# The Efficacy, Safety, and Logistics of Nirsevimab for RSV Prevention

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NATIONWIDE CHILDREN'S
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THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

**Partners for Kids, virtual, 9/25/2023**

# DISCLOSURE STATEMENT

Dr. Pablo Sánchez has no financial relationship to disclose.

# RSV Prevention: Outline

- The Process of approval: FDA, CDC
- RSV: The Problem and the Virus
- Preventive strategies:
  - **Nirsevimab** (Beyfortus™)
  - **Maternal prefusion F protein-based RSV vaccine** (Abrysvo™)
- Recommendations
- Implementation

# RSV Prevention: The Process!

- **VRBPAC** (Vaccines and Related Biological Products Advisory Committee) → **FDA** (Antimicrobial Drugs Advisory Committee (AMDAC)
- **ACIP** (Advisory Committee on Immunization Practices) → **CDC**
- **Nirsevimab** (Beyfortus™):*
    - Recommended by the Antimicrobial Drugs Advisory Committee (AMDAC), approved by FDA on July 17, 2023
    - Recommended by ACIP and CDC on August 3, 2023
    - MMWR published on August 25, 2023
- Maternal prefusion F Protein-based **RSV vaccine** (recombinant RSVpreF vaccine, Abrysvo™):**
    - Approved by FDA on August 21, 2023; Approved by ACIP/CDC on 9/22/2023

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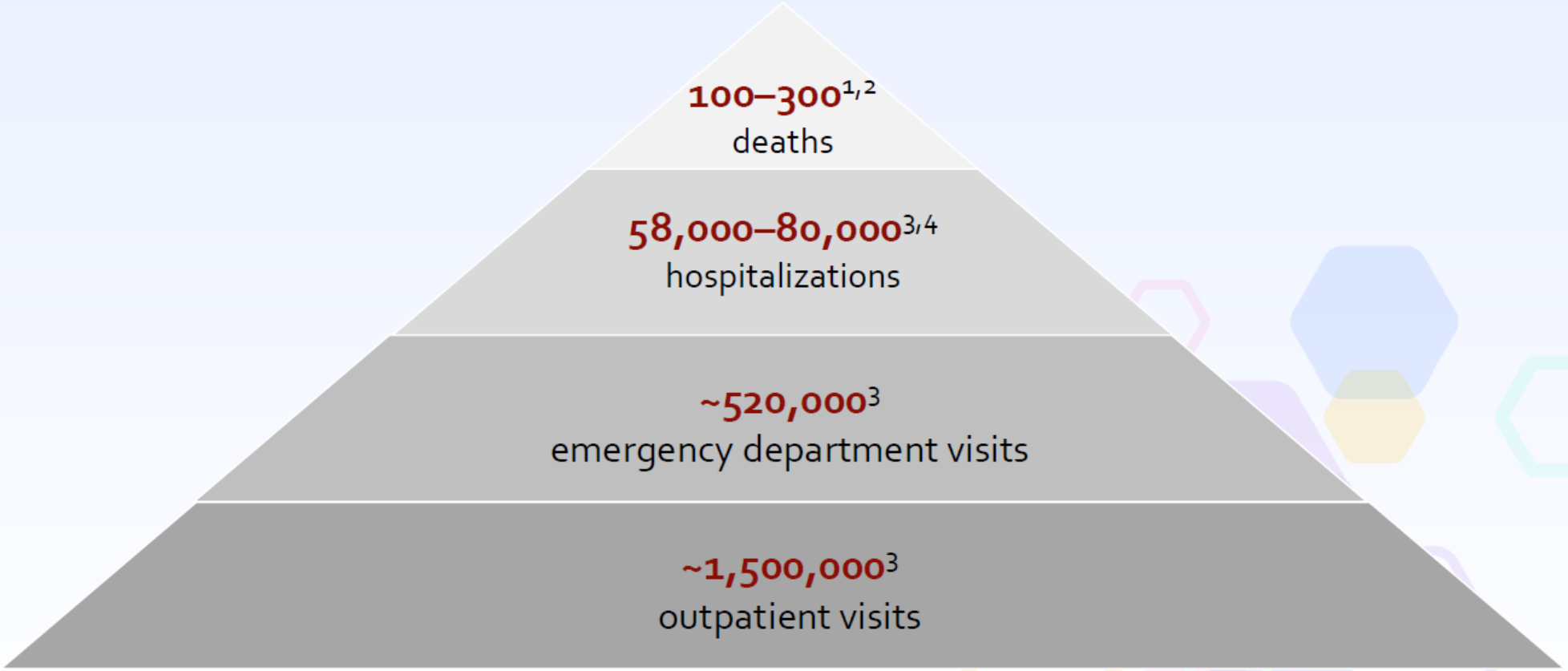
*Griffin et al.NEJM, 2020
**Kampmann et al NEJM, 2023

# Each year in U.S. children aged less than 5 years, RSV is associated with…




[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022 (*estimate 80,000 hospitalizations in infants <1y)

# RSV is the leading cause of hospitalization in U.S. infants[1]

- Most (68%) infants are infected in the first year of life and nearly all (97%) by age 2 years[2]
- 2-3% of young infants will be hospitalized for RSV[3,4,5]
- RSV is a common cause of lower respiratory tract infection in infants
- Highest RSV hospitalization rates occur in first months of life and risk declines with increasing age in early childhood[3,5]
- 79% of children hospitalized with RSV aged <2 years had no underlying medical conditions[3]

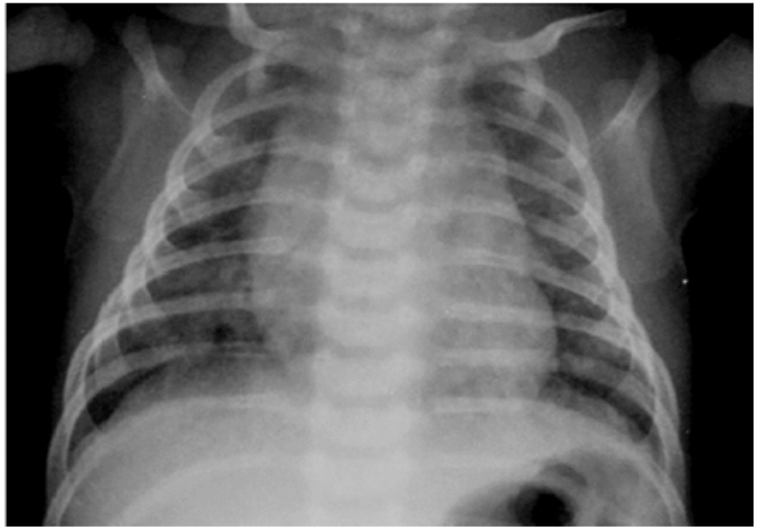
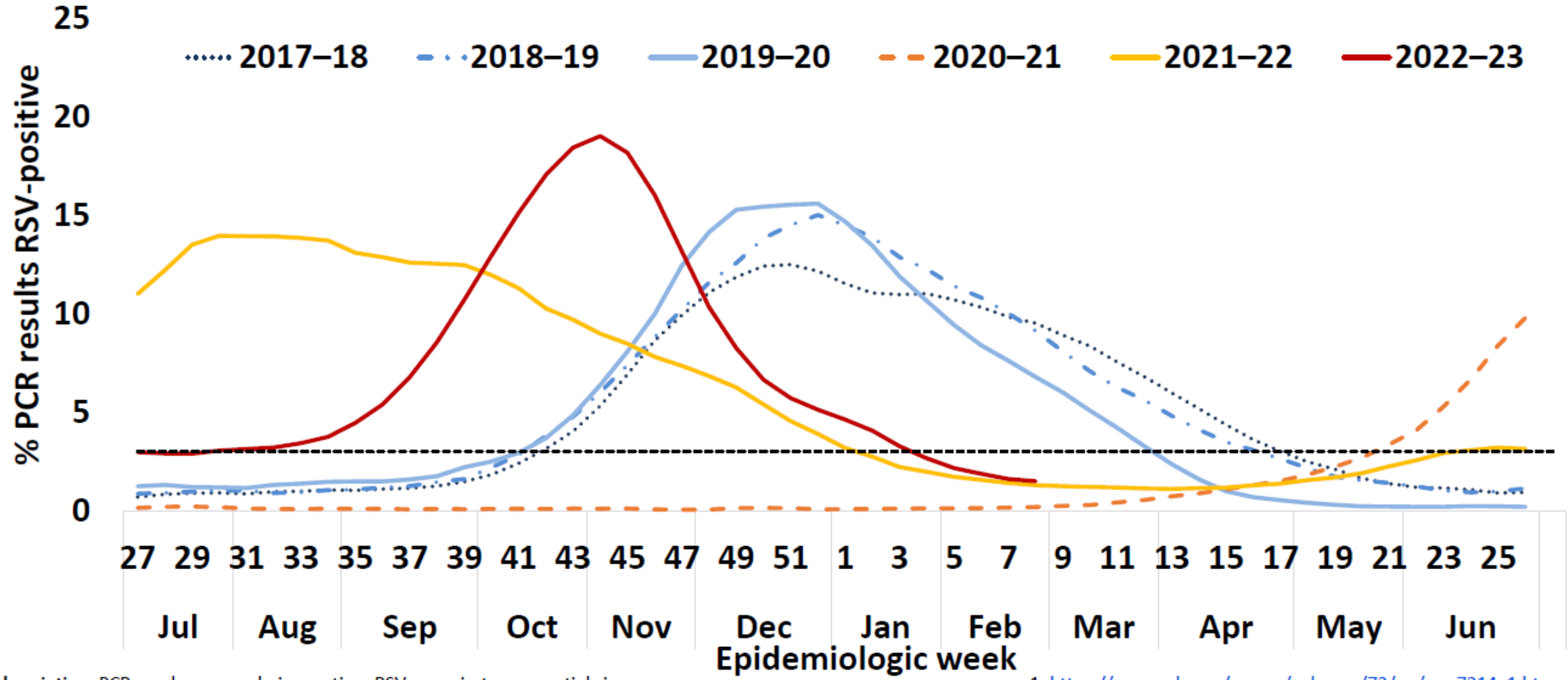


