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*: Comirnaty®

*also available generically

Special Alerts:

Emergency Use Authorization (EUA) Changes for COVID-19 Vaccine (Pfizer-BioNTech): On October 20, 2020, November 19, 2021, December 9, 2021, and January 3, 2022, FDA reissued the EUA for COVID-19 vaccine (Pfizer-BioNTech) to authorize use as an additional (third) primary series dose in certain immunocompromised individuals ≥5 years of age, use as a single homologous booster dose in individuals ≥12 years of age who have completed the primary vaccination series, and use as a single heterologous booster dose in individuals ≥18 years of age who have completed primary vaccination with another authorized or approved COVID-19 vaccine. Additionally, on October 29, 2021, the FDA EUA for the Pfizer-BioNTech COVID-19 vaccine was reissued to permit use of the vaccine for primary vaccination in children 5–11 years of age and to also authorize a manufacturing change to include an additional formulation of the Pfizer-BioNTech COVID-19 vaccine that uses tromethamine (Tris) buffer instead of the phosphate buffered saline (PBS) used in the originally authorized vaccine.

The EUA for the COVID-19 vaccine (Pfizer-BioNTech) now permits use of the vaccine to provide:

- A 2-dose primary vaccination series in individuals ≥5 years of age.
- An additional (third) primary series dose administered at least 28 days following the second dose of the COVID-19 vaccine (Pfizer-BioNTech) in certain immunocompromised individuals ≥5 years of age (i.e., those who are solid organ transplant recipients or diagnosed with conditions considered to have an equivalent level of immunocompromise).
- A single homologous booster dose in individuals ≥12 years of age, administered at least 5 months after completion of the primary series of the COVID-19 vaccine (Pfizer-BioNTech).
- A single heterologous booster dose in individuals ≥18 years of age after completion of a primary vaccination series with another authorized or approved COVID-19 vaccine. When a heterologous vaccine product is used for the booster dose, the dosing interval is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

The Pfizer-BioNTech COVID-19 vaccine is supplied in various formulations and vial presentations. There are important differences between these formulations such as method of preparation, requirement for dilution or no dilution, dose volume, and storage requirements; consult the manufacturer's labeling (for the Comirnaty® product) or the FDA EUA Fact Sheets for the Pfizer-BioNTech COVID-19 vaccine authorized for use under an EUA for specific instructions on each formulation. The various formulations and vial presentations are distinguished by different color vial caps and labels. The Pfizer-BioNTech COVID-19 vaccine supplied in a multiple dose vial (10 mg/cap/0.2 mL) with an orange cap and a label with an orange border is authorized for use in children 5–11 years of age; this formulation should not be used in individuals ≥12 years of age. There are 2 formulations of the Pfizer-BioNTech COVID-19 vaccine authorized for use in individuals ≥12 years of age; both formulations contain 30 mg in each 0.3-mL dose. One formulation is supplied in a multiple dose vial with a purple cap; this formulation must be diluted prior to use. The other formulation does not require dilution and is supplied in a multiple dose vial with a gray cap. The Comirnaty® Pfizer-BioNTech COVID-19 vaccine and the 2 EUA authorized formulations (purple cap and gray cap) of the Pfizer-BioNTech COVID-19 vaccine for individuals ≥12 years of age can be used interchangeably when prepared according to their respective instructions for use. The formulations authorized for use in individuals ≥12 years of age should not be used in individuals 5–11 years of age because of the potential for vaccine administration errors, including dosing errors.

For additional information, consult the EUA at https://www.fda.gov/media/144636/download and the fact sheet for healthcare providers at https://www.fda.gov/media/144637/download

National Alert Network (NAN) Alert Regarding Age-Related COVID-19 Vaccine Mix-ups: On December 6, 2021, the National Alert Network (NAN) issued an alert to make vaccine providers aware of reports of accidental mix-ups between the pediatric formulation of the Pfizer BioNTech COVID-19 vaccine intended for children 5–11 years of age (10 mcg/0.2 mL with an orange cap) and the adult formulation of the Pfizer BioNTech COVID-19 vaccine intended for individuals ≥12 years of age (30 mcg/0.3 mL with a purple cap). Multiple cases of such errors have been reported to the ISMP National Vaccine Errors Reporting Program (ISMP VERS). In some cases, children ≥12 years of age received the formulation intended for children 5–11 years of age, resulting in underdoses; in other cases, children 5–11 years of age received the formulation intended for individuals ≥12 years of age, resulting in overdoses. Possible causes include vial and syringe mix-ups and incorrect assumption that the formulations are interchangeable. The pediatric vaccine is specifically formulated to be less concentrated to ensure accurate dose measurement; use of the adult formulation to prepare doses for children 5–11 years of age is likely to result in delivery of an inaccurate volume of vaccine to the patient. The NAN alert provides recommendations for preventing such vaccine mix-ups including segregate storage, proper labeling of syringes, and vaccine verification at the time of administration. For additional information, see https://www.ismp.org/sites/default/files/attachments/2021-12/NAN-20211206.pdf.

National Alert Network (NAN) Alert Regarding Influenza and COVID-19 Vaccine Mix-ups: On October 15, 2021, the National Alert Network (NAN) issued an alert to make vaccine providers aware of reports of accidental mix-ups between the influenza (flu) and COVID-19 vaccines. The alert is based on 16 cases reported to the Institute for Safe Medication Practices (ISMP) error reporting programs. Most of the reports ISMP has received involve administration of one of the COVID-19 vaccines instead of an influenza vaccine; in 3 cases, patients received an influenza vaccine instead of a COVID-19 vaccine. Because most of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, possible contributing factors include increased demand for vaccination services, the ability to administer the flu and COVID-19 vaccines during the same visit, syringes located next to each other, unlabelled syringes, distractions, and staffing shortages. The alert provides recommendations for preventing such vaccine mix-ups. For additional information, consult the NAN alert at https://www.ismp.org/sites/default/files/attachments/2021-10/NAN-20210105.pdf.

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 being investigated for and is currently available under an FDA emergency use authorization (EUA) for active immunization to prevent COVID-19 in individuals 5 years of age or older, for use as a third primary dose in certain immunocompromised individuals 5 years of age or older, use as a single homologous booster dose in individuals 12 years of age or older, and use as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine in individuals 18 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)

- Prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age as a 2-dose primary vaccination series.
- Although efficacy and safety not established, available under an FDA emergency use authorization (EUA) for use as a 2-dose primary vaccination series in adolescents 12 through 15 years of age, a third dose in the primary vaccination series in certain immunocompromised individuals ≥12 years of age, and a single booster dose after completion of a primary series in adults ≥15 years of age, adults 18 through 64 years of age at high risk of severe COVID-19, and adults 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk for serious complications of COVID-19, including severe COVID-19.
- On December 11, 2020, FDA issued the initial EUA that permitted use of the Pfizer-BioNTech COVID-19 vaccine in individuals ≥16 years of age, use as a single homologous booster dose in individuals ≥12 years of age, and use as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine in individuals 18 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.

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[BLA] approval and use as a third (additional) primary series dose ≥28 days after the second dose in certain immunocompromised individuals ≥12 years of age. On September 22, 2021, FDA again reassured the EUA for the Pfizer-BioNTech COVID-19 vaccine to permit use as a single booster dose in certain adults ≥6 months after completion of a primary series of the vaccine.

- The EUA requires that the vaccine be administered by vaccination providers 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 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 of the vaccine outweigh known and potential risks.

- 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 the vaccine, the EUA includes certain mandatory requirements (e.g., providing the recipient or caregiver with information consistent with the vaccine information 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.)


- CDC's Advisory Committee on Immunization Practices (ACIP) issued recommendations for use of the Pfizer-BioNTech COVID-19 vaccine as a 2-dose primary series for prevention of COVID-19 in individuals ≥16 years of age. ACIP also issued interim recommendations for use of the vaccine as a 2-dose primary series in adolescents 12 through 15 years of age, use as a third (additional) primary dose in certain immunocompromised individuals, and use as a single booster dose in certain adults after completion of a primary series of the vaccine.

- There currently are 3 different COVID-19 vaccines available for use in the US, including 2 mRNA vaccines (Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine) and a viral-vector vaccine (Janssen COVID-19 vaccine). ACIP does not state a preference for any specific COVID-19 vaccine approved or authorized by FDA when the vaccines are used within the scope of their respective BLA or EUA and states that individuals should be encouraged to receive the earliest vaccine available to them. However, the Pfizer-BioNTech COVID-19 vaccine (distributed either as Comirnaty® or without a trade name) is not interchangeable with other COVID-19 vaccines, including the Moderna COVID-19 vaccine and the Janssen COVID-19 vaccine. (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, including the Pfizer-BioNTech COVID-19 vaccine; 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 primary series of 2 doses given 3 weeks 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 additional vaccine dose(s); counsel about the importance of completing the 2-dose primary vaccination series to optimize protection against COVID-19.

- Provide vaccine recipient or their caregiver with 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.

- Anti-pyretics or analgesics (e.g., acetaminophen, NSAIDs) may be taken to treat postvaccination local or systemic symptoms, if medically appropriate. However, routine premedication for the purpose of preventing postvaccination symptoms in vaccinees is not currently recommended since information not available regarding possible impact on antibody response to 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 and are considered partially or fully vaccinated against COVID-19 (see Dosage under Dosage and Administration) and those who have received a third primary dose or a booster dose of the vaccine to follow current CDC guidance to protect themselves and others. For fully vaccinated individuals, this may include wearing a mask in certain settings with substantial or high levels of viral transmission; following applicable federal, state, local, tribal, or territorial laws, rules, and regulations; and following CDC travel guidance and any applicable local business or workplace guidance. (See Limitations of Vaccine Effectiveness under Cautions.)

Administration

IM Administration

- Administer only by IM injection into the deltoid.

The Pfizer-BioNTech COVID-19 vaccine labeled as Comirnaty® or provided without a trade name is supplied as a frozen suspension concentrate in multiple-dose vials that are shipped at ultra-low temperatures and must be stored frozen at specific temperatures. (See Storage under Stability.)

- The frozen vaccine suspension concentrate must be thawed and then diluted with 0.9% sodium chloride injection only. Single-use vials of 0.9% sodium chloride injection are provided with Pfizer-BioNTech COVID-19 vaccine labeled as Comirnaty®, but are shipped separately. Vials of 0.9% sodium chloride injection are not provided with Pfizer-BioNTech COVID-19 vaccine that is not labeled with a trade name and must be sourced separately for dilution of the vaccine.

- For solution compatibility information, see Compatibility under Stability.

The frozen vaccine suspension concentrate must be thawed and then diluted with 0.9% sodium chloride injection only. Single-use vials of 0.9% sodium chloride injection are provided with Pfizer-BioNTech COVID-19 vaccine labeled as Comirnaty®, but are shipped separately. Vials of 0.9% sodium chloride injection are not provided with Pfizer-BioNTech COVID-19 vaccine that is not labeled with a trade name and must be sourced separately for dilution of the vaccine.

- 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 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.

- Discard any vaccine remaining in the vial that does not constitute a full 0.3-mL dose; do not pool with vaccine from other vials to create a dose.

- Although data not available regarding safety and immunogenicity of concomitant administration with other vaccines, ACIP states that COVID-19 vaccines may be administered without regard to timing of other vaccines. (See Vaccines under Interactions.)
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 1 month 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 COVID-19 vaccine (Pfizer-BioNTech) in a primary vaccination series of two 0.3-mL doses given 3 weeks apart in individuals ≥16 years of age and adolescents 12 through 15 years of age.

Immunocompromised individuals (i.e., solid organ transplant recipients or those diagnosed with conditions considered to have an equivalent level of immunocompromise) may receive a third 0.3-mL primary dose administered ≥28 days after the second dose. Certain adults can receive a single 0.3-mL booster dose of the Pfizer-BioNTech COVID-19 vaccine administered ≥6 months after completion of the primary series of the vaccine.

Each 0.3-mL dose contains 30 mcg of mRNA.

A 2-dose regimen of the Pfizer-BioNTech COVID-19 vaccine is considered a complete primary vaccination series. Individuals should not receive more than one complete 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).

