Win-Win: Why Birthing Hospitals Choose VFC

Tuesday, June 18, 2024 12:00 pm – 1:00 pm



Questions

During today's webinar, please use the Q&A panel to ask your questions so CDPH VFC Program panelists and subject matter experts (SMEs) can respond.





Housekeeping

Reminder to Attendees:



Today's session is being recorded. For slides, webinar recordings, and other postings, see the **EZIZ VFC page for birthing hospitals**.

To be added to the CDPH VFC email messaging listserv for providers, please email your request to MyVFCvaccines@cdph.ca.gov



If you have post-webinar-related questions, please email leslie.amani@cdph.ca.gov

Reminder to Panelists:



Please mute yourself when not speaking.

Please monitor the Q&A panel for questions you may be able to answer.

Tuesday, June 18, 2024

No.	Item	Speaker(s)	Time (PM)
1	Welcome	Leslie Amani (CDPH)	12:00 – 12:05

Claudia Aguiluz (CDPH)

Overview: "Vaccines for Children"

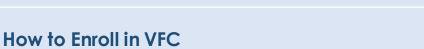
Targeted Outreach Efforts: Why You Were Invited

Claudia Aguiluz (CDPH)

Leslie Amani (CDPH)

Why Enroll in VFC: Save Costs / Save Infants

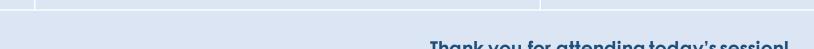
Kelley Leung, RN (CDPH)



Erik Smith and Claudia Aguiluz (CDPH)



Kelsey Florio, RN (CDPH)



Thank you for attending today's session!

Resources

Q&A

3

4

12:05 - 12:10

12:10 – 12:15

12:15 – 12:25

12:25 - 12:35

12:35 - 12:45

12:45 - 1:00

What is Vaccines For Children?

Claudia Aguiluz, CDPH



Vaccines for Children (VFC) Program

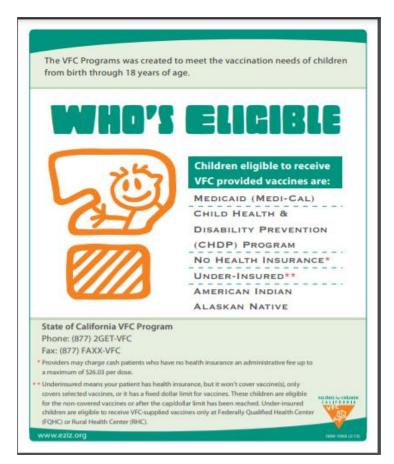
- VFC is a federally funded program which provides all routine vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost to the participating healthcare provider.
- In California, over 50% of children under 19 years of age are eligible to receive VFC supplied vaccines.
- Eligible <u>children are entitled</u> to receive all Advisory Committee on Immunization Practices (ACIP) recommended vaccines through VFC.
- Any healthcare provider authorized in the State of California to prescribe vaccines may enroll in the California Vaccines for Children Program and offer age-appropriate ACIP recommended vaccines.



Who is Eligible to Receive VFC Vaccines

Children from birth through 18 years of age that meet one of the following criteria:

- Enrolled or eligible for Medi-Cal/Medicaid
- Uninsured/No health insurance
- American Indian or Alaska Native
- Underinsured (at an FQHC or RHC)



Job Aid: Who is Eligible to Receive VFC Vaccines?

Vaccine Purchase

- VFC Vaccines are purchased in bulk, at reduced pricing through vaccine manufacturer contracts negotiated by CDC on an annual basis
 - Purchased vaccines constitute national vaccine supply and stockpile supply
 - Purchased vaccines are based on:
 - Each state's population estimates
 - ACIP Recommended dosing and schedules and
 - pre-defined spend plans for each vaccine, down to the NDC level
- Purchased vaccines are stored at 2 national vaccine distribution locations in the nation: Aurora, CO and Memphis, TN

Vaccine	Brandname/ Tradename	NDC	Packaging	CDC Cost/ Dose	Private Sector Cost/ Dose	Contract End Date	Manufacturer	Contract Numb
Dengue Tetravalent Vaccine, Live [7]	Dengvaxia	49281- 0605- 01	1 pack – 1 dose vial	\$98.81	\$104.01	3/31/2025	Sanofi Pasteur	75D30124D18
DTaP [<u>1</u>]	Daptacel®	49281- 0286- 10	10 pack – 1 dose vial	\$21.688	\$29.311	3/31/2025	Sanofi Pasteur	75D30124D18
DTaP [<u>1</u>]	Infanrix®	58160- 0810- 52	10 pack – 1 dose syringe	\$21.658	\$28.795	3/31/2025	GlaxoSmithKline	75D30124D18
DTaP-IPV [2]	Quadracel™	49281- 0564- 10	10 pack – 1 dose vial	\$47.906	\$62.206	3/31/2025	Sanofi Pasteur	75D30124D18
		49281- 0564- 15	10 pack – 1 dose syringe	\$47.906	\$62.206			
DTaP-IPV [2]	Kinrix®	58160- 0812- 52	10 pack – 1 dose syringe	\$48.279	\$61.079	3/31/2025	GlaxoSmithKline	75D30124D18
DTaP-Hep B-IPV [4]	Pediarix®	58160- 0811- 52	10 pack – 1 dose syringe	\$66.069	\$97.967	3/31/2025	GlaxoSmithKline	75D30124D18
DTaP-IP-HI [4]	Pentacel®	49281- 0511- 05	5 pack – 1 dose vial	\$70.186	\$114.524	3/31/2025	Sanofi Pasteur	75D30124D18

Targeted Outreach Efforts: Why You Were Invited

Claudia Aguiluz, CDPH



Birth Hospitals in California

238 hospitals currently provide birthing services

- 64 (27%) already enrolled in VFC Program
- 174 (73%) not currently enrolled,
 - In 2022, these facilities delivered 114,487 Medi-Cal births

Goal: Identify top birthing hospitals, considering % of their Medi-Cal births among other criteria for prioritization, and focus enhanced outreach/support for VFC Program enrollment by August 31, 2024

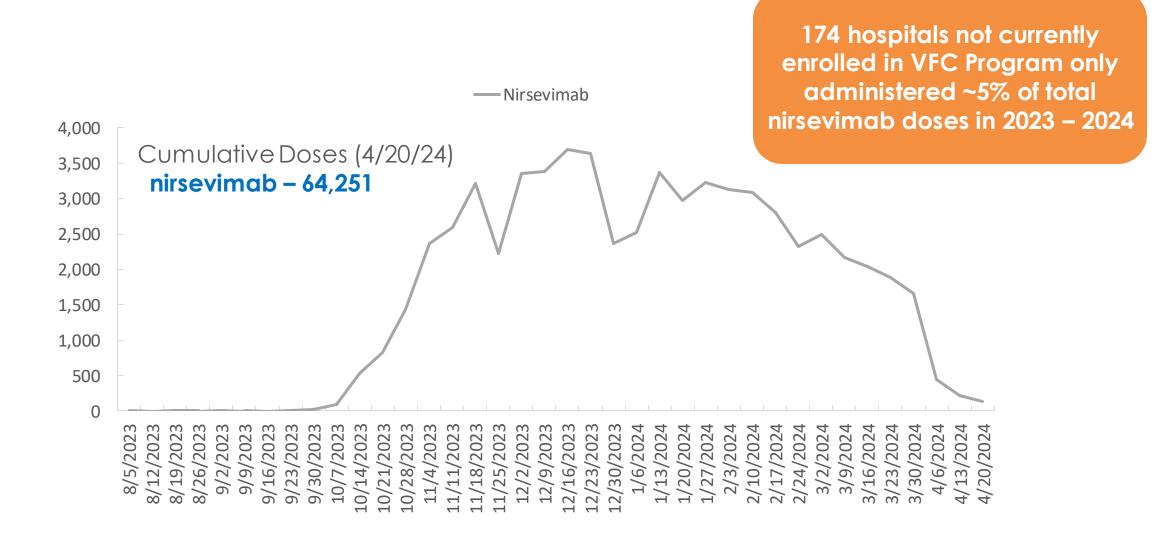
While the Ultimate goal is to enroll all 174 birth hospitals, initial prioritization for outreach is 50 hospitals.







