# Weekly Vaccine Digest 10/13

# Los Angeles County Department of Public Health

Dear Colleagues and Partners,

Below are the LACDPH weekly vaccine administration and order updates, upcoming webinars, and newsworthy events. Attached to this email you will find a pdf version of this digest and the links shared during the LA DPH and CDPH Office Hours. To view the CDPH recording and slides please visit <a href="https://eziz.org/">https://eziz.org/</a>. Bridge Access Program COVID vaccine inventory supply remains extremely limited. Please order small quantities and you can order on a weekly basis. Orders will be reduced or rejected based on our available inventory.

If you received this email and would like to be added to our listserv, please contact our COVID-19 Provider Vaccine Call Center at covidvaccinereq@ph.lacounty.gov

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### **Order and Administration Reminders**

- <u>REMINDER:</u> Please place all State General Flu (SGF) orders in myCAvax by 5pm on Monday,
   10/16. See <u>Ordering and Distribution Cadence Calendar</u> for more information. Please note that DPH is also filling SGF orders through local fulfillment.
- <u>REMINDER:</u> Please place all BAP orders in myCAvax by 5 pm on Monday, 10/16. CDPH has
  distributed additional doses to support provider requests. When inventory becomes limited,
  orders may be cancelled or reduced.
- Order a 1-2 week supply of vaccine for flu and BAP and order weekly as necessary.
- Vaccine delivered from the DPH warehouse will be delivered 3-7 business days after the order is
  place in myCAvax. Please present a photo ID (work badge, school ID, driver's license, etc.) and
  sign for the delivery when received.
- REMINDER: Job aid for Vaccine and Clinic Eligibility by Funding Source can be found here.

## **Respiratory Syncytial Virus (RSV)**

- NEW: Visit CDPH's new Respiratory Virus webpage here.
- NEW: Find RSV Immunization Resources here
- Clinical Guidance: RSV Immunizations
  - o 2023 CDC Immunization Schedules Update
    - CDC Immunization Schedules typically updated in February
    - New addenda summarize recommendations adopted in 2023 for COVID19, RSV, poliovirus, and influenza:

- Recommended Child and Adolescent Immunization Schedule, United States, 2023
- Recommended Adult Immunization Schedule, United States, 2023
- By publishing updated official schedules now, CDC reduces the time between new recommendations and insurance coverage for the new recommendations, as required by the Affordable Care Act.
- RSV Immunization Products Overview
  - Infants and Toddlers
    - One dose of nirsevimab is recommended for all infants younger than 8 months of age who are born during —or entering — their first RSV season
    - One dose of nirsevimab is recommended for infants 8 through 19 months of age who are at higher risk of severe disease shortly before, or during, their second RSV season.
  - o Pregnant People
    - RSV vaccine administered between 32 36 weeks of pregnancy, between September-January
    - Maternal RSVpreF vaccine may be simultaneously administered with other recommended vaccinations during pregnancy (Tdap, Flu, COVID-19)
  - o Older Adults
    - Adults 60 years and older may be eligible for an RSV vaccine, under shared clinical decision making with their health care provider

Who Does Protect?		Is It for Everyone in Group?	
Adults 60 and over	RSV vaccine	Talk to your doctor first	
Babies	RSV antibody given to baby	All infants entering or born during RSV season. Small group of older babies for second season.	
Babies	RSV vaccine given during pregnancy	Can get if you are 32–36 weeks pregnant during September–January	

 RSV Vaccines Approved for Adults Ages ≥ 60 Years Single dose, Intramuscular Injection Infants and Toddlers

### RSVPreF3 (AREXVY™, GSK)

- 120ug RSVpreF3
- Adjuvant: AS01E^
- 83% reduction in risk of RSVassociated lower respiratory tract disease\*

### RSVPreF (ABRYSVO™, Pfizer)

- 60ug each of RSVpreF A and RSVpreF B
- No adjuvant
- 86% reduction in risk of RSV-associated lower respiratory tract disease\* with ≥3 symptoms

RSV Vaccines for Older Adults: Safety

Frequency of Adverse Event	RSVPreF3 (AREXVY™, GSK)	RSVPreF (ABRYSVO™, Pfizer)
Pain at injection site	61%	11%
Fatigue	34%	16%
Myalgia	29%	10%
Headache	27%	13%
Arthralgia	18%	Not reported

Serious adverse events under monitoring:

