

# **Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group**

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**Co-Lead, Maternal/Pediatric RSV Work Group**

**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\*

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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)

# Work group members (external)

## ACIP Members

Helen Chu (chair)

Oliver Brooks

Denise Jamieson

## Liaisons

James McAuley (IDSA)

Nicole Chaisson (AAFP)

Sean O’Leary (AAP)

Jennifer Schuster (PIDS)

Molly Howell (AIM)

Stacy Buchanan (NAPNAP)

Caitlin Newhouse (CSTE)

## Ex Officio Members

Lucia Lee (FDA-CBER)

Yodit Belew (FDA-CDER)

Prabha Viswanathan (FDA-CDER)

Yugenia Hong-Nguyen (FDA-CDER)

Sonnie Kim (NIH-NIAID)

April Killikelly (Public Health Agency of Canada)

Elissa Abrams (Public Health Agency of Canada)

Jessica Lee (CMS/CMCS)

Terry Dalle-Tezze (HRSA)

Matthew Clark (IHS)

## Consultants

Cody Meissner (Dartmouth Geisel School of Medicine)

Kevin Ault (Western Michigan University)

Pablo Sanchez (Nationwide Children’s Hospital)

# Work group members (CDC)

## CDC

Jefferson Jones (co-lead)  
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## CDC ACIP Staff

Melinda Wharton  
Stephanie Thomas  
Jessica MacNeil



# Thank you

For more information, contact CDC  
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.