Nirsevimab Doses Administered in CA during 2023 – 2024



2023: Percent of Nirsevimab Doses Administered by Clinical Setting

Clinical Setting	Nirsevimab
Medical practice - other specialty	28.8
Other	8.6
Medical practice - pediatrics	28.8
Hospital	12.3
Medical practice - family medicine	4.3
Public health provider - Federally Qualified	10.3
Health center - community	3.3
Medical practice - internal medicine	0.7
Public health provider - public health clinic	1.6
Medical practice - OB/GYN	0.3
Unknown	0.4
Tribal health	0.6

Data: CAIR2 from 08/01/2023-05/28/2024



FROM:

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



November 3, 2023

IZB-FY-23-24-10

TO: California Vaccines for Children (VFC) Providers

Robert Schechter, M.D., Chief / LL Suc-

Center for Infectious Diseases

Division of Communicable Disease Control, Immunization Branch

SUBJECT: Initial Allocation of Limited Nirsevimab (Beyfortus™) Supply;

Interim CDC Clinical Guidance

BACKGROUND

On October 13, 2023, CDC paused ordering of nirsevimab for VFC programs in the US due to a shortage in supply. The shortage is expected to continue in both the public and private sector supplies throughout the 2023-2024 RSV season. According to the manufacturer, the anticipated supply of 100mg doses of nirsevimab is insufficient to protect all eligible infants and children weighing ≥5 kg this season. Supplies of 50mg doses will be less limited. As additional limited supplies are made available by the manufacturer, CDC is allocating these doses to states, at an interval currently estimated at every 2 to 3 weeks.

NIRSEVIMAB VFC ORDERING

The current allocation to the California VFC Program for both 50mg and 100mg formulation for nirsevimab is too small to resume ordering for all VFC providers. As a result, this current allocation is available only to hospitals, Tribal Health Clinics, selected Federally Qualified Health Centers (FQHCs)/Rural Health Centers (RHCs) and Public Health Department Clinics. Additional doses will be made available to additional VFC Providers as more doses are received. The VFC Program will provide timely updates on availability and ordering policies.

VFC ORDERING LIMITS

VFC orders for nirsevimab are limited, based on prior utilization of Hepatitis B vaccine birth doses at hospitals and pneumococcal conjugate vaccine for outpatient providers. The limits may be changed depending on supply.

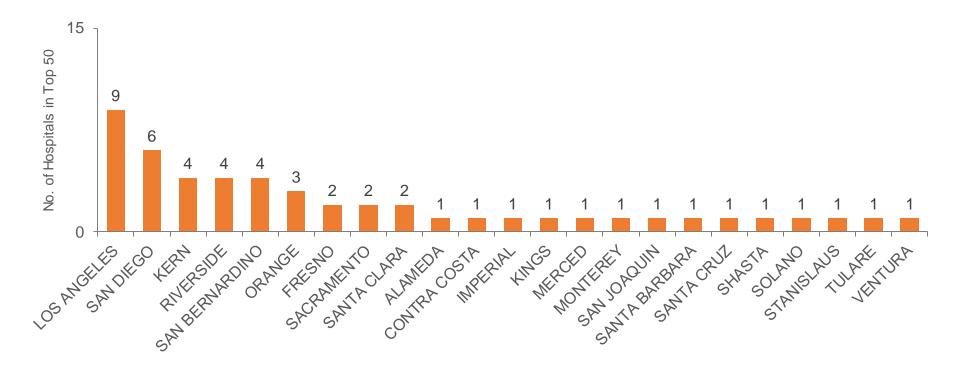
California Vaccines for Children Program
850 Marina Bay Parkway, Building Pt. 2nd Floor, Richmond, CA 94804
[877] 243-8832 * FAX (877) 329-9832 * Internet Address: www.eziz.org



Hospital Enrollment Prioritization Strategy

Top 50 hospitals with highest priority scores represent:

