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Hot Topics Webinar Series

Respiratory Syncytial Virus (RSV): Treatment & Vaccine Updates

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Stephanie Gretsch, MPH	Faculty/Presenter Planning Committee Member	No	N/A
Lynn Yee, MD	Faculty/Presenter	No	N/A
Tonya Scardina, PharmD, BCPS, BCIDP	Faculty/Presenter	No	N/A
Sameer J. Patel, MD MPH	Faculty/Presenter	No	N/A
Philip Martinez, LCPC	Planning Committee Member	No	N/A
Nicole Anania, DO, MS, FAAP	Faculty/Presenter Other	No	N/A
Ranjiv Matthews, MD	CME Reviewer	No	N/A
Joseph Hageman	CME Reviewer	Yes	Owlet - Royalties
Stephanie Atella	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.

Learning Objectives

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

- Summarize patient eligibility, duration of protection and pharmacology of the newest product for prevention of RSV (Nirsevimab).
- Explain the impact of RSV among children and infants, including those who are at increased risk for severe disease.
- Discuss the benefits of the Nirsevimab.
- Identify resources for information on the implementation and clinical guidance of Nirsevimab in Illinois.

Speakers

- **Lynn M. Yee,** MD, MPH
- **Tonya Scardina,** PharmD, BCPS, BCIDP
- **Sameer J. Patel,** MD, MPH

Update on Maternal RSV Vaccination

Lynn M Yee, MD, MPH

Associate Professor

Co-Director of Northwestern Memorial Hospital (NMH) Women's Infectious Diseases Program

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No conflicts of interest

Research Support from NIH, CDC, Friends of Prentice, Northwestern Woman's Board.
No research or personal interest in Pfizer.

FDA Guidance

- Priority Review status and Fast Track process of approval
- Abrysvo – RSV vaccine – 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
- FDA is requiring postmarketing surveillance for
  - PTB – “numerical imbalance in preterm births in Abrysvo recipients (5.7%) occurred compared to those who received placebo (4.7%)
  - Preeclampsia (1.8% vs 1.4%)
- FDA guidance is for a different gestational age window than the study

https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants

What's New? As of 8/22/23…

Home / News & Events / FDA Newsroom / Press Announcements / FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

FDA NEWS RELEASE

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants

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For Immediate Release: August 21, 2023

Español

Today, the U.S. Food and Drug Administration approved Abrysvo (Respiratory Syncytial Virus Vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. Abrysvo is approved for use at 32 through 36 weeks gestational age of pregnancy. Abrysvo is administered as a single dose injection into the muscle. The FDA approved Abrysvo in May for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

"RSV is a common cause of illness in children, and infants are among those at highest risk for severe disease, which can lead to hospitalization," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "This approval provides an option for healthcare providers and

Content current as of:
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https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants

FDA Guidance

- Priority Review status and Fast Track process of approval
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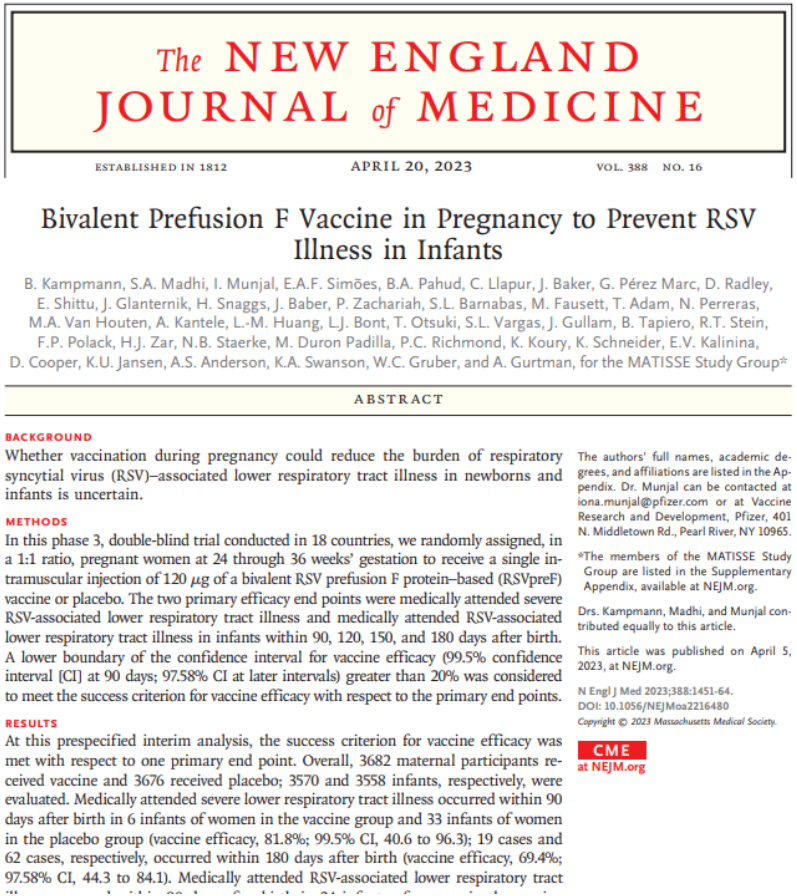
- FDA guidance is for a different gestational age window than the study

https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants

What drove the FDA decision to approve abrysvo for pregnancy?



The NEW ENGLAND JOURNAL of MEDICINE

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Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants

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ABSTRACT

BACKGROUND

Whether vaccination during pregnancy could reduce the burden of respiratory syncytial virus (RSV)–associated lower respiratory tract illness in newborns and infants is uncertain.