Individuals are considered fully vaccinated against COVID-19 ≥2 weeks after receiving the second dose of a 2-dose vaccination series of an mRNA vaccine (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) or ≥2 weeks after receiving a single dose of the Janssen COVID-19 vaccine. For public health purposes, ACIP states that administration of a third (additional) primary dose of an mRNA COVID-19 vaccine in individuals with moderate to severe immunocompromise or administration of a booster dose in adults with the primary vaccination series is not required to be considered fully vaccinated. Those who have a contraindication to vaccination or who otherwise cannot complete a vaccination series are not considered fully vaccinated.

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 primary vaccination series.

FDA specifies an interval of 3 weeks between the first and second vaccine doses. ACIP states schedule individuals to receive the second vaccine dose as close to the recommended day as possible, but not earlier than 3 weeks after the first dose; however, individuals who receive a second dose of the vaccine administered up to 4 days before or at any time after the recommended date can be considered fully vaccinated.

Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) and Pfizer-BioNTech COVID-19 vaccine provided without a trade name have the same formulation and can be used interchangeably to provide the vaccination series without any safety or efficacy concerns.

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 approved or authorized by FDA 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 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 for the primary series in such situations (or inadvertently), ACIP states such individuals are considered fully vaccinated against COVID-19 ≥2 weeks after receiving the second dose of mRNA vaccine.

Safety and efficacy regarding use of the viral-vectorized 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 complete 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-productclinical-considerations.html.

**Pediatric Patients**

**Primary Vaccination Series**

- **Adolescents 12 through 15 Years of Age**
  - IM: FDA EUA permits two 0.3-mL doses of the vaccine administered 3 weeks apart.

- **Adolescents 16 through 17 Years of Age**
  - IM: Two 0.3-mL doses of the vaccine administered 3 weeks apart.

- **Third Primary Dose in Immunocompromised Adolescents 12 Years of Age**
  - IM: FDA EUA permits administration of a third 0.3-mL primary dose ≥28 days after the second dose in solid organ transplant recipients or those diagnosed with conditions considered to have an equivalent level of immunocompromise. (See Individuals with Altered Immunocompetence under Cautions.)

**Adults**

**Primary Vaccination Series**

- **Third Primary Dose in Immunocompromised Adults**
  - IM: FDA EUA permits administration of a third 0.3-mL primary dose ≥28 days after the second dose in solid organ transplant recipients or those diagnosed with conditions considered to have an equivalent level of immunocompromise. (See Individuals with Altered Immunocompetence under Cautions.)

**Booster Dose**

- IM: FDA EUA permits a single 0.3-mL booster dose administered ≥6 months after completion of the primary vaccination series in adults ≥65 years of age, adults 18 through 64 years of age at high risk of severe COVID-19, and adults 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 (including severe COVID-19).

**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**

**Hypersensitivity Reactions**

- **Sensitivity 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 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, contrast media, or food (5 of these had a history of anaphylaxis). Median interval from receipt of vaccine to onset of anaphylaxis 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 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 that history of anaphylaxis to an mRNA COVID-19 vaccine (e.g., following receipt of Janssen 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. US 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. US 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 giving a single dose of the Janssen 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. US 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 or more of which is a component of a COVID-19 vaccine), but it is not known which component elicited the reaction: ACIP considers this a precaution, but not a contraindication, to the COVID-19 vaccine.

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 (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html) and at https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

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

**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. Some experts suggest scheduling routine screening mammography or ultrasound prior to first dose of an mRNA COVID-19 vaccine or 4–6 weeks following second dose of the vaccine, if possible, and if this would not unduly delay appropriate care.

Consider that increased axillary lymph node or deltoid uptake has been detected on positron emission tomography (PET) or other imaging performed in individuals who recently received an mRNA vaccine; some experts suggest obtaining detailed history regarding COVID-19 vaccination (date of vaccination, arm used for vaccine injection) to guide optimal follow-up and avoid unnecessary biopsies in patients undergoing such imaging.

**Myocarditis and Pericarditis**

Rare reports of acute myocarditis or pericarditis in recipients of mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) during post-authorization and post-marketing surveillance; these reports suggest an increased risk of myocarditis and pericarditis following vaccination, particularly within 7 days following the second dose. Symptom onset typically within 2–7 days (range: 0–40 days) after receipt of a dose of an mRNA COVID-19 vaccine; reported more frequently after the second vaccine dose than the first dose.

Data to date indicate myocarditis and pericarditis following vaccination with an mRNA COVID-19 vaccine have occurred predominantly in male adolescents and young adults (range: 12–29 years of age). Observed risk of myocarditis and pericarditis is higher among males <40 years of age than among females and older males and is highest in males 12 through 17 years of age. Although most patients were hospitalized for short periods and some required intensive care support, available data from short-term follow-up suggest that the majority of these individuals responded to conservative treatment involving medications and rest with rapid improvement or resolution of symptoms. Additional data needed regarding potential for long-term sequelae.

Consider the possibility of myocarditis and pericarditis in the differential diagnosis for adolescents or young adults with acute chest pain, shortness of breath, or palpitations. During initial evaluation of suspected cases, query the patient about prior COVID-19 vaccination and pertinent medical, travel, and social history; in addition, consider assessing ECG, troponin levels, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. Consider expert consultation regarding diagnosis, management, and follow-up.

Individuals who developed myocarditis or pericarditis after a dose of an mRNA COVID-19 vaccine: Because it is unclear whether such individuals are at increased risk of further adverse cardiac effects following a subsequent dose of the vaccine, experts recommend deferring subsequent doses until additional safety data are available. ACIP states there may be certain circumstances when administration of a subsequent dose can be considered, taking into account the individual's personal risk of severe COVID-19 (e.g., age, underlying conditions), level of COVID-19 in the community and personal risk of infection, availability of additional data on risk of myocarditis or pericarditis in such situations, and availability of additional data on long-term outcomes. Those who choose to receive a subsequent dose should wait until their episode of myocarditis or pericarditis has completely resolved, including resolution of symptoms attributed to myocarditis or pericarditis with no evidence of ongoing heart inflammation or sequelae as determined by the individual’s clinical team, which may include a cardiologist, and special testing to assess cardiac recovery.