- 76,415 (67%) Medi-Cal births (2022)
- 23 different counties

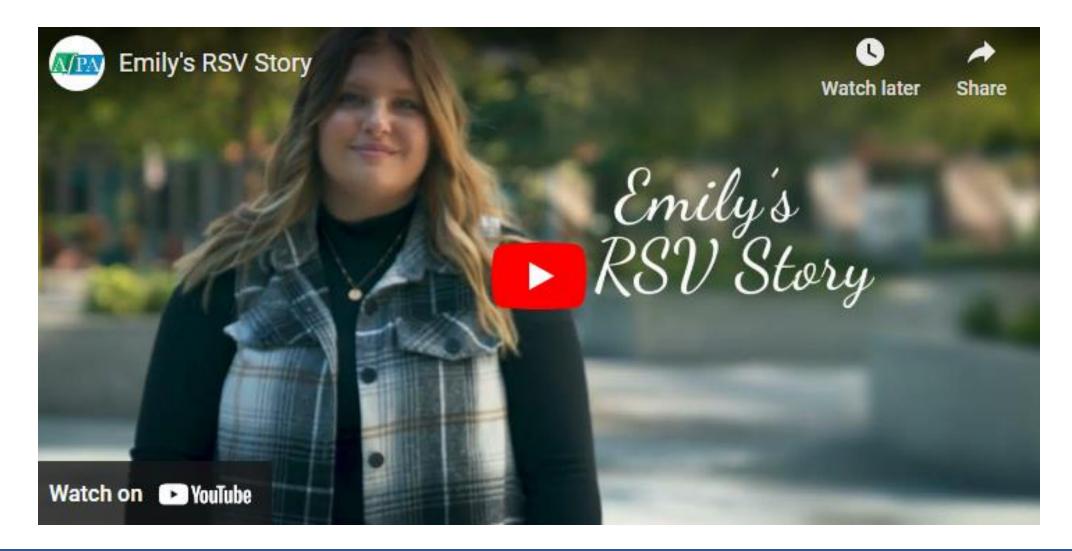


Why You Should Enroll

Kelley Leung, RN, CDPH



Emily's story



Save Costs, Save Infants

- Each year in the U.S., RSV causes approximately 58,000-80,000 hospitalizations, and 100-500 deaths in children under 5 years of age.
 - Unimmunized Infants admitted for RSV infection have an average cost of over \$11,000.
- Early estimates indicate <u>nirsevimab is 90%</u>
 <u>effective</u> at preventing RSV hospital
 admissions in infants.
- Over 50% of California's newborns qualify for VFC.

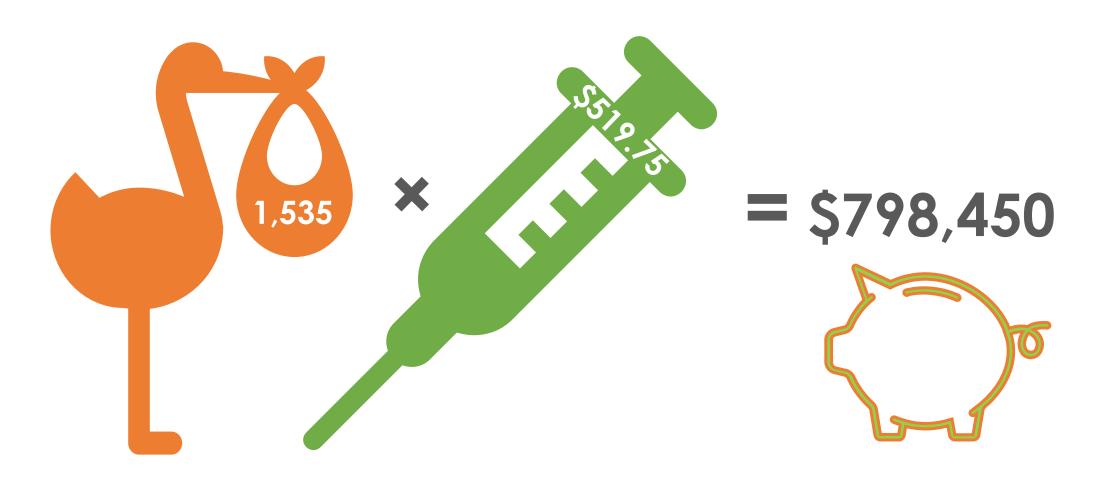


Benefits of VFC Program Enrollment for Birth Hospitals

VFC Program covers the entire cost of immunizations for eligible patients:

- Single dose of Hep B at birth was previously the only immunization recommended for newborns
 - Commercial Cost: ~\$28 / dose
- Nirsevimab is now recommended for newborns at birth during respiratory virus season
 - Commercial Cost: ~\$520 / dose
- The financial impact for the implementation of nirsevimab is significant.
 - Based on 2022 Medi-Cal Births alone (114, 487) among non enrolled hospitals, Cost of nirsevimab = \$59.5 M

NO Upfront Vaccine Supply Costs*



Hospitals Can Help Bridge a Gap

Hospitals play a critical role in ensuring access to vulnerable babies!

- Infants born during RSV season are recommended to receive nirsevimab within the first 7 days of life.
- Infants with a prolonged hospital stay should receive nirsevimab shortly before discharge.
- Hospitals have been identified as <u>the best point of access</u> for nirsevimab doses.



Healthcare Access Gaps

 Access to routine appointments is sub-optimal; across all insurance types, California ranked <u>49th</u> (out of 51 states & DC) in percentage of kids receiving a check up.

 For infants with publicly funded insurance, approximately 1 in 4 babies were unable to get an outpatient visit within the recommended 5 days of discharge.



Immunization-Friendly Birthing Hospital Honor Roll

Be publicly recognized on our website!



Enroll in VFC and administer VFC-doses of nirsevimab to VFC-eligible infants.

Poll

Is your hospital planning on offering RSV immunizations to all newborns this fall?

- a. Yes. I reserved doses with Sanofi for privately-insured patients.
- b. Yes, but we have not reserved doses.
- c. No. We don't plan to purchase doses.
- d. Not sure.

How to Enroll in VFC and Access to Vaccines

Erik Smith and Claudia Aguiluz, CDPH



Birthing/Neonatal Hospitals & VFC Requirements

VFC providers must maintain an adequate supply of vaccines for all ageappropriate, ACIP-recommended vaccines for their patient population—excluding influenza, which is allocated separately.

- Only required to carry Hep B and nirsevimab
- Can also order ABRYSVO[™] for pregnant teens (during RSV season)
- Potential to use replacement model may impact how hospitals meet inventory management, eligibility screening, and vaccine ordering requirements.

Enrollment Support and Requirements –

- Hospital Enrollment Checklist info needed for application
- EZIZ Training
- Storage & Handling/
 - Refrigerators
 - Digital Data Loggers
- Enroll in CAIR or RIDE
- Specialized support for enrolling in VFC
 - Email <u>vfcenrollment@cdph.ca.gov</u> with questions
 - Schedule a call to verify readiness



VFC Program Enrollment is a Simple Process!

- Submit VFC enrollment application via myCAvax
 - Active or previous myCAvax Account
 - Need to enroll in myCAvax
- Prioritized enrollment for hospitals

VFC

Vaccines for Children

The Vaccines for Children (VFC) Program helps families by providing vaccines at no cost to providers who serve eligible children from birth through 18 years of age.

Enroll your organization



VFC Enrollment: Setting up for Success

- Once VFC application is submitted:
 - Field Staff personnel will contact you with any questions or clarifications.
 - Schedule enrollment site visit
 - Review and assist with meeting VFC program requirements and best practices
 - Provide resources and education
 - Answer your questions

CA VFC Hospital Enrollments: Preparing to offer VFC Vaccine Replacement Model Enrollment

Vaccine Replacement: A process for vaccine replacement of private vaccine stock used for VFC eligible children, which is allowable (and approved by CDC) only if:

- An individual provider has the capacity to purchase private stock for VFC eligible children
- The provider utilizes an electronic system for documenting patient eligibility at the dose-level.
- The state's Immunization program has the capacity to perform oversight of the vaccine replacement process and ensure that doses replaced directly reflect the VFC eligible children served by the provider.



Replacement model enrollments have an added layer of enrollment approvals. These must be approved in writing by CDC.

Participating provider types in CA eligible for this model are specific to large HMOs, birthing hospitals, and pharmacies.

Key elements include:

- ✓ VFC screening and documentation during each immunization encounter or visit.
- ✓ Capturing patient's eligibility status at the dose level through CAIR and the provider's EHR system
- ✓ The total public vaccine inventory reported with vaccine orders must represent the public portion of the Provider's inventory on hand.
- ✓ Public vaccine returns must be submitted to represent the public portion of the total vaccine returns.
- ✓ Compliance with all other CA VFC Program Requirements.
- ✓ CA's VFC Program assessment of doses administered data prior to fulfilling replacement vaccine requests

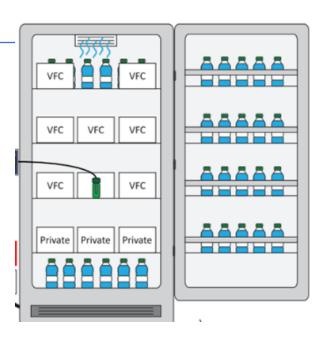
Standard vs. Replacement Model

Standard

- Order doses in advance report usage on VFC orders
- Stock:
 - Privately purchased and VFC-provided
 - Separate inventory
- Eligibility screening:
 - Completed prior to vaccine administration

