

Appendix A: COVID-19 Ultra-Cold Temperature Vaccine(s)

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Read the full provider guide: [Interim COVID-19 Vaccine Provider Guide \(www.health.state.mn.us/diseases/coronavirus/vaccine/guide.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/guide.pdf).

Pfizer-BioNTech COVID-19 Vaccine

Summary of Pfizer vaccine

Age indication	Dose/route	Schedule	Presentation/preparation	Storage and handling	Notes
16 years and older	0.3 mL IM	0, 21 days	Multi-dose: up to 6 doses per vial* Reconstitute with diluent; diluent ships separately from vaccine.	<p>Ultra-cold freezer (-80°C to -60°C/-112°F to -76°F): up to 6 months.</p> <p>Thermal shipper: (-90°C to -60°C /-130°F to -76°F): up to 30 days from delivery, if replenished with dry ice upon receipt and every five days.</p> <p>Refrigerator: (2 to 8°C/36°F to 46°F): up to 120 hours (five days). If not used, discard.</p> <p>Room temperature: Thawed vials must be reconstituted within two hours. Once reconstituted, must use within six hours (discard unused vaccine).</p>	<p>Not interchangeable with other COVID-19 vaccines.</p> <p>Use vaccine within 6 hours once vial is punctured.</p> <p>Cannot place thawed vaccine back in ultra-cold storage.</p>

*The Pfizer-BioNTech COVID-19 vaccine multi-dose vial may contain up to six doses of 0.3 milliliter (mL). Low dead-volume syringes and/or needles can be used to extract up to six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Each dose must contain 0.3 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials. If you need additional ancillary supplies, email health.mdhvaccine@state.mn.us.

Refer to Fact Sheet for Healthcare Providers Administering Vaccine at [Pfizer-BioNTech COVID-19 Vaccine Resources \(www.cvdvaccine-us.com/resources\)](https://www.cvdvaccine-us.com/resources).

Find more information from FDA on doses in Pfizer-BioNTech vaccine vials at [Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions \(www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions\)](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions).

Shipping

Ultra-cold vaccine will be shipped from the manufacturer in thermal shippers packed with dry ice. In addition to vaccine, each site will receive ancillary kits and an initial dry ice resupply. Each shipper will have a GPS-enabled temperature monitoring device (logger) that the manufacturer uses to track the vaccine and monitor for out-of-range temperatures.

- The thermal shipping container has about 23 kilograms of dry ice and is estimated to weigh about 36 kilograms (81 pounds). It is not recommended to transport vaccine in the shipping container to alternate sites.
- The shipping container needs to be returned to the manufacturer after 30 days, along with the GPS logger. Instructions will be included inside the container.

Upon thermal shipper arrival:

- Work in a well-ventilated area before opening the shipper and when working with dry ice.
- Never handle dry ice with bare hands. Wear waterproof insulated (cryogenic) gloves and safety glasses with side shields or safety goggles to remove the dry ice pod from the shipper.
 - Review the Dry Ice Safety Data Sheet included with the shipper. Read more on dry ice safety at [CDC: Pfizer-BioNTech COVID-19 Vaccine \(www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html).
 - Dry ice disposal: Once you are done with the shipper, open the container and leave it at room temperature in a well-ventilated area where the dry ice will change from a solid to a gas.
 - **Do not** leave dry ice in an unattended area.
 - **Do not** place dry ice in a drain or flush down a toilet.
 - **Do not** place dry ice in a closed area.
- Open and unpack the shipper, following manufacturer's instructions.
 - **CAUTION:** During the unpacking process, you might feel resistance when trying to remove the box that holds the vial trays. Do not apply force to remove the box. Use the two bands wrapped around each vial tray to remove the trays from the thermal shipping container.
 - **Press and hold the stop button for 5 seconds** on the temperature monitoring device.

