

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 March 29, 2022, the EUA for the Pfizer BioNTech COVID-19 vaccine was reissued to permit use of the vaccine as a second booster dose at least 4 months after receipt of a first booster dose of any FDA-authorized or approved COVID-19 vaccine product to individuals ≥50 years of age and certain immunocompromised individuals ≥12 years of age (i.e., those who are solid organ transplant recipients or diagnosed with conditions considered to have an equivalent level of immunocompromise). On June 17, 2022, the EUA for Pfizer BioNTech COVID-19 vaccine was reissued to permit use of the vaccine as a 3-dose primary vaccination series in individuals 6 months to 4 years of age. For additional information, consult the EUA at <https://www.fda.gov/media/150386/download> and the fact sheet for healthcare providers at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>

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, which include 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, unlabeled 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-20211015.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. 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

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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. Comirnaty® is the FDA-approved Pfizer-BioNTech COVID-19 vaccine labeled for prevention of COVID-19 in individuals ≥16 years of age.
- Although efficacy and safety have not been established, the Pfizer-BioNTech COVID-19 vaccine is also available under an FDA emergency use authorization (EUA) as a 2-dose primary vaccination series in individuals ≥5 years of age†; as an additional (third) primary dose† in certain immunocompromised individuals ≥5 years of age; as a single homologous booster dose† after completion of the primary series with the Pfizer-BioNTech COVID-19 vaccine in individuals ≥12 years of age; and as a single heterologous booster dose† in individuals ≥18 years of age who have received primary vaccination with another FDA authorized or approved COVID-19 vaccine.
- 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. The EUA was amended and reissued multiple times since then as the scope of authorization changed. For the most current version, consult the Pfizer-BioNTech COVID-19 COVID-19 vaccine EUA letter of authorization at <https://www.fda.gov/media/144636/download/media/144636/download>.
- The EUA requires that the vaccine be administered by vaccination providers as authorized, and that vaccination providers participate and comply with terms and training required by CDC's COVID-19 vaccination program.
- The EUA includes certain mandatory requirements (e.g., providing the recipient or caregiver with information consistent with the vaccine information fact sheet, 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).
- Consult the Pfizer-BioNTech COVID-19 vaccine EUA fact sheet for healthcare providers (<https://www.fda.gov/media/144413/download>), and EUA vaccine information fact sheet for recipients and caregivers (<https://www.fda.gov/media/144414/download>) for additional information.
- Consult the CDC's Advisory Committee on Immunization Practices (ACIP) interim recommendations and clinical considerations for use of COVID-19 vaccines, including dosage and administration, specific populations and situations, and cautionary information.
- 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-vectored vaccine (Janssen COVID-19 vaccine). COVID-19 vaccination is currently recommended for individuals ≥5 years of age in the US for prevention of COVID-19; however, the age groups approved or authorized to receive vaccination vary by vaccine product. In most situations, ACIP states that the mRNA vaccines are preferred over the Janssen COVID-19 vaccine for primary and booster vaccination because of the risks associated with the Janssen vaccine; however, the Janssen COVID-19 vaccine may be offered in certain situations. In patients eligible for an additional (third) primary mRNA COVID-19 vaccine dose (e.g., certain immunocompromised individuals), ACIP states the same mRNA COVID-19 vaccine product should generally be used.

Dosage and Administration

General

Pretreatment Screening

- Screen all individuals for contraindications and precautions to vaccination.

Patient Monitoring

- Monitor all individuals who receive a COVID-19 vaccine for immediate adverse reactions according to CDC (ACIP) guidelines. ACIP states that the following individuals should be observed for 30 minutes after receiving the vaccine: those with a history of immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapy; those with a contraindication to a different type of COVID-19 vaccine (i.e., viral vector); those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine; and those with a history of anaphylaxis due to any cause. All other individuals should be observed for 15 minutes. A longer period of observation may be indicated for some individuals based on clinical concern (e.g., vaccine recipient develops pruritus and swelling at the injection site during the observation period).

- Instruct vaccine recipients to seek immediate medical care if they develop signs or symptoms of an allergic reaction after the observation period is complete. (See Hypersensitivity Reactions under Cautions.)

Premedication and Prophylaxis

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

Dispensing and Administration Precautions

- Appropriate medications and supplies for managing immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines. Healthcare personnel who are trained and qualified to recognize signs and symptoms of anaphylaxis and administer IM epinephrine should be available at vaccination sites at all times. Vaccination locations that anticipate vaccinating large numbers of people (e.g., mass vaccination clinics) should plan adequate staffing and supplies (including epinephrine) for assessment and management of anaphylaxis. (See Hypersensitivity Reactions under Cautions.)
- Syncope (vasovagal or vasodepressor reaction; fainting) may occur following administration of parenteral vaccines; such reactions usually occur within 15 minutes following vaccine administration and are reported most frequently in adolescents and young adults. Take appropriate measures to decrease the risk of injury if the vaccine recipient becomes weak or dizzy or loses consciousness (e.g., instruct the vaccine recipient to sit or lie down during and for 15 minutes after vaccination). If syncope occurs, observe the individual until symptoms resolve.

Other General Considerations

- The Pfizer-BioNTech COVID-19 vaccine is administered in a primary series of 2 doses given 3 weeks apart. At the time the first dose is administered, a vaccination record card that provides the date when the recipient needs to return for additional vaccine dose(s) should be given to the vaccine recipient or their caregiver; vaccine recipients should be counseled on the importance of completing the 2-dose primary vaccination series to optimize protection against COVID-19.
- Provide vaccine recipients or their caregiver with information on CDC's v-safe program, a voluntary smartphone-based tool that uses text messaging and web surveys to monitor for adverse effects in individuals who have received a COVID-19 vaccine. (See EUA Requirements for Postvaccination Monitoring and Mandatory Vaccine Adverse Event Reporting under Cautions.)
- Prior to vaccination, counsel vaccine recipient or their caregiver about local and systemic adverse effects that may occur following vaccination. Unless a contraindication to vaccination exists, ACIP recommends that vaccine recipients should be encouraged to complete the 2-dose vaccination series even if they experience a local or systemic adverse effect following the first dose since this optimizes protection.
- Individuals who receive COVID-19 vaccines should follow current CDC guidance to protect themselves and others. This may include wearing a mask in certain settings with substantial or high levels of viral transmission; following application 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.

For solution compatibility information, see Compatibility under Stability.

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, 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.

Comirnaty[®] Vials with Purple Caps

The Pfizer-BioNTech COVID-19 vaccine labeled as Comirnaty[®] with a purple cap *must* be diluted with 0.9% sodium chloride injection prior to use; the vaccine is supplied as a frozen suspension in multiple-dose vials that *must* be thawed prior to dilution.

Frozen vaccine can be thawed and stored for up to 1 month in a refrigerator (2–8°C) or thawed at room temperature (up to 25°C). If the room temperature method is used, allow the vial

to sit at room temperature for 30 minutes. Using either thawing method, vials *must* reach room temperature before dilution and *must* be diluted within 2 hours.

Thawed vaccine *must* not be refrozen.

Prior to dilution, gently invert vial 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 or narrower needle) and inject into vial of thawed vaccine suspension.

To equalize vial pressure, withdraw 1.8 mL of air into empty diluent syringe before removing the needle from the vial. 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.

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 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.

To administer a dose, withdraw 0.3 mL of the diluted 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; however, 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. 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 obtain a dose.

Comirnaty[®] Vials with Gray Cap

The COVID-19 vaccine (Pfizer-BioNTech) labeled as Comirnaty[®] with a gray cap *must NOT* be diluted prior to use; the vaccine is supplied as a frozen suspension in multiple-dose vials that *must* be thawed prior to administration.

Vials may be thawed either in a refrigerator (2–8°C) or at room temperature (up to 25°C). If the room temperature method is used, allow the vials to sit at room temperature for 30 minutes. Vials may be stored at room temperature for up to 12 hours prior to first use.

Record the date and time of first vial puncture on the vial label. After the first puncture, the vaccine should be stored between 2–25°C; discard any unused vaccine 12 hours after first vial puncture.

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

The thawed vaccine may contain white to off-white opaque amorphous particles. Prior to use, gently invert the vial 10 times; do not shake. After gently inverting the vial, the vaccine should appear as a white to off-white suspension with no visible particulates. Do not use if the liquid is discolored or if particles are observed.

To administer a dose, withdraw 0.3 mL of the 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; however, a standard 1-mL syringe can be used if a low dead-volume syringe is not available.

Each thawed multiple dose Comirnaty[®] vial with a gray cap 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, the volume of remaining 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 and do not pool with vaccine from other vials to obtain a dose.

Multiple Dose Vials with Purple Cap Authorized for Use Under EUA

The Pfizer-BioNTech COVID-19 vaccine supplied in a multiple dose vial with a purple cap and label is one of the formulations authorized under an FDA EUA for use in individuals ≥12 years of age; do not use this formulation in children 5–11 years of age because of the potential for vaccine administration errors, including dosing errors.

The multiple dose vials with a purple cap contain Pfizer-BioNTech COVID-19 vaccine formulated using phosphate buffered saline (PBS) buffer; each 0.3-mL dose of the vaccine contains 30 mcg modRNA. The vaccine is shipped in thermal containers with dry ice at ultra-low temperatures and *must* be stored frozen at specific temperatures.