Image: Goncalves et al. Critical Care Research and Practice 2012

[1]Suh et al. JID 2022. [2]Glezen et al, Arch Dis Child, 1986; [3]Hall et al, Pediatrics, 2013; [4]Langley & Anderson, PIDJ, 2011; [5]CDC NVSN data

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



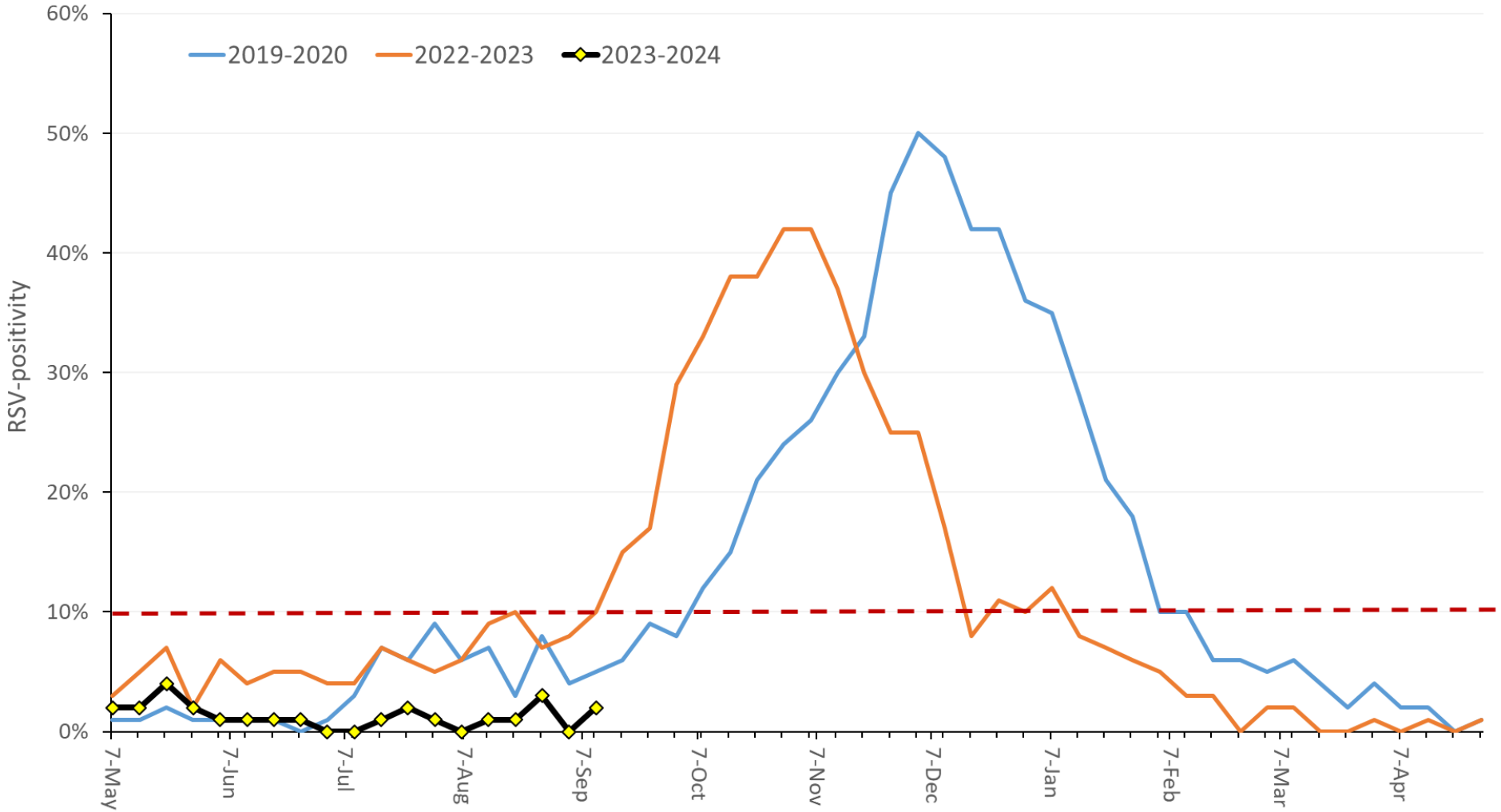



**Abbreviation**: PCR = polymerase chain reaction; RSV = respiratory syncytial virus.

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).

# 2023-2024 RSV Season Predictions: NCH RSV-Positivity (9/10)



# Evolution of AAP Statements Regarding RSV Prophylaxis

**Volume 134, Issue 2**
August 2014


FROM THE AMERICAN ACADEMY OF PEDIATRICS | POLICY STATEMENT | AUGUST 01 2014

**Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection**

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE; Michael T. Brady, MD; Carrie L. Byington, MD; H. Dele Davies, MD; Kathryn M. Edwards, MD; Mary Anne Jackson, MD; Yvonne A. Maldonado, MD; Dennis L. Murray, MD; Walter A. Orenstein, MD; Mobeen H. Rathore, MD; Mark H. Sawyer, MD; Gordon E. Schutze, MD; Rodney E. Willoughby, MD; Theoklis E. Zaoutis, MD; Shawn L. Ralston, MD; Allan S. Lieberthal, MD; H. Cody Meissner, MD; Brian K. Alverson, MD; Jill E. Baley, MD; Anne M. Gadomski, MD; David W. Johnson, MD; Michael J. Light, MD; Nizar F. Maraqa, MD; Eneida A. Mendonca, MD; Kieran J. Phelan, MD; Joseph J. Zorc, MD; Danette Stanko-Lopp, MA; Sinsi Hernández-Cancio, JD

*Pediatrics* (2014) 134 (2): 415–420.
https://doi.org/10.1542/peds.2014-1665

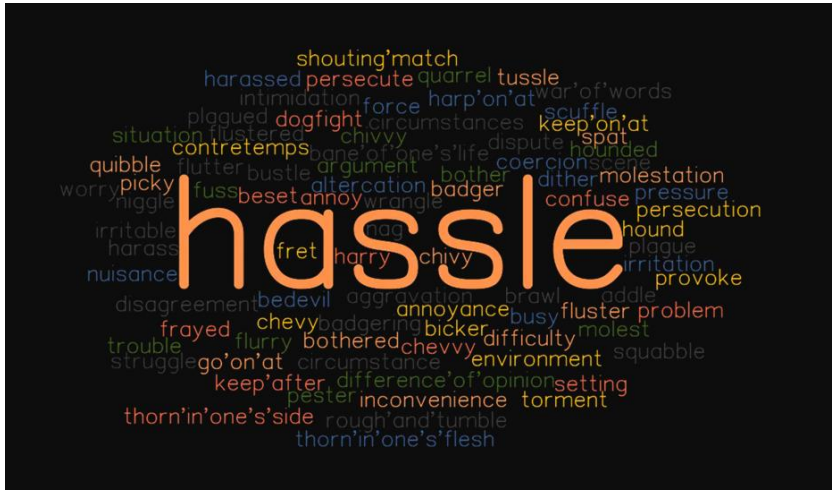
Dec 2009 AAP Policy Statement : Modified recommendations for use of palivizumab for prevention of RSV

'12 Red Book no major changes

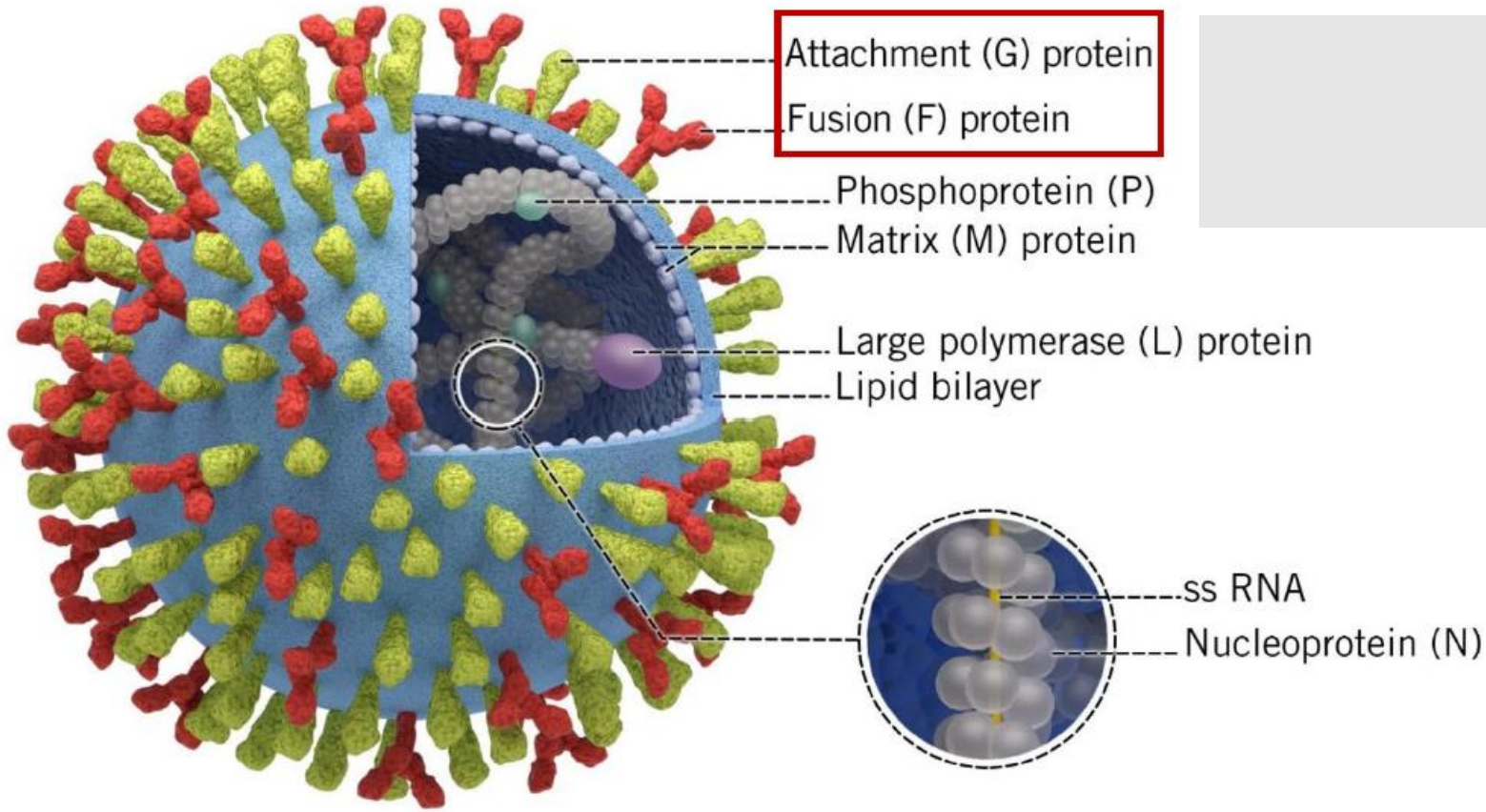
Mar 2013 Policy Statement retired
2012 RB reaffirmed

# Palivizumab

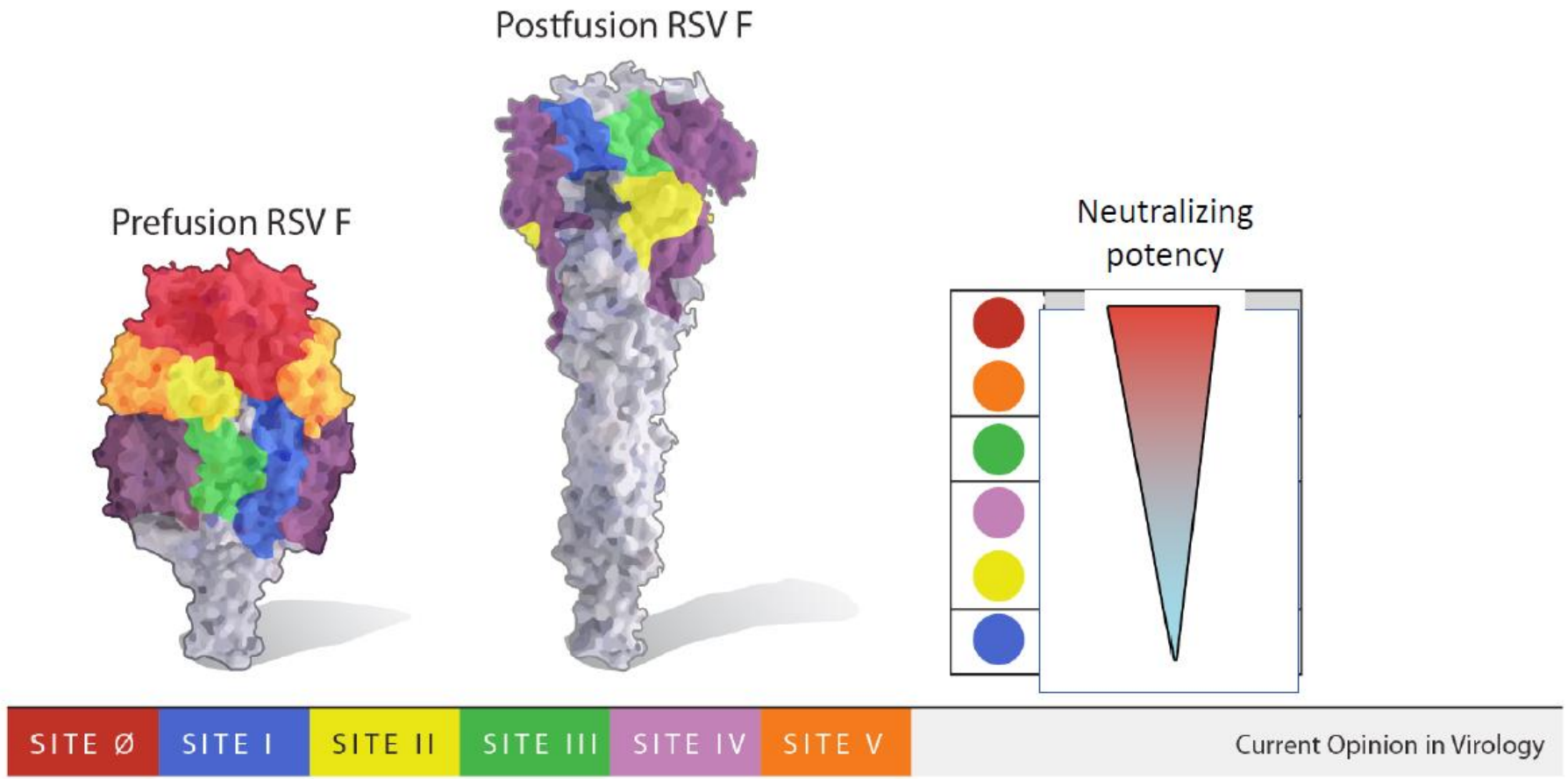
- Expensive!
- Restrictions on eligible population: “high risk” only!
- Pre-authorization process
- Monthly dosing during RSV season
- RSV seasonality: onset, offset of RSV activity

