Maternal/Pediatric Respiratory Syncytial Virus (RSV) Session

Session Introduction

Advisory Committee on Immunization Practices Meeting
June 25, 2025

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

- RSV can infect the small airways in the lungs, particularly in infants
- 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 are hospitalized for RSV[3,4,5]
  - ~80% of children hospitalized with RSV age <2 years have no underlying medical conditions[3]
- Prior to 2023, no long-acting* products were available for the prevention of severe RSV disease

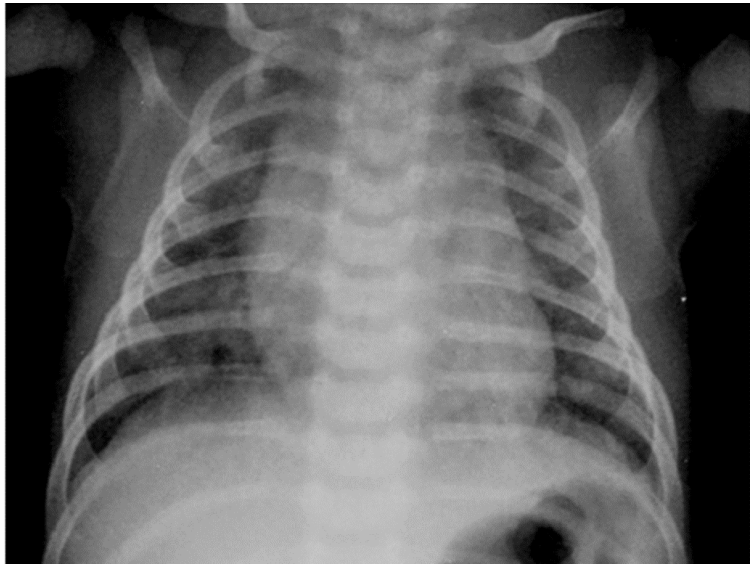


Image: Goncalves et al. Critical Care Research and Practice 2012

*Long-acting is defined as any product that requires one dose to provide protection during an RSV season

References: 1) Suh et al, JID (2022): https://doi.org/10.1093/infdis/jiac120 2) Glezen et al, Arch Dis Child (1986): https://doi.org/10.1001/archpedi.1986.02140200053026 3) Hall et al, Pediatrics (2013): https://doi.org/10.1542/peds.2013-0303 4) Langley et al, PIDJ (2011): https://doi.org/10.1097/INF.0b013e3182184ae7 5) Curns et al, Pediatrics (2024): https://doi.org/10.1542/peds.2023-062574

In 2023 two products were approved by FDA and subsequently recommended by CDC and ACIP

Maternal RSV vaccine

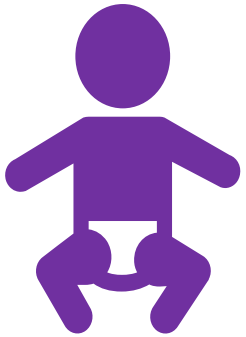
Abrysvo, Pfizer

Pregnant women 32 through 36 weeks' gestation

Administer September through January in most of the continental United States†

Nirsevimab

Beyfortus, Sanofi & AstraZeneca



All infants ages <8 months*

Second season dose for children ages 8–19 months at increased risk of severe RSV disease

Administer October through March in most of the continental United States† (as early as possible¥)

*_**Either**_ maternal RSV vaccine or nirsevimab is given to protect infants against severe RSV disease – only one is needed in most instances

† Timing of administration for RSV immunization may differ in jurisdictions with RSV seasonality that differs from most of the continental United States; ¥ The optimal timing for nirsevimab administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization.)

Today the committee will be considering a recommendation for a newly FDA-approved product

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Clesrovimab

Enflonasia, Merck

Approved by FDA on 6/9/2025

All infants ages <8 months*

Administer October through March in most of the continental United States† (as early as possible¥)

*_**Either**_ maternal RSV vaccine or an infant antibody is given to protect infants against severe RSV disease – only one is needed in most instances

† Timing of administration for RSV immunization may differ in jurisdictions with RSV seasonality that differs from most of the continental United States; ¥ The optimal timing for nirsevimab administration is shortly before the RSV season begins (e.g., October–November), or within a baby's first week of life if born October through March (ideally during the birth hospitalization.)

Timeline of work group and ACIP review of clesrovimab

- **September 2024:** Maternal/pediatric RSV work group reviewed and discussed data from Merck on safety and efficacy of clesrovimab
- **October 2024:** ACIP reviewed and discussed data from Merck on safety and efficacy of clesrovimab and the maternal/pediatric work group's interpretation of these data
- **November 2024 – April 2025:** Maternal/Pediatric RSV work group reviewed and discussed
  - GRADE[1,2] (Grading of Recommendations, Assessment, Development, and Evaluations) for clesrovimab
  - Evidence to Recommendation Framework[2] for clesrovimab
- **April 2025:** ACIP reviewed and discussed the Evidence to Recommendation Framework and GRADE for clesrovimab
- **June 2025 (Today):** ACIP will be presented with recap of the Evidence to Recommendations Framework and vote on clesrovimab

References: 1) Ahmed et al, Vaccine (2011): https://doi.org/10.1016/j.vaccine.2011.08.005 2) Lee et al, MMRW (2018): https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a4.htm

Additional data reviewed by the work group since the April 2025 ACIP meeting

- **April – June 2025:** The work group reviewed data on uptake, safety, and effectiveness of maternal RSV vaccine and long-acting monoclonal antibody from the 2024-2025 season
- **June 2025 (Today):** ACIP will be presented with these data as well as the work group interpretation

Today’s agenda: June 25, 2025

- **Updates on administration and uptake of maternal RSV vaccine and long-acting monoclonal antibody**— Dr. Georgina Peacock (CDC/NCIRD)
- **Updates on effectiveness and impact of maternal RSV vaccine and long-acting monoclonal antibody**— Dr. Adam MacNeil (CDC/NCIRD)
- **Safety of maternal RSV vaccine and long-acting monoclonal antibody**— Dr. Malini DeSilva (HealthPartners Institute) & Dr. Matthew F. Daley (Kaiser Permanente Institute for Health Research)
- **Evidence to Recommendation Framework: Clesrovimab**— Dr. Adam MacNeil (CDC/NCIRD)
- **Clinical considerations and work group interpretation**— Dr. Adam MacNeil (CDC/NCIRD)

Thank you

For more information, contact CDC
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