McLeod Health

Nirsevimab: A Shot at Protection Against RSV for Infants & Neonates

A Presentation for HealthTrust Members
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Somer Pye, PharmD
PGY-1 Pharmacy Resident
McLeod Regional Medical Center
Florence, SC

Preceptors:
Lindsey McDaniel, PharmD
Tabitha Martin, PharmD
Pediatric Clinical Pharmacy Specialists

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Objectives

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Recall the mechanism of action and role of nirsevimab in preventing respiratory syncytial virus (RSV) in infants.

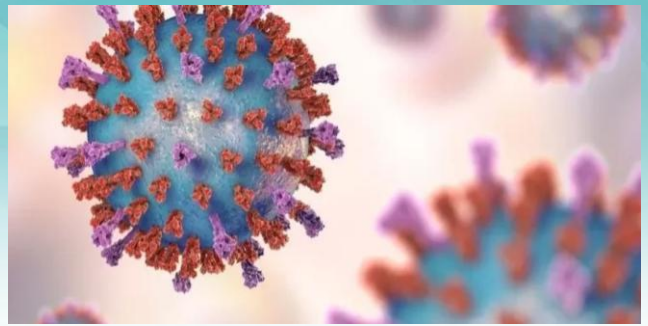
Identify current evidence-based recommendations from the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) regarding eligibility and timing for nirsevimab administration.

Recognize the key clinical evidence and best practices supporting the safety and efficacy of nirsevimab in the infant population.

Abbreviations

RSV: respiratory syncytial virus
SOB: shortness of breath
RVP: respiratory viral panel
LRTI: lower respiratory tract infection
URTI: upper respiratory tract infection
AAP: American Academy of Pediatrics
CDC: Centers for Disease Control and Prevention
CBC: complete blood count
PCR: polymerase chain reaction
IM: intramuscular
UK: United Kingdom
U.S.: United States
WHO: World Health Organization
IgG1k: immunoglobulin G1 kappa
RNA: ribonucleic acid
FDA: Food and Drug Administration
WBC: white blood cell

Respiratory Syncytial Virus (RSV)



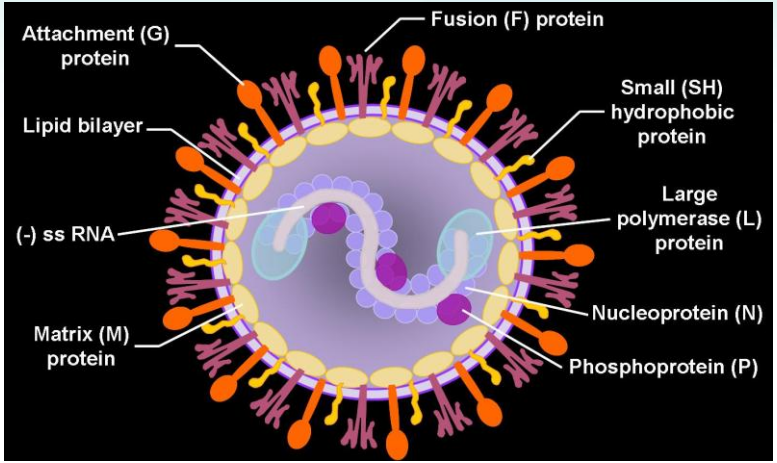
Source: *National Foundation for Infectious Diseases* (2026).

- A common and highly contagious respiratory virus
- Can lead to severe respiratory infections in infants and older adults
- RNA virus that belongs to the *Pneumoviridae* family
- Specific for humans and infects cells along the respiratory tract, from the nose to the lungs
- Causes a wide spectrum of respiratory infections, from upper respiratory tract infections to life threatening lower respiratory tract infections

Source: *World Health Organization (2023).*

RSV Seasonality

- In the U.S., most RSV infections occur October through March/April
- Causes seasonal epidemics in late fall and winter, but can vary depending on location and climate



Source: *ruleof6ix.fieldofscience.com*

Source: *World Health Organization (2023).*

RSV Transmission

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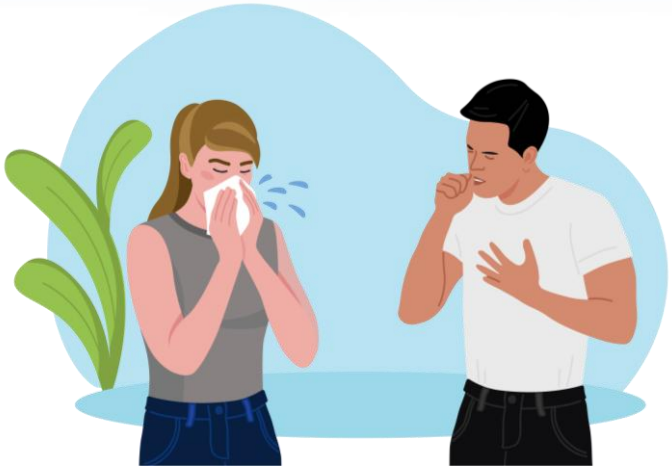
1. Infectious respiratory particles through the air from an infected person
   - Example(s): cough, sneeze

2. Direct contact with an infected person
   - Example(s): kissing, holding infant, daycare

3. Through contaminated surfaces or objects
   - Example(s): gloves, countertops, glass, paper, cardboard, etc.



Source: *hydroliq.com/news/how-are-germs-spread*

Source: *World Health Organization (2023).*

RSV Transmission

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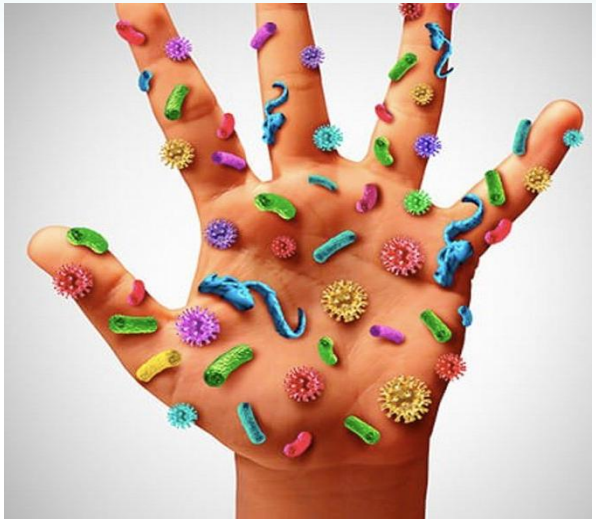
- RSV can live up to:
  - 6 hours on countertops, glass, and metals
  - 5 hours on gloves
  - 2 hours on paper, cardboard, and fabric
  - 30 minutes on the skin



Source: *Irish Independent* (2019).

Source: *Sanofi (2025)*.

