INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## Hot Topics Webinar Series Respiratory Syncytial Virus (RSV): Nirsevimab and Maternal Vaccine Updates

December 8, 2023

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## **CME Accreditation Statement**



The Illinois Chapter, American Academy of Pediatrics designates each live webinar for a maximum of 1 AMA PRA Category 1 *Credit(s)*<sup>M</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurses and Nurse Practitioners can submit Certificates of Attendance to their accrediting board to claim credit for participation in the live webinars.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

## CME Disclosure Grid

Name	Role	Conflicts of Interest	Disclosures
	Faculty/Presenter		
Marielle Fricchione, MD		No	N/A
	Faculty/Presenter/Planning		
Diana Balabrin, MSN,	Committee Member,		
APRN	Content Reviewer	No	N/A
Kevin Hansen	Faculty/Presenter	No	N/A
Danial Goodman	Faculty/Presenter	Yes	McKesson and Pfizer Stocks
Philip Martinez, LCPC	Planning Committee Member	No	N/A
Ranjiv Matthews, MD	CME Reviewer	No	N/A
Joseph Hageman	CME Reviewer	Yes	Owlet - Royalties
Stephanie Atella	Staff	No	N/A
Monica Del Ciello	Staff	No	N/A
Erin Moore	Staff	No	N/A

None of the Planning Committee members, faculty/presenters, content reviewers, CME application reviewers or anyone in control of the training content disclosed a relevant financial relationship with a commercial interest/ineligible company.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

## Learning Objectives

As a result of this webinar, participants will be able to:

Use 2023/2024 clinical guidance for the administration of Nirsevimab and Abrysvo.

## Explain the clinical burden of RSV for infants.

Discuss the limited supply of RSV prevention products and the implications of these shortages.

Describe jurisdictional guidance and coverage for Nirsevimab and Abrysvo, and how this impacts VFC programs.

Explain the mechanism of action for Nirsevimab and Abrysvo.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



**Speakers** 

- Marielle Fricchione, MD, FAAP
- ▶ Diana Balbarin, MSN, ANP-BC CDPH
- Kevin Hansen CDPH
- Daniel Goodman IDPH

# Burden of RSV Illness

## **Burden of RSV Disease**

- Most common cause of hospitalization in U.S. infants
- 58,000-80,000 hospitalizations among children <5 years old</p>
- 100–300 deaths in children <5 years old</p>
- 2.1 million outpatient visits
- Risk declines by increasing age throughout infancy and early childhood
- Prematurity and other chronic diseases increase risk of RSV-associated hospitalization, but most hospitalizations are in healthy, term infants

# Changes in seasonality of RSV transmission following SARS-CoV2 introduction— NREVSS<sup>1</sup>, 2017–2023



\* 3-week centered moving averages of percentage of RSV-positive PCR results nationwide. The black dotted line represents the threshold for a seasonal epidemic (3% RSV-positive laboratory PCR results).

Jones J. Evidence to recommendations framework: nirsevimab updates [Presentation slides]. Presented at the Advisory Committee on Immunization Practices meeting, Atlanta, GA; August 3, 2023. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-08-3/02-RSV-jones-508.pdf

### 2023 - 2024 Season: National

Monthly Rates of RSV Associated Hospitalizations, by Season 20 15 Hospitalization rate per 100,000 10 March April October November December January February May June August September Surveillance Month

### Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

https://www.cdc.gov/rsv/research/rsv-net/dashboard.html



INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

## 2023-2024 Season: Illinois

#### RSV Admissions by Age Group



https://dph.illinois.gov/content/dam/soi/en/web/idph/publications/idph/topics-and-services/diseases-and-conditions/respiratory-disease/surveillance/respiratory-report\_45.pdf

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



### 2023 – 2024 Season: Chicago

11



### Percent of ED Visits in Children (<5 years) for RSV by Season

https://www.chicago.gov/content/dam/city/depts/cdph/H1N1\_swine\_flu/FluUpdate/2023/Influenza-and-Respiratory-Virus-Surveillance-Report-Week-46\_11.27.2023.pdf

## Nirsevimab (Beyfortus<sup>TM</sup>) for Prevention of Respiratory Syncytial Virus Disease

## Nirsevimab-alip (Beyfortus™)

Monoclonal antibody for RSV prevention (FDA approved: July 2023)

### Mechanism of Action

13

- Recombinant human immune globulin G1 kappa monoclonal antibody that provides passive immunity, binds the highly conserved site Ø epitope present on the prefusion conformation of the respiratory syncytial virus (RSV) fusion protein
- Neutralizes RSV by inhibiting changes of the F protein needed for viral entry via fusion of viral and cellular membranes
- ► Triple amino acid substitution in the Fc region ↑ binding to the Fc receptor → extending half-life

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

### 6

## Storage and Handling: Beyfortus<sup>TM</sup>

14

- Store refrigerated at 36°F to 46°F (2°C to 8°C)
  - May be kept at room temperature 68°F to 77°F (20°C to 25°C) for a maximum of 8 hours
  - After removal from refrigerator, must be used within 8 hours or discarded
- Store in its original carton until time of use
- Do not freeze, shake, or expose to heat
- Can be returned after it expires (like other Sanofi products)

## **Preparation and Administration**

- Available in 50mg and 100mg pre-filled syringes (single use):
  - 50 mg: purple plunger rod (for those < 5kg body weight)</p>
  - 100mg: light blue plunger rod (for those ≥ 5kg body weight)
- Should not be mixed with any vaccines or medications in the same syringe or vial
- Administered intramuscularly as one or two injections
  - Preferably in the anterolateral aspect of the thigh
    - Gluteal muscle should not be used due to risk of damage to the sciatic nerve

	NDC 48081 674 15	Reoff
	Beyfortus <sup>™</sup> (100 mg/mL)	
	(nirsevimab-alip)	
	For Intramuscular Injection Only Source free on their energies in engine carbon to present from light used time of use Must be administered by a beatman provider	
R.	Prov 1 rel, single-case precised syringes	
	sanofi	

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023

Esposito S, Abu-Raya B, Bonanni P et al. Frontiers in Immunology 2021

ACIP Meeting notes (August 2023)- Proposed Clinical Consideration Updates for Nirsevimab

.

15

Beyfortus. Product information. AstraZeneca AB. Accessed August 10, 2023: <u>https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-</u>

information en.pdf

### Administration

- May be given concomitantly with childhood vaccines
  - Administer in separate syringes, at different injection sites
- Palivizumab should not be administered if nirsevimab was administered in the same season
- If palivizumab was administered initially for the RSV season and < 5 doses were administered, 1 dose of nirsevimab may be administered. No further palivizumab should be administered

Nirsevimab may be administered prior to or during second RSV season in children 8-19 months old who are eligible for nirsevimab and who received palivizumab in their 1<sup>st</sup> RSV season

• If nirsevimab is not available, palivizumab should be administered

## **Contraindications/Warnings**

### **Contraindications:**

- Infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of its excipients
  - Excipients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose, and water for injection

### Warnings/Precautions:

- Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human immunoglobulin G1 (IgG1) monoclonal antibodies
  - Initiate appropriate medications and/or supportive therapy if signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur
- As with other intramuscular (IM) injections, nirsevimab-alip should be given with caution to infants and children with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy

### **Adverse Reactions**

### Rash

Injection site reaction

Where to report adverse events depends:

- Administered alone, reports should go to MedWatch
- If it was administered simultaneously with any vaccine, reports should go to Vaccine Adverse Event Reporting System (VAERS)

## ACIP Recommendation: First RSV Season

20

### All infants aged < 8 months born during or entering their first RSV season

Infants born October 2023 – March 2024	•	Immunize within 1 week of birth during birth hospitalization or in outpatient setting Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge
All other infants younger than age 8 months	•	Administer nirsevimab as soon as possible

#### Optimal time: Before the start of the RSV season (typically October through the end of March)

Jones JM, Fleming-Dutra KE, Prill MM, et al. 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. MMWR Morb Mortal Wkly Rep 2023;72:920–925. DOI: http://dx.doi.org/10.15585/mmwr.mm7234a4.

## **ACIP Recommendation: Second RSV Season**

Infants and children aged 8–19\* months with increased risk for severe disease:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have either 1) manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable), or 2) weight-forlength <10th percentile</p>
- American Indian or Alaska Native children
- This group should receive (2) 100mg doses administered at the same time.

