Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy
- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure
- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 21 days.*
- Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Pfizer-BioNTech COVID-19 Vaccine.
- Pfizer-BioNTech COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.

Screen for 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 3.
  - 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)
  - Moderate to severe acute illness
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - 16 through 18 years of age: 1-inch needle is recommended.
    - 19 years of age and older: See table below.

### Table: Needle Gauge, Needle Length, and Injection Site

<table>
<thead>
<tr>
<th>Sex and Weight of Patient</th>
<th>Needle Gauge</th>
<th>Needle Length</th>
<th>Injection Site¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female or male fewer than 130 lbs</td>
<td>22–25</td>
<td>⅜ – 1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female or male 130–152 lbs</td>
<td>22–25</td>
<td>1&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 152–200 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 153–260 lbs</td>
<td>22–25</td>
<td>1–1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Female 200+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
<tr>
<td>Male 260+ lbs</td>
<td>22–25</td>
<td>1½&quot;</td>
<td>Deltoid muscle of arm</td>
</tr>
</tbody>
</table>

*If the second dose Pfizer-BioNTech COVID-19 Vaccine was given as early as 17 days after the first dose, then do not repeat a second dose.

±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.

¹Alternatively, the anterolateral thigh also can be used.

¹Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).
Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

- Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer’s instructions. Follow manufacturer’s guidance for storing/handling mixed vaccine.
- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.
- Document 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 (e.g., 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:
    » Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    » Vaccination record 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): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer’s website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    » 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
- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse. For more information, please see:
  » Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at https://www.immunize.org/catg.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to 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 requirements per the Food and Drug Administration’s conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    » Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the ________________________________ effective ____________ until rescinded or until ______________.

Medical director (or other authorized practitioner)
________________________________________/_____________________________________

Adapted with appreciation from the Immunization Action Coalition (IAC) standing orders
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 and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

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</tr>
<tr>
<td>Lipids</td>
<td>2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide</td>
<td>PEG2000-DMG: 1, 2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol</td>
</tr>
<tr>
<td></td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
<td>1,2-distearoyl-sn-glycero-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)</td>
<td>SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate</td>
</tr>
<tr>
<td>Salts, sugars, buffers</td>
<td>Potassium chloride</td>
<td>Tromethamine</td>
</tr>
<tr>
<td></td>
<td>Monobasic potassium phosphate</td>
<td>Tromethamine hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
<td>Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Dibasic sodium phosphate dihydrate</td>
<td>Sodium acetate</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
<td>Sucrose</td>
</tr>
</tbody>
</table>

*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 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. 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
1. Vaccine will be delivered by FedEx or UPS.

2. Examine the shipping container for signs of physical damage.
   - If the thermal shipping container appears damaged — STOP. Contact Pfizer with questions or concerns.
   - If the thermal shipping container appears to be in good condition, continue to Step 3.

3. Place the thermal shipping container on the floor to unpack (may weigh up to ~80 pounds).

4. The thermal shipping container contains dry ice
   Before opening:
   - Collect PPE, including goggles and insulated gloves.
   - Place the thermal shipping container in an area with proper ventilation. A leak in a confined area may create an oxygen-deficient environment and result in suffocation.

5. Open the thermal shipping container.

6. Press and hold the “Stop Shipment” button on the temperature monitoring device (TMD) for 5 seconds.
   - This triggers an e-mail report from the manufacturer on the temperature status of the container during transit. The report will be sent to the provider (facility) e-mail address associated with the order.
   - The LED indicator light on the TMD will change from blinking to a solid light.

7. Proceed based on the color of the LED indicator light.
   - **Green**: Vaccine can be unpacked. Continue to step 8.
   - **Red or no color**: STOP! Wait for the status report on the vaccine.
     - Contact the manufacturer immediately if the status report indicates a temperature excursion has occurred.
     - Continue to step 8 if the vaccine can be used.

8. Wearing PPE, continue to unpack the shipping container following the manufacturer’s guidance. Materials outlining the unpacking process can be found inside the container immediately after opening the lid.
   - Inspect the tray(s) of vaccine for damage. Ensure the correct number of trays were delivered.
   - Place the tray(s) with the vials upright in the storage unit.
     - If storing vaccine at ultra-cold temperatures between -80°C and -60°C (-112°F and -76°F), do NOT open the tray(s) or touch the vials. Return tray to ultra-cold storage within 5 minutes.
     - If storing the vaccine at refrigerator temperatures between 2°C and 8°C (36°F and 46°F), the vaccine must be used within 120 hours (5 days).
     - Thawed vaccine cannot be refrozen.
   - Dispose of the dry ice according to the manufacturer’s directions.

9. If using the thermal shipping container to store vaccine,* replenish the container with dry ice pellets (sized 10 mm to 16 mm) within 24 hours of delivery. Unless you have opted out of receiving dry ice when the order was placed, dry ice will be provided for the first re-icing. Close the container using packing tape.

10. Respond to the manufacturer’s status report email regarding ongoing temperature monitoring of the thermal shipping container.
    - If storing vaccine in an ultra-cold freezer or refrigerator, click on the link to opt out of ongoing temperature monitoring.
    - If storing vaccine in the thermal shipping container,* an additional e-mail will be sent. Add additional contacts to be notified of the temperature status of the container. Include after-hours phone numbers.