METHODS

In this phase 3, double-blind trial conducted in 18 countries, we randomly assigned, in a 1:1 ratio, pregnant women at 24 through 36 weeks' gestation to receive a single intramuscular injection of 120 μg of a bivalent RSV prefusion F protein–based (RSVpreF) vaccine or placebo. The two primary efficacy end points were medically attended severe RSV-associated lower respiratory tract illness and medically attended RSV-associated lower respiratory tract illness in infants within 90, 120, 150, and 180 days after birth. A lower boundary of the confidence interval for vaccine efficacy (99.5% confidence interval [CI] at 90 days; 97.58% CI at later intervals) greater than 20% was considered to meet the success criterion for vaccine efficacy with respect to the primary end points.

RESULTS

At this prespecified interim analysis, the success criterion for vaccine efficacy was met with respect to one primary end point. Overall, 3682 maternal participants received vaccine and 3676 received placebo; 3570 and 3558 infants, respectively, were evaluated. Medically attended severe lower respiratory tract illness occurred within 90 days after birth in 6 infants of women in the vaccine group and 33 infants of women in the placebo group (vaccine efficacy, 81.8%; 99.5% CI, 40.6 to 96.3); 19 cases and 62 cases, respectively, occurred within 180 days after birth (vaccine efficacy, 69.4%; 97.58% CI, 44.3 to 84.1). Medically attended RSV-associated lower respiratory tract

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Munjal can be contacted at iona.munjal@pfizer.com or at Vaccine Research and Development, Pfizer, 401 N. Middletown Rd., Pearl River, NY 10965.

*The members of the MATISSE Study Group are listed in the Supplementary Appendix, available at NEJM.org.

Drs. Kampmann, Madhi, and Munjal contributed equally to this article.

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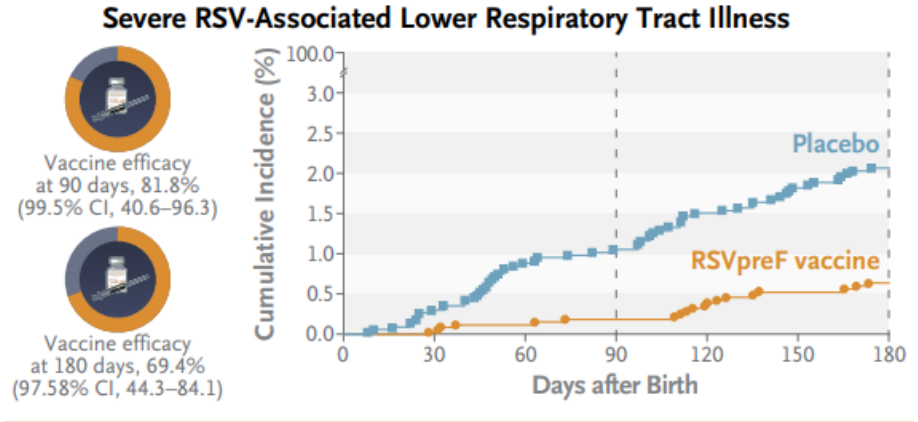
N Engl J Med 2023;388:1451-64.
DOI: 10.1056/NEJMoa2216480

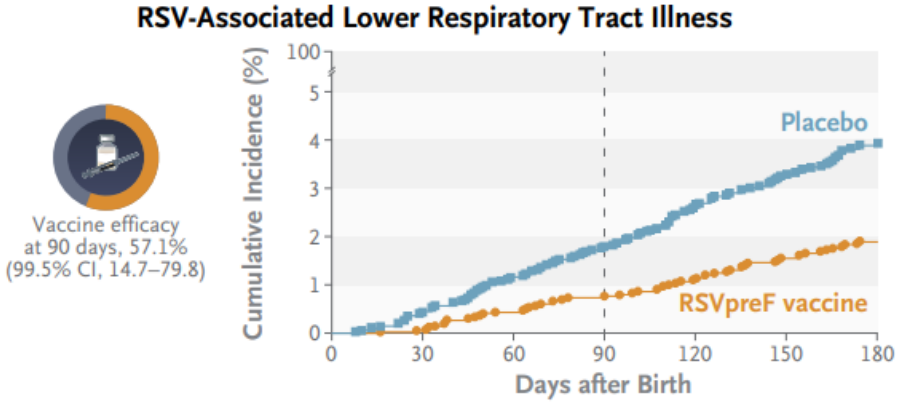
CME at NEJM.org

MATISSE Trial:

