Immunization Service Provider Call

October 2022

Please place your name, and provider in the chat.

OKLAHOMA
State Department of Health

Agenda

- State Data / COVID Administration Guidance
- COVID-19 Vaccine Ordering Update
- Vaccine Storage and Handling
- Vaccine Ordering & Distribution
- OSIIS Updates
- Guest Speaker

  Dr. Gitanjali Pai, MD,AAHIVS, FIDSA
  - Monkey Pox Update
- Looking Forward

COVID-19 Vaccine State Data & Administration Guidance

Rishu Garg, Adult Vaccine Coordinator

OKLAHOMA State Department of Health

STATEWIDE COVID-19 VACCINE ADMINISTRATION (AS OF 9/26/2022)

2,280,122 people have received **at least 1 dose*** of the COVID-19 vaccine

1,937,737 people are **fully vaccinated**** with the COVID-19 vaccine

852,377 people have received a **3rd dose^** or **booster dose^^** of the COVID-19 vaccine

194,736 people have received a **4th dose** or **2nd booster dose** of the COVID-19 vaccine

73,082 people have received the **bivalent booster dose** of the COVID-19 vaccine

Across Oklahoma, a total of **5,134,917 COVID-19 vaccine doses** have been **administered** since 12/14/2020

*Refers to eligible individuals (ages 5 years+) receiving Pfizer and Moderna COVID-19 vaccines and/or receiving single shot of J&J/Janssen Vaccine; **Refers to eligible individuals (ages 5 years+) fully vaccinated after receiving either Pfizer and/or Moderna COVID-19 vaccines (both doses) and/or receiving single shot of J&J/Janssen Vaccine; ^3rd dose (Pfizer or Moderna) for individuals moderately to severely immunocompromised to be received at least 28 days after a second dose; ^^Booster dose for individuals 65+ or certain other adults at high risk of severe COVID-19 to be received at least six months after completion of the primary mRNA vaccine series or two months after receiving single dose of J&J/Janssen vaccine.

Note: Total vaccines administered does not include doses administered by federal entities (Bureau of Prisons, Veterans Heath, Indian Health Service, or Department of Defense).

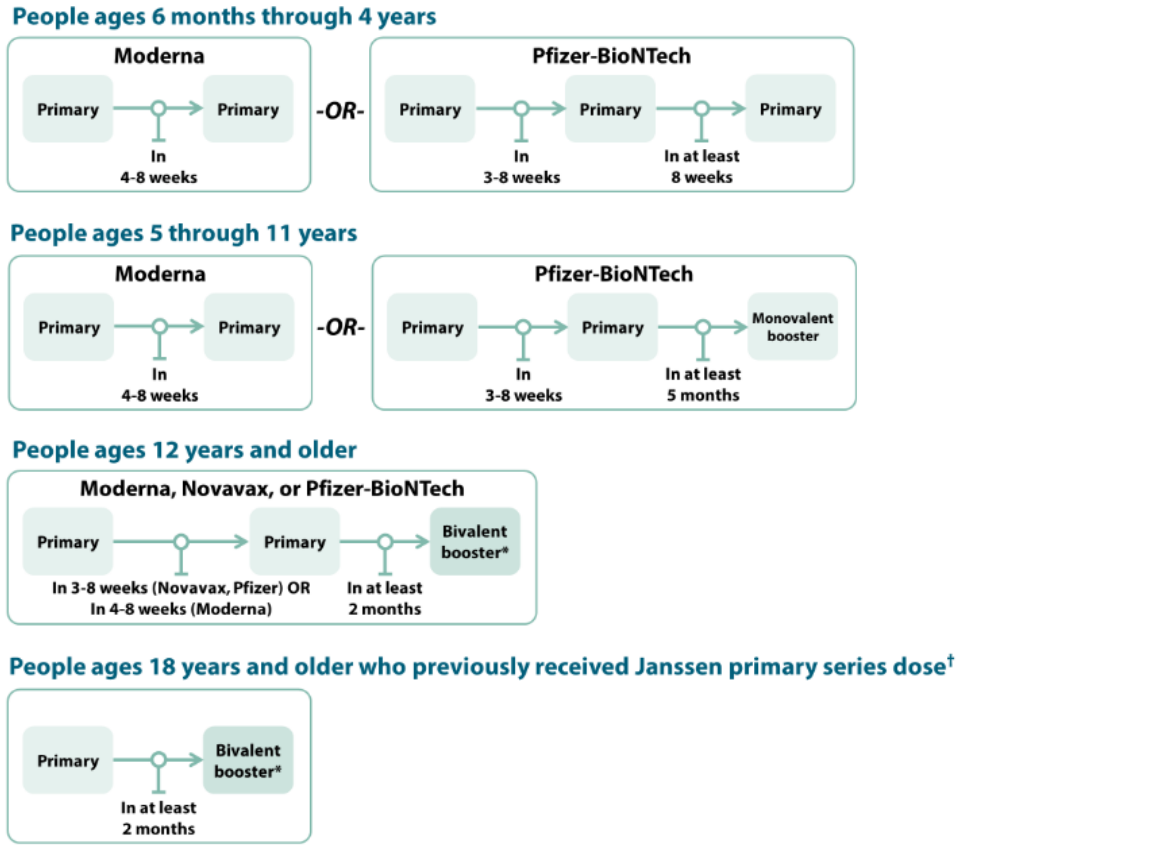
Not for public distribution, data intended for internal planning purposes.

Data Source: COVID-19 Vaccination Reporting Specification (CVRS) Dataset - Oklahoma State Immunization Information System (OSIIS); Data reflect information entered as of 11:59PM 9/26/2022

Covid-19 Vaccination Schedule

(Non-Immunocompromised)

COVID-19 Vaccination Schedule for People who are NOT Moderately or Severely Immunocompromised

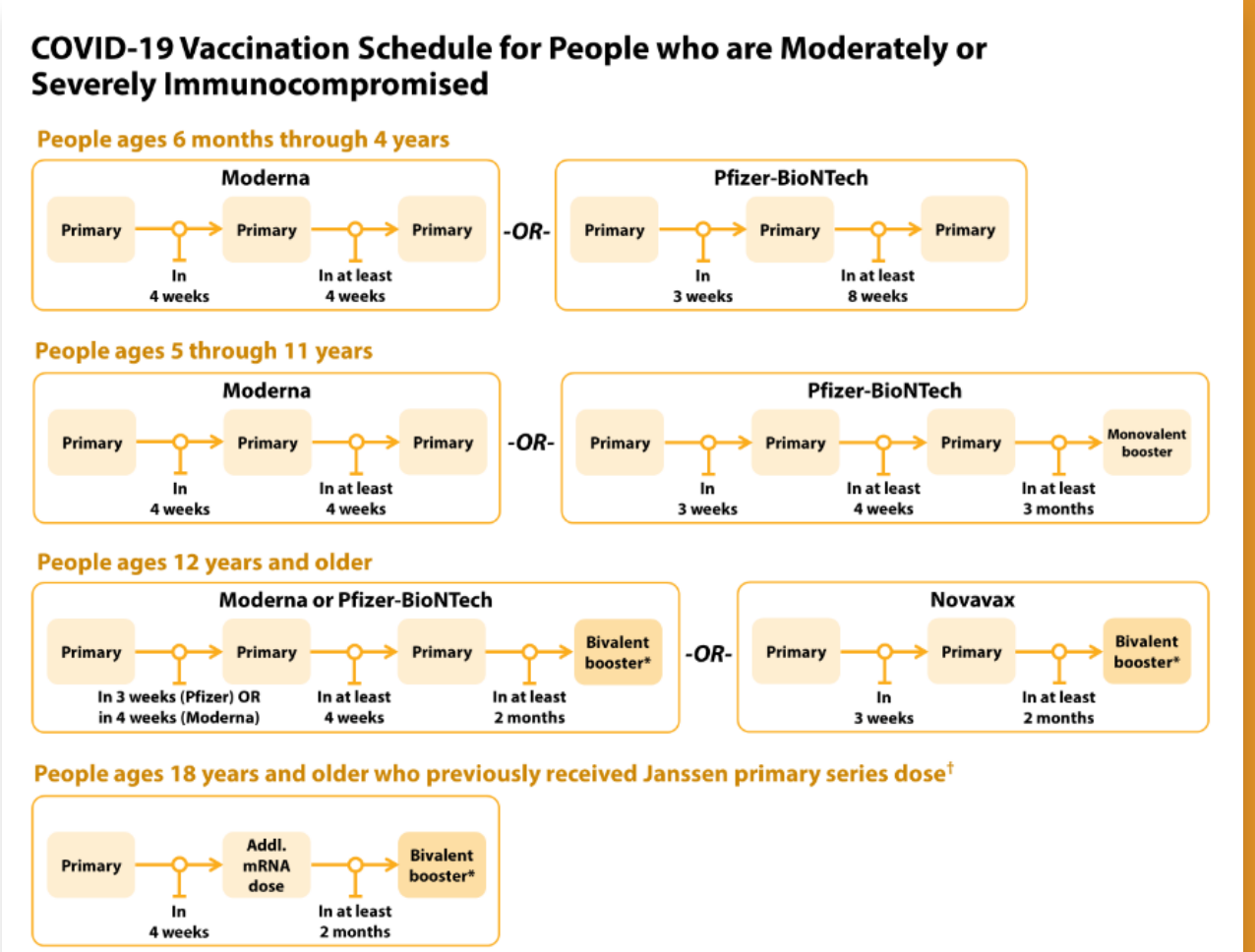


*The bivalent booster dose is administered at least 2 months after completion of the primary series.
For people who previously received a monovalent booster dose(s), the bivalent booster dose is administered at least 2 months after the last monovalent booster dose.
*Janssen COVID-19 Vaccine should only be used in certain limited situations.
See https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

[Clinical Guidance for COVID-19 Vaccination | CDC]

Covid-19 Vaccination Schedule

(Immunocompromised)



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*Janssen COVID-19 Vaccine should only be used in certain limited situations.
See https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-a

[Clinical Guidance for COVID-19 Vaccination | CDC]

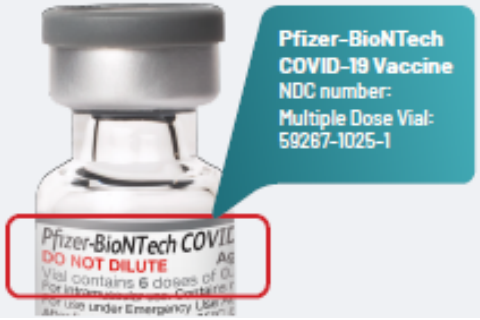
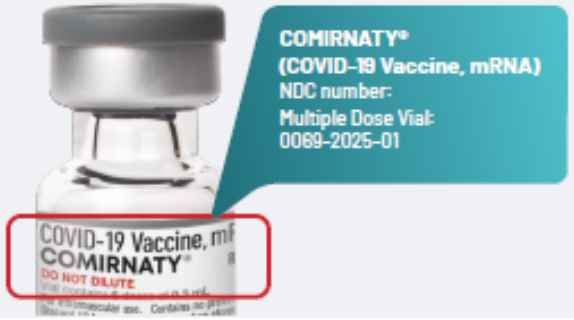
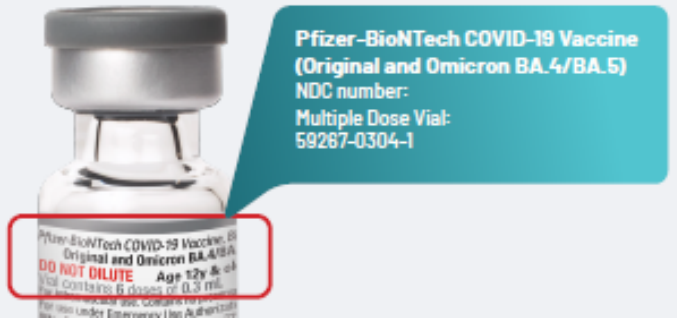
	Pfizer			
	Infant/Toddler 6 months–4 years*	Pediatric 5–11 years	Adol/Adult 12+ years	Bivalent Booster 12+ years
				
Packaging	Maroon Cap	Orange Cap	Gray Cap	Gray Cap
Doses Per Vial	10 doses	10 doses	6 doses	6 doses
Carton Size	100 doses	100 doses	60 doses	60 doses
Min. Standard Order	100 doses	100 doses	300 doses	300 doses
NDC-Unit of Use (vial)	59267-0078-01	59267-1055-01	59267-1025-01	59267-0304-01
CVX Code	219	218	217	300
Administration				
Diluent (supplied)	2.2 mL per vial	1.3 mL per vial	**Do not dilute.**	**Do not dilute.**
Dose Volume–Primary/Additional	0.2 mL† (3 mcg dose)	0.2 mL† (10 mcg dose)	0.3 mL (30 mcg dose)	N/A
Dose Volume–Booster	N/A	0.2 mL†	**Do not use for boosters.**	0.3 mL (30 mcg dose)
Refrigerator Thaw Time (2° to 8°C/ 36°F to 46°F) (Do not refreeze)	Up to 2 hours in carton	Up to 4 hours in carton	Up to 6 hours in carton	Up to 6 hours in carton

Storage Limits Before Puncture: Label vaccine with expiration and use-by dates.	
ULT (-90°C to -60°C)	Until expiration
Thermal Shipper	
Freezer	
Refrigerator (2–8°C)	Up to 10 weeks (write the date on carton)
Expiration Date	12 months from manufacture date printed on vial and carton or check product website.

Room Temp Thaw Time	Vial: 30 minutes at up to 25°C (77°F)
Total Time at Room Temp (Do not refreeze)	Up to 12 hours (including thaw time) at 8°C to 25°C (46°F to 77°F)
Storage Limits After Puncture: Record puncture and use-by time on vial label.	
Use-By Limit (Discard Time After 1st Puncture)	Discard after 12 hours at 2°C to 25°C (35°F to 77°F)

* Labels for Pfizer 6 months-4 years product may not reflect expanded age ranges. Refer to Provider Letter.
† Syringes in ancillary kits may require estimating volume between lines, or using private stock.

Distinguishing Between Gray Cap Vials

	PRIMARY SERIES		BOOSTER DOSE ONLY
Name	**Pfizer-BioNTech COVID-19 Vaccine** DO NOT DILUTE	**COMIRNATY® (COVID-19 Vaccine, mRNA)** DO NOT DILUTE	**Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)** DO NOT DILUTE
Variant Composition	**Monovalent: 30 mcg modRNA-Original** ["Monovalent" refers to vaccine that encodes the spike protein of only the Original SARS-CoV-2]		**Bivalent: 15 mcg modRNA-Original and 15 mcg modRNA-Omicron BA.4/BA.5**
Authorized Use (AU) or Indication	**Primary Series AU:** as a 2-dose primary series to individuals 12 years of age and older; and a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise*	**Primary Series AU:** as a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise* **Primary Series Indication:** as a 2-dose primary series to individuals 12 years of age and older	**Bivalent AU:** for 12 years of age and older as a single booster dose administered at least 2 months after: • completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or • receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine
Cap Color & Label *Gray caps and labels with gray borders*			