Replacement*

 Order VFC vaccine to replace VFC doses used on VFC eligible patients (must use private stock)

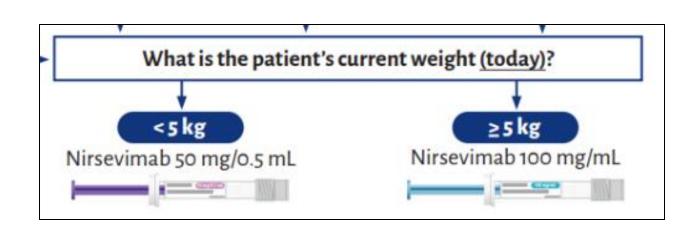


- Stock:
 - Do not need to separate inventory
- Eligibility screening:
 - May be done on the backend

^{*}Involves application that is submitted to CDC. Approval must be obtained before using replacement model.

VFC Ordering Guidelines

- Ordering through myCAvax
- Typical RSV Season October to the end of March
- Infants born during RSV season or infants <8
 months entering their first RSV season should receive one
 weight-based dose:
 - <5kg= 50mg nirsevimab
 - >5 kg= 100mg nirsevimab



Nirsevimab vs. Palivizumab

	Nirsevimab	Palivizumab
Trade Name	Beyfortus™	Synagis®
What is it?	Long-acting monoclonal antibody (5+ months)	Monoclonal Antibody
Who can receive it?	ALL Infants and babies <8 born during or entering their 1st RSV season	High risk children <24 months of age at increased risk for severe RSV disease (e.g. premature infants)
When to administer	October through March	October through March
How many doses?	1 dose (Some infants will need a second dose)	Once a month during the entire RSV Season (5+ doses possible)
Cost per dose	~\$520/ dose	~\$4139/100 mg vial
Is it offered by VFC?	Yes!	No

Resources

Kelsey Florio, RN, CDPH



Enrollment Support

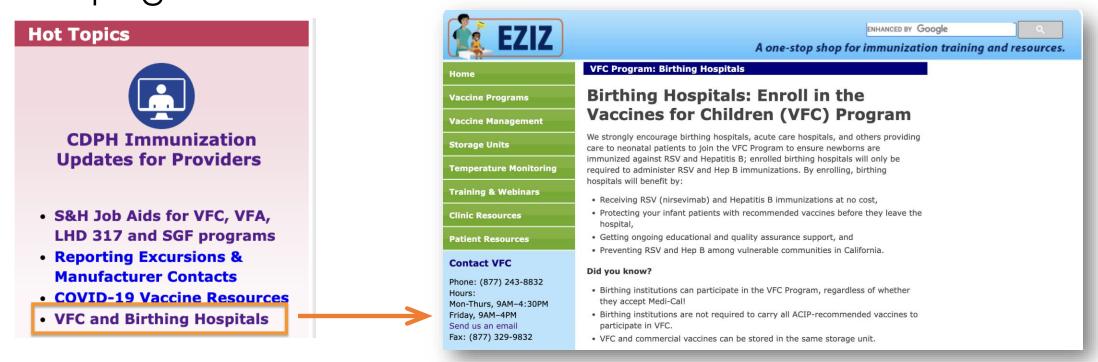
- Starts in July!
- Learn from established VFC enrolled hospitals
- Peer-to-peer enrollment webinars facilitated by CDPH VFC staff to assist with developing processes and workflows and have questions answered in real time



Interested? Please enter name and best contact in the Q&A so we may contact you.

Birthing Hospital Webpage

- **EZIZ.org** is our providers' website
- Birthing Hospital webpage linked under "Hot Topics" on EZIZ homepage





A one-stop shop for immunization

Home

Vaccine Programs

Vaccine Management

Storage Units

Temperature Monitoring

Training & Webinars

Clinic Resources

Patient Resources

Contact VFC

Phone: (877) 243-8832

Hours:

Mon-Thurs, 9AM-4:30PM

Friday, 9AM-4PM Send us an email

Fax: (877) 329-9832

- ▶ VFC Field Representatives
- ► Find VFC providers
- ► Sign up for EZIZ emails
- Frequently Asked Ouestions

VFC Program: Birthing Hospitals

Want to become a VFC-enrolled birthing hospital?

