Gemeinsamer Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (G-BA) 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

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a paragraph 3 SGB V, the G-BA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient gadopiclenol (Elucirem) was listed for the first time on 1 April 2024 in the “LAUER-TAXE®”, the extensive German registry of available drugs and their prices.

On 22 January 2026, gadopiclenol received marketing authorisation for a new therapeutic indication to be classified as a major type 2 variation as defined according to Annex 2, number 2, letter a to Regulation (EC) No. 1234/2008 of the Commission of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 from 12.12.2008, sentence 7).

On 19 February 2026, i.e. at the latest within four weeks of informing the pharmaceutical company about the approval for a new therapeutic indication, the pharmaceutical company submitted a dossier in accordance with Section 4, paragraph 3, number 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5 Section 8, paragraph 1, number 2 of the Rules of Procedure (VerfO) of the G-BA on the active ingredient gadopiclenol with the new therapeutic indication "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 in body areas".

The G-BA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 June 2026 on the G-BA website at (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

Based on the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements submitted in the written statement and oral hearing procedure, the G-BA decided on the question on whether an additional benefit of risankizumab compared with the appropriate comparator therapy could be determined – Annex XII - Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V. In order to determine the extent of the additional benefit, the G-BA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5 Section 5, paragraph 7 VerfO. The methodology proposed by IQWiG according to the General Methods was not used in the benefit assessment of gadopiclenol – Annex XII - Resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

In the light of the above, and taking into account the statements received and the oral hearing, the G-BA have made the following assessment:

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

2.1.1 Approved therapeutic indication of gadopiclenol (Elucirem) in accordance with the product information

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 20.08.2026):

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.

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

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

Criteria according to Chapter 5 Section 6 of the Rules of Procedure of the G-BA and Section 6 paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5 Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.
3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the G-BA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the G-BA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible add-on therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

Justification based on the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:

On 1. In addition to gadopiclenol, the approved active ingredients gadobenic acid, gadobutrol, gadoteridol, gadoteric acid and gadoxetic acid from the group of paramagnetic MRI contrast agents are available for contrast enhancement in magnetic resonance imaging (MRI) within the scope of the therapeutic indication.

On 2. Non-medicinal treatments are not considered in the present therapeutic indication.

On 3: Within the scope of this therapeutic indication, a resolution on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V is already available for the active ingredient gadopiclenol (resolution of 19 September 2024).

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V.

When determining the appropriate comparator therapy for gadopiclenol in 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, the evidence search identified a systematic review alongside one American and one Canadian guideline that investigate contrast-enhanced imaging procedures in various clinical pictures of, e.g., cardiovascular and neurological diseases as well as hepatocellular carcinoma.

Available evidence and recommendations by scientific-medical societies endorse the use of gadolinium-containing contrast agents.

The gadolinium-containing contrast agents listed above are generally approved for the therapeutic indication under assessment. The therapeutic indication includes contrast enhancement in MRI of the areas of brain, spine and associated tissues of the central nervous system as well as the areas of liver, kidneys, pancreas, breast, lungs, prostate and musculoskeletal system. The active ingredients gadobutrol, gadoteridol and gadoteric acid are eligible according to the marketing authorisation for the contrast enhancement of cranial or spinal MRI as well as for imaging MR examinations of pathological structures in the entire body.

Due to the limitations - specified in the respective marketing authorisations - to the contrast-enhanced examination of only certain organs and body regions, the active ingredients gadobenic acid and gadoxetic acid, which are only approved for MRI examinations of the liver, are not considered to be equally appropriate compared to the active ingredients gadoteric acid, gadobutrol and gadoteridol.

Based on the available evidence, the active ingredients gadoteric acid, gadobutrol and gadoteridol are equally appropriate therapy options in the present therapeutic indication. The marketing authorisation of gadolinium-containing contrast agents must be observed.

The appropriate comparator therapy determined here includes several therapy options. These therapy options are equally appropriate for the comparator therapy. The additional benefit can be demonstrated compared to one of the several therapy options mentioned.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the G-BA based on a prior review of the criteria set out in Chapter 5 Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of gadopiclenol is assessed as follows:

An additional benefit is not proven for 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.