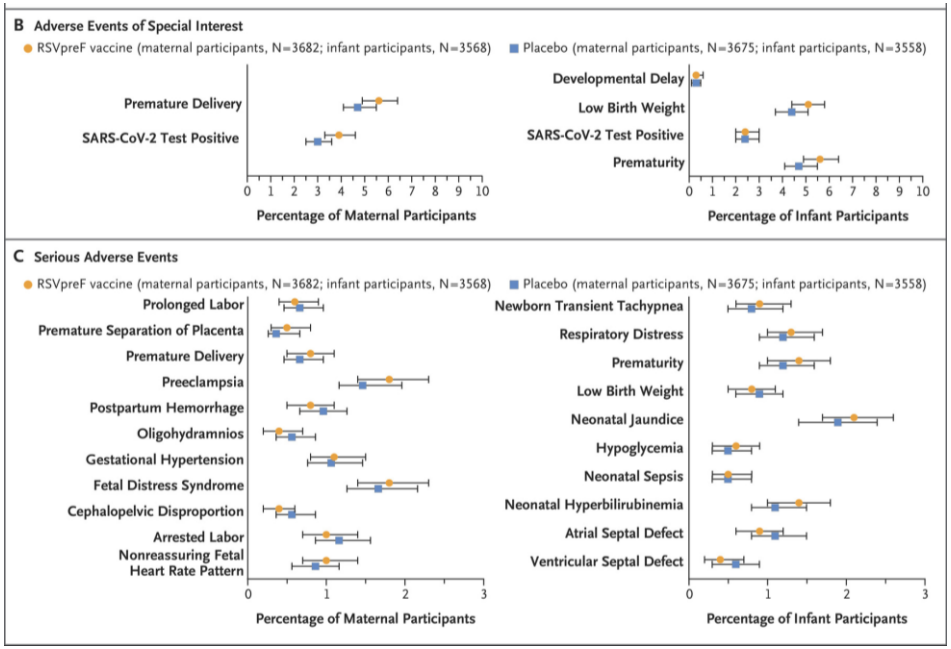
- RCT examined efficacy and safety of RSVpreF vaccine between 24-26 weeks
- International
- Phase 3
- Double-blind, placebo-controlled
- Met criteria for vaccine efficacy at the prespecified interim analysis

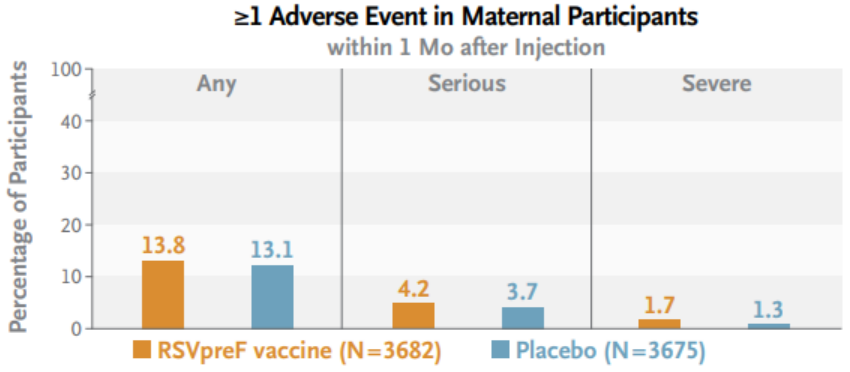
Vaccine Efficacy

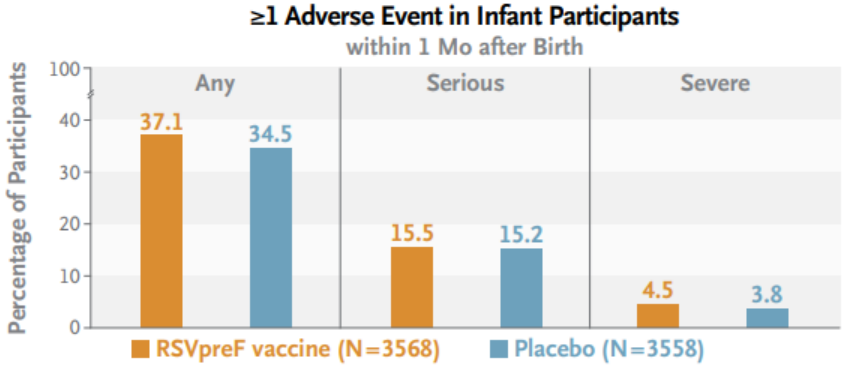




Vaccine Safety and Side Effects







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

Areas to Watch

- Post-marketing surveillance is required
  - Future study in high-risk (for PTB and for RSV) populations
  - Study in low-income countries
- ACOG and SMFM guidance
- CDC Advisory Committee on Immunization Practices (ACIP) guidance
- Insurance coverage and vaccine distribution

Thank you!

