Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary

General Information

Vaccine: COVID-19 vaccine (Pfizer)

Diluent: 0.9% sodium chloride (normal saline, preservative-free)

Multidose vial: Up to 6 doses per vial

Dosage: 0.3 mL

Vaccine MUST be mixed with diluent before administration.

Age Indications

16 years of age and older

Schedule

2-dose series separated by 21 days
A series started with COVID-19 vaccine (Pfizer) should be completed with this product.

Administer

Intramuscular (IM) injection in the deltoid muscle

Thawing Frozen Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature. Do **NOT** refreeze thawed vaccine.
- **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)
  - 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
  - Fewer number of vials will take less time.
- **Room temperature:** Up to 25°C (77°F) between 30 minutes and 2 hours
  - Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.

Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*	
Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing. After 2 hours, return unmixed vials to the refrigerator.	
Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent. The expiration date for the diluent and the vaccine is located on the vial.	
With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial**. If the vial is shaken, discard the vaccine. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.	10x
Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent. Do **NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.	1.8 ml
Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.	
Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.	
Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake**. If the vial is shaken, discard the vaccine.	10x
Note the date and time the vaccine was mixed on the vial.	
Keep mixed vaccine at room temperature (2°C to 25°C [36°F to 77°F]) and administer within 6 hours. **Discard any unused vaccine after 6 hours.** Do not return to refrigerator or freezer storage.	

*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

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Administer the Vaccine

Assess recipient status:
- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If all low-dead syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringe (e.g., 3 low dead-volume syringes and 3 non-low dead-volume syringes) per vial.

Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe.
- If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents.
- Do not combine vaccine from multiple vials to obtain a dose.

Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine, unless contaminated or damaged. Ensure the prepared syringe is not cold to the touch.

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.

Observe recipients after vaccination for an immediate adverse reaction:
- **30 minutes:** Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
- **15 minutes:** All other persons

*Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

Scheduling Doses

Vaccination History*‡	And	Then	Next Dose Due
0 doses	→	Give dose 1 today	Give dose 2 at least 21 days after dose 1
1 dose (Pfizer)	It has been at least 21 days since dose 1	Give dose 2 today	Series complete; no additional doses needed
	It has not been at least 21 days from dose 1	No dose today	Give dose 2 at least 21 days after dose 1†
2 doses (Pfizer) at least 21 days apart†	→	→	Series complete; no additional doses needed
2 doses (1 product unknown) at least 28 days apart†	→	→	Series complete; no additional doses needed

*mRNA COVID-19 vaccines should not be administered at the same time as other vaccines. Separate mRNA COVID-19 vaccines from other vaccines by 14 days before or after the administration of mRNA COVID-19 vaccine.

‡ Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.

†Second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are considered valid. Doses inadvertently administered earlier than the grace period should not be repeated. Additionally, if it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, you may schedule the second dose up to 6 weeks (42 days) after the first dose.

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Contraindications and Precautions

Contraindications:

- Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine
- Immediate allergic reaction* of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [PEG†]). See Table 1 of vaccine components on page 4.
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG†)

Precautions:

- History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
  - This includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another vaccine component, or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction.
  - This does NOT include subcutaneous immunotherapy for allergies ("allergy shots").
- Moderate to severe acute illness

Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

Document each recipient's vaccine administration information in the:

- **Medical record:**
  - Vaccine and the date it was administered
  - Manufacturer and lot number
  - Vaccination site and route
  - Name and title of the person administering the vaccine
- **Personal vaccination record card (shot card):** Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
- **Immunization information system (IIS) or "registry":** Report the vaccination to the appropriate state/local IIS.

Management of Anaphylaxis

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine. Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times. Equipment and medications should be available, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.

For more information, please see IInterim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.

Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at www.cvdvaccine.com.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

†These persons should not receive mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna) at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

»Table 1: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

An immediate allergic reaction to any component or previous dose of an mRNA COVID-19 vaccine is a contraindication to vaccination with both the Pfizer-BioNTech and Moderna vaccines. The following is a list of ingredients for the Pfizer-BioNTech https://www.fda.gov/media/144413/download and Moderna COVID-19 vaccines https://www.fda.gov/media/144637/download, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

*Neither vaccine contains eggs, gelatin, latex, or preservatives.

Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called "pegylation" to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity can occur between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur.

Information on whether a medication contains PEG, a PEG derivative, or polysorbates as either active or inactive ingredients can be found in the package insert. The National Institutes of Health DailyMed database (https://dailymed.nlm.nih.gov/dailymed/index.cfm) may also be used as a resource. As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in CDC's Vaccine Excipient Summary [https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf]). Medications that contain PEG and/or polysorbate are also described in the supplementary materials of Stone CA, et al. Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized. *The Journal of Allergy and Clinical Immunology: In Practice* 7.5 (2019): 1533–1540. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf