



December 21, 2021

Dear COVID-19 Vaccination Program Providers,

The FDA has approved a shelf-life extension for the Pfizer pediatric COVID-19 vaccine (orange cap, ages 5 to 11, diluent required) and the soon to be available adolescent/adult Tris (gray cap, ages 12 and older, no diluent) effective immediately. These approvals are available at [Healthcare Providers for 5-11 years of age, orange cap \(must dilute\) \(fda.gov\)](#) and [Healthcare Providers for 12 years of age and older, gray cap \(no dilution\) \(fda.gov\)](#). **This extension applies to vaccine stored at ultracold temperatures (ULT frozen) only.**

As a reminder, the date printed on the Pfizer vaccine for ages 5 to 11 (orange cap) and vaccine for ages 12 and older (gray cap) vaccine vials indicate the manufacture date and **not** the expiration date. Originally, the expiration date was 6 months from the manufacture date. **The expiration date for the Pfizer orange and gray cap vaccines has now been extended to 9 months (while held at ULT frozen).** The orange and gray cap vaccines can both be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 10 weeks, if within 9 months after the manufacture date. The updated expiration dates for both the orange and gray cap vials based on 9 months from the date of manufacture are provided below.

Printed Manufacturing Date	9-Month Expiration Date*
06/2021	Feb. 28, 2022
07/2021	Mar. 31, 2022
08/2021	Apr. 30, 2022
09/2021	May 31, 2022
10/2021	Jun. 30, 2022
11/2021	July 31, 2022
12/2021	Aug. 31, 2022
01/2022	Sept. 30, 2022
02/2022	Oct. 31, 2022

\*Date of expiration always falls on the last day of the month

**The QR code provided on the Pfizer pediatric vaccine carton provides a link to the Emergency Use Authorization (EUA) but does not provide information on expiration dates.**

Please follow EUA recommendations for storage:

**Pfizer 5 to 11 years of age vaccine (orange cap)**

- If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.



NEW YORK CITY DEPARTMENT OF

HEALTH AND MENTAL HYGIENE

Dave A. Chokshi, MD, MSc

*Commissioner*

- Vaccine may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to dilution.
- After dilution, the vial should be held at 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

**Pfizer ages 12 and older vaccine (gray cap)**

- Frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F). Do **not** store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen.
- Vials may be transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiration date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 6 hours to thaw at this temperature.

**Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.**

Please email [COVIDVax@health.nyc.gov](mailto:COVIDVax@health.nyc.gov) with questions. Thank you for protecting the health of New Yorkers.

Sincerely,

A handwritten signature in black ink that reads 'Jane R. Zucker'.

Jane R. Zucker, MD, MSc  
Assistant Commissioner  
Bureau of Immunization

# COVID-19 Vaccination Program Update : New Pfizer Vaccine Formulation

Vaccine Operations Center

Bureau of Immunization

New York City Department of Health & Mental Hygiene

December 20, 2021

The information in this presentation is current as of the time of  
presentation and subject to change.

# Pfizer-BioNTech COVID-19 Vaccines

Description	Formulations		
	<i>Dilute Prior to Use</i>	<i>Do Not Dilute</i>	<i>Dilute Prior to Use</i>
Age Group	12 years and older	12 years and older	5 to <12 years*
Vial Cap Color	<b>PURPLE</b> 	<b>GRAY (Coming soon)</b> 	<b>ORANGE</b> 
Dose	30 mcg	30 mcg	10 mcg
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	2.25 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	<b>NO DILUTION</b>	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
<b>Storage Conditions</b>			
ULT Freezer (-90°C to -60°C)	9 months	<b>9</b> months	<b>9</b> months
Freezer (-25°C to -15°C)	2 weeks	<b>N/A</b>	<b>N/A</b>
Refrigerator (2°C to 8°C)	1 month	10 weeks	10 weeks

\*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)

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# Pfizer Tris Sucrose Formulation - Gray Cap (Comirnaty)

- Will replace the current Pfizer purple cap formulation
- Indicated for individuals 12 years of age and older
- **Does not require dilution**
- Available in smaller 300-dose packages

# Vaccine Indications

- The Pfizer gray cap product can be used for:
  - Two-dose primary series in individuals 12 years of age and older
  - Third dose (additional dose) in individuals 12 years of age and older who have been determined to be moderately or severely immunocompromised and who completed a primary series with Pfizer-BioNTech COVID-19 Vaccine (or Comirnaty)
  - Single booster dose for individuals 16 years of age and older who completed a primary series with Pfizer-BioNTech COVID-19 Vaccine (or Comirnaty)
  - Single booster dose for individuals 18 years of age and older who completed primary vaccination with a different FDA-authorized COVID-19 vaccine (Moderna or Johnson&Johnson/Janssen)

# Vaccine Indications (2)

- Under Emergency Use Instruction,\* the Pfizer-gray cap can be used for:
  - Third dose (additional dose) to individuals 12 years of age and older who have been determined to be moderately to severely immunocompromised and who completed a primary series with a WHO-listed (non-FDA authorized or approved) COVID-19 vaccine
  - Single booster dose to individuals 16 years of age and older who have completed primary vaccination with a WHO-listed (non-FDA authorized or approved) COVID-19 vaccine