Prior to use, the vials *must* be thawed and then diluted with 0.9% sodium chloride injection *only*; do not use other diluents (e.g., bacteriostatic 0.9% sodium chloride injection). The vaccine may be thawed and stored for up to 1 month in a refrigerator (2–8°C), or thawed at room temperature (up to 25°C). If the room temperature method is used, allow the vials to sit at room temperature for 30 minutes. Using either thawing method, vials *must* reach room temperature before dilution and *must* be diluted within 2 hours.

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

Prior to dilution, gently invert the vials 10 times; do not shake. Inspect the liquid in the vial; the thawed vaccine should appear as a white to off-white suspension, but may contain white to off-white opaque amorphous particles. Do not use if the liquid is discolored or contains other particles.

Using aseptic technique, withdraw 1.8 mL of 0.9% sodium chloride injection into a 3- or 5-mL transfer syringe (21-gauge or narrower needle) and inject into the vial of thawed Pfizer-BioNTech COVID-19 vaccine suspension. To equalize vial pressure, withdraw 1.8 mL of air into the empty diluent syringe before removing the needle from the vial.

Gently invert the vial 10 times to mix; do not shake.

Following dilution, the vaccine should appear as an off-white suspension and should *not* be used if it is discolored or contains particulates.

Vials containing diluted COVID-19 vaccine (Pfizer-BioNTech) may be stored between 2–25°C, but *must* be used within 6 hours after dilution (regardless of storage temperature). Unused diluted vaccine remaining in vials should be discarded if not used within 6 hours after dilution.

To administer a dose of the thawed and diluted vaccine, withdraw 0.3 mL of the 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; however, a standard 1-mL syringe can be used if a low dead-volume syringe is not available.

Each diluted multiple dose vial with purple caps and labels 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, the volume of remaining 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 obtain a dose.

Multiple Dose Vials with Gray Cap Authorized for Use Under EUA

The Pfizer-BioNTech COVID-19 vaccine supplied in a multiple dose vial with a gray cap and label is one of the formulations authorized for use under an FDA EUA for individuals ≥12 years of age; do not use this formulation in children 5–11 years of age because of the potential for vaccine administration errors, including dosing errors.

The multiple dose vials with a gray cap contain Pfizer-BioNTech COVID-19 vaccine formulated using tromethamine (Tris) buffer; each 0.3-mL dose of the vaccine contains 30 mcg modRNA.

The vaccine formulation with a gray cap is supplied as a frozen suspension that *must not* be diluted prior to use. The vials may arrive frozen in thermal containers with dry ice at ultra-low temperatures; once received, the frozen vials may be immediately transferred to the refrigerator and stored for up to 10 weeks, or stored in an ultra-low temperature freezer. Alternatively, the Pfizer-BioNTech COVID-19 vaccine vials with gray caps and labels may arrive at 2–8°C; in this case, the vials should be stored at 2–8°C after receipt.

Regardless of storage condition, the vaccine should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Prior to use, the frozen vaccine must be thawed. Vials may be thawed either in a refrigerator (2–8°C) or at room temperature (up to 25°C). If the room temperature method is used, allow the vials to sit at room temperature for 30 minutes. Vials may be stored at room temperature for up to 12 hours prior to first puncture.

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

Record the date and time of first vial puncture on the vial label. After the first puncture, the vaccine should be stored at 2–25°C; discard any unused vaccine after 12 hours.

The thawed Pfizer-BioNTech COVID-19 vaccine may contain white to off-white opaque amorphous particles. Prior to use, gently invert the vials 10 times; do not shake. After gently inverting the vial, the vaccine should appear as a white to off-white suspension with no visible particulates. Do not use if the liquid is discolored or if particles are observed.

To administer a dose of the thawed vaccine, withdraw 0.3 mL of the 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; however, a standard 1-mL syringe can be used if a low dead-volume syringe is not available.

Each multiple dose vial with a gray cap 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, the volume of remaining 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 and do not pool with vaccine from other vials to obtain a dose.

Multiple Dose Vials with Orange Cap Authorized for Use Under EUA

The Pfizer-BioNTech COVID-19 vaccine formulation authorized for use in children 5–11 years of age is supplied in a multiple dose vial with an orange cap and label and uses Tris buffer; each 0.2-mL dose contains 10 mcg modRNA.

The vaccine formulation with an orange cap is supplied as a frozen suspension concentrate that *must* be diluted before use.

Vials may arrive frozen in thermal containers with dry ice at ultra-low temperatures; once received, the frozen vials may be transferred immediately to the refrigerator and stored for up to 10 weeks, or stored in an ultra-low temperature freezer. Alternatively, the Pfizer-BioNTech COVID-19 vaccine vials with orange caps and labels may arrive at 2–8°C; in this case, the vials should be stored at 2–8°C after receipt.

