California Department of Public Health
Respiratory Syncytial Virus (RSV)
Webinar

Monday, October 16, 2023
12PM – 1PM
## Agenda: Monday, October 16, 2023

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<td>Leslie Amani (CDPH)</td>
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<td>Epidemiology</td>
<td>Cora Hoover, MD (CDPH)</td>
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<td>Priyanka Saxena, DO, MPH (CDPH)</td>
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<td>VFC Enrollment</td>
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Thank you for attending today’s webinar!
Questions

During today's webinar, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.

Resource links will be dropped into, “Chat”
Housekeeping

Reminder to Panelists:
- Please mute yourself when not speaking.
- Please monitor the Q&A panel for questions you may be able to answer.

Reminder to Attendees:
- Today's session is being recorded. Access today’s slides and archived presentations at: CDPH Immunization Updates for Providers on EZIZ
- If you have post-webinar questions, please email leslie.amani@cdph.ca.gov
Announcements
Leslie Amani, CDPH
New RSV Resources Webpage

- RSV FAQs
- Nirsevimab Timing Guide
- CDC Clinical Recommendations
- Patient Resources

RSV Immunization Resources
Epidemiology
Cora Hoover, MD, CDPH
RSV Overview

- Common respiratory virus that usually causes mild, cold-like symptoms.
- Infants and older adults are more likely to develop severe RSV and need hospitalization.
- RSV is the most common cause of hospitalization among infants.
- One of the most common causes of childhood illness and frequent cause of respiratory infections in older adults.
- RSV testing often not performed.
- No specific recommended treatment.
Burden of Hospitalization and Death Due to RSV

Adults aged ≥65 years

- ~177,000\(^1\) hospitalizations/year
- ~14,000\(^1\) deaths/year

Children aged <5 years

- 58,000-80,000\(^5,6\) hospitalizations/year
- 100-300\(^3,4\) deaths/year

\(^1\) National Health and Nutrition Examination Survey (2009-2010), \(^3,4\) National Center for Health Statistics, \(^5,6\) National Immunization Survey

ACIP June 23, 2022
Overlapping Seasonality of Flu, COVID-19, RSV

Respiratory Virus Activity
Select your state or territory:
California

End Date of Week

Percent of Total ED Visits

COVID-19  Influenza  RSV  Combined
Monitoring RSV Activity

National

Respiratory Syncytial Virus (RSV)
Percent Positive

Table: Percent positive respiratory syncytial virus tests in the United States, by week

California

Figure 12. Percentage of RSV detections at Clinical Sentinel Laboratories, 2018–2024 Season to Date

Note: Data have been shifted so that Week 1 aligns across seasons.

CDC: RSV National Trends
CDPH: Influenza, RSV and Other Respiratory Viruses Weekly report (linked at bottom of webpage)
Nirsevimab Background

- Nirsevimab (Beyfortus™) is a monoclonal antibody that provides protection against severe RSV disease in infants and toddlers
- It is a form of passive immunization that provides RSV antibodies directly to the recipient
- Confers long-lasting protection from RSV, expected to last at least 5 months (about the length of a typical RSV season)
- Fills an unmet need: There is no other approved prophylaxis or recommended treatment for RSV for the general infant population and most infants have no specific protection against RSV.
How Nirsevimab Works

- Nirsevimab binds to RSV virus and inhibits fusion of RSV to the cell membrane.
- This prevents viral entry, replication, and severe RSV disease.
Nirsevimab Inclusion in VFC Program

- CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children (VFC) program
  - No statutory definition of vaccine in the statute for the Vaccines for Children (VFC) program (section 1928 of the Social Security Act)
  - No statutory definition of vaccine in the Affordable Care Act (section 2713 of PHS Act), or its implementing regulations, which has a provision that mandates coverage of vaccine recommendations included on CDC’s immunization schedules
Safety & Efficacy

- Safety
  - Most (97%) adverse events were mild to moderate in intensity.
  - Adverse reactions that were more common among infants who received nirsevimab than placebo include:
    - Rash occurring within 14 days of injection (0.9% of nirsevimab versus 0.6% of placebo)
    - Injection site reactions occurring within 7 days of injection (0.3% of nirsevimab versus 0% of placebo).