Justification:

No comparator studies were presented by the pharmaceutical company for the assessment of the additional benefit of gadopiclenol. The two single-arm GDX-44-015 and GDX-44-014 studies were presented additionally, but were not used to derive an additional benefit.

The GDX-44-015 study is a non-randomised, single-arm study in children from birth to 23 months of age who were scheduled to undergo routine gadolinium-enhanced MRI of any body area (including the CNS). The pharmaceutical company additionally presented the paediatric, non-randomised, single-arm cohort of the GDX-44-014 study, which enrolled children and adolescents from birth to 18 years of age with an indication for contrast-enhanced MRI of the CNS or the body.

The GDX-44-015 and GDX-44-014 studies do not allow for a comparison with the appropriate comparator therapy and, due to their study design, are unsuitable for mapping the diagnostic-therapeutic pathway with gadopiclenol compared to the diagnostic-therapeutic pathway of the active ingredients in the appropriate comparator therapy.

However, an investigation of the entire diagnostic-therapeutic pathway would not be necessary if it were shown or were sufficiently certain that gadopiclenol has direct patient-relevant advantages over the established contrast agent and their therapeutic consequences do not differ significantly (concordance question). It is assumed that gadopiclenol as a new diagnostic agent is only intended to replace the contrast agents specified in the appropriate comparator therapy, without identifying or excluding additional or other patients.

In their dossier, the pharmaceutical company did not take into account the possibility of a concordance question. Accordingly, they did not gather information that would be suitable for ensuring that all relevant studies for responding to a concordance question are identified.

Overall, no data that fulfil the necessary requirements for the assessment of additional benefit were presented. In the overall assessment, an additional benefit of gadopiclenol compared to the appropriate comparator therapy is therefore not proven.

2.1.4 Summary of the assessment

The present assessment is the benefit assessment of a new therapeutic indication for the active ingredient gadopiclenol.

The therapeutic indication assessed here is as follows: "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."

The G-BA determined therapy with gadobutrol or gadoteridol or gadoteric acid as the appropriate comparator therapy.

The pharmaceutical company did not provide any comparator studies. The two single-arm GDX-44-015 and GDX-44-014 studies were presented additionally, but were not used to derive an additional benefit.

The data presented do not allow for a comparison of the diagnostic-therapeutic pathway, nor do they allow for an assessment of the concordance with regard to the treatment decision following diagnosis, compared to the appropriate comparator therapy.

Overall, no data that fulfil the necessary requirements for deriving an additional benefit were presented. In the overall assessment, an additional benefit of gadopiclenol compared to the appropriate comparator therapy is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

The G-BA takes into account the patient numbers stated in the pharmaceutical company's dossier. Due to the limited epidemiological data basis on the incidence and prevalence of this therapeutic indication, these patient numbers are determined on the basis of the number of MRI examinations performed on an outpatient and inpatient basis per year. The methodological approach of the pharmaceutical company in the dossier is subject to uncertainties overall due to the inclusion of services that are not covered by the therapeutic indication of gadopiclenol, missing information on day-patient services, inclusion of an unreliable mean growth rate and unclear age adjustments. As a result, an overestimation of the patient numbers can therefore be assumed.

2.3 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

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

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 June 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

According to the product information for gadopiclenol, gadobutrol, gadoteridol and gadoteric acid, these active ingredients are diagnostic agents. They should only be used if the diagnostic information is necessary and data cannot be collected without contrast-enhanced MRI. The use of the diagnostic agents was therefore limited to a single dose.

For dosages based on body weight, the average body measurements of neonates from birth from the "German Health Interview and Examination Survey for Children and Adolescents (KiGGS)[1]" were applied. For the analysed age group, the reference percentiles of the Robert Koch Institute were used. Based on the average body weights of boys and girls, the average body weight of neonates is 3.46 kg. The average body measurements for children under the age of 2 were taken from the official representative statistics "2025 Microcensus – Body measurements of the population[2]". The average body weight of a child under the age of 2 is 12.7 kg.

