

Pediatric Pfizer and Moderna COVID-19 Vaccine Update

June 14, 2022

Agenda

- Providing Access
- Packaging/Vial Description
- Initial Allocation and Ordering
- Special Considerations
- Pediatric Order Form Walk Through
- Q&A

Pediatric Moderna and Pfizer Vaccines

- FDA VRBPAC Committee is scheduled to meet on June 15th to discuss data on Moderna for 6 months through 5 years of age and Pfizer for 6 months through 4 years of age. CDC's ACIP is then scheduled to meet within several days of VRBPAC on June 17th and 18th
- **Initial pediatric vaccine deliveries will begin the week of June 20th**
- Providing as many COVID-19 pediatric providers as possible with vaccine is critical to achieving equitable vaccine access during product roll out
- Even if ordering a small amount of vaccine, avoiding missed opportunities is critical during vaccine roll out




Packaging/Diluent

- The packaging configuration for both products will be 10-dose vials in cartons of 10 vials each (**100 doses total**) pending FDA authorization
- Based on current information, its anticipated that once a vial is opened, doses must be used within 12 hours
- Both Pfizer and Moderna products have the same storage conditions as each manufacturer's other COVID-19 vaccine products
 - Pfizer: 12 months ULT Freezer and/or 10 weeks for Refrigerator
 - Moderna: 6 months Freezer and/or 30 days Refrigerator (check lot number <https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup>)
- **Pfizer COVID-19 pediatric vaccines will require diluent**
 - The diluent will be provided with ancillary supplies which are configured specifically for use in this age group. NOTE – reconstitution of the product for use on 6 months–5-year-olds uses a different volume of diluent than the 5-11-year old formulation and the adult formulation

Pfizer Vials

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 mos 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	12 months	12 months	12 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 Use the diluent (Sterile 0.9% Sodium Chloride Injection, USP) included in the ancillary supply kit. Do not use any other normal saline or diluent.

^c Regardless of storage condition, vaccines should not be used after 12 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.

Pfizer Ancillary Kit

Ancillary Kit Overview

PURPLE (Ages 12+)	GRAY (Ages 12+) DO NOT DILUTE	ORANGE (Ages 5 thru 11)	MAROON (Ages 6 months thru 4)
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- Purchased by the US Government and distributed by McKesson at the direction of the US Government
- Vaccination sites will receive supplies for appropriate pack size shipment
- Upon receipt of the ancillary kit, take inventory to confirm all necessary components are present and in correct ratios

Purple Cap	Gray Cap	Orange Cap	Maroon Cap
<ul style="list-style-type: none"> • Needles (22-25G X 1") • Needles (22-25G X 1.5") • Mixing needles (21-25g x1.5") • Syringes (1 mL) • Syringes (3 mL or 5 mL) • Alcohol pads • Vaccination record cards • Needle gauge and length charts • Face shields • Surgical masks • Diluent vials (2 mL) 	<ul style="list-style-type: none"> • Needles (22-25G X 1") • Needles (22-25G X 1.5") • Syringes (1 mL) • Alcohol pads • Vaccination record cards • Needle gauge and length charts • Face shields • Surgical masks 	<ul style="list-style-type: none"> • Needles (25G X 1") • Mixing needles (21-25g x1.5") • Syringes (1 mL) • Syringes (3 mL or 5 mL) • Alcohol pads • Vaccination record cards • Needle gauge and length charts • Face shields • Surgical masks • Diluent vials (10 mL) 	<ul style="list-style-type: none"> • Needles (25G X 1") • Mixing needles (21-25g x1.5") • Syringes (1 mL) • Syringes (3 mL or 5 mL) • Alcohol pads • Vaccination record cards • Needle gauge and length charts • Face shields • Surgical masks • Diluent vials (10 mL)

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










Before administration of the vaccine, please see full Prescribing Information: 16+ years of age (DILUTE BEFORE USE/Purple Cap) and 16+ years of age (DO NOT DILUTE/Gray Cap) 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

