

PL-06

Nirsevimab as a key strategy to prevent respiratory syncytial virus among newborns and children: real-world evidence from Italy and Sicily

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Background. Respiratory syncytial virus (RSV) is one of the leading causes of lower respiratory tract infections and hospitalization during the first year of life. The introduction of the next-generation long-acting monoclonal antibody Nirsevimab across the Italian Regions, starting from the 2024/25 season, has substantially changed RSV prevention. Administered as a single dose, Nirsevimab has extended protection to all infants during their first RSV season, thereby overcoming the main limitations associated with Palivizumab.

Materials and Methods. A non-systematic review of the scientific literature was conducted, focusing on real-world effectiveness (RWE) studies carried out in Italy following the introduction of Nirsevimab during the 2024/2025 season. The main outcomes analyzed included hospitalizations, disease severity, and admissions to intensive care units (ICUs).

Results. Real-world effectiveness data available in the scientific literature from different Italian regions have confirmed the high effectiveness of Nirsevimab observed in clinical trials, in line with findings reported in the international literature. A recent meta-analysis of 27 studies conducted in Europe and the United States estimated an 83% reduction in hospitalizations, an 81% reduction in intensive care unit admissions, and a 75% reduction in the incidence of RSV lower respiratory tract infections (LRTIs). Studies conducted in Italy have reported immunization effectiveness in real-world settings exceeding 85% in preventing severe RSV disease, over 80% in preventing RSV-related hospitalizations in neonatal intensive care units (NICUs) or pediatric wards, and over 70% in preventing emergency department visits for RSV-related illness. Studies based on Italian and Sicilian Hospital Discharge Records have also shown that RSV-related hospitalizations were more than halved during the first season of monoclonal antibody use across different Italian regions, including Sicily.

Conclusions. The Italian experience suggests that Nirsevimab represents a paradigm shift in the natural history of RSV disease, with a substantial impact on both the hospital and community healthcare burden. The effectiveness of Nirsevimab can translate into a meaningful public health benefit only if high immunization coverage is achieved, ensuring protection for both in-season and out-of-season births, the latter currently representing a key challenge, with lower uptake rates. It is also important to document informed parental refusal among those who decline prophylaxis and to ensure re-immunization during the second RSV season for vulnerable children (i.e., the former palivizumab-eligible cohort). Furthermore, RespivirNet surveillance data should guide the definition of the immunization window on an annual basis, including consideration of a possible extension of immunization at birth through April 30, in view of the progressively later onset of RSV circulation at both the community and hospital levels, particularly in Southern Italian regions. In summary, nirsevimab represents not merely a new preventive strategy, but a paradigm shift: a true revolution in RSV prevention.

Note. The project is part of the Italian Complementary National Plan PNC-I.1 "Research initiatives for innovative technologies and pathways in the health and welfare sector" D.D. 931 of 06/06/2022, "DARE - DigitAl lifelong pRevEntion" initiative, "Digivax" Pilot Project - code PNC0000002, CUP: B53C22006460001.

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