

Comparative Analysis of Reported Adverse Events with Nirsevimab and Palivizumab: A FAERS Observational Study

Ibrahim Touffaha, MS-2¹, Elizabeth Ablah, Ph.D.², Hayrettin Okut, Ph.D.²,
Gretchen Homan, M.D.³

¹The University of Kansas School of Medicine-Wichita, Wichita, Kansas

²The University of Kansas School of Medicine-Wichita, Wichita, Kansas, Department of
Population Health

³The University of Kansas School of Medicine- Wichita, Wichita, Kansas, Department of
Pediatrics

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Introduction. Respiratory syncytial virus (RSV) is a leading cause of hospitalization among infants worldwide. Passive immunization remains central to prevention. Palivizumab has been used for over two decades, whereas nirsevimab, approved in 2023, provides extended protection with a single dose. However, comparative post-marketing safety data between these agents remain limited. Authors compared post-marketing adverse event profiles of nirsevimab and palivizumab using the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS).

Methods. FAERS reports from July 2023 to March 2025 were analyzed. Reports were included if patients were ≤ 2 years of age and either nirsevimab or palivizumab was listed as the primary suspect drug. Duplicate and incomplete records were excluded. Adverse events were classified using Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) categories. Group comparisons were performed using chi-square or Fisher's exact tests as appropriate. Logistic regression was used to identify SOCs disproportionately associated with each drug.

Results. A total of 2,021 reports met inclusion criteria (nirsevimab = 641; palivizumab = 1,380). Hospitalization was reported in 50% of nirsevimab cases and 70% of palivizumab cases, while deaths were reported in 5.9% and 9.8% of cases, respectively. Logistic regression identified three SOCs reported more frequently with nirsevimab: injury, poisoning, and procedural complications (OR 11.9, $p < 0.0001$), nervous system disorders (OR 2.9, $p = 0.029$), and skin and subcutaneous tissue disorders (OR 4.5, $p = 0.002$). No SOCs were reported more frequently with palivizumab.

Conclusions. Nirsevimab and palivizumab demonstrated broadly comparable post-marketing safety profiles. Higher reporting of administration-related adverse events for nirsevimab likely reflects its recent introduction and reporting patterns rather than inherent differences in safety.