COVID-19 Vaccine Commercialization Updates: Session 7

October 27, 2023
Agenda

• Vaccine uptake
• CDC VFC resolutions
• Nirsevimab challenges

Recording and slides from previous sessions are all posted here:
illinoisaap.org/covid-19/
Disclaimer

• This is not official guidance and information is subject to change.
• Views expressed are not necessarily those of IDPH and CDPH staff or organizational policies.
Speakers

Karyn Lyons, MS, RN – Chief, Immunization Section, IDPH
Kevin Hansen – Vaccine Manager, CDPH
COVID-19 Vaccine Coverage so Far

Vaccine Coverage 6 months+ (%), United States

Note: Covid-19 vaccine coverage in 2023 is measured differently than 2022 due to the end of the public health emergency.

Chart: YLE/Katelyn Jetelina • Source: CDC • Created with Datawrapper
Why Might this Be?

1. **COVID-19 circulates year-round.**
   - ~15% of the population was infected with COVID-19 this summer and do not need the fall vaccine.

2. **Debate on eligibility.**

3. **Lack of access.**

4. **Fatigue.**

5. **Lack of resources.**

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_Fall 2023 vaccine coverage and reaching "passive positives" 10.24.23_
What Can We Do About it?

All of us—friends, family, neighbors, schools, pharmacies, doctor offices, health departments, employers—need to be laser-focused on “passive positives.”

Passive positive = people who have gotten COVID shots in the past and generally approve of vaccination but, are unlikely to expend energy to find another shot and are likely ambivalent about receiving one.

This is a large group—perhaps 35–40 percent of the vaccine-eligible population.
What Can We Do About it?

Remind people that they have good feelings about vaccines.
• Actively encourage patients to focus on the benefits of vaccination.

Share information about eligibility.
• People may be confused.

Remind patients about vaccines even during visits for other reasons.
CDC VFC Resolutions

CDC relaxes VFC rules for nirsevimab, COVID-19 immunizations

October 18, 2023

These resolutions will be implemented locally.
COVID-19 Vaccine Resolution

These resolutions will be implemented locally.

Nirsevimab-alip (Beyfortus™)

- Monoclonal antibody for RSV prevention.
- The Food and Drug Administration (FDA) has approved, and the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), and CDC recommended nirsevimab for:
  - All infants < 8 months born during or entering their first RSV season. Infants < 8 months old born outside of RSV season should receive nirsevimab starting in October unless local epidemiology suggests atypical timing of RSV season.
  - High-risk children 8-19 months during their second season.
    - Chronic lung disease of prematurity requiring medical support at any time during the 6-month period before the start of the second RSV season.
    - Children with severe immunocompromise.
    - Certain children with cystic fibrosis.
    - Native American and Alaskan Native children.
    - Nirsevimab can be co-administered with childhood vaccinations.

See [CDC guidance](https://www.cdc.gov) for additional details.
Additional Considerations

Nirsevimab – VFC Resolution

These resolutions will be implemented locally.

Inventory
- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for nirsevimab if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 1, 2024.
  - This includes VFC providers who serve only Medicaid-eligible patients and no privately insured children; they are not required to privately purchase nirsevimab.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their nirsevimab-insured private patients to access nirsevimab (i.e., from another local in-network practice or system that does have private inventory of nirsevimab, or FQHC, RHC, or deputized VFC provider authorized to immunize uninsured children).
- CDC recognizes that with current supply and demand issues, this may not be possible, but if supply changes, we encourage providers to assist their private patients in identifying access routes.
- In locations where providers report that demand for nirsevimab is low, awardees are to allow providers to order the minimum packaging of VFC nirsevimab that is feasible. In these cases, site visit reviewers will observe that nirsevimab inventory is a much lower quantity than other ACIP-recommended vaccines.
- At the discretion of the awardee, certain specialty VFC providers, including birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of VFC vaccines, based on the populations served in their facility. VFC-enrolled birthing facilities offering nirsevimab must offer hepatitis B vaccine at birth as well (and vice versa).

Eligibility Criteria
- A child’s eligibility criteria for VFC nirsevimab are the same as for other VFC vaccines.

Borrowing
- For those VFC providers who maintain private stock of nirsevimab and vaccinating privately insured children, bidirectional borrowing of nirsevimab will be allowed for the 2023-2024 respiratory virus season as described below.
- CDC’s borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdictional.
Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023-2024 Respiratory Virus Season

• CDC had paused ordering through the VFC program.