Lynn.yee@northwestern.edu

Nirsevimab (Beyfortus™) for Prevention of Respiratory Syncytial Virus Disease

Sameer Patel, MD, MPH and Tonya Scardina, PharmD, BCPS, BCIDP

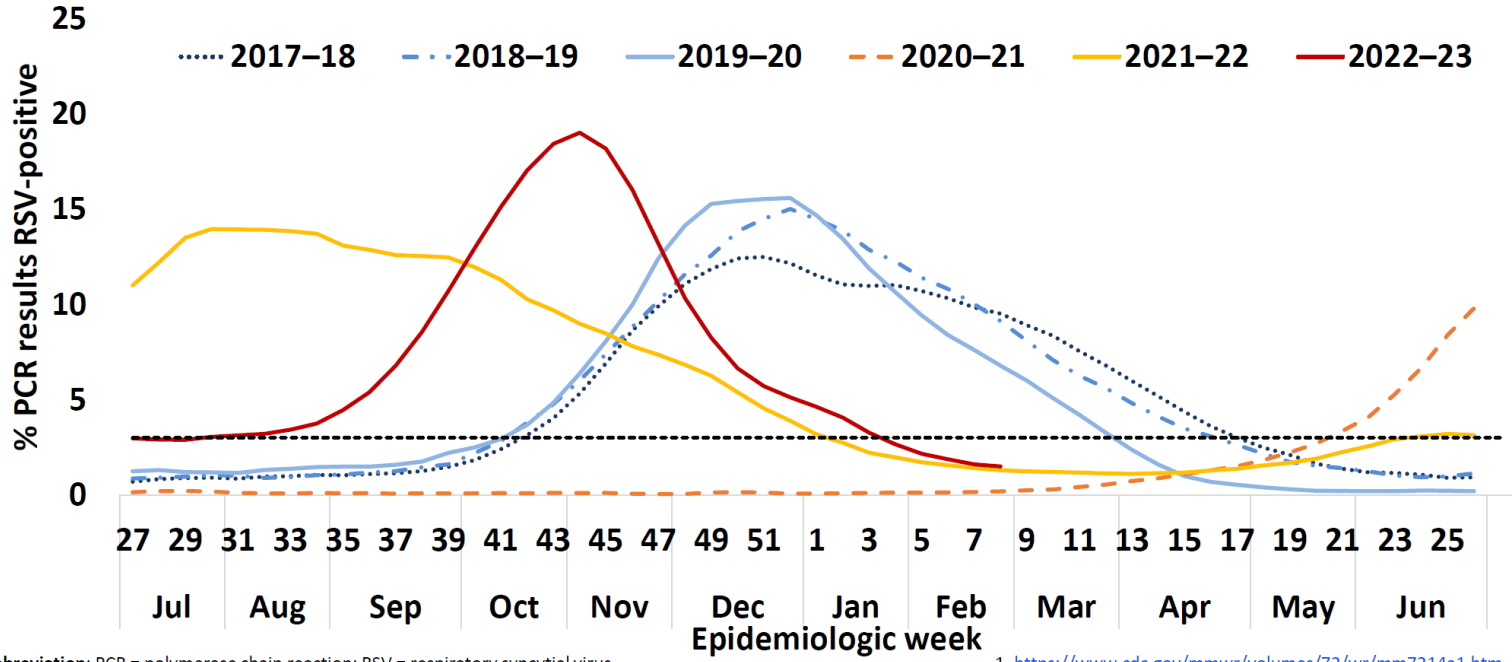
Prepared: September 3rd, 2023

Burden of RSV Disease

- Most common cause of hospitalization in U.S. infants
- 58,000-80,000 hospitalizations among children <5 years old.
- 100–300 deaths in children <5 years old.
- 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.

CDC Respiratory Syncytial Virus Infection.2023 https://www.cdc.gov/rsv/index.html; Hall CB. *New Engl J Med*. 2009; Rha B. *Pediatrics* 2020

Changes in seasonality of RSV transmission following SARS-CoV2 introduction— NREVSS[1], 2017–2023



7

Abbreviation: PCR = polymerase chain reaction; RSV = respiratory syncytial virus.

1. https://www.cdc.gov/mmwr/volumes/72/wr/mm7214a1.htm

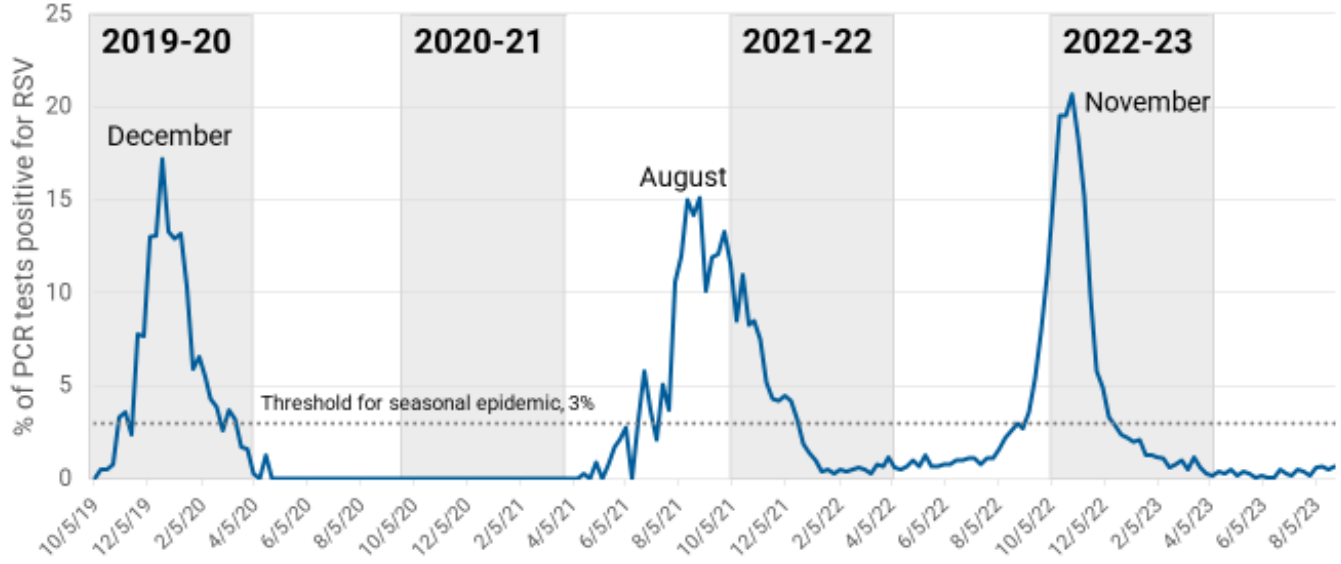
* 3-week centered moving averages of percentage of RSV-positive PCR results nationwide. The black dotted line represents the threshold for a seasonal epidemic (3% RSV-positive laboratory PCR results).

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

RSV in Chicago

While RSV seasonality in Chicago has been disrupted since the COVID-19 pandemic, RSV activity has been low this summer.

Local epidemiology supports October start to nirsevimab administration.