The costs of an MRI examination are not included in the cost representation as they are incurred for both the medicinal product under assessment and the appropriate comparator therapy.

Children aged 0 to 2 years of age 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

[1] Contributions to Federal Health Reporting. Reference percentiles for anthropometric statistics and blood pressure from the German Health Interview and Examination Survey for Children and Adolescents (KiGGS) (2013, both sexes, from birth), https://edoc.rki.de/handle/176904/3254

[2] Federal Health Reporting. Average body measurements of the population (2025, both sexes), www.gbe-bund.de

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Gadopiclenol	Single dose	1	1	1
Appropriate comparator therapy				
Gadobutrol	Single dose	1	1	1
Gadoteridol	Single dose	1	1	1
Gadoteric acid	Single dose	1	1	1

Consumption:

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

Designation of the therapy	Dosage/ application	Dose/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Gadopiclenol	0.1 ml/kg BW = 0.35 ml[3] – 1.27 ml	0.35 ml – 1.27 ml	1 x 0.35 ml – 1 x 1.27 ml	1	1 x 0.35 ml – 1 x 1.27 ml
Appropriate comparator therapy					
Gadobutrol	0.1 ml/kg BW = 0.35 ml[4] – 1.27 ml	0.35 ml – 1.27 ml	1 x 0.35 ml – 1 x 1.27 ml	1	1 x 0.35 ml – 1 x 1.27 ml
Gadoteridol	0.2 ml/kg BW = 0.7 ml[5] – 2.54 ml	0.7 ml – 2.54 ml	1 x 0.7 ml – 1 x 2.54 ml	1	1 x 0.7 ml – 1 x 2.54 ml
Gadoteric acid	0.2 ml/kg BW = 0.7 ml[6] – 2.54 ml	0.7 ml – 2.54 ml	1 x 0.7 ml – 1 x 2.54 ml	1	1 x 0.7 ml – 1 x 2.54 ml

[3] 1 ml = 279.3 mg gadoteridol
[4] 1 ml = 604.72 mg gadobutrol
[5] 1 ml = 279.3 mg gadoteridol
[6] 1 ml = 279.32 mg gadoteric acid

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Gadopiclenol 3.64 g (0.5 mmol/ml)	1 SFI	€ 144.64	€ 1.77	€ 7.67	€ 135.20
Medicinal product to be assessed					
Gadobutrol 4.535 g (1.0 mmol/ml)	1 PS	€ 650.41	€ 1.77	€ 83.54	€ 565.10
Gadoteridol 2.79 g (0.5 mg/ml)	1 SFI	€ 118.29	€ 1.77	€ 6.16	€ 110.36
Gadoteric acid 3.77 g (0.5 mmol/ml)	1 SFI	€ 87.61	€ 1.77	€ 10.08	€ 75.76
Abbreviations: PS = prefilled syringe; SFI = solution for injection					

LAUER-TAXE® last revised: 15 June 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 10 February 2026, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

On 19 February 2026, the pharmaceutical company submitted a dossier for the benefit assessment of gadopiclenol to the G-BA in due time in accordance with Chapter 5 Section 8, paragraph 1, number 2 VerfO.

By letter dated 19 February 2026 in conjunction with the resolution of the G-BA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the G-BA commissioned the IQWiG to assess the dossier concerning the active ingredient gadopiclenol.

The dossier assessment by the IQWiG was submitted to the G-BA on 28 May 2026, and the written statement procedure was initiated with publication on the G-BA website on 1 June 2026. The deadline for submitting written statements was 22 June 2026.

The oral hearing was held on 6 July 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 11 August 2026, and deliberation of the draft resolution was concluded.

At their session on 20 August 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	10 February 2026	Determination of the appropriate comparator therapy
Working group Section 35a	1 July 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	6 July 2026	Conduct of the oral hearing,

Working group Section 35a	15.07.2026; 05.08.2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	11 August 2026	Concluding discussion of the draft resolution
Plenum	20 August 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 20 August 2026

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

Dr Optendrenk