

NYS Department of Health COVID-19 Vaccination Program
Ordering Guidance for the COVID-19 Vaccine for Young Children
June 2, 2022

ALERT: Pre-Orders Open in NYSIIS Friday, June 3, 2022, for COVID-19 Vaccine for Young Children

Two COVID-19 vaccine products for young children are nearing the final stages of the Emergency Use Authorization (EUA) process. Pfizer-BioNTech is submitting data on a THREE-dose primary series for a vaccine for children ages six months through FOUR years of age (6m–4y). Moderna is submitting data on a TWO-dose primary series for children ages six months through FIVE years of age (6m–5 y). The authorization is a multi-step clinical and regulatory process, and **no vaccine can be administered until the final recommendation is issued by the CDC Director, Dr. Walensky**. In preparation, this guidance includes details about BOTH products.

Providers in New York City should follow instructions from NYCDOHMH and CIR.

Pharmacy providers enrolled in the Federal Retail Pharmacy Program should follow instructions from CDC. Please note: The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements. For example, the Declaration authorizes pharmacists, pharmacy interns and pharmacy technicians nationwide to order and/or administer COVID-19 vaccines, influenza vaccines, and other vaccines authorized by FDA and recommended by CDC for **children three years of age or older** (Please see:

<https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>).

Anticipated timeline:

1. The Vaccines and Related Biological Products Advisory Committee (VRBPAC) (FDA’s advisory group) is scheduled to meet on Wednesday, June 15, 2022.
2. FDA regulatory action/EUA issued (shipment of pre-ordered vaccine could commence)
3. The Advisory Committee on Immunization Practices (ACIP) (CDC’s advisory group) is expected to meet within several days of VRPBAC; the meeting will be posted here once scheduled: <https://www.cdc.gov/vaccines/acip/index.html>
4. CDC recommendation via Dr. Walensky statement – NYS providers CAN administer these products **once this final recommendation is issued by the CDC Director, following all instructions contained in the latest EUA FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE.**
5. Clinical considerations to support operations are released.
6. Guidance to NYS providers is released, summarizing and amplifying the latest information.

Important Information about Pfizer-BioNTech and Moderna COVID-19 vaccines for young children[‡]

Info	Pfizer-BioNTech	Moderna
Age indication	6 months through 4 years*	6 months through 5 years
Shipping	Directly from Pfizer at -80° C on dry ice in a single-use shipper. Shipment notification email will come from Pfizer.logistics@controlant.com or donotreply@pfizer.com	From McKesson at -20° C. Shipment notification email will come from CDCCustomerService@McKesson.com
Storage after received	Up to 12 months from manufacture date at ultra-cold temperatures of -90°C to -60°C OR Up to 10 weeks at refrigerated temperatures of 2°C to 8°C (36°F to 46°F). NOTE: NO standard freezer storage is approved for this formulation.	Until expiration at standard freezer temperatures -50°C to -15°C (-58°F to 5°F). Expiration dates found at https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup OR Up to 30 days at refrigerated temperatures of 2°C to 8°C (36°F to 46°F)
Vial caps/labels	Maroon cap and vial labels with maroon border	Blue cap vial
Dose	3 micrograms/0.2mL	25 micrograms/0.25mL
Series	3 dose primary series	2 dose primary series
Dilution	2.2 mL (diluent provided in ancillary kit)	Not required
Ordering NDC	59267-0078-04	80777-0279-99
Packaging configuration	10-dose vials in cartons of 10 vials each	10-dose vials in cartons of 10 vials each
Minimum order quantity	100 doses	100 doses
Post-puncture	Use/discard within 12 hours**	Use/discard within 12 hours

[‡]This information is current as of June 2, 2022, and subject to change. Always follow the most current Emergency Use Authorization (EUA) Fact Sheet for Health Care Providers for updates.

*Maroon Cap vial labels and cartons may state 2 years to <5years of age or 6 months through 4 years of age. Vials with labels that state for use in individuals 2 years to <5 years of age can be used for individuals 6 months through 4 years of age.

**Maroon Cap vial labels and cartons may state that a vial should be discarded 6 hours after the first dilution. The information in the EUA Fact Sheet (12 hours) supersedes the number of hours printed on vial labels and cartons.

Label Characteristics

Maroon Cap Ages 6 months through 4 years



If authorized by the FDA, Maroon Cap vaccine vials and cartons you receive will be labeled as Pfizer-BioNTech COVID-19 Vaccine

Initial shipments of Maroon Cap vials and cartons will have the following label characteristics:

Maroon Cap vaccine requires dilution prior to use

*Maroon Cap vial labels and cartons may state that a vial should be discarded 6 hours after the first dilution. Results from recent stability studies will supersede the current vial label and support discarding the vaccine after 12 hours from the time of dilution.