- Guillain-Barré Syndrome & other immune-mediated demyelinating conditions
- Supraventricular arrhythmias
- Older Adult RSV Vaccine Recommendations
  - Adults aged 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
  - Give as early as vaccine supply becomes available and continue to offer vaccination to eligible adults who remain unvaccinated.
  - Co-administration of RSV vaccines with other adult vaccines during the same visit is a recommended option.
- Shared Clinical Decision-Making Guidance can be found here.
- RSV Immunizations to Protect Infants & Toddlers
  - CDC Recommends RSV Vaccine for Pregnant People
    - RSV vaccine (RSVpreF, ABRYSVOTM) is recommended for pregnant people at 32 through 36 weeks of pregnancy during the months of September through January to prevent RSV infections in their infants.
    - People can receive the RSV vaccine on the same day as other vaccines recommended during pregnancy, including Tdap, COVID-19, and influenza.
    - Most infants will likely only need protection form either the prenatal RSV vaccine or infant immunization, but not both.

<sup>\*</sup>Lower respiratory tract disease signs/symptoms include cough, sputum, and difficulty breathing. ^Similar to adjuvant used for Shingrix (half dose of same components)

- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient.
- RSV Immunization for Infants and Toddlers
  - An RSV immunization called nirsevimab (BeyfortusTM) can help protect infants and toddlers from severe RSV illness.
  - o The antibodies in nirsevimab are just like those that develop after a typical vaccine.
  - o RSV immunization is recommended for:
    - All infants aged < 8 months born during or entering their first RSV season, including those recommended by the AAP to receive palivizumab.
    - Infants and children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season, including those recommended by AAP to receive palivizumab

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## **Nirsevimab: Dosing and Timing of Administration**

- 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
- The Nirsevimab Guide can be found <u>here.</u>
- Nirsevimab: 8 -19-Month-Old High-Risk Eligibility Criteria
  - Chronic lung disease (CLD) of prematurity who required medical support at any time during the 6 months (steroids, diuretics, oxygen) before the start of RSV season.
  - Severe immunocompromise
  - Cystic fibrosis who have either 1) severe lung disease or 2) weight for length.
  - American Indian and Alaska Native children (this group is newly recommended in contrast to current palivizumab recommendations).
  - Detailed information on palivizumab eligibility can be found in <u>AAP Red Book</u> and the 2014 guidance for palivizumab for RSV prophylaxis.
- Nirsevimab: Frequently Asked Questions can be found here.
- Efficacy of RSV Immunizations to Protect Infants

Product	Age	Reduction in RSV- associated lower respiratory tract disease (LRTD)	Reduction in severe RSV-associated LRTD
Abrysvo™ Vaccine given at 32-36 weeks of pregnancy	Infants ≤90 days old	34.7%	91.1%
Abrysvo™ Vaccine given at 32-36 weeks of pregnancy	Infants ≤180 days old	57.3%	76.5%
Beyfortus™ (Nirsevimab)	Infants ≤ 150 days old	79%	80.6%

\*lower respiratory tract disease signs/symptoms include cough, sputum and difficulty breathing

### • RSV Immunization Safety

- Prenatal RSV Vaccine
  - In the clinical trials, the side effects most often reported by pregnant people were pain at the injection site, headache, muscle pain, and nausea.
  - Pre-eclampsia occurred in 1.8% of pregnant people who received the RSV vaccine compared to 1.4% of pregnant people who received a placebo.
  - The clinical trials identified a small increase in the number of preterm births in vaccinated pregnant people. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.

### Nirsevimab

 Side effects after nirsevimab were uncommon in clinical trials. The most common side effects are pain, redness, or swelling at the injection site, and a rash. No serious allergic reactions occurred in the clinical trials

### Reporting Adverse Events

- Report adverse events following vaccination to <u>VAERS</u>
- o Nirsevimab considerations: o
  - Report side effects that happen after getting nirsevimab to the MedWatch website or by calling 1-800-FDA-1088.
  - If a child also received any vaccine on the same day as nirsevimab, the side effects also may be reported to VAERS.

### RSV Vaccine Insurance Coverage

- RSV Vaccine Covered by Medi-Cal & Medicare Part D
- o Currently covered only as a pharmacy benefit currently for Medi-Cal & Medicare Part
- o Managed Medi-Cal may possibly be covered in MD office per plan.