RSV Life Cycle

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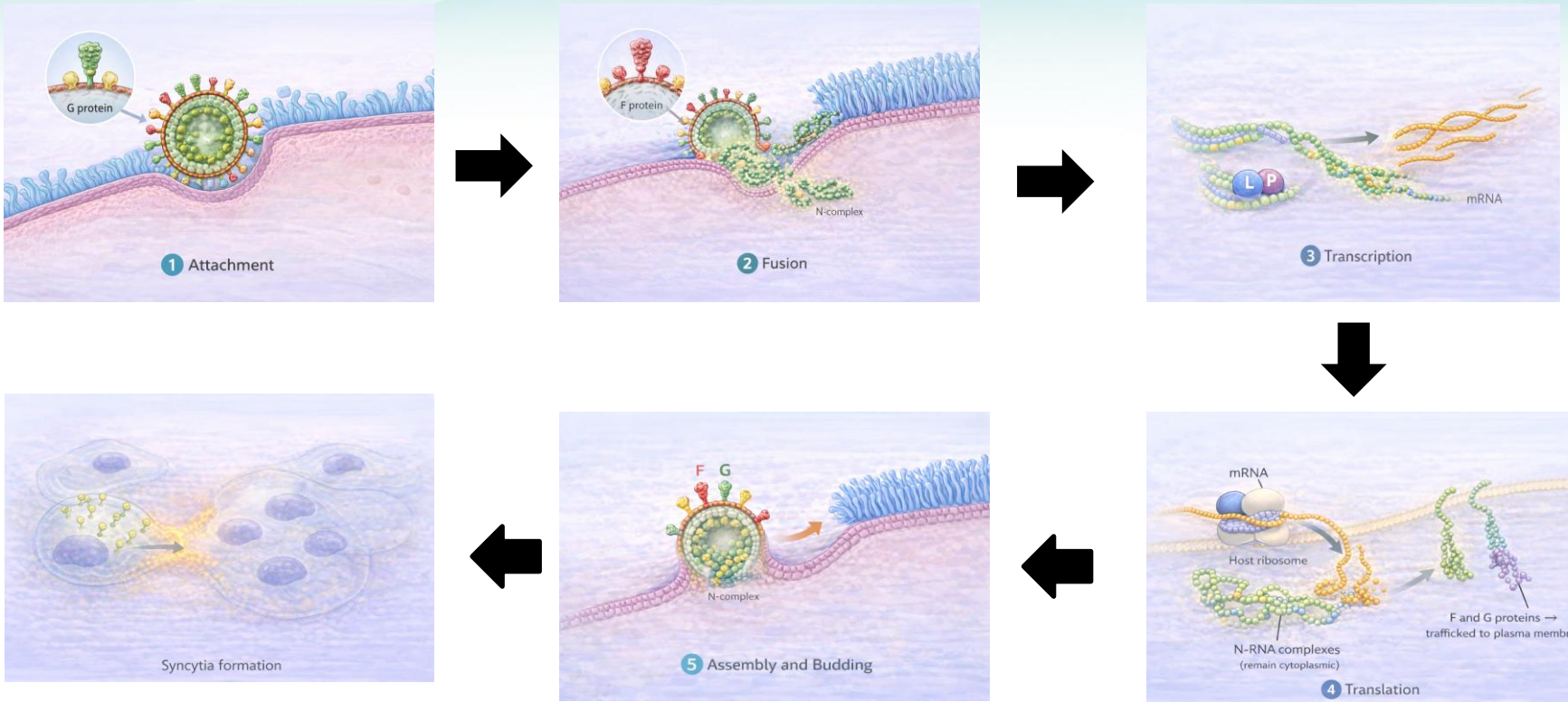
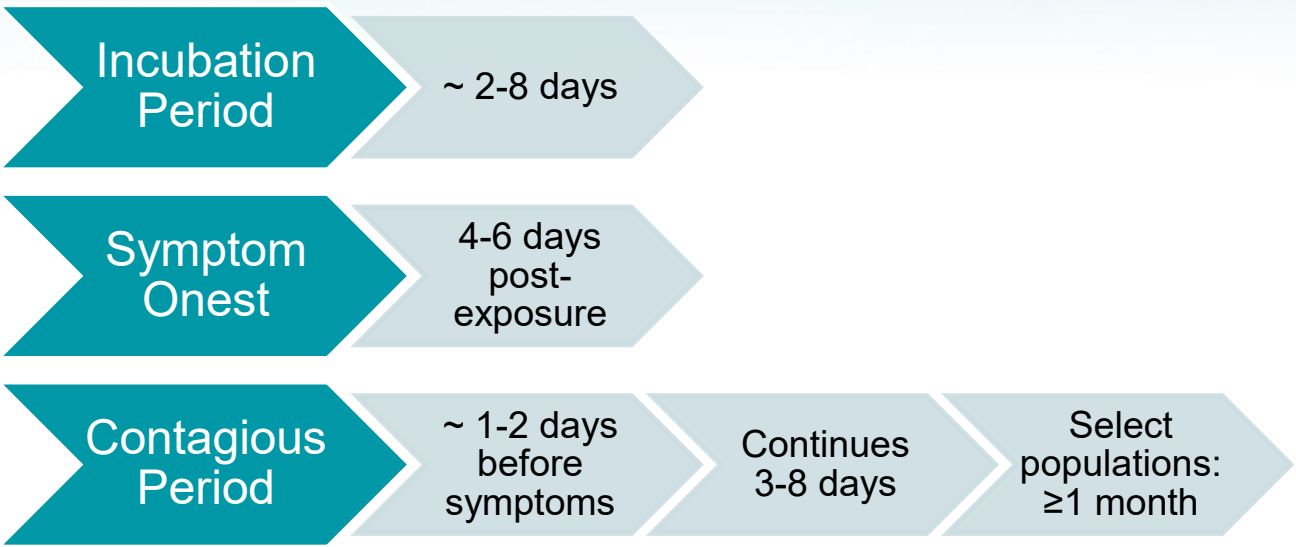


Source: *ChatGPT (2026).*

RSV Stages



Source: *Sanofi (2025)*.

RSV Signs/Symptoms

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Common	More Severe
• Fever • Congestion • Runny nose • Cough • Sore throat • Sneezing • Headache • Fatigue	• Wheezing • SOB • Nasal flaring • Tachypnea • Cyanosis • Irritability

Source: *Mayo Clinic (2024).*

RSV Risk Factors

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- Infants:
  - Premature infants (less than 37 weeks' gestation)
  - Less than 6 months of age

- Children with:
  - Chronic lung disease or congenital heart disease
  - Weakened immune systems
  - Severe cystic fibrosis
  - Neuromuscular disorders

Source: *Emergency Medicine Residents' Association* (2021).

~80% of children less than 2 years old who are hospitalized with RSV do not have risk factors

Source: *CDC (2024).*

RSV Burden

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During the 2024-2025 RSV season in the U.S., RSV led to:

3.6-6.8 million outpatient visits	190,000-370,000 hospitalizations	11,000-24,000 deaths

Source: *CDC (2026)*.

RSV Burden, *continued*

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- Most common cause of hospitalization in children less than 1 year old
- For children <5 years of age, each year RSV leads to:

WHO	CDC
• 3.6 million hospitalization • ~100,000 deaths	• 2.1 million outpatient visits • ~ 58,000-80,000 hospitalizations • ~ 100 to 300 deaths

Sources: *WHO (2023). AAP (2025).*

RSV Diagnosis

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- Suspected based on physical exam findings and time of year

- Physical exam findings can include, but not limited to:
  - Rhinorrhea
  - Pharyngitis
  - Wheezing
  - Coarse/fine crackles (rales)
  - Tachypnea
  - Nasal flaring
  - Intercostal/subcoastal retractions
  - Cyanosis
  - Prolonged expiration

Source: *ChatGPT* (2026).

