccination series to optimize protection against COVID-19. Give the vaccine recipient or their caregiver a vaccination card that provides the date when the recipient needs to return for the second vaccine dose and inform them of the importance of bringing the card when they return for the second dose.
- Provide the vaccine recipient or their caregiver with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects; live telephone follow-up is provided if a medically important health impact is reported. Information on v-safe is available at <https://www.cdc.gov/vsafe>.
- Inform vaccine recipients or their caregivers that FDA authorized the emergency use of the Moderna COVID-19 vaccine, which is an investigational vaccine that has not received FDA approval, for use in individuals ≥18 years of age. Advise them that clinical trials have shown that a 2-dose series of the vaccine can prevent COVID-19; however, the duration of protection following vaccination is unknown and the vaccine may not protect everyone who receives it.
- Inform vaccine recipients or their caregivers that they have the option to accept or refuse the vaccine.
- Provide vaccine recipients or their caregivers with information on available alternative vaccines and the risks and benefits of those alternatives.
- Inform vaccine recipients or their caregivers about the significant known and potential risks and benefits of the Moderna COVID-19 vaccine, and the extent to which such risks and benefits are unknown. Inform them that local adverse effects (injection site pain, swelling, redness; tenderness and swelling of lymph nodes in the injected arm) and systemic adverse effects (fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever) have been reported in recipients of the Moderna COVID-19 vaccine.
- Importance of vaccine recipient informing the vaccination provider of any allergies or fever. Advise vaccine recipients or their caregivers that there is a remote chance that the vaccine could cause a severe allergic reaction and such reactions would usually occur within a few minutes to 1 hour after receiving a dose of the vaccine and may include difficulty breathing, swelling of the face and throat, fast heartbeat, bad rash all over the body, and dizziness and weakness.
- Importance of vaccine recipient informing the vaccination provider if they have had a severe allergic reaction to any ingredient in the vaccine (e.g., PEG) or if they had a severe allergic reaction after receiving the first dose of the 2-dose vaccination series; importance of such individuals *not* receiving the vaccine. (See Contraindications under Cautions.)
- Importance of vaccine recipient informing vaccination provider if they previously received any other COVID-19 vaccine, have any medical conditions (e.g., bleeding disorders, immunocompromising diseases), or are receiving anticoagulants or immunosuppressive therapy.
- Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed.

Stability

Storage

Parenteral

Suspension, for IM Use

Supplied as a frozen suspension in multiple-dose vials that *must* be shipped and stored (long-term) at a temperature between -50 to -15°C.

Do *not* store the Moderna COVID-19 vaccine on dry ice or at temperatures less than -50°C.

If transport at -50 to -15°C not feasible, available data support transport of one or more thawed multiple-dose vials for up to 12 hours at 2–8°C when shipped using shipping containers that are qualified to maintain a temperature of 2–8°C and if such transport occurs under routine road and air transportation conditions with minimal shaking and vibration. Vials transported at 2–8°C should not be refrozen and should be stored at 2–8°C until use.

Store multiple-dose vials of the vaccine in the original carton to protect from light. Thawed vials may be handled in room light conditions.

Consult EUA fact sheet for healthcare providers for the Moderna COVID-19 vaccine and information provided by CDC and the manufacturer for information on storage, handling, and stability of the vaccine. Storage and handling information contained in the EUA fact sheet for healthcare providers supersedes storage and handling information on vaccine vials and carton labels. Various documents and videos describing shipping, storage, and handling requirements and procedures are available at the manufacturer's website at <https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling>.

Prior to first use, may thaw and store multiple-dose vials of the Moderna COVID-19 vaccine in a refrigerator (2–8°C) for up to 30 days. May store unused (i.e., unpunctured) vials for up to 24 hours at 8–25°C.

After withdrawing first dose of vaccine from the multiple-dose vial, vial should be held between 2–25°C and *must* be discarded if not used within 12 hours after first vial entry.

Once thawed, do *not* refreeze.

Expiration dates are not marked on vials and cartons of the Moderna COVID-19 vaccine. Scan the QR code on the vial or carton to reach an online resource that provides the expiration date based on the lot number printed on the packaging. Alternatively, obtain expiration dates by entering the lot number at the manufacturer's website at <https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup>. Because it is possible that expiration dates may be extended as more stability data become available, contact the manufacturer prior to discarding vaccine to determine if the expiration date has been extended.

Actions

- Nucleoside-modified mRNA vaccine formulated in lipid nanoparticles (LNPs).

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

COVID-19 vaccine (Moderna) is not commercially available. FDA issued an emergency use authorization (EUA) for the Moderna COVID-19 vaccine that permits use of the vaccine for the prevention of COVID-19† in individuals ≥ 18 years of age. Allocation of the vaccine for use under the EUA is being directed by the US government. The vaccine will be supplied directly from the manufacturer or authorized US distributor(s) and distributed to emergency response stakeholders as directed by the US government, including the CDC and/or other designee.

COVID-19 Vaccine, mRNA (Moderna)

Parenteral

Suspension, for IM use

100 mcg (of mRNA) per
0.5-mL dose

**Moderna COVID-19
Vaccine, ModernaTX**

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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