\*Package inserts state the product may be administered up to 24 months of age. Follow the ACIP recommendation and only administer up to 19 months

### **Administration for Premature Infants**

22

- There are no lower age and/or weight cut-offs for eligibility for nirsevimab
- There are limited data available in extremely premature infants <8 weeks of age</p>
- No clinical data available in infants with a postmenstrual age (gestational age at birth plus chronological age) of <32 weeks</p>
- Dosing in infants with a body weight <1.6kg is based on extrapolation and no clinical data are available</p>
- IM dosing maybe challenging in smallest infants
- ACIP and AAP guidance states that infants with prolonged hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge

# Palivizumab should be considered when nirsevimab is not available or the patient is not eligible for nirsevimab.

- Acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures
- Cyanotic heart disease in consultation with cardiology
- Moderate to severe pulmonary hypertension
  - Cardiomyopathy or infants with surgically corrected cardiac lesions requiring medication for heart failure
  - Cystic fibrosis with clinical evidence of chronic lung disease and/or nutritional compromise
- Other underlying chronic lung disease, including ciliary disorders and those with tracheostomy/ventilatory support
  - Neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
  - Preterm infants with chronic lung disease of prematurity
- Severe immunocompromise including primary immunodeficiency, solid organ/bone marrow transplant, or receipt of immunomodulating therapies (e.g., chemotherapy)

## Summary and Potential Approach

24



Note that weight cut offs are specific to Lurie Children and are still being revised.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



**Product Shortages** 

25

- CDC published a HAN on 10/23/23 to acknowledge limited availability of Nirsevimab
- Sanofi has repeatedly closed and opened ordering capabilities
  - Currently, ordering is only open for 50mg doses for providers who have an assigned allocation
  - Sanofi should be in contact with these providers
  - Orders for 100mg doses are no longer being accepted – not expected to reopen this season

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

<u>Print</u>



Distributed via the CDC Health Alert Network October 23, 2023, 3:30 PM ET CDCHAN-00499

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

### 6

### As of 12/7/23

26

#### Important Update Regarding Beyfortus™ (nirsevimab-alip) 50 mg and 100 mg Injection Supply

There has been an unprecedented demand for Beyfortus. Despite an aggressive supply plan built with the goal of outperforming past pediatric immunization launches, the actual market demand has been much higher across both the 50 mg and 100 mg presentations.

At the present time, demand has now consumed the supply currently available for this season for both the 50 mg and 100 mg.

The Centers for Disease Control and Prevention (CDC) has issued a Health Alert Network (HAN) Health Advisory to provide options for clinicians to protect infants from RSV in the context of limited Beyfortus supply. <u>Click here</u> to learn more about the CDC Health Alert.

We understand the significant impact the supply shortage will have on parents and providers and apologize for this unfortunate circumstance. We are working earnestly to help make available future supplies of Beyfortus. Thank you for your patience.

Please contact your Sanofi representative to discuss any additional questions or **sign up for updates**.

#### Pop-Up on Beyfortus Website

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## 27 Potential Implications

- Frustration and confusion among families and providers
- Infants remain vulnerable
- Inequitable distribution
- Misinformation and distrust

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

## 28 Interim Clinical Guidance

- Prioritize 100mg doses for infants at highest risk of severe disease, including the youngest infants, those with certain underlying medical conditions and those who are American Indian or Alaska Natives
- Refer patients to other providers when your practice does not have available stock
- Encourage maternal vaccination during 32-36 weeks of pregnancy
- Do not use two 50 mg doses for children who need 100 mg. Doing so is not part of FDA approval and may not be covered by insurance
- Suspend using nirsevimab in palivizumab-eligible children aged 8–19 months for the 2023–2024 RSV season
- Recommendations for using 50mg doses remain unchanged at this time

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## Ordering

29

- > VFC:
  - Distributed to state immunization programs using an allocation system more on ordering from CDPH and IDPH later
- Commercial/Private Stock:
  - Within VaccineShop.com customer accounts, customers can click on the "View Details" button to see a "Quantity Limit" pop up window with the following information:
    - Total Allocation: shipped units + open orders year to date + units remaining to order
    - Units Ordered to Date: shipped units + open orders year to date
    - Units Remaining: units remaining to order (deadline is 12/15)
  - If allocations are not accepted during the 30-day period, Sanofi will first offer declined doses to those customers without allocations