• Ordering has resumed but only for 50 mg prefilled syringes.
  - CDC will use an allocation system that initially will target awardees who have not yet ordered or who ordered a small amount.
  - Additional products are expected to be made available every two to three weeks.

• Sanofi does not anticipate accepting new orders for the 100 mg formulation of nirsevimab this season.
  - 100 mg doses are expected to be used to fill existing orders and to supply the state VFC programs.

Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET
CDC-HAN-0499

Summary
The Centers for Disease Control and Prevention (CDC) is issuing this Health Alert Network (HAN) Health Advisory to provide options for decisions to protect infants from respiratory syncytial virus (RSV) in the context of a limited supply of nirsevimab, a long-acting monoclonal antibody immunization product recommended for preventing RSV-associated lower respiratory tract disease in infants.

https://emergency.cdc.gov/han/2023/han00499.asp
Interim Recommendations For the 2023-’24 Season ONLY

CDC interim recommendations focus on the youngest children and those most at risk of severe RSV disease.

- Recommendations have not changed for children weighing less than 5 kilograms (kg). Those born before October 2023 should get a 50 mg dose now, and those born in October 2023 and throughout the RSV season should receive a 50 mg dose in the first week of life.

- For infants weighing 5 kg or more, prioritize using 100 mg doses in those at highest risk of severe disease:
  - infants under 6 months of age,
  - American Indian/Alaska Native (AI/AN) infants under 8 months of age and
  - infants 6 to less than 8 months of age with certain conditions that put them at high risk of severe RSV disease such as premature birth at less than 29 weeks’ gestation, chronic lung disease of prematurity, hemodynamically significant congenital heart disease, severe immunocompromise, severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile), neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions.

- Give palivizumab instead of nirsevimab to children ages 8-19 months who are eligible for palivizumab per AAP recommendations.

- Offer nirsevimab to AI/AN children ages 8-19 months who are not eligible for palivizumab and who live in areas that are remote or have high rates of severe RSV among older infants and toddlers.

- Follow AAP recommendations for palivizumab-eligible infants under 8 months when the appropriate dose of nirsevimab is not available.

- Avoid using two 50 mg doses of nirsevimab for infants weighing more than 5 kg. It may not be covered by insurance and could exacerbate supply issues.

- Encourage pregnant people to receive the new RSVpreF vaccine at 32-36 weeks’ gestation. Most infants do not need protection from both nirsevimab and RSVpreF.

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Support

• Do you have site specific questions?
• Fill out an implementation support request form on the website below for one-on-one support!

Illinoisvaccinates.com/implementation-support
Resources

**Pfizer**
- [COVID-19 Vaccine Training Webinars led by Pfizer](#)
- [Comirnaty](COVID-19 Vaccine, mRNA) (2023-2024 Formula) 12 years of age and older
- [Pfizer-BioNTech COVID-19 Vaccine](2023-2024 Formula) 6 months to 11 years of age
- [Pfizer Dear HCP Letter](#)
- [Comirnaty Information for Recipients and Caregivers](#)

**Moderna**
- [Moderna Training Webinars led by Moderna](#)
- [Moderna COVID-19 Vaccine](2023-2024 Formula)
- [Moderna Dear HCP Letter](#)
- [Spikevax](COVID-19 Vaccine, mRNA) (2023-2024 Formula)
- [Spikevax Information for Recipients and Caregivers](#)

**Novavax**
- [Novavax COVID-19 Vaccine](2023-2024 Formula) 12 Years of Age and Older
- [Novavax Fact Sheet for Healthcare Providers](#)
- [Novavax Fact Sheet for Recipients and Caregivers](#)

**COVID-19 Vaccine VIS**

**CDC Standing Orders:**
- [Standing orders for Pfizer, ages 6 months through 4 years](#)
- [Standing orders for Moderna, ages 6 months through 4 years](#)
- [Standing orders for Pfizer, ages 5 years and older](#)
- [Standing orders for Moderna, ages 5 years and older](#)

**HFS COVID fee schedule** – 9.15.23

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Communication

• Chicago Department of Public Health:
  • If you are not receiving HANs, please enroll here.

• Illinois Department of Public Health:
  • If you are not receiving SIRENs, please enroll here.