Source: *Mayo Clinic (2024).*

RSV Diagnosis

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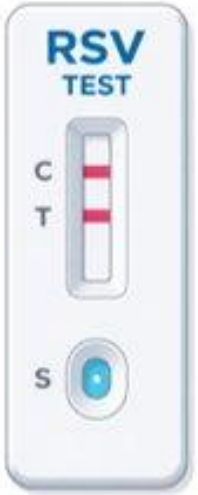
- Laboratory and imaging tests are not always needed, but can be helpful
  - CBC: elevated WBC
  - Chest X-ray: hyperinflation or infiltrates
  - PCR swab (usually an RVP)

- Differential diagnoses can include, but not limited to:
  - Other viral respiratory infections
  - Bacterial or viral pneumonia
  - Asthma or reactive airway disease
  - Croup
  - Bronchiolitis
  - Upper respiratory tract infections



Source: *ChatGPT* (2026).

Source: *Mayo Clinic (2024).*

RSV Treatment

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- No specific treatment
- Management of severe RSV involves supportive care
  - Nasal suction of secretions
  - IV fluids for hydration
  - Supplemental oxygen

Source: *The Lancet Respiratory Medicine.* (Volume 7, Issue 4, 301-302.

Source: *WHO (2023).*

RSV Prevention

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Patient Population	Immunization(s)	Age	Available
Adults	Abrysvo Arexvy mResvia	Ages 50-74 at an increased risk for severe RSV **AND** All adults age 75 and older	Any time, but best is late summer and early fall
Pediatrics	Nirsevimab Clesrovimab	All infants whose mother did not receive RSV vaccine during pregnancy **AND** some children ages 8-19 months at an increased risk for severe RSV	October-March*
Pregnancy	Abrysvo	32-36 weeks gestation	September-January

Source: *CDC (2025).*

RSV Prevention, *continued*

McLeod Health

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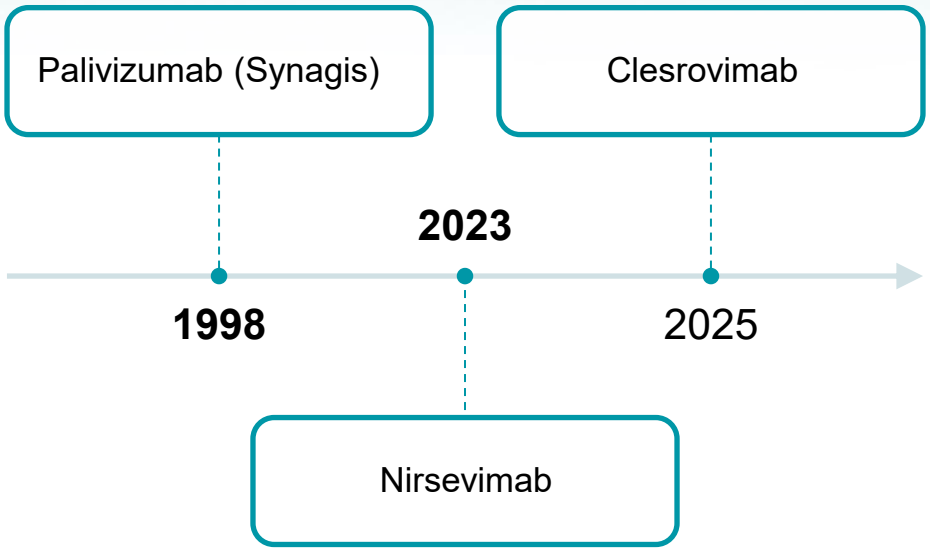
Source: *CDC (2025).*

RSV Prevention, *continued*



Sources: *CDC (2025). FDA (2026).*

Palivizumab (Synagis)

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- **MOA:** Monoclonal antibody that inhibits the F fusion protein of RSV
- **Dose:** 15 mg/kg IM
- **Frequency:** Once monthly throughout RSV season
  - Max of 5 doses per season

1st RSV Season

- Premature infants
  - Born < 29 weeks' gestation
  - < 12 months of age
- CLD of prematurity
- CHD

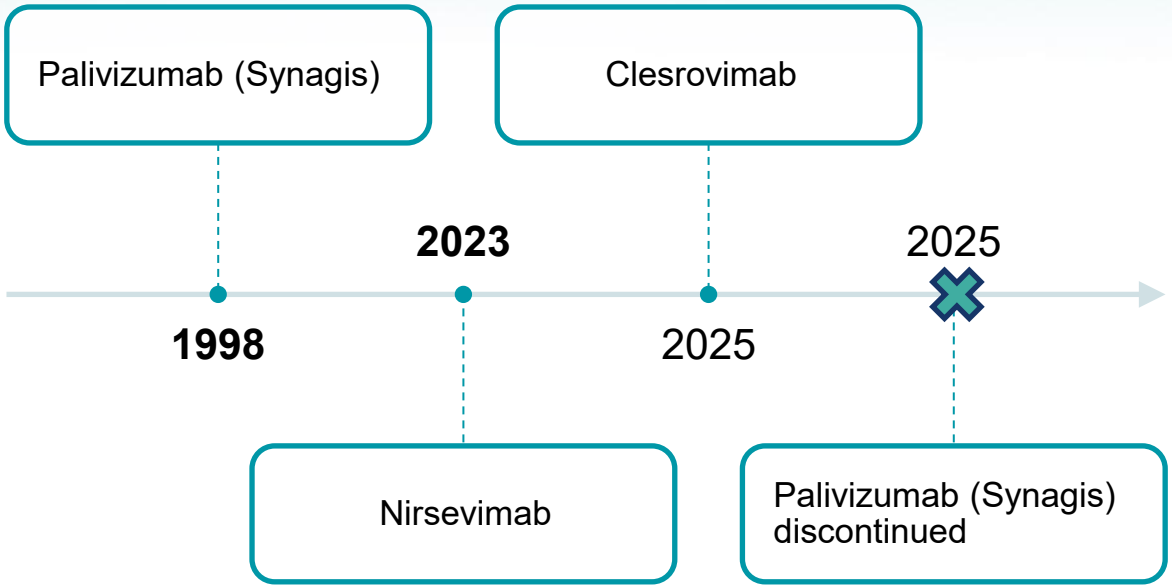
2nd RSV season

- <24 months of age
- Recommended ONLY if child still required medical support in the previous 6 months
  - Oxygen
  - Chronic steroids

