

## COVID-19 Vaccine, mRNA (Moderna)

### 80:12 • Vaccines (AHFS primary)

#### Special Alerts:

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■ COVID-19 vaccine (Moderna) is a nucleoside-modified mRNA vaccine used to stimulate active immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

#### Uses

##### ■ Prevention of Coronavirus Disease 2019 (COVID-19)

COVID-19 vaccine (Moderna) is an mRNA vaccine being investigated and used for the prevention of coronavirus disease 2019<sup>†</sup> (COVID-19) caused by SARS-CoV-2. The Moderna COVID-19 vaccine is one of various COVID-19 vaccines being evaluated for the prevention of COVID-19.

Although efficacy and safety of COVID-19 vaccine (Moderna) have not been definitely established, the vaccine is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals 18 years of age or older.

The US Centers for Disease Control and Prevention (CDC) 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 or older. 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 the 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 currently authorized 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.)

##### Emergency Use Authorization

On December 18, 2020, FDA issued an EUA that permits use of COVID-19 vaccine (Moderna) to prevent COVID-19 in individuals 18 years of age or older. 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 the 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 (e.g., requirements concerning obtaining, tracking, and handling vaccine) and requirements concerning reporting of 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 COVID-19 vaccine (Moderna) after concluding that emergency use of the vaccine for the 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 Moderna COVID-19 vaccine may be effective in preventing COVID-19 and, when used under the conditions described in the authorization, the known and potential benefits outweigh the known and potential risks; and there are no adequate, approved, and available alternatives to the emergency use of the vaccine to prevent COVID-19.

Issuance of the EUA for COVID-19 vaccine (Moderna) was based on FDA review of safety and efficacy data from an ongoing phase 3 clinical trial that included approximately 30,000 adults randomized 1:1 to receive the vaccine or saline placebo. (See Clinical Experience under Uses.)

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 the risks of this unapproved vaccine, the EUA requires that vaccination providers administering the Moderna COVID-19 vaccine comply with certain mandatory requirements. These requirements include providing the recipient or caregiver with information consistent with the EUA fact sheet for recipients and caregivers and 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.)

For additional information, the Moderna COVID-19 vaccine EUA letter of authorization, EUA fact sheet for healthcare providers, and EUA fact sheet for recipients and caregivers should be consulted.

##### Clinical Experience

Efficacy and safety of COVID-19 vaccine (Moderna) for the prevention of COVID-19 are being evaluated in an ongoing multicenter, randomized, double-blind, placebo-controlled, phase 3 clinical trial in adults 18 years of age or older with no known history of SARS-CoV-2 infection (NCT04470427; mRNA-1273-P301; COVE study). At the time of FDA's efficacy review of the vaccine for the EUA, the efficacy analysis population had been followed for a median of 9 weeks after the second dose and data indicated that the Moderna COVID-19 vaccine was 94.1% effective in preventing symptomatic, laboratory-confirmed COVID-19 occurring at least 14 days after the second dose of the 2-dose vaccination series compared with placebo.

The phase 3 trial enrolled adults 18 years of age or older who were randomized 1:1 to receive 2 IM doses given 28 days apart of the Moderna COVID-19 vaccine (100 mcg for each dose) or normal saline placebo, and randomization was stratified by age and risk criteria into 3 groups (18 to less than 65 years of age without comorbidities [not at risk for progression to severe COVID-19], 18 to less than 65 years of age with comorbidities [at risk for progression to severe COVID-19], 65 years of age and older with or without comorbidities). The study allowed for inclusion of participants with stable preexisting medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection; immunocompromised individuals and those with a known history of SARS-CoV-2 infection were excluded. The primary efficacy end point is efficacy of the vaccine in preventing laboratory-confirmed, symptomatic COVID-19 (as defined in the protocol) with onset at least 14 days after the second dose in participants with negative SARS-CoV-2 status at baseline. Among the 28,207 per-protocol participants included in the primary efficacy analysis (14,134 in the vaccine group and 14,073 in the placebo group), there were 11 cases of symptomatic COVID-19 with onset at least 14 days after the second dose among vaccine recipients and 185 cases among placebo recipients; this corresponds to 94.1% vaccine efficacy.

