



## Preventing RSV Infections in Infants

### CLINICAL QUESTION

**How safe and effective are monoclonal antibodies to prevent respiratory syncytial virus (RSV) infections in infants?**

### BOTTOM LINE

**In high-risk infants (premature and/or congenital heart or lung conditions), palivizumab (4-5 doses monthly during RSV season) reduces RSV hospitalization (4.5% versus 10% placebo). Nirsevimab (one dose) reduces RSV hospitalizations in healthy premature infants (0.8% versus 4%) and term infants (0.3-0.4% versus 1.5-2.0%). Side effects are similar to placebo.**

### EVIDENCE

- From highest quality systematic review or key randomized controlled trials (RCTs). Comparisons statistically different unless indicated.
- Palivizumab: 4-5 doses monthly during RSV season;
  - Systematic review (5 RCTs, 3443 infants)<sup>1</sup> with two dominant placebo-controlled RCTs: Infants born <35 weeks or with bronchopulmonary dysplasia<sup>2</sup> or congenital heart disease.<sup>3</sup> At two years:
    - RSV hospitalization: 4.4% versus 9.8% (placebo), relative risk reduction (RRR)=55%; number needed to vaccinate (NNV)=19.
    - Mortality: 1.3% versus 2.3% placebo (not statistically different).

- Nirsevimab: Single-dose; given before/during RSV season.<sup>4-7</sup>
  - Versus placebo:
    - Premature, healthy: 1453 infants (born between 29-35 weeks).<sup>4</sup> At 150 days:
      - RSV hospitalization: 0.8% versus 4.1% (placebo); RRR=81%; NNV=3.
      - Mortality (after one year) 0.2% versus 0.6% placebo, not statistically different (PEER calculation).
    - Term/near-term, healthy: 3012 infants.<sup>5,6</sup> At 150 days:
      - RSV hospitalizations: 0.4% versus 2.0% (placebo): RRR=78%; NNV=63.
      - Deaths (after one year): 3 nirsevimab versus 0 placebo (none attributed to nirsevimab or RSV).
  - Versus no treatment (unblinded):
    - 8058 infants: 85% born  $\geq$ 37 weeks.<sup>7</sup> At three months:
      - RSV hospitalizations: 0.3% versus 1.5% (no treatment); RRR=82%, NNV=82.
      - One-year data forthcoming.
- Adverse events: Similar between palivizumab, nirsevimab and placebo.<sup>1,4-8</sup>
- Limitations: Many RCT authors were shareholders/employees of industry funder.<sup>4,5</sup>

## CONTEXT

- In Canada, RSV responsible for ~2,500 childhood hospitalizations annually.<sup>9</sup> Of those hospitalized:
  - ~80% had no underlying medical conditions, were <2 years old.<sup>10</sup>
  - Mortality: 2/1000.
- In Canada, palivizumab recommended for high-risk infants:<sup>11</sup>
  - Prematurity (<30 weeks).
  - <2 years with chronic lung/congenital heart disease.
  - Living in remote/northern communities.
- Nirsevimab:
  - Anticipated Canadian availability/guidance/pricing:<sup>12</sup> 2024.
  - Versus palivizumab: Less costly (per patient).<sup>13</sup>
  - In US, recommended for all infants <8 months entering first RSV season.<sup>10</sup>
    - Second season: for high-risk infants (8-19 months).

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