#### **S**DHCS Medi-Cal Rx Contract Drugs List Effective 10/01/2023 Strength/ Billing UM **Drug Name** Dosage Code I Package Size Unit Type **Topical & Local Preparations: Vaccines** Abrysvo (Respiratory 120 mcg/0.5 ml \* Use of this vaccine must be based on Syncytial Virus the guidelines published by the Centers for Disease Control and Prevention Vaccine) \* (CDC). 120 mcg/0.5 ml \* Restricted to: 1) Medi-Cal beneficiaries Arexvy (Respiratory Syncytial Virus 60 years of age and older. 2) Use of this Vaccine, vaccine must be based on the Adjuvanted) \* quidelines published by the Centers for Disease Control and Prevention (CDC).

### Nirsevimab Coverage

- Definition of "Vaccine"
  - 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
- Nirsevimab is recommended by ACIP
  - covered by insurance
  - included in the VFC program
  - important for ensuring equitable access to nirsevimab
- Approximately 10% of birthing hospitals participate in the VFC program
- Pharmacy involvement: unknown unlikely in the first season.
- Information and Education: RSV
  - Winter Virus Tip Sheet
  - o Fall-Winter 2023-24 Immunizations Infographics
  - o **RSV FAQs**
  - RSV Immunizations Overview
  - o RSV Immunizations for Infants and Young Children
  - RSV Vaccine for Pregnant People
  - o Nirsevimab Timing Guide

## **Upcoming Webinars**

- Webinar: Respiratory Syncytial Virus (RSV)
  - When: Monday October 16, 2023 12pm-1pm. Registration link can be found here.

- Crucial Conversations Webinar: Talking with Patients about the Fall COVID-19, Flu, and RSV Season
  - o When: Wednesday October 18, 2023 12pm-1pm. Registration link can be found here.
- SGF Flu Vaccine Management 102 for Providers
  - o When: Monday October 23, 2023 12pm-1pm. Registration link can be found here.
- Bridge Access Program myCAvax Office Hours
  - o When: Thursday October 26, 2023 11am-11:30am. Registration link can be found here.
- STI Clinical Update Webinar: California Mpox Update for Healthcare Providers
  - When: Thursday, October 26, 2023 Time: 12PM 1PM, PDT Register here.
- Nirsevimab implementation strategies in outpatient practices (AAP)
  - When: Tuesday, October 17, 2023, at 5PM, PST Register here
- Clinical Update on the 2023 Respiratory Virus Season (CDC Current Issues in Immunization Webinar)
  - When: Wednesday, October 18, 2023. Time: 9:00am-10:00am Registration is not needed. Join the webinar here.

## **Novavax Update**

- Novavax 2023-2024 COVID-19 Vaccine Now Authorized
  - Individuals 12 years of age and older previously vaccinated with a COVID-19 vaccine (and who have not already been vaccinated with a recently updated mRNA COVID-19 vaccine) are eligible to receive one dose at least 2 months after their last dose.
  - Unvaccinated individuals are eligible receive two doses.
  - Immunocompromised individuals are eligible for an additional dose of Novavax COVID19 Vaccine, Adjuvanted (2023-2024 Formula) at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula). Additional doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at the discretion of the healthcare provider,
  - Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States and should no longer be used.
- Novavax Vaccine Resources
  - Detailed CDC clinical guidance expected soon; ACIP not expected to meet again, as data was already reviewed at recent ACIP meeting.
    - Check CDC Product Page for updated Novavax standing orders (not yet posted)
  - Fact Sheet for Healthcare Providers Administering Vaccine
  - Fact Sheet for Recipients and Caregiver
  - Novavax vaccine 12Y+ fact sheet and receiving instructions
- What to Do with Deauthorized Novavax Vaccine
  - Quarantine deauthorized Novavax vaccine to prevent administration errors!
  - Report doses as "Waste" in myCAvax and use "Other" to add comment "deauthorized"!
  - Dispose of vaccines following practice protocols; vaccines may be disposed of in a
  - pharmaceutical waste container, or a comingled pharmaceutical/Sharps waste
  - container!

- My Turn added the recently authorized Novavax product and mapped the current vaccine supply to this product on Wednesday, October 11, 2023. Please update your clinic vaccine inventory and de-activate the deauthorized Novavax inventory.
  - NOTE: If you remove the de-authorized inventory, historical bulk upload will not be available for that clinic.
- Commercial purchase of Novavax
  - Novavax updated COVID-19 vaccine (packaged as 5-dose vials, minimum order 10 doses) is available for purchase through the following wholesale distributors: <u>Amerisource</u>
     Bergen, <u>Cardinal Health</u>, <u>FFF Enterprises</u>, <u>Henry Schein</u>, <u>McKesson Medical Surgical</u>, and McKesson Plasma & Biologics.