Additional primary efficacy analyses indicated that vaccine efficacy generally was consistent across subgroups defined by age, sex, race, ethnicity, and risk for severe disease. Vaccine efficacy in participants 65 years of age or older was 86.4% compared with 95.6% in younger adults. (See Geriatric Use under Cautions.)

Per the phase 3 study protocol, secondary efficacy end points include prevention of severe COVID-19, asymptomatic COVID-19, death due to COVID-19, and COVID-19 occurring at least 14 days after the first dose. At the time of FDA's efficacy review for the EUA, there were a total of 30 cases of severe COVID-19 (as defined in the protocol) reported at least 14 days after the second dose (9 required hospitalization, 1 fatality) in the per-protocol participants and these severe cases all occurred in the placebo group, suggesting benefit of the vaccine in preventing severe COVID-19. Data

were insufficient to assess other secondary end points. (See Limitations of Vaccine Effectiveness under Cautions.)

## Dosage and Administration

### ■ General

Appropriate medications and supplies used to assess and manage immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines, including COVID-19 vaccine (Moderna). Healthcare personnel who are trained and qualified to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination sites 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, all individuals should be screened for contraindications and precautions to vaccination. Those with a contraindication should not receive the Moderna COVID-19 vaccine. (See Contraindications and see Warnings/Precautions under Cautions.)

*All individuals who receive a COVID-19 vaccine should be monitored for immediate adverse reactions according to CDC (ACIP) guidelines.* When individuals with no contraindications to vaccination with an mRNA COVID-19 vaccine receive the Moderna COVID-19 vaccine, ACIP states that 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 should be observed for 30 minutes after receiving the vaccine, and that all other individuals should be observed for 15 minutes. A longer period of observation may be indicated for some individuals based on clinical concern (e.g., vaccinee develops pruritus and swelling confined to the injection site during their observation period). Vaccine recipients should be instructed 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. Appropriate measures should be taken to decrease the 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, the patient should be observed until symptoms resolve.

COVID-19 vaccine (Moderna) 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 of the Moderna COVID-19 vaccine is administered, vaccine recipients or their caregivers should be given a vaccination record card that provides the date when the recipient needs to return for the second dose of the vaccine and counseled on the importance of completing the 2-dose vaccination series to optimize protection against COVID-19.

Vaccine recipients or their caregivers should be provided with information on, and encouraged to participate in, CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in individuals who have received a COVID-19 vaccine. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Prior to vaccination, vaccine recipients or their caregivers should be counseled about local and systemic adverse effects that may occur following vaccination. (See Cautions and see Advice to Patients.) Unless an individual has a contraindication to vaccination with an mRNA COVID-19 vaccine (see Contraindications under Cautions), ACIP recommends that vaccinees should be encouraged to complete the 2-dose vaccination series of the Moderna COVID-19 vaccine even if they experience local or systemic adverse effects following the first dose since this optimizes protection.

Antipyretics or analgesics (e.g., acetaminophen, nonsteroidal anti-inflammatory agents) may be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in individuals receiving a COVID-19 vaccine is *not* currently recommended because information regarding possible impact on antibody response to the vaccine is not available at this time. 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 lead to a delay in the diagnosis and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)

Individuals who receive COVID-19 vaccine (Moderna) should be counseled to continue to follow all current guidance to protect themselves and others. This includes wearing a mask, staying at least 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,

the unknown duration of vaccine-induced protection, and the unknown extent of protection against emerging SARS-CoV-2 variants. (See Limitations of Vaccine Effectiveness under Cautions.)

### ■ Administration

COVID-19 vaccine (Moderna) is administered *only* by IM injection into the deltoid.

Data are not available regarding concomitant administration of COVID-19 vaccine (Moderna) 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 Drug Interactions.)

### IM Injection

COVID-19 vaccine (Moderna) is supplied as a frozen suspension in multiple-dose vials.

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

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

*The Moderna COVID-19 vaccine should not be diluted.*

Thawed, unused vials (i.e., unpunctured) may be stored for up to 24 hours at 8–25°C.

After the first dose of Moderna COVID-19 vaccine is withdrawn from the multiple-dose vial, the vial should be held between 2–25°C and *must* be discarded if not used within 12 hours after first vial entry. The date and time of first use should be recorded on the vial label.

Vials of vaccine should be swirled gently after thawing and between withdrawal of each dose and should *not* be shaken.