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Moderna Vials

Moderna COVID-19 Vaccine Presentations

**DRAFT – SUBJECT TO
CHANGE PENDING
REGULATORY
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Age Group	Primary Series Dose: 12 years of age and older Booster Dose: 18 years of age and older	Booster Dose: 18 years of age and older	Primary Series Dose: 6 months-5 years of age
Dose Volume	Primary Series Dose: Each 0.5 mL Booster Dose: 0.25 mL	Booster Dose: 0.5 mL	Primary Series Dose: Each 0.25 mL
Dose Per Vial	Primary Series Doses only: maximum of 11 doses (range: 10-11 doses) Booster Doses only: maximum of 20 doses Combination of Primary Series Doses and Booster Doses: maximum of 20 doses	Booster Doses: 5 doses	Primary Series Doses only: maximum of 10 doses
Vial Cap Color	Red 	Dark Blue 	Dark Blue 
Vial Label	Blue border  NDC 80777-273-10	Purple border  NDC 80777-275-05	Magenta border  NDC 80777-279-05
Carton	Blue border  NDC 80777-273-99	Purple border  NDC 80777-275-99	Magenta border  NDC 80777-279-99

Slide 2

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Moderna Vials

Storage and Handling

All Vial Presentations

Local Storage Options for Unpunctured Vials

(up to the Date of Expiration)



Freezer

-50° to -15°C (-58° to 5°F)

- Do not store on dry ice or below -50°C (-58°F)



Refrigerator

2° to 8°C (36° to 46°F) up to 30 days
prior to first use



Room Temperature

8° to 25°C (46° to 77°F) for a total of
24 hours

- Store in original carton to protect from light
- Do not refreeze a thawed vial

Transportation of Thawed Vials at 2° to 8°C (36° to 46°F)

- If transport at -50° to -15°C (-58° to 5°F) is not feasible, thawed vials may be transported for up to 12 hours at 2° to 8°C (36° to 46°F), under these conditions:
 - Shipped using shipping containers qualified to maintain 2° to 8°C (36° to 46°F)
- **AND**
 - Routine road and air transport conditions with shaking and vibration minimized
- Once thawed and transported at 2° to 8°C (36° to 46°F), vials should not be refrozen
- Thawed and transported vials should be stored at 2° to 8°C (36° to 46°F) until use

For full information on storage and handling, please see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers).

Moderna COVID-19 Vaccine Full EUA Prescribing Information. Moderna; Updated March 29, 2022.

Slide 3

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Pediatric Vaccine: Second and Third Doses

- Pediatric doses will not have an automatic second dose sent 3 weeks later, as occurred with initial adult vaccine allocation
- LA also does not know what our future allocation of pediatric vaccine will look like so providers should order enough doses to cover 1st and 2nd doses for Moderna and 1st, 2nd, and 3rd doses for Pfizer
- Ex. If you expect to vaccinate 100 individuals in the first 2-3 weeks of pediatric vaccine availability, you will need to submit an order for 200 doses of Moderna vaccine (100 for first doses, and 100 for second doses) or 300 doses of Pfizer (100 for first doses, 100 for second doses and 100 for third doses)

Pediatric Vaccine: Minimum Pre-Order

- *The minimum direct order size for both Pfizer and Moderna will be 100 doses (10-10 Dose vials)*
- **However, LDH will not require this large of a minimum order – M& D will be filling all orders the first couple weeks**
- By shipping our entire initial allocation to M&D, we will continue our low and wide approach/allow providers to pre-order **as little as 30 doses of Pfizer** (3-Dose Series) or **20 doses of Moderna** (2-Dose Series)
- **“Pre-ordering” has begun this week in LINKS and will be open through 5:00 p.m. Tuesday, June 14th.**

The few slides explain how the Pfizer and Moderna vaccines will be delivered in minimum doses of 100 after the first wave of deliveries is completed. Vaccine will **NOT** be delivered like this initially to provider sites, as M & D will be repackaging all vaccine for delivery during the first wave.

