

# State of California—Health and Human Services Agency California Department of Public Health



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TO: California Vaccines for Children (VFC) Providers

FROM: Robert Schechter, M.D., Chief / L. Succession Scheduter, M.D., Chief / L. Succession Sched

Center for Infectious Diseases

Division of Communicable Disease Control, Immunization Branch

SUBJECT: COVID-19 Vaccine Ordering Through the VFC Program

## Dear VFC Provider,

After being licensed by the US Food and Drug Administration (FDA) and recommended by the federal Advisory Committee on Immunization Practices (ACIP), the updated monovalent COVID-19 vaccine is now available for ordering through the VFC Program.

# Key updates include:

- The 2023-2024 COVID-19 vaccine formulation has been updated to a monovalent vaccine based on the Omicron XBB.1.5 sublineage of SARS-CoV-2.
- The bivalent (original and Omicron BA.4/BA.5) formulation is no longer authorized and should not be used.

# CDC has posted related guidance regarding:

 General recommendations, similar to those for the bivalent COVID vaccine: <u>updated</u> Interim Clinical Considerations for Use of COVID-19 Vaccines:

#### For ages 6 months through 4 years:

- Unvaccinated children should receive 2 doses of updated Moderna updated COVID-19 vaccine or 3 doses of updated Pfizer COVID-19 vaccine.
- Previously vaccinated children should receive 1 or 2 doses of updated mRNA vaccine (same brand as prior doses), depending on the number of previous doses.

# For ages 5 years and older:

- All children should receive 1 dose of an updated mRNA COVID-19 vaccine regardless of previous vaccination history.
- Transitioning from a younger to older age group
- Vaccination for people who are moderately or severely immunocompromised



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- <u>Interchangeability of COVID-19 vaccines</u> website for children 5 years and older. In general, children ages 6 months – 4 years should receive all doses of COVID-19 vaccine from the same manufacturer.
- Coadministration of COVID-19 vaccine with other routine vaccines is recommended.
- Report all doses administered into a <u>CAIR</u> or <u>Healthy Futures/RIDE</u> per <u>AB1797</u>. VFC funded COVID-19 vaccine doses must be identified with the appropriate VFC Eligibility Funding Category when entering administration information into CAIR.
- Refer patients to the <u>California Digital Vaccine Record (DVR) portal</u> to request copies of their vaccination record. Information is available in:

EnglishKoreanArabicSpanishSimplified ChineseTagalogTraditional ChineseVietnamese

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

<sup>^</sup>Products authorized by FDA for emergency use (EUA)

<sup>\*</sup>Not yet available through VFC.

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The mRNA COVID-19 vaccines are currently available for ordering through the VFC Program. Novavax's presentation for children and adults aged at least 12 years will be available for ordering from VFC at a future date.

# Storage and Handling

Storage of the updated COVID-19 vaccines has not changed from the prior formulations. The beyond use date of each product depends on how it is stored.

#### Moderna:

- Freezer Can be stored in the freezer up to expiration, which is typically 9 to 12 months from the date of manufacture.
- o Refrigerator Can be used for up to 30 days if stored in the refrigerator.
- o If stored at normal room temperature must be used within 24 hours.

#### Novavax:

- Refrigerator Can be used until expiry, which is typically 9 months from the date of manufacture.
- o If stored at normal room temperature must be used within 12 hours

#### Pfizer:

- Ultra low temperature (ULT) freezer Can be used until expiration, which is typically 12 to 18 months from the date of manufacture.
- o Refrigerator Can be used for up to 10 weeks if stored in the refrigerator.
- o Once vials are thawed, they should not be refrozen.
- Thawed Comirnaty and reconstituted Pfizer COVID vaccines may be stored for 12 hours at normal room temperature.

Pfizer formulation for ages 6 months - 4 years (Yellow Cap) is supplied with diluent. Diluent is shipped separately from vaccines. Do not freeze diluent.

# **Dosage and Administration**

Dosage and preparation of Pfizer COVID-19 Vaccine varies by age group. For details, please refer to the <u>CDPH COVID-19 Vaccine Product Guide</u>.

#### Dosage Pfizer

•	6 months through 5 years	3 micrograms/dose (Dilution required)
•	6 years through 11 years	10 micrograms/dose
•	12 years and older	30 micrograms/dose

#### Dosage Moderna

•	6 months through 11 years	25 micrograms/dose
•	12 years and older	50 micrograms/dose

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For reference regarding timing, number of doses, and intervals from prior COVID-19 doses, please see the <u>CDPH COVID-19 Vaccine Timing</u> job aid. Interim COVID-19 immunization schedules for children aged 6 months-17 years can also be found at the <u>Stay Up to Date with COVID-19 Vaccines Including Boosters</u> site.

#### Administration with Other Vaccines

COVID-19 vaccines may be administered without regard to timing of other vaccines, including on the same day as other vaccines. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. Muscles that may be used for multiple injections include:

• Ages ≥3 years: Deltoid

Ages 6 months–2 years: Vastus lateralis of the anterolateral thigh

#### **ELIGIBILITY**

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

#### **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 must be enrolled in the VFC program in order to receive and administer VFC supplied COVID-19 vaccines. Unlike the US Government COVID-19 Program, which allowed routine redistribution of vaccines form several approved depot locations, **NO REDISTRIBUTION of VFC supplied vaccines is allowed**. Doses must be shipped to enrolled providers directly from VFC.

#### **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

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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 vaccine from more than one brand/manufacturer.

#### **Initial COVID-19 Vaccine Orders**

During the initial launch of COVID-19 vaccine ordering in the VFC Program, providers may 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 <a href="COVID-19 Vaccine Product Guide">COVID-19 Vaccine Product Guide</a> 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 may request up to 100 doses;
- High and Very High volume providers may request up to 990 doses.

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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. Please keep in mind that the ordering should be for a one-month period.

# **COVID-19 Vaccine Shipments**

Moderna and Novavax vaccines will be shipped by McKesson. COVID-19 vaccine orders will follow the same shipping timelines for routine vaccines (shipping within about 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. NOTE: Pfizer formulation for ages 6 months—4 years is supplied with diluent. Diluent is shipped separately from vaccines and should arrive prior to or at the same time as vaccine shipments.

Shipping conditions will vary by each product. Moderna vaccines ship frozen between -50°C and -15°C (-58°F and 5°F). Novavax vaccine ships like other routine refrigerated vaccines at temperatures between 2° to 8°C (36° to 46°F). Pfizer vaccines ship from the manufacturer with dry ice and between -90°C and -60°C (-130°F to -76°F). Please ensure receiving staff have been properly trained on shipment inspection, dry ice safety and storage in the corresponding units.

# 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 <a href="MyVFCVaccines">MyVFCVaccines</a> 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, and doses reported as expired or spoiled are returned to McKesson Speciality.

**Important Note**: 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. Do <u>not</u> return deauthorized vaccines from the previous US Government COVID-19 Vaccine Program to the VFC Program.

# **Temperature Logs**

Temperature monitoring for storage units containing your VFC COVID-19 Vaccine can be documented on your regular <a href="VFC Temperature Logs">VFC Temperature Logs</a>. 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.

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# **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 to purchase, if your practice has an ultra-low temperature (ULT) freezer for storing Pfizer vaccines, please add this storage unit to your VFC Practice Profile in order to update your clinic's vaccine storage unit information in <a href="MyVFCVaccines">MyVFCVaccines</a>. Click on "Update Practice Information" on your <a href="MyVFCVaccines">MyVFCVaccines</a> account and select "ultracold 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.

# BILLING FOR VFC COVID-19 VACCINES CHDP Providers

Claims may be submitted for VFC-supplied doses of COVID-19 vaccine administered to CHDP-eligible patients through age 18 years. Please refer to the CHDP Provider manual and relevant <a href="CHDP Provider Information Notice">CHDP Provider Information Notice</a>. For additional questions, CHDP providers may contact their County CHDP Program.

## Medi-Cal Fee-For-Service (FFS)

To bill Medi-Cal FFS for administration of VFC-supplied COVID-19 vaccine doses, use the appropriate CPT-4 code, followed by the "-SL" modifier (e.g., for Moderna 6 months-11 years, Medi-Cal FFS billing code is 91321-SL). For billing codes and more information on the COVID-19 vaccine products, refer to the updated <a href="COVID-19 Vaccine Product Guide">COVID-19 Vaccine Product Guide</a>. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS-eligible patients.

For specific information and details on Medi-Cal billing, please refer to the <u>Medi-Cal provider manual on VFC</u>. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

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# Medi-Cal Managed Care

Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

#### REPORTING VACCINE ADMINISTRATION TO CAIR

All active participants of California's VFC Program are required to enter all vaccine doses administered into CAIR or RIDE, in accordance with AB 1797, and as indicated in the 2023 VFC Provider Participation Agreement. Please make sure all doses administered are reported into a California immunization registry (<u>CAIR</u> or <u>Healthy Futures/RIDE</u>) AND the appropriate VFC Eligibility category is recorded.

Please ensure CAIR Accepted Values for VFC Eligibility Funding Status are reported with your clinic's data exchange information when documenting vaccine administration in the clinic's electronic medical record system, and then exchanging information with CAIR or Healthy Futures.

#### Resources

- ACIP Child and Adolescent Immunization Schedule
- CDC COVID-19 Interim Clinical Considerations
- VFA/VFC Vaccine Eligibility Guidelines Table
- VFC resolutions
- COVID Commercialization Quick Guide
- Commercialization FAQs