# RSV – virion structure

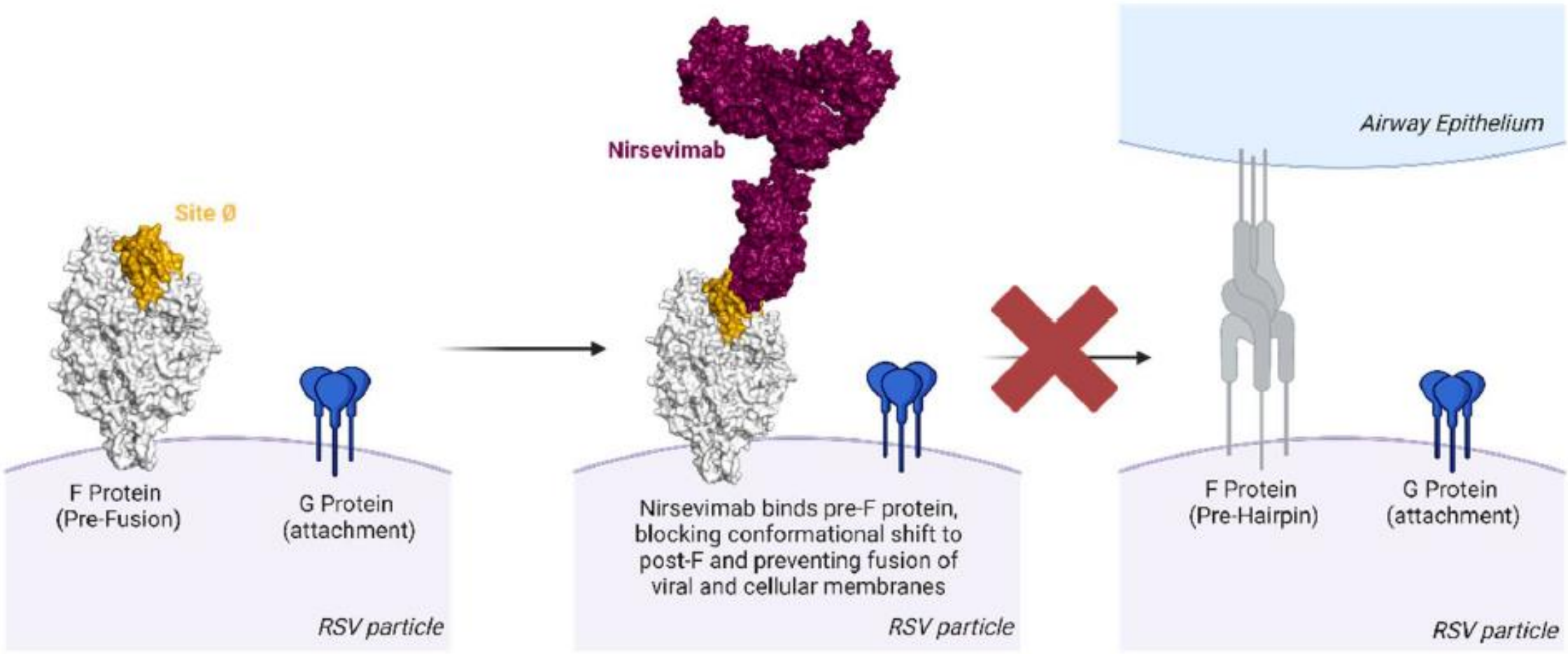


# The fusion (F) protein exists in two or more structural forms, which bind different antibodies




Graham B. Current Opinion in Virology. 23: 107-112. 2017.

# Mechanism of Action



# Nirsevimab: Mechanism and Duration of Action

- Nirsevimab (Beyfortus™) is a recombinant human immune globulin G1 kappa monoclonal antibody that binds to the prefusion conformation of the RSV fusion protein resulting in enhanced neutralizing activity compared with palivizumab
- Modification of the Fc region promotes extension of the half-life
- Clinical trials demonstrated efficacy through at least 150 days and therefore only needs to be administered once per season*
- No decline in efficacy; administered intramuscularly

*Repeat dosing after cardiopulmonary bypass

Nirsevimab (Beyfortus®) (package insert). Swiftwater, PA. Sanofi Pasteur, Inc. 2023.

# Nirsevimab: Clinical Trial Data

| Trial | Population | Results | Conclusion |
|---|---|---|---|
| **Phase 2B**<br>Griffin et al. | 1453 healthy **preterm** infants (29-34 wks GA) | Efficacy (vs. placebo)<br>•Primary outcome: Medically attended lower respiratory tract infection<br>• *Relative risk reduction of 70.1% (95% CI: 52.3 to 81.2; p<0.001)*<br>•Secondary outcome: Hospitalization due to RSV<br>• *Relative risk reduction of 78.4% (95% CI: 51.9 to 90.3, p<0.001)*<br>Safety<br>•Adverse effects related to trial drug:<br>• Occurred in 2.3% of nirsevimab group and 2.1% placebo group | Nirsevimab demonstrated a 70-80% relative risk reduction for medically attended RSV-related LRTIs compared to placebo.<br><br>The safety profile was favorable with minor differences compared to placebo. |
| **Pooled analysis of Phase 3 MELODY trial**<br>Hammitt et al.<br>Muller et al. | 3012 healthy **term and late preterm infants** (≥35 wks GA) | Efficacy (vs. placebo)<br>•Primary outcome: Medically attended lower respiratory tract<br>• *Relative risk reduction of 74.9% (95% CI: 50.6, 87.3; p<0.001)*<br>•Secondary outcome: Hospitalization due to RSV<br>• *Relative risk reduction of 60.2% (95% CI: -14.6, 86.2; p=0.09)*<br>Safety<br>•Adverse effects related to trial drug:<br>• Rash: 0.9% of the nirsevimab group and 0.6% of the placebo group<br>• Injection site reactions: 0.3% of the nirsevimab and 0.0% of the placebo group | |
| **MEDLEY Phase 2/3 trial**<br>Domachowske J, et al. | 925 infants in 2 cohorts:<br>•**Preterm (≤35 wks GA)**<br>•**±CHD or CLD** | Safety (vs. palivizumab)<br>•Outcome: treatment-related adverse effects of nirsevimab compared to palivizumab<br>• Preterm cohort: 1.5% of nirsevimab group and 1.9% of palivizumab group<br>• CHD/CLD cohort: 1.9% of nirsevimab group and 2.0% of palivizumab group<br>Pharmacokinetics<br>•Day 151: nirsevimab levels similar to those in MELODY trial | |


Griffin MP, et al. *NEJM.* 2020;383(5):415-425
Hammitt LL, et al. *NEJM.* 2022;386(9):837-846
Muller WJ, et al. *NEJM.* 2023;388(16):1533-1534
Domachowske J, et al. *NEJM.* 2022;386(9):892-894

# Nirsevimab Efficacy Estimates

| Outcome | Efficacy estimate* |
|---|---|
| Benefits | |
| Medically attended RSV LRTI | 79.0% (95% CI: 68.5%–86.1%) |
| RSV LRTI with hospitalization | 80.6% (95% CI: 62.3%–90.1%) |
| RSV LRTI with ICU admission | 90.0% (95% CI: 16.4%–98.8%) |
| Death due to RSV respiratory illness | None recorded |
| All-cause medically attended-LRTI | 34.8% (95% CI: 23.0–44.7%) |
| All-cause LRTI-associated hospitalization | 44.9% (95% CI:24.9%–59.6%) |

*Pooled phase 2b (excluding underdosed) and phase 3 trial estimate comparing nirsevimab arm to placebo arm

# ACIP Vote: August 3, 2023

## RSV maternal/pediatric – Vote #1

- Infants aged <8 months born during or entering their first RSV season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg).