Regardless of storage condition, the vaccine should not be used after 9 months from the date of manufacture printed on the vial and cartons.

Prior to use, the frozen vaccine must be thawed and diluted with 0.9% sodium chloride injection only; do not use bacteriostatic 0.9% sodium chloride injection or any other diluent.

Vials may be thawed in a refrigerator (2–8°C) or at room temperature (up to 25°C); if the room temperature method is used, allow the vials to sit at room temperature for 30 minutes. Vials may be stored at room temperature for up to 12 hours prior to use.

The thawed vaccine should appear as a white to off-white suspension, but may contain white to off-white opaque amorphous particles; do not use the vaccine if it is discolored or contains other particles.

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

To dilute the thawed vaccine, gently invert the vial 10 times; do not shake. Using aseptic technique, withdraw 1.3 mL of 0.9% sodium chloride injection into a 3- or 5-mL transfer syringe (21-gauge or narrower needle) and add to the thawed vaccine vial.

To equalize vial pressure, withdraw 1.3 mL of air into the empty diluent syringe before removing the needle from the vial.

After addition of diluent, gently invert the vial 10 times to mix; do not shake.

Following dilution, the vaccine should appear as an off-white suspension; do not use if the solution is discolored or contains particulates.

The diluted vaccine may be stored at 2–25°C, but must be used within 12 hours after dilution (regardless of storage temperature). Discard any unused vaccine remaining in vials if not used within 12 hours after dilution.

Prior to vaccine administration, verify that the vial of Pfizer-BioNTech COVID-19 vaccine has an orange plastic cap and a label with an orange border that states “Age 5 y to <12 y.”

To administer a dose of the thawed and diluted vaccine, withdraw 0.2 mL of 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; however, a standard 1-mL syringe can be used if a low dead-volume syringe is not available.

Each multiple dose vial with an orange cap provides ten 0.2-mL doses when low dead-volume syringes and needles are used to extract doses from the vial. If standard syringes and needles are used, the volume of remaining vaccine may be insufficient to extract 10 doses from the vial.

Irrespective of the type of syringe and needle used, each dose must contain 0.2 mL of vaccine. Discard any vaccine remaining in the vial that does not constitute a full 0.2-mL dose and do not pool with vaccine from other vials to obtain a dose.

Dosage

Pfizer-BioNTech COVID-19 vaccine is available in various formulations and vial presentations. Ensure the correct age-appropriate formulation is selected for administration. Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) and the 2 EUA authorized 30 mcg/0.3 mL formulations should not be used for individuals 5–11 years of age in order to avoid vaccine administration errors, including dosing errors.

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

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 (Comirnaty®) and Pfizer-BioNTech COVID-19 vaccine 30 mcg/0.3 mL formulations (purple and gray cap and label) without a trade name can be used interchangeably when prepared based on their respective instructions.

Doses for the primary vaccination series and the additional primary dose, if indicated, should be completed with the same vaccine product. 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 with a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If 2 doses of *different* mRNA COVID-19 vaccines are administered for the primary series in such situations (or inadvertently), the primary series is considered complete.

ACIP additionally 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. In such exceptional circumstances, the individual should be considered to have received complete single-dose vaccination with the Janssen COVID-19 vaccine, not a mixed vaccination series.

For booster doses, ACIP states use of an mRNA COVID-19 vaccine is preferred in individuals ≥ 18 years of age even for those who received the Janssen COVID-19 vaccine for their single-dose primary series. However, if an mRNA vaccine cannot be given, offering the Janssen COVID-19 vaccine as a booster is preferable to not providing any COVID-19 vaccine booster. In individuals 12–17 years of age, only the Pfizer-BioNTech COVID-19 vaccine can be used for the booster dose.

See Table 1 for recommended doses and dosing intervals for the Pfizer-BioNTech COVID-19 Vaccine.

Table 1. Pfizer-BioNTech COVID-19 Vaccine Primary Series, Additional Primary Dose, and Booster Dose Recommendations

	PRIMARY SERIES	PRIMARY SERIES	BOOSTER DOSE
Indicated population	All individuals ≥ 12 years of age	Individuals 5–11 years of age	All individuals ≥ 12 years of age
Vial cap and label	Purple or gray	Orange	Purple or gray
Dose	30 mcg	10 mcg	30 mcg
Injection volume	0.3 mL	0.2 mL	0.3 mL
Recommended doses and interval	2 doses, administered 21 days apart Additional (third) primary dose of 0.3 mL recommended ≥ 28 days after completion of primary series in immunocompromised individuals	2 doses, administered 21 days apart Additional (third) primary dose of 0.2 mL recommended ≥ 28 days after completion of primary series in immunocompromised individuals	1 dose, administered ≥ 5 months after completion of primary series (including additional dose)

Pediatric Patients

Primary Vaccination Series

>Children 5 through 11 Years of Age†

IM: For primary vaccination in this age group, the FDA EUA authorizes two 0.2-mL doses of the Pfizer-BioNTech COVID-19 vaccine 10 mcg/0.2 mL formulation (orange cap) administered 3 weeks apart.