Individuals with a history of myocarditis or pericarditis unrelated to mRNA COVID-19 vaccination (e.g., prior to COVID-19 vaccination): Data are limited regarding the safety and efficacy of COVID-19 vaccines in such individuals. ACIP states that any COVID-19 vaccine approved or authorized by FDA can be administered after the episode of myocarditis or pericarditis unrelated to COVID-19 vaccination has completely resolved, including resolution of symptoms attributed to myocarditis or pericarditis with no evidence of ongoing heart inflammation or sequelae as determined by the individual’s clinical team, which may include a cardiologist, and special testing to assess cardiac recovery.

Inform individuals receiving an mRNA COVID-19 vaccine, especially males 12–29 years of age, about the possibility of myocarditis or pericarditis after receiving the vaccine and the possibility of myocarditis or pericarditis occurring following SARS-CoV-2 infection and advise them to seek medical care if symptoms of myocarditis or pericarditis occur after vaccination.

If myocarditis or pericarditis occurs after receipt of a COVID-19 vaccine, report the case to VSDX (See EUI Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)

**Thrombocytopenia**

Very rare reports of thrombocytopenia, including immune thrombocytopenia (ITP), in recipients of mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) during post-authorization surveillance. As of February 4, 2021, ~18 million doses of the Pfizer-BioNTech COVID-19 vaccine and ~16 million doses of the Moderna COVID-19 vaccine had been administered in the US, and FDA had identified 15 cases of thrombocytopenia in recipients of the Pfizer-BioNTech COVID-19 vaccine and 13 cases in recipients of the Moderna COVID-19 vaccine (reporting rates of 0.8 per million doses for both mRNA vaccines). FDA stated that this number of post-vaccination cases of thrombocytopenia does not suggest a safety concern attributable to mRNA COVID-19 vaccines.

As of April 24, 2021, data from the Vaccine Safety Datalink (VSD) regarding reports of cerebral venous sinus thrombosis (CVST) in recipients of mRNA COVID-19 vaccines identified 11 CVST cases (3 in recipients of the Pfizer-BioNTech vaccine and 8 in recipients of the Moderna vaccine). However, only 6 were considered to be potential incident cases of CVST since 5 of the cases were ruled out based on patient history (e.g., history of head injury, history of cavernous sinus syndrome); thrombocytopenia was not reported in any of these patients. At the time of this analysis, 6.3 million doses of mRNA COVID-19 vaccines had been administered at the healthcare organizations included in the VSD network, and there were no confirmed cases of CVST with thrombocytopenia in recipients of the Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine.

**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 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 period after initial infection, but may increase with time due to waning immunity.

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 since this avoids potential exposing healthcare personnel and other individuals to SARS-CoV-2 during the vaccination visit and avoids diagnostic confusion between possible adverse effects of the vaccine and symptoms of COVID-19. This recommendation

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includes 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) who have had a known COVID-19 exposure or are undergoing screening: 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. Those waiting for results of SARS-CoV-2 testing 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.

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 asymptomatic or asymptomatic SARS-CoV-2 infection, including those with prolonged post-COVID-19 symptoms. Completion of a COVID-19 primary vaccination series in previously infected individuals decreases the risk of future 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 a History of Multisystem Inflammatory Syndrome

Data not available to date regarding safety and efficacy of COVID-19 vaccines in adults or children with a history of multisystem inflammatory syndrome (MIS-A or MIS-C, respectively). Mechanisms of MIS-A and MIS-C are not well understood, but include a dysregulated immune response to SARS-CoV-2 infection. It is unclear whether those with a history of MIS-A or MIS-C are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to COVID-19 vaccination. ACIP recommends weighing these theoretical concerns against the known risks of COVID-19 following reinfection and the benefits of protection following COVID-19 vaccination. Although children with MIS-C have high antibody titters to SARS-CoV-2, it is unclear whether this correlates with protection against reinfection and the duration of protective antibody levels in such children is not known.

ACIP states that individuals with a history of MIS-A or MIS-C may choose to be vaccinated. Although a conversation between the patient, the guardian(s), and their clinical team or a specialist may assist with decisions regarding COVID-19 vaccination in such individuals, a conversation with a healthcare provider is not required before vaccination. When making decisions regarding COVID-19 vaccination in those with a history of MIS-A or MIS-C, considerations include clinical recovery from MIS-C or MIS-A (including return to normal cardiac function), personal risk of severe acute COVID-19 (e.g., age, underlying conditions), level of COVID-19 transmission in the community and personal risk of reinfection, lack of safety data regarding administration of COVID-19 vaccines following MIS-A or MIS-C, and timing of any immunomodulatory therapies.

Current evidence suggests that the risk of reinfection with SARS-CoV-2 is low in the months after initial infection, but may increase with time due to waning immunity. ACIP states that individuals with a history of MIS-A or MIS-C should consider deferring COVID-19 vaccination until they have recovered from their illness and for 90 days after the date MIS-A or MIS-C was diagnosed, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following the initial infection.

If MIS-A or MIS-C associated with a confirmed SARS-CoV-2 infection develops after receipt of a COVID-19 vaccine, consider referral to a specialist in infectious diseases, rheumatology, or cardiology. US healthcare providers and health departments can also request a clinical consultation from the Clinical Immunization Safety Assessment COIVDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html).

If MIS-A or MIS-C 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 Underlying Medical Conditions

ACIP states that individuals with altered immunocompetence or certain underlying medical conditions may receive any COVID-19 vaccine approved or authorized by FDA, 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.

US healthcare providers and health departments can request a clinical consultation from the Clinical Immunization Safety Assessment COIVDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html) if they have concerns about vaccinating individuals with certain underlying medical conditions.

Individuals with Altered Immunocompetence

FDA-approved or FDA-authorized mRNA COVID-19 vaccines (Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine) are not live vaccines and, therefore, can be safely administered to immunocompromised individuals.

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.

Clinical trial data indicate immunocompromised individuals (e.g., solid organ transplant recipients, those with lymphoid malignancies) may have reduced immune responses following a 2-dose vaccination series of an mRNA COVID-19 vaccine compared with those who are not immunocompromised. There also is evidence that vaccinated immunocompromised individuals may have a higher rate of breakthrough SARS-CoV-2 infections than vaccinated individuals in the general population.