IMPORTANT INFORMATION

- The vial and carton labels may state **2 years to <5 years of age or 6 months through 4 years of age.**
- Vials with labels that state for use in individuals **2 years to <5 years of age** can be used for individuals **6 months through 4 years of age.**

*Note: Prior to preparation of the vaccine, please review the EUA Fact Sheet (if authorized by the FDA) as the timeframe for use post-dilution has been extended to **12 hours**

Pfizer Medical FOR TRAINING PURPOSES ONLY – THE VACCINE HAS NOT BEEN AUTHORIZED FOR USE IN INDIVIDUALS YOUNGER THAN 5 YEARS OF AGE

Comparison of current Pfizer-BioNTech COVID-19 Vaccine Products

Pfizer-BioNTech COVID-19 Vaccine Products

**PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL;
CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY**

	Current Products		Future Product
Age Indications^a	12 years and older	5 through 11 years	6 months through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY	ORANGE	MAROON
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use
Amount of Diluent Needed per Vial^b	Do Not Dilute	1.3 mL	2.2 mL
Dose Volume/Dose	0.3 mL/30 mcg	0.2 mL/10 mcg	0.2 mL/3 mcg
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions			
ULT Freezer (-90°C to -60°C)^c	9 months	9 months	9 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

^a Use the appropriate product based on the age of the recipient. ^b Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. ^c Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons. ^d The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.

Important Ordering Information

- To ensure efficient rollout of this vaccine supply, CDC is allowing pre-ordering of vaccines. Providers may begin to place their Pfizer-BioNTech COVID-19 vaccine orders for ages 6m-4y and Moderna COVID-19 vaccine orders for 6m-5y in NYSIIS on **Friday, June 3, 2022**.
- Wave 1 pre-orders: It is anticipated that orders entered in NYSIIS between June 3rd and June 7th will deliver on Monday, June 20th.
 - **IMPORTANT: June 20th is the observance of the Juneteenth holiday. If you place your order in wave 1 you **must** be available to accept vaccine delivery on June 20th.**
 - You must add an order note in NYSIIS indicating whether you will be able to accept delivery on June 20th. Without confirmation that you will be available to accept delivery on June 20th your order will not be sent to CDC until wave 2.
- Wave 2 pre-orders: Orders placed between June 8th and June 13th should begin delivering June 21st (see Anticipated Order and Delivery Timeline below). If you will not be open/available to accept delivery on June 20th, please wait until June 8th to place your pre-order.
- You may order each product if you want to offer brand choice. Pay close attention to storage and handling and administration differences.
- Place your pre-orders separate from ALL other COVID and non-COVID vaccine orders. If you want to pre-order both products you may include them on the same order.
- Shipment of COVID-19 vaccine for young children is planned to begin once FDA issues the EUA. However, vaccine administration can only begin following the CDC recommendation.
- Minimum ordering quantities will be 100 doses (10 vials). Providers are strongly encouraged to directly order this product rather than rely on redistribution.
- New York State has a limited quantity of doses available for ordering in the pre-order period. Please limit your order to what you anticipate administering in the first 3 weeks after approval (or minimum order quantity, whichever is larger).
- Responsible wastage policies remain in effect. Providers should plan to minimize waste to the best of their ability but should not miss the opportunity to vaccinate a willing individual, even if it results in other wasted doses.
- There is no limit on frequency of orders placed after the pre-order period (i.e., after June 20th) and will take approximately one week to deliver.

Anticipated Order and Delivery Timeline*

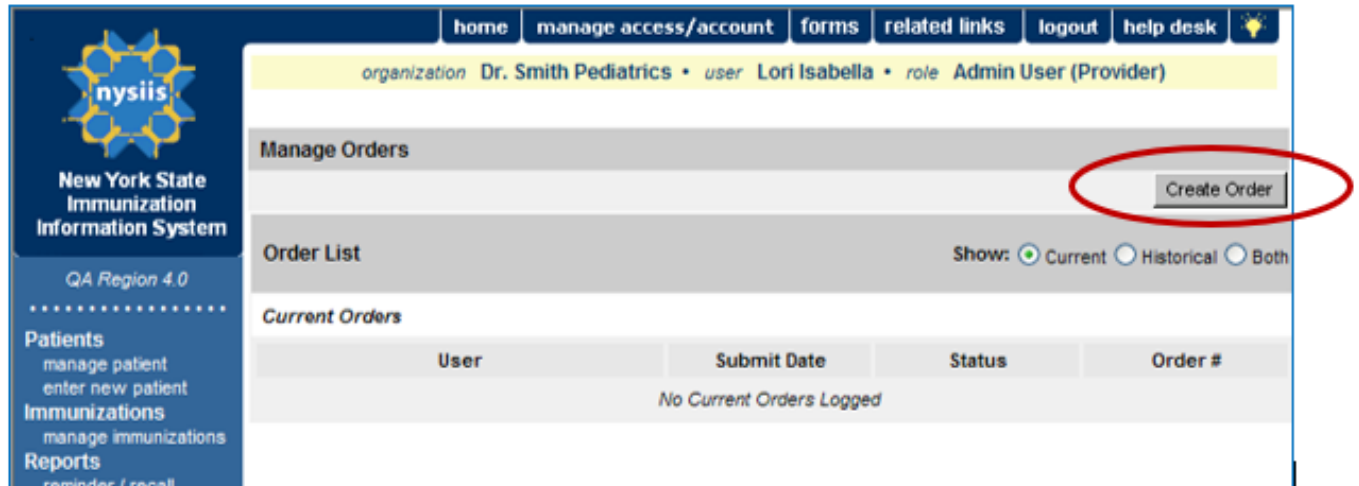
Date Order Placed in NYSIIS	Anticipated Delivery Date
Friday June 3 rd to Tuesday June 7 th by 3PM (must add note indicating availability for 6/20 delivery)	Monday, June 20, 2022 (Federal Holiday)
Tuesday June 7 th after 3PM to Monday June 13 th by 3PM	Beginning Tuesday, June 21, 2022*
Monday June 20 th or later	Approximately one week after order placed in NYSIIS

