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 Rimegepant (acute treatment of migraine)

of 20 November 2025

At their session on 20 November 2025, the Federal Joint Committee (G-BA) resolved not 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 Rimegepant as follows:

Rimegepant

Resolution of: 20 November 2025
Entry into force on: 20 November 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 25 April 2025):

VYDURA is indicated for the

- Acute therapy of migraine with or without aura in adults;
- Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

Therapeutic indication of the resolution (resolution of 20 November 2025):

Acute therapy of migraine with or without aura in adults.

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

<u>Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches</u>

Appropriate comparator therapy for rimegepant:

An individualised therapy with selection of

- selective serotonin 5HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), and
- non-steroidal anti-inflammatory drugs (acetylsalicylic acid, diclofenac, ibuprofen)

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

An additional benefit is not proven.

Study results according to endpoints:

Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
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 with migraine with or without aura who require acute therapy for the treatment of migraine headaches

Approx. 2,825,000 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 Vydura (active ingredient: rimegepant) at the following publicly accessible link (last access: 14 November 2025):

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

4. Treatment costs

Annual treatment costs:

Adults with migraine with or without aura who require acute therapy for the treatment of migraine headaches

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Rimegepant	€ 455.36 – € 1,707.60[1]
Appropriate comparator therapy[2]:	
Almotriptan	€ 0 – € 258.34[1, 3]
Eletriptan	€ 19.19 – € 276.90[1]
Frovatriptan	€ 14.60 – € 274.30[1]
Naratriptan	€ 0 – € 274.30[1, 3]
Rizatriptan	€ 14.68 – € 238.93[1]
Sumatriptan	€ 0 – € 279.60[1, 3]
Zolmitriptan	€ 14.31 – € 281.90[1]
Diclofenac	€ 25.31 – € 458.00[1]

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 September 2025)

Costs for additionally required SHI services: not applicable

[1] The annual treatment costs are different from patient to patient depending on the frequency of attacks. For the purpose of comparability, the costs are given for an exemplary range of 1 to 60 migraine attacks per year.

[2] The appropriate comparator therapy comprises pharmacy-only, non-prescription medicinal products. These are excluded from care according to Section 31 SGB V. An exceptional case according to Section 34 paragraph 1 sentence 2 SGB V does not exist. Thus, the prescription of these medicinal products is not allowed at the expense of the statutory health insurance. Therefore, the cost representation for these preparations is omitted in the resolution according to Section 35a paragraph 3 SGB V.

[3] Both prescription-only and pharmacy-only, non-prescription medicinal products are available for the active ingredients almotriptan, naratriptan and sumatriptan. The annual treatment costs are represented with a lower limit of € 0, taking into account the availability of non-prescription, non-reimbursable alternatives in accordance with Section 34 SGB V and Section 12 Pharmaceuticals Directive.

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 with migraine with or without aura who require acute therapy for the treatment of migraine headaches

- No medicinal product with new active ingredients that can be used in a combination therapy that 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.

6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V

The medicinal product VYDURA is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5% of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 20 November 2025.**

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

Berlin, 20 November 2025

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

Prof. Hecken