Data from small studies demonstrated that administration of an additional dose of mRNA COVID-19 vaccine after the initial 2-dose vaccination series may enhance immune responses to the vaccine in some immunocompromised individuals. Results of a study evaluating safety and effectiveness of a third dose of the Pfizer-BioNTech COVID-19 vaccine in solid organ transplant recipients indicate the third dose is only moderately effective in increasing potentially protective antibody titers in such patients.

Data indicate that the frequencies of solicited local and systemic adverse effects following administration of the Pfizer-BioNTech COVID-19 vaccine in individuals with chronic, stable HIV infection (defined as viral load <50 copies/mL and CD4+ T-cell counts >200 cells/mm3 within 6 months before enrollment and on stable antiretroviral therapy for ≥6 months) are similar to or lower than those observed overall in individuals ≥16 years of age who received the vaccine in clinical trials.

FDA EUA for the Pfizer-BioNTech COVID-19 vaccine permits administration of a third dose of the vaccine at least 28 days after completion of the initial 2-dose vaccination series in individuals ≥12 years of age who are solid organ transplant recipients or diagnosed with conditions considered to have an equivalent level of immunocompromise.

ACIP states that, although clinical benefit of a third (additional) dose of an mRNA COVID-19 vaccine after an initial 2-dose vaccination series in immunocompromised individuals is still under investigation, the potential for increased immune response and the acceptable safety profile of mRNA COVID-19 vaccines support the recommendation for a third dose in individuals with moderate to severe immunocompromise resulting from a medical condition or receipt of immunosuppressive medications or treatments. For public health purposes, ACIP states that immunocompromised individuals are considered fully vaccinated ≥2 weeks after the second dose of the 2-dose primary vaccination series of an mRNA COVID-19 vaccine.

ACIP recommends that a third dose of the Pfizer-BioNTech COVID-19 vaccine be considered after the initial 2-dose primary series for individuals with moderate to severe immunocompromise including, but not limited to, the following:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR) T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (CD4+ T-cell counts <200 cells/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., prednisone dosage at least 20 mg daily or equivalent given for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blocking agents, and other biologic agents that are immunosuppressive or immunomodulatory

ACIP states that factors to consider when assessing the general level of immune competence include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immunosuppressive treatment. Do not use age or place of residence alone (e.g., residence in a long-term care facility), independent of a patient’s medical condition, to determine the level of immune competence because the balance of benefits and risks of a third primary dose for individuals who are not moderately to severely immunocompromised is currently unknown.

Counsel immunocompromised individuals, including those who receive a third dose of the Pfizer-BioNTech COVID-19 vaccine, about the known safety profile and effectiveness of COVID-19 vaccines in immunocompromised populations and the potential for reduced immune responses. Advise them of the need to continue following all current CDC guidelines for fully vaccinated individuals (e.g., wearing a mask in certain settings with substantial or high levels of viral transmission) to protect themselves from COVID-19. Encourage close contacts of immunocompromised individuals to be vaccinated against 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 COVID-19 vaccine approved or authorized by FDA, unless they have a contraindication to the vaccine. Individuals with autoimmune conditions were included in clinical trials evaluating mRNA COVID-19 vaccines and safety and efficacy of the vaccines in this population were similar to that in the general population.

Recommendations for individuals with altered immunocompetence apply to individuals with autoimmune conditions who are immunocompromised because of drug therapy (e.g., high-dose corticosteroids, biologic agents). (See Individuals with Altered Immune Function under Cautions.)

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. These experts state vaccination against COVID-19 is strongly recommended because of increased risk of morbidity and mortality in adults with chronic liver disease, especially those with cirrhosis. AASLD also recommends that those with chronic liver disease receiving treatment with prednisone, antimitabolites, or biologic therapies and those with hepatocellular carcinoma who receive an mRNA COVID-19 vaccine should receive a third (additional) dose of the vaccine administered ≥28 days after the 2-dose primary series.

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; however, those with recent infections or fever should not receive the vaccine until they are medically stable.

AASLD states that liver transplant candidates should receive COVID-19 vaccination prior to transplantation, whenever possible, to help ensure an adequate immune response. The optimal 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 4 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.

Reducing immunosuppressive therapy in liver transplant recipients solely as an effort to elicit an immune response to COVID-19 vaccination not recommended because of the risk of acute cellular rejection (ACR) with lower immunosuppression. AASLD recommends that COVID-19 vaccination be avoided in liver transplant recipients with active ACR, those being treated for ACR, and those receiving high daily doses of corticosteroids until the episode has resolved and the patient’s baseline immunosuppression is reestablished.

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 any COVID-19 vaccine approved or authorized by FDA, 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 and 2 cases in placebo 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 vaccine dose in the other individuals. FDA stated that these 4 cases in the vaccine group do not represent a frequency greater than that expected in the general population, and currently available information is insufficient to determine a causal relationship to the vaccine.

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 to 2.5 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).

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

Individuals Vaccinated Outside the US

Some individuals in the US may have previously received vaccination against COVID-19 in another country using a vaccine not approved or authorized by FDA and/or not listed for emergency use by WHO. ACIP provides guidance on COVID-19 vaccination in such individuals.

Limitations of Vaccine Effectiveness

May not protect all vaccine recipients against COVID-19.

The Pfizer-BioNTech COVID-19 vaccine is administered in a primary vaccination series of 2 doses given 3 weeks 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 breakthrough 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 the limited duration of vaccine-induced protection and unknown extent of protection against emerging SARS-CoV-2 variants, counsel individuals who receive COVID-19 vaccination and are considered fully vaccinated (see Dosage under Dosage and Administration) and those who have received a third primary dose or a booster dose of the vaccine to continue to follow current CDC interim guidance for fully vaccinated individuals to protect themselves and others. This may include wearing a mask in certain settings with substantial or high levels of viral transmission; following federal, state, local, tribal, or territorial laws, rules, and regulations; and following CDC travel guidance and any applicable local business or workplace guidance. 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.

Data limited to date regarding vaccine protection in some immunocompromised individuals, including those receiving immunosuppressive drugs (e.g., drugs such as mycophenolate and rituximab used to suppress rejection of transplanted organs or to treat rheumatologic conditions); such individuals should discuss the need for personal protective measures after COVID-19 vaccination with their healthcare provider.