Full Presentation Guide: https://webfiles.pfizer.com/formulation-guide

Moderna COVID-19 Vaccine Presentations

	Moderna COVID-19 Vaccine Primary Series (12 years of age and older)	Moderna COVID-19 Vaccine Primary Series* (6 through 11 years of age)	Moderna COVID-19 Vaccine Primary Series (6 months through 5 years of age)	Moderna COVID-19 Vaccine, Bivalent Booster Dose (18 years of age and older)
Dose Per Vial	Primary Series Doses only: **maximum of 11 doses (range: 10-11 doses)**	Primary Series Doses: **5 doses**	Primary Series Doses: **10 doses**	Bivalent Booster Dose: **5 doses**
Dose Volume	Primary Series Dose: **Each 0.5 mL**	Primary Series Dose: **Each 0.5 mL**	Primary Series Dose: **Each 0.25 mL**	Bivalent Booster Dose: **Each 0.5 mL**
Vial Label	Blue border  NDC 80777-273-10	Purple border  NDC 80777-275-05	Magenta border  NDC 80777-279-05	Gray border  NDC 80777-282-05
Carton	Blue border  NDC 80777-273-99	Purple border  NDC 80777-275-99	Magenta border  NDC 80777-279-99	Gray border  NDC 80777-282-99

Updated FDA Recommendations 9.1

- **Bivalent Booster Authorized**

- On August 31, 2022:
  - Moderna COVID-19 Vaccine, Bivalent authorized for use in people ages 18 years and older; Pfizer-BioNTech COVID-19 Vaccine, Bivalent authorized for use in people ages 12+ years
- Authorized as a single booster dose administered at least 2 months after either:
  - Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
  - Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

- **mRNA COVID-19 Vaccines No Longer Authorized as Booster Doses for People Ages 12+ Yrs**

- Monovalent mRNA COVID-19 vaccines are *no longer authorized* as booster doses for individuals ages 12 years and older, meaning monovalent booster doses can no longer be given to people ages 12 years and older, even if the person had not previously received a monovalent booster dose.

- **Bivalent Booster Recommendations**

- Everyone aged 12 years+ is recommended to receive 1 age-appropriate bivalent mRNA booster dose after completion of any FDA-approved or FDA-authorized monovalent primary series or last monovalent booster dose.
  - *Age-appropriate homologous and heterologous boosters allowed; there is no preference*

➢ At this time, no changes to schedules for children ages 6 months through 11 years.

- **Previous Monovalent Booster Recommendations**

- The bivalent booster recommendation **replaces** previous booster recommendations for people ages 12 years and older.
- This means that everyone ages 5 years+ who are eligible for a booster dose will now only be eligible for ONE booster dose.
  - People ages 5-11 years (who received Pfizer-BioNTech primary series): 1 monovalent booster dose
  - People ages 12 years and older: 1 bivalent booster dose

Novavax

Dosage, Administration, and Schedule

- Administered intramuscularly in persons aged 12+ as a primary series of two doses (0.5mL each) **3 weeks apart**.

- Once opened, each vial must be used within 6 hours.

- **Booster Doses**
  - Adolescents ages 12–17 years: A 2-dose primary series and 1 age-appropriate* bivalent mRNA booster dose administered at least 2 months after completion of the primary series is recommended.
    - Currently, the bivalent Pfizer-BioNTech booster dose is authorized for this age group.
  - Adults ages 18+ years: A 2-dose primary series and 1 bivalent mRNA booster dose (Moderna or Pfizer-BioNTech) administered at least 2 months after completion of primary series is recommended.

Providers need to remain aware of the expiry date of vaccines in their inventory. Expiration dates can be obtained using the Novavax Expiry Date Checker

Johnson & Johnson/Janssen

Primary Series

- One dose (0.5 mL each).

Booster Doses

- Recommended that individuals 18+ years receive an **mRNA Bivalent Booster** at least *2 months* after initial dose.
- Moderately or Severely Immunocompromised individuals 18+ years may receive an additional mRNA dose *4 weeks* after the primary dose, and a Bivalent booster at least *2 months* after the second dose.

Changes to the J&J/Janssen EUA (as of May 5, 2022)

- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Pages 4-5, 13: Immune Thrombocytopenia

Federal Allocation has resumed for a limited time. Any order placed for the minimum amount (100) will be directly shipped. Orders requesting less than the minimum amount will be fulfilled by local County Health Departments.

- Providers need to remain aware of the expiry date of vaccines in their inventory.
- The expiration date can be obtained by entering the lot number from the carton or vial using the website www.vaxcheck.jnj

Mixing and Matching Boosters

	COVID Vaccine Received:			
	PFIZER	MODERNA	JANSSEN	Novavax
Who Should Get a Booster	* Everyone 5+	* Everyone 18+	* Everyone 18+	*Everyone 12+
When to Get a Booster	* At least 2 months after completing primary COVID 19 Vaccination Series	* At least 2 months after completing primary COVID 19 Vaccination Series	* At least 2 months after completing primary COVID 19 Vaccination Series	* At least 2 months after completing primary COVID 19 Vaccination Series
Which Booster can you get	5-11: Pfizer Monovalent Booster ONLY 12+: any mRNA COVID Bivalent Booster	18+: any mRNA COVID Bivalent Booster vaccine 12-17: Pfizer Bivalent Booster ONLY	18+: any mRNA COVID Bivalent Booster vaccine	12-17: Pfizer Bivalent Booster ONLY 18+: any mRNA COVID Bivalent Booster Vaccine
	*non-mRNA can be used to booster in special circumstances, please consult Primary Care Physician			

Co-Administration

- Administer vaccinations that may be more likely to cause a local reaction in different limbs, if possible.

- When deciding whether to co-administer other vaccine(s) with COVID-19 vaccine, consider:
  - Whether the patient is behind or at risk of becoming behind on recommended vaccines.
  - The patient's risk of vaccine-preventable disease.
  - The reactogenicity profile of the vaccines.
  - The likelihood of avoiding a missed opportunity to vaccinate.

COVID- 19 Vaccine Ordering Updates

Margaret Archer, MPH, and Muhammad Khalil, BSM
Covid-19 Vaccine Ordering Team

OKLAHOMA State Department of Health

COVID-19 Vaccines available in OSIIS

- OSIIS offers 13 Covid-19 vaccines across all age groups.
- Bivalent vaccines are available on page 2 when ordering vaccines.
- If you wish to order less than the minimum doses, please specify the number of doses you would like to order under the clinic comments before submitting the order.
- Pfizer has submitted an EUA application for Bivalent Booster 5Y-11Y to FDA and awaiting approval. Orders can be placed for this vaccine in OSIIS at this time and will be processed and shipped once fully authorized.

COVID-19 Vaccines available in OSIIS (cont.)

CVX	Name on OSIIS ordering page	NDC	Manufacturer	Minimum doses for direct-ship	Age Group	Ancillary Opt-Out	Primary or Booster
207	Moderna SPIKEVAX (10 x 5.5mL Vials)	80777-0100-99	MODERNA	100	12+	YES	PRIMARY ONLY
207	Moderna COVID-19 (10 x 10 dose 5.0 mL MDV)	80777-0273-99	MODERNA	100	12+	YES	PRIMARY ONLY
211	NOVAVAX	80631-0100-10	NOVAVAX, INC.	100	12+	YES	PRIMARY ONLY
212	Janssen COVID-19 (20 x 5 dose 5.0 mL MDV)	59676-0580-15	JANSSEN	100	18+	YES	PRIMARY ONLY
217	Pfizer Comirnaty COVID-19 (MDV6; 10 pack)	00069-2025-10	PFIZER, INC.	300	12+	YES	PRIMARY ONLY
217	PFR COVID Tris-sucrose (10 x 6 (0.3mL/dose) MDV)	59267-1025-04	PFIZER, INC.	300	12+	YES	PRIMARY ONLY
218	COVID-19 Pfizer 5-11Yrs (10X10 (0.2mL/dose) MDV)	59267-1055-04	PFIZER, INC.	100	5Y-11Y	NO, DUE TO DILUENT	PRIMARY & BOOSTER
219	PFR COVID Tris-suc 6m-4y (10 x 10(0.2mL/dose) MDV)	59267-0078-04	PFIZER, INC.	100	6M-4Y	NO, DUE TO DILUENT	PRIMARY ONLY
221	MOD COVID-19 6 to 12/Adu Booster(10x 2.5mL Vials)	80777-0275-99	MODERNA	100	6Y-12Y	YES	PRIMARY ONLY
228	Moderna COVID-19 Ped 6mo - 5yr (10 x 2.5mL Vials)	80777-0279-99	MODERNA	100	6M-5Y	YES	PRIMARY ONLY
229	COV-19 (Moderna); Bivalent; MDV5	80777-0282-99	MODERNA	100	18+	YES*	BOOSTER ONLY
300	PFR COVID-19 Bivalent Bstr 12+yrs (10x2.0mL MDV)	59267-0304-02	PFIZER, INC.	300	12+	YES*	BOOSTER ONLY
301	Pfizer COVID-19 Booster 5-11 yrs (10 x 2.0mL MDV)**	59267-0565-02	PFIZER, INC.	100	5Y-11Y	NO, DUE TO DILUENT	BOOSTER ONLY**

*If you wish to opt-out from receiving ancillary kits with the order, please specify it under the clinic comments before submitting the order.
**Awaiting FDA, CDC and ACIP recommendations. Orders will ship once fully authorized.

Vaccine Storage and Handling

Sonja Claborn LPN,
Immunization Field Consultant

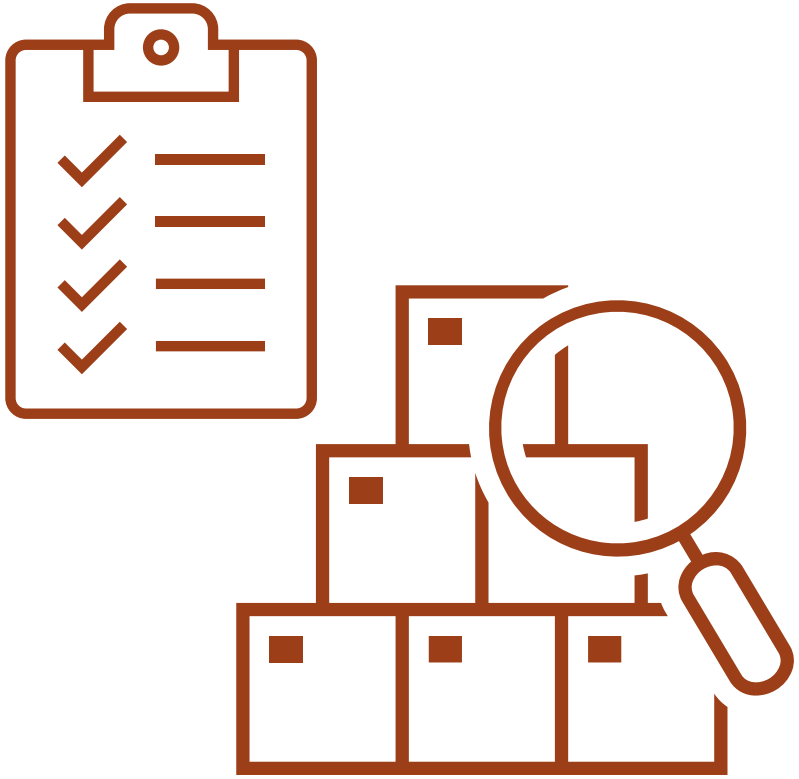
OKLAHOMA
State Department
of Health

Best Practice for Inventory Management

- To reduce waste, providers should be aware of vaccines in their inventory that are nearing expiration dates and prioritize their administration.

- Providers should enroll in the CDC Code Management Service to access the most up-to-date Expiration Information for all Vaccines.
  - Vaccine Lot Number and Expiration Date Webpage
  - Click the "Register" button in the upper right-hand corner to complete the registration form to request access.

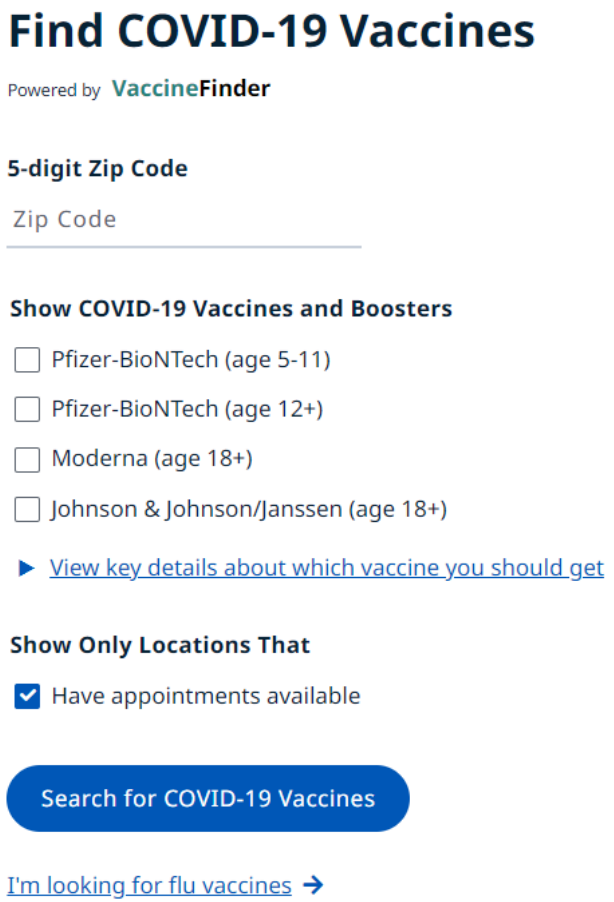
- Moderna, Novavax, Pfizer, J&J Vaccine Expiration Lookup & Reference Information:
  - Moderna Vial Expiration Data Look Up Tool
  - J&J Expiration Date Look Up Tool
  - Pfizer-BioNTech Covid-19 Lot Expiry Tool
  - Novavax Expiry Date Checker Tool



Inventory Update Required Vaccine Finder, OSIIS

Failure to maintain an updated inventory may impact vaccine orders.

- **Per the CDC, starting May 1st providers are required to update inventory in Vaccine Finder on a *weekly* basis.**
- Inventory will be listed by vaccine name and age designation, *not* cap color.
- Training Videos and Guides:
  - https://www.vaccines.gov/covid-provider-resources/
- Step By Step Instructions:
  - https://www.vaccines.gov/resources/QSG.for.Add.Vaccine.Flow_Clean_06_04_21_FINAL.pdf
  - For assistance in updating Vaccine Finder or OSIIS please call Immunization Services at (405) 426-8580.