- Severely immunocompromised
- Profound airway abnormalities
- Cystic fibrosis

Source: *AAP (2014).*

RSV Prevention, *continued*



Sources: *CDC (2025). FDA (2026).*

RSV Life Cycle

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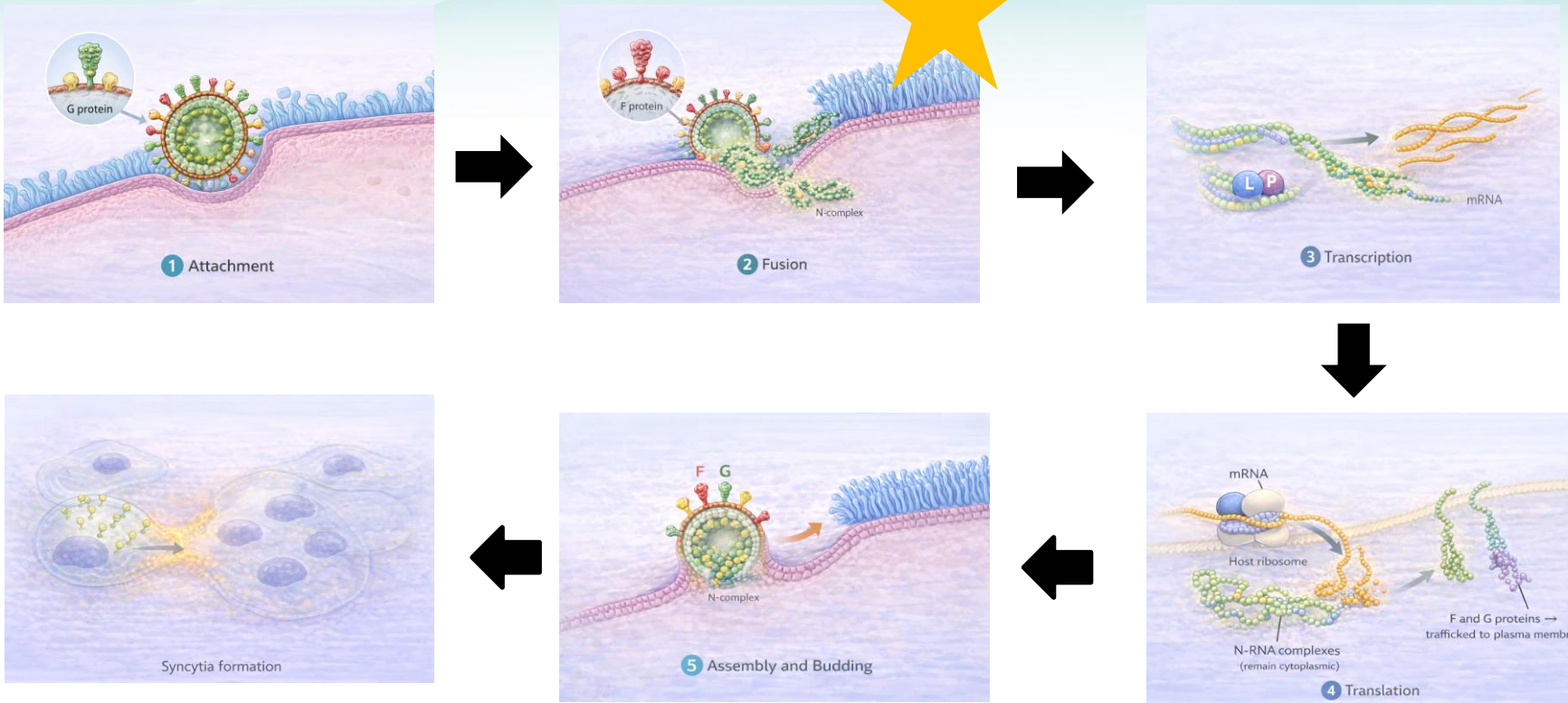

Nirsevimab

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- Recombinant human IgG1k monoclonal antibody injection that provides passive immunity to prevent severe RSV in newborns, infants, and young children during their first RSV season

Source: *Sanofi (2025)*.

Nirsevimab, *continued*

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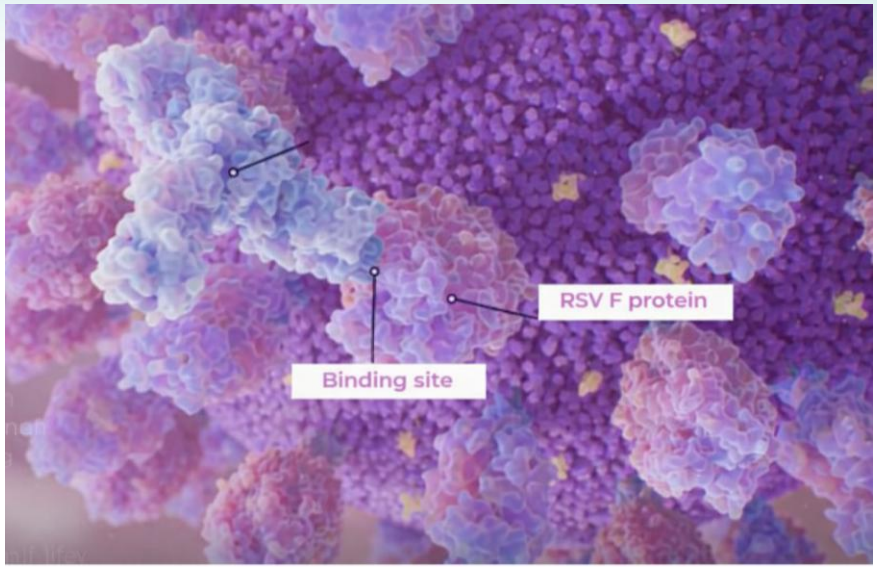
- **MOA:** neutralizes RSV by inhibiting conformation changes in the F protein necessary for fusion of the viral and cellular membranes and viral entry



Source: *Sanofi (2025)*.

Nirsevimab, *continued*

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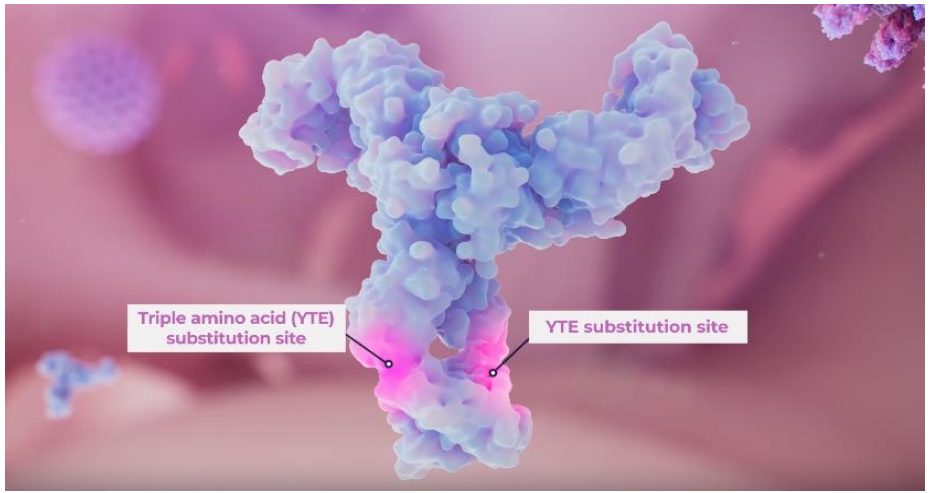
- Long-acting due to a triple amino acid substitution (YTE) in the Fc region which increases binding to the neonatal Fc receptor and thereby extends serum half-life



Source: *Sanofi (2025)*.

