

NYS Department of Health COVID-19 Vaccination Program

Pediatric Pfizer COVID-19 Vaccine Ordering Guidance – 10/19/21

ALERT – Pediatric COVID-19 Pre-Orders Open NOW!

An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 5-11 years old has been submitted to the FDA and is likely to receive authorization before other vaccines for this age group. 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.

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 October 26th
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 November 2nd and 3rd
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 5-11 year olds**
6. Clinical considerations to support operations are released

Important Information about Pfizer-BioNTech COVID-19 Vaccine for children 5-11 years old

- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a **new product configuration with new packaging, new preparation, and a new national drug code (NDC)**.
- The current product for adults and adolescents **CANNOT** be used in children.
- 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 newly updated product shipper at -80°C (on dry ice). However, please note that the minimum order quantity for the first week of orders will be 300 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 6 months at ultra-cold temperatures of -90 to -60°C**. **NOTE: No standard freezer storage is approved for the new pediatric formulation.**
- It is anticipated that once a vial is reconstituted, all 10 doses must be used within 6 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.
- COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children. **NOTE – reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation.**

Comparison of current Pfizer-BioNTech Adult/Adolescent vaccine formulation vs Pediatric formulation

Pfizer-BioNTech COVID-19 Vaccines		
PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL		
Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	Dilute Prior to Use	Dilute Prior to Use
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



Orange Cap – Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



NOTE: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)
**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old

Important Ordering Information

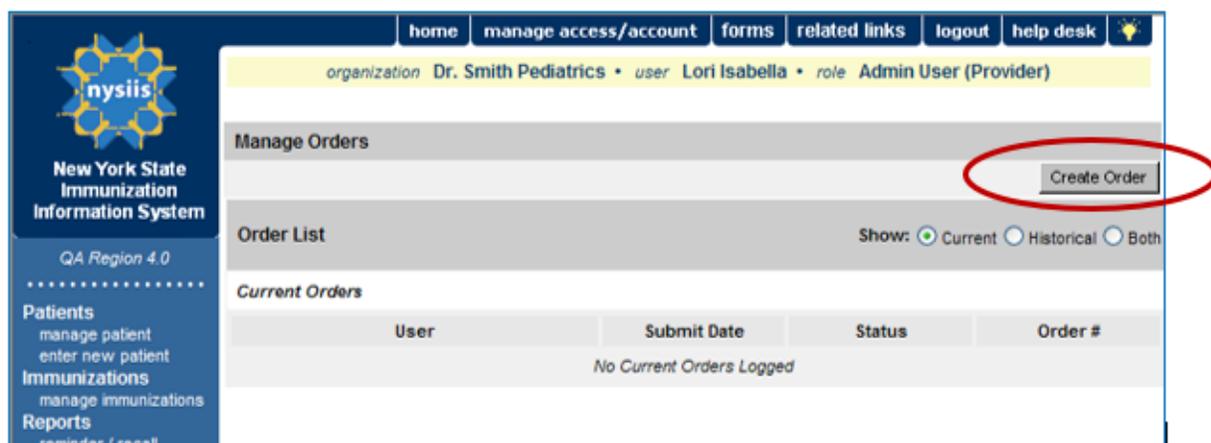
- To ensure efficient rollout of vaccine supply, CDC is allowing pre-ordering of pediatric vaccines. Providers may begin to place their pediatric Pfizer-BioNTech COVID-19 vaccine orders in NYSIIS on **Tuesday, October 19, 2021**.
- Only larger, non-pharmacy providers that can receive, store, and administer **at least 300 doses** of pediatric Pfizer-BioNTech COVID-19 vaccine within the first month of roll out will be eligible to place their orders between October 19th and **Noon October 25th**. Pre-orders during this first week have a 300-dose minimum and must be placed in 300-dose increments (300, 600, 900, etc.). See further guidance below for providers that want to order less than 300-doses of pediatric Pfizer-BioNTech COVID-19 vaccine.
- Providers should evaluate 1st and 2nd dose needs when ordering. Second dose administration is expected to be recommended at least 21 days after the first dose, pending final recommendations.
- Shipment of approved pre-orders of pediatric Pfizer-BioNTech COVID-19 vaccine will commence following FDA regulatory action. Confirmation of order shipment will not be sent until after EUA issuance.
- Although vaccine may be pre-positioned, administration of vaccine cannot begin until both FDA approval and ACIP recommendations are received, and the CDC Director issues the final recommendation.**

- **Beginning October 27th**, providers that want to order less than 300 doses of pediatric Pfizer-BioNTech COVID-19 vaccine can begin entering their orders in NYSIIS in **100-dose increments**.
 - Please do not place an order for 100-200 doses prior to October 27th.
- **During the one-week pre-order period it is important to place pediatric Pfizer-BioNTech COVID-19 vaccine orders separate from all other vaccine orders (including other COVID-19 vaccines). COVID-19 vaccines should never be entered on the same order as VFC or influenza vaccines.**

How to Place Pediatric Pfizer-BioNTech COVID-19 Vaccine Order in NYSIIS

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

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



The pediatric Pfizer-BioNTech COVID-19 vaccine 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 pediatric Pfizer-BioNTech COVID-19 vaccine orders separate from all other vaccine orders (including other COVID-19 vaccines, VFC and influenza).**

Create Order

VFC PIN: TRAINI	Delivery Contact: JULIE SCHENKMAN	<input type="button" value="Save"/> <input type="button" value="Save & Submit"/> <input type="button" value="Cancel Order"/> <input type="button" value="Exit Page"/> <input type="button" value="Current Inventory"/>
Initiating Organization: Smalltown Pediatrics	Delivery Address: 100 TRAINING ROAD TRAININGVILLE, NY 12303	
Initiating User: Lyndsey Hoyt	Delivery Days/Hours:	
Org Phone: (518) 473-2839	Tues 7:00AM - 12:00PM	
Org Fax: (518) 473-2839	Wed 7:00AM - 12:00PM	
Order Created Date: 10/19/2021	Thur 7:00AM - 12:00PM	
Order Submitted Date:	Delivery Instructions:	
Previous Order Date:		
Order Status:		

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 (FOQ)	Doses on Hand	Doses Ordered
PFR COV-19 TS ped 5-11	Pfizer PED ONLY 300 doses; 10-dose vials, 30 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 140 doses; 14-dose vials, 10 pack	80777-0273-98	0	0	<input type="text"/>
Pfizer C-19 (Comirnaty)	Pfizer Age 12+ ONLY 1170 doses; 195 vials	59267-1000-02	0	0	<input type="text"/>

Step 2: Enter the number of doses **in 300-dose increments** in the Doses Ordered box. Pediatric Pfizer-BioNTech COVID-19 vaccine must be entered under the NDC 59267-1055-04 highlighted above.

Note: If you enter an amount that is not in 300-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.

After the pre-ordering period, the packaging description will be updated to reflect the reduced minimum ordering quantity of 100 doses (see below).

Pediatric Intention

Trade Name	Packaging	NDC Number	Doses Admin (EOQ)	Doses on Hand	Doses Ordered
PFR COV-19 TS ped 5-11	Pfizer PED ONLY 100 doses; 10-dose vials, 10 vials	59267-1055-04	0	0	<input type="text"/>