\*CDC. COVID-19 Vaccine Emergency Use Instructions (EUI) Fact Sheet for Healthcare Providers. Available at: <https://www.cdc.gov/vaccines/covid-19/eui/index.html>

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# Storage and Handling

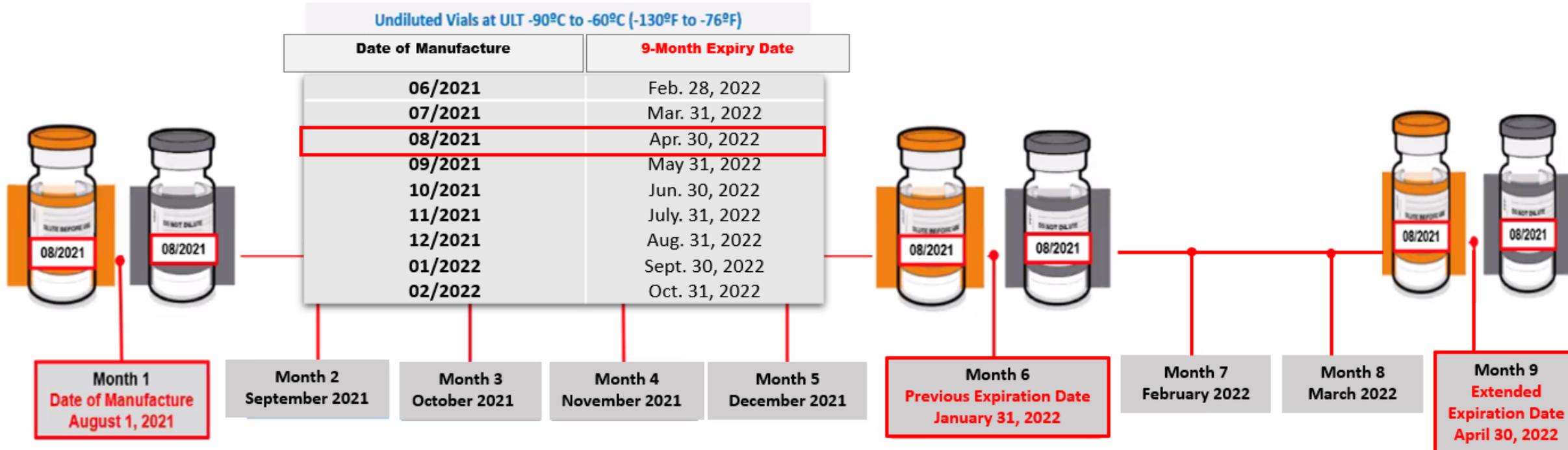
- May be stored in an ultracold vaccine storage for up to **9** months after the manufacture date and in a refrigerator at 2-8°C (36-46°F) for up to 10 weeks.
  - **The 10 weeks is within the 9 months after the manufacture date**
- Cannot be stored in a regular freezer
- Pfizer thermal shippers cannot be used for temporary storage of this product
- Once punctured, the vial must be discarded after 12 hours (the packaging may indicate 6 hours, but this has been updated in the FDA fact sheet)

# Date of Manufacture and Expiry

Date of manufacture printed on the vial, not the date of expiry

Applicable to the following cap colors:  
**ORANGE** (Ages 5 thru 11) | **GRAY** (Ages 12+) DO NOT DILUTE

Undiluted vials can be stored up to **9 months** in an **Ultra Low Temperature (ULT) freezer -90°C to -60°C (-130°F to -76°F)**  
 Regardless of storage conditions, vaccines should not be used after 9 months from the date of manufacture printed on the vials and cartons



Once the vials are thawed and moved to the **refrigerator (2°C to 8°C; 35°F to 46°F)**, the vials may be stored for up to **10 weeks**  
 This 10-week refrigerated expiry date should be recorded on the carton at the time of transfer

Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheets for Vaccination Providers:

12+ years of age (DILUTE BEFORE USE/Purple Cap), 12+ years of age (DO NOT DILUTE/Gray Cap) and 5 through 11 years of age (DILUTE BEFORE USE/Orange Cap).

For the most recent prescribing information and fact sheets, please visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)



# Beyond Use Dates

- Label cartons and vials with beyond use dates when vaccine is first placed in the ultracold freezer or refrigerator
  - Beyond Use Date labels [Pfizer 12+](#)
- If the Pfizer-gray cap vaccine is moved from the ultracold freezer to the refrigerator, the label needs to be updated with the date and time and new beyond use date (up to 10 weeks)
- Vials should be relabeled when first punctured

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FORMULATION: 5 Through 11 Years of Age  
**Pfizer-BioNTech COVID-19 Vaccine**

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): 123456A

Today's date: 06 / 01 / 2021 Time: 2:30 PM

**USE BY\***

Date: 08 / 10 / 2021 Time: 2:30 PM

\*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

Name: Amy Nurse RN



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

Store vaccine between 2°C and 8°C (36°F and 46°F) for up to 10 weeks.