2025 Guideline Recommendations: CDC/ACIP and AAP

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<8 months of age born during or entering their first RSV season	8-19 months of age at high risk of severe RSV and entering their second RSV season
Mother did not receive Abrysvo	Chronic lung disease of prematurity who required medical support at any time during the 6-month period before the start of the second RSV season
Mother's RSV vaccination status is unknown	Severe immunocompromised status
Born <14 days after the mother received Abrysvo	Cystic fibrosis who have either 1) manifestations of severe lung disease or 2) weight-for-length that is <10th percentile
	American Indian or Alaska Native

Sources: *CDC/ACIP (2025). AAP (2025).*

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Nirsevimab: 1st RSV Season

Infants born in these months should receive nirsevimab in October

Infants born in these months should receive nirsevimab during hospitalization or within one week of birth

Source: *CDC (2025).*

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Nirsevimab: 1st RSV Season, *cont.*

	Infants born October-March	Infants born April-September
Mother did not receive Abrysvo	Administer during birth hospitalization	Administer shortly before start of RSV season
Mother's RSV vaccination status is unknown		
Mother received Abrysvo in previous pregnancy		
Mother received Abrysvo <14 days prior to delivery		
Mother received Abrysvo at least 14 days prior to delivery	Not needed, but can be considered	Not needed, but can be considered

Source: *CDC (2025).*

Nirsevimab

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<8 months of age born during or entering their first RSV season	8-19 months of age at high risk of severe RSV and entering their second RSV season
<5 kg: 1 dose of 50 mg IM ≥5 kg: 1 dose of 100 mg IM	1 dose of 200 mg Administered as 2 IM injections of 100 mg

Sources: *CDC/ACIP (2025). AAP (2025).*

Nirsevimab, *continued*

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- **Contraindications:**
  - Hypersensitivity reactions, including anaphylaxis, to nirsevimab
- **Warnings/Precautions:**
  - Hypersensitivity reactions, including anaphylaxis
  - Use in individuals with clinically significant bleeding disorders
- **Adverse Reactions:**
  - Rash (0.9%)
  - Injection site reactions (0.3%)

Source: *Sanofi (2025)*.

Nirsevimab, *continued*

Source: The Scientist (2025).

- **Storage:**
  - Refrigerate between 36-46°F (2-8°C)
  - Protect from light
  - Stable at room temperature for a maximum of 8 hours
  - **DO NOT:**
    - Freeze
    - Shake
    - Expose to heat

- **Administration:**
  - IM injection in the anterolateral aspect of the thigh

Source: *Sanofi (2025).*

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The Evidence Behind Nirsevimab

The Framework

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MEDLEY Trial

- Phase II/III trial designed to evaluate safety and tolerability of nirsevimab in preterm infants and infants at high risk eligible to receive Synagis
- Study completed but not formally published – 90% of high-risk children entering their second RSV season achieved serum concentrations meeting the desired PK profile
- Safety profile similar to palivizumab

Source: *N Engl J Med*. 2022;386(9):837-846.

MELODY Trial

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Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants

Laura L. Hammitt, M.D., Ron Dagan, M.D., Yuan Yuan, Ph.D., Manuel Baca Cots, M.D., Miroslava Bosheva, M.D., Shabir A. Madhi, Ph.D., William J. Muller, Ph.D., Heather J. Zar, Ph.D., Dennis Brooks, M.D., Amy Grenham, M.Sc., Ulrika Wählby Hamrén, Ph.D., Vaishali S. Mankad, M.D., Pin Ren, Ph.D., Therese Takas, B.Sc., Michael E. Abram, Ph.D., Amanda Leach, M.R.C.P.C.H., M. Pamela Griffin, M.D., and Tonya Villafana, Ph.D., for the MELODY Study Group*

Purpose: to evaluate the efficacy and safety of nirsevimab in healthy late-preterm and term infants entering their first RSV season

Source: *N Engl J Med*. 2022;386(9):837-846.

Study Design

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- Multinational/global phase 3, randomized, double-blind, placebo-controlled clinical trial
- **Randomization:** 2:1 ratio according to hemisphere of residence and age to receive nirsevimab or placebo
- **Follow up:** 150 days (~5 months)
- **Funding:** AstraZeneca/Sanofi

Source: *N Engl J Med*. 2022;386(9):837-846.

Study Design, *continued*

- **Intervention:**

Nirsevimab

- < 5 kg: 50 mg IM injection for 1 dose
- ≥ 5 kg: 100 mg IM injection for 1 dose

Placebo (Normal Saline)

- < 5 kg: 0.5 mL IM injection for 1 dose
- ≥ 5 kg: 1 mL IM injection for 1 dose

Source: *N Engl J Med*. 2022;386(9):837-846.

Study Design, *continued*

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Primary Efficacy Endpoint

- Medically attended RSV-associated LRTI through 150 days after the injection

Secondary Efficacy Endpoint

- Hospitalization for RSV-associated LRTI through 150 days after the injection

Safety Endpoint

- Hypersensitivity reaction (including anaphylaxis)
- Immune-complex disease
- Thrombocytopenia

Source: *N Engl J Med*. 2022;386(9):837-846.

Study Design, *continued*

McLeod Health

Inclusion	Exclusion
• Healthy infants • Born at gestational age of ≥35 weeks • ≤1 year of age • Entering into first RSV season	• Met national or local criteria to receive palivizumab (Synagis) • Fever or acute illness within 7 days before randomization • RSV before or at time of randomization • History of chronic lung disease/bronchopulmonary dysplasia

Source: *N Engl J Med*. 2022;386(9):837-846.

Statistical Analysis

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Primary Endpoint

- Intention-to-treat
- Sample size of ~1500 participants would give the trial at least 99% power to detect a 70% lower relative risk
- Two-sided alpha of 0.05 under the assumption of an 8% incidence of the primary endpoint in the placebo group
- Poisson regression model with robust variance

Secondary Endpoint

- Intention-to-treat
- Tested only if statistical significance with respect to the primary endpoint was shown

Safety Endpoint

- Per protocol

Source: *N Engl J Med*. 2022;386(9):837-846.

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Baseline Characteristics

Characteristic	Nirsevimab (N=994)	Placebo (N=496)	Total (N=1490)
Age			
≤3 months	58%	57.5%	57.9%
>3 to ≤6 months	31.9%	32.7%	32.1%
>6 months	10.1%	9.9%	10%
Gestational Age			
≥35 to <37 weeks	13.3%	15.4%	14%
≥37 weeks	86.7%	84.6%	86%
Female Sex	46.8%	51.8%	48.4%
Race			
White	52.9%	54.8%	53.5%
Black	28.9%	27.4%	28.4%
American Indian or Alaska Native	5.8%	5.2%	5.6%
Asian	3.6%	3.6%	3.6%

Source: *N Engl J Med*. 2022;386(9):837-846.

Results

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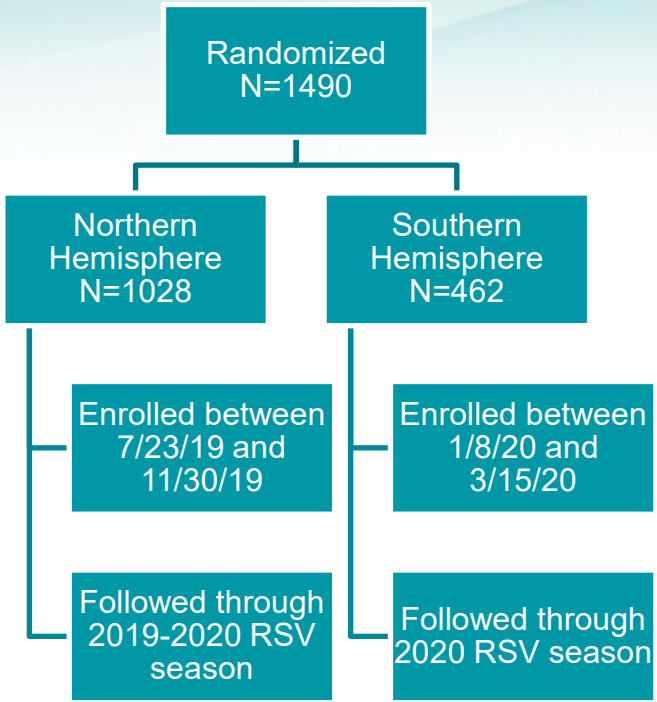