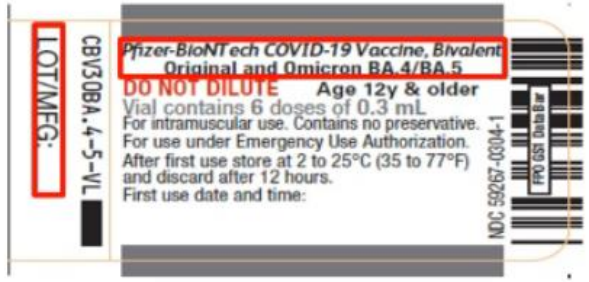


Pfizer Expiry Information

Pfizer-BioNTech COVID-19 Vaccine vials all have **DATE OF MANUFACTURE** printed on the label

(Ages 12+) BIVALENT, Booster Dose

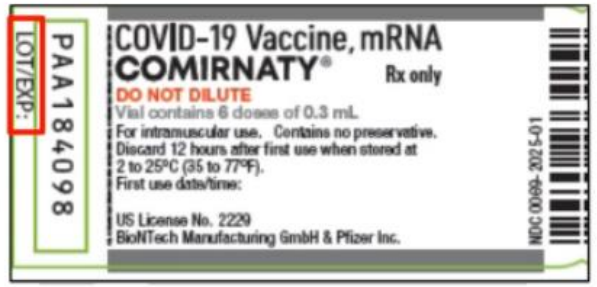
DATE OF MANUFACTURE



COMIRNATY® (COVID-19 Vaccine, mRNA) labeled vials are the only vials with **DATE OF EXPIRY** printed on the label

(Ages 12+), Primary Series, COMIRNATY

DATE OF EXPIRY



Pfizer Expiry Dates

(Based on 12 Months from Date of Manufacturer)

Orange Cap

Printed Manufacturing Date	12-Month Expiry Date
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

Maroon Cap

Printed Manufacturing Date	12-Month Expiry Date
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023

Regardless of storage condition, the vaccine should not be used after 12 months from the date of manufacture printed on the v ial & cartons.

https://lotexpiry.cvdvaccine.com/

Expiry Information

Pfizer-BioNTech COVID-19 Vaccine

Ages 12 years and older
DO NOT DILUTE Gray Cap

Date of Manufacture

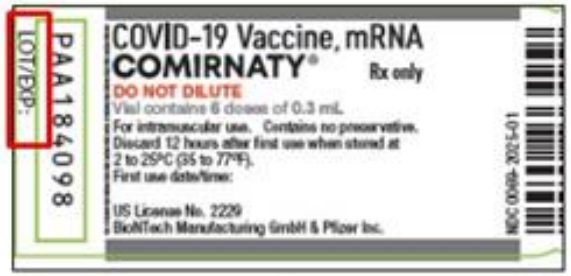
Printed Manufacturing Date	12-Month Expiry Date
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-Oct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

Refer to the EUA Fact Sheet for the most recent expiry date information

COMIRNATY® (COVID-19 Vaccine, mRNA)

Ages 12 years and older
DO NOT DILUTE Gray Cap

Date of Expiry



Printed Expiry Date	Updated Expiry Date
9/2022	31-Dec-2022
10/2022	31-Jan-2023
Additional expiry dates will be provided at a later date	

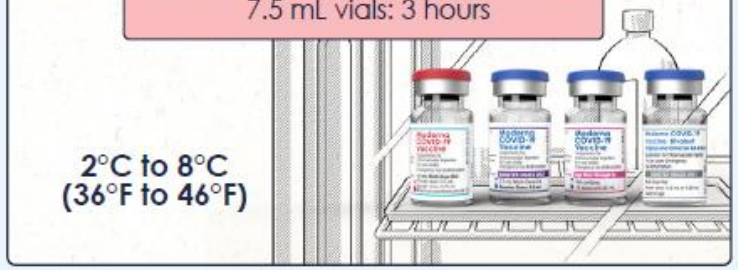
Contact Pfizer US Medical Information for more information

Moderna COVID-19 Vaccine Storage and Handling

Thaw Each Vial Before Use

Vial images for illustrative purposes only

Refrigerator
2.5 mL vials: 2 hours
5.5 mL vials: 2 hours 30 minutes
7.5 mL vials: 3 hours



OR

Room Temperature
2.5 mL vials: 45 minutes
5.5 mL vials: 1 hour
7.5 mL vials: 1 hour 30 minutes

Let vial sit at room temperature for 15 minutes before administering

Thawed Shelf Life

Unpunctured Vial

Maximum times

30 days — Refrigerator
2°C to 8°C (36°F to 46°F)

24 hours — Cool storage up to room temperature
8°C to 25°C (46°F to 77°F)

After First Dose Has Been Withdrawn

Maximum time

12 hours — Refrigerator or room temperature

Vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the vial label.

Discard punctured vial after 12 hours.

NEVER refreeze thawed vaccine

Moderna and Janssen Expiration

Important for <u>all vaccines</u>:

- Check the expiration dates upon receiving vaccines.
- Due to increased studies about stability data, check the expiration date again later (before administering vaccines and during weekly reconciliation).
- Please note that Moderna expiration extensions only apply to vaccines that ***have not been thawed or refrigerated.***
- ***Reminder: Janssen should never be stored in the freezer or ultracold.***
- How to check expiration dates?
  - Scan QR code and it will take you to the website showing the expiration date.
  - Locate lot number on the package and type into the website.
    - Janssen website
    - Moderna website
    - https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page

Pfizer

The expiration date is written on the vial.

Moderna

A QR code on the vial is scanned and a website provides the expiration date.

J&J/Janssen

Scan the QR code located on the outer carton, or
call 1-800-565-4008, or go to www.vaxcheck.jnj

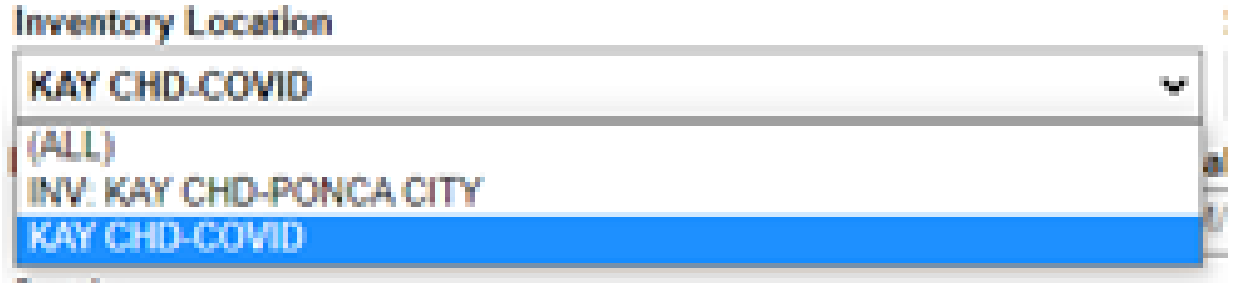
Vaccine Ordering and Distribution

Teja Paruchuri, MPH

Reconciliation

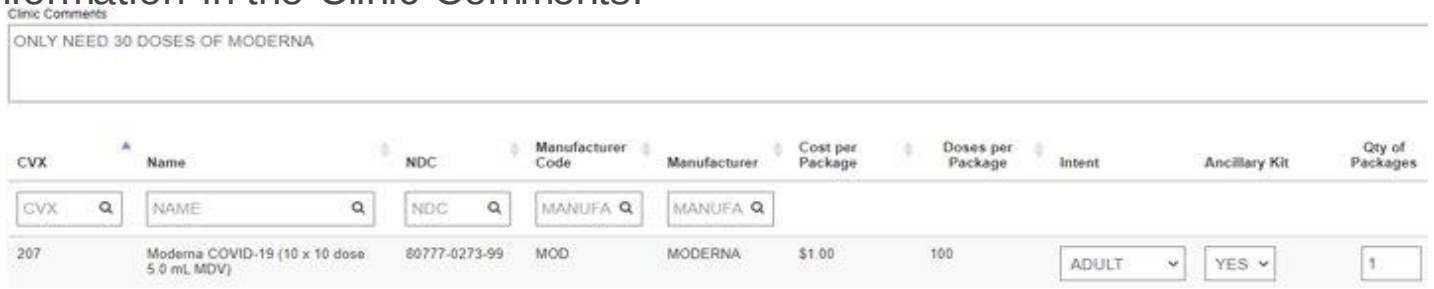
Reconciliation – weekly

- Providers are required to reconcile their inventory during the ordering time frame: **Tuesday through Monday.**
- If a clinic does not reconcile COVID inventory for 7 days, they will not be able to create a vaccine order.
- An informational video on COVID 19 vaccine reconciliation and ordering can be accessed at https://vimeo.com/528424790
- Inventory Reconciliation



Ordering Process

- Providers can create orders in OSIIS during the ordering timeframe which is **Tuesday through Monday**.
- Vaccines can be ordered based on the need. If less than the minimum quantity is needed, providers will need to place an order for the minimum quantity and add a comment in the Clinic Comments text area indicating the number of doses needed.
- Providers now have the option to opt-out from receiving vaccine ancillary kits with their vaccine order. This doesn't apply for Pediatric Pfizer and Pediatric Pfizer Bivalent booster.
  - If you wish to opt-out, please specify this information in the Clinic Comments.
- Please do not refuse any vaccine shipments.