- Efficacy: In clinical trials nirsevimab was approximately 80% effective in preventing hospitalization for RSV infection, and 90% effective against admission for intensive care.
Timing

- Typical RSV Season is from October through the end of March
  - Local RSV activity data are available at the National Respiratory and Enteric Virus Surveillance System.
  - Providers may adjust timing of administration based on guidance from public health authorities or regional medical centers.
- Optimal timing of administration is just before the start of the RSV season
- Nirsevimab administration should continue throughout the season
Guidance for Infants < 8 Months

- Dosing for infants younger than 8 months: 50 mg for infants <5 kg and 100 mg for infants ≥5 kg

- Infants with prolonged hospitalization (e.g., preterm infants) should be ideally immunized shortly before or promptly after discharge.
  - If dose cannot be administered in the birth hospital, it can be given in outpatient clinic.
  - For infants born outside the RSV season, administration should be targeted shortly before the start of their first RSV season.

FDA Full Prescribing Information
Screening for RSV Vaccine in Pregnancy

- Infants younger than 8 months of age who were born during or are entering their first RSV season should receive a single dose of nirsevimab in the first week of life if:
  - The birth parent did not receive RSV vaccine during pregnancy*
  - The birth parent’s RSV vaccination status is unknown
  - The infant was born within 14 days of prenatal RSV vaccination

*RSV vaccine during pregnancy is another option available to protect young infants from severe RSV disease and is given to pregnant persons between 32-36 weeks of gestation
Guidance for Children 8 Months – 19 Months

- Children ages 8 months and older who are **not** at increased risk of severe RSV disease should not receive nirsevimab.

- Nirsevimab is recommended for children ages 8 months through 19 months who are at increased risk of severe RSV disease:
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis

- Administration of a single 200 mg dose of nirsevimab for these children should be targeted shortly before the start of their second RSV season.
Dosing and Timing Summary

• Dose depends on age and weight

• Infants born shortly before and during the RSV season should receive nirsevimab within the first week of life, including in hospital settings.

• Offer nirsevimab now, as soon as supplies become available.

• Protection is expected to last at least 5 months, about the length of an RSV season

• Co-administration of nirsevimab with other routine pediatric vaccines during the same visit is a recommended option.
Answers to Common Questions

- Co-administration with age-appropriate vaccines is recommended; nirsevimab can be given with birth dose of Hepatitis B vaccine
- Nirsevimab is recommended for those with a prior history of RSV infection or hospitalization
- Providers licensed to administer nirsevimab in California include physicians, physician assistants, nurses, medical assistants, pharmacists, and pharmacy interns, as long as they meet their usual conditions for immunizing.
- **If nirsevimab is not available, monthly infusions of palivizumab should be administered to high-risk children as previously recommended.** Further considerations for the use of nirsevimab or palivizumab in infants and young children at increased risk for severe RSV disease are available at [ACIP and AAP Recommendations for Nirsevimab.](#)
Updated CDPH Tools for Clinicians

Immunization Timing 2023

Immunization Schedule with Combination Vaccines
EZIZ Resources & FAQs

- RSV Immunization FAQs
- RSV Resources for Providers and Patients
CDC Resources

- [CDC MMWR](https://www.cdc.gov/mmwr): Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
- [CDC Healthcare Providers: RSV Prevention Information](https://www.cdc.gov)
- [CDC Frequently Asked Questions About RSV Immunization for Children 19 Months and Younger](https://www.cdc.gov)
- [ACIP and AAP Recommendations for Nirsevimab, Red Book Online](https://www.cdc.gov)
- [AAP Nirsevimab Frequently Asked Questions](https://www.cdc.gov)
- [RSV ACIP Vaccine Recommendations](https://www.cdc.gov)
Let's Hear From You: Implementation

Cindy Blifeld, MD, Lompoc Valley Medical Center
Vaccines for Children (VFC) and Enrollment

Claudia Aguiluz, CDPH
Pediatric RSV in VFC!

Beyfortus™ is became available for ordering through the Vaccines for Children (VFC) Program on October 11, 2023. Detailed information regarding Beyfortus™ and ordering was communicated to all VFC Providers.

Note: The new prenatal RSV vaccine from Pfizer, ABRYSVO, is expected to be available through the VFC Program for pregnant adolescents. Information will be forthcoming.
• On Friday October 13, 2023, CDC announced a temporary stop in Nirsevimab ordering in light of high demand and limited supply.

• VFC ordering is expected to resume this week, with vaccine allocations in place to ensure equitable availability across the US for VFC supply.

• The % of doses allocated to each state will be in accordance with VFC vaccine ordering history for vaccines used in a comparable cohort.

• Doses ordered must be used according to VFC eligibility guidelines-use in VFC-eligible patients ONLY.
Nirsevimab, Hospitals, and VFC

**Birthing Hospital Enrollment in VFC**

- This fall, birthing institutions can play a critical role in increasing equitable access to birth dose Immunizations, including RSV protection.
  - Number of Medi-Cal Hospital births 2020: 172,293

- Participation in VFC will significantly reduce supply up-front costs - VFC provides vaccines at no cost to enrolled providers for VFC-eligible children.

