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Drug assessment at a glance: A26-67[1]

Clesrovimab (secondary prevention of RSV lower respiratory tract disease)

21 October 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-67. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Children during their first RSV season with an indication for secondary prevention of RSV lower respiratory tract disease
Intervention	clesrovimab
Comparator	nirsevimab or palivizumab (for children with risk factors as specified in the respective marketing authorisation)
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity (RSV lower respiratory tract infection)	↔	–
Symptoms	ø	–
Health-related quality of life	ø	–
Side effects	↔	–
	ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage

Evidence base and noteworthy aspects

- Evidence base: MK-1654-007, a partially blinded RCT comparing clesrovimab (N = 502) with palivizumab (N = 501) in children during their first and second RSV seasons

- The study population may have included children who are not covered by the research question. These included preterm infants aged ≥6 months, as well as children with bronchopulmonary dysplasia who had not received any treatment in the previous 6 months.
- The recording of the outcomes in the side effects category was potentially incomplete and notably shortened.
- Structural equality between the groups was not maintained for the follow-up of SAEs during the second RSV season for children who did not again receive secondary prevention, as these children were either further followed up on the basis of progression parameters or again received secondary prevention and were therefore excluded from the analysis.

Key study findings

Study Outcome category Outcome	clesrovimab N	clesrovimab Patients with event n (%)	palivizumab N	palivizumab Patients with event n (%)	clesrovimab vs. palivizumab RR [95% CI]; p-value
MK-1654-007					
Mortality					
All-cause mortality	497	8 (1.6)	499	4 (0.8)	2.01 [0.61; 6.63]; 0.248
Morbidity (Day 180)					
RSV lower respiratory tract infection	495	16 (3.2)	485	16 (3.3)	0.98 [0.50; 1.94]; 0.997
Hospitalisations	495	–	485	–	–
Outpatient care	495	–	485	–	–
Health-related quality of life	Outcomes from this category were not recorded.				
Side effects					
AEs (Day 42; shown as supplementary information)	497	364 (73.2)	499	345 (69.1)	–
SAEs	497	122 (24.5)	499	137 (27.5)	0.89 [0.72; 1.10]; 0.302
Severe AEs (Day 42)	497	47 (9.5)	499	48 (9.6)	0.98 [0.67; 1.44]; 0.952
Discontinuation due to AEs	497	0	499	0	–

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Clesrovimab (Sekundärprophylaxe von RSV-Erkrankungen der unteren Atemwege); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 08.09.2026]. URL: https://doi.org/10.60584/A26-67.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Clesrovimab (Sekundärprophylaxe von RSV-Erkrankungen, Kinder während ihrer 1. RSV-Saison) [online]. 2026 [Accessed: 08.09.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1352/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-67.html.

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