Gray boxes represent typical RSV season, October-March. Source: Aggregate, weekly PCR test results from a convivence sample of Chicago hospital laboratories and a commercial laboratory serving Chicago healthcare facilities. Data reported through 8/26/2023.

Nirsevimab-alip (Beyfortus™)

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

Mechanism of Action

- Recombinant human immune globulin G1 kappa monoclonal antibody, 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

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

Pharmacokinetics

Absorption:

- Bioavailability: 84-85%
- Median time to maximum concentration is 6 days (range 1-28 days)
  - In clinical trials, predicted area under the curve (AUC) above 12.8 mg day/mL was associated with lower incidence of medically attended RSV lower respiratory tract infections

Distribution:

- The estimated total volume of distribution (Vd): 477 mL for infants weighing 5 kg
  - Vd increases with increasing body weight

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
Jorgensen SCJ. *J Antimicrob Chemother*. 2023;78(5):1143-49

Pharmacokinetics

Metabolism:

Nirsevimab-alip is degraded into small peptides by catabolic pathways via lysosomal degradation

- No clinical studies have evaluated the effects of renal and hepatic impairment on elimination
  - Effects of renal and hepatic impairment on nirsevimab-alip pharmacokinetics are not expected

Excretion:

- Half-life: 63-73 days
- Estimated clearance: 3.38-3.42 mL/day for an infant weighing 5 kg
- Clearance increases with increasing body weight

Duration of protection:

- 5 months

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
Jorgensen SCJ. J Antimicrob Chemother. 2023;78(5):1143-49

Citation	Study Participants	Outcomes	Adverse Effects
Griffin MP *et al*. *N Engl J Med* 2020	Healthy preterm infants (gestational age 29 weeks and 0 days through 34 weeks and 6 days) entering 1st RSV season Nirsevimab group: n=969 Placebo: n=484	Incidence of medically attended RSV-associated LRTI was 70% ↓ with nirsevimab than placebo (95% CI, 52.3-81.2; p<0.001) Incidence of hospitalization was 78.4% ↓ with nirsevimab than placebo (95% CI, 51.9-90.3; p<0.001)	Type and frequency were similar between two groups No anaphylaxis or other notable hypersensitivity reactions were reported Effects considered to be related to nirsevimab: • Rash (n=4) • Petechiae (n=1)

Abbreviations: CI=confidence interval, LRTI=lower respiratory tract infection, RSV=respiratory syncytial virus

Citation	Study Participants	Outcomes	Adverse Effects
Hammitt LL *et al*. *N Engl J Med* 2022	Healthy late preterm and term infants (gestational age of at least 35 weeks and 0 days) entering 1st RSV season Nirsevimab group: n=987 Placebo: n=491	Efficacy† of nirsevimab against medically attended for RSV-associated LRTI: 74.5% (95% CI, 49.6-87.1; p<0.001) Efficacy† of nirsevimab against hospitalization for RSV-associated LRTI: 62.1% (95% CI, -8.6-86.8; p=0.07)	Type and frequency were similar between two groups Effects considered to be related to nirsevimab: Generalized macular rash (n=1)

†Efficacy was defined as the relative risk reduction
Abbreviations: CI=confidence interval, LRTI=lower respiratory tract infection, RSV=respiratory syncytial virus

Citation	Study Participants	Outcomes	Adverse Effects
Muller WJ *et al*. *N Engl J Med* 2023	Healthy late preterm and term infants (gestational age of at least 35 weeks and 0 days) entering 1st RSV season Nirsevimab group: n=2009 Placebo: n=1003	Efficacy against medically attended for RSV-associated LRTI: 76.4% (95% CI, 62.3-85.2) Efficacy against very severe medically attended for RSV-associated LRTI: 78.6% (95% CI, 48.8-91) Efficacy against hospitalization for RSV-associated LRTI: 76.8% (95% CI, 49.4-89.4)	Nirsevimab: 1.3% Placebo: 1.5%

Abbreviations: CI=confidence interval, LRTI=lower respiratory tract infection, RSV=respiratory syncytial virus

Citation	Study Participants	Outcomes
Simões EA *et al*. *Lancet Child Adolesc Health* 2023	Healthy preterm infants (gestational age 29 weeks and 0 days through 34 weeks and 6 days) entering 1st RSV season Healthy late preterm and term infants (gestational age of at least 35 weeks and 0 days) entering 1st RSV season Extrapolation of efficacy on the basis of pharmacokinetic data to infants with CLD of prematurity, CHD or extremely preterm (<29 weeks gestational age)	Efficacy against medically attended for RSV-associated LRTI: 79.5% (95% CI, 65.9-87.7; p<0.0001) Efficacy against very severe medically attended for RSV-associated LRTI: 86% (95% CI, 62.5-94.8; p<0.0001) Efficacy against hospitalization for RSV-associated LRTI: 77.3% (95% CI, 50.3-89.7; p<0.0002)

Abbreviations: CHD=congenital heart disease, CLD=chronic lung, LRTI=lower respiratory tract infection, RSV=respiratory syncytial virus

<u>AUCs above the pharmacokinetic target based on sub-population:</u>
Infants with CLD: 94%
Infants with hemodynamically significant CHD: 80%
Preterm infants born at less than 29 weeks gestational age: 94%