To administer a dose of the thawed Moderna COVID-19 vaccine, 0.5 mL of the vaccine should be withdrawn from the vial using aseptic technique and an appropriate syringe and needle and administered 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 the 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 should *not* be pooled with vaccine from other vials to create a dose.

### Thawing.

Thawing in a refrigerator (2–8°C): Multiple-dose vials of frozen Moderna COVID-19 vaccine containing 11 or 15 doses should be thawed for 2.5 or 3 hours, respectively, in a refrigerator. Unopened vials of the vaccine may be stored in a refrigerator (2–8°C) for up to 30 days prior to first use.

Thawing at room temperature (15–25°C): Multiple-dose vials of frozen Moderna COVID-19 vaccine containing 11 or 15 doses may be allowed to sit at room temperature for 1 or 1.5 hours, respectively, to thaw. Unopened vials of the vaccine may be stored for up to 24 hours at 8–25°C.

Thawed COVID-19 vaccine (Moderna) should appear as a white to off-white suspension and may contain white or translucent product-related particles. The thawed vaccine should *not* be used if it is *discolored* or contains other particles.

Vaccine that has been thawed *must not* be refrozen.

### ■ Dosage

COVID-19 vaccine (Moderna) is administered 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 (see Description).

The 2-dose regimen of 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., a 2-dose regimen of an mRNA vaccine [Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine] or a single dose of Janssen COVID-19 vaccine).

Clinicians should 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.

The EUA that permits use of COVID-19 vaccine (Moderna) specifies an interval of 1 month (28 days) between the 2 vaccine doses. ACIP states that individuals should not be scheduled to receive the second dose of the vaccine earlier than 1 month after the first dose; however, a second dose administered within a grace period of 4 days earlier than the recommended date is still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, ACIP states that the second dose may be administered up to 6 weeks (42 days) after the first dose;

only limited data are available regarding efficacy if the second dose of an mRNA COVID-19 vaccine is administered more than 6 weeks after the first dose.

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

Safety and efficacy of a mixed vaccination series of mRNA COVID-19 vaccines have not been evaluated, and individuals who receive a dose of the Moderna COVID-19 vaccine should complete the series using the same vaccine. Every effort should be made to determine which mRNA COVID-19 vaccine was used for the 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 the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered 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 that 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 have not been 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), a single dose of the Janssen COVID-19 vaccine administered at least 28 days after the first dose of mRNA COVID-19 vaccine may be considered. (See Hypersensitivity Reactions under Cautions.) An individual who receives a dose of an mRNA COVID-19 vaccine followed by a single dose of the Janssen COVID-19 vaccine under such exceptional circumstances should be considered to have received valid, single-dose vaccination with Janssen COVID-19 vaccine, not a mixed vaccination series.

All vaccine administration errors and deviations from the currently recommended dosage and vaccination schedule should be reported 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 how to prevent and report COVID-19 vaccine administration errors and recommendations for specific actions to take if an administration error or deviation from the recommended vaccination schedule occurs are available at the CDC website at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

### Adult Dosage

The FDA EUA that permits use of COVID-19 vaccine (Moderna) for the prevention of COVID-19† (see Emergency Use Authorization under Uses) states that adults 18 years of age or older 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 Description.)  
ACIP considers the following to be contraindications to vaccination with *both* mRNA COVID-19 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.

At the time that FDA's safety and efficacy analysis of data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial evaluating COVID-19 vaccine (Moderna) was performed for the EUA, hypersensitivity reactions had been reported in 1.5% of vaccine recipients and 1.1% of placebo recipients, but there were no reports of anaphylactic or severe hypersensitivity reactions with close temporal relation to the vaccine. Hypersensitivity events reported in the vaccine group that were likely related to vaccination included injection site rash and injection site urticaria. The trial excluded participants with known or suspected history of allergic reaction to components of the Moderna COVID-19 vaccine, but did not exclude participants with other allergies.

