

Vaccines for Children Program

September 19, 2023

COVID-19 Vaccine is Now Available on the VFC Order Form!

Dear VFC Provider,

The US Food and Drug Administration (FDA) has licensed and the federal Advisory Committee on Immunization Practices (ACIP) has issued recommendations for the COVID-19 Vaccine which is now available for ordering through the VFC Program.

ELIGIBILITY

COVID-19 vaccines made available through the VFC Program can only be given to VFC-eligible patients 18 years of age or younger. Patients with private health insurance must be given privately-purchased vaccines. Uninsured/underinsured adult patients 19 years of age or older can receive COVID-19 vaccines through enrolled Bridge Access Program (BAP) providers.

COVID-19 VACCINE PRODUCTS

The following COVID-19 vaccine products will be made available for ordering through the VFC Program for eligible patients 6 months through 18 years of age.

Vaccine Group	Vaccine Name	NDC
COVID (6 months - 4 years)^	(Pfizer) 3 Dose Vial – 30 doses/10 Vials Per Box	59267-4315-02
COVID (6 months - 11 years)^	(Moderna) Single Dose Vials - 10 Per Box*	80777-0287-92
COVID (5 years - 11 years)^	(Pfizer) Single Dose Vials - 10 Per Box	59267-4331-02
COVID (12 years - 18 years)	Comirnaty (Pfizer) Single Dose Vials - 10 Per Box	00069-2362-10
	Novavax 5 Dose Vial – 10 doses/2 Vials Per Box*	80631-0105-02
	Spikevax (Moderna) Single Dose Vials - 10 Per Box	80777-0102-95

^{*}Not yet available through VFC. ^ Products approved for emergency use (under EUA)

However, Moderna's pediatric presentation for children 6m-11y and Novavax's presentation for children and adults aged 12y+ will be available for ordering at a future date.

VFC ORDERING

VFC Providers Are Required to Order COVID-19 Vaccine

As agreed upon during initial enrollment and recertification, all actively enrolled VFC Providers must "order all ACIP-recommended vaccines (including flu and special-order vaccines) to meet the needs of the total VFC-eligible patient populations reported for the VFC PIN" (*Provider Agreement Addendum 8A*). Enrolled VFC Providers will be expected to order COVID-19 vaccines for all their VFC-eligible patients.

IMPORTANT: Providers that would like to receive COVID-19 vaccines from VFC must be enrolled in the program and receive vaccines directly. No Redistribution of VFC supplied vaccines allowed.

Order Form

VFC providers will order COVID-19 vaccine using the same order process they do for all other routine vaccines on the VFC order form of your MyVFCVaccines account. VFC Providers do not need to enroll in myCAvax.

COVID-19 Vaccine Brand Preference

The California VFC Program offers a choice of vaccine brands and presentations and selection is at the discretion of providers. To minimize confusion on vaccine administration, storage, and handling, it is recommended that VFC providers select one brand/manufacturer for their COVID-19 vaccine ordering across the different age groups. However, if you need more than one brand to complete the series with the same manufacturer for patients 6 months through 4 years of age, you may order more than one brand/manufacturer.

Initial COVID-19 Vaccine Orders

During the initial launch of COVID-19 vaccine ordering in the VFC Program, providers can place supplemental orders for COVID-19 vaccine even if it is not yet time for your routine order. For your first order, your practice will not be expected to list prior formulations of COVID-19 vaccine as part of your VFC on-hand inventory since previous mRNA COVID-19 vaccines have now been deauthorized and should be wasted following local regulations and practice protocols for disposing of regulated medical waste.

However, depending on when your last routine VFC vaccine order was submitted, you may or may not need to include on-hand inventory of all your other non-COVID VFC vaccines.

- If it has been *less* than 30 days since your last routine VFC vaccine order:
 - o Reporting of on-hand inventory of your other VFC vaccines will <u>not</u> be required.
- If it has been *more* than 30 days since your last routine VFC vaccine order:
 - You must report on-hand inventory for all other VFC vaccines to avoid accountability errors.