Citation	Study Participants	Outcomes	Adverse Effects
Domachowske J *et al*. *N Engl J Med* 2022	Preterm infants (born on or before gestational age of 35 weeks) with CLD requiring therapeutic intervention within 6 months or uncorrected, partially corrected, or medically treated CHD or preterm infant without CHD or CLD CHD-CLD cohort: n=310 Preterm cohort: n=615 Randomized to receive nirsevimab or palivizumab	Incidence of medically attended RSV-associated LRTI with nirsevimab: 4 of 616 infants (0.6%) Incidence of medically attended RSV-associated LRTI with palivizumab: 3 of 309 infants (1%)	Incidence was similar between treatment groups and cohorts Heparin-induced thrombocytopenia occurred in an infant with CHD that received nirsevimab

Abbreviations: CHD=congenital heart disease, CLD=chronic lung, LRTI=lower respiratory tract infection, RSV=respiratory syncytial virus

Recommended Dose

Age	Body Weight	Recommended dose
Infants aged < 8 months born during or entering their 1st RSV season	< 5 kg*	Nirsevimab-alip 50 mg IM as a single dose
	≥ 5 kg	Nirsevimab-alip 100 mg IM as a single dose
Children aged 8-19 months who are at increased risk of severe RSV disease and entering their 2nd RSV season**	N/A	Nirsevmab-alip 200 mg (2 x 100mg) IM as two simultaneous IM injections

* Exposure in infants < 1 kg may led to higher exposure. The benefits and risks of nirsevimab use in infants < 1 kg should be carefully considered.

**Increased risk defined as:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during 6-month period before start of second RSV season
- Children with severely immunocompromised
- Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length < 10th percentile
- American Indian and Alaska Native children

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP and AAP Recommendations for nirsevimab. Red Book: 2021–2024 Report of the Committee on Infectious Diseases (32nd edition)
Beyfortus. Product information. AstraZeneca AB. Accessed August 10, 2023. https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf

Replacement Doses

- After initial administration, replacement doses of nirsevimab should be administered to patients undergoing cardiopulmonary bypass
  - Administer as soon as the infant is stable after surgery

First RSV Season:

Timing of Surgery	Body Weight	Recommended dosage
Surgery within 90 days after receiving nirsevimab-alip	< 5 kg at time of additional dose	Nirsevimab-alip 50 mg IM once
	≥ 5 kg at time of additional dose	Nirsevimab-alip 100 mg IM once
Surgery more than 90 days after receiving nirsevimab-alip	N/A	Nirsevimab-alip 50 mg IM once

Second RSV Season:

Timing of Surgery	Body Weight	Recommended dosage
Surgery within 90 days after receiving nirsevimab-alip	N/A	Nirsevimab-alip 200 mg IM once (2 x 100mg) as two simultaneous IM injections
Surgery more than 90 days after receiving nirsevimab-alip	N/A	Nirsevimab-alip 100 mg IM once

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

Preparation and Administration

- Available in 50mg and 100mg pre-filled syringes (single use):
  - 50 mg: purple plunger rod
  - 100mg: light blue plunger rod
- 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.

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP Meeting notes (August 2023)- Proposed Clinical Consideration Updates for Nirsevimab
Esposito S, Abu-Raya B, Bonanni P et al. *Frontiers in Immunology* 2021
Beyfortus. Product information. AstraZeneca AB. Accessed August 10, 2023: https://www.ema.europa.eu/en/documents/product-information/beyfortus-epar-product-information_en.pdf

Timing of Administration

- Optimal time:
  - Before the start of the RSV season (typically October through the end of March)
  - Can adjust administration schedules based on local epidemiology
- Infants born shortly before or during the RSV season should receive nirsevimab within 1 week of birth
  - Administration can occur during the birth hospitalization or in the outpatient setting
  - May be administered to age-eligible infants and children who have not yet received a dose at any time during the season
- Infants with prolonged birth hospitalizations related to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge
  - No evidence is available to support use of nirsevimab for prevention of hospital-acquired RSV infection, and nirsevimab is not recommended for this indication

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.

Timing of Administration

	Administration Setting	Administration Timing	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March
During RSV Season (Oct-Mar)	Hospital (or within 1 week of discharge)	1 dose at birth							●					
Outside RSV season (Apr-Sept)	Office	1 dose prior to start of their first RSV season						●						

Chart adapted from Sanofi's RSV National Expert Program

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 1st RSV season

- If nirsevimab is not available, palivizumab should be administered

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP and AAP Recommendations for nirsevimab. Red Book: 2021–2024 Report of the Committee on Infectious Diseases (32nd edition)

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.

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP Meeting notes (August 2023)- Nirsevimab: Implementation Considerations

Adverse Reactions

Rash

- Injection site reaction.

Reporting of Adverse Reports:

- **Administered alone:** report to MedWatch.
- **Administered simultaneously with any vaccine:** report to Vaccine Adverse Event Reporting System (VAERS).

Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023
ACIP Meeting notes (August 2023)- Nirsevimab: Implementation Considerations

Drug Interactions

- Efgartigimod alfa – may diminish therapeutic effect of Fc receptor-binding agents.
  - Recommended to monitor therapy.
- Rozanolixizumab – may diminish therapeutic effect of Fc receptor-binding agents.
  - Recommended to monitor therapy.
- Nirsevimab-alip is not predicted to be a substrate of, inhibitor, or inducer of cytochrome P450 enzymes or transporter systems.