- It will help ensure equitable access to nirsevimab to vulnerable newborns and protect them prior to discharge.
  - Approximately 10% of all U.S. VFC provider enrollments are “birthing hospitals”.
  - For California, only 4% of provider enrollments are identified as birthing hospitals.

- Will support vaccine supply limitations during the initial rollout of nirsevimab. Beyfortus TM supply for the 50 mL formulation for babies under 5kg may not be as limited as that for babies over 5 kg.

Cost of nirsevimab estimated at $495 per dose in the private sector
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.

- 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.
Vaccines for Children (VFC) Program Participating Requirements

• Vaccinate VFC eligibles patients, 0 through 18 years of age who meet one or more of the following criteria:
  • Medicaid-eligible
  • Uninsured
  • American Indian or Alaska Native (AI/AN)
  • Underinsured (Underinsured children can only be vaccinated at a Federally Qualified Health Center [FQHC] or Rural Health Center [RHC])

• Hospitals may enroll in VFC to provide Hepatitis B and RSV Vaccines only

• VFC Program requirements are summarized in the Program Participation Requirements at a Glance and defined in the VFC Provider Agreement (federal agreement) and California VFC Program Provider Agreement Addendum.
VFC Enrollment
Colleen Mallen and Kelley Leung, RN, CDPH
Enrollment Checklist for Birthing and Pediatric Hospitals

- CDPH has developed a checklist to assist providers in meeting VFC enrollment requirements and preparing your site to receive nirsevimab.

- Contains useful links to CDPH, VFC, CDC, and CAIR resources as well as a brief summary of nirsevimab clinical guidance.

- This document will be available through RSV – California Vaccines for Children (VFC) (eziz.org)
Enrolling in VFC: Key Practice Staff

1. **PROVIDER OF RECORD (POR):** Responsible for the clinic’s overall compliance with VFC Program requirements. Must be a licensed MD, DO, NP, PA, Pharmacist or a Certified Nurse Midwife.

2. **PROVIDER OF RECORD Designee:** An on-site staff member designated by the clinic’s POR to act on his/her behalf for VFC Program related matters when the POR is unavailable.

3. **VACCINE COORDINATOR:** A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice.

4. **BACKUP VACCINE COORDINATOR:** A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice when the Vaccine Coordinator is unavailable.
ALL KEY STAFF MUST take the following EZIZ lessons as relevant

Tip 1: Register as a “New Enrollment” to receive the necessary user ID and completion code, then start the training.

Tip 2: Complete all training modules:
- VFC Program Requirements
- Storing Vaccines
- Monitoring Storage Unit Temperatures
- Conducting a Vaccine Inventory (Not required for Provider of Record or their Designee)
- Provider Operations Manual (Review and Acknowledgement)
- Vaccine Management Plan (Review and Acknowledgement)

Tip 3: After completing all the required lessons, each registered EZIZ user from your clinic will receive a unique User ID and Confirmation Code that will be visible on your Learning History page.
Ensure you have a process in place to verify what type of insurance the patient has.
VACCINE MANAGEMENT PLAN

Complete a vaccine management plan (VMP) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZIZ lessons for key practice staff.
The California Immunization Registry (CAIR) or Health Futures (Alpine, Amador, Calaveras, Mariposa, Merced, San Joaquin, Stanislaus, and Tuolomne counties) is a secure, confidential, statewide computerized immunization information system for California residents.

Helps providers track patient immunization records, reduce missed opportunities, and help fully immunize residents of all ages. Reporting immunizations to the registry is required by law.

There are two ways in which a provider can submit data to CAIR: 1) Through your EHR via data exchange or 2) via manual entry of the vaccine into the registry.

CAIR Training is available online for regular or power users and Help Desk services are available to assist with any questions.