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

## **Beyfortus™ Coding**

30

Proprietary Name	Manufacturer	Unit of Sale NDC11	CVX description CVX Code Code		CPT Code	
BEYFORTUS	Sanofi Pasteur Inc.	49281-0575-15	RSV, mAb, nirsevimab-alip, 0.5 mL, neonate to 24 months	o, 0.5 306 PMC		90380
BEYFORTUS	Sanofi Pasteur Inc.	49281-0574-15	RSV, mAb, nirsevimab-alip, 1 mL, neonate to 24 months307PMC		90381	
Administration Codes: <ul> <li>96380: to report the counseling and administration of nirsevimab</li> <li>96381: to report the administration of nirsevimab on a different date than the counseling by a physician or qualified health care professional</li> </ul>						
Do not report immunization administration codes <b>90461–90462</b> or <b>90471–90472</b> for the injection of nirsevimab, as these codes are limited to the administration of vaccine and toxoid products. For claim dates of Oct. 6 or later, do not report code <b>96372</b> for administering nirsevimab.						

<u>Provider Notice 12/8/23</u>: HFS allows an administration fee for VFC Program-enrolled providers who obtain Beyfortus immunization through the VFC program for neonates and infants.



INCORPORATED IN ILLINOIS

#### American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

### **AAP Advocacy**

#### Federal action on equitable distribution, coding, and more

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Headquarter 345 Park Blvd Inners II desay Phone: 630/626-600 Fax: 847/414-8000 www.aap.org

Reply to AAP Washington Office not 13th St NW. Suite 400N

ashington, DC 20005 Phone 202/147-8600 E-mail kidstst@aan.org

**Executive** Committee Sandy L Chung, MD, FAAP

President-Elect Benjamin D. Hoffman, MD. FAAP Immediate Past President Moira A. Szilagyi, MD, FAAF Secretary/Treasurer Dennis M. Cooley. MD. FABP **CEO/Executive Vice President** 

Board of Directors Patricia Flanagan, MD, FAAP District II Varren M. Seigel, MD, FAAP District III Margaret C. Fisher MD FAAP District IV Michelle D. Fiscus, MD, FAAP District V leannette "Lia" Gaggino, MD, FAAP District VI Dennis M. Cooley, MD, FAAP District VII Cary W. Floyd, MD, FAAP District VIII Martha C. Middlemist MD FAAP District IX

ko Fukuda, MD, FAAP District X Madeline M. Joseph. MD. FAAP

At Large Charles C. Macias. MD. FAAP At Large Constance S. Houck, MD, FAAP

At Large elle N. Simpson, MD, FAAP

Chiquita Brooks-LaSure Administrator Centers for Disease Control and Prevention Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Dear Dr. Cohen and Ms. Brooks-LaSure:

July 31, 2023

1600 Clifton Road

Atlanta, GA 30329

Director

Mandy K. Cohen, MD, MPH

On behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well being of all infants, children, adolescents, and young adults, I write to ask for your urgent help with the implementation of nirsevimab-alip (Beyfortus) for the prevention of respiratory syncytial virus (RSV). While this product has the potential to significantly reduce severe RSV cases and hospitalizations in young children, its promise will not be realized without effective and equitable administration. Our members will face severe financial pressures and challenging administrative burdens associated with delivering this expensive product, and as such we need the federal government to take urgent and decisive action to ensure the success of this roll out and to protect the long-term success and viability of the Vaccines for Children (VFC) program.