Ordering Process

- The cut-off to create orders in OSIIS – Monday, 5pm.
- To make any changes or cancellations to orders after the deadline, providers must reach out ASAP.
  - To request a change, a provider should email to OSDH VaccineHelp <VaccineHelp@health.ok.gov>
  - If provider doesn't receive a confirmation of changes/cancellation within 24h, provider must call the OSDH Immunization Service 405.426.8580 to ensure that the order has been cancelled.
- Orders with at least min quantity, will be approved in OSIIS and directly shipped to providers – subjected to CHANGE depending on the available weekly threshold amounts.
- Orders with less than min quantity will be rejected in OSIIS with a note that County Health Department (CHD) will fulfill the order and get in touch with the provider via email or phone.
  - Example of the message: *"Your order will be fulfilled by your County Health Department. Watch for e-mail communication about the process and phone calls to arrange vaccine transfer."*
  - CHDs will deliver vaccines to providers on the same or the following week. Delivered by CHD employees, national guard, or courier service.

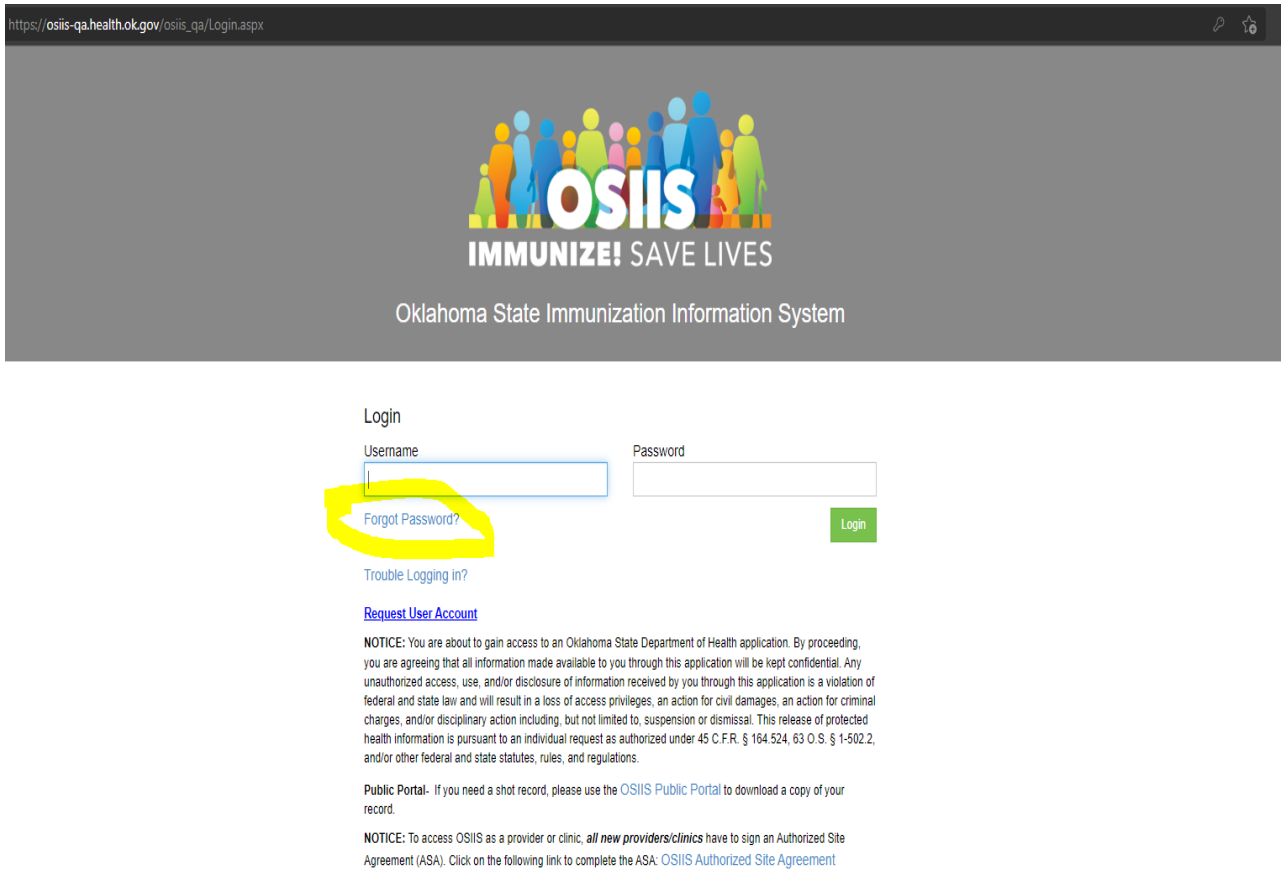
Ordering Process

- Upon delivery of vaccine by CHD, the provider should complete 4 steps:
  1. Sign a Bill of Lading and keep a copy.
  2. Check that delivered vaccines are viable.
  3. Immediately place vaccines into storage according to the guidelines and label appropriately indicating expiration and/or Beyond-use dates (BUDs).
  4. **Accept transfer in OSIIS.**
- Questions about orders:
  - OSIIS: OSIISHELP@health.ok.gov
  - Vaccine ordering process: VaccineHelp@health.ok.gov
  - Order fulfillment/delivery: Contact CHDs (contacts will be shared in the follow-up email).

OSIIS Updates

Martin Lansdale, MPH
OSIIS Data Quality Coordinator

Updating Passwords in OSIIS



Shot Records: Public Portal

- OSIIS has a public portal that can be found at the below link:
  - https://osiis.health.ok.gov/osiis_public/Application/PublicPortal
  - **DISCLAIMER:** Not all shots are recorded in OSIIS as reporting private vaccine is not required.

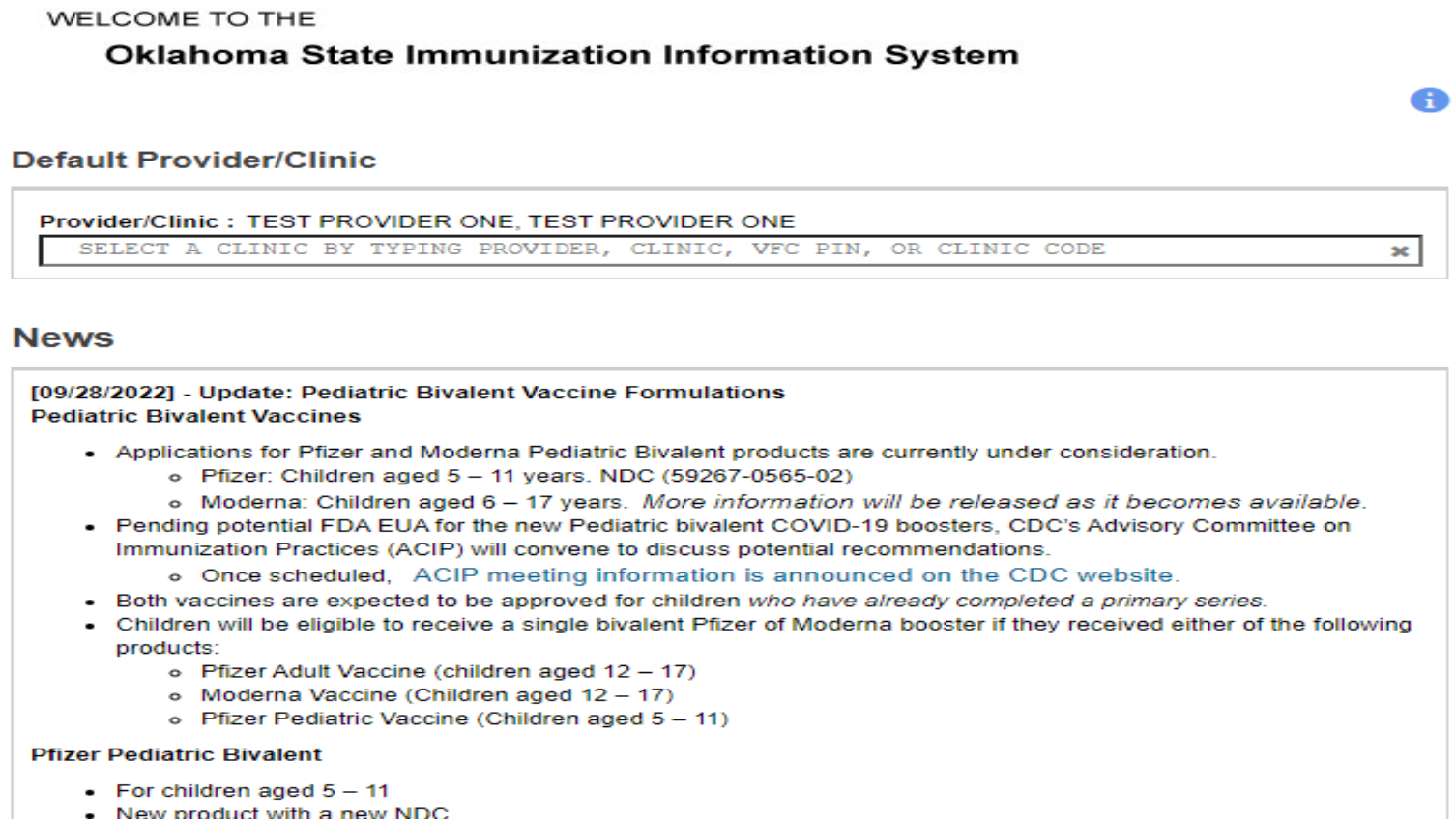
- Patients can search and download a copy of their shot record for just covid shots or their complete immunization history through the portal.

- The public portal uses **patient name, date-of-birth, email, and phone number** for verification purposes (all have to be on the shot record in OSIIS or patients cannot pull their shot record).

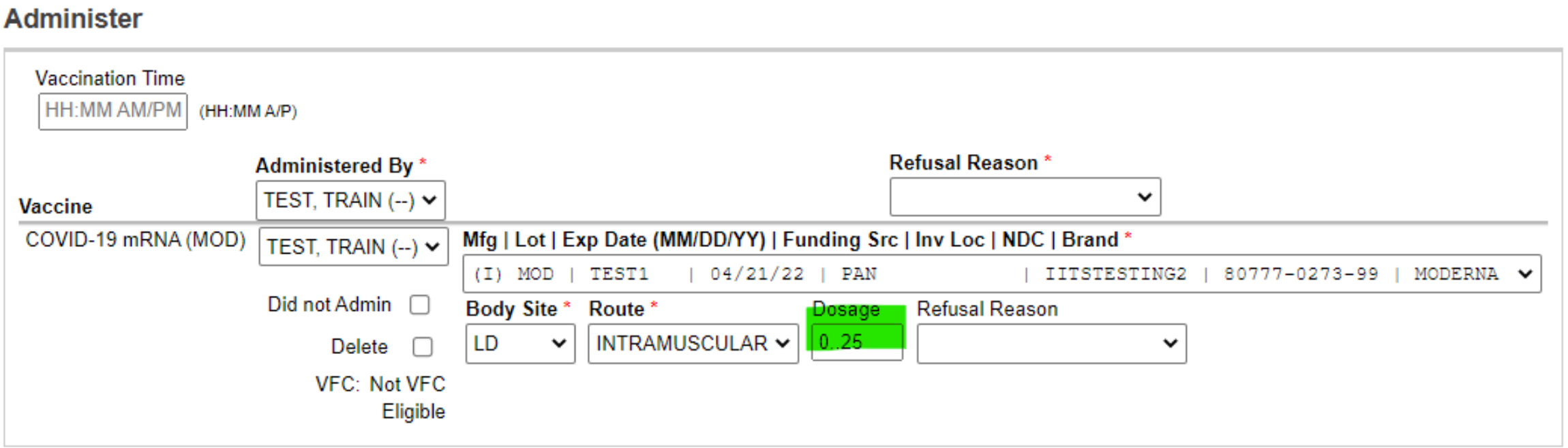
- Currently OSIIS has a high amount of missing emails/phone numbers.

- Providers need to make sure to document email and phone number for the patient **and add/send it to OSIIS** with the shot record in order to increase the likelihood of a records match in the portal.

News


WELCOME TO THE
Oklahoma State Immunization Information System
Default Provider/Clinic
Provider/Clinic : TEST PROVIDER ONE, TEST PROVIDER ONE
SELECT A CLINIC BY TYPING PROVIDER, CLINIC, VFC PIN, OR CLINIC CODE
News
[09/28/2022] - Update: Pediatric Bivalent Vaccine Formulations
Pediatric Bivalent Vaccines
Applications for Pfizer and Moderna Pediatric Bivalent products are currently under consideration.
Pfizer: Children aged 5 – 11 years. NDC (59267-0565-02)
Moderna: Children aged 6 – 17 years. More information will be released as it becomes available.
Pending potential FDA EUA for the new Pediatric bivalent COVID-19 boosters, CDC's Advisory Committee on Immunization Practices (ACIP) will convene to discuss potential recommendations.
Once scheduled, ACIP meeting information is announced on the CDC website.
Both vaccines are expected to be approved for children who have already completed a primary series.
Children will be eligible to receive a single bivalent Pfizer of Moderna booster if they received either of the following products:
Pfizer Adult Vaccine (children aged 12 – 17)
Moderna Vaccine (Children aged 12 – 17)
Pfizer Pediatric Vaccine (Children aged 5 – 11)
Pfizer Pediatric Bivalent
For children aged 5 – 11
New product with a new NDC

Moderna Booster in OSIIS



How To Guides

"How To" Guides

- Moderna Booster OSIIS Guide
- How to Turn On User Default Order Notifications
- Inventory Reconciliation
- How to Place a Covid-19 Vaccine Order
- Immunizing a Patient for COVID
- How to add an extra dose
- Wastage

Dr. Gitanjali Pai, MD., AAHIVS, FIDSA
Chief Medical Officer
Oklahoma State Dept of Health

OKLAHOMA
State Department
of Health

MONKEY POX

GITANJALI PAI MD AAHIVS FIDSA

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OKLAHOMA STATE DEPARTMENT OF HEALTH

OKLAHOMA
State Department of Health

MONKEYPOX VIRUS

- Monkeypox - disease caused by infection with monkeypox virus
- Monkeypox virus belongs to the *Orthopoxvirus* genus
  - *Orthopoxviridae* genus includes Variola virus (which causes smallpox), Vaccinia virus (used in the smallpox vaccine), and Cowpox virus
- First discovered in 1958 following two outbreaks of a pox-like disease in colonies of monkeys kept for research (hence the name 'monkeypox')
- Specific animal reservoir unknown, but likely small African mammals

MONKEYPOX: CLINICAL ILLNESS - '*CLASSIC*'

- **Incubation period:** 5–13 days on average (range 4–17 days)
- **Prodrome:** fever, malaise, headache, weakness, and lymphadenopathy that may be generalized or localized to several areas (e.g., neck and armpit)
- **Rash:** appears shortly after prodrome starts
  - Typically lesions develop simultaneously and evolve together on any given part of the body
  - Four stages – macular, papular, vesicular, to pustular – before scabbing over and resolving
  - Well-circumscribed, deep seated with umbilication, painful
  - When disseminated tend to be centrifugal: more on arms, legs, hands, feet
  - Can involve palms and soles
- Illness duration is typically 2–4 weeks