## myCAvax Release 44 (October 20, 2023)

- myCAvax R44 is the last scheduled production release until February 2024. There may be ad-hoc releases for key system updates as needed.
- My Turn production releases will continue their usual monthly cadence. Updates will be shared at our weekly webinars for both platforms as usual.
- Expanded SGF Capabilities
  - Be able to record temperature excursions for SGF vaccines and select products on 'Excursion' pop-up window based on the program selected
  - Be able to record waste events for SGF vaccines and select products on the 'New Waste Report' pop-up window based on the program selected
  - Receive LHD initiated SGF transfers

### Provider Community Site

- See the new BAP logo on the program tile on the landing page
- See a dropdown on the SGF program tile with new site functionalities for the SGF program
- See an updated 'State General Fund Home' page with new site functionalities
- See Program Locations on the 'Locations' page based on the program selected
- See the new 'Program Type' picklist on the COVID-19 'Shipment Incidents' and 'Orders' pages
- See the new 'USG COVID-19 Program' checkbox on the COVID-19 Program Location applications and related lists of COVID-19 Program Locations
- See relabeled shipping address fields on the Location Account form
- NOTE: On Friday, October 20, 2023, the 'Vaccine Administration Address' field will be removed from myCAvax. To comply with CDC policy, providers must be prepared to receive vaccine shipments at the same address in which they are administering vaccine, and the shipping address listed on their Location Accounts must be used for all Program Locations.
  - PROVIDERS MUST: Providers, if you need to update your shipping address to comply
    with the single shipping address requirement, contact the Provider Call Center at
    providercallcenter@cdph.ca.gov or (833) 502 1245. Note that the secondary address
    line may be customized at each Program Location to specify a specific suite, building,
    etc. Be sure to confirm your shipping hours

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## **Bridge Access Program**

- An overview of CDC's Bridge Access Program can be found here.
- BAP provider operations manual
- BAP Requirements at a Glance
- BAP order cadence calendar
- Eligibility guidelines by funding source
- If you are a Provider administering BAP vaccine, be sure to set your location on Vaccines.gov by follow the steps in this job aid.
- If you are a BAP-eligible provider interested in receiving BAP vaccine doses, complete program enrollment in the myCAvax Provider Community by Friday, October 27, 2023.

### **Bridge Access Program Retail Pharmacies**

- Work directly with eTrueNorth to enroll your pharmacy location in the Bridge Access Program.
- eTrueNorth makes participation easy by providing a secure online platform for convenient patient sign-up and participating pharmacy reimbursement.
- Interested pharmacies can visit Enrolling Bridge Access Program: joinetruenoth.com
- The pharmacy component of the Bridge Access Program acts on a reimbursement model
  - This *differs* from the public health component which used a separate stock provided via allocation.
  - There is NOT a separate BAP inventory supply for pharmacies.
  - Commercial products will be purchased and then be reimbursed. eTrueNorth will reimburse for the invoiced cost of the vaccine and CDC will reimburse the \$40 admin fee
  - More information is in the onboarding packet from eTrueNorth

## **LACDPH & CDPH Provider Office Hours Link**

LA County Department of Public Health Provider Immunization Office Hours Information

- Every other Wednesday from 9am-10am Next meeting: 10/25/23
  - o NOTE: Effective 2/01/23 the Office Hours will be held on a biweekly basis
- This has been meeting amended to discuss COVID, Mpox, Flu and RSV vaccines. The meeting link will remain the same.
- MS Teams meeting link below; please create a recurring calendar invite with this link.
- To request meeting slides, please email covidvaccinereq@ph.lacounty.gov

Microsoft Teams meeting

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

+1 323-776-6996,,350547595# United States, Los Angeles

Phone Conference ID: 350 547 595#

## California Department of Public Health Provider Office Hours Registration Link

- Every Friday from 9am-10:30am.
- Complete one-time registration here.
- Meeting recordings and slides can be found here.

Providers should add staff names to the Provider Listserv to receive weekly emails and updates. To be added, please email <a href="mailto:blanca.corona@cdph.ca.gov">blanca.corona@cdph.ca.gov</a>