Although immediate allergic reactions have not been reported to date in clinical trials evaluating the Moderna COVID-19 vaccine, severe allergic reactions, including

anaphylaxis, have been 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 a documented history of allergies or allergic reactions to drugs or medical products, foods, or insect stings (7 with a history of anaphylaxis, including one after receipt of a dose of rabies vaccine and another after receipt of influenza vaccine). The median interval from receipt of the vaccine dose to onset of anaphylaxis symptoms was 13 minutes (range: 2–150 minutes); 15 of the 21 individuals with anaphylaxis (71%) had onset of symptoms within 15 minutes after receiving the dose and 19 (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 a documented history of allergies or allergic reactions to drugs, contrast media, or food (5 with a history of anaphylaxis). The median interval from receipt of the vaccine dose to onset of 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 individuals 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 for individuals who received the first dose of the Moderna COVID-19 vaccine identified 43 cases of nonanaphylactic allergic reactions; 26 of these cases (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 the vaccine dose to onset of symptoms was 15 minutes (range: less than 1 minute to 24 hours); in 30 cases (73%), onset of symptoms occurred within 30 minutes.

Delayed-onset local reactions (e.g., erythema, induration, pruritus, tenderness) around the injection site area have been reported in some vaccine recipients, including some clinical trial participants, after the 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 reactions after the 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 dose of the vaccine. ACIP states that a 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 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, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

Because anaphylactic reactions have been reported rarely following administration of COVID-19 vaccines, ACIP has issued interim guidance with contraindications and precautions for use of COVID-19 vaccines pending further investigation. For the 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. Vaccination providers should attempt to determine whether reactions reported following vaccination with an mRNA COVID-19 vaccine 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, such as vasovagal reactions or postvaccination adverse effects, that are not considered contraindications to receiving 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 COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine. ACIP states that consideration can be given to 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), consultation with an allergist-immunologist should be considered 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 have not been 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), a single dose of the Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days after the dose of mRNA COVID-19 vaccine. (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 COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine. ACIP states that consideration can be given to 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), consultation with an allergist-immunologist should be considered 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 have not been 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), a single dose of the Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days after the dose of mRNA COVID-19 vaccine. (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 that polysorbate allergy is a contraindication to vaccination with the Janssen COVID-19 vaccine and that use of an mRNA COVID-19 vaccine (Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine) can be considered in such individuals. However, polysorbates are structurally related to PEG and there is potential for cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered 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), the vaccine should be administered *only* in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

**History of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., IM, IV, or subcutaneous vaccines or therapies):** ACIP considers this a **precaution**, but not a contraindication, to COVID-19 vaccination. ACIP states that a history of allergic reaction to subcutaneous 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 allergic reactions related to food, pets, insects, 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 the first dose of an mRNA COVID-19 vaccine:** ACIP states that these local reactions are **not** a contraindication or precaution for administration of the second dose of the mRNA COVID-19 vaccine. Such individuals should receive the second dose using the same mRNA COVID-19 vaccine used for the first dose at the recommended interval, preferably in the opposite arm.

If a **precaution** for COVID-19 vaccination is identified, ACIP recommends that a risk assessment be performed to help decide whether the individual should be vaccinated. The risk assessment should consider the 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), the 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 that 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 should be observed for 30 minutes after the vaccine dose, and that all other individuals should be observed for 15 minutes. In addition, vaccine recipients should be instructed 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 the clinical signs and symptoms of anaphylaxis is important since such reactions require immediate treatment. Individuals with suspected anaphylaxis should be immediately treated 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 and 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**

A decision to administer or delay vaccination in an individual with a current or recent febrile illness depends 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 states that a risk assessment should 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 that COVID-19 vaccination should be offered to individuals regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

Data are not available to date regarding the 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 SARS-CoV-2 Antibody Therapies under Drug Interactions.)

#### **Individuals with Current SARS-CoV-2 Infection.**

ACIP recommends that COVID-19 vaccination be deferred 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. While there is no recommended minimum interval between SARS-CoV-2 infection and COVID-19 vaccination, evidence to date suggests that the 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 the 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 is *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 COVID-19 vaccines are 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 is *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. Clinical trials of COVID-19 vaccines have 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 Immunosuppressive Agents under Drug 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) have been included in the ongoing randomized, double-blind, placebo-controlled, 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, such individuals should be counseled about the unknown safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses and the 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 is *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 are not currently available regarding the 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.**

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

Although safety and efficacy data regarding use of COVID-19 vaccines in individuals with chronic liver disease are limited and additional studies are needed, safety and efficacy of the vaccines in such individuals are expected to be similar to the general population. AASLD states that individuals with chronic liver disease who are receiving antiviral treatment for hepatitis B virus (HBV) or hepatitis C virus (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, patients with hepatocellular carcinoma undergoing locoregional or systemic therapy should be considered for COVID-19 vaccination without interruption of treatment.

Although solid organ transplant recipients, including liver transplant recipients, were not included in clinical trials of COVID-19 vaccines and efficacy and safety in such individuals are 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 at least 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.

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

#### **Individuals with a History of Guillain-Barré Syndrome.**

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

ACIP states that individuals with a history of Guillain-Barré syndrome (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, the case should be reported 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 has not been established, several cases of Bell's palsy have been reported in clinical trials in individuals who received the Moderna COVID-19 vaccine or the Pfizer-BioNTech COVID-19 vaccine.

Data from the ongoing randomized, double-blind, placebo-controlled, 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, the case should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

#### **Individuals with Increased Bleeding Risk.**

Individuals who have bleeding disorders or are receiving anticoagulant therapy and/or their caregiver should be advised 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, a fine needle (23 gauge or smaller) should be used to administer the vaccine and firm pressure applied to the injection site (without rubbing) for at least 2 minutes. In individuals receiving therapy for hemophilia, IM vaccines can be scheduled for administration shortly after a dose of such therapy.

Individuals receiving anticoagulation therapy presumably have the same bleeding risk as patients with clotting factor disorders and should follow the same guidelines for IM administration. If possible, IM vaccines could be scheduled 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 within 1–2 days after vaccination. This effect has been reported when the vaccine was administered 2 weeks to 6 months or longer after the last dermal filler injection, and appears to be temporary and resolves with medical treatment, including corticosteroid therapy. A similar inflammatory reaction at the site of dermal filler injections (lips, cheeks, tear troughs) was reported in at least one unvaccinated individual who was diagnosed with COVID-19 approximately 2 weeks after their last dermal filler injection and has been reported after natural influenza-like illness. Although the mechanism of these reactions is not known, it has been suggested that localized swelling at the site of dermal filler injection may be due to an inflammatory reaction resulting from an interaction between the immune response after vaccination and the dermal filler.

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

### **Lymphadenopathy**

Lymphadenopathy, lymphadenitis, lymph node pain, injection-site lymphadenopathy, axillary swelling/tenderness, and axillary mass have been reported in clinical trials evaluating COVID-19 vaccine (Moderna). At the time that FDA's

safety and efficacy analysis of data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial evaluating the vaccine was performed for the EUA, lymphadenopathy (axillary swelling and tenderness on the vaccination arm) was reported in 21.4% of vaccine recipients younger than 65 years of age and 12.4% of vaccine recipients 65 years of age or older compared with 7.5 and 5.8% of placebo recipients in those age groups, respectively, and was reported more frequently after the second dose than the first dose.

Cases of unilateral axillary adenopathy, including palpable axillary mass, have been 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 the same side as the vaccination site was seen on breast ultrasound performed 5–13 days after receipt of an mRNA COVID-19 vaccine. Vaccine-induced hyperplastic axillary adenopathy should be considered in the differential diagnosis if unilateral axillary adenopathy is identified on breast imaging in individuals who recently received an mRNA COVID-19 vaccine.

### **Limitations of Vaccine Effectiveness**

COVID-19 vaccine (Moderna) 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 randomized, double-blind, placebo-controlled, phase 3 trial evaluating the Moderna COVID-19 vaccine indicate that estimated vaccine efficacy is 80.2% following the first dose compared with 94.1% following the second dose. Vaccine recipients should be counseled 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 the 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 the currently limited information on the extent to which vaccination may reduce viral transmission in the general population, the unknown duration of vaccine-induced protection, and the unknown extent of protection against emerging SARS-CoV-2 variants, individuals who receive COVID-19 vaccination should be counseled to continue to follow current guidance to protect themselves and others. This includes wearing a mask, staying at least 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 has 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). These recommendations (available at the CDC website at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>) should be consulted 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 is 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, information about such cases should be reported to VAERS. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

### **Duration of Immunity**

The duration of protection against SARS-CoV-2 infection following completion of the 2-dose vaccination series of COVID-19 vaccine (Moderna) has not been 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 have not been established. Additional vaccine doses beyond those recommended for a complete, valid vaccination series (see Dosage under Dosage and Administration) are *not* recommended at this time. Recommendations on revaccination or additional doses of COVID-19 vaccines may be updated when additional information is 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. All vaccines should be inspected on delivery and monitored during storage to ensure that the recommended storage temperatures are maintained.