Nirsevimab. Lexi-Drugs. Hudson, OH: Lexicomp, 2023. http://online.lexi.com/. Updated August 1, 2023. Accessed August 8, 2023.
Beyfortus (nirsevimab-alip) [package insert]. AstraZeneca AB; 2023

ACIP Recommendation: First RSV Season

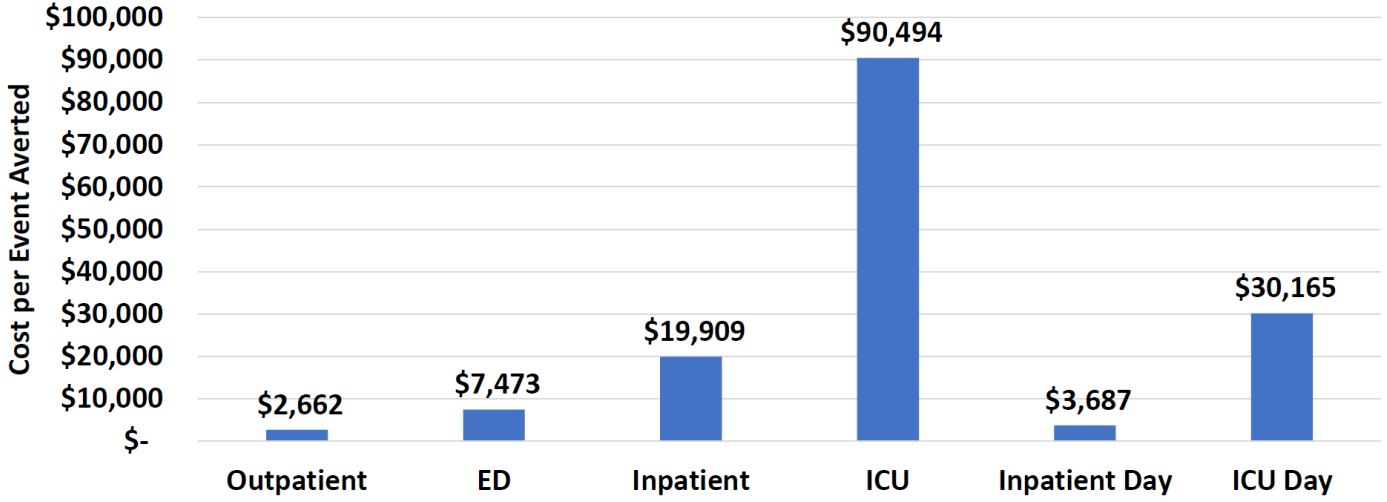
All infants aged < 8 months born during or entering their first RSV season.

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-for-length <10th percentile.
- American Indian or Alaska Native children.

Cost per health event averted



Cost of $445 per dose

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

Patients Not Eligible For Nirsevimab by Age or Clinical Criteria May be Eligible for Palivizumab

- 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).

Administration for Premature Infants

- 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.
- No clinical data available in infants with a postmenstrual age (gestational age at birth plus chronological age) of <32 weeks.
- Dosing in infants with a body weight <1.6kg is based on extrapolation and no clinical data are available.
- 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.

https://publications.aap.org/redbook/resources/25379/ACIP-and-AAP-Recommendations-for-Nirsevimab

ACIP Draft Clinical Considerations for Scenarios if Maternal Vaccine (RSVPreF) Was Given during Pregnancy

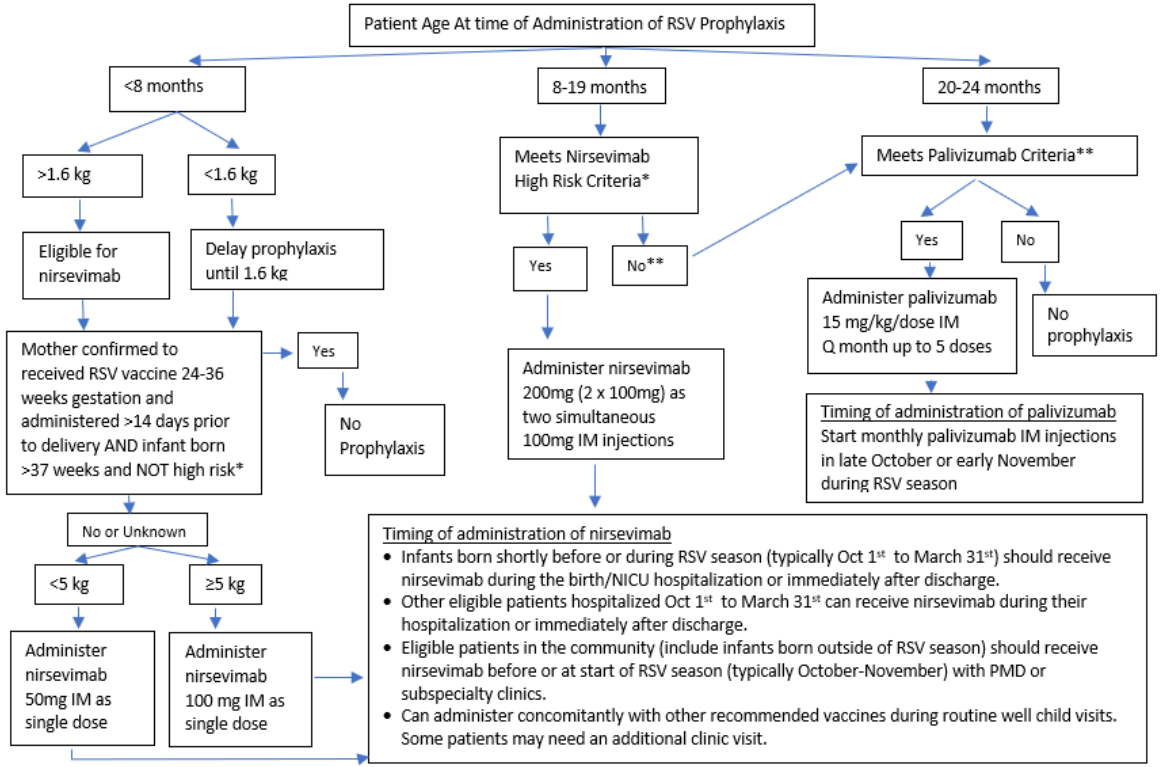
- Either maternal vaccination with RSVPreF or nirsevimab is recommended to prevent RSV disease, but both products are not needed for most infants.
- Risks and benefits of both RSVPreF and nirsevimab should be considered when deciding on maternal vaccination.
- If mother vaccinated, nirsevimab can be considered if infant considered to have insufficient protection from vaccine or is at high risk of severe disease.