Yes: 10; No: 0

## RSV maternal/pediatric – Vote #2

Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg).

Yes: 10 ; No: 0

# Nirsevimab recommendations for infants and children at increased risk of severe RSV

- Nirsevimab is recommended for infants aged <8 months born during or entering their first RSV season, including those recommended to receive palivizumab by AAP[1]
- Nirsevimab is recommended for children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season, including those recommended to receive palivizumab by AAP[1]
- Per FDA label, children who have received nirsevimab should not receive palivizumab for the same RSV season[2]

[1]American Academy of Pediatrics. Committee on Infectious Diseases [Respiratory Syncytial Virus.] In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book : 2021 Report of the Committee on Infectious Diseases. Itasca, IL: American Academy of Pediatrics, 2021.
[2]FDA label for nirsevimab



Jones et al, MMWR 2023

# Children aged 8–19 months recommended to receive nirsevimab when entering their second RSV season because of increased risk of 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 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 weight-for-length <10th percentile
- American Indian and Alaska Native children



Jones et al, MMWR 2023

# Timing of nirsevimab

- Providers should target administration[1]:
  - In the first week of life for infants born shortly before and during the season
  - Shortly before the start of the RSV season for infants aged <8 months
  - Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease
- Based on pre-pandemic patterns, this means nirsevimab could be administered in most of the continental United States from October through the end of March
- Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules based on local epidemiology
- Nirsevimab should be administered within 1 week of birth.
  - Administration can be during the birth hospitalization or in the outpatient setting
- Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after discharge

# Nirsevimab: Indications and Dosage

| Advisory Committee on Immunization Practices (ACIP) Recommendations | | |
|---|---|---|
| **Eligible Population** | **Dosage (Single Dose)** | **Timing** |
| **All neonates and infants < 8 months (1st season)** | Weight < 5 kg: 50 mg IM<br>Weight ≥ 5 kg: 100 mg IM<br>Storage and Handling | Typical RSV Season in Ohio#:<br>November through March<br><br>Duration of action is at least 150 days; administration at start of season will provide protection throughout season |
| **High-risk* 8-19 months (2nd season)** | 200 mg IM, regardless of body weight | |

* See AAP and ACIP guidance for defined high risk population
# Post-COVID-19 pandemic RSV seasons have been more variable than usual, adjust administration timing based on local RSV-activity if needed

Jones JM et al. MMWR Morb Mortal Wkly Rep. 2023 Aug 25;72(34):920-925.

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# Nirsevimab: Storage and Handling

- Prefilled syringes
- Store refrigerated at 36 - 46º F (2 - 8º C)
- May be at room temperature for 8 hours 68 - 77º F (20 - 25º C)
- 50 mg doses will be in purple syringes and 100 mg in blue syringes


50 mg by IM injection


100 mg by IM injection

Nirsevimab (Beyfortus®) (package insert). Swiftwater, PA. Sanofi Pasteur, Inc. 2023.

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Return to previous

# Nirsevimab: Adverse Reactions/Reporting

- Adverse reactions that occurred more frequently than placebo:
  - Rash (0.9%)
  - Injection site reactions (0.3%)

- Reporting Adverse Reactions
  - If administered alongside vaccines: report to VAERS
  - If administered alone: report to FAERS (MedWatch)

- ImpactSIIS
  - Documentation will occur in ImpactSIIS for nirsevimab administrations per ODH

Nirsevimab (Beyfortus®) (package insert). Swiftwater, PA. Sanofi Pasteur, Inc. 2023.

# Nirsevimab: Challenges

## Hospital Administration

- Approximately 10% of birthing hospitals participate in the VFC program
- Bundled payment model for newborn care
  - Hepatitis B vaccine more feasible to cover at ~$13–16/dose
  - Will nirsevimab be included in bundled payments?
- Critical to ensure documentation of in-hospital nirsevimab administration in records sent to primary care provider
  - Potential challenges entering nirsevimab in the immunization information system (IIS)
  - Comprehensive maternal-neonatal records will become even more critical if maternal RSV vaccine is licensed and recommended

CDC Vaccine Price List

Nirsevimab: $495/dose; $395/VFC
Pre-F RSV vaccine: $295

# Nirsevimab: NCH implementation plan

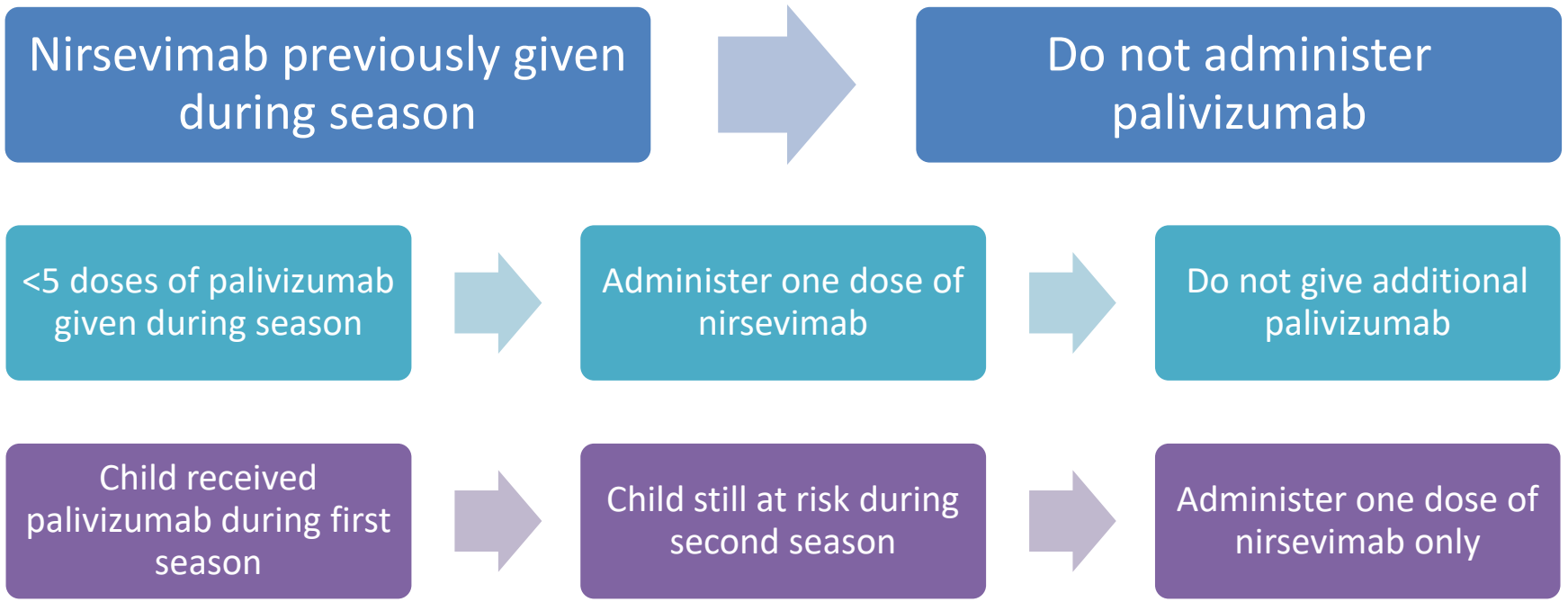
- Outpatient Administration
  - Stocking in primary care clinics for all eligible patients
  - Stocking in other outpatient clinics with high risk patients (e.g. pulmonary, complex care, BPD, cardiology)

- Inpatient Administration*
  - Neonates in NCH NICUs at discharge
  - Other qualifying admitted patients at discharge

*This may not be the approach of birthing hospitals due to reimbursement structures and other factors

# Palivizumab Considerations

- The AAP recommends palivizumab for eligible high risk patients *only if* nirsevimab is not available or not feasible to administer.