- Inspect the vaccine shipment upon receiving it and complete the inspection in less than five minutes. After that, the shipper can be opened only twice per day, for no more than three minutes each time.
 - Confirm quantity and that vials are not broken.
- If you have an ultra-cold temperature freezer available, transfer closed-lid vial trays (containing 195 vials) from the shipper to the unit. These trays may be at room temperature (less than 25 degrees Celsius/77 degrees Fahrenheit) **for up to five minutes** for transfer between ultra-cold temperature environments.
 - Open-lid vial trays or vial trays that contain less than 195 vials removed from ultra-cold storage (less than minus 60 degrees Celsius/minus 76 degrees Fahrenheit) may be at room temperature (less than 25 degrees Celsius/77 degrees Fahrenheit) **for up to three minutes** for transfer between ultra-cold temperature environments.
 - After vial trays are returned to ultra-cold storage following exposure to room temperature, **they must remain in frozen storage for at least two hours** before they can be removed again.
 - Once vaccine is moved out of the shipper into an ultra-cold temperature freezer, the temperature monitoring device from the shipper cannot be used in the ultra-cold freezer. A digital data logger (or other appropriate monitoring method) must be used.
- If using the thermal shipper for temporary vaccine storage, refer to manufacturer instructions. Review Pfizer BioNTech vaccine thermal shipper materials at [Pfizer-BioNTech COVID-19 Vaccine Resources \(www.cvdvaccine-us.com/resources\)](http://www.cvdvaccine-us.com/resources).
 - To use the Controlant Real-Time Monitor that came with the thermal shipper, contact Controlant customer service at 701-540-4039.

Large quantity orders (for larger provider sites only)

- Minimum order: 975 doses.
- Maximum order: about 4,875 doses.

Storage and temperature monitoring

Storing and handling ultra-cold COVID-19 vaccine correctly is very important. If the cold chain is not properly maintained, vaccine may be damaged and unusable. There are four acceptable vaccine handling timelines to ensure viable vaccine. **Sites must strictly follow the timelines below during redistribution and off-site vaccination.**

- Option 1: Place vaccine in an ultra-cold temperature freezer where it is stable at minus 80 to minus 60 degrees Celsius (minus 112 to minus 76 degrees Fahrenheit) for up to six months. Use a continuous temperature monitoring device to check the temperature.
- Option 2: Maximize use of the thermal shipping container by re-icing with dry ice within 24 hours of receiving the ultra-cold vaccine. Re-ice at a minimum of every five days (based on normal use) making sure dry ice consistently refilled to the top of the container. Vaccine in the shipper should

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be stored at minus 90 to minus 60 degrees Celsius (minus 130 to minus 76 degrees Fahrenheit). Storage within this temperature range is not considered an excursion from the recommended storage condition. On day 30, place the vaccine in the refrigerator at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit), where it is stable for 120 hours/five days. Vaccine can be stored for 35 days total (30 days in shipper at ultra-cold temperatures plus 5 days at refrigerated temperatures).

- If your site does not have a standard way to access dry ice, email Health.R-LSC@state.mn.us. You will need to provide at least 48 hours' notice for delivery. Please provide the following information:
 - Name of facility
 - Shipping address
 - Amount of dry ice needed
 - Date needed (at least 48 hours' notice required)
 - Point of contact (POC) name, phone number, and email
- If you are using the shipping container as temporary storage, refer to the re-icing guidelines packed in the original thermal container for instructions. **You cannot open the shipping container more than twice per day and for no longer than three minutes each time.** If the shipper is left open longer than three minutes, the recommendation is to re-ice more frequently, as needed. You are required to keep a log of when the shipping container is opened.
- You must use a continuous temperature monitoring device to ensure the temperature in the thermal shipping container is stable. If you do not have a monitor on-site, you can reactivate the continuous temperature monitoring device that comes in the manufacturer shipper.
- **Option 3:** Re-ice the thermal shipping container with dry ice within 24 hours of receiving ultra-cold vaccine. After five days, place the ultra-cold vaccine in the refrigerator at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit), where it is stable for 120 hours/five days. Vaccine can be stored for no more than 10 days total.
- **Option 4:** Immediately place vaccine in the refrigerator at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit). Vaccine can be stored for no more than five days total.

Providers must report all temperature excursions (any out-of-range temperatures) to MDH in a timely manner.

For more information about COVID-19 vaccine storage and handling, please see CDC's COVID-19 Vaccine Storage and Handling Addendum in the [CDC: Vaccine Storage and Handling Toolkit \(www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf\)](http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf).

Redistribution

MDH has specific guidance for Pfizer BioNTech vaccine if it is to be redistributed to another site. Please find more information at [COVID-19 Vaccine: Redistribution and Off-site Vaccination Guide \(www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf\)](http://www.health.state.mn.us/diseases/coronavirus/vaccine/vaxredistribution.pdf).

Vaccine exposed to out-of-range temperatures should not be used until the manufacturer is contacted about the viability of the vaccine. Refer to the Managing out-of-range temperatures (excursions) section in the provider guide.