Pediatric Pfizer Packaging

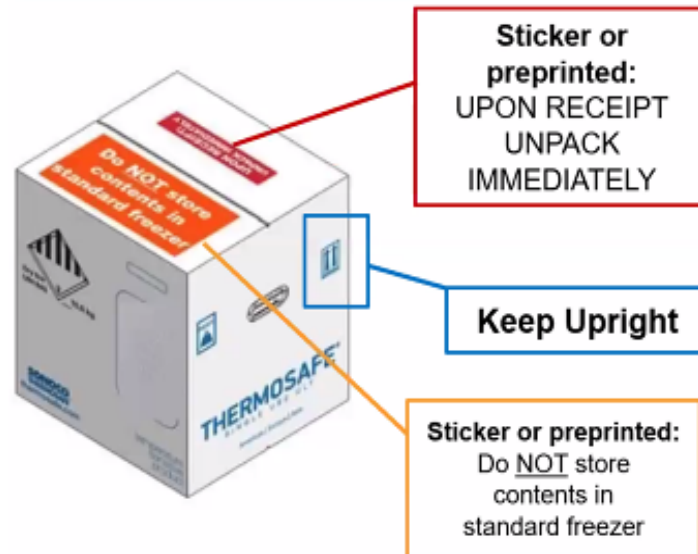
Product Packaging: Thermal Shippers

Applicable to the following cap colors:

GRAY	ORANGE	MAROON
(Ages 12+) DO NOT DILUTE	(Ages 5 thru 11)	(Ages 6 month thru 4)

For more information on unpacking the medium ULT and single use thermal shipping containers, storage, handling and return of the thermal shipping container and/or temperature monitors, please see

<https://www.cvdvaccine-us.com>



SINGLE USE ● ● ●

25-PACK CARTON ●

Between 1 and 4 cartons stacked in the box that holds the vial packs.

10-PACK CARTON ● ● ●

Between 1 to 10 cartons stacked in the box that holds the vial cartons.

The Single-Use Thermal Shipping Container **cannot** be used for temporary storage.

The single use shipper should be disposed of after unpacking the vaccine. However, **the Controlant monitor will need to be returned.**

The above is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.
Read all instructions included with the thermal shipping container and its components

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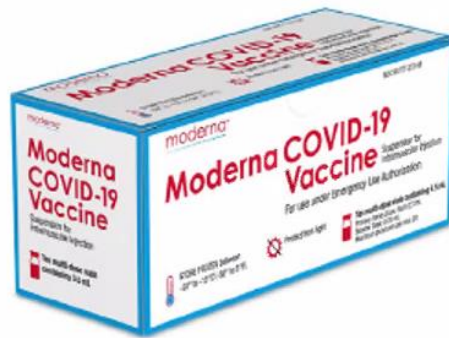
Note: M&D will be shipping all initial orders of pediatric COVID-19 vaccine so vaccine may arrive in a different shipper than below (particularly if you are ordering in quantities less than 100):

Pediatric Pfizer Packaging



Note: real packages of Pfizer will have Maroon-cap vials for age 6 months - 4 years vaccine. NOT grey or orange cap vials. This is just a model picture of the 10-pack carton.

Pediatric Moderna Packaging



For full information on storage and handling, please see Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers)

COVID-19, coronavirus disease 2019; EUA, Emergency Use Authorization; FDA, US Food and Drug Administration; US, United States.

Note: Packages of Moderna will have a blue colored cap and a magenta labeled border for age 6 months - 5 years vaccine. This is a model picture of the vial and 10-pack carton.



