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Drug assessment at a glance: A26-13[1]

Gadopiclenol (contrast-enhanced magnetic resonance imaging, from birth to < 2 years)

29 July 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 A26-13. The G-BA decides on the added benefit.

Research question for the benefit assessment

Population	Children from birth to < 2 years of age for contrast-enhanced MRI to improve detection and visualization of pathologies with disruption of the blood-brain-barrier and/or abnormal vascularity of: ▪ the brain, spine and associated tissues of the CNS ▪ the liver, kidney, pancreas, breast, lung, prostate and musculoskeletal system It should be used only when diagnostic information is essential and not available with unenhanced MRI.
Intervention	gadopiclenol
Comparator	gadoteric acid or gadobutrol or gadoteridol
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ 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 (no suitable data)

Evidence base and noteworthy aspects

- No suitable data were available. Due to the study designs, the data presented for the single-arm gadopiclenol studies GDX-44-015 and GDX-44-014 did not allow for a comparison versus the comparator therapy.

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Gadopiclenol (kontrastverstärkte Magnetresonanztomografie, ab Geburt bis < 2 Jahre); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 29.07.2026]. URL: https://doi.org/10.60584/A26-13.

Gemeinsamer Bundesausschuss. Nutzenbewertungsverfahren zum Wirkstoff Gadopiclenol (Neues Anwendungsgebiet: Kontrastverstärkte Magnetresonanztomographie, 0 bis < 2 Jahre) [online]. 2026 [Accessed: 29.07.2026]. URL: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1316/.

English translations for this project are published at https://www.iqwig.de/en/projects/a26-13.html.

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