Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Gadopiclenol (new therapeutic indication: contrast-enhanced magnetic resonance imaging, 0 to < 2 years)

From 20 August 2026

At their session on 20 August 2026, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after number 5 to the information on the benefit assessment of gadopiclenol in accordance with the resolution of 19 September 2024:

Gadopiclenol

Resolution of: 20 August 2026
Entry into force on: 20 August 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 22 January 2026):

This medicinal product is for diagnostic use only.

Gadopiclenol is indicated in adults and children from birth for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of:

- the brain, spine, and associated tissues of the central nervous system (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.

Therapeutic indication of the resolution (resolution of 20 August 2026):

Gadopiclenol is indicated in children from birth up to the age of 2 years for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of:

- the brain, spine, and associated tissues of the central nervous system (CNS);
- the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Children from birth up to the age of 2 years for whom contrast-enhanced magnetic resonance imaging is indicated to improve detection and visualization of pathologies with disruption of the blood-brain-barrier and/or abnormal vascularity in body areas

Appropriate comparator therapy:

- Gadoteric acid or gadobutrol or gadoteridol

Extent and probability of the additional benefit of gadopiclenol compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Children from birth up to the age of 2 years for whom contrast-enhanced magnetic resonance imaging is indicated to improve detection and visualization of pathologies with disruption of the blood-brain-barrier and/or abnormal vascularity in body areas

No assessable data versus the appropriate comparator therapy available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.c.	There are no assessable data.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.c.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: no data available n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

Children from birth up to the age of 2 years for whom contrast-enhanced magnetic resonance imaging is indicated to improve detection and visualization of pathologies with disruption of the blood-brain-barrier and/or abnormal vascularity in body areas

Approx. 20,600 to 22,200 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Elucirem (active ingredient: gadopiclenol) at the following publicly accessible link (last access: 11 August 2026):

https://www.ema.europa.eu/en/documents/product-information/elucirem-epar-product-information_en.pdf

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-13), unless otherwise indicated.

Treatment with gadopiclenol should only be initiated and monitored by trained healthcare professionals with technical experience in performing contrast-enhanced MRIs with gadolinium.

4. Treatment costs

Annual treatment costs:

Children from birth up to the age of 2 years for whom contrast-enhanced magnetic resonance imaging is indicated to improve detection and visualization of pathologies with disruption of the blood-brain-barrier and/or abnormal vascularity in body areas

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Gadopiclenol	€ 135.20
Appropriate comparator therapy:	
Gadobutrol	€ 113.02
Gadoteridol	€ 110.36
Gadoteric acid	€ 75.76

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2026)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the G-BA website on 20 August 2026.

The justification for this resolution will be published on the G-BA website at www.g-ba.de.

Berlin, 20 August 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk