COVID-19 Vaccine, mRNA (Pfizer-BioNTech) (Systemic)

Nucleoside-modified mRNA (modRNA) 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:

On May 10, 2021, FDA reissued the emergency use authorization (EUA) for COVID19 vaccine (Pfizer-BioNTech) to permit use of the vaccine in adolescents 12 through 15 years of age in addition to individuals 16 years of age and older. FDA reviewed efficacy and safety data from an ongoing phase 1, 2, 3 trial that has enrolled approximately 46,000 participants, including 2260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive the Pfizer-BioNTech COVID-19 vaccine or saline control. FDA's analysis of available descriptive efficacy data from 1983 trial participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after the second vaccine dose confirm that the Pfizer-BioNTech COVID-19 vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (no COVID-19 cases occurred in the vaccine group compared to 16 COVID-19 cases in the placebo group). FDA's review of available safety data for 2260 trial participants 12 through 15 years of age who were followed for a median of 2 months after receiving the second dose of the vaccine did not identify specific safety concerns that would preclude issuance of an EUA for this age group. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of the Pfizer-BioNTech COVID-19 vaccine in a subset of trial participants who had no serologic or virologic evidence of past SARS-CoV-2 infection confirm that the geometric mean antibody titer (GMT) in trial participants 12 through 15 years of age was noninferior to the GMT in participants 16 through 25 years of age. FDA reissued the EUA after concluding that it is reasonable to believe that the Pfizer-BioNTech COVID-19 vaccine may be effective in individuals 12 through 15 years of age and that is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of the vaccine outweigh known and potential risks for the prevention of COVID-19 in those 12 through 15 years of age.

For additional information, the Pfizer-BioNTech COVID-19 vaccine EUA letter of authorization (https://www.fda.gov/media/144412/download), EUA fact sheet for healthcare providers (https://www.fda.gov/media/144413/download), and EUA fact sheet for recipients and caregivers (https://www.fda.gov/media/144414/download) should be consulted.

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are cautioned that COVID-19 Vaccine (Pfizer-BioNTech) is not an approved vaccine for coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, but rather, is being investigated for and is currently available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals 12 years of age or older. The American Society of Health-System Pharmacists, Inc. makes no representations or warranties, express or implied, including, but not limited to, any implied warranty of merchantability and/or fitness for a particular purpose, with respect to the information contained in the accompanying monograph, and specifically disclaims all such warranties. Readers of this information are advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information contained in the monograph in any and all practice settings. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The entire monograph for a drug should be reviewed for a thorough understanding of the drug's actions, uses and side effects. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

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 (Pfizer-BioNTech) is available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals ≥12 years of age.
- On December 11, 2020, FDA issued an EUA that permitted use of the Pfizer-BioNTech COVID-19 vaccine in individuals ≥16 years of age. FDA reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine on May 10, 2021 to permit use of the vaccine in individuals ≥12 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 Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine was based on FDA review of safety and efficacy data from an ongoing phase 1, 2, 3 clinical trial indicating that a 2-dose regimen of the vaccine was 95% effective in preventing COVID-19 occurring ≥7 days after the second dose.
- The EUA for the Pfizer-BioNTech 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 Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine for prevention of COVID-19. 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 (Pfizer-BioNTech COVID-19 vaccine and Moderna 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 manage immediate allergic reactions in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine, including COVID-19 vaccine (Pfizer-BioNTech). 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 Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine is administered in a series of 2 doses given 3 weeks (21 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 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 local or systemic adverse effects occur following the first dose since this optimizes protection.
- Antipyretics or analgesics (e.g., acetaminophen, NSAIAs) 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 the vaccine. 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 Pfizer-BioNTech 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 guidelines, and following any applicable workplace or school guidance. This recommendation is based on the currently limited information on whether the vaccine 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

Administered *only* by IM injection into the deltoid.

The Pfizer-BioNTech COVID-19 vaccine is supplied as a frozen suspension concentrate in multiple-dose vials that *must* be shipped at ultra-low temperatures (between -80 to -60°C) and stored frozen at specific temperatures. (See Storage under Stability.)

Must be thawed and then diluted with 0.9% sodium chloride injection *only*.

For solution compatibility information, see Compatibility under Stability.

To administer a dose, withdraw 0.3 mL of thawed and diluted Pfizer-BioNTech COVID-19 vaccine from the vial using aseptic technique and an appropriate syringe and needle and administer immediately. A 1-mL low dead-volume syringe and needle is preferred for administration of the vaccine; a standard 1-mL syringe can be used if a low dead-volume syringe is not available.

Each multiple-dose vial of thawed and diluted Pfizer-BioNTech COVID-19 vaccine provides six 0.3-mL doses when low dead-volume syringes and needles are used to extract doses from the vial. If standard syringes and needles are used, remaining volume of vaccine may be insufficient to extract a sixth dose from the vial. Irrespective of the type of syringe and needle used, each dose *must* contain 0.3 mL of vaccine.

FDA states that it is acceptable to use every full dose obtainable from the multiple-dose vial despite the fact that some vial labels and cartons may state that the vial contains five 0.3-mL doses. However, because the vaccine does not contain preservatives, it is critical that any vaccine remaining in the vial that does not constitute a full 0.3-mL dose should be discarded and *not* pooled with vaccine from other vials to create a dose.

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

Thawing

Frozen Pfizer-BioNTech COVID-19 vaccine suspension concentrate may be thawed either in a refrigerator (2–8°C) or at room temperature (up to 25°C).

Thawing in a refrigerator (2–8°C): A full carton or tray containing 25 or 95 vials of frozen suspension concentrate may take up to 2 or 3 hours, respectively, to thaw; less time is required to thaw fewer vials. May store vials of thawed vaccine in a refrigerator (2–8°C) for up to 5 days (120 hours) before dilution.

Thawing at room temperature (up to 25°C): Allow vial(s) to sit at room temperature for 30 minutes to thaw; may be kept at room temperature for up to a total of 2 hours. After 2 hours at room temperature, thawed vaccine should be diluted or placed in a refrigerator (2–8°C).

Thawed Pfizer-BioNTech COVID-19 suspension concentrate should appear as a white to off-white suspension and may contain white to off-white opaque amorphous particles; do *not* use if it is discolored or contains other particles.

Thawed vaccine *must* not be refrozen.

Dilution

Thawed Pfizer-BioNTech COVID-19 vaccine suspension concentrate *must* equilibrate to room temperature prior to dilution and *must* be diluted within 2 hours after reaching room temperature.

Prior to dilution, invert vial(s) containing thawed vaccine suspension concentrate 10 times; do *not* shake.

Using aseptic technique, withdraw 1.8 mL of 0.9% sodium chloride injection into a 3- or 5-mL transfer syringe (21-gauge needle or narrower) and inject into vial of thawed vaccine suspension concentrate; do not add more than 1.8 mL of diluent to the vial. To equalize vial pressure, withdraw 1.8 mL of air into empty diluent syringe before removing the needle from the vial. Do *not* use any other diluents (e.g., bacteriostatic 0.9% sodium chloride injection).

After adding 0.9% sodium chloride diluent, gently invert vial 10 times to mix; do *not* shake.

Following dilution, the Pfizer-BioNTech COVID-19 vaccine should appear as an off-white suspension; do *not* use if it is discolored or contains particulates.

Must record date and time of dilution on the vaccine vial.

May store vials containing diluted Pfizer-BioNTech COVID-19 vaccine between 2–25°C, but *must* use diluted vaccine within 6 hours after dilution (regardless of storage temperature). Discard any unused diluted vaccine remaining in vials if not used within 6 hours after dilution.

Dosage

Administer the Pfizer-BioNTech COVID-19 vaccine in a series of two 0.3-mL doses given 3 weeks (21 days) apart. Each 0.3-mL dose contains 30 mcg of modRNA.

The 2-dose regimen of the Pfizer-BioNTech 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 [Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine] or single dose of Janssen COVID-19 vaccine).

Ensure that individuals who receive the first dose of the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 vaccine specifies an interval of 3 weeks (21 days) between the 2 vaccine doses. ACIP states do not schedule individuals to receive the second vaccine dose earlier than 3 weeks 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 recommended interval not feasible and a delay is unavoidable, ACIP states may administer second dose of an mRNA vaccine 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 Pfizer-BioNTech COVID-19 vaccine is *not* interchangeable with the Moderna 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 Pfizer-BioNTech 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.

Pediatric Patients

Prevention of COVID-19

>Adolescents ≥12 Years of Age

IM: FDA EUA that permits use for prevention of COVID-19† (see Prevention of Coronavirus Disease 2019 [COVID-19] under Uses) states that adolescents ≥12 years of age should receive two 0.3-mL doses of the vaccine administered 3 weeks (21 days) apart.

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 0.3-mL doses of the vaccine administered 3 weeks (21 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 COVID-19 vaccines (Pfizer BioNTech COVID-19 vaccine and Moderna 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

Although immediate allergic reactions not reported to date in clinical trials evaluating the Pfizer-BioNTech 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 occurring between December 14–23, 2020 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).

Between December 14–23, 2020, VAERs identified 83 cases of nonanaphylactic allergic reactions after administration of the first dose of the Pfizer-BioNTech COVID-19 vaccine; 87% of these cases were classified as nonserious and 67% had a documented history of allergies or allergic reactions. Median interval from receipt of the vaccine dose to onset of such symptoms was 12 minutes (range: less than 1 minute to 20 hours); 85% had onset of symptoms within 30 minutes. Hypersensitivity reactions reported with the vaccine have included rash, pruritus, urticaria, itchy/scratchy sensations in the throat, angioedema, and mild respiratory symptoms.

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. These local reactions may begin 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 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 immediate allergic reactions that would contraindicate additional doses of mRNA COVID-19 vaccines 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 Pfizer-BioNTech and the Moderna 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 Pfizer-BioNTech and the Moderna 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 Pfizer-BioNTech COVID-19 vaccine and the Moderna 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 (Pfizer-BioNTech COVID-19 vaccine or Moderna 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 Pfizer-BioNTech 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 patients 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 vaccine adverse effects on the underlying illness or mistakenly concluding that a manifestation of the underlying illness resulted from vaccine administration.

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 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 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 Pfizer-BioNTech COVID-19 vaccine.

Although some individuals with altered immunocompetence (e.g., stable HIV infection) were included in the ongoing phase 2/3 trial of the Pfizer-BioNTech COVID-19 vaccine, the

number of such individuals was insufficient to evaluate safety and efficacy 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 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 are 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 Pfizer-BioNTech or the Moderna COVID-19 vaccines.

Data from the ongoing phase 2/3 trial evaluating the Pfizer-BioNTech COVID-19 vaccine identified 4 cases of Bell's palsy (facial paralysis) in vaccine recipients. Onset of facial paralysis in one individual occurred on day 37 after first vaccine dose (participant did not receive second dose) and onset occurred on days 3, 9, or 48 after second dose in the other individuals; no cases of Bell's palsy reported in the placebo group. FDA stated that these 4 cases in the vaccine group do not represent a frequency greater than that expected in the general population.

ACIP states, 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 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 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 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 reported in clinical trials evaluating COVID-19 vaccine (Pfizer-BioNTech). Data from the ongoing phase 2/3 trial evaluating the Pfizer-BioNTech COVID-19 vaccine indicate lymphadenopathy reported in 0.3% of vaccine recipients. Lymphadenopathy lasted an average of 10 days, occurred more frequently in vaccine group than placebo group, and was temporally associated with the vaccine.

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 Pfizer-BioNTech COVID-19 vaccine is administered as a series of 2 doses given 3 weeks (21 days) apart (see Dosage under Dosage and Administration). Data from the ongoing phase 2/3 trial indicate that estimated vaccine efficacy is 52% following the first dose and 95% 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 *not* currently recommended. ACIP states that, because 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 assess the effect of the Pfizer-BioNTech 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 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 assess effect of the PFizer-BioNTech 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 needed, including data from clinical trials and from use of the vaccine after issuance of the EUA, to assess 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 extent of protection against emerging SARS-CoV-2 variants, counsel individuals who receive COVID-19 vaccination to continue to follow 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.

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 Pfizer-BioNTech COVID-19 vaccine or the Moderna 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 vaccination with a 2-dose regimen of the Pfizer-BioNTech COVID-19 vaccine 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 >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 Pfizer-BioNTech 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. (See Storage under Stability.)

Contact the manufacturer at 800-666-7248 or 877-829-2619 for guidance if there are concerns about mishandling, including inadvertent temporary temperature excursions.

EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting

Safety and efficacy not established. FDA issued an EUA that permits use of the Pfizer-BioNTech COVID-19 vaccine for prevention of COVID-19† in individuals ≥12 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 are 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 Pfizer-BioNTech 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 "Pfizer-BioNTech COVID-19 Vaccine EUA" in description section of the report. Obtain additional 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 (Pfizer) at https://www.pfizersafetyreporting.com, 866-635-8337 (fax), or 800-438-1985 (phone).

Consult FDA fact sheet for healthcare providers for the Pfizer-BioNTech COVID-19 vaccine available at FDA website and at https://www.cvdvaccine.com 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 Pfizer-BioNTech 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 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 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 Pfizer-BioNTech COVID-19 vaccine to inform vaccine-associated risks during pregnancy.

A reproductive and developmental toxicity study in female rats using a vaccine formulation containing same quantity of mRNA and other ingredients as the Pfizer-BioNTech COVID-19 vaccine 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 pregnancy is not a contraindication to use of the Pfizer-BioNTech 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 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 Rh_o(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.)

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 Pfizer-BioNTech COVID-19 vaccine administered to a woman who is breast-feeding has any effects on breast-fed infant or milk production.

FDA states that breast-feeding is not a contraindication to use of the Pfizer-BioNTech 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

FDA EUA permits use of the Pfizer-BioNTech COVID-19 vaccine for prevention of COVID-19† in adolescents ≥12 years of age based on safety and efficacy in this age group and in adults.

The Pfizer-BioNTech COVID-19 vaccine is not authorized for use in children <12 years of age.

Geriatric Use

At the time of FDA's safety and efficacy analyses of data from the ongoing phase 2/3 trial, 21.4% of vaccine recipients were ≥65 years of age and 4.3% were ≥75 years of age.

Common Adverse Effects

Local adverse effects reported in clinical trials: Injection site pain (84.1%), swelling (10.5%), erythema (9.5%). Most local reactions have been mild to moderate in severity; severe pain reported in <1% of vaccine recipients across all age groups. After second dose of the 2-dose vaccination series, median duration of adverse local effects is 2.3–2.6 days (range: 1–36 days).

Systemic adverse effects reported in clinical trials: Fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.1%), nausea (1.1%), malaise (0.5%), lymphadenopathy (0.3%). Systemic adverse effects reported more frequently after second dose of the 2-dose vaccination series and reported more frequently in those 16–55 years of age than in those ≥56 years of age. Generally observed within first 1–2 days after vaccination and resolved within a few days. Use of antipyretic or pain medication within 7 days after receiving the first or second vaccine dose reported in 27.8 or 45%, respectively, of those 18–55 years of age and in 19.9 or 37.7%, respectively, of those ≥56 years of age.

In study participants 16–55 years of age, serious adverse events reported in 0.4% of vaccine recipients and 0.3% of placebo recipients; in those ≥56 years of age, serious adverse events reported in 0.8 or 0.6% of vaccine or placebo recipients, respectively.

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 (Pfizer-BioNTech) with other vaccines.

ACIP recommends giving the 2-dose vaccination series of the Pfizer-BioNTech 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 treatment decisions, including use of SARS-CoV-2 antibody therapies, or timing of such treatment
Immune globulin and antibody therapies *not* specific for SARS-CoV-2 (e.g., immune globulin IV [IGIV], Rh_o[D] immune globulin)		May give COVID-19 vaccine concurrently with or at any interval before or after immune globulin or antibody therapies *not* specific for SARS-CoV-2; ACIP states there is no recommended minimum interval between receipt of antibody therapies not specific for SARS-CoV-2 and COVID-19 vaccination
Immunosuppressive agents (e.g., cancer chemotherapy, corticosteroids, radiation)	Possible decreased or suboptimal antibody responses to vaccines, including the Pfizer-BioNTech COVID-19 vaccine Data insufficient to date to inform optimal timing of	ACIP states that individuals receiving immunosuppressive therapy may receive COVID-19 vaccination if they have no contraindications to the vaccine

	COVID-19 vaccination for individuals planning to receive immunosuppressive therapies	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
SARS-CoV-2-specific monoclonal antibodies (bamlanivimab, bamlanivimab and etesevimab, casirivimab and imdevimab)	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

Stability

Storage

Parenteral

Suspension Concentrate, for IM Use

Supplied as a frozen suspension concentrate in multiple-dose vials that *must* be shipped at ultra-low temperatures (between -80 to -60°C) and stored frozen at specific temperatures. Provided in cartons or vial trays that are shipped in specialized thermal shipping containers with dry ice and a temperature-monitoring device to ensure that the vials are maintained at required ultra-low temperatures during transport.

After thermal shipping containers containing the frozen multiple-dose vials of suspension concentrate are received, immediately remove the vial trays from the thermal container and *preferably* store in an ultra-low-temperature freezer (between -80 to -60°C); alternately, may store frozen multiple-dose vials at -25 to -15°C for up to 2 weeks. Vials stored at -25 to -15°C for up to 2 weeks may be returned one time to recommended storage condition of -80 to -60°C; however, track total time vials are stored at -25 to -15°C and do not exceed 2 weeks at this temperature. If ultra-low-temperature freezer not available, may use the thermal shipping container as *temporary* storage if consistently replenished with dry ice per instructions provided with the thermal container to ensure that temperature between -90 to -60°C is maintained. Keep multiple-dose vials upright and store in the vial trays protected from light; must be kept frozen until ready to thaw to prepare doses for administration.

If local redistribution of frozen Pfizer-BioNTech COVID-19 vaccine needed and transport at preferred temperature of -90 to -60°C not possible, may transport full cartons of frozen multiple-dose vials at -25 to -15°C; however, must include any hours used for transport at -25 to -15°C in the 2-week limit for storage at this temperature. May return frozen vials transported at -25 to -15°C one time to recommended storage temperature of -80 to -60°C.

Consult EUA fact sheet for healthcare providers and information provided by CDC and the manufacturer for information on storage, handling, and stability of the vaccine. Various documents and videos describing shipping, storage, and handling requirements and procedures, including specifics about temperature requirements and temperature monitoring, thermal shipping containers, ultra-low-temperature freezers, and safe handling of dry ice, are available at the manufacturer's website at https://www.cvdvaccine.com.

Immediately contact manufacturer at 800-666-7248 or 877-829-2619 if there are concerns about mishandling.

Multiple-dose vials of frozen suspension concentrate that have been thawed in a refrigerator (2–8°C) per manufacturer's directions: May store for up to 5 days (120 hours) in the refrigerator prior to dilution with 0.9% sodium chloride per manufacturer's directions.

Multiple-dose vials of frozen suspension concentrate that have been thawed at room temperature (up to 25°C) per manufacturer's directions: Dilute with 0.9% sodium chloride injection immediately after reaching room temperature per manufacturer's directions; alternatively, may be stored for up to 2 hours at room temperature (including thawing time) prior to dilution. If not used within 2 hours, place thawed vials in a refrigerator.

If transport of one or more vials of thawed Pfizer-BioNTech COVID-19 vaccine needed, available data support transport of such vials at 2–8°C for up to 12 hours; however, must include any hours used for transport at 2–8°C in the 120-hour limit for storage at this temperature.

Following dilution with 0.9% sodium chloride: May be stored between 2–25°C, but must be used within 6 hours after dilution. Discard any unused diluted vaccine 6 hours after dilution.

Once thawed, do *not* refreeze.

During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. May handle thawed vaccine vials in room light conditions.

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.

Compatibility

Parenteral

Solution Compatibility

Compatible
Sodium chloride 0.9%
Incompatible
Bacteriostatic sodium chloride 0.9%

Actions

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

- The modRNA contained in the Pfizer-BioNTech COVID-19 vaccine encodes a membrane-anchored, full-length spike (S) glycoprotein receptor-binding domain (RBD) antigen of SARS-CoV-2 with 2 proline modifications that lock the S protein in an antigenically preferred prefusion conformation. Following IM injection, the LNPs in the vaccine enable delivery of the modRNA into host cells where it is released and translated to the encoded S antigen of SARS-CoV-2. The S antigen is then incorporated into cellular membranes and elicits an immune response to provide protection against SARS-CoV-2.
- Data from clinical trials in adults indicate that a 2-dose vaccination series of the Pfizer-BioNTech COVID-19 vaccine induces SARS-CoV-2 neutralizing titers and S1-binding IgG levels. Antibody responses are evident after first vaccine dose and substantially boosted after second vaccine dose, supporting need for a 2-dose vaccination series. Some evidence from animal studies that the vaccine can elicit strong $CD4^+$ and $CD8^+$ T-cell responses.
- COVID-19 vaccine (Pfizer-BioNTech) available for use under the FDA EUA is provided as a frozen suspension concentrate in multiple-dose vials. Following thawing and dilution with 0.9% sodium chloride as directed by the manufacturer, each 0.3-mL dose of the Pfizer-BioNTech COVID-19 vaccine contains 30 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2. Each dose also contains LNPs composed of 4 different lipids in a defined ratio (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(PEG)-2000]-*N*,*N*-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol) and potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, 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 (Pfizer-BioNTech), must provide vaccine recipient or their caregiver with information consistent with the Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 12 Years of Age or Older and either give them a copy of the fact sheet or direct them to the manufacturer's website at https://www.cvdvaccine.com to obtain the fact sheet.
- At the time that the first dose of the Pfizer-BioNTech COVID-19 vaccine is administered, inform vaccine recipient or their caregiver that the vaccine is administered in a series of 2 doses given 3 weeks (21 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 vaccine recipient or their caregiver a vaccination card that provides the date when recipient needs to return for second vaccine dose and inform them of the importance of bringing the card when they return for the second dose.
- Provide 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 emergency use of the Pfizer-BioNTech COVID-19 vaccine, which is an investigational vaccine that has not received FDA approval, for use in individuals ≥12 years of age. Advise them that clinical trials have shown that a 2-dose series of the vaccine can prevent COVID-19; however, 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 vaccine, and the extent to which such risks and benefits are unknown. Inform them that local adverse effects (injection site pain, swelling, redness) and systemic adverse effects (tiredness, headache, muscle pain, chills, joint pain, fever, nausea, feeling unwell, swollen lymph nodes [lymphadenopathy], nonsevere allergic reactions [rash, pruritus, hives, facial swelling]) have been reported in recipients of the vaccine.
- Importance of vaccine recipient informing 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 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 first dose of the 2-dose vaccination series; importance of such individuals *not* receiving the vaccine.
- Importance of vaccine recipient informing the 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.

Preparations

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

COVID-19 vaccine (Pfizer-BioNTech) is not commercially available. FDA issued an emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine that permits use of the vaccine for the prevention of COVID-19† in individuals ≥12 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 (Pfizer-BioNTech)

Parenteral

Suspension concentrate, for IM use

30 mcg (of modRNA) per 0.3-mL dose	**Pfizer-BioNTech COVID-19 Vaccine**, Pfizer

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