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

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If COVID-19 breakthrough infection occurs in an individual who has received one or more doses of a COVID-19 vaccine, prior receipt of the vaccine should not affect treatment decisions, including use of SARS-CoV-2-specific monoclonal antibodies, convalescent plasma, antivirals, or corticosteroids. For purposes of surveillance, breakthrough infections in fully vaccinated individuals are defined as detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected at least 14 days after completion of a primary vaccination series. If breakthrough infection occurs in a fully vaccinated individual and results in hospitalization or death, report the case 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.

**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 for use authorized under the FDA EUA. FDA issued an EUA that permits use of the Pfizer-BioNTech COVID-19 vaccine for prevention of COVID-19 when used as a 2-dose primary vaccination series in adolescents 12 through 15 years of age; a third dose in the primary vaccination series in certain immunocompromised individuals ≥12 years of age, and a single booster dose after completion of the primary series in adults ≥65 years of age, adults 18 through 64 years of age at high risk of severe COVID-19, and adults 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk for serious complications of COVID-19 (including severe COVID-19). (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 faxes 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 800-822-7697 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 administering the Pfizer-BioNTech COVID-19 vaccine under the EUA that is available at FDA website (https://www.fda.gov/media/144413/download) and manufacturer's website (https://www.cdcvaccine.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) are not affected by prior COVID-19 vaccination.
- Use a test that specifically evaluates IgM/IgG to the nucleocapsid protein to assess for evidence of prior infection in an individual with a history of COVID-19 vaccination (e.g., for public health surveillance or diagnosis of MIS-C or MIS-A).
- Antibody testing not currently recommended to assess the need for COVID-19 vaccination in an unvaccinated individual or 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.

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. If antibody testing was done after the first dose of an mRNA COVID-19 vaccine, complete the vaccination series regardless of antibody test results.

**Interpretation of Tuberculosis Tests in Vacciinated Individuals**

- ACIP states do not delay COVID-19 vaccination in situations when an immune-based method of tuberculosis testing (i.e., intradural tuberculin skin test [TST] or serum interferon gamma release assay [IGRA]) is required or indicated.
- If TST or IGRA required, perform such testing before, after, or during same visit that COVID-19 vaccine is administered. Although ACIP previously recommended delaying TST or IGRA testing until 34 weeks after completion of COVID-19 vaccination out of an abundance of caution to minimize potential theoretical interference between vaccination and TB testing, ACIP now states such testing can be administered without regard to timing 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.

Available data suggest that, while the absolute risk is low, pregnant and recently pregnant women with COVID-19 are at increased risk of severe illness, including illness resulting in hospitalization, admission to an intensive care unit (ICU), mechanical ventilation, extracorporeal membrane oxygenation (ECMO), or death compared with nonpregnant women. Pregnant and recently pregnant women with comorbidities such as obesity and diabetes mellitus may be at even higher risk of severe COVID-19. Additionally, pregnant women with COVID-19 are at increased risk of preterm birth and may be at an increased risk of adverse pregnancy complications or outcomes, such as preeclampsia, coagulopathy, and stillbirth.

Post-authorization surveillance safety data are accumulating regarding COVID-19 vaccination during pregnancy and clinical trials evaluating safety and efficacy of COVID-19 vaccines in pregnant women are underway or planned. There is some evidence that pregnant women who receive an mRNA vaccine (Pfizer-BioNTech COVID-19 vaccine or Moderna COVID-19 vaccine) during pregnancy have immune responses comparable to those observed in nonpregnant individuals and may develop anti-SARS-CoV-2 antibody titers greater than those observed in women diagnosed with SARS-CoV-2 infection during pregnancy. The Pfizer-BioNTech COVID-19 vaccine cannot cause SARS-CoV-2 infection in the pregnant woman or her fetus.

FDA states pregnancy is not a contraindication to use of the Pfizer-BioNTech COVID-19 vaccine; pregnant women should discuss potential benefits and risks of vaccination with their healthcare providers.

ACIP states vaccination against COVID-19 is recommended for pregnant women. These experts state that evidence regarding safety and efficacy of COVID-19 vaccines available from both animal and human studies indicates that benefits of vaccination against COVID-19 during pregnancy outweigh any known or potential risks. ACIP does not state a preference for any specific FDA-approved or FDA-authorized COVID-19 vaccine in pregnant women. For purposes of decisions regarding administration of both the primary vaccination series and a booster dose, ACIP states consider pregnant and recently pregnant women (up until at least 42 days following the end of pregnancy) in the same group as individuals with underlying medical conditions.

ACOG recommends that pregnant women be vaccinated against COVID-19. When recommending the COVID-19 vaccine to pregnant women, ACOG suggests that clinicians review available data on risks and benefits of vaccination, including risks of not getting vaccinated, in the context of the individual patient’s current health status and risk of exposure (e.g., possibility for exposure at work or home) and possibility for exposing high-risk household members. In addition, take into account the individual patient’s values and perceived risk of various outcomes; autonomous decision-making should be respected and supported.

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; however, such a conversation is not required and written permission is not needed prior to vaccination. ACIP and ACOG recommend 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.

ACOG states do not withheld RB(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.)

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.

Encourage women who receive the Pfizer-BioNTech COVID-19 vaccine during pregnancy to enroll in a pregnancy exposure registry at https://mothertobebaby.org/ongoing-study/covid-19-vaccines/. Also 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 vaccination against COVID-19 recommended for women currently trying to become pregnant and those who might become pregnant in the future. 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 FDA-approved or FDA-authorized COVID-19 vaccines affect current or future fertility. FDA states there is no scientific evidence to suggest that Pfizer-BioNTech COVID-19 vaccine could cause infertility in women. In addition, infertility not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility.

**Lactation**

Not known whether Pfizer-BioNTech COVID-19 vaccine is distributed into milk. Data not available to assess whether the vaccine administered to a woman who is breast-feeding has any effects on breast-fed infant or milk production.

Consider benefits of breast-feeding and the importance of the Pfizer-BioNTech COVID-19 vaccine to the woman along with any potential adverse effects on the breast-fed child from the vaccine or from the underlying maternal condition (i.e., susceptibility to SARS-CoV-2 infection).

FDA states breast-feeding is not a contraindication to the use of the Pfizer-BioNTech COVID-19 vaccine; breast-feeding women should discuss benefits and risks of vaccination with their healthcare providers.

ACIP states that vaccination against COVID-19 recommended for lactating women.

FDA-approved COVID-19 vaccines administered to breast-feeding women cannot cause SARS-CoV-2 infection in women or their infants; therefore, breast-feeding women can receive COVID-19 vaccination.

ACOG recommends that lactating women be vaccinated against COVID-19. 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.

Although there is some evidence that antibodies that develop following vaccination with mRNA COVID-19 vaccines are present in breast milk, additional data needed to determine if these antibodies convey protection against SARS-CoV-2 infection in breast-fed infants.

**Pediatric Use**

Safety and effectiveness for prevention of COVID-19 in individuals 16 through 17 years of age is based on safety and effectiveness data in this age group and in adults. Safety and effectiveness of the vaccine have not been fully established in individuals <16 years of age.

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 adolescents and adults.

The Pfizer-BioNTech COVID-19 vaccine is not authorized for use in children <12 years of age and is not authorized for use as a booster dose in individuals <18 years of age.

**Geriatric Use**

Data from the ongoing clinical trial evaluating the Pfizer-BioNTech COVID-19 vaccine indicates that, as of March 13, 2021, 20.7% of individuals who received a 2-dose primary series of the vaccine were ≥65 years of age and 4.2% were ≥75 years of age. No overall differences in safety or effectiveness observed between those ≥65 years of age and younger recipients of the vaccine.

Safety of a single booster dose in individuals ≥65 years of age is based on safety data for 12 individuals 65 through 85 years of age and 306 individuals 18 through 55 years of age who received a booster dose of the vaccine in the ongoing clinical trial; effectiveness in individuals ≥65 years of age is based on data for 306 individuals 18 through 55 years of age who received a booster dose of the vaccine in the trial.

**Common Adverse Effects**

Local adverse events (≥10%) in adults and adolescents ≥16 years of age following any dose in clinical trials: Injection site pain (88.6%), and swelling (10.6%) in those 16 through 55 years of age and injection site pain (78.2%), erythema (10.4%), and swelling (11.8%) in those ≥56 years of age. Generally mild to moderate in severity; severe pain reported in up to 1.5% of vaccine recipients. Mean duration of adverse local effects following the second dose of the 2-dose vaccination series was 2.1–3 days (range: 1–70 days for injection site pain, 1–34 days for erythema, and 1–34 days for swelling).

Systemic adverse effects (≥10%) in adults and adolescents ≥16 years of age following any dose in clinical trials: Fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), and fever (17.3%) in those 16 through 55 years of age and fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), and fever (11.5%) in those ≥56 years of age. Systemic adverse effects reported more frequently after second dose of the 2-dose primary 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 45.2%, respectively, of those 18–55 years of age and in 19 or 37%, respectively, of those ≥56 years of age. In study participants 16–55 years of age, serious adverse events reported in 0.8% of vaccine recipients and 0.5% of placebo recipients; in those ≥56 years of age, serious adverse events reported in 1.8 or 1.7% of vaccine or placebo recipients, respectively.

Adolescents 12 through 15 years of age who received a 2-dose primary series: Local adverse events reported in a clinical trial were injection site pain (90.5%), swelling (9.2%), and erythema (8.6%); mean duration of pain at injection site was 2.4 days (range: 1–10 days) after first dose of the 2-dose vaccination series. Systemic adverse events were fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), lymphadenopathy (0.8%), and nausea (0.4%). Use of antipyretic or pain medication within 7 days after receiving the first or second vaccine dose reported in 36.6 or 50.8%, respectively. Serious adverse events reported in 0.4% of vaccine recipients and 0.1% of placebo recipients.

Third dose in solid organ transplant recipients: Adverse event profile following a third dose in transplant (heart, kidney, liver, lung pancreas) recipients was similar to that following the second dose; no grade 3 or 4 adverse events reported during 1 month of follow-up after third dose.

Single booster dose administered approximately 6 months after 2-dose primary series in adults 18 through 55 years of age: Local adverse events were pain (83%), erythema (5.9%), and swelling (9%); mean duration was 2.6 days (range: 1–8 days) for pain at the injection site, 2.2 days (range: 1–15 days) for erythema, and 2.2 days (range: 1–8 days) for swelling. Systemic adverse events were fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), fever (8.7%), diarrhea (8.7%), and vomiting (1.7%). Use of antipyretic or pain medication within 7 days after receiving the booster dose reported in 46.7%. No serious adverse events reported during events reported 30 days after the booster dose.

Other adverse effects reported during post-authorization and post-marketing surveillance include cardiac effects (myocarditis, pericarditis), GI effects (diarrhea, vomiting), hypersensitivity reactions (anaphylaxis, rash, pruritus, urticaria, angioedema), extremity pain (arm), and syncope.

**Interactions**

**Vaccines**

Data not available to date to assess safety and immunogenicity of concomitant administration of COVID-19 vaccine (Pfizer-BioNTech) with other vaccines.

Extensive experience with non-COVID-19 vaccines demonstrated that immunogenicity and adverse event profiles are generally similar whether vaccines are administered concomitantly or alone. However, it is not known whether reactogenicity of COVID-19 vaccines is increased when administered concomitantly with other vaccines, including those known to be more reactogenic (e.g., adjuvanted vaccines). Base decisions to administer a COVID-19 vaccine concomitantly with other vaccine(s) on whether routine immunizations with the other vaccines have been delayed or missed, the individual's risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and reactogenicity profiles of the vaccines.

ACIP states that COVID-19 vaccines may be administered without regard to timing of other vaccines, including simultaneous administration on the same day. If a COVID-19 vaccine is administered concomitantly with other vaccines, give each parenteral vaccine at a different injection site and, if possible, separate injection sites by ≥2 inch. ACIP states that, although >1 vaccine can be given IM into the deltoid muscle in adolescents and adults, give COVID-19 vaccines and vaccines likely to cause a local reaction in different limbs, if possible.

**Specific Drugs**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Interaction</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Antiviral agents</td>
<td>Antiviral agents given at any interval before or after COVID-19 vaccination unlikely to impair development of vaccine-induced protective antibody responses</td>
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<tr>
<td>COVID-19 convalescent plasma</td>
<td>Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine</td>
<td>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</td>
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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.