https://www.cdc.gov/vaccines/acip/meeting/downloads/slides-2023-06-21-23/05-RSV-Mat-Ped-Jones-508.pdf#page32

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.

Summary and Potential Approach



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

Questions?

Contact information:

- *Sameer Patel (sjpatel@luriechildrens.org)*
- *Tonya Scardina (tscardina@luriechildrens.org)*

Storage and Handling: Beyfortus™

- Store refrigerated at 36ºF to 46ºF (2ºC to 8ºC)
  - May be kept at room temperature 68ºF to 77ºF (20ºC to 25ºC) 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).

Beyfortus™ Coding

Proprietary Name	Manufacturer	Unit of Sale NDC11	CVX description	CVX Code	MVX Code	CPT Code
BEYFORTUS	Sanofi Pasteur Inc.	49281-0575-15	RSV, mAb, nirsevimab-alip, 0.5 mL, neonate to 24 months	306	PMC	90380
BEYFORTUS	Sanofi Pasteur Inc.	49281-0574-15	RSV, mAb, nirsevimab-alip, 1 mL, neonate to 24 months	307	PMC	90381
Administration Code: Do not report immunization administration codes **90461–90462** or **90471–90472** for the injection of nirsevimab, as these codes are limited to the administration of vaccine and toxoid products.						96372

Follow state specifications for reporting the immunization when the immunoglobulin product is provided through the Vaccines for Children program. For example, report 90380 SL to indicate state-supplied product.

American Medical Association's (AMA's) Current Procedural Terminology (CPT)

The American Academy of Pediatrics (AAP) is Advocating for Adequate Coding

[Full letter to payers here]

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

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July 31, 2023

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

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

Dear Dr. Cohen and Ms. Brooks-LaSure:

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-alip. 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 burdens. 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 nirsevimab-alip 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.**

Resources

- Full prescribing information
- AAP's RedBook Online
- AAP's Nirsevimab Frequently Asked Questions
- CDC information
- AAP Page on RSV Prevention Products

- Handout for patients
  - English
  - Spanish
- Handout for providers
- CDC HAN 9.5.23


Increased Respiratory Syncytial Virus (RSV) Activity in Parts of the Southeastern United States: New Prevention Tools Available to Protect Patients

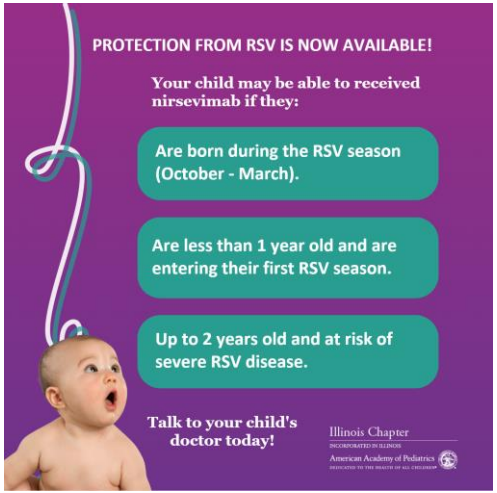
Print

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
September 05, 2023, 2:00 PM ET
CDCHAN-00498

Outreach



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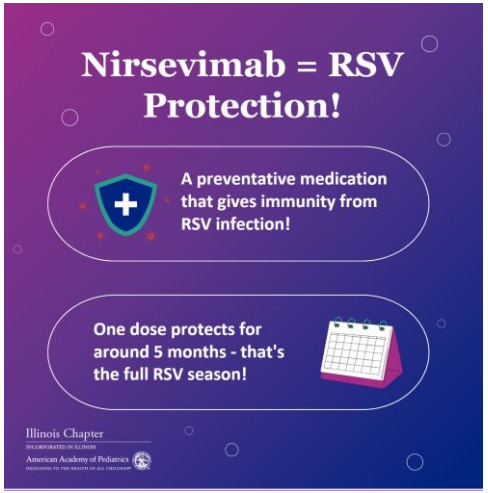

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Upcoming Events

Illinois Chapter
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- Bi-weekly COVID-19 Commercialization Updates
- ICAAP Immunizations Webinar: Flu & COVID Vaccines
  - Tuesday, September 19 at 12PM
- Vaccine Summits – In-Person!

Register at illinoisaap.org/events

SCAN ME TO REGISTER

JOIN ICAAP FOR THE 2023

ANNUAL EDUCATION CONFERENCE

November 9 &10, 2023
Northern Illinois University Naperville

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- ⇒ Network and earn CME.
- ⇒ Hear the latest on “hot topics” and recent practical advances on a variety of subspecialty areas.
- ⇒ Keynote topics include:
  Pediatric Firearm Injuries and Fatalities
  &
  Pediatric Mental Health

Register today!

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Thank You!