* CDC recommends using the thermal shipping container for temporary storage only.
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.

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.

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.

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.
Pfizer-BioNTech COVID-19 Vaccine
Vaccine Preparation and Administration Summary

» Administer the Vaccine

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

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.

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.

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.

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.

*Scheduling Doses

<table>
<thead>
<tr>
<th>Vaccination History*</th>
<th>And</th>
<th>Then</th>
<th>Next Dose Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 doses</td>
<td></td>
<td>Give dose 1 today</td>
<td>Give dose 2 at least 21 days after dose 1</td>
</tr>
<tr>
<td>1 dose (Pfizer)</td>
<td>It has been at least 21 days since dose 1</td>
<td>Give dose 2 today</td>
<td>Series complete; no additional doses needed</td>
</tr>
<tr>
<td></td>
<td>It has NOT been at least 21 days since dose 1</td>
<td>No dose today</td>
<td>Give dose 2 at least 21 days after dose 1</td>
</tr>
<tr>
<td>2 doses (Pfizer) at least 21 days apart†</td>
<td></td>
<td></td>
<td>Series complete; no additional doses needed</td>
</tr>
</tbody>
</table>

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

†Vaccine doses administered at/after day 17 are considered valid. The 4-day grace period should not routinely be used to schedule doses.
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 3.
- 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)
- 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 patient’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
Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and should be competent in treating these events at the time of vaccine administration. Equipment and medications should be available, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.


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 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.
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**Yes:**

1. Mix the vaccine using a NEW vial of diluent and a NEW vial of the vaccine EVERY TIME.*
2. Use 1.8 mL of 0.9% sodium chloride (normal saline, preservative-free) ONLY.
3. Discard diluent vial after mixing the vaccine.

**No:**

1. Do NOT use all the diluent in the vial.
2. Do NOT use bacteriostatic normal saline or other diluents.
3. Do NOT use or save the remaining vaccine diluent to mix additional vaccine or for other uses.

*Use a 21-gauge needle or narrower.

**CDC injection safety website:** [www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html)
Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer’s instructions for returning the thermal shipping container.
- Each thermal shipping container holds up to 5 trays of vaccine.
  » Each tray contains 195 multidose vials (975 doses).

Deliveries

Vaccine

When vaccine is delivered:
1. Open the thermal shipping container. Press on the stop shipment button on the temperature monitor device for 5 seconds.
2. The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
4. Follow the manufacturer’s guidance for unpacking the vaccine. Inspect the trays.
  » Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
  » If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.

Dry Ice Safety

1. Dry ice is needed to maintain proper temperatures in the thermal shipping container.
2. Dry ice requires special handling.
3. Ensure staff is trained to handle dry ice safely and have proper PPE.
4. Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause an oxygen-deficient atmosphere.

Ancillary Supply Kit

Ancillary supply kit will be delivered separately from the vaccine and includes:
- Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads.
  » Do NOT use mixing supplies to administer vaccine.
- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE supplies

Each ancillary supply kits contains enough supplies to mix and administer 1 tray of vaccine.

Ultra-Cold Freezer

Vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures. Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred) Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Option 2: 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.

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.

Thermal Shipping Container

CDC recommends providers consider 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 on regular maintenance.

Use the Controlant Temperature Monitoring Device (TMD), included with the thermal shipping container, to monitor
the temperature.

- Up to 4 contacts can be identified to receive e-mails and text alerts on the temperature status of the container.
- Review daily e-mails on the status of the container.
- Save the final e-mail (full summary of status reports).

Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days after. Follow manufacturer’s guidance for adding dry ice.

- Dry ice will be sent for the first re-icing.
- Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

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.

Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), remove any remaining vials from the refrigerator and discard following the manufacturer’s and your jurisdiction’s guidance on proper disposal.

Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1: Minimum/Maximum (Min/Max) Temperature (Preferred)** Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: 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.

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

- Place vaccine vials removed from frozen storage at the same time together in a resealable plastic bag or similar container.
- Complete the information on the storage label and attach it to the container holding the unmixed vaccine vials.
- Once labeled, store unmixed vaccine vials upright in the refrigerator.

Thawed vaccine cannot be refrozen.

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.

Mixed Vaccine

- Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.
- Discard any remaining vaccine after 6 hours.
- Mixed vaccine does not need to be protected from light.

Thawed vaccine cannot be refrozen.
Ages: 16 years of age and older
Use for: Any dose in the 2-dose series. COVID-19 vaccines are NOT interchangeable. Both doses MUST be COVID-19 vaccine (Pfizer).
Route: Intramuscular (IM) injection
Prior to administration, mix with 0.9% sodium chloride (normal saline, preservative-free) diluent ONLY.
Beyond Use Time: Use within 6 hours of mixing.
Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction.

Product name: ____________________  Manufacturer: ____________________  Original Expiration Date: ____________________

Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)

<table>
<thead>
<tr>
<th>Date</th>
<th>Lot Number</th>
<th>Updated Expiration Date</th>
<th>Info Source</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example:</td>
<td>ABC123DEF456</td>
<td>06/30/2021</td>
<td>Website</td>
<td>Susie Smith RN</td>
</tr>
</tbody>
</table>