>Adolescents 12 through 15 Years of Age†

IM: For primary vaccination in this age group, the FDA EUA authorizes two 0.3-mL doses of the Pfizer-BioNTech COVID-19 vaccine 30 mcg/0.3 mL formulation administered 3 weeks apart.

>Adolescents 16 through 17 Years of Age

IM: For primary vaccination, administer two 0.3-mL doses of the Pfizer-BioNTech COVID-19 vaccine 30 mcg/0.3 mL formulation 3 weeks apart.

>Third Primary Dose in Immunocompromised Children ≥ 5 Years of Age†

IM: FDA EUA permits administration of an additional (third) 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. The additional primary dose is 0.2 mL (using the 10 mcg/0.2 mL formulation [orange cap]) in children 5–11 years of age or 0.3 mL (using the 30 mcg/0.3 mL formulation [purple or gray cap]) in adolescents ≥ 12 years of age.

>Homologous Booster Dose in Children ≥ 12 Years of Age†

IM: FDA EUA permits a single 0.3-mL booster dose administered ≥ 5 months after completion of the primary vaccination series in adolescents ≥ 12 years of age.

Adults

Primary Vaccination Series

IM: Two 0.3-mL doses of the vaccine administered 3 weeks apart.

>Third Primary Dose in Immunocompromised Adults†

IM: FDA EUA permits administration of an additional (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.

Homologous Booster Dose†

IM: FDA EUA permits a single 0.3-mL booster dose administered ≥ 5 months after completion of the primary vaccination series in adults.

Heterologous Booster Dose†

IM: FDA EUA permits a single 0.3-mL booster dose administered after completion of a primary vaccination series with another authorized or approved COVID-19 vaccine in adults. When a heterologous booster dose is used, the dosing interval is the same as that authorized for a booster dose of the vaccine product used for primary vaccination.

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]).
- Known (diagnosed) allergy to a component of the vaccine (e.g., PEG).

Warnings/Precautions

Sensitivity Reactions

Hypersensitivity Reactions

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).

Delayed-onset local reactions (e.g., erythema, induration, pruritus, tenderness) around the injection site area reported in some vaccine recipients, after first dose of an mRNA COVID-19 vaccine. 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.

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 have been 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.

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 the mRNA 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.

Known (diagnosed) allergy to a component of the vaccine (e.g., PEG): ACIP considers this a **contraindication** to vaccination with the mRNA 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.

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 the 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.

ACIP states to observe the following individuals for 30 minutes after vaccination: those with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy, those with a contraindication to a different type of COVID-19 vaccine (i.e., viral vector), those with a history of a non-severe, immediate allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of anaphylaxis due to any cause not considered a contraindication; 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 manage immediate allergic reactions (e.g., epinephrine) *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. Immediately treat individuals with suspected anaphylaxis with IM epinephrine.

ACIP interim guidance regarding preparation for and management of anaphylaxis at COVID-19 vaccination sites are available at the CDC website at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html> and <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

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

Lymphadenopathy

Lymphadenopathy reported in clinical trials evaluating COVID-19 vaccine (Pfizer-BioNTech).

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. 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.

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). 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. Observational data have suggested an increased risk with the Moderna COVID-19 vaccine compared with other authorized or approved COVID-19 vaccines.

Data to date indicate that myocarditis and pericarditis following vaccination with an mRNA COVID-19 vaccine have predominantly occurred 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. Although most patients were hospitalized and some required intensive care support, the majority of cases responded to conservative treatment. 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.

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.

Inform individuals receiving an mRNA COVID-19 vaccine, about the possibility of myocarditis or pericarditis after receiving the vaccine and advise them to seek medical care if symptoms occur after vaccination.

If myocarditis or pericarditis occurs after receipt of a COVID-19 vaccine, report the case to VAERS. (See EUA 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 April 24, 2021, 11 cases of cerebral venous sinus thrombosis (CVST) have been reported in recipients of mRNA COVID-19 vaccines (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; 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, 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.

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.

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). ACIP recommends weighing theoretical concerns of dysregulated immune response to SARS-CoV-2 against the known risks of COVID-19 following reinfection and the benefits of protection following COVID-19 vaccination.