* Based upon current CDC planning assumptions. Exact delivery date will depend on total orders received (nationally) and may take several days for all pre-orders to deliver. Orders are shipped in the order they are received by CDC. **Do not schedule appointments until you receive your shipping notification email from Pfizer or McKesson.** Creating a call or wait list is acceptable and encouraged.

How to Place Pediatric COVID-19 Vaccine Order in NYSIIS

(Providers in New York City should follow instructions from NYCDOHMH and CIR.)

Step 1: Navigate to the Manage Orders screen and click Create Order.



The pediatric COVID-19 vaccines for young children (Pfizer-BioNTech COVID-19 for 6m-4y and Moderna COVID-19 for 6m-5y) will appear under Pediatric Intention list. If you are also enrolled with Vaccines for Children (VFC), you will see these vaccines among the other vaccines in your Pediatric Intentions, listed alphabetically by trade name.

It is important to place PRE-ORDERS separate from all other vaccine orders (including all other COVID-19 vaccines, VFC, VFA, and influenza).

Create Order

VFC PIN: TRAINI

Initiating Organization: Smalltown Pediatrics
 Initiating User: [REDACTED]
 Org Phone: (518) 473-2839
 Org Fax: (518) 473-2839
 Order Created Date: 06/02/2022
 Order Submitted Date:
 Previous Order Date:
 Order Status:

Delivery Contact: [REDACTED]
 Delivery Address: 100 TRAINING ROAD
 TRAININGVILLE, NY 12303

Delivery Days/Hours:
 Tues 7:00AM - 12:00PM
 Wed 7:00AM - 12:00PM
 Thur 7:00AM - 12:00PM

Delivery Instructions:

Order the number of doses of vaccine that are needed.
 Allow approximately 2 weeks for delivery.

Order Notes:
 Enter text 150 character maximum.

Inventory Verified
 By checking this box, I attest that the physical inventory count matches the Doses on Hand in NYSIIS.

Orderable Vaccines

Pediatric Intention

Trade Name	Packaging	NDC Number	Doses Admin (EOQ)	Doses on Hand	Doses Ordered
ModernaCOV-19 Ped 6M-5Y	Moderna PED 6m-5y 100 doses; 10-dose vial, 10 vials	80777-0279-99	0	0	<input type="text"/>
PFR COV-19 TS 6mo-4yr	Pfizer PED 6m-4y 100 doses; 10-dose vial; 10 vials	59267-0078-04	0	0	<input type="text"/>
PFR COV-19 TS ped 5-11	Pfizer PED 5-11 100 doses; 10-dose vials, 10 vials	59267-1055-04	0	0	<input type="text"/>

Adult Intention

Trade Name	Packaging	NDC Number	Doses Admin (EOQ)	Doses on Hand	Doses Ordered
Janssen COVID-19 Vaccine	J&J 100 doses; 5-dose vials, 2 boxes of 10 vials	59676-0580-15	0	0	<input type="text"/>
Moderna COVID-19 Vaccine	Moderna 100 doses; 10-dose vials, 10 pack	80777-0273-99	0	0	<input type="text"/>
PFR COV-19 TS 12+	Pfizer 12+ Gray 300 doses; 6-dose vials, 50 vials	59267-1025-04	0	0	<input type="text"/>

If ordering before June 8th, you must add a note here indicating whether you will be available for June 20th delivery

- Step 2: Enter the number of doses in **100-dose increments** in the Doses Ordered box.
- Pfizer-BioNTech COVID-19 vaccine for 6m-4y must be entered under the NDC 59267-0078-04 highlighted above in yellow. Select carefully since the Pfizer orange cap for 5 to 11 year-olds is also listed under pediatric intention.
 - Moderna COVID-19 vaccine for 6m-5y must be entered under the NDC 80777-0279-99 highlighted above in blue. This NDC is listed under the Pediatric Intention section compared to the current formulation for adults.
 - If you enter an amount that is not in 100 dose increments NYSIIS will round up to the next multiple upon saving.

Step 3: Add any relevant order notes in the text box located above the Orderable Vaccines table. If you are pre-ordering prior to June 8th, you must add an order note indicating whether you will be available for delivery June 20th. If you are placing a large order (over 300 doses), it is always helpful to add order notes with information about your vaccination plans.

Step 4: Check the Inventory Verified box – be sure your NYSIIS inventory accurately reflect actual doses on hand!!

Step 5: Click Save & Submit.

Note: If you only click Save button, your order will not be submitted to the Vaccine Program for review.