We understand that the Advisory Committee on Immunization Practices (ACIP) will meet on August 3 to consider recommendations for the use of nirsevimab-alio. In the event that ACIP recommends universal use of nirsevimab-alip consistent with the FDA approval, it is vital that the administration provide the necessary infrastructure supports to ensure equitable distribution and access. This infrastructure does not currently exist. and pediatricians and other providers face the prospect of moral injury resulting from having an available product without the ability to administer it given financial and administrative barriers and hurdens. Families living in lower-income and under-resourced communities as well as those with infants at greatest risk for severe RSV illness, may face challenges accessing nirsevimab-alip in the absence of additional infrastructure support. Consequently, we encourage the CDC and CMS to adopt the following recommendations to better support pediatricians and other providers in protecting infants from severe RSV illness this fall/winter:

- 1. Develop a comprehensive strategy to ensure equitable access to nirsevimabalip in hospitals, birthing centers, and ambulatory practice settings.
- 2. Assuming that ACIP votes to recommend that nirsevimab-alip be included in VFC, enhance VFC payment policies and minimize VFC administrative burden to encourage VFC participation.
- 3. Support the continued use of palivizumab as an option for the prevention of RSV disease in high-risk infants for the upcoming season given the likely implementation challenges with nirsevimab-alip.

#### Fax: 847/434-8000

Executive Committee Sandy L Chung MD F&AP President-Flect Registric D. Hoffman MD EAAP Immediate Past President Moira A. Szilagyi, MD, FAAP CEO/Execution Vice President Mark Del Monte 1D

> Board of Directory District I

District II Warren M. Seigel, MD. FAAI District III Manuaret C Eaber MD EAAP District IV Michelle D. Fiscus, MD. FAAP Distaire M leannette "Lia" Carreino MD FAAI District VI Dennis M Cooley MD FAAP District VII Canult/ Road MD EAAR District VIII MarthaC Middlemist MD FAAP District IX Yasuko Fukuda, MD, FAAP District X Madeline M. Joseph. MD. FAAP

At Large Charles C. Macias, MD, FAAP At Large Constance S. Houck MD. FAAP

At Large Joelle N. Simpson, MD, FAAP



Dear Paver-

Secretary/Treasurer Depnis M. Cooley MD. FAAP

Datainia Conserve MO CAAD

children by paying for the administration of nirsevimab, palivizumab, or both, to children as deemed necessary by their pediatrician.

stronaly urges payers to:

- Update your payment policies to allow for the administration of both palivizumab and/or nirsevimab during the 2023-2024 season
- administration code (96372) when used in conjunction with the nirsevimab product code pending approval of a new nirsevimab administration code; and
- and the nirsevimab specific administration code as soon as it is approved and available to ensure timely and appropriate payment to pediatricians

the upcoming RSV season.

If you have questions, need additional information, or would like to arrange a follow-up discussion on the AAP guidance on nirsevimab and palivizumab prophylaxis, please contact Stefanie Muntean-Turner, Health Policy & Coding Specialist at Smunteantumer@aap.org or 630-626-6790.

Sincerely

Sandy Chung, MD, FAAP President



Letter to payers

DEDICATED TO THE HEALTH OF ALL CHILDREN®

#### August 23, 2023

Re: Use of Palivizumab Prophylaxis for the 2023-2024 Respiratory Syncytial Virus Season

I write today on behalf of the American Academy of Pediatrics (AAP), a non-profit professional organization of 62,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, to share the Academy's clinical guidance, AAP Recommendations for the Use of the Monoclona Antibody Nirsevimab for the Prevention of RSV Disease

We urge you to update your policy to support these clinical recommendations, including the use of nirregimab for the presention of respiratory synoptial virus (RSV) during the 2022-2024 season. As with any new product, nirsevimab may not be readily available in all clinical settings during this first season of implementation. We, therefore, urge you to support the continued use of palivizumab when necessary and appropriate, as outlined in the guidance linked above. Infants and at-risk toddlers must have equitable access to these products during the rapidly approaching RSV season, without delay, to ensure they receive appropriate treatment and avoid unnecessary ED visits and hospitalizations

Specifically, per the AAP guidance, high-risk infants who are recommended to receive palivizumab in the first or second year of life should continue to be treated with palivizumab, as in prior seasons, if nirsevimab is not available. Further, infants who receive palivizumab at the beginning of the RSV season should be allowed to receive nirsevimab once available in lieu of additional doses of palivizumab.