ACIP states that individuals with a history of MIS-A or MIS-C may choose to be vaccinated.

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 COVIDvax 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. Current FDA-approved or FDA-authorized COVID-19 vaccines are not live vaccines, so they may be safely administered to immunocompromised individuals.

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

Individuals with Altered Immunocompetence

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

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.

Administration of an additional dose of mRNA COVID-19 vaccine after the initial 2-dose vaccination series may enhance immune responses to the vaccine. Results of a study indicated

that a third dose of the Pfizer-BioNTech COVID-19 vaccine in solid organ transplant recipients is only moderately effective in increasing protective antibody titers in such patients.

Local and systemic adverse effects following administration of the Pfizer-BioNTech COVID-19 vaccine in individuals with chronic, stable HIV infection 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 an additional (third) dose of the vaccine at least 28 days after completion of the initial 2-dose vaccination series in individuals ≥ 5 years of age who are solid organ transplant recipients or diagnosed with conditions considered to have an equivalent level of immunocompromise.

ACIP recommends that individuals who are moderately or severely immunocompromised follow booster recommendations for the general population.

Counsel immunocompromised individuals about the unknown 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.

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 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, antimetabolites, 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.

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.

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 individuals who received the Pfizer-BioNTech or the Moderna COVID-19 vaccines.

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 about the risk of hematoma from IM injections.

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

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

History of Dermal Filler Use

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

ACIP states that individuals who have received injectable dermal fillers may receive COVID-19 vaccination, unless they have a contraindication. Advise such individuals to contact their healthcare provider for evaluation 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 patients.

Limitations of Vaccine Effectiveness

May not protect all vaccine recipients against COVID-19.

Use of COVID-19 vaccines for outbreak management or for postexposure prophylaxis to prevent SARS-CoV-2 infection in individuals with a specific known exposure to the virus is unlikely to be effective, and *not* currently recommended.

The FDA-approved or FDA-authorized COVID-19 vaccines are both efficacious and effective against symptomatic SARS-CoV-2 infection, including severe forms of disease. A substantial amount of data is available that has evaluated the effectiveness of COVID-19 vaccines in real world conditions.

The high vaccine efficacy against symptomatic COVID-19 and other evidence suggests that transmission risk is substantially reduced after vaccination. Vaccination against COVID-19 has substantially reduced the burden of disease in the US through prevention of serious disease in vaccinated individuals and interruption of chains of transmission.

Based on the unknown 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 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. Consult 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.

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.

The immunogenicity of COVID-19 vaccines has been demonstrated through 6 to 8 months after completion of the primary vaccine series. However, waning antibody levels and reduced neutralization of variants have been documented.

Improper Storage and Handling

Improper storage or handling of vaccines may reduce or destroy vaccine potency resulting in inadequate or no immune response in vaccine recipients. 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.

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 uses authorized under the FDA EUA. (See Prevention of Coronavirus Disease 2019 [COVID-19] under Uses.)

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

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

Provide vaccine recipients or their caregivers with information on, and encourage participation in, CDC's voluntary smartphone-based tool (v-safe) that uses text messaging and web surveys to check in with individuals who have received a COVID-19 vaccine to identify potential adverse effects. Information on v-safe is available at <https://www.cdc.gov/vsafe>.

It is mandatory that vaccination providers administering the Pfizer-BioNTech COVID-19 vaccine report all vaccine administration errors (even if not associated with an adverse event) and serious adverse events (irrespective of attribution to vaccination) that occur following vaccination and also report all cases of multisystem inflammatory syndrome (MIS) and COVID-19 that result in hospitalization or death in vaccine recipients to VAERS. Can complete and submit VAERS reports online at <https://vaers.hhs.gov/reportevent.html> or by faxing to 877-721-0366; include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in description section of the report. Obtain additional information on submitting a VAERS report by calling 800-822-7967 or emailing info@vaers.org. To the extent feasible, also provide a copy of the VAERS form to the manufacturer (Pfizer) at <https://www.pfizersafetyreporting.com>, 866-635-8337 (fax), or 800-438-1985 (phone).

Consult FDA fact sheet for healthcare providers 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.cvdvaccine.com>) for requirements and instructions regarding reporting of adverse reactions and vaccination errors.

Interpretation of SARS-CoV-2 Testing in Vaccinated Individuals

Results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests) 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).

Interpretation of Tuberculosis Tests in Vaccinated Individuals

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

If TST or IGRA is required, ACIP states that 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 women who are not pregnant. 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. Early data from VAERS, v-safe active surveillance, and v-safe pregnancy registry have not identified any safety concerns in pregnant women who were vaccinated late in their pregnancy or their infants; additional evidence has not found an increased risk for miscarriage with receipt of a mRNA vaccine before 20 weeks gestation. 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. 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 withhold Rh₀(D) immune globulin when indicated in an individual who is planning to receive or recently received a COVID-19 vaccine. (See Specific Drugs under Interactions.)

