Novavax Available for Ordering

#### Immunization providers,

On August 30, 2024, the FDA amended the emergency use authorization (EUA) of the Novavax COVID-19 Vaccine, Adjuvanted, to include the 2024-2025 formula. Providers must remove any remaining 2023-2024 COVID-19 vaccines from inventory following the instructions below. The Immunization Information System (IIS), or ImmTrac2, will update reporting codes once they are made available from the CDC.

The updated 2024-2025 Novavax COVID-19 presentation is available for ordering in the Vaccine Allocation and Ordering System (VAOS).

### **Recommendations for COVID-19 Vaccines**

The CDC recommends everyone ages 6 months and older receive an updated 2024-2025 COVID-19 vaccine to protect against the potentially serious outcomes of COVID-19 this fall and winter whether or not they have previously been vaccinated with a COVID-19 vaccine.

### Ordering

The vaccine below is available for ordering in VAOS.

Upon receipt of the Novavax COVID-19 vaccines, please note the expiration date because the initial supply of the updated Novavax COVID-19 vaccines is October 31, 2024. Novavax is pursuing a shelf-life extension for this and future lots of their vaccine, which will be communicated once information is available.

Given the current shelf life, the CDC will distribute Novavax up to 18 days before expiry. Providers are encouraged to initially place smaller, more frequent orders to prevent vaccine loss.

TVFC COVID-19 Vaccines					
Manufacturer	NDC	Brand	Description		
Novavax	80631-0107-10	Novavax 2024-2025 formula for ages 12+	10 Pack – single dose syringe		

## **Provider Vaccine Choice**

The updated 2024-2025 COVID-19 vaccines have been added to the <u>vaccine</u> <u>choice page in VAOS</u>. Providers should adjust their vaccine choice as needed. To update vaccine choices, follow these steps:

- Access the VAOS Provider Portal and select Vaccine Choice from the top menu bar.
- Select the ordering facility from the drop-down menu and make your choice of selections. Once completed, click submit.
- Return to the homepage and select Reporting and Ordering to place a vaccine order.

# Removing 2023-2024 COVID-19 Vaccines from Inventory

With the authorization of the updated 2024-2025 COVID-19 formulations, all 2023-2024 COVID-19 vaccines must be removed from inventory.

Administration of a 2023–2024 COVID-19 vaccine dose on or after the date FDA authorized or approved the 2024–2025 COVID-19 vaccine is an administration error. Reporting requirements vary based on the product. A VAERS report is required for COVID-19 vaccines under EUA. A VAERS report is strongly encouraged for the licensed COVID-19 vaccines. To file an electronic report, see the <u>VAERS</u> <u>website</u>. For additional details, see reporting of vaccine adverse events in the Clinical Guidance for COVID-19 Vaccination | CDC.

Program	Manufacturer	NDC	Brand
TVFC/ASN	Novavax	80631-0105-02	Novavax for 12y+, 5- dose MDV, 2023-2024
TVFC	Moderna	80777-0287-92	Moderna for 6m to 11y, SDV 10-Pack,2023- 2024
TVFC/ASN	Moderna	80777-0102-95	SPIKEVAX for 12y+, SDV 10-pack, 2023- 2024
TVFC	Pfizer	59267-4315-02	Pfizer for 6m to 4y, MDV 30-pack, 2023- 2024
TVFC	Pfizer	59267-4331-02	Pfizer for 5y to 11y, SDV 10-pack, 2023- 2024

The vaccines below should be removed from inventory if present.

TVFC/ASN	Pfizer		Pfizer for 12y+, SDV 10-pack, 2023-2024
TVFC/ASN	Pfizer	1111169-/3//-111	Pfizer for 12y+, PFS 10- pack, 2023-2024

According to TVFC/ASN program policy, any unopened, untampered vials of COVID-19 vaccines must be shipped back to the central distributor, McKesson. McKesson accepts the return of all publicly purchased non-viable (spoiled or expired) vaccines from providers, including influenza vaccines and direct-ship vaccines, and arranges for the return of non-viable vaccines to McKesson at no cost to the provider.

Providers may report vaccine loss for 2023-2024 COVID-19 vaccines in the VAOS by completing the following steps:

1. Upon accessing the VAOS Provider Portal, select Waste from the Specialized Reporting section.

2. Select the ordering facility from the drop-down menu and select continue.

3. Select the 2023-2024 COVID-19 inventory, and enter the vaccine loss details, include quantity wasted, reason for waste, description, and methods for preventing future losses.

4. Click Save.

5. Select the Download Vaccine Loss Report (VLR) button to save a copy of the VLR.

If applicable, a return label will be sent to your facility's Primary Vaccine Coordinator email within seven days of submitting the vaccine loss in VAOS. All returns should be sent to McKesson within six months after their spoilage or expiration date. However, vaccines that have expired more than six months previously will still be accepted.

Detailed instructions for reporting waste in VAOS can be found on the <u>VAOS</u> <u>Reporting Waste Job Aide</u>.

## Resources

Refer to the following resources for more information on updated 2024-2025 COVID-19 vaccines:

- FDA Novavax COVID-19 Vaccine Authorization
- FDA's COVID-19 Vaccines for 2024-2025
- <u>CDC Release on 2024-2025 COVID-19 Vaccines</u>
- FDA Recommendation for 2024-2025 COVID-19 Vaccines
- <u>CDC's Staying Up to Date with COVID-19 Vaccines Resource</u>
- <u>COVID-19 Product Information</u>
- <u>Package Insert Novavax COVID-19 Vaccine (2024-2025</u> <u>Formula)</u>

For any questions regarding the updated COVID-19 vaccines in the TVFC or ASN programs, contact your Responsible Entity (RE).

Thank you for your continued participation in the immunization program.

Texas Department of State Health Services Immunization Program