Centers for Disease Control and Prevention

Pfizer-BioNTech COVID-19 Vaccine (Purple Cap) Age 12 and Over

CDC has updated its recommendations for COVID-19 vaccines with a preference for people to receive an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna). Read CDC's media statement.

Information specific to the Pfizer BioNTech COVID-19 Vaccine for children 5-11 years of age

Summary of Recent Changes and Updates

Webpage content and individual PDFs are updated when there's new guidance concerning the Pfizer-BioNTech COVID-19 Vaccine. Expand each section below to see a summary of new and updated items.

General Information Updates

Updates on 12/21/2021

- Pfizer materials have been updated to include the updated Interim Clinical Considerations for the Use of COVID-19 Vaccines Currently Authorized in the United States posted on December 17, 2021. This includes new materials for the Pfizer-BioNTech COVID-19 vaccine formulation for 12 years of age and older (gray cap).

Preparation and Administration Information Updates

Updates on 12/21/2021

The following have been updated to reference the Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States: December 17, 2021

- Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary for Persons 12 years of age and older (purple cap)
- Pfizer-BioNTech COVID-19 Vaccine Standing Orders for Persons 12 years of age and older (purple cap)

Materials for Pfizer-BioNTech COVID-19 Vaccine 12 years of age and older (gray cap) formulation have been added:

- Standing orders
- Preparation and administration summary

Storage and Handling Information Updates

Updates on 12/21/2021

Materials for Pfizer-BioNTech COVID-19 Vaccine 12 years of age and older (gray cap) formulation have been added:

- Beyond-use date labels
- Storage and handling labels
- Storage and handling summary

General Pfizer-BioNTech Vaccine Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine (purple cap)

Diluent: 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free)
Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Dosing Information

Vaccine MUST be mixed with diluent before administration Prepare the vaccine using a NEW vial of diluent EVERYTIME. Discard the diluent vial and remaining diluent after mixing the vaccine.
Multidose vial: Up to 6 doses per vial
Dosage: 0.3 mL

Age Indications

12 years of age and older

Schedule for Primary Series and Booster Dose

Primary Series:

2-dose series separated by 21 days*
A series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product

Additional Primary Dose:

Moderately and severely immunocompromised people: Administer an additional primary dose at least 28 days after the initial 2-dose primary series.

Booster Dose:
Administer a booster dose at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., the 2nd dose or additional primary series dose for moderately or severely immunocompromised people).

- Should be given to people 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 people 16 and 17 years of age based on their individual benefits and risks

Administration

Intramuscular (IM) injection in the deltoid muscle

- Emergency Use Authorization (EUA)
- Emergency Use Instructions (EUI)
- Interim Clinical Considerations
- Pfizer BioNTech COVID-19 Vaccine by Age and Cap Color
- Pfizer BioNTech Covid-19 Vaccine FAQs
- ACIP Recommendations

Get the Pfizer-BioNTech COVID-19 Vaccine Training Module for Healthcare Professionals

Administration Overview

Before administering vaccine, screen recipients for contraindications and precautions, even if the recipient is schedule to receive the second dose. The recipient's health condition or recommendations regarding contraindications and precautions for vaccination may change from one visit to the next.

To assess recipients correctly and consistently, vaccination providers should use a standardized, comprehensive screening tool.

Contraindications and Precautions

What are the 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

Precautions

- History of an immediate allergic reaction†to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes non-COVID-19 vaccines or injectable therapies with multiple components, and the component(s) that elicited the reaction is unknown.
- History of an immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Contraindication to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen) ±
- Moderate to severe acute illness

†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

a vaccine or medication.

± 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 COVID vax Project. 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.

How to Thaw, Prepare, and Administer the Pfizer-BioNTech Vaccine

How to Thaw the Vaccine

- Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C and 8°C (36°F and 46°F)
  - Unpunctured vials can be stored in the refrigerator for up to 1 month (31 days).
- Room temperature: Up to 25°C (77°F)
  - Unpunctured vials may be held at room temperature for up to 2 hours (including thaw time).
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

How to Prepare the Vaccine

1. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
2. Remove vaccine from the freezer or refrigerator. **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 boarder on the label.** 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.
3. Before mixing check the:
   - Expiration date on the vaccine and diluent
   - Any beyond use dates or times
   - NEVER use expired vaccine or diluent
   - NEVER use vaccine after the beyond-use dates or times
4. With the vaccine at room temperature, gently invert the 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.
5. Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials.
6. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL**of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. After use, discard diluent vial and any remaining diluent.
   - Do NOT use or save the remaining diluent to mix additional vaccine or for other uses.
   - Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.

7. Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.
8. Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.
9. 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 If the vial is shaken, contact the manufacturer.
10. Note the date and time the vaccine was mixed on the vial.
11. Keep mixed vaccine between 2°C and 25°C (36°F and 77°F) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to freezer storage.
    - Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
12. Choose the correct vaccine formulation based on the age of the recipient and equipment, including the correct needle size.
    - The vial for persons 12 years of age and older that must be diluted has a purple cap and may have a purple border on the label. Do NOT administer vaccine with an orange cap or orange bordered label on the vial.
    - Use a new, sterile needle and syringe for each injection.
    - Low dead-volume syringes/needles can be used to extract 6 doses from a vial. If all low dead-volume syringes are not available use a combination of low dead-volume syringes and non-low dead-volume syringes.
13. 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. Ensure the prepared syringe is not cold to the touch.
    - Regardless of the type of syringe used, ensure the amount of vaccine in the syringe is 0.3mL.
    - If the amount of vaccine remaining in the vial cannot provide a full 0.3mL dose discard the vial and contents.
    - Do NOT combine vaccine from multiple vials to obtain a dose.
14. 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, unless contaminated or damaged. Check the vial label, again, to ensure it is the correct formulation based on the age of the recipient.

*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.

†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.

How to Administer the Vaccine

1. Assess recipient status:
    - Screen for contraindications and precautions.
    - Review vaccination history.
    - Review medical considerations.
2. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration. **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 boarded label on the vial.
3. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients (if tolerated).
4. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
5. 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 non-COVID-10 vaccine or injectable therapies
        - 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

*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

- Persons age 12 years and older should receive **2 doses at least 21 days apart**.
    - **Second doses should be administered as close to the recommended interval as possible.**
        - Doses inadvertently given before the 4-day grace period (i.e., less than 17 days apart) should be repeated.
    - Both doses should be Pfizer-BioNTech COVID-19 Vaccine.
        - Every effort should be made to determine which vaccine product was received as the first dose.
        - In exceptional situations, if the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- Moderately to severely immunocompromised people: Administer an additional dose at least 28 days after the initial 2-dose primary series.
    - For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- Administer a booster dose at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., the 2nd dose or additional primary series dose for moderately or severely immunocompromised people).
    - Should be given to people 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 people 16 and 17 years of age based on their individual benefits and risks
- COVID-19 vaccines and other vaccines may be coadministered with other vaccines, including simultaneous administration.

COVID-19 Vaccine (Pfizer) Administration Resources

Pfizer COVID-19 Vaccine Standing Orders (12 years of age and older) (updated 12/22/21)

Preparation and Administration Summary (updated 12/22/21)

Preparation Infographic

Vaccine administration training and clinical materials

Examples of Workers Who May Get Pfizer-BioNTech Booster Shots

Pfizer-BioNTech COVID-19 Vaccine Dosage Chart

Prevaccination Screening Form

Download a prevaccination checklist in multiple languages.

English | Spanish

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 for the jurisdiction (i.e., immunization information system) as soon as practicable and no later than 72 hours after administration.

Storage and Handling Overview

Store vaccine in an ultra-cold freezer, freezer, thermal shipping container, or refrigerator.
See guidance below for each storage unit.

- Vaccine will arrive at a temperature between -90°C and -60°C (-130°F to -76°F) in a thermal shipping container with dry ice. The vial for people 12 years of age and older has a purple cap and purple border on the label.
- Diluent and an ancillary supply kits will arrive separately from the vaccine.
- Unpack the thermal shipping container following the manufacturer's directions .

How to Store the Pfizer-BioNTech COVID-19 Vaccine

Storing in the Thermal Shipping Container

CDC recommends using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance.

Use the Controlant temperature monitoring device (TMD), included with the thermal shipping container, to monitor the temperature.

