- Despite 50 years of vaccine research, there is no safe and effective vaccine for respiratory syncytial virus (RSV), and passive immunity with palivizumab is the only means available for the prevention of serious lower respiratory tract infection (LRTI) caused by RSV in pediatric patients at high risk of RSV disease.
- We conducted a comprehensive systematic literature review of randomized controlled trials, open-label non-comparative clinical trials, and prospective observational studies/registries to describe the safety, efficacy, and effectiveness of palivizumab for reducing the risk of serious RSV LRTI in high-risk infants and children.
- A meta-analysis of the RSV-related hospitalization rate from 5 randomized, placebo-controlled trials yielded an overall odds ratio of 0.41 (95% CI, 0.31–0.55) in favor of palivizumab prophylaxis over placebo (P <0.00001).
- Rates of RSV hospitalizations and RSV hospitalization–related endpoints have remained consistently low over time in more than 42,000 pediatric subjects who received prophylaxis with palivizumab across 7 randomized controlled trials, 4 open-label non-comparative trials, and 8 observational studies or registries conducted in 34 countries.
- Palivizumab has shown an acceptable safety profile, including a low incidence of anti-palivizumab antibodies, in children with bronchopulmonary dysplasia, infants with a history of prematurity, and children with hemodynamically significant congenital heart disease.

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