Vaccine Recommendations for Pfizer BioNTech COVID-19 vaccine

- Pfizer BioNTech COVID-19 vaccine is a two-dose series administered 3 weeks apart (Days 0 and 21).
- Every attempt should be made to schedule the person to return 21 days or shortly thereafter for their second dose. Schedule the appointment for the second dose when the person receives their first dose.
- With this vaccine, there is a four-day grace period for the second Pfizer BioNTech dose (i.e., day 17-21) where the dose will be considered valid.
- If it has been more than 21 days since the first dose, the second dose should be administered at the earliest opportunity (but no doses need to be repeated).
- Pfizer BioNTech vaccine is not interchangeable with other COVID-19 vaccine products.
 - If two doses of different mRNA COVID-19 products are inadvertently administered, no other additional doses of either vaccine is recommended at this time.
- Pfizer BioNTech COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration of any other vaccines.
 - If this vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Refer to the recommendations for mRNA COVID-19 vaccines in the full provider guide for information on people with current or prior history of COVID-19 infection and special populations.

Contraindications and precautions

Refer to the Contraindications and Precautions sections in the main guide for more information regarding adverse reactions.

Ingredient listing for Pfizer-BioNTech BNT162b2 COVID-19 Vaccine

Each dose of the Pfizer-BioNTech BNT162b2 COVID-19 Vaccine includes the following ingredients:

- lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- 0.05 mg 2[(polyethylene glycol)-2000]- N,N-ditetradecylacetamide
- 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol
 - 0.01 mg potassium chloride
 - 0.01 mg monobasic potassium phosphate
- 0.36 mg sodium chloride

- 0.07 mg dibasic sodium phosphate dihydrate
- 6 mg sucrose

More information:

- Diluent: 0.9% Sodium Chloride Injection, USP
- The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative.
- The vial stoppers are not made with natural rubber latex.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION PFIZER-BIONTECH COVID-19 VACCINE* found in [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers \(www.fda.gov/media/144413/download\)](https://www.fda.gov/media/144413/download).

Appropriate medical treatment used to manage immediate allergic reactions (e.g., epinephrine) must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following the administration of vaccine. Refer to the Allergic reaction (anaphylaxis) section in the provider guide.

Potential side effects (adverse events)

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, redness, and/or swelling; fatigue (feeling tired); headache; muscle pain; chills; joint pain; fever; nausea; malaise; and lymphadenopathy (swollen glands).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Vaccine preparation

Overview

- Each multi-dose vial must be reconstituted with 1.8 milliliters 0.9% sodium chloride injection (normal saline) before using. Use the diluent that is provided.
- After reconstitution, each **preservative-free** multi-dose vial has enough volume for six 30 microgram doses in 0.3 milliliter injections.
 - See note on the first page of this appendix for information on number of doses in a vial.
- Administer the vaccine via an intramuscular route.
- All doses in a multi-dose vial must be administered within six hours of reconstitution. **Discard any unused vaccine six hours after reconstitution.**

Thawing vials

It is important to plan how to thaw your vials and administer vaccine to avoid wasting vaccine. Before taking vaccine out of the ultra-cold temperature storage unit or thermal shipper, ensure you will have the correct quantities to vaccinate your population. Once the ultra-cold vaccine is removed from ultra-cold temperature storage (either to the fridge or to room temperature), it must be used within a certain amount of time and cannot be returned to ultra-cold storage or the thermal shipper once thawed.

Follow these instructions:

- Plan your day: You need one multi-dose vial for every five to six people, depending on your needle and syringe. Plan to have several people on stand-by to be vaccinated in case you have no-shows.
- When removing a tray from the thermal shipper, remember to minimize the time the shipper is open. It can be opened only twice a day, for no more than three minutes at a time.
 - If less than a full tray is needed, remove the number of vials needed from the tray as quickly as possible and return the tray to frozen storage.
 - Trays should not be exposed to room temperature for more than a few minutes, as the vials can thaw very quickly.
- Thawed or reconstituted vaccine can be handled in normal room light. Avoid exposure to direct sunlight or ultraviolet light.
- Gloves allowing manual dexterity should be worn while handling frozen vials (i.e., unsterile gloves in the correct size). It is not necessary to use insulated (cryogenic) gloves to handle vials.
- Thawing methods for Pfizer-BioNTech COVID-19 vaccine:
 - Transfer the frozen vials immediately to a refrigerator at 2 to 8 degrees Celsius (36 to 46 degrees Fahrenheit). An entire tray will take about three hours to thaw; a smaller number of vials may thaw more quickly.
 - Vials may be stored in the refrigerator prior to reconstitution for up to 120 hours (five days). If the vaccine is not used within five days, it must be discarded.
 - Vials needed for immediate use can be removed directly from ultra-cold storage and thawed at room temperature (up to 25 degrees Celsius or 77 degrees Fahrenheit) for 30 minutes prior to reconstitution.
 - Using either thawing method, vials must reach room temperature before reconstitution and must be reconstituted within 2 hours. Do not place thawed vaccine back into ultra-cold temperature storage or the thermal shipper.