See the VFC Program Enrollment process to get started. Contact the VFC Program Call Center (877) 243-8832 or at VFCEnrollment@cdph.ca.gov with any questions.

Resources for hospitals enrolling in VFC

- Hospital Enrollment Checklist allows your facility to gather information needed to complete your VFC application expeditiously
- Birthing Institutions and the Vaccines for Children Program (AIM)
- VFC Recruitment Letter from Dr. Robert Schechter, Immunization Branch
- VFC Administration/Inventory Log HepB/nirsevimab only

Resources for updating your EHR/EMR for VFC

- Example EHR solutions from VFC-enrolled hospitals
- For hospitals using **Epic:**
 - Use this guide and reference "Immunization Setup and Support"
 - Contacts
 - jbraschl@epic.com (Jacob Braschler)
 - ibrown@epic.com (Ian Brown)
- For hospitals using Oracle/Cerner:
 - Guides to use when designing your VFC eligibility screening/documentation process in your EHR
 - Configure the Workflow Immunizations Component Reference Pages Cerner Wiki

Enrollment Checklist

Enrollment Checklist for Birthing and Pediatric Hospitals: Nirsevimab (Beyfortus™)





This planning checklist is for birthing hospitals and hospitals with birthing wards who want to enroll in California's Vaccines For Children (VFC) Program which offers eligible newborns no-cost immunizations at birth to prevent respiratory syncytial virus (RSV) and Hepatitis B. This checklist will help your site meet VFC enrollment requirements and prepare to receive RSV immunization nirsevimab (BeyfortusTM). A brief summary of nirsevimab clinical guidance is available at the end of this document.

Nirsevimab Planning Checklist

✓	Facility Protocol and Education				
	Ensure that your facility is enrolled in the <u>California VFC Program</u> . Your facility should establish a process to document <u>VFC eligibility</u> in your EMR/patient record and/or CAIR for each dose administered. Email program enrollment questions to <u>VFCEnrollment@cdph.ca.gov</u> .				
	Update billing processes for private insurance and VFC-eligible children if needed.				
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Download the CDPH Nirsevimab timing tool . Dosage depends on patient age and weight:				
	 Age 0-8 months old: 50 mg if <5 kg, 100 mg if ≥5 kg Age 8-19 months old at high risk of severe RSV: 200 mg (2x100 mg) 				
	Plan how to communicate nirsevimab availability, priority groups, safety, and efficacy to patients. Share nirsevimab <u>effectiveness</u> and safety information from <u>CDC</u> , including <u>Nirsevimab Immunization Information Sheet</u> (IIS), and the <u>FDA</u> .				
	Ensure education on documentation needs (EMR, electronic birth certificate, etc.) are provided to staff.				
	Develop a process to screen newborns for birth parent's RSV vaccine status during pregnancy.				
	Establish a process to obtain parental consent for nirsevimab. Share with parents the <u>CDC's</u> <u>Nirsevimab Immunization Information Sheet</u> (IIS).				
	Update current facility vaccination/medication administration protocols, if needed.				
	Implement standing orders for your practice, if applicable. See templates and FAQs.				
	Determine when nirsevimab will be administered post-delivery and pre-discharge at the hospital Infants with prolonged hospitalization (e.g., preterm infants) should be immunized ideally shortly before discharge or promptly after discharge.				
	Develop a process for outpatient clinic administration to eligible infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.), including outreach to parents/caregivers about coming to clinic for RSV immunization ahead of their first RSV season. Providers should use every opportunity to administer nirsevimab to eligible infants. This includes administration during well-child visits as well as other visits to ensure no missed opportunities for immunization.				
	Develop a process for administration to children 8 to 19 months old at increased risk of severe RSV entering their second RSV season. Note: ACIP recommendations for second RSV season administration include all American Indian and Alaska Native children. Report adverse events:				
	 If nirsevimab is administered alone, report adverse events to <u>MedWatch</u>. If nirsevimab is co-administered with a vaccine, report adverse events to <u>VAERS</u> only. 				