COVID-19 vaccine (Moderna) 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. Vaccine that has been mishandled or has not been stored at the recommended temperatures should not be administered. (See Stability.)

If there are concerns about mishandling or defective or damaged vaccine, the manufacturer should be contacted at 866-663-3762 for guidance.

### **EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting**

Safety and efficacy of COVID-19 vaccine (Moderna) have not been established. The FDA issued an EUA that permits use of the vaccine for the prevention of COVID-19† in individuals 18 years of age or older when administered according to the 2-dose vaccination series specified in the EUA. (See Emergency Use Authorization under Uses.)

Some data are available regarding adverse effects associated with use of the Moderna COVID-19 vaccine. (See Common Adverse Effects under Cautions.) Additional adverse effects, some of which may be serious, may become apparent with more widespread use of the vaccine.

All vaccine recipients should be monitored for immediate adverse reactions according to CDC (ACIP) guidelines. (See General under Dosage and Administration.)

Vaccine recipients or their caregivers should be provided with information on, and encouraged to participate 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 COVID-19 vaccine (Moderna) 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.** VAERS reports can be completed and submitted online at <https://vaers.hhs.gov/reportevent.html> or faxed to 877-721-0366; the words “Moderna COVID-19 Vaccine EUA” should be included in the description section of the report. Information on submitting a VAERS report can be obtained by calling 800-822-7967 or emailing [info@vaers.org](mailto:info@vaers.org). To the extent feasible, a copy of the VAERS form should also be provided to the manufacturer (Moderna) at [ModernaPV@moderntx.com](mailto:ModernaPV@moderntx.com) (email), 866-599-1342 (fax), or 866-663-3762 (phone).

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

### **Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals**

ACIP states that results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests) are 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. To evaluate for evidence of prior infection in an individual with a history of COVID-19 vaccination, a test that specifically evaluates IgM/IgG to the nucleocapsid protein should be used.

Antibody testing is *not* currently recommended to assess for immunity to COVID-19 following COVID-19 vaccination because the clinical utility of post-vaccination testing has not been established. 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, the serologic

correlates of protection against SARS-CoV-2 have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection. If antibody testing is performed following COVID-19 vaccination, additional doses of the same or different COVID-19 vaccine beyond the recommended vaccination series should *not* be administered based on results of antibody testing.

### **Interpretation of Tuberculosis Tests in Vaccinated Individuals**

ACIP states that COVID-19 vaccination should *not* be delayed 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 is required according to administrative policies (e.g., healthcare employment, admission to long-term care facilities), such testing can be performed before or during the same visit when a COVID-19 vaccine is administered. If such tuberculosis testing cannot be done prior to or at the same time as COVID-19 vaccination, ACIP recommends that it be delayed until at least 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 and consideration should be given to repeating a negative TST or IGRA test at least 4 weeks after completion of COVID-19 vaccination. In addition, if the TST was performed as the initial test, consideration should be given to the possibility that boosting could be a factor if results of a repeat TST are positive.

ACIP states that individuals who have active tuberculosis disease or an illness that is being evaluated as active tuberculosis disease can receive COVID-19 vaccination; however, 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 a contact investigation after exposure to contagious tuberculosis disease), a decision to delay such testing until at least 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 that consideration should be given to retesting at least 4 weeks after completion of COVID-19 vaccination.

### **Specific Populations**

#### **Pregnancy.**

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

In a developmental toxicity study in female rats, there was no evidence of vaccine-related adverse effects on female fertility, fetal development, or postnatal development when a vaccine formulation (same quantity of mRNA and other ingredients as that in a single human dose of the Moderna COVID-19 vaccine) was given IM on days 28 and 14 prior to mating and on gestation days 1 and 13.

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, mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death. Additionally, such women might be at 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, and 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.

The American College of Obstetricians and Gynecologists (ACOG) recommends that COVID-19 vaccines should 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, these experts recommend that the pregnant woman and her healthcare provider 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. Pregnant women who experience fever following COVID-19 vaccination should be counseled to take acetaminophen; acetaminophen also may be offered 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.