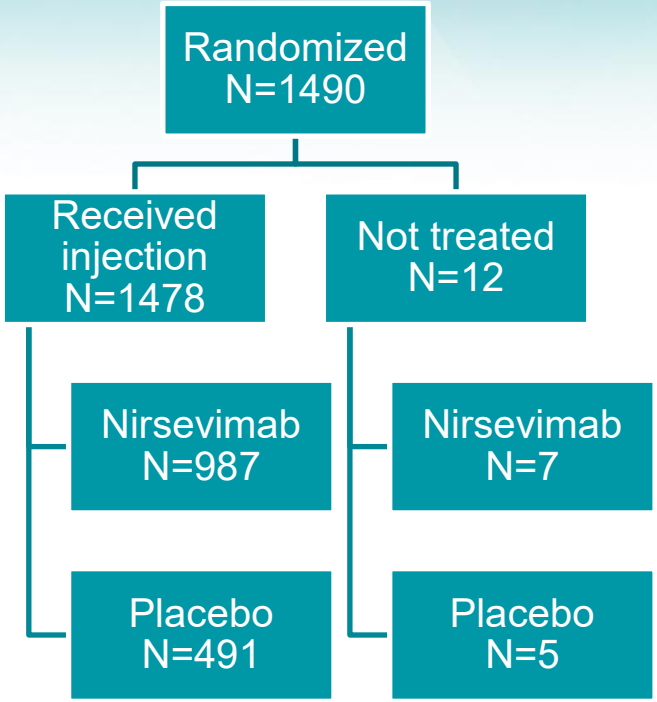

Source: *N Engl J Med*. 2022;386(9):837-846.

Results, *continued*

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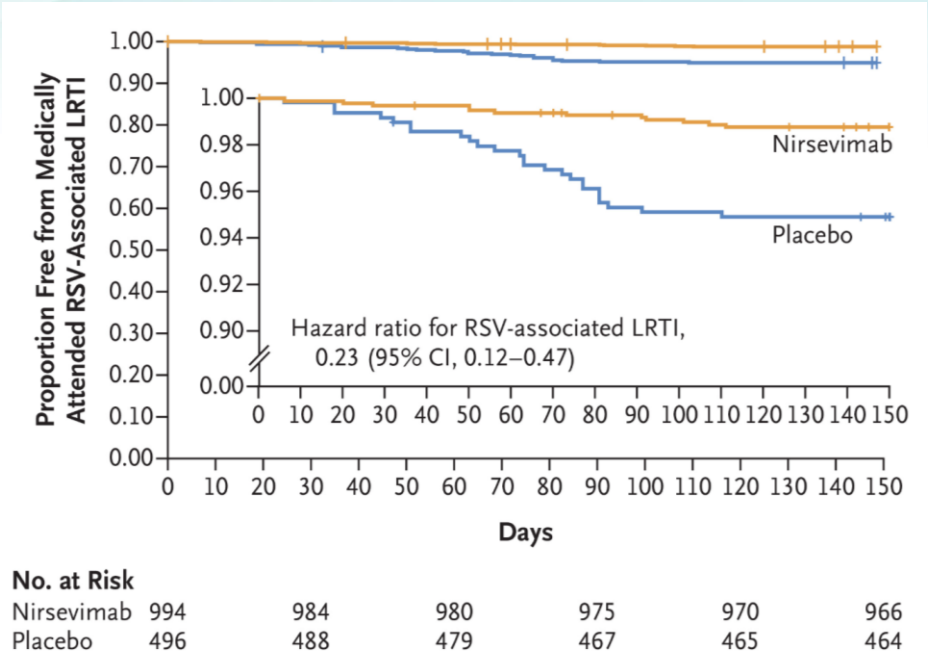
Endpoint and Analysis	Nirsevimab (N= 994)	Placebo (N= 496)	Efficacy (95% CI)	P Value
Medically attended RSV-associated LRTI			74.5 (49.6 to 87.1)	<0.001
Observed events	12 (1.2%)	25 (5%)		
Participants with imputation of data	15 (1.5%)	6 (1.2%)		
Hospitalization for RSV-associated LRTI			62.1 (-8.6 to 86.8)	0.07
Observed events	6 (0.6%)	8 (1.6%)		
Participants with imputation of data	15 (1.5%)	6 (1.2%)		

Source: *N Engl J Med*. 2022;386(9):837-846.

Results, *continued*



Source: *N Engl J Med*. 2022;386(9):837-846.

Results: Safety

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Variable	Nirsevimab (N= 987)	Placebo (N= 491)	Total (N=1478)
Any adverse event Considered to be related to trial regimen	863 (87.4%) 10 (1%)	426 (86.8%) 7 (1.4%)	1289 (87.2%) 17 (1.2%)
Adverse event that resulted in death	3 (0.3%)	0	3 (0.2%)
Serious adverse event Considered to be related to trial regimen	67 (6.8%) 0	36 (7.3%) 0	103 (7%) 0

Source: *N Engl J Med*. 2022;386(9):837-846.

Strengths & Limitations

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Strengths	Limitations
• PCR-confirmed RSV infections • Multinational study • Collected serum samples to assess pharmacokinetics • Assessed antidrug antibodies	• Generalizability to high-risk infants is limited • Sponsored by manufacturer

Source: *N Engl J Med*. 2022;386(9):837-846.

Conclusions

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Author's Conclusions

- A single fixed dose of monoclonal antibody nirsevimab provided protection against medically attended RSV-associated LRTI when given to healthy late-preterm and term infants before an RSV season.

Presenter's Conclusions

- Nirsevimab shows promising results for use in healthy late-preterm and term infants to prevent RSV infections requiring medical intervention.
- However, based on this trial alone, it does not provide evidence for infants that are most at risk for severe RSV infections and more studies are needed to evaluate generalizability to these populations.

Source: *N Engl J Med*. 2022;386(9):837-846.

HARMONIE Trial

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Nirsevimab for Prevention of Hospitalizations Due to RSV in Infants

S.B. Drysdale, K. Cathie, F. Flamein, M. Knuf, A.M. Collins, H.C. Hill, F. Kaiser, R. Cohen, D. Pinquier, C.T. Felter, N.C. Vassilouthis, J. Jin, M. Bangert, K. Mari, R. Nteene, S. Wague, M. Roberts, P. Tissières, S. Royal, and S.N. Faust, for the HARMONIE Study Group*

Purpose: to determine the efficacy and safety of a single IM injection of nirsevimab as compared with standard care in preventing RSV-associated hospitalizations in infants ≤12 months of age who are ineligible to receive palivizumab

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Study Design

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- Ongoing pragmatic phase 3b, open-label, two-group, randomized trial from August 8, 2022, through February 28, 2023
- **Randomization:** 1:1 ratio with stratification according to country and age group to receive nirsevimab or standard care
- **Location:** 235 sites in France, Germany, and the UK
- **Follow up:** 366 days

