

CONTENTS

Vaccine Ordering
VFC Ordering
Bridge Ordering
Commercial Ordering
Creating a Standard Operating Procedure 4-7
Vaccine Storage
Determining How Much to Order
Vaccine Shipment Packaging 4-10
Unpacking & Labeling
Storage & Handling
Organizing Vaccine Stock 4-17
Expiration Dates 4-18

VACCINE ORDERING

Vaccine ordering will typically take place within I-CARE. Below is a chart for the ordering of the XBB1.5 vaccine products released in September 2023.

FORMULATION	CPT CODE	PRESENTATION	MINIMUM ORDER QTY	HOW TO ORDER	PRIVATE SECTOR COST/DOSE
Novavax					
Patient age 12 years and older	91304	Multi-dose vials containing 5 doses	50 doses	 Through VFC and other state programs Wholesaler/distribution channels 	\$130.00
Pfizer					
Patient age 6 months-4 years	91318	Multi-dose vials containing 3 doses	30 doses	 Through VFC and other state programs Pfizer Prime: 100% returns for unused or partially used multi-dose vials Wholesaler/distribution channels 	Pfizer 6 mos-4 yrs: \$57.50
Patient age 5 years-11 years	91319	Single-dose vials			Pfizer 5-11 yrs: \$77.00
Patient age 12 years and older	91320	Single-dose vials or single-dose prefilled syringes*	10 doses	Wholesaler, distribution charmers	Pfizer 12+ yrs: \$115.00
Moderna					
Patient age 6 months-11 years	91321	Single-dose vials that come in 10-count cartons		Through VFC and other state programs Moderna Direct: 100% returns for	Moderna 6 mos-11 yrs: \$128.00
Patient age 12 years and older	91322	Single-dose prefilled syringes sold in 10-count cartons with a blister pack option	10 doses	6 months-11 years vaccine Wholesaler/distribution channels	Moderna 12+ yrs: \$128.00

^{*}There will be limited quantities of prefilled syringes and they will not be available for initial stocking orders.

Sources: www.pfizer.com/news/announcements/pfizer-and-biontech-submit-applications-us-fda-omicron-xbb15-adapted-monovalent https://publications.aap.org/aapnews/news/25384?autologincheck=redirected

Commercialization is the transition from direct government supplied vaccines to getting COVID-19 through public programs (VFC, Bridge Access) or through purchasing for privately insured patients. The distribution of free government purchased COVID-19 vaccines ended in August 2023.

VFC Ordering

The following COVID-19 vaccine products are available for ordering through the VFC Program eligible for children aged 6 months through 18 years of age:

VACCINE	NDC CODE
Pfizer-BioNTech COVID-19 (2023-2024 6m-4y); PFR; MDV3; 10-pack	59267-4315-02
Pfizer-BioNTech COVID-19 (2023-2024 5-11 years); PFR; SDV; 10-pack	59267-4331-02
Comirnaty COVID-19 (2023-2024 12+ years); PFR; SDV; 10-pack	00069-2362-10
Moderna COVID-19 (2023-2024 6m-11y); MOD; SDV; 10-pack	80777-0287-92
Spikevax COVID-19 (2023-2024 12+ years); MOD; SDV; 10-pack	80777-0102-95
Novavax COVID-19 (2023-2024 12+ years); NVX; MDV5; 2-pack	80631-0105-02

IDPH - COVID-19 vaccines through VFC are ordered the same way as all other vaccines in I-CARE.

CDPH - Email both covid19vaccine@cityofchicago.org and chicagovfc@cityofchicago.org to request doses.

Bridge Ordering

IDPH - The COVID-19 vaccine will always be considered a limited quantity order. For providers who have been enrolled in the Bridge Access Program, it can now be ordered in I-CARE through the COVID tab. Click on "Vaccine Requests", then click on the "Add Order" button.

The Order Intent is defaulted to "Bridge". Search for the vaccine in the "Add Vaccine" field, add your desired quantity, and complete the remainder of the order process as usual. This includes adding your delivery hours for the upcoming weeks, ensuring that inventory on the "Vaccines" tab is up to date and that your vaccine storage unit temperatures are logged on the "Temp Logs" tab.



CDPH - After you have completed Bridge Program enrollment and been approved, email both **covid19vaccine@cityofchicago.org** and **chicagovfc@cityofchicago.org** to request doses.

Commercial Ordering

You can order vaccines directly from the manufacturer for patients with private health insurance.