AAP Red Book Online. August 15, 2023

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COVID-19
VACCINE
Live Attenuated


TDAP AND
FLU VACCINES
DURING
PREGNANCY
THE BEST
SHOT

# FDA approval for RSVpreF vaccine

- On August 21, 2023, FDA approved Pfizer RSVpreF vaccine for use in pregnant people for the prevention of RSV lower respiratory tract disease and severe lower respiratory tract disease in infants from birth to 6 months of age
- Approved as a single dose to be given at 32–36 weeks gestation
  - In phase 2b and 3 trials, vaccination was given during 24–36 weeks gestation
  - A numerical imbalance in preterm births was observed in RSVpreF vaccine compared to placebo recipients in two clinical studies.
  - Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF
  - Starting dosing at 32 weeks gestation can mitigate the potential risk of early preterm birth until additional safety data are available
- FDA is requiring postmarketing studies to assess preterm birth and hypertensive disorders of pregnancy, including pre-eclampsia

FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants | FDA
Package Insert - ABRYSVO (STN 125768) (fda.gov)

# Phase 3 Efficacy Endpoints Defined

**Weekly active surveillance for ARI symptoms**
Symptoms trigger nasal swab and possibly a visit

| Primary Endpoints | Criteria |
|---|---|
| **Medically attended RSV LRTI** | Medically attended visit **and ≥1**:<br>• tachypnea (RR ≥60 (<2 m [60 days]) or ≥50 (≥2 to 12 m)<br>• peripheral capillary oxygen saturation (SpO2) measured in room air <95%<br>• chest wall indrawing |
| **Medically attended severe RSV LRTI** | Medically attended visit **and ≥1**:<br>• tachypnea (RR ≥70 (<2 m [60 days]) or ≥60 (≥2 to 12 m)<br>• SpO2 measured in room air <93%<br>• high-flow nasal cannula or mechanical ventilation<br>• ICU admission for >4 hours; unresponsive/unconscious |

**Positive validated RT-PCR** in central laboratory

Medically attended visit: Infant participant taken to or seen by a healthcare provider (e.g. outpatient or inpatient visit, emergency room, urgent care, or home visit)

LRTI: Lower respiratory tract illness; SpO2: peripheral capillary oxygen saturation

C3671008: https://clinicaltrials.gov/ct2/show/NCT04424316?term=C3671008&draw=2&rank=1

# Effect estimates, benefits: Pfizer maternal RSVpreF vaccine comparing 24–36 weeks vs 32–36 weeks dosing interval

| Outcome | Trial dosing interval (24–36 weeks) | Approved dosing interval (32–36 weeks) |
|---|---|---|
| | Manufacturer calculated vaccine efficacy (97.58% or 99.17% CI) [1] | Manufacturer calculated vaccine efficacy (95% CI) [2] |
| **Benefits** | | |
| Medically attended RSV-associated lower respiratory tract infection in infants (0–180 days) | 51.3% (29.4, 66.8) | 57.3% (29.8, 74.7) |
| Hospitalization for RSV-associated lower respiratory tract infection in infants (0–180 days) | 56.8% (10.1, 80.7) | 48.2% (-22.9, 79.6) |
| ICU admission from RSV hospitalization in infants (0–180 days) | | 1 event in the vaccine group<br>2 events in the placebo group |
| Mechanical ventilation from RSV hospitalization in infants (0–180 days) | | 0 events in the vaccine group<br>2 events in the placebo group |
| All-cause medically attended lower respiratory tract infection in infants (0–180 days) | 2.5% (-17.9, 19.4) | 7.3% (-15.7, 25.7) |
| All-cause hospitalization for lower respiratory tract infection in infants (0–180 days) | | 34.7% (-18.8, 64.9) |

CI= confidence interval; ICU=Intensive care unit

1 Vaccine efficacy was calculated as 1–(P/[1–P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using the Bonferroni procedure and accounting for the primary endpoints results. 97.58% confidence interval used for medically attended RSV-associated lower respiratory tract infection in infants, 99.17% confidence interval used for other endpoints.

2 Vaccine efficacy was calculated as 1-(hP/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases and h is the ratio of number of participants at risk in the placebo group to the number of participants at risk in the RSVpreF group.

# Primary Endpoints:

Vaccine Efficacy by Cumulative Days after Birth for Two Primary Endpoints

| | Maternal Vaccine Group (as Randomized) | | |
|---|---|---|---|
| **RSV-Positive Severe MA-LRTI** | RSVpreF 120 µg (N[a]=3495) | Placebo (N[a]=3480) | |
| Time Interval | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (CI*)** |
| 90 Days after birth | 6 (0.2) | 33 (0.9) | 81.8 (40.6, 96.3) |
| 120 Days after birth | 12 (0.3) | 46 (1.3) | 73.9 (45.6, 88.8) |
| 150 Days after birth | 16 (0.5) | 55 (1.6) | 70.9 (44.5, 85.9) |
| 180 Days after birth | 19 (0.5) | 62 (1.8) | 69.4 (44.3, 84.1) |
| **RSV-Positive MA-LRTI** | | | |
| Time Interval | **Number of Cases (%)** | **Number of Cases (%)** | **Vaccine Efficacy[b] (%) (CI*)** |
| 90 Days after birth | 24 (0.7) | 56 (1.6) | 57.1 (14.7, 79.8) |
| 120 Days after birth | 35 (1.0) | 81 (2.3) | 56.8 (31.2, 73.5) |
| 150 Days after birth | 47 (1.3) | 99 (2.8) | 52.5 (28.7, 68.9) |
| 180 Days after birth | 57 (1.6) | 117 (3.4) | 51.3 (29.4, 66.8) |

*99.5% CI for 90 days, 97.58% CI for 120/150/180 days. CI LB >20% for all time points.

Abbreviations: RSV = respiratory syncytial virus. a. N = number of participants (at risk) in the specified group. These values are used as the denominators for the percentage calculations. b. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results.

Pfizer

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# Proposed clinical considerations for use of maternal RSV vaccine

- Maternal vaccine recommended for pregnant people during 32 through 36 weeks gestation, with seasonal administration
  - During September through January in most of the continental United States
  - In jurisdictions with seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climates), providers should follow state, local, or territorial guidance on timing of administration
- Maternal RSVpreF vaccine may be simultaneously administered with other indicated vaccinations [1]

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

# Maternal vaccination and considerations for use of nirsevimab in infants born <34 weeks gestation

- As proposed, maternal RSV vaccine recommendation is for administration beginning at 32 weeks gestation
- From time of maternal vaccination, 14 days or more likely needed for development and transplacental transfer of maternal antibodies to protect the infant,[1] and nirsevimab is recommended for infants born within 14 days of vaccination
- Therefore, the earliest an infant can be born and have maternal vaccine-induced protection is at 34 weeks gestation
- Infants born <34 weeks gestation will be recommended to receive nirsevimab

[1] https://www.cdc.gov/vaccines/pregnancy/vacc-during-after.html.