How to Enroll (ca.gov)
CAIR User FAQs
**Enrolling in VFC: Handling and Storage - Refrigerator**

**MUST**
- Maintain temperatures 36 °F - 46 °F (2 - 8 °C)
- Must be pharmacy or biologic grade if 11 cubic feet or smaller
- Must have enough space to store all vaccines
- Use VFC supplied temperature logs
- Post **DO NOT UNPLUG** stickers on electrical outlets and circuit breakers

**ACCEPTABLE**
- Acceptable to store along with other refrigerated vaccines including privately supplied vaccines
- Only order Nirsevimab and Hepatitis B if your practice only provides care to babies
Enrolling in VFC: Storage and Handling Requirements

DIGITAL DATA LOGGERS (DDLs)

- VFC vaccine must be monitored with an acceptable digital data logger
- Digital data loggers read and record temperatures at set time intervals and store data in an internal memory
  - Clinic staff can download and save the data as an electronic file on a computer and analyze vaccine storage unit temperature trends over time
- DDLs provide alerts when temperatures are out of the recommended range
- DDLs must have acceptable certificates of calibration
Enrolling in VFC: Storage and Handling Requirements

TEMPERATURE LOGS

• Current, minimum and maximum temperatures must be recorded twice daily on VFC supplied temperature logs.
• Action must be taken on out of range temperatures.
Enrolling in VFC: Enrollment Process

Key Practice staff identified, and training completed

Upload photos or scans of:

- VFC Temperature Logs
- Digital Data Logger downloads
- Digital Data Logger Certificate of Calibration
- Vaccine Storage Units including the interior and exterior
- DO NOT UNPLUG sticker
- Completed Vaccine Management Plan
Completing enrollment application on eziz

- Information about your site
  - CAIR ID
  - Type of practice
  - Contact information, address, insurance accepted, patient population, hours of operation, when can you receive VFC vaccine
  - License numbers of medical staff
  - Information about your vaccine storage unit(s) and DDLs
  - Signature of the provider of record
Enrolling in VFC: Enrollment Process

VFC application is submitted to the VFC Central Office to review application
Sent to VFC staff member who will contact within 5 business days

- Review any information missing
- Schedule Enrollment Site Visit
  - Enrollment visits will be scheduled asap. Depending on staffing some enrollment visits may have to be virtual.
Enrolling in VFC: Enrollment Visits

Storage & Handling

• Vaccine storage units
• Digital data loggers
  • Certificates of calibration
  • Downloads
• Temperature logs
• Setup of Vaccine Storage Unit

Eligibility

• Knowledge of eligible patients
• Measures in place complete eligibility screening and maintain eligibility history
Resources, Q&A, and Poll

Leslie Amani and CDPH Subject Matter Experts (SMEs)
Stay Healthy this Virus Season

6 Tips for Staying Healthy this Virus Season

Reduce your risk of catching and spreading respiratory viruses like flu, COVID-19 and RSV.

Stay Up to Date on Vaccines
Vaccines are the best protection against severe illness. Visit MyVaccine.gov to schedule your vaccines or contact your health care provider.
- Flu and COVID-19 vaccines are available for everyone 6 months and older.
- RSV immunizations are available for infants and some young children, pregnant people and adults 60 years and older.

Stay Home If You’re Sick
Stay home and away from others if you have any symptoms of flu, COVID-19, or RSV.

Test and Treat
Test for COVID-19 and flu if you have symptoms. If you test positive, contact your health care provider and ask about medications. Medications work best when started right after symptoms begin. Learn more about COVID-19 treatments.

Consider Wearing a Mask
Consider wearing a mask in public indoor or crowded spaces especially if you or your family is at higher risk for severe illness.

Wash Your Hands
Wash your hands often, with soap and warm water, for at least 20 seconds. If soap and water are not available, use a hand sanitizer with at least 60% alcohol.

Cover Your Cough or Sneeze
Cough or sneeze into your elbow, arm, or a disposable tissue. Make sure to wash your hands or sanitize and dispose of your tissue after.

Winter Virus Tip Sheet (CDPH)

FALL-WINTER 2023-24 IMMUNIZATIONS

Who is eligible? What immunizations are recommended? When should I get it?

Influenza
6 months and older
Preventing target 4 strains of flu and are available as a shot or nasal spray. Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year.
September or October are ideal, but catching up later can still help.

COVID-19
6 months and older
Updated COVID-19 vaccines target the Omicron BQ.1 strain to protect against COVID-19 this fall and winter
Get it now to help protect against severe disease (if at least two months since your last COVID-19 shot)

RSV (Pregnant Persons)

Pregnant persons during weeks 32-36 of pregnancy
RSV vaccine to reduce the risk of severe RSV disease in infants (baby will receive protection that lasts for months after birth)
Recommended from September to January to help protect your baby during RSV season

OR

RSV (Infants and Toddlers)

All infants from birth to age 2 and children 2-19 months at high risk of severe RSV disease
Immunization contains preventive antibodies that fight RSV infections and protect children from getting very sick
Before or during RSV season, usually October–March

RSV (Older Adults)

60 years and older
RSV vaccine to protect older adults against RSV disease
Available now – Talk with your doctor to determine if vaccination is right for you.