- Pfizer Prime
- Moderna Direct
- Novavax vaccines can be ordered through the following retailers:
 - Cardinal Health (Item #5862974)
 - FFF Enterprises (Item #NOV010502)
 - Henry Schein, Inc (Item #145-6160)
 - McKesson Medical-Surgical Inc. (Item #1237250)
 - McKesson Plasma and Biologics (Item #2847283)

COVID-19 Commercial Vaccines Cost

- Pfizer age 12+ years: \$115 per dose
- Pfizer age 5-11 years: \$77 per dose
- Pfizer age 6 months-4 years: \$57.50 per dose
- Moderna: \$128 per dose
- Novavax: \$130 per dose

Creating a Standard Operating Procedure

Establishing a clear standard operating procedure (SOP) for vaccine storage, handling, and administration is an easy way to minimize vaccine waste. You can view an example of a thorough SOP from the CDC here. Consider designating a primary and secondary vaccine coordinator for the facility who can:

- Order vaccines
- Oversee storage and handling
- Document vaccine inventory
- Dispose of expired vaccines



Remember, you cannot use adult vaccine products on pediatric populations. See Section 5: Vaccine Administration for more information on vaccine interchangeability.



Note:

Ancillary kits are no longer shipped with COVID-19 vaccines.

VACCINE STORAGE

Before You Order, Make Sure You Select the Necessary Storage Equipment

The equipment you choose should be carefully selected to ensure that they are reliable and allow for temperatures to remain stable. As with all vaccines, you must verify your facility is meeting proper storage requirements to ensure the vaccine does not lose its potency. You do not need a separate unit for COVID-19 vaccines.

Cold-chain storage and handling requirements for each COVID-19 vaccine product will vary.

Maintaining Appropriate Storage Temperatures

You will need a calibrated thermometer or temperature recording device (TMD) inside each piece of storage equipment. CDC recommends a specific type of TMD called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Per CDC recommendations your vaccine storage unit temperature should be checked at the start and end of each workday and documented on a physical log that is kept on the storage unit. Once a day the clinic needs to document on the physical log the units minimum and maximum temperature.

To ensure your facility is adhering to proper storage guidelines, be sure to have cold chain procedures in place that are routinely reviewed and monitored. If an error occurs, <u>corrective action should be taken as soon as possible</u>. Per CDC and VFC guidelines, keep the temperature logs for three years so they can be analyzed for long-term trends and/or reoccurring problems.

See the CDC's resource for Handling a Temperature Excursion in Your Vaccine Storage Unit here.

DETERMINING HOW MUCH TO ORDER

When determining how much vaccine to order, please consider the following key ordering criteria:

- Order for estimated use and maintain enough inventory to last 3 weeks; inventory should not exceed a one-month supply
- · Geography and concentration of vaccine locations or events
 - Remember, pharmacies cannot vaccinate children under 3 years of age
- Patient population size and percent that is expected to uptake
- Example: You have a pediatric population of 4,900 between ages 6 months to 4 years
 - CDC estimates 20 30% will get vaccinated
 - Order 980 to 1100 doses



TIP: You can survey patients to better understand what phase individuals are in (early adopters, laggards) as this may impact content and provider ordering.



The goal is to vaccinate every eligible and interested patient!

VACCINE SHIPMENT PACKAGING

Shippers

Vaccine manufacturers have developed packaging and storage to support the different locations these products are being sent. Vaccines may arrive in specially designed, temperature-controlled thermal shippers; some may even have dry ice to maintain recommended storage temperatures.



It's important to be prepared to move vaccines from shippers to on-site storage in a timely fashion.



The Pfizer products will be shipped with a SAGA Data Logger that tracks detailed temperature information during shipment. Vaccine coordinators will get an email with temperature updates during shipping, including any breaches in protocol. The SAGA shipper must be returned in the provided packaging after vaccine receipt.

The Moderna products are shipped with a TagAlert temperature monitor. Check the TagAlert temperature monitoring device by pressing the blue "start and stop' button. Read indicator Status to determine if the appropriate temperature was maintained during transit. If left arrow points to a green checkmark: the vaccine is ready to use. Store the vaccine at proper temperatures immediately. If right arrow points to red X: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label DO NOT USE! Call the phone number indicated in the instructions or your jurisdiction's immunization program IMMEDIATELY. Return small shipper following McKesson's return instructions. Give the cooler to your regular UPS delivery person for return or call 1-800-PICK-UPS to schedule a pickup. Dispose of medium and large shippers and packing materials.

Further information about vaccine storage guidelines is available on the CDC's Pinkbook and Vaccine Storage and Handling Toolkit (Jan 2023).