Pediatric Pfizer Vials

Applicable to the following cap colors:

MAROON
(Ages 6 months
thru 4)

Label Characteristics Maroon Cap Ages 6 months through 4 years

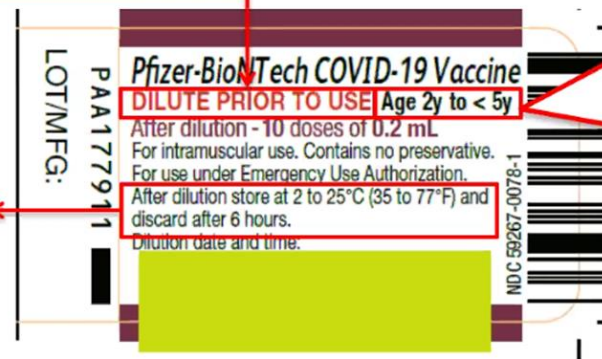


If authorized by the FDA, **Maroon Cap** vaccine vials and cartons you receive will be labeled as Pfizer-BioNTech COVID-19 Vaccine

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**

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

Initial Allocation

- Federal Government currently has enough pediatric doses on hand to meet the need of 6 month-5yr old US population, but doses will be allocated initially to prevent stockpiling/over ordering relative to demand
- Louisiana will receive an initial allocation of vaccine (to avoid a strain on the federal supply chain)
- We will then receive a weekly allocation for at least the first 3 weeks

Initial Allocation

- Please submit your initial order of vaccine through LINKS any time before **5:00 p.m. on Tuesday, June 14th**
- Even though doses will not ship until later this month, **all initial COVID-19 vaccine orders need to be submitted during the pre-order period.**
- Depending on the quantity of provider orders, and quantity of our state allocation, your order submission may be adjusted
- The Immunization Program will make every effort to ensure every provider who orders vaccine receives vaccine in this initial roll-out

Initial Allocation

- Providers will be notified of adjustments to their pediatric order quantity via email on June 17th , so they can begin any necessary planning
- Pending timely delivery from the federal government, vaccine deliveries may begin prior to ACIP/CDC recommendation
- Providers should prepare to receive and store doses early **but not begin administration** until full CDC and LDH authorization is given
- “Projected” pediatric vaccine administration start date is **the week of June 20th**
- Reminder – do not set appointments until vaccines are physically received
- Deliveries involved in this initial pre-order wave of vaccines could arrive into the week of June 27th

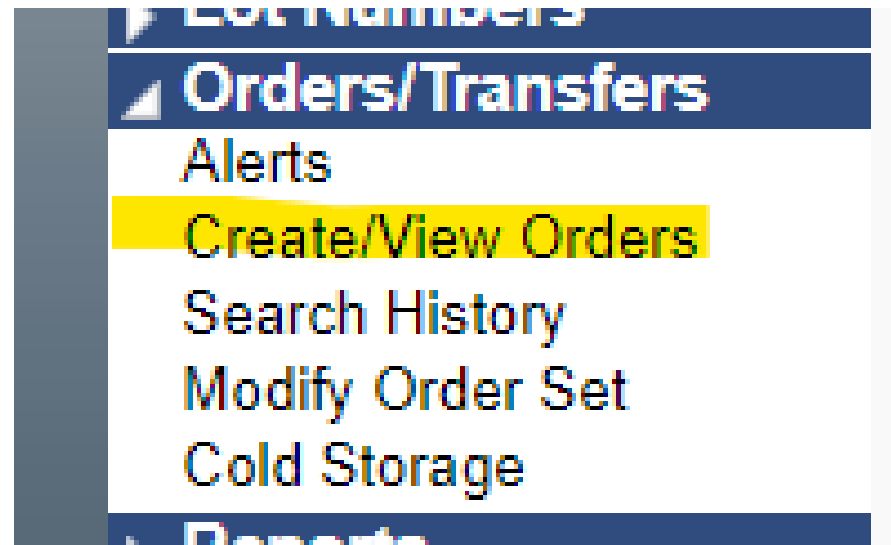
Other Planning Considerations

- Pharmacies in the Federal Retail Pharmacy Program will be able to order vaccine to select pharmacy locations, however many pharmacies in Louisiana have indicated they do not plan to order
- To support increased logistics needed to push out large number of pediatric doses during the first week, other vaccine products, from both the federal government and Morris and Dickson, may experience delays during initial 6-month-5-year rollout

COVID-19 Vaccine Order Form Walkthrough

Ordering COVID Pediatric Vaccines Through LINKS

- Log in to LINKS
- Go to the navigation menu. Click **Orders/Transfers**, then click **Create/View Orders**.



