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 (contrast-enhanced magnetic resonance imaging, ≥ 2 years)

of 19 September 2024

At its session on 19 September 2024, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Gadopiclenol as follows:

Gadopiclenol

Resolution of: 19 September 2024
Entry into force on: 19 September 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 7 December 2023):

This medicinal product is for diagnostic use only.

Elucirem is indicated in adults and children aged 2 years and older 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 19 September 2024):

See therapeutic indication according to marketing authorisation.

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

Adults, adolescents and children aged 2 years and older 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 for gadopiclenol:

- Gadobutrol or gadoteridol or gadoteric acid

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:

Adults, adolescents and children aged 2 years and older 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 suitable data versus the appropriate comparator therapy available.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	n.a.	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

Adults, adolescents and children aged 2 years and older 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. 2,900,000 to 3,300,000 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) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 10 September 2024):

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

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:

Adults, adolescents and children aged 2 years and older 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	€ 134.97- € 177.16
Appropriate comparator therapy:	
Gadobutrol	€ 564.87- € 1,861.15
Gadoteridol	€ 104.72 - € 380.80[1]
Gadoteric acid	€ 75.53 - € 338.47

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2024)

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adults, adolescents and children aged 2 years and older 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 the following areas

- No medicinal product with new active ingredients that can be used in a combination therapy and fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

[1] Manufacturer sales price plus 19% VAT

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 September 2024.

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

Berlin, 19 September 2024

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken