Next Steps for the ACIP Maternal & Pediatric RSV Work Group

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ACIP General Meeting
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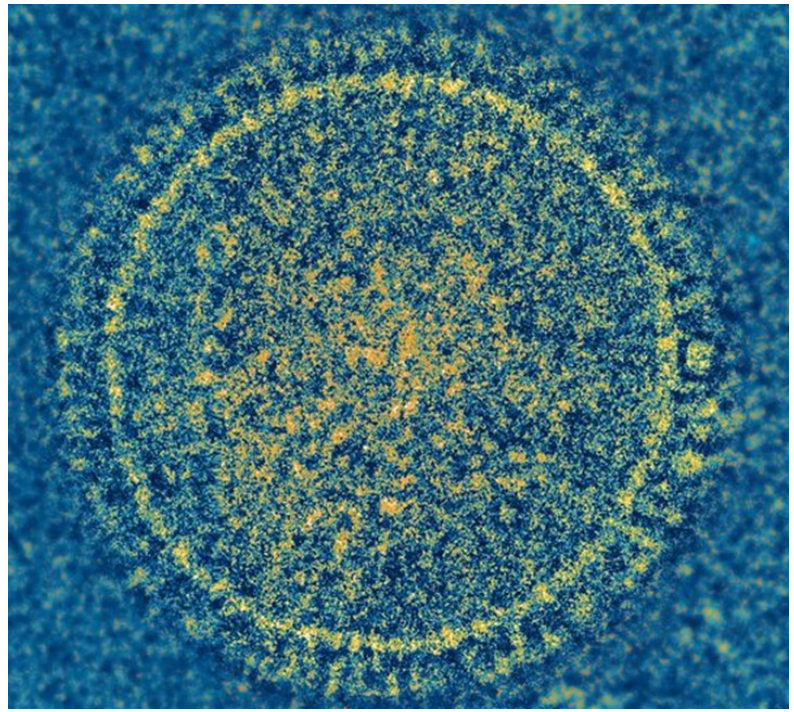

Policy questions being considered by the work group

- Should nirsevimab be recommended for all infants <8 months of age entering their first RSV season and all infants born during the RSV season?

- Should nirsevimab be recommended for children <24 months of age entering their second RSV season who remain at increased risk of severe disease?

Evidence reviewed by the work group includes but not limited to

- Epidemiology and burden of RSV in infants
  - RSV seasonality in the United States
  - Outpatient, emergency department visits, hospitalizations, and deaths
- Virology
- Safety and efficacy of nirsevimab
  - Phase 3 study in infants born ≥35 weeks gestation (initial and updated results)
  - Phase 2b study in infants born 29–34 weeks gestation
  - Phase 2/3 safety and pharmacokinetic study in infants eligible for palivizumab (including 2nd season)

Evidence to be reviewed by the work group

- Review evidence to identify children <24 months of age entering their second RSV season who remain at increased risk of severe disease
- GRADE of evidence
- Cost effectiveness analysis
- Evidence to Recommendations (EtR)
  - Public health problem
  - Benefits and harms
  - Values
  - Equity
  - Resource use
  - Acceptability
  - Feasibility

Proposed timeline of future ACIP presentations (tentative)

- February 2023
  - Summary of GRADE
  - Cost effectiveness analysis
  - EtR
- June 2023
  - ACIP vote (if product is licensed by this time)

- Agenda items might be added if data on additional products become available

For more information, contact CDC
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