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.

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 are shipped in thermal containers with dry ice at ultra-low temperatures and must be stored frozen at specific temperatures.

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
The modRNA contained in the Pfizer-BioNTech COVID-19 vaccine encodes a membrane-compatibility ultraviolet light. May handle thawed vaccine vials in room light conditions. 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 mg 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)azidenediyly]bis(hexane-6,1-diyl)[bis(2-hexyldecoanoate), 2[(PEG)-2000]-N,N-dietracyclooctatridecyl, 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) labeled as Comirnaty® or without a trade name, must provide vaccine recipient or their caregiver with information consistent with the vaccine information fact sheet for recipients and caregivers of the Pfizer-BioNTech COVID-19 vaccine 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.
- Inform vaccine recipients or their caregivers that the Pfizer-BioNTech COVID-19 vaccine is approved by FDA for use as a 2-dose primary series in individuals ≥16 years of age and is authorized by FDA under an EUA for use as a 2-dose primary series in adolescents 12 through 15 years of age, a third dose in the primary series in individuals ≥12 years of age with certain kinds of immunocompromise, and a single booster dose in certain adults ≥18 years of age. Advise them that clinical trials have shown that a 2-dose series of the vaccine can prevent COVID-19; however, the duration of protection following vaccination is unknown and the vaccine may not protect everyone who receives it.
- 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 primary doses given 3 weeks 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 additional vaccine dose(s) and inform them of the importance of bringing the card when they return for the next dose.
- Inform individuals who are immunocompromised that they may receive a third primary dose of the Pfizer-BioNTech COVID-19 vaccine at least 4 weeks after the second dose. Advise such individuals that the third dose may still not provide full immunity to COVID-19 and they should continue to follow preventative measures (e.g., wearing a mask) to help prevent COVID-19. In addition, inform immunocompromised individuals that their close contacts should be vaccinated as appropriate.
- Advise vaccine recipients to report any adverse reactions that occur following vaccination to VAERS at 800-822-7967 or http://www.vaers.hhs.gov/.
- 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 the vaccination provider cannot charge them for the vaccine dose, any out-of-pocket vaccine administration fees, or any other fees for COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (e.g., private insurance, Medicare, Medicaid, US Health Resources & Services Administration [HRSA] COVID-19 assistance program for non-insured recipients). Individuals who become aware of any potential violations of these requirements are encouraged to report them to the Office of the Inspector General, US Department of Health and Human Services by phone (800-HHS-TIPS) or online (https://tips.oig.hhs.gov).
- Provide vaccine recipients or their caregivers that, under the EUA, they have the option to accept or refuse the vaccine.
- Inform vaccine recipients or their caregivers 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], decreased appetite, diarrhea, vomiting, fainting in association with injection of the vaccine) have been reported in recipients of the vaccine.
- Inform vaccine recipients or their caregivers that myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) reported rarely in some recipients of the Pfizer-BioNTech COVID-19 vaccine with symptom onset usually within a few days after the second vaccine dose. Importance of immediately seeking medical attention if chest pain, shortness of breath, or fast-beating, fluttering, or pounding heart occurs.
- 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.

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 S-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.
- Data from clinical trial in adolescents 12 through 15 years of age indicate immune responses 1 month after the second vaccine dose are noninferior (within 1.5-fold) compared with immune responses in those 16 through 25 years of age.
- COVID-19 vaccine (Pfizer-BioNTech) labeled as Comirnaty® or without a trade name is provided as a frozen concentration 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 mg 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)azidenediyly]bis(hexane-6,1-diyl)[bis(2-hexyldecoanoate), 2[(PEG)-2000]-N,N-dietracyclooctatridecyl, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol) and potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.
- Solution Compatibility

<table>
<thead>
<tr>
<th>Parenteral Compatibility</th>
<th>Solution Compatibility</th>
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<tbody>
<tr>
<td><strong>Compatible</strong></td>
<td>Sodium chloride 0.9%</td>
</tr>
<tr>
<td><strong>Incompatible</strong></td>
<td>Bacteriostatic sodium chloride 0.9%</td>
</tr>
</tbody>
</table>

- **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 S-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.
- Data from clinical trial in adolescents 12 through 15 years of age indicate immune responses 1 month after the second vaccine dose are noninferior (within 1.5-fold) compared with immune responses in those 16 through 25 years of age.
- COVID-19 vaccine (Pfizer-BioNTech) labeled as Comirnaty® or without a trade name is provided as a frozen concentration 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 mg 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)azidenediyly]bis(hexane-6,1-diyl)[bis(2-hexyldecoanoate), 2[(PEG)-2000]-N,N-dietracyclooctatridecyl, 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.
● 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 ever fainted in association with an injection, have any medical conditions (e.g., bleeding disorders, myocarditis or pericarditis, 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. Encourage women who receive a COVID-19 vaccine around the time of conception or during pregnancy to enroll in the pregnancy registry at https://mothertobaby.org/ongoing-study/covid19-vaccines/. Also encourage those who receive a COVID-19 vaccine during pregnancy or become pregnant within 30 days after receiving a COVID-19 vaccine to participate in CDC’s v-safe program.

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) received FDA approval under a biologics license application (BLA) for use as a 2-dose primary vaccination series for prevention of COVID-19 in individuals ≥16 years of age. COVID-19 vaccine (Pfizer-BioNTech) also is available under an FDA emergency use authorization (EUA) that permits use of the vaccine as a 2-dose primary vaccination series in adolescents 12 through 15 years of age†, a third dose† in the primary series in certain immunocompromised individuals ≥12 years of age, and a single booster dose† after completion of the primary vaccination series in certain adults. The FDA-approved Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) and the FDA-authorized Pfizer-BioNTech COVID-19 vaccine without a trade name have the same formulation; vaccine labeled as Comirnaty® and Pfizer-BioNTech COVID-19 vaccine distributed under the EUA can be used interchangeably to provide the vaccination series without any safety or efficacy concerns. Allocation of Pfizer-BioNTech COVID-19 vaccine (with and without a trade name) is being directed by the US government. The vaccine will be supplied either directly from the manufacturer or through authorized US distributor(s) 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

Comirnaty®, Pfizer
Pfizer-BioNTech COVID-19 Vaccine, Pfizer

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