Expedite your application

process: Use the **enrollment**

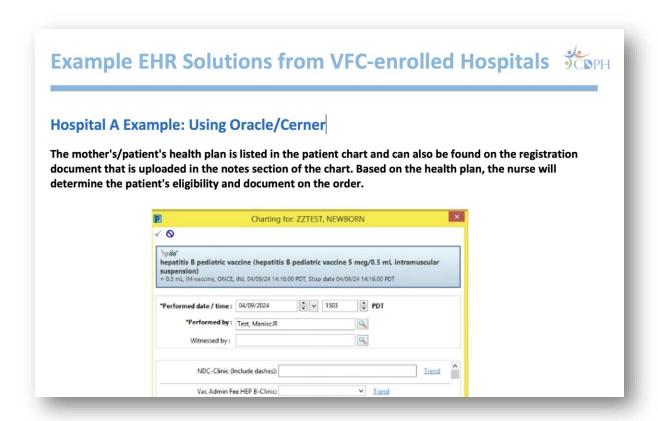
checklist to gather all needed

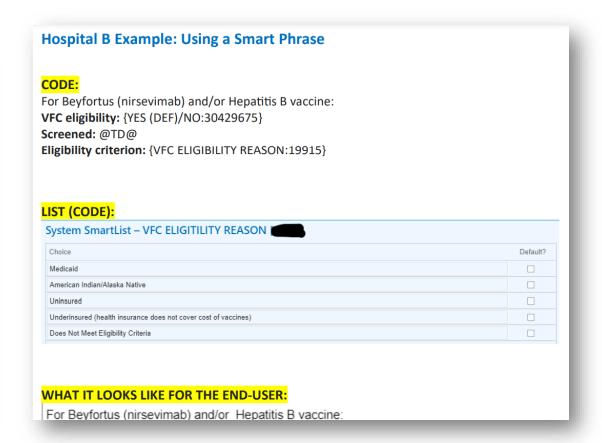
info prior to starting your application.

California Department of Public Health, Immunization Branch

IMM-1485 (6/10/24) Page 1

Electronic Health Record (EHR) Resources





Example EHR Solutions from VFC-enrolled Hospitals

Poll

Following today's webinar, do you plan to enroll in VFC?

- a. I have already started the enrollment process!
- b. I am interested but have not yet applied.
- c. I am undecided.
- d. I do not plan to apply.
- e. I am already enrolled.



Questions

During today's webinar, please use the Q&A panel to ask your questions so CDPH VFC Program panelists and subject matter experts (SMEs) can respond.





Common Ways to Handle Dispensing Logistics

Dispensing logistics

- You can integrate inventory selection by funding source into your electronic health record (EHR), so pharmacy dispenses the proper dose
- You can train nursing staff to select proper dose from unit on the floor (pt VFC-eligibility banner in EHR, log, note from ordering provider)

Your Questions Answered....

Q: Could we apply local restrictions or are we mandated to administer Beyfortus to all neonates as soon as they are born?

A: Enrolled facilities must follow VFC Program guidelines and administer doses to all eligible babies.

Q: Would it be possible to keep track of how many neonates were qualified for the VFC program and submit the # at the end of the year?

A: Hospitals approved to enroll in VFC as a Vaccine Replacement Model may administer private doses of nirsevimab and submit replacement requests to VFC on a monthly basis.

Your Questions Answered....

Q: Can supply chain meet the patient needs yet?

A: Supply levels for nirsevimab are expected to support program needs.

Q: How are allocations awarded?

A: Based on available supply, and eligible VFC populations, CDC will provide upfront allocations to states to begin ordering.

Your Questions Answered....

Q: What do hospital audits for VFC typically entail?

A: The VFC team works closely with all VFC providers, including birthing hospitals, to ensure that they feel supported. While we do have compliance visits, we always strive to lead with education. Our goal is to keep providers abreast on program requirements and expectations. We are always here as a resource. Our main objective is to keep providers enrolled in the program and offer support from the get-go. We don't have a separate visit process or tool; it is a compliance visit.

Questions

During today's webinar, please use the Q&A panel to ask your questions so CDPH VFC Program panelists and subject matter experts (SMEs) can respond.





Upcoming CDPH Webinar Opportunities

CDPH IZB Bi-weekly Updates for Providers

Next session: Friday, June 28, 2024

9:00 am - 10:30 am, PT



California Department of Public Health Immunization Branch

Thank you for attending!

For support, please email VFCEnrollment@cdph.ca.gov



California Department of Public Health
Immunization Branch