Order Frequency

To allow for smaller but more frequent orders, the VFC Program is allowing all providers to order COVID-19 vaccines monthly. High and Very-High Volume providers, can already order monthly, so there is no change to their regular order frequency. However, Low and Medium Volume providers, can now order monthly for COVID-19 vaccines (but report full inventory if last order was more than 30 days ago). Order enough vaccine that can be used within the monthly order timeframe. Vaccine requests may be reduced based on available supply allocations from CDC.

As you decide on how many doses to order, keep in mind storage limits of each vaccine depending on its method of storage, as some vaccines may have different beyond use dates if stored in an

ultra-low temperature freezer, in a freezer, or in a refrigerator. Refer to the <u>COVID-19 Vaccine</u> Product Guide for more information.

Order Caps

As with our other routine vaccines, the VFC Order form has a cap based on provider volume.

- Low and Medium volume providers can request up to 100 doses;
- High and Very High volume providers can request up to 990 doses.

If a provider needs more doses than what is capped, enter a justification in the comments and the VFC Central Office will review and can increase the request beyond what was submitted on the order form.

COVID-19 Vaccine Shipments

Moderna and Novavax vaccines will be shipped by McKesson. COVID-19 vaccine orders will follow same shipping timelines for routine vaccines (shipping approximately within 3 days of order receipt at McKesson). Pfizer vaccines will ship directly from Pfizer (Direct Ship Vaccines). CDC contract stipulates vaccines must be delivered within 15 days of order receipt by CDC. For vaccines with diluent (6m-4y) diluent will be shipped separately and will arrive at the same time of before vaccines arrive.

Reporting Wasted, Spoiled, Expired Vaccine

Just like with all other routine VFC vaccines, VFC providers will be required to account for all COVID-19 vaccine doses ordered on their MyVFCVaccines account, including reporting on-hand inventory, and doses administered. Unlike the previous US Government COVID-19 Vaccine Program, wasted, spoiled, and expired COVID-19 doses must be reported to VFC.

Temperature Logs

Temperature monitoring for storage units containing your VFC COVID-19 Vaccine can be documented on your regular VFC Temperature Logs. It is not required to have a separate COVID-19 Vaccine Temperature Log. Continue to use calibrated, compliant data loggers to record vaccine storage unit temperatures twice daily on VFC-supplied logs, take immediate action for out-of-range temperatures, and report temperature excursions immediately on the Storage and Handling Online Triage System (SHOTS) on your MyVFCVaccines account.

Vaccine Storage Considerations

When ordering, ensure that you have enough vaccine storage space to accommodate your routine VFC vaccines, flu vaccine, private-purchase vaccines and COVID vaccines. Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements (*Provider Agreement Addendum 13G*).

Although not required, if your practice has an ultra-low temperature (ULT) freezer for storing Pfizer vaccines, you can now add this storage unit to your VFC Practice Profile. Click on "Update Practice Information" on your MyVFCVaccines account and select "ultra-cold freezer" on the Storage and Temperature Monitoring Equipment Page to update this information.

Special Event Clinics

Special event clinics, health fairs, special school clinics, and mass vaccination clinics require prior approval from the VFC Program at least 4 weeks before the scheduled event; frozen vaccines may not be administered off-site; the practice must submit a summary report that includes doses administered within 15 days after the end of the clinic (*Provider Agreement Addendum 15A*). Submit your request to host a special event clinic to your regional VFC field representative.

For more information about COVID-19 vaccine recommendations and commercialization:

- CDC Recommends Updated 2023-2024 COVID-19 Vaccines for Everyone 6 Months and Older
- FDA Authorizes Updated COVID-19 mRNA Vaccines
- Commercialization FAQs
- Commercialization at a Glance: Provider Transition Guide

Thank you,



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