# Proposed recommendations for use of nirsevimab in setting of an available maternal RSV vaccine

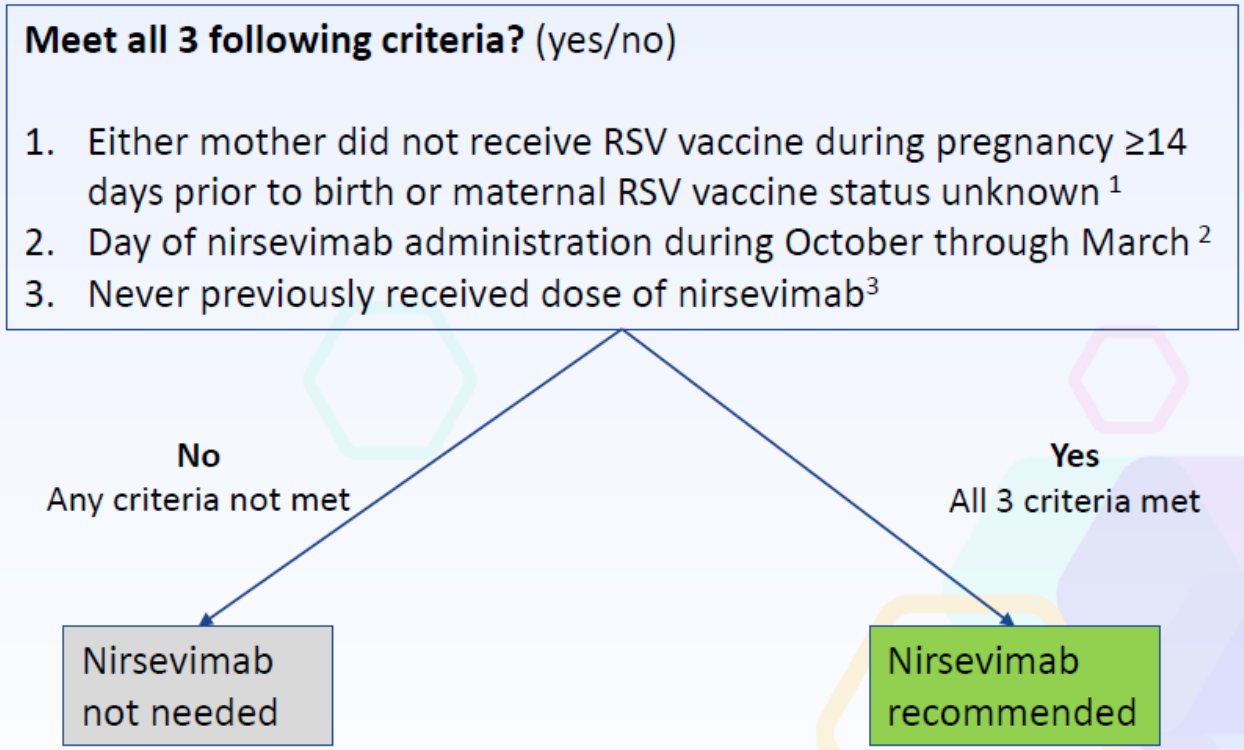
- Nirsevimab is recommended for infants aged <8 months born during or entering their first RSV season if
  - Mother did not receive RSV vaccine or unknown if mother received RSV vaccine
  - Mother vaccinated but infant born <14 days after vaccination
- Nirsevimab is not needed for most infants born ≥14 days after maternal vaccination

# Circumstances for which nirsevimab can be considered when mother has received RSV vaccine ≥14 days prior to birth

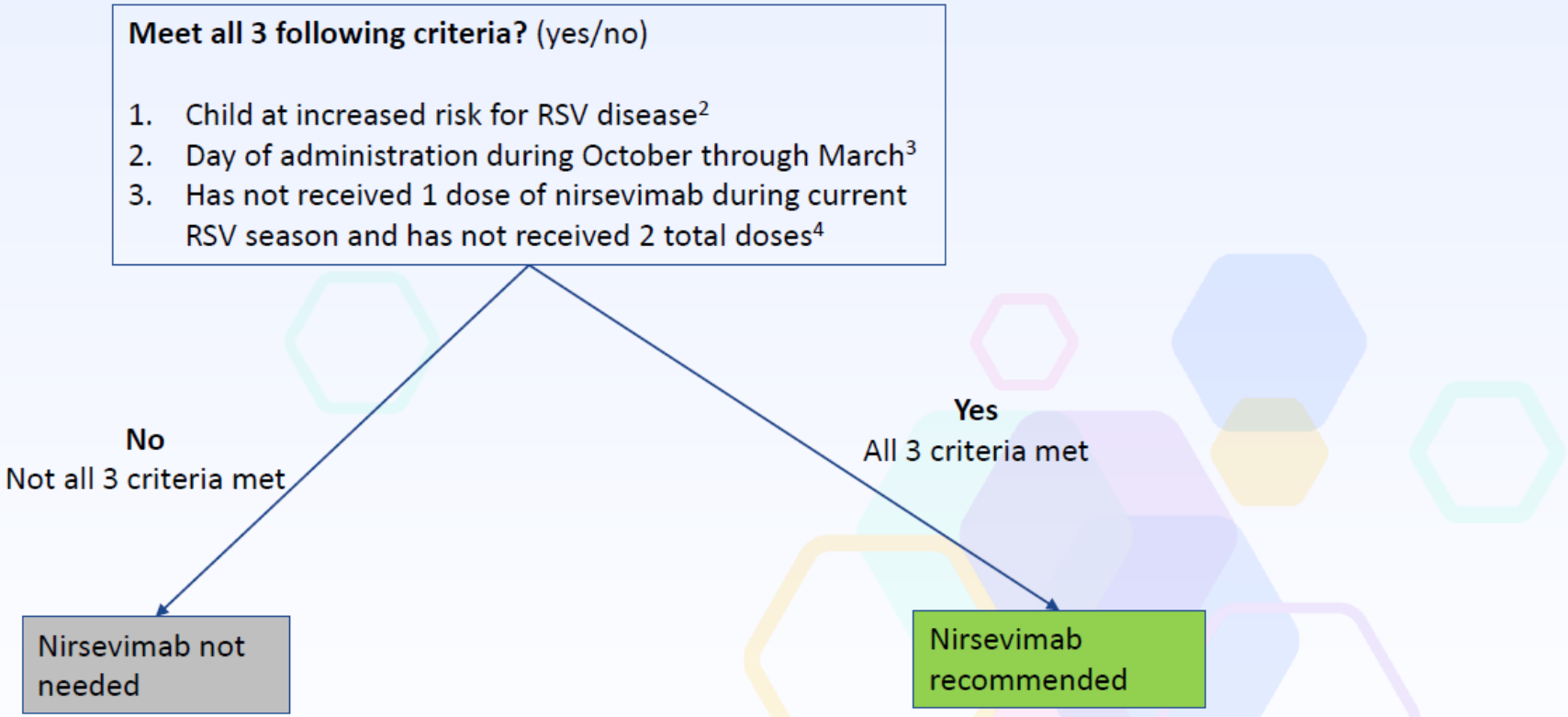
- Nirsevimab can be considered in rare circumstances when, per the clinical judgment of the healthcare provider, the potential incremental benefit of administration is warranted
  - Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., people with immunocompromising conditions) or have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)[1]
  - Infants who have undergone cardiopulmonary bypass, leading to loss of maternal antibodies[2]
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

[1] Palmerira Clin Dev Immunol 2012. [2] Feltes J Pediatr 2003.