Lot number(s): 123456A

Today's date: 06 / 01 / 2021 Time: 2:30 PM

**USE BY\***

Date: 08 / 10 / 2021 Time: 2:30 PM

\*As the 10 week deadline approaches, contact the manufacturer for guidance if you will not be able to use the vaccine.

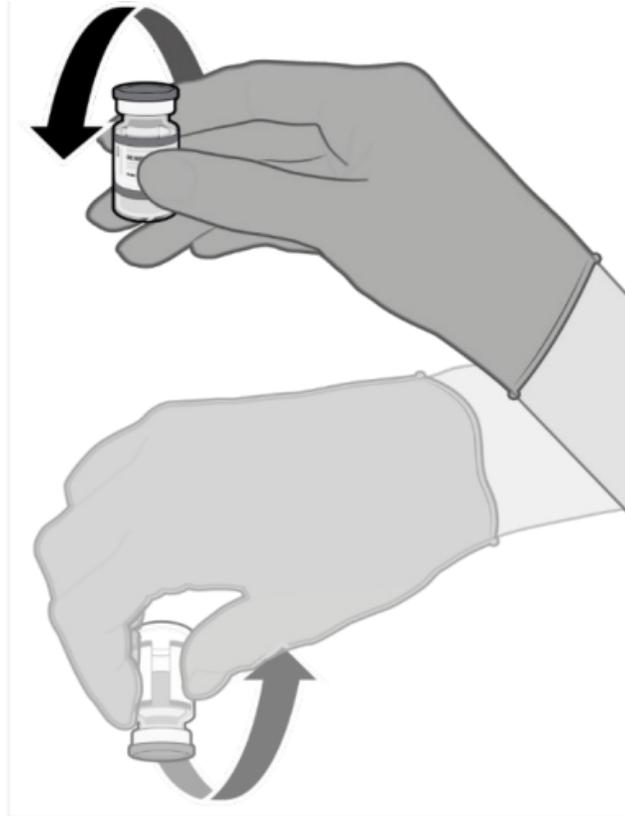
Name: Amy Nurse RN



# Vaccine Preparation and Administration

- Check expiration and beyond use dates before utilizing any vial
- Verify that the vial has a gray plastic cap and a label with a gray border
- **Do not reconstitute/do not dilute**
- Mix by inverting vaccine vial gently 10 times (do not shake)
- Label vial at time of first puncture – discard any unused vaccine 12 hours after first puncture
- Administer 0.3 mL via intramuscular injection
  - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess vaccine – do not pool a dose from 2 separate vials

# Vaccine Preparation and Administration (2)



**Gently × 10**

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discolored or if particles are observed after mixing.

FDA. Pfizer-BioNTech Fact Sheet for Healthcare Providers. Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>

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# Staff Training

- Require and document staff training
  - All clinical staff: screeners, vaccinators, site supervisors, clinical leads, head clinicians
  - All vaccine management staff
  - Include review of the up-to-date Fact Sheet for Healthcare Providers Administering Vaccine
    - Require review of Fact Sheets each time they are updated
  - Include the CDC Training – Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know <https://www2.cdc.gov/vaccines/ed/covid19/pfizer/index.asp>
    - Require training each time vaccine indications change
- Conduct a staff huddle at the start of every clinical shift
  - Review key details of each vaccine being used: age, dose, dilution requirements, beyond use timing

# Storage, Handling and Administration Errors

- Report all storage, handling and administration errors to the NYC Department of Health and Mental Hygiene
  - Email: [COVIDvax@health.nyc.gov](mailto:COVIDvax@health.nyc.gov)
- For storage and handling errors, submit storage and administration information to the manufacturer – ask for a written response on viability of vaccine
- Report all vaccine administration errors (including those due to improper storage and handling of vaccine) to VAERS
  - <https://vaers.hhs.gov/reportevent.html>

# Considerations for Inventory Management

- Providers should deplete their inventory and finish any remaining Pfizer-purple cap before ordering the new 300 tray Pfizer gray cap vaccine
- In order to avoid mistakes during this period of transition when both products may be in circulation, these products should not be offered or administered at the same time
- Providers with multiple vaccination sites should consider consolidating all remaining Pfizer purple cap vaccine at a particular site(s) during the transition or transitioning one site at a time

# Pfizer-Gray Cap Ordering

- The CIR Online Registry will be updated on December 21, 2021
  - 300 minimum dose quantity
  - Sites will no longer be able to order Pfizer-purple cap
- The US government will retire the current Pfizer-purple cap and transition to the Pfizer-gray cap on December 23 for jurisdictions and federal entities

# Reporting to the Citywide Immunization Registry

- Providers should reach out to their electronic health record vendor for guidance on adding the new gray cap vaccine codes
  - CVX Code: 217
  - NDC: 59267-1025-04
- Note there is no change to the Pfizer-orange cap (Pfizer vaccine for ages 5 to 11)
  - CVX Code: 218
  - NDC: 59267-1055-04

# Questions?

[COVIDvax@health.nyc.gov](mailto:COVIDvax@health.nyc.gov)

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