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Study Design, *continued*

- **Intervention:**

Nirsevimab

- < 5 kg: 50 mg IM injection for 1 dose
- ≥ 5 kg: 100 mg IM injection for 1 dose

Standard care

- No intervention

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Study Design, *continued*

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Primary Endpoint

- Hospitalization for RSV-associated LRTI during the RSV season

Secondary Endpoints

- Very severe RSV-associated LRTI
- Hospitalization for RSV-associated LRTI in each country
- Hospitalization for LRTI from any cause

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Study Design: Safety

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Nonserious adverse events

Adverse events of special interest

- Hypersensitivity reactions, including anaphylaxis, immune complex disease, and thrombocytopenia

Medically attended adverse events

- Prompted the infant's parents or legal guardians to seek unplanned in-person medical advice in any clinical setting

Serious adverse events

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Study Design, *continued*

McLeod Health

Inclusion	Exclusion
• Healthy infants • Born at gestational age of ≥29 weeks • ≤1 year of age • Entering into first RSV season	• Met eligibility to receive palivizumab (Synagis) • RSV at time of randomization • LRTI at the time of randomization • Moderate or severe illness or febrile illness on day of intervention administration • Known or suspected congenital or acquired immunodeficiency • Thrombocytopenia • Bleeding disorder or anticoagulant in the 3 weeks prior to randomization • Mother received RSV vaccine during pregnancy

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Statistical Analysis

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Utilized cluster-adjusted regression models

Primary Endpoint

- Event driven analysis
- 61 infants hospitalized for RSV-associated LRTI in three countries combined

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Baseline Characteristics

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Characteristic	Nirsevimab (N=4037)	Standard (N=4021)
Age		
≤3 months	48.6%	48.6%
>3 to ≤6 months	23.8%	23.7%
>6 months	27.6%	27.7%
Gestational Age		
<37 weeks	14%	13.5%
≥37 weeks	85.1%	85.4%
Male Sex	51.7%	52.4%
Country		
France	27%	27%
Germany	22.2%	22.2%
United Kingdom	50.8%	50.7%

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Results

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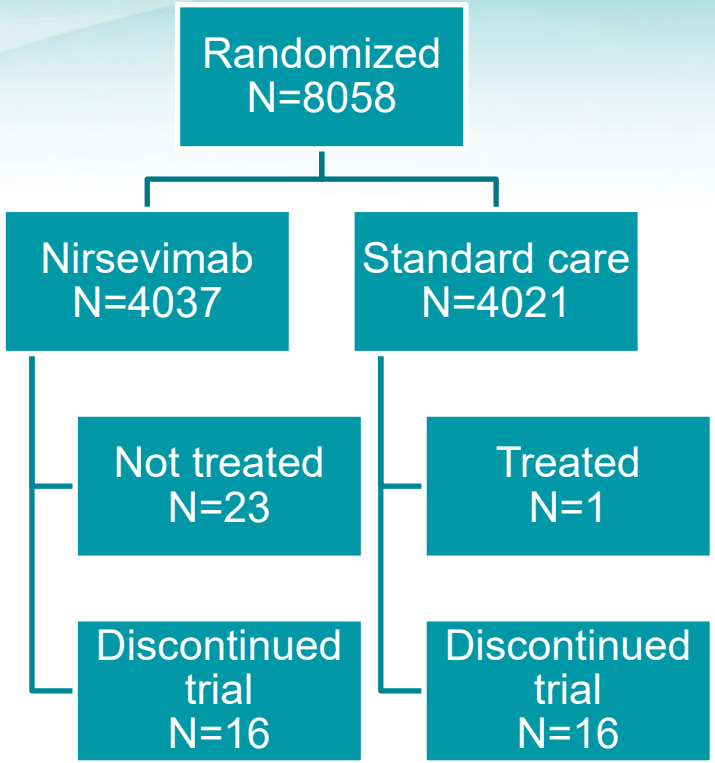


Source: *N Engl J Med*. 2023;389(26):2425-2435.

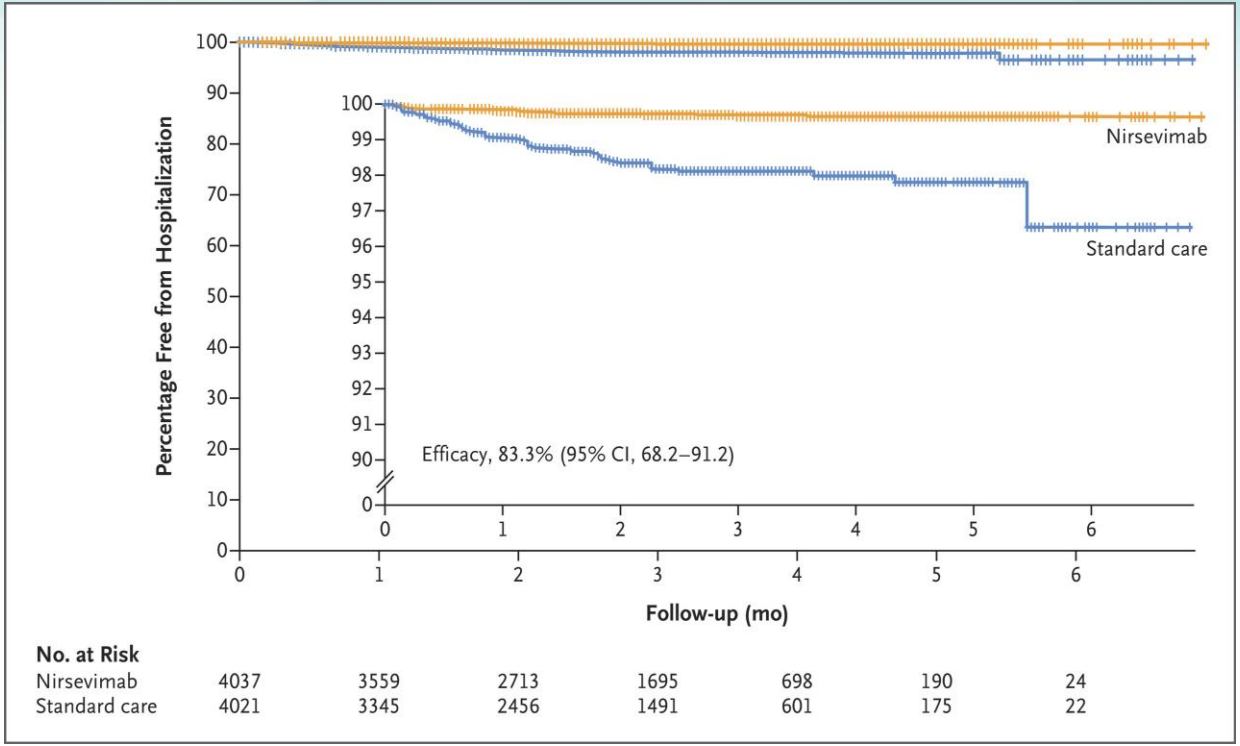
Results, *continued*

McLeod Health

Endpoint and Analysis	Nirsevimab (N= 994)	Standard (N= 496)	Efficacy (95% CI)	P Value
Hospitalization for RSV-associated LRTI	11 (0.3%)	60 (1.5%)	83.2 (67.8 to 92)	<0.001
Very severe RSV-associated LRTI	5 (0.1%)	19 (0.5%)	75.7 (32.8 to 92.9)	0.004
Prevention of hospitalization				
France			89.6 (58.8 to 98.7)	<0.001
Germany			74.2 (27.9 to 92.5)	0.006
United Kingdom			83.4 (34.3 to 97.6)	0.003
Hospitalization for LRTI of any cause	45 (1.1%)	98 (2.4%)	58 (39.7 to 71.2)	

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Results, *continued*



No. at Risk							
Nirsevimab	4037	3559	2713	1695	698	190	24
Standard care	4021	3345	2456	1491	601	175	22

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Results: Safety

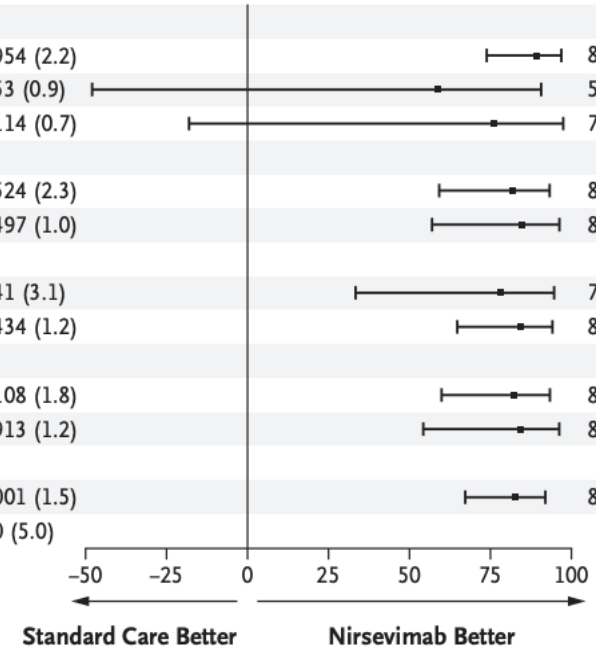
McLeod Health

Variable	Nirsevimab (N= 4015)	Standard (N= 4020)
Any adverse event	1479 (36.8%)	1326 (33%)
Serious Event	89 (2.2%)	67 (1.7%)
Any medically attended event	1185 (29.5%)	1102 (27.4%)
Overall respiratory, thoracic, and mediastinal disorders	184 (4.6%)	196 (4.9%)
Overall gastrointestinal disorders	168 (4.2%)	151 (3.8%)

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Results

Subgroup	Nirsevimab	Standard Care	Efficacy (95% CI)
	no. of infants with event/total no. (%)		
Age at randomization			
≤3.0 mo	5/1962 (0.3)	43/1954 (2.2)	89.6 (73.8 to 96.8)
>3.0 to 6.0 mo	4/959 (0.4)	9/953 (0.9)	58.7 (–47.9 to 90.7)
>6.0 mo	2/1116 (0.2)	8/1114 (0.7)	76.5 (–17.9 to 97.6)
Weight at randomization			
<5 kg	7/1537 (0.5)	35/1524 (2.3)	82.1 (59.1 to 93.3)
≥5 kg	4/2500 (0.2)	25/2497 (1.0)	85.2 (57.0 to 96.2)
Gestational age			
<37 wk	4/567 (0.7)	17/541 (3.1)	78.3 (33.5 to 94.7)
≥37 wk	7/3434 (0.2)	41/3434 (1.2)	84.4 (64.9 to 94.1)
Sex			
Male	7/2087 (0.3)	37/2108 (1.8)	82.4 (60.0 to 93.4)
Female	4/1950 (0.2)	23/1913 (1.2)	84.4 (54.2 to 96.1)
Timing of randomization			
During the RSV season	11/4020 (0.3)	59/4001 (1.5)	83.0 (67.3 to 91.9)
Before the RSV season	0/17 (0.0)	1/20 (5.0)	NC



Source: *N Engl J Med*. 2023;389(26):2425-2435.

Strengths & Limitations

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Strengths	Limitations
• Administration more closely reflective of real-world practice • Multinational population • Clinically meaningful primary endpoint	• Events rate lower than expected • Hospitalization is clinician dependent • Open-label

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Conclusions

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Author's Conclusions

- The HARMONIE trial showed that nirsevimab prevented hospitalization for RSV-associated LRTI and very severe RSV-associated LRTI in a broad population of healthy preterm and term infants.

Presenter's Conclusions

- This trial showed nirsevimab in the context of real-world administration was still effective at preventing hospitalization for RSV-associated LRTI in healthy term and preterm infants.
- Inclusion of preterm infants broadened generalizability, but further postmarketing data will need to be assessed to better inform use in other high-risk populations.

Source: *N Engl J Med*. 2023;389(26):2425-2435.

Future Directions

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Effectiveness in high-risk populations

- Observational, post-marketing assessment

Second RSV season use

- Optimization of repeat dosing strategies

Integration with maternal vaccination

- Defining complementary prevention strategies

Clesrovimab (Enflonsia)

McLeod Health

- **MOA:** neutralizes RSV by inhibiting conformation changes in the F protein necessary for fusion of the viral and cellular membranes and viral entry
- **Dose:** 105 mg administered as a single IM injection
- **Indication:** prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season

Source: *Merck (2025)*.

Clesrovimab (Enflonsia)

McLeod Health

	MELODY (Nirsevimab)	CLEVER (Clesrovimab)
Trial Phase	Phase 3	Phase 2b–3
Design	Randomized, double-blind, placebo-controlled	Randomized, double-blind, placebo-controlled
Population	~1,490 healthy late-preterm & term infants	~3,614 healthy preterm & term infants
Dose	Weight-based (50 mg / 100 mg)	Fixed 105 mg IM
Primary Endpoint	RSV-associated medically attended LRTI	RSV-associated medically attended LRTI
Primary Efficacy	~74.5% reduction	60.4% reduction
RSV Hospitalization Reduction	~62%	84.2%
Follow-Up	150 days	150 days
Safety	Similar to placebo	Similar to placebo

Source: *Merck (2025).*

Knowledge Check #1

McLeod Health

Which of the following best describes the mechanism of action of nirsevimab in preventing respiratory syncytial virus (RSV)?

A. Stimulates the infant's immune system to produce RSV-specific antibodies
B. Directly neutralizes RSV by binding to the viral F protein, preventing fusion and entry into cells
C. Activates T-cell-mediated immunity against RSV
D. Inhibits viral replication through RNA polymerase suppression

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McLeod Health

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Knowledge Check #2

McLeod Health

Which of the following are evidence-based recommendations from the CDC and AAP regarding the eligibility and time of administration for nirsevimab?

A. Only preterm infants born before 35 weeks
B. All infants younger than 8 months entering or during their first RSV season
C. Only infants with chronic lung or heart disease
D. Infants 12-24 months old during RSV season

Knowledge Check #2

McLeod Health

Which of the following are evidence-based recommendations from the CDC and AAP regarding the eligibility and time of administration for nirsevimab?

A. Only preterm infants born before 35 weeks
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D. Infants 12-24 months old during RSV season

Knowledge Check #3

McLeod Health

Utilizing key clinical evidence and best practices, which conclusion best reflects the findings of the MELODY trial regarding the safety and efficacy of nirsevimab?

A. Nirsevimab significantly reduced RSV-related hospitalizations with a safety profile comparable to placebo.
B. Nirsevimab increased adverse reactions compared with placebo.
C. Palivizumab was found to be more effective in preventing RSV infection.
D. Nirsevimab required monthly dosing for consistent protection.

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Thank you!!

Somer Pye, PharmD
PGY-1 Pharmacy Resident
somer.pye@mcleodhealth.org