# Nirsevimab administration algorithm for children aged <8 months on the day of administration



# Nirsevimab administration algorithm for children aged 8 through 19 months on day of administration[1]



## Proposed ACIP Voting Language

- Maternal RSV vaccine is recommended for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants

Vote: Yes 11

No 1

## VFC Vote Language

- Approve the Vaccines for Children (VFC) resolution for RSV maternal vaccine

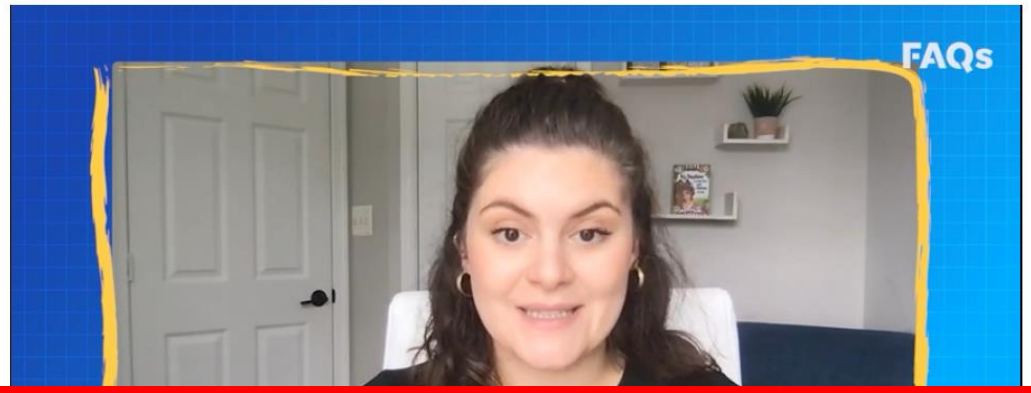
Vote: Yes 11

No 1

# New RSV vaccine, COVID-19 booster available by mid-October, ODH officials say

**Lily Carey** Columbus Dispatch

Published 12:58 p.m. ET Aug. 17, 2023 | **Updated 1:01 p.m. ET Aug. 17, 2023**





**NOT A VACCINE!!!**

A new vaccine for Respiratory Syncytial Virus could be available for newborns and infants as soon as mid-October, Ohio Department of Health officials announced at a Thursday press conference.

# Both nirsevimab and maternal RSV vaccine provide passive immunity

- A person develops active immunity from infection or vaccination
  - Triggers an immune response
  - Immunologic memory provides prolonged protection that may be lifelong

- Passive immunity is transfer of preformed antibody produced externally to provide protection to the recipient
  - From mother to baby through transplacental or breastmilk transfer
  - Direct administration of antibodies, such as IVIG or monoclonal antibodies
  - Provides temporary protection that wanes with time

IVIG= Intravenous Immunoglobulin Therapy
https://www.cdc.gov/vaccines/vac-gen/immunity-types.htm

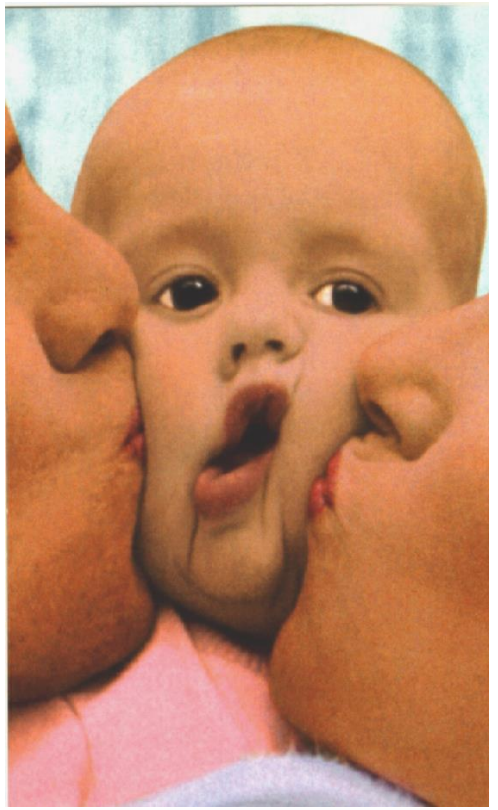
# Definition of "Vaccine"

- No statutory definition of vaccine in the statute for the Vaccines for Children 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
- **CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children program**

Program For Distribution Of Pediatric Vaccines
Coverage of Certain Preventive Services Under the Affordable Care Act

# RSV Prevention

- Spread by contact
- Portal of entry: eye/nose
- Stress handwashing!
- Avoid the exposure!



# Nationwide Children's Hospital

# Center for Perinatal Research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**RESEARCH SAVES BABIES!**

# Dayton Children's Hospital (DCH) & Nirsevimab

# DCH & Nirsevimab

- DCH RSV Prevention Clinic
  - Formerly known as the "Synagis® Clinic"
  - Prior RSV seasons
    - Palivizumab administration for referrals meeting *American Academy of Pediatrics* (AAP) eligibility criteria
  - Upcoming RSV season
    - Will offer option of palivizumab *or* nirsevimab for eligible high-risk* referrals

*High-risk => infants who qualify for palivizumab receipt during their 1st or 2nd RSV season based on AAP eligibility criteria

# DCH & Nirsevimab

- DCH Neonatal Intensive Care Unit (NICU) Patients
  - All eligible high-risk* infants < 8 months
    - Will be offered nirsevimab in the NICU upon hospital discharge

- Dayton Children's Pediatrics (DCP) Practices (Child Health Pavilion, Hope Center)
  - Availability through Vaccines for Children (VFC) program
  - To be determined: Patients of DCP Practices with private insurance coverage
    - Private payors will begin coverage for nirsevimab this year, but their timelines may vary over the next several months

*High-risk => infants who qualify for palivizumab receipt (based on AAP eligibility criteria)

# DCH & Nirsevimab

- DCH Recommendations for parents of children < 8 months of age
  - Availability and coverage by payors varies
  - Recommend checking with your child's primary care provider to see if nirsevimab is available
  - If covered by private insurance, recommend checking with your child's insurance provider to determine if nirsevimab is covered under your child's insurance plan
  - DCH will continually monitor situation and update recommendations as supply and payor coverage become clearer

# Additional Resources

# Nirsevimab: Timeline

Projections

July 17 2023: Approval

August 3, 2023: ACIP recommendation and VFC approval

Will be included in CDC immunization schedule and will be part of VFC program

September 2023: Available to order

September 20: Orders to begin shipping

Beginning of October: Health department receives supply, VFC shipments begin

October: Private insurances *may* begin covering

# Nirsevimab: Cost and Billing

Wholesale acquisition cost (WAC):

- Commercial: $495 per dose (same price for 50mg and 100 mg syringes)
- Medicaid: No cost to offices enrolled in the Ohio Department of Health VFC program

| CPT Codes for Medication and Administration | |
|---|---|
| 90380 | Administration of 0.5 mL dose (50 mg) of nirsevimab |
| 90381 | Administration of 1 mL dose (100 mg) of nirsevimab |
| 96372 | Therapeutic, Prophylactic, and Diagnostic Injections and Infusions |

AAP website with billing info and helpful vignettes

https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-coding--payment/

Partners For Kids | Nationwide Children's When your child needs a hospital, everything matters. | dayton children's

# Nirsevimab: Private Insurances

- Due to inclusion in CDC immunization schedule, private payors are more likely to cover nirsevimab, similar to other routine immunizations

- Example commercial nirsevimab policies:
  - https://www.aetna.com/cpb/medical/data/1000_1099/1038.html
  - Preventive Care Services: Vaccine Codes (uhcprovider.com)
  - https://www.anthem.com/dam/medpolicies/abc/active/policies/mp_pw_a044155.html

- Example of commercial policies currently referencing ACIP guidance:
  - https://www.anthem.com/dam/medpolicies/abc/active/policies/mp_pw_a044155.html
  - Preventive Care Services (cigna.com)

# Nirsevimab: Acquisition Resources

- The manufacturer has extended it requirement to pay invoices to 150 days if purchased directly
- Expired medication, if returned within 1-year of expiration, can be exchanged for credit if ordered directly from manufacturer
- Stock and cost estimation tools are available through the manufacturer to help with supply predictions

# Provider Resources

- Nirsevimab
  - Nirsevimab Package Insert
  - Manufacturer Website (Beyfortus)
  - ACIP and AAP Combined Recommendations for Nirsevimab

- RSV
  - Rethink RSV website
  - AAP Redbook- RSV

# Patient Resources

- Nirsevimab
  - Manufacturer Website (Beyfortus)
- RSV
  - Knowing RSV website
  - RSV: When It's More Than Just a Cold - HealthyChildren.org

# RSV Prevention Resource Page

Available at: https://partnersforkids.org/news-updates/

- Resource links for providers and patients
- Partners For Kids developed resources
  - News and updates
  - Recorded webinar
  - Frequently asked questions page (in-development)
- Regularly updated with new information as it becomes available