Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

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Presenting on behalf of
Helen Chu, MD, MPH
Chair, Maternal/Pediatric RSV Work Group

ACIP Meeting

April 16, 2025

CDC and ACIP recommend all infants should be protected against severe RSV disease with either maternal RSV vaccine or nirsevimab

Maternal 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 <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 we will be reviewing data on a second, long-acting monoclonal antibody for protection of infants from severe RSV disease

Maternal 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 <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¥)

Clesrovimab

Merck

Currently not FDA approved

Target action date: 6/10/25

All infants <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 Maternal/Pediatric RSV 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 work group interpretation of these data
- **November 2024 – April 2025**
  - Maternal/Pediatric RSV work group reviewed and discussed
    - GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) for clesrovimab
    - Evidence to Recommendations Framework for clesrovimab

Today’s agenda: April 16, 2025

- **Evidence to Recommendation Framework: Clesrovimab** — Ms. Danielle Moulia (CDC/NCIRD)
- **Clinical Considerations** — Dr. Jefferson Jones (CDC/NCIRD)

Clesrovimab: Looking forward

- FDA has set a Prescription Drug User Fee Act (PDUFA) date, or target date for regulation action, of June 10, 2025, for clesrovimab.
- **June 2025** ACIP meeting
  - Presentation of any updates to the Evidence to Recommendation Framework and Clinical Consideration for clesrovimab
  - Vote on recommendation of clesrovimab (pending FDA regulatory action)

Source: Merck Press Release, 12/17/2024: https://www.merck.com/news/merck-announces-fda-acceptance-of-biologics-license-application-for-clesrovimab-an-investigational-long-acting-monoclonal-antibody-designed-to-protect-infants-from-rsv-disease-during-their-first-rsv/

Work group members (external)

ACIP Members

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Liaisons

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Work group members (CDC)

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Suzanne Heitfeld

Molly Gaines-McCollom

Amber Rose Kautz

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Thank you

For more information, contact CDC
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