

12 Years of Age and Older (Purple Cap) Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary



General Information

Vaccine: Pfizer-BioNTech, 12 years of age and older (purple cap)

Use the correct formulation based on the age of the recipient

Diluent: 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Prepare the vaccine using a NEW vial of diluent EVERYTIME. Discard the diluent vial and remaining diluent after mixing the vaccine.

Age Indications

12 years of age and older

Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator or at room temperature:
 - **Refrigerator:** Between 2°C and 8°C (36°F and 46°F)
Unpunctured vials may be stored in the refrigerator for up to 1 month (31 days).
 - **Room temperature (for immediate use):** Up to 25°C (77°F)
Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.

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 storage unit. **Check the vial label to ensure it is the correct formulation based on the age of the recipient. The vial for persons 12 years of age and older has a purple cap and purple border on the label.** Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing.



Before mixing, check the:

- expiration date on the vaccine and diluent
- any beyond-use dates/times

NEVER use expired vaccine or diluent. **NEVER** use vaccine after the beyond-use date or times.



- **Do NOT** refreeze thawed vaccine.
- Use vials in the refrigerator before removing vials from ultra-cold temperature or freezer storage.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

Schedule for Primary Series and Booster Dose

- 2-dose series separated by 21 days*
- Moderately and severely immunocompromised people: Administer an additional Pfizer-BioNTech dose at least 28 days after the initial 2-dose primary series.*
- A primary series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product.
- A booster dose, at least 6 calendar months after the last dose of a COVID-19 mRNA primary series[†] (i.e., after the 2nd dose or after the additional [3rd] dose for moderately or severely immunocompromised persons)
 - Should be given to persons 18 years of age and older (use of heterologous – mix and match – booster doses is allowed; however, mRNA COVID-19 vaccines are preferred)
 - May be given to persons 16 and 17 years of age based on their individual benefits and risks

Administration

Intramuscular (IM) injection in the deltoid muscle

With the vaccine at room temperature, gently invert vial 10 times. **Do not shake the vial.** If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.



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 every time. **Do NOT** use bacteriostatic normal saline or other diluents to mix the vaccine.



* For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>.

† Persons vaccinated with Janssen COVID-19 Vaccine: Administer a booster dose at least 2 months (8 weeks) after primary dose 1.

‡ 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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Prepare the Vaccine Continued

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, contact the manufacturer.



Note the date and time the vaccine was mixed on the vial.



Keep mixed vaccine between 2°C and 25°C (36°F to 77°F), minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Administer within 6 hours.

Discard any unused vaccine after 6 hours. Do not return to freezer storage.



Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.



Choose the correct equipment, including the correct needle size.

- Use a new, sterile needle and syringe for each injection. Use low dead-volume syringes/needles to extract 6 doses from a single vial. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes per vial (e.g., 4 low dead-volume syringes and 2 non-low dead-volume syringes).



- **The vial for persons 12 years of age and older has a purple cap and may have a purple border on the label.** Do NOT administer vaccine with an orange cap or has an orange bordered label on the 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.



- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.3 mL.
- 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 significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine. 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.



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).



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:
 - » A contraindication to another type of COVID-19 vaccine product
 - » Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine
 - » Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
 - » Anaphylaxis due to any cause
- **15 minutes:** All other persons

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

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Dose Scheduling for Primary Series

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-BioNTech COVID-19 Vaccine)	It has been at least 21 days since dose 1	Give dose 2 today	<ul style="list-style-type: none"> Persons 12–15 years of age: Series complete; no more doses needed at this time[§] Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster dose 6 months after completion of primary series (or additional primary dose) based on individual benefits and risks Persons 18 years of age and older: Administer booster dose 6 months after completion of primary series (or additional primary dose)[¶]
	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-BioNTech COVID-19 Vaccine) at least 21 days apart‡			<ul style="list-style-type: none"> Persons 12–15 years of age: Series complete; no more doses needed at this time[§] Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster dose 6 months after completion of primary series (or additional primary dose) based on individual benefits and risks Persons 18 years of age and older: Administer booster dose 6 months after completion of primary series (or additional primary dose)[¶]
2 doses (1 product unknown) at least 28 days apart †			<ul style="list-style-type: none"> Persons 12–15 years of age: Series complete; no more doses needed at this time[§] Persons 16 and 17 year of age: May receive a Pfizer-BioNTech booster dose 6 months after completion of primary series (or additional primary dose) based on individual benefits and risks Persons 18 years of age and older: Administer booster dose 6 months after completion of primary series (or additional primary dose)[¶]

* COVID-19 vaccines may be coadministered with other vaccines, including simultaneous administration. When deciding whether to administer COVID-19 vaccines and other vaccines, providers should consider whether the person is behind or at risk of becoming behind on recommended vaccines. They should also consider the person's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

† Every effort should be made to determine which vaccine product was received as the first dose. In exceptional situations in which the vaccine product given for the first dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at least 28 days after the first dose.

‡ **Administer the second dose as close as possible to the recommended interval (21 days).** It is not necessary to restart the series if the dose is given after the recommended interval. Primary series doses inadvertently administered before the 4-day grace period (i.e., less than 17 days apart) should be repeated.

§ Moderately or severely immunocompromised persons should receive an additional primary series dose (3rd) at least 28 days after completion of a 2-dose primary series.

¶ The booster dose may be a different product than the primary series. An mRNA COVID-19 vaccine is preferred.

Contraindications and Precautions

Contraindications:

History of a:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C> for a list of vaccine components)

Precautions:

- Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
- Immediate allergic reaction** to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
 - This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine

** 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.

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- Contradiction to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen)*
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- 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.

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

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.

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>

* Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax Project (<https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html>). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 Vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.