

NYS Department of Health COVID-19 Vaccination Program
Pfizer COVID-19 Vaccine Ordering Guidance for Children 6 Months – 4 Years Old
February 9, 2022

ALERT – Pfizer COVID-19 Vaccine for ages 6 months through 4 years Pre-Orders Open NOW!!

An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 6 months through 4 years old has been submitted to the FDA. Data were submitted for two doses of what is anticipated to be a three-dose series. 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 the anticipated Pfizer-BioNTech pediatric product for ages 6 months through 4 years.

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.

Anticipated timeline:

1. The Vaccines and Related Biological Products Advisory Committee (VRBPAC) (FDA’s advisory group) is scheduled to meet on February 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 VRBPAC; the meeting will be posted here once scheduled: <https://www.cdc.gov/vaccines/acip/index.html>
4. NYS Clinical Advisory Task Force deliberates.
5. CDC recommendation via Dr. Walensky statement – **until this final recommendation is issued by the CDC Director, no pediatric vaccine can be administered to children 6 months through 4 years old.**
6. Clinical considerations to support operations are released.

Important Information about Pfizer-BioNTech COVID-19 Vaccine for children 6 months through 4 years old




- The Pfizer-BioNTech vaccine for 6 months through 4 years ships at -80°C, like all current Pfizer COVID-19 vaccines, and has a similar product configuration to the 5–11 year old vaccine, but with a **different color cap (maroon), different dose (3 micrograms/0.2mL), different amount of diluent added (2.2mL), and a new national drug code (NDC).**
- The vials will have a maroon cap and vial labels with a maroon border.
- The current products for adults, adolescents, and children ages 5-11 years **CANNOT** be used in children 6 months through 4 years.
- The packaging configuration will be 10-dose vials in cartons of 10 vials each (100 doses total) pending FDA authorization. The product will be delivered in a single-use product shipper at -80°C (on dry ice).
- **The minimum order quantity will be 100 doses.**

- Once the product arrives at the provider site, it **can be stored for up to 10 weeks at refrigerated temperatures of 2 to 8°C and up to 9 months at ultra-cold temperatures of -90 to -60°C**. **NOTE: No standard freezer storage is approved for this formulation.**
- Once a vial is reconstituted, all 10 doses must be used within 12 hours.
- 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.
- Pfizer COVID-19 pediatric vaccine for 6 months through 4 years will require diluent. The diluent will be provided with ancillary supplies. **NOTE – reconstitution of the product for use in 6 months through 4 year olds uses a different volume of diluent (2.2 mL) than the pediatric 5-11 (orange cap) product (1.3 mL).**

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 in NYSIIS on **Wednesday, February 9, 2022**.
- Place your pre-orders for Pfizer-BioNTech COVID-19 vaccine for ages 6m–4y separate from other vaccine orders.
- Shipment of Pfizer-BioNTech COVID-19 vaccine for ages 6m–4y is planned to begin once FDA issues the EUA. However, vaccine administration can only begin following the CDC recommendation.

- It is anticipated that orders entered in NYSIIS on February 9th and 10th will deliver on Monday, February 21st. **Because this is President’s Day (federal holiday), NYS will only approve your order for potential delivery that day if you enter an order note in NYSIIS stating “will be available for delivery 2/21.”** If this order note is not entered on orders placed prior to February 11th, we will hold on submitting your order to CDC until after February 11th to ensure delivery after February 21st.
- Orders placed after February 10th should begin delivering February 22nd (see anticipated Order and Delivery Timeline below).
- 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).
- There is no limit on frequency of orders placed after the pre-order period (i.e. after 2/24) and will take approximately one week to deliver.

Anticipated Order and Delivery Timeline*

Date Order Placed in NYSIIS	Anticipated Delivery Date
Wednesday 2/9 – 4 PM Thursday 2/10 (must add note indicating available for 2/21 delivery)	Monday, February 21, 2022 (Federal Holiday)
4 PM Thursday 2/10 – Noon Wednesday 2/16	Beginning Tuesday, February 22, 2022
Noon Wednesday 2/16 – Noon Friday 2/18	Beginning Wednesday, February 23, 2022
Noon Friday 2/18 – 4 PM Thursday 2/24	Week of February 28, 2022

* Based upon current CDC planning assumptions. Exact delivery date will depend on total orders received by Pfizer (nationally). Orders are shipped in the order they are received by Pfizer. **Do not schedule appointments until you receive your shipping notification email from Pfizer.** Creating a call or wait list is encouraged.

How to Place Pfizer-BioNTech 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.

organization Dr. Smith Pediatrics • user Lori Isabella • role Admin User (Provider)

Manage Orders

Create Order

Order List Show: Current Historical Both

Current Orders

User	Submit Date	Status	Order #
No Current Orders Logged			

The pediatric Pfizer-BioNTech COVID-19 vaccines will appear under Pediatric Intention. If you are also enrolled with Vaccines for Children (VFC) it will be in the list with your other pediatric vaccines. **It is important to place Pfizer-BioNTech COVID-19 vaccine PRE-ORDERS for 6m-4y separate from all other vaccine orders (including all other COVID-19 vaccines, VFC and influenza).**

Create Order

VFC PIN: TRAINI

Initiating Organization: Smalltown Pediatrics
 Initiating User: Lyndsey Hoyt
 Org Phone: (518) 473-2839
 Org Fax: (518) 473-2839

Order Created Date: 02/08/2022
 Order Submitted Date:
 Previous Order Date:
 Order Status:

Delivery Contact: JULIE SCHENKMAN
 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
PFR COV-19 TS 6m-4y	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"/>

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.

Note: If you enter an amount that is not in 100 dose increments NYSIIS will round up to the next multiple upon saving.

If you are placing a large order, it is always helpful to add Order Notes with information about your vaccination plans (text box located above the Orderable Vaccine boxes).

Step 3: Check the Inventory Verified box.

Step 4: Click Save & Submit.

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