Diluent

As with other vaccines that require reconstitution, this vaccine must use only the diluent specified by the manufacturer. Diluent (2 milliliters) will be provided in the mixing kit (along with syringes, needles, and other needed supplies). Store diluent at room temperature.

- Reconstitute each thawed vial with exactly 1.8 milliliters of 0.9% sodium chloride injection, USP.

- DO NOT use bacteriostatic saline or other diluents.
- The optimal diluent vial size is 2 milliliters of 0.9% sodium chloride injection.
 - **IMPORTANT:** If using a larger volume vial of 0.9% sodium chloride injection, you can use it **only once** for reconstitution (i.e., after removing 1.8 milliliters, discard remaining diluent).

Reconstitution steps

When reconstituting vaccine, use an aseptic technique to prevent contamination (e.g., hand hygiene, etc.). On-site reconstitution is required. Reconstitute vaccine just prior to administration.

To reconstitute ultra-cold vaccine:

- Invert vial gently 10 times to mix. Do not shake!
- Clean the top of the 0.9% sodium chloride vial with a single-use alcohol swab.
- Draw up 1.8 milliliters of diluent with a 3 milliliter or 5 milliliter syringe using a 21 gauge or narrower needle.
- Clean the top of the thawed Pfizer BioNTech vaccine vial with a single-use alcohol swab.
- Add 1.8 milliliters of 0.9% sodium chloride into the vaccine vial.

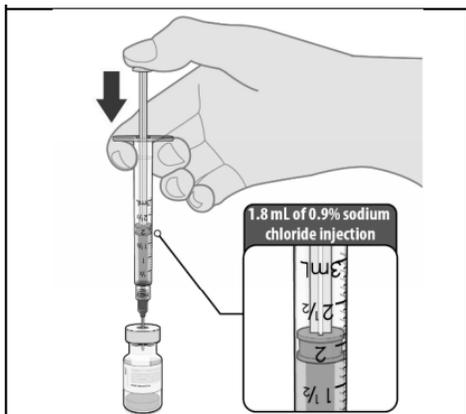


Photo from Pfizer-BioNTech

- Before removing the needle from the vial, equalize pressure in the vial by withdrawing 1.8 milliliters of air into the empty diluent syringe.

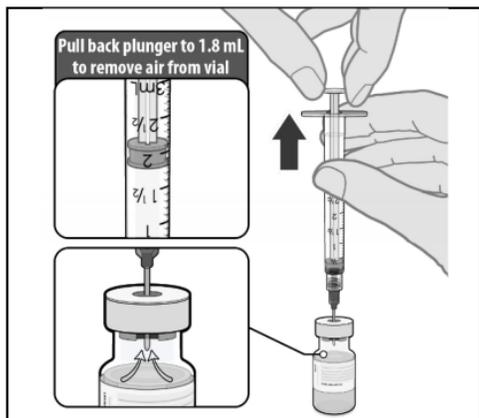


Photo from Pfizer-BioNTech

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- Remove needle/syringe from the vial, invert the vial, and gently mix 10 times. Do not shake! Vaccine will be an off-white suspension. There should be no particulates or discoloration.

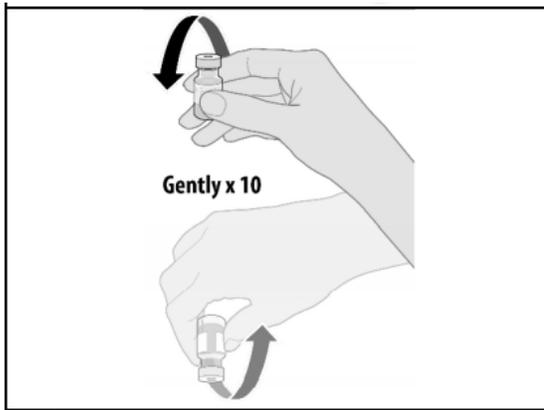


Photo from Pfizer-BioNTech

- Record date and time of reconstitution on the Pfizer BioNTech COVID-19 vaccine label.