- Review contact information.
  - If the contact for your order (inVTrckS) is not valid, you will NOT be notified in the event of a temperature excursion. Contact your jurisdiction's immunization program for assistance.
  - If your contact is valid and you are not receiving e-mails or cannot load email hyperlinks, refer to Controlant for troubleshooting.
  - Identify up to 4 contacts to receive e-mails and text alerts on the temperature status of the container.
- Review **DAILY**e-mails on the status of the container.
- Click the link in daily emails to access and download all temperature data. Save the Excel file summarizing all temperature data for at least 3 years.
- Save the return shipping label provided in your shipping container at delivery. Use the shipping label to return the thermal shipping container with the Controlant TMD within 10 days.*

Limit temporary storage in the thermal shipping container to 10 days when possible.*

- Arrange for dry ice to maintain the appropriate temperature in the thermal shipping container. Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days thereafter. Follow manufacturer's guidance for adding dry ice.
- Dry ice will NOT be provided to replenish the container.
- Transfer any vaccine remaining in the thermal shipping container after 10 days* to a:
  - Freezer for up to 2 weeks, then
  - Refrigerator for up to 1 month (31 days)

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.

Store vaccine vials upright in the tray and protect from light.

*It is preferred to return the shipping container within 10 days; however, if maintained properly, the thermal shipping container can be used for up to 30 days.

Storing in an Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -90^{0}C and -60^{0}C (-130^{0}F and -76^{0}F).

Vaccine may be stored until the expiration date. The expiration date could be extended as more stability data become available. Store vaccine vials upright in the tray and protect from light.

Storing in the Freezer

Before mixing, vaccine may be stored in a freezer between -25°C and -15°C (-13°F to 5°F) for up to 2 weeks. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks. Use CDC's beyond-use date labels to track how long the vaccine has been in the freezer.

- These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.

Store vaccine vials upright in the tray and protect from light.

Vials stored in the freezer can be transferred to the refrigerator for up to 1 month (31 days). Once thawed, they cannot be refrozen.

Vials stored in the freezer can be returned one time to ultra-cold temperature storage. Once returned, the 2-week time frame is suspended.

Storing in the Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2^{0}C and 8^{0}C (36^{0}F and 46^{0}F) for up to 1 month (31 days). After one month (31 days), remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.

Use beyond-use date labels to track how long the vaccine has been in the refrigerator.

Thawed vaccine cannot be refrozen.

Monitoring Temperature

Ultra-cold freezer, freezer, refrigerator: Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Frozen and refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

- **Option 1 (preferred): Minimum/Maximum (Min/Max) Temperatures** Most DDLs display min/max temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: Current Temperature**If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

Thermal shipping container: Use the Controlant temperature monitoring device.

For CDC temperature logs, see Storage and Handling Resources below.

Storing Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

Temperature Excursions

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges is considered a temperature excursion. Responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Completing the Vaccine Troubleshooting Record can help provide needed information for manufacturers to determine the viability of the vaccine.

COVID-19 Vaccine (Pfizer) Storage and Handling Resources

- Transporting The Vaccine
- Transport Temperature Log
- Storage and Handling Summary
- Pfizer BUD Guidance and Labels
- Storage and Handling Labels
- Vaccine Expiration Date Tracking Tool
- Freezer Storage Temperature Log (Fahrenheit) (new)
- Freezer Storage Temperature Log (Celsius) (new)
- Refrigerator Storage Temperature Log (Celsius)
- Refrigerator Storage Temperature Log (Fahrenheit)
- Ultra-Cold Vaccine Storage Temperature Log (Fahrenheit)
- Ultra-Cold Vaccine Storage Temperature Log (Celsius)
- Vaccine Storage Troubleshooting Record for Temperature Excursions
- Dry Ice Safety

Report Adverse Events

Adverse events that occur in a recipient after COVID-19 vaccination are required to be reported to the Vaccine Adverse Event Reporting System (VAERS). FDA requires vaccination providers to report vaccine administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after

What to Expect after a COVID-19 Vaccination

Print information for your patients on common side effects, helpful tips, and when to call a doctor after a COVID-19 vaccination.

Get Email Updates

To receive email updates about this page, enter your

administration of COVID-19 vaccine under an EUA. Reporting is encouraged for other clinically significant adverse events, even if it is not clear that a vaccine caused the adverse event. Complete and submit reports to VAERS online .

For further assistance with reporting to VAERS, call 1-800-822-7967.

email address:

Email Address

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