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://mothertobaby.org/ongoing-study/covid19-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 that breast-feeding is not a contraindication to 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-authorized 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 16–17 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 in adults. The FDA EUA further permits use of the COVID-19 vaccine (Pfizer-BioNTech) 10 mcg/0.2 mL formulation for prevention of COVID-19 in children 5–11 years of age† based on safety and effectiveness in this age group in addition to data from the adolescent and adult populations.

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

Geriatric Use

Data from the ongoing clinical trial evaluating the Pfizer-BioNTech COVID-19 vaccine indicate 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 data from 12 individuals 65–85 years of age and 306 individuals 18–55 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 18–55 years of age who received a booster dose of the vaccine in the trial.

Common Adverse Effects

Local adverse effects (≥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 (17.8%) 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 0.9% 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 effects 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 effects 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.

Additional (third) primary 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 effects 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 effects 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 through 30 days after the booster dose.

Children 5–11 years of age † who received a 2-dose primary series: Local adverse effects reported in a clinical trial were pain at the injection site (84.3%), injection site redness (26.4%), injection site swelling (20.4%); mean duration of pain at the injection site after second dose was 2.3 days in children. Systemic adverse effects were fatigue (51.7%), headache (38.2%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%). Use of antipyretic or pain medication within 7 days after receiving the first or second vaccine dose was reported in 14.4 or 19.7%, respectively, of these children. No serious adverse events were reported that were considered related to vaccination.

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 ≥1 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

Drug	Interaction	Comments
Antithrombotic agents		ACIP does not recommend taking aspirin or an anticoagulant before

Antiviral agents

Antiviral agents given at any interval before or after COVID-19 vaccination unlikely to impair development of vaccine-induced protective antibody responses

COVID-19 convalescent plasma

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

vaccination with any currently FDA-approved or FDA-authorized COVID-19 vaccine, unless the patient is taking these drugs as part of their routine medications

To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥90 days after such antibody therapy if received for treatment and ≥30 days if received for post-exposure prophylaxis based on estimated half-life of SARS-CoV-2 antibody therapies and evidence suggesting reinfection uncommon in first 90 days after initial infection; however, COVID-19 vaccination not contraindicated in those who received passive antibody therapy within the past 90 days and COVID-19 vaccine doses received <90 days after receipt of passive antibody therapy do not need to be repeated

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

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

May give COVID-19 vaccine concurrently with or at any interval before or after immune globulin or antibody therapies not specific for SARS-CoV-2; ACIP states there is no recommended minimum interval between receipt of antibody therapies not specific for SARS-CoV-2 and COVID-19 vaccination

Immunosuppressive agents (e.g., cancer

Possible decreased or suboptimal antibody

ACIP states that individuals receiving

chemotherapy, corticosteroids, radiation)	<p>responses to vaccines, including the Pfizer-BioNTech COVID-19 vaccine</p> <p>Data insufficient to date to inform optimal timing of COVID-19 vaccination for individuals planning to receive immunosuppressive therapies</p>	<p>immunosuppressive therapy may receive COVID-19 vaccination if they have no contraindications to the vaccine</p> <p>Based on general best practices for vaccination of immunocompromised individuals, ACIP states COVID-19 vaccination should ideally be completed ≥ 2 weeks before initiation or resumption of immunosuppressive therapies whenever possible; consider individual's risks related to their underlying condition and response to the vaccine if making decisions to delay immunosuppressive therapy to complete COVID-19 vaccination</p> <p>Revaccination with a primary vaccine series at least 3 months (12 weeks) after undergoing hematopoietic cell transplant or CAR-T-cell therapy in individuals who previously received doses of COVID-19 vaccine is recommended; an additional primary dose is recommended if the individual is revaccinated with an mRNA COVID-19 vaccine and continues to have moderate or severe immune compromise</p> <p>Corticosteroids given topically or by local injection (e.g., intra-articular, intrabursal, or tendon injection): COVID-19 vaccines may be administered without regard to timing of corticosteroid administration</p> <p>If COVID-19 subsequently develops in a vaccinated individual, ACIP states prior receipt of COVID-19 vaccine should not affect treatment decisions, including use of corticosteroids, or timing of such treatment</p>
SARS-CoV-2-specific monoclonal antibodies (bamlanivimab and etesevimab, casirivimab and imdevimab, sotrovimab)	<p>Data not available; not known whether prior receipt of such antibody therapy interferes with immune response to the vaccine</p>	<p>To avoid potential interference with vaccine immune response, ACIP recommends deferring COVID-19 vaccination for ≥ 90 days after such antibody therapy if</p>

received for treatment and ≥ 30 days if received for post-exposure prophylaxis 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

Prescribing information or the EUA fact sheet for healthcare providers and information provided by CDC and the manufacturer should be consulted for additional information on storage, handling, and stability of the vaccine. Various documents that describe the shipping, storage, and handling requirements and procedures for the Pfizer-BioNTech COVID-19 vaccine, including specifics about temperature requirements and temperature monitoring, thermal shipping containers, ultra-low-temperature freezers, and safe handling of dry ice, are available at <https://www.cvdvaccine.com>.