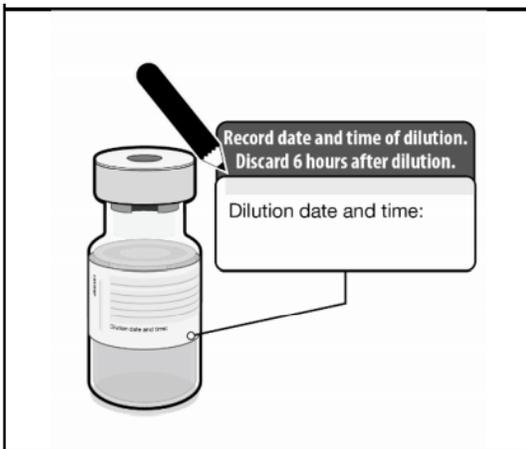


Photo from Pfizer-BioNTech

- Store reconstituted vaccine at 2 to 25 degrees Celsius (35 to 77 degrees Fahrenheit).
- **Once the multi-dose vial has been reconstituted, you must discard it after six hours, even if all doses have not been administered.**
 - Important: Administering this vaccine after six hours of being reconstituted may cause harm, as it poses a risk of bacterial infection.

Preparing of individual doses

Follow strict aseptic technique when preparing the vaccine dose for administration.

- Clean the reconstituted Pfizer-BioNTech vaccine multi-dose vial stopper with a single-use alcohol swab.
- Using a 1 milliliter syringe with a 23 or 25 gauge attached needle in the appropriate length, withdraw a 0.3 milliliter dose from the multi-dose vaccine vial.

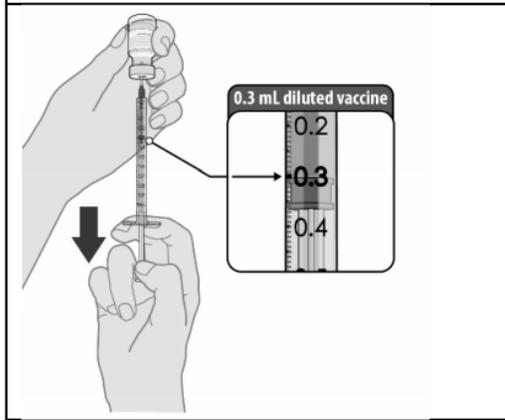


Photo from Pfizer-BioNTech

- Do not use any vaccine that remains in the vial if it does not contain a full 0.3 mL dose. Discard vial appropriately.
- Before administering the vaccine, inspect each dose in the dosing syringe. Reconstituted vaccine will be in an off-white suspension.
 - Verify final dosing volume of 0.3 milliliters.
 - Confirm the vaccine in the syringe has no particulates and is not discolored.
- Administer immediately.

Don't waste vaccine

Don't reconstitute vials in advance as to avoid wasting vaccine. Once you have punctured the vial:

- All the doses need to be administered within 6 hours, or they must be discarded.
 - Make a plan to administer all the doses in the vial.
 - Consider having a waiting list.
 - Be aware of people who may be able to come at short notice to get vaccinated.
- If you have doses left in the vial, and no one immediately available to give them to, try your best to give these to priority groups. **But, above all else, do not waste vaccine.**

Resources

- CDC: [Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites \(www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html)
- Morbidity and Mortality Weekly Report: [The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020 \(www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm\)](https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm)
- Pfizer: [Pfizer-BioNTech COVID-19 Vaccine Resources \(www.cvdvaccine-us.com/resources\)](https://www.cvdvaccine-us.com/resources)
 - Vaccine preparation and administration

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- Storage and handling
- EUA Fact Sheet for Healthcare Providers; EUA Fact Sheet for Recipients and Caregivers
- Contact information:
 - Medical Information: [PfizerMedicalInformation.com](https://www.pfizer.com/medical-information), 1-800-438-1985
 - General Product Inquiries: 1-877-829-2619
 - Shipment Support US Trade Customer Service: 1-800-666-7248 (option 8) for vaccine viability questions or email CVGovernment@Pfizer.com
- CDC: [Pfizer-BioNTech COVID-19 Vaccine \(www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html)
 - Pfizer beyond-use date (BUD) guidance and labels
 - Temperature log: Ultra-cold vaccine storage (Fahrenheit) PDF
 - EUA Fact Sheet for Healthcare Providers; EUA Fact Sheet for Recipients and Caregivers
- [Immunization Courses: Webcasts and Self Study \(www.cdc.gov/vaccines/ed/courses.html\)](https://www.cdc.gov/vaccines/ed/courses.html)
 - Course: Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know
- CDC: [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States \(www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html\)](https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html)
- Vaccine protocol template: [COVID-19 Pfizer-BioNTech BNT162b2 Vaccine \(www.health.state.mn.us/people/immunize/hcp/protocols/covidpfizer.docx\)](https://www.health.state.mn.us/people/immunize/hcp/protocols/covidpfizer.docx)



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