Administration of other vaccines (e.g., diphtheria and tetanus toxoids and acellular pertussis vaccine adsorbed [DTaP], influenza vaccine) in pregnant women should be deferred for 14 days after COVID-19 vaccination. (See Vaccines under Drug Interactions.) ACOG states that Rh<sub>0</sub>(D) immune globulin should not be withheld when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Immune Globulins and Antibody Therapies under Drug Interactions.)

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

Individuals who receive a COVID-19 vaccine during pregnancy and those who become pregnant within 30 days after receiving a COVID-19 vaccine should be encouraged 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 is *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.**

Data are not available to assess whether COVID-19 vaccine (Moderna) 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, and women who are breast-feeding 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 that COVID-19 vaccines should be offered to lactating women, similar to other individuals. ACOG also states that theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine and there is no need to avoid initiating breast-feeding or to discontinue breast-feeding in those who receive a COVID-19 vaccine.

#### **Pediatric Use.**

Safety and efficacy of COVID-19 vaccine (Moderna) have not been assessed in individuals younger than 18 years of age.

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

#### **Geriatric Use.**

Individuals 65 years of age or older have been included in clinical trials evaluating COVID-19 vaccine (Moderna), and data from such individuals contribute to the overall assessment of safety and efficacy of the vaccine.

At the time that FDA's safety and efficacy analysis of data from the ongoing randomized, double-blind, placebo-controlled, phase 3 trial was performed for the EUA, 24.8% of participants were 65 years of age and older and 4.6% were 75 years of age and older. Subgroup efficacy analysis based on age indicated that vaccine efficacy in participants 65 years of age and older was 86.4% compared with 95.6% in those 18 to less than 65 years of age. Overall, there were no notable differences in safety profiles between participants 65 years of age and older and younger adults.

### **■ Common Adverse Effects**

Data regarding the safety of COVID-19 vaccine (Moderna) are available from several clinical trials, including the ongoing randomized, double-blind, placebo-controlled, phase 3 trial (NCT04470427; mRNA-1273-P301; COVE study). At the time that FDA's safety analysis of the phase 3 trial was performed for the EUA, a total of 30,351 study participants 18 years of age or older (15,185 in the vaccine group and 15,166 in the placebo group) had received at least one dose.

Local adverse effects reported following administration of the Moderna COVID-19 vaccine in clinical trials include injection site pain (92%), swelling (14.7%), and erythema (10%).

Systemic adverse effects reported following administration of the Moderna COVID-19 vaccine 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%), and fever (15.5%).

Data indicate that solicited local and systemic adverse effects usually occurred within the first 1–2 days after a dose of the Moderna COVID-19 vaccine, 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 was 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 or older.

At the time that FDA's safety analysis of the phase 3 trial was performed for the EUA, serious adverse events had been 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).

Although immediate allergic reactions have not been reported to date in clinical trials evaluating the Moderna COVID-19 vaccine, severe allergic reactions, including anaphylaxis, have been reported rarely when mRNA COVID-19 vaccines were administered outside of clinical trials. (See Hypersensitivity Reactions under Cautions.)

## Drug Interactions

### ■ Immune Globulins and Antibody Therapies

Individuals receiving immune globulin (e.g., immune globulin IV [IGIV], Rh<sub>0</sub>(D) immune globulin) and antibody therapies *not* specific for SARS-CoV-2 may receive COVID-19 vaccination, either concurrently with or at any interval before or after the immune globulin or antibody therapy since such products are unlikely to substantially impair immune responses to the COVID-19 vaccine. ACIP states that there is no recommended minimum interval between receipt of antibody therapies not specific for SARS-CoV-2 and COVID-19 vaccination.

#### ***SARS-CoV-2 Antibody Therapies***

Data are not available regarding the safety and efficacy of administering COVID-19 vaccines to individuals who have received passive antibody therapy with investigational SARS-CoV-2-specific monoclonal antibodies (e.g., bamlanivimab, bamlanivimab and etesevimab, casirivimab and imdevimab) or investigational COVID-19 convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of SARS-CoV-2 antibody therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, ACIP recommends that COVID-19 vaccination should be deferred for at least 90 days after such therapies as a precautionary measure until additional information becomes available since this avoids potential interference of the antibody therapy with immune responses to the COVID-19 vaccine. This recommendation applies to individuals who received such antibody therapy before receiving any vaccine doses and those who received such antibody therapy after the first dose of an mRNA COVID-19 vaccine but before the second dose of the vaccine, in which case the second vaccine dose should be deferred for at least 90 days following receipt of the antibody therapy. However, COVID-19 vaccination is not contraindicated in individuals who have received passive antibody therapy within the past 90 days, and COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated.