RSV remains the leading cause of hospitalization among US infants. During this first RSV season, where nirsevimab is available, and following last year's unprecedented surge in RSV, all steps must be taken to protect infants and toddlers. As such, payers must remove all barriers and support recommended care for

To support pediatricians in providing palivizumab and nirsevimab doses to eligible children, the AAP

- 2. Update your payment system to allow payment for the use of the current immunoglobulin

2 Undate your payment systems to reflect the new product codes for pirseyimab (00280-00281)

Thank you for your partnership to support recommended RSV prophylaxis for infants and toddlers during

# Maternal RSV Vaccination

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



### Abrysvo

33

- Vaccine for RSV prevention in those 60+ and pregnant individuals
- Mechanism of Action
  - Active Immunization: ABRYSVO induces an immune response against RSV pre F that protects against lower respiratory tract disease caused by RSV.
  - Passive Immunization: Antibodies to RSV antigens from individuals vaccinated in pregnancy are transferred transplacentally to protect infants younger than 6 months of age against lower respiratory tract disease (LRTD) and severe LRTD caused by RSV.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

## ACIP Recommendations

34

- Pfizer's bivalent RSVpreF vaccine (Abrysvo) approved for 32-36 weeks gestational age as a single IM dose for prevention of lower respiratory tract disease in infants from birth to 6 months
  - Recommended to be administered September January
  - Infants born 14+ days after vaccination of the mother will not need nirsevimab
- Should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine

## 35

## Scenarios to Consider Administration of Nirsevimab When Mother Has Been Vaccinated

- Receipt of maternal vaccine not confirmed by healthcare record
- Infant born within 14 days of vaccination
- Infant born premature
- Healthcare provider recommends maximizing protection because infant at high risk of severe disease
  - Especially important if born >3 months prior to peak of RSV season
  - High risk infants in their second RSV season should receive nirsevimab regardless of maternal vaccination

# Abrysvo is **not** approved for and should **not** be administered to infants.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## Conclusions

- When administered to pregnant people in pregnancy, the RSVpreF vaccine was effective against medically attended severe RSV-associated respiratory tract illness in infants
- No safety signals detected in mothers or infants
- Limitations:
  - High-risk pregnancies excluded
  - Study may be too small to know if the PTB difference is significant
  - Limited data from low-income countries
  - Conducted during COVID-19 pandemic disruption of typical RSV circulation

INCORPORATED IN ILLINOIS

Disadvantagos

American Academy of Pediatrics DEDICATED TO THE HEALTH OF ALL CHILDREN®



### **Relative Advantages and Disadvantages of Each Product**

Advantages

Nirsev

		Auvantages		Disauvaillages
Maternal RSV vaccine	•	Immediate protection after birth Might be more resistant to potential mutations in F protein	•	Potentially reduced protection in some situations (e.g., pregnant person is immunocompromised or infant born soon after vaccination) Potential risk for preterm birth and hypertensive disorders of pregnancy
Nirsevimab	•	Protection from nirsevimab may wane more slowly than from maternal RSV vaccine Direct receipt of antibodies rather than relying on transplacental transfer No risk for adverse pregnancy outcomes	•	Potentially limited availability during 2023–24 RSV season Requires infant injection

Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 | MMWR (cdc.gov)

## 38 Storage and Handling: Abrysvo™

- Kit contains:
  - Vial of Lyophilized Antigen Component (a sterile white powder)
  - Prefilled syringe containing Sterile Water Diluent Component
  - Vial adapter
- Before reconstitution:
  - Store vaccine & diluent between 2°C and 8°C (36°F and 46°F)
  - Do not freeze
- After reconstitution:
  - Administer immediately
  - If not administered immediately, store at room temperature 15°C to 30°C (59°F to 86°F)
  - DO NOT refrigerate or freeze



INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

## 39 Abrysvo™ Coding

Proprietary Name	Manufacturer	Unit of Sale NDC11	CVX description	CVX Code	MVX Code	CPT Code
	Pfizer Inc.	00069-0344-01	0.5 mL solution for intramuscular injection, 1-dose carton	205		00070
ABRYSVU		00069-0344-05	0.5 mL solution for intramuscular injection, 5-dose carton	305 PFR		90078
Administration Code: 90471 Immunization administration (includes percutaneous, intradermal, subcutaneous or intramuscular						
injection(s);one vaccine (single or combination vaccine/toxoid)						

<u>12/8/23 Provider Notice</u>: HFS cover Abrysvo for pregnant Illinois Medicaid customers with a gestational age of 32 weeks through 36 weeks. It is available via medical billing without a prior authorization. Abrysvo is also available through pharmacy billing with a physician-submitted prior authorization for pregnant customers with the same gestational age requirements.



Diana Balbarin, MSN & Kevin Hansen

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

## SIREN 11/20/23: Nirsevimab Updates

VFC Coverage

41

- O VFC Resolution 9/2023
  - RSV Maternal Vaccine (Abrysvo by Pfizer)
    - Pregnant People aged < 19 years</p>
  - RSV Monoclonal Antibody (nirsevimab, Beyfortus)
    - Infants aged < 8 months born during or entering their 1st RSV season</p>
    - Children 8-19 months who are at increased risk of severe RSV disease and entering their 2nd RSV season



## Program Flexibilities: RSV Monoclonal Antibody

### Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



- With a finite number of Nirsevimab doses being distributed nationwide,
   CDPH received a very limited supply for the remainder of the season
- Borrowing NOT permitted for Beyfortus
  - Due to the shortage of nirsevimab on the private market, CDPH does NOT allow bidirectional borrowing
  - VFC providers are NOT required to meet the private inventory requirement for nirsevimab until 8/1/2024



Daniel Goodman





## Program Flexibilities: RSV Monoclonal Antibody

### Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



- Due to the extremely limited quantities of Nirsevimab available, Nirsevimab has been moved out of the limited quantity order intent. A survey of our safety net providers has been conducted and orders have been placed to ensure the widest possible distribution. Any additional allocations will be reviewed distributed to our safety net providers.
- Borrowing NOT permitted for Nirsevimab
  - Due to the shortage of Nirsevimab on the private market, IDPH does NOT allow bidirectional borrowing
  - VFC providers are NOT required to meet the private inventory requirement for Nirsevimab until 8/1/2024

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## 45 Limited Quantity Order Intent

### **ORDERING INSTRUCTIONS**

Adult RSV vaccines will now be ordered through the Adult/317 Limited Qty order intent.

From the VFC tab in I-CARE, click on Vaccine Requests, click on the Add Order button, and then scroll down to the "Order Intent" field. Change the order intent to Adult/317 Limited Qty. Search for the vaccine in the Add Vaccine field to add the RSV vaccine and complete your order as usual.

Orde	er Intent:	○ Pediatric/VFC	O Adult/317	○ Pediatric/VFC Limited Qty	Adult/317 Lin	nited Qty	
Grder	Priority:						~
Order S	ummary:	Empty order					_
Add	Vaccine:					All Vaccines -	
		Enter coarch for your	na hu araun bran	d name manufacturer or NDC Or se	last from All Vassings		

Enter search for vaccine by group, brand name, manufacturer, or NDC. Or select from All Vaccines.

INCORPORATED IN ILLINOIS

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

# **Questions**?

### Resources

- Full prescribing information
- AAP's RedBook Online
- AAP's Nirsevimab Frequently Asked Questions
- CDC information
- AAP Page on RSV Prevention Products
- How to use new CPT codes for administration of RSV immunizations

### Illinois Chapter

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



### **ICAAP** handouts

- Handout for patients on Nirsevimab
  - English
  - <u>Spanish</u>
- Handout for providers (FAQ on Nirsevimab)
- ▶ <u>CDC HAN 10.23.23</u>

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



Distributed via the CDC Health Alert Network October 23, 2023, 3:30 PM ET CDCHAN-00499

Print

48

### Outreach



#### Download <u>here</u>



#### Download <u>here</u>



INCORPORATED IN ILLINOIS

American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN®

### Help Stop the Spread of Germs Cover your cough/sneeze Wash your hands Get vaccinated!

Illinois Chapter INCORFORMED IN ILLINOIS American Academy of Pediatrics

Download <u>here</u>

INCORPORATED IN ILLINOIS

American Academy of Pediatrics



## **Upcoming Events**

49

- ICAAP Immunizations Webinar: A Review of 2023 Vaccine Updates and What to Expect in 2024
  - Tuesday, December 19 at 12PM

<b>Register at</b>
illinoisaap.org/events



INCORPORATED IN ILLINOIS

American Academy of Pediatrics

# **Thank You!**