UNPACKING & LABELING

Vaccines Arrived - Now What?

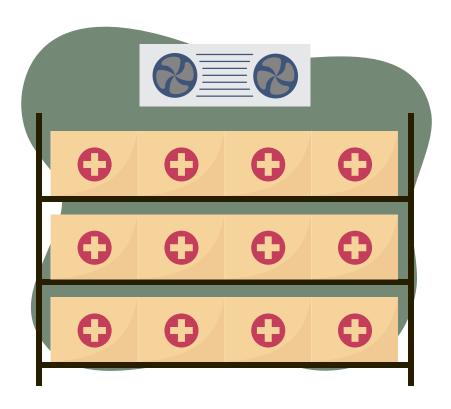
- Vaccines should be carefully unpacked and moved into the appropriate storage unit as soon as they arrive.
- Examine the shipping containers for the correct quantity and any signs of damage.
- If there are any issues or discrepancies notify IDPH, CDPH, and/or the vaccine manufacturer immediately.



TIP: Use color coded labels to sort each shipment – this will make it easier to see which vaccines are closest to their expiration date.

Moderna Notes

Both Moderna products have a blue cap. The 6 month–11 year old product has a green label and the 12 years and older product has a blue label. Take care to differentiate between these 2 products and ensure the correct one is administered.



STORAGE & HANDLING

Make Sure You Do Not Miss an Important Storage Alert



Be sure to add these contacts to your safe sender lists so that you receive order, shipping, and temperature monitoring alerts:

- cvgovernment@pfizer.com
- Pfizer.logistics@controlant.com
- onsitemonitoring@controlant.com



Check out the CDC's At-A-Glance Resource Guide on Vaccine Administration, Storage, and Handling

View PDF

Pfizer-BioNTech, Moderna, and Novavax Vaccine Shipping & Delivery Information

VACCINE MANUFACTURER/PRODUCT	THERMAL SHIPPER AS TEMPORARY STORAGE?	OPTIONS FOR STORAGE UPON ARRIVAL
Pfizer-BioNTech 6 mos through 4 years ("Age 2y to <5y" or "Age 6m to < 5y" on vial label) Yellow cap/yellow label 5 through 11 years ("Age 5y to <12y" on vial label) Blue cap/blue label Adult (12+) Gray top SHIPPED FROM PFIZER	NO Remove the temperature monitoring device from the shipping container and check the temperature monitor for any excursion warnings, turn the monitor off. Return device using the included prelabeled foldable return box. Dispose of the single-use thermal shipping container.	 Ultra-low temperature freezers (-90°C + -60°C) (-130°F and -76°F) for up to 12 months Refrigeration units that are commonly available in hospitals and pharmacies: The vaccine has shown improved stability and can be stored for up to 10 weeks at refrigerated 2 - 8°C conditions (36°F and 46°F) Cannot be stored in freezers at -25°C to -15C° (-13°F and 5°F) Visit here for updated guidance
Moderna 6 mos-11 years Blue cap with green label 12 years and older Blue cap with blue label SHIPPED FROM McKESSON DISTRIBUTION SITES	N/A: Remove from packaging. Once vaccine vials are thawed, they cannot be refrozen. Keep the vials in their original package to protect them from light.	 Shipped to your location frozen. Can be stored frozen between -50° to -15°C (-58° to 5°F) until the expiration date. Do not store on dry ice or below -50°C (-58°F). Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. If you believe any vials experienced a temperature excursion, use Temperature Excursion Tool here for further instructions.
Novavax 12 years and older Blue cap Monovalent	N/A: The vaccine will arrive between 2° to 8°C (36°F to 46°F) in a qualified shipping container. Unpack vaccine immediately upon arrival at the clinic. Store in original packaging to protect from light.	 Store between 2°C and 8°C (36°F and 46°F) until the expiration date. Once punctured, Novavax COVID-19 Vaccine must be used within 12 hours. Note when (time) the vial is first punctured and use within 12 hours. Discard vial and any remaining vaccine after 12 hours.