If an individual who received COVID-19 vaccination subsequently develops COVID-19, ACIP states that prior receipt of COVID-19 vaccine should not affect treatment decisions, including the use of SARS-CoV-2-specific monoclonal antibodies or COVID-19 convalescent plasma, or the timing of such treatment.

### ■ Immunosuppressive Agents

Individuals receiving immunosuppressive therapy (e.g., cancer chemotherapy, corticosteroids, radiation) may have diminished or suboptimal antibody responses to vaccines, including the Moderna COVID-19 vaccine.

Although data are not currently available to establish safety and efficacy in individuals receiving immunosuppressive therapy, ACIP states that such individuals may receive COVID-19 vaccination if they have no contraindications to the vaccine. (See Individuals with Altered Immunocompetence under Cautions.)

Data are insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised individuals, ACIP states that COVID-19 vaccination should ideally be completed at least 2 weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccination series (i.e., a 2-dose regimen of the Moderna COVID-19 vaccine or Pfizer-BioNTech COVID-19 vaccine or a single dose of the Janssen COVID-19 vaccine) in advance, individuals receiving immunosuppressive therapy can still receive COVID-19 vaccination. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the individual's risks related to their underlying condition.

Based on currently available information, ACIP states that revaccination after immune competence is regained is not recommended in individuals who received COVID-19 vaccination during chemotherapy or treatment with other immunosuppressive drugs. If an individual who received COVID-19 vaccination subsequently develops COVID-19, ACIP states that prior receipt of COVID-19 vaccine should not affect treatment decisions, including the use of corticosteroids, or the timing of such treatment.

### ■ Vaccines

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

Because of the lack of data on safety and efficacy of simultaneous administration of COVID-19 vaccines with other vaccines, ACIP states that the 2-dose vaccination series of the Moderna COVID-19 vaccine should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. However, a shorter interval may be used in situations when the benefits of vaccination outweigh the 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 the time of admission or onboarding). If a COVID-19 vaccine is administered within 14 days of another vaccine, ACIP states that it is not necessary to repeat doses of either vaccine.

## Description

COVID-19 vaccine (Moderna) is a nucleoside-modified mRNA vaccine formulated in lipid nanoparticles (LNPs).

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 a phase 1 clinical trial in healthy adults 18 years of age or older 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 Moderna COVID-19 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 or older 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).

In a SARS-CoV-2 rhesus challenge model, 2 IM doses of the Moderna COVID-19 vaccine or saline control were given 4 weeks apart followed by a combined intratracheal and intranasal SARS-CoV-2 challenge given 4 weeks after the second dose. In the vaccinated animals, neutralizing and binding antibodies were detected after the first vaccine dose and increased further after the second dose; Th1 CD4 T-cell responses were reported with low or undetectable Th2 or CD8 T-cell responses. Following the SARS-CoV-2 challenge, viral RNA was detected in bronchoalveolar lavage samples from all 8 control animals but was not detected in animals that had received 100-mcg doses of the vaccine.

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 COVID-19 vaccine (Moderna) contains 100 mcg of mRNA encoding the S glycoprotein of SARS-CoV-2. Each dose of the vaccine also contains 4 different lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The Moderna COVID-19 vaccine 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 or older. 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., polyethylene glycol) 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 the vaccination provider if they have 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.

**Overview<sup>®</sup> (see Users Guide). It is *essential* that the Emergency Use Authorization (EUA) prescribing information contained in the Fact Sheet for Healthcare Providers that is available at the FDA website and at <http://www.modernatx.com/covid19vaccine-eua> be consulted for more detailed information on dosage and administration, cautions, precautions, and contraindications, and for complete information on the conditions for use of the vaccine for the prevention of coronavirus disease 2019 (COVID-19) under the EUA, including mandated record keeping and reporting requirements.**

## **Preparations**

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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 or older. 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)**

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#### **Parenteral Suspension, for IM use**

100 mcg (of mRNA) per 0.5-mL  
dose

**Moderna COVID-19 Vaccine,  
ModernaTX**

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

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