Compatibility

Parenteral
Solution Compatibility

Compatible
Sodium chloride 0.9%
Incompatible
Bacteriostatic sodium chloride 0.9%

Actions

- Nucleoside-modified mRNA (modRNA) vaccine formulated in lipid nanoparticles (LNPs).
- The modRNA contained in the Pfizer-BioNTech COVID-19 vaccine encodes a membrane-anchored, full-length spike (S) glycoprotein receptor-binding domain (RBD) antigen of SARS-CoV-2 with 2 proline modifications that lock the S protein in an antigenically preferred prefusion conformation. Following IM injection, the LNPs in the vaccine enable delivery of the modRNA into host cells where it is released and translated to the encoded S antigen of SARS-CoV-2. The S antigen is then incorporated into cellular membranes and elicits an immune response to provide protection against SARS-CoV-2.
- Data from clinical trials in adults indicate that a 2-dose vaccination series of the Pfizer-BioNTech COVID-19 vaccine induces SARS-CoV-2 neutralizing titers and S1-binding IgG levels. Antibody responses are evident after first vaccine dose and substantially boosted after second vaccine dose, supporting need for a 2-dose vaccination series. Some evidence from animal studies that the vaccine can elicit strong CD4⁺ and CD8⁺ T-cell responses.
- 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 16–25 years of age. Similarly, data from a separate clinical trial in children 5–11 years of age demonstrated that neutralizing antibody titers achieved after the second dose in such individuals met immunobridging criteria for both geometric mean

antibody titers and seroresponse rates compared to a random sample of individuals 16–25 years of age.

- There are 2 dosage formulations of COVID-19 vaccine (Pfizer-BioNTech) authorized for use, which are provided in 3 different multiple-dose vials, which are distinguished by different colored vial caps and labels. COVID-19 vaccine (Pfizer-BioNTech) labeled as Comirnaty[®] is additionally available in multiple-dose vials.
- For multiple dose vials with purple caps and labels, each 0.3-mL dose contains 30 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2. Each dose of the vaccine also contains LNPs composed of 4 different lipids in a defined ratio (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol) and potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.
- For multiple dose vials with gray caps and labels, each 0.3-mL dose contains 30 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2. Each dose of the vaccine also contains LNPs composed of 4 different lipids in a defined ratio (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol) and tromethamine, tromethamine hydrochloride, and sucrose.
- For multiple dose vials with orange caps and labels, each 0.2-mL dose contains 10 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2. Each dose of the vaccine also contains LNPs composed of 4 different lipids in a defined ratio (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol) and tromethamine, tromethamine hydrochloride, and sucrose.
- All formulations do 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 individuals ≥5 years of age†, an additional (third) primary dose† in certain immunocompromised individuals ≥5 years of age, a homologous booster dose† in individuals ≥12 years of age, and a heterologous booster dose† in individuals ≥18 years of age. Advise them that clinical trials have shown that a 2-dose series of the vaccine can prevent COVID-19; however, the duration of protection following vaccination is unknown and the vaccine may not protect everyone who receives it.
- 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. Provide vaccine recipient or their caregiver with 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).
- Advise vaccine recipients to report any adverse reactions that occur following vaccination to VAERS at 800-822-7967 or <https://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 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) have been 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.
- 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.

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

10 mcg (of modRNA) per
0.2-mL dose

**Pfizer-BioNTech
COVID-19 Vaccine**
(formulated with Tris
buffer; available in
multiple dose vials with
orange caps and labels),
Pfizer

30 mcg (of modRNA) per
0.3-mL dose

Comirnaty[®] (available in
multiple dose vials with
purple caps and labels
or gray caps and labels),
Pfizer

**Pfizer-BioNTech
COVID-19 Vaccine**
(formulated with PBS
buffer; available in
multiple dose vials with
purple caps and labels),
Pfizer

**Pfizer-BioNTech
COVID-19 Vaccine**
(formulated with Tris
buffer; available in
multiple dose vials with
gray caps and labels),
Pfizer

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

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