

Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group

Jefferson Jones MD MPH FAAP
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

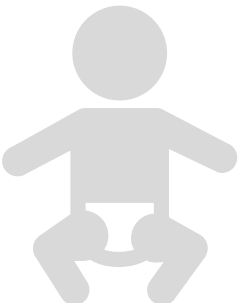


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Clesrovimab

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

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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)
Danielle Moulia (co-lead)
Meredith McMorrow
Mila Prill
Natalie Thornburg
Ismael Ortega-Sanchez
Melissa Coughlin
Jamison Pike
Lauren Roper
Tami Skoff
Angie Campbell
Michael Melgar
Amadea Britton

Amanda Payne
Noelle Molinari
Fiona Havers
Pragna Patel
Ruth Link-Gelles
Monica Godfrey
Heidi Moline
Hannah Rosenblum
Manisha Patel
Heather Scobie
Michele Hlavsa

Monica Patton
Jarrett Gartin
Dennis Wang
Jordan Singleton
Fatimah Dawood
Agustin Lopez
Lakshmi Panagiotakopoulos
Suzanne Heitfeld
Molly Gaines-McCollom
Amber Rose Kautz
Allison Ciesla

Christine Olson
Anne Hause
Andrew Leidner
David Shay
Pedro Moro
Tarayn Fairlie
John Su
Micheal McNeal
Julianne Gee
Naomi Tepper
Ellen Boundy
Alaya Koneru
Melissa Taylor
Ebony Thomas

CDC ACIP Staff

Melinda Wharton
Stephanie Thomas
Jessica MacNeil

Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 [cdc.gov](https://www.cdc.gov)

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.