MONKEYPOX: CLINICAL ILLNESS - '*2022 LESIONS*'

- **Pattern:** scattered or localized to a body site rather than diffuse

- Rash often starts in **mucosal areas** (e.g., genital, perianal, oral mucosa) and may not develop simultaneously in all body areas
  - Balanitis/urethritis: complicated by phimosis
  - Proctitis: anorectal pain (lancinating), tenesmus, and rectal bleeding; associated with visible perianal vesicular, pustular, or ulcerative skin lesions and proctitis
  - Oropharyngitis: complicated by tonsillar swelling, abscess, dysphagia

- "**Prodromal**" symptoms can be absent or follow rash onset

MONKEYPOX: TRANSMISSION

- Spread person-to-person through:
  - Direct contact with the infectious rash, scabs, or body fluids
  - Respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
  - Touching items (such as clothing or linens) that previously touched the infectious rash or body fluids
  - Through placenta in an infected pregnant person to their fetus

- Patients are infectious once symptoms begin (whether prodromal or rash symptoms) and remain infectious until lesions form scabs, scabs fall off, and a fresh layer of skin forms

MONKEYPOX: EXAMINATION AND DIAGNOSIS

- Collect a complete sexual and travel history for past 21 days
  - Consider possibility of foreign or domestic animal or animal product contact
- Perform a thorough skin and mucosal examination (e.g., genital, anal, oral) in a room with good lighting
- If rash present, consider a broad differential (e.g., syphilis, varicella zoster, herpes simplex, molluscum contagiosum), especially if the person has epidemiologic risk factors for monkeypox infection in the current outbreak
- Evaluate for STIs per the 2021 CDC STI Treatment Guidelines
  - Persons with monkeypox have had STIs including acute HIV

MONKEYPOX: MANAGEMENT

Management of most patients

- Most immunocompetent patients recover with pain management and other supportive care
- **Tecoviromat** should be considered for some conditions
  - Severe disease: hemorrhagic disease, large number of lesions, sepsis, encephalitis, ocular or periorbital infections, other conditions requiring hospitalization
  - Lesions involving anatomic areas that could cause severe infection (e.g., pharynx, penile foreskin, vulva, vagina, urethra, anus)
  - Lesions in persons who are at high risk for severe disease
    - ✓ Immunocompromise
    - ✓ Pediatric populations
    - ✓ Pregnant or breastfeeding
    - ✓ Condition affecting skin integrity

https://www.cdc.gov/poxvirus/monkeypox/clinicians/pain-management.html
https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

MONKEYPOX: STOMP TRIAL

- ACTG Trial [ClinicalTrials.gov Identifier: NCT05534984]

- A Randomized, Placebo-Controlled, Double-Blinded Trial of the Safety and Efficacy of Tecovirimat for the Treatment of Human Monkeypox Virus Disease

- Inclusion criteria
  - 530 participants; all ages, confirmed MPX less than 14 days
  - Will include those at risk for severe illness (higher dosing), peds, pregnant patients with open label use of tecovirimat

- Primary Outcome: Time to clinical resolution

MONKEYPOX: JYNNEOS VACCINE

- **JYNNEOS**
  - Third-generation smallpox vaccine based on a live attenuated non-replicating orthopoxvirus, Modified Vaccinia Ankara (MVA)
  - Only FDA-licensed vaccine in the US to prevent monkeypox disease in individuals 18 years of age and older
  - Also licensed to prevent smallpox disease in this age group
  - Requires two doses (Days 1 and 28)

- Non-replicating viral vectored vaccine using Modified Vaccinia Ankara (MVA-BN) originally developed as alternative to ACAM2000 (live replicating vaccinia virus-based smallpox vaccine)
  - For use in the event of a bioterrorist attack in immunocompromised individuals in whom such a live replicating virus vaccine was relatively or absolutely contraindicated

MONKEYPOX: JYNNEOS VACCINATION SCHEDULE

Table 2. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Standard regimen[1]				
People age ≥18 years	Subcut	0.5 mL	2	28 days (4 weeks)
People age <18 years[2]	Subcut	0.5 mL	2	28 days (4 weeks)
Alternative regimen (preferred for current outbreak)				
People age ≥18 years	ID	0.1 mL	2	28 days (4 weeks)

https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html#coadministration

MONKEYPOX: JYNNEOS INTERCHANGEABILITY

- A person aged 18 years or older who received one JYNNEOS vaccine dose with the standard (subcutaneous) regimen may receive a second dose with the alternative (intradermal) regimen to complete the vaccination series

- For example, a person who received only one dose of the standard regimen before August 9 may receive one dose with the alternative regimen to complete the series

- Also, a person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen

MONKEYPOX: JYNNEOS DURATION OF IMMUNITY AND DOSING INTERVALS

- Peak immunity is expected **14 days after** the second dose

- Duration of immunity after two doses of JYNNEOS is unknown

- Recommended interval: 28 days (or up to 35 days)
  - If the second dose is not administered during the recommended interval, it should be administered as soon as possible
  - There is no need to restart or add doses to the series if there is an extended interval between doses

- Minimum interval: 24 days
  - 4-day grace period applies

MONKEYPOX: JYNNEOS VACCINE RESOURCE

JYNNEOS Vaccine

Updated September 28, 2022 Print

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On This Page

MONKEYPOX: RESOURCES

- https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html
- https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/overview.html
- https://www.cdc.gov/poxvirus/monkeypox/index.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html

THANK YOU

Questions/Suggestions

Looking Forward:
Next Call
December 2nd, 2022
at 12pm

OKLAHOMA State Department of Health

Resources

Testing:

- Nasopharyngeal, throat, saliva
- Testing@health.ok.gov

Monoclonal Antibodies: (Amanda Cavner)

- Antivirals@health.ok.gov
- https://oklahoma.gov/covid19/what-you-should-know/monoclonal-antibody-therapies.html

Vaccine:

- COVID-19 Vaccines | FDA
- PREP Act Guidance
- Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC
- COVID-19 Vaccination for Children | CDC
- Pfizer: Home (cvdvaccine-us.com)
- Moderna: What is Moderna COVID-19 Vaccine (EUA)? | How Does It Work? (modernatx.com)
- J&J: Resources for COVID-19 Vaccine Education | Johnson & Johnson (jnj.com)
- Novavax: https://us.novavaxcovidvaccine.com/hcp

Resources/Tools

- OSIIS Training: https://osiis.health.ok.gov/osiis/Application/ApplicationHelp/Index

Vaccine Inventory Adjustment: On-Hand Expired Vaccines

- **When reconciling inventory, check that your facility has no expired inventory on hand.**
  - Navigate to the *Vaccine Inventory On-Hand* screen by selecting:
    - **Inventory** > **Vaccines** > **On-Hand** from the left-hand menu.
- Change the Status from On-Hand to Depleted/Expired
- Locate the Filter tab
- Locate the vaccine inventory item requiring an inventory adjustment.
- Click the corresponding **Action** button and select **Adjustment**.
- Complete the following required fields:
  - **Date** (enter the actual date on which the inventory was wasted)
  - **Reason** (select Vtrcks Other)
  - **Modification** (if a value does not default, select Add or Subtract to make the corresponding adjustment)
  - **Doses Adjusted** (enter the number of doses wasted for the selected reason)
  - **Comments** (Expired)
- Click the **Create** button.
- Click the **On-Hand** menu item to return to the *Vaccine Inventory On-Hand* screen where you can verify the inventory was adjusted correctly.
- **See attached video on Resources/Tools**

QAs From Live Call