Where to get vaccinated?
- Contact your doctor or local pharmacy. Influenza and COVID-19 vaccines continue to be free for most people through their private, Medi-Cal or Medicare insurance plans.
- Check with your insurance on timing of RSV immunization coverage.
- You can receive influenza, COVID-19 and/or RSV immunizations during the same visit.
- Adults without health insurance can get no cost COVID-19 vaccine at many pharmacies and clinics participating in the Zweig Access Program. Visit vaccines.gov to find the nearest location.
- Children who are Medi-Cal eligible, American Indian/Alaska Native, uninsured and underinsured may get no cost vaccines through the Vaccines for Children Program.

Thanks to Kristy Metzler, PA2, MPH and Caitlin River, PhD, MPH for allowing CDPH to adapt this resource.

Fall-Winter 2023-24 Immunizations Infographic (CDPH)
CDC RSV Resources

- RSV Immunizations Overview
- RSV Immunization for Infants and Young Children
- RSV Vaccine for Pregnant People
Vaccine Support

Provider Call Center

Dedicated to medical providers and Local Health Departments in California, specifically addressing questions about State program requirements, enrollment, and vaccine distribution.

- For myCAvax Help Desk inquiries: myCAvax.hd@cdph.ca.gov
- For My Turn Clinic Help Desk inquiries: MyTurn.Clinic.HD@cdph.ca.gov
- For all other inquiries: providercallcenter@cdph.ca.gov
- Phone: (833) 502-1245, Monday through Friday from 8AM–5PM

myCAvax

- Virtual Assistant resolves many questions but will direct you to the Provider Call Center queue for live assistance!
- Knowledge Center houses key job aids and videos that are updated every release. Once logged in, you can access job aids from the myCAvax homepage (or at various places throughout the system) using the links as shown below.
# CDPH Provider Webinars and Trainings

## Week of October 16, 2023

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<td><strong>Live Webinars and Training</strong></td>
<td><strong>Intro to My Turn Onboarding (v. 1/4/22)</strong></td>
<td><strong>COVID-19 Crucial Conversations Webinar:</strong> Talking with Patients about the Fall COVID-19, Flu, and RSV Season 12:00 pm – 1:00 pm</td>
<td><strong>Bi-Weekly State General Fund (SGF) Program Office Hours</strong> 11:00 am – 11:30 am</td>
<td><strong>CDPH Immunization Updates for Providers</strong> 9:00 am – 10:30 am</td>
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<td><strong>View On Demand</strong></td>
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## Help Desk
- myCAvax Help Desk Email: mycavax.hd@cdph.ca.gov
- My Turn Help Desk Email: myturn.clinic.hd@cdph.ca.gov
- My Turn Onboarding Email: myturnonboarding@cdph.ca.gov

## General
- CDPH Provider Call Center: 1-833-502-1245, 8am-5pm, Mon-Fri
- Email: providercallcenter@cdph.ca.gov
- Vaccines: COVID-19 Vaccines
- Therapeutics: COVID-19 Therapeutics

## Mpox
- Email: stdcb@cdph.ca.gov
- General Website: Mpox Website
- Vaccines: Mpox Vaccines Website

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Last Updated: 10/12/23
American Academy of Pediatrics Webinar

When: Tuesday, October 17, 2023
Time: 5PM, PST

Nirsevimab implementation strategies in outpatient practices (AAP)

Please register using the [Registration Link](#)
**Upcoming COVID-19 Crucial Conversations Webinar**

**Topic:** Talking with Patients about the Fall COVID-19, Flu, and RSV Season

**Description:** Learn how to effectively communicate with patients about the upcoming respiratory virus season and strategies for increasing vaccine administration.

**Speaker:** Dr. Ilan Shapiro

**When:** Wednesday, October 18, 2023

**Time:** 12PM - 1PM PT

Please register [here](#)
During today's webinar, please use the Q&A panel to ask your questions so CDPH subject matter experts can respond directly.

Resource links will be dropped into, “Chat”
Poll: VFC Enrollment

1. Are you currently enrolled in the VFC Program?
   - Yes
   - No
   - N/A

2. After attending today’s RSV webinar, do you feel that enrollment in VFC is feasible for your organization?
   - Yes
   - No
   - N/A

3. What resources or information would your organization need to assist you in successfully enrolling in the Vaccines for Children (VFC) program?
   [Short Answer]

4. What are the biggest barriers to VFC enrollment for your organization?
   [Short Answer]
Upcoming Webinar Opportunities

CDPH Immunization Updates for Providers

Next session: Friday, October 20, 2023
9AM – 10:30AM