Ordering COVID Pediatric Vaccines Through LINKS

- Click on **Create Order**. This will bring you to your reconciliation page.
- Before you can proceed you will need to reconcile your inventory. Once completed, click **Submit Monthly Inventory**.

Reconcile										
Vaccine	Number		Quantity on Hand	Physical Inventory	Adjustment (+/-)	Category	Reason	Funding Source	Inactive	Add Row
COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose (Covid-19 0.3 (Pfizer))	25256645	10/31/2021	10	<input type="text" value="10"/>	0.0	--No Category Required--	--No Reason Required--	PUB	<input type="checkbox"/>	<input data-bbox="2127 935 2165 963" type="button" value="+"/>
MMR	1234567	06/20/2022	10	<input type="text" value="10"/>	0.0	--No Category Required--	--No Reason Required--	PUB	<input type="checkbox"/>	<input data-bbox="2127 1120 2165 1149" type="button" value="+"/>

[Inventory Last Submitted: 10/19/2021](#)

Ordering COVID Pediatric Vaccines Through LINKS

- Once you submit your monthly inventory, your Create Order page will be visible.
- Select your *Order Set* (for this case will be COVID-19 Pediatric/Distributor). Enter the *Order Quantity* (For COVID-19 pediatric vaccine, the minimum is 30 for Pfizer and 20 for Moderna). Select the *Vaccine Name*.
- Click **Submit Order**.
- It will take you to the Order/Transfer List and show; ex **Order 529475 Successfully created and Pending State Approval**. You will know your order has been completed and is awaiting approval.

Create Order

Organization: TEST IRMS
Facility: TEST FACILITY
Phone Number: (318)222-6666
Phone Extension:
Email: ADRIENNE.MERCADEL@LA.GOV

First Name: JANE
Middle Name:
Last Name: PIGGY
Address: 560 MOCCASIN LANE
City: NEW ORLEANS
State: LA
Zip: 70112

Monday: ☒ 08:00 12:00 13:30 17:00
Wednesday: ☐ 09:00 12:00 13:00 17:00
Friday: ☐ 09:00 12:00 13:00 17:00

Tuesday: ☒ 09:00 12:00 13:30 17:00
Thursday: ☒ 08:00 11:00 13:00 17:00

PIN: 88TEST
Order Date: 06/09/2022
Submitter: JUDI GREENE (JGREENE)
Comments:
Inventory Last Submitted: 06/07/2022
Last Order Submitted: 06/08/2022 02:07:29 PM
Order Set: COVID-19 PEDIATRIC / Distributor
Inventory Transaction Report Lot Number Summary Edit Temperature

Order Frequency: Order Timing:
Order Schedule:

Order Details

Vaccine	Vaccine Name	Funding Source	Dose Used Last Month	Physical Inventory	Order Quantity	Urgent	Priority Reason	Comments
COVID-19, mRNA, LNP-S, PF, 3 mcg/0.2 mL dose, tris-sucrose	Covid-19 ped(Pfizer maroon cap 6m-4y)	PAN	0	0		<input type="checkbox"/>	--select--	
COVID-19, mRNA, LNP-S, PF, pediatric 25 mcg/0.25 mL dose	Covid-19 (Moderna 6m-5y)	PAN	0	0		<input type="checkbox"/>	--select--	

Cancel Save Order Submit Order

Q&A