Pfizer-BioNTech Storage & Handling Information

AGE INDICATIONS AND FORMULATION	6 Months-4 Years	5-11 Years	12+ Years	12+ Years Prefilled Plastic Syringe	12+ Years Prefilled Glass Syringe
VIAL CAP COLOR	Yellow	Blue	Gray	N/A	N/A
VIAL LABEL BORDER COLOR	Yellow	Blue	Gray	N/A	N/A
PREPARATION	Dilute	Do Not Dilute	Do Not Dilute	N/A	N/A
DOSE	3 mcg/0.3 mL dosage	10 mcg/0.3 mL dosage	30 mcg/0.3 mL dosage	30 mcg/0.3 mL dosage	30 mcg/0.3 mL dosage
DOSES PER VIAL	3	1	1	1 – Prefilled Syringe	1 – Prefilled Syringe
ULT FREEZER (-90°C TO -60°C)	12 Months	12 Months	18 Months	9 Months	DO NOT STORE
FREEZER (-50°C TO -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE	DO NOT STORE
REFRIGERATOR (2°C TO 8°C)	10 Weeks	10 Weeks	10 Weeks	10 Weeks	Up to 6 Months
ROOM TEMPERATURE (8°C TO 25°C)	12 Hours Prior to First Puncture	12 Hours Prior to Use	12 Hours Prior to Use	4-12 Hours*	12 Hours*
AFTER FIRST PUNCTURE (2°C TO 25°C)	Discard After 12 Hours	N/A	N/A	N/A	N/A
THAW TIME	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	In Refrigerator: Up to 2 hours At Room Temp: 30 mins	Thawed in carton: In Refrigerator: Up to 2 hours At Room Temp: 60 mins	N/A

^{*}Thawed in carton: 12 hours prior to use. Thawed outside of carton: Use within 4 hours of thawing.

Moderna Storage & Handling Information

AGE INDICATIONS AND FORMULATION	6 Months-11 Years 12+ Years		
VIAL CAP COLOR	Dark Blue	Dark Blue	
VIAL LABEL BORDER COLOR	Green	Dark Blue	
PREPARATION	Do Not Dilute	Do Not Dilute	
DOSE	25 mcg/0.25 mL dosage	50 mcg/0.5 mL dosage	
DOSES PER VIAL	1	1 – Single-dose Vial or Prefilled Syringe	
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE DO NOT STORE		
FREEZER (-50°C TO -15°C)	Until Expiration Until Expiration		
REFRIGERATOR (2°C TO 8°C)	30 Days	30 Days	
ROOM TEMPERATURE (8°C TO 25°C)	24 Hours	24 Hours	
AFTER FIRST PUNCTURE (2°C TO 25°C)	N/A 12 Hours or Discard After Single Us		
THAW TIME	In Refrigerator: 45 mins At Room Temp: 15 mins	Single-Dose Vial: Prefilled Syringe: In Refrigerator: 45 mins In Refrigerator: 1 hour At Room Temp: 15 mins At Room Temp: 45 mins	

Novavax Storage & Handling Information

AGE INDICATIONS	12 years and older
VIAL CAP COLOR/ LABEL WITH COLOR BORDER	Royal Blue Cap
PREPARATION	Do Not Dilute
DOSE	0.5 mL
DOSES PER VIAL	5
ULT FREEZER (-90°C TO -60°C)	DO NOT STORE
FREEZER (-25°C TO -15°C)	DO NOT STORE
REFRIGERATOR (2°C TO 8°C) ^a	Until Expiration Date
ROOM TEMPERATURE (8°C TO 25°C) INCLUDING ANY THAW TIME	12 Hours
AFTER FIRST PUNCTURE (2°C TO 25°C)	12 Hours

^a Regardless of storage condition, vaccines should not be used after the expiration date.

ORGANIZING VACCINE STOCK

MINIMIZING RISK FOR VACCINE LOSS

- Review the CDC Toolkit for <u>Vaccine Storage</u> and <u>Handling</u>
- Organize stock to allow for vaccine that expires first to be used first
- Place water bottles on the top shelf and floor of the refrigerator and in the door racks to help maintain stable storage temperatures
- Do not place or store any items other than vaccines, refrigerated diluents, and water bottles inside clinic storage units
- · Store vaccines in original packaging
- Arrange vaccines in rows and allow space between them to promote air circulation
- Note the expiration date on vial and updates to expiration date announcements



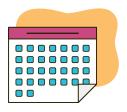
View the <u>CDC's learning module on vaccine</u> <u>storage and handling</u> to learn more!

EXPIRATION DATES

Always use the online look up tools below to check the expiration date of a vial before discarding it.

TIP: Register to access: CDC's
COVID-19 Vaccine Lot Number and
Expiration Date Report

EUAs supersede the expiration date information on the vial.



Expired vaccine should be discarded regardless of storage conditions.

MANUFACTURER	HOW TO FIND
Moderna (Spikevax)	 Scan QR code on the vial or carton Website: Look up tool
Pfizer	Website: Look up tool See EUA fact sheets for providers
Novavax	Scan QR code on outer carton Website: Look up tool