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 (prophylaxis 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. In Annex XII, the following information shall be added after Number 6 to the information on the benefit assessment of Rimegepant in the version of the resolution of 20 November 2025 on the therapeutic indication "Acute treatment of migraine":**

**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):**

Preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month.

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

a) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and are eligible for conventional migraine prophylactics

**Appropriate comparator therapy:**

- Amitriptyline *or*
- erenumab *or*
- flunarizine (only considered if treatment with beta-blockers is contraindicated or has not shown sufficient effect) *or*
- metoprolol *or*
- propranolol

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

An additional benefit is not proven.

b) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and do not respond, are ineligible or intolerant to any of the medicinal therapies/ product classes (amitriptyline, flunarizine, metoprolol, propranolol)

**Appropriate comparator therapy:**

- Eptinezumab *or*
- erenumab *or*
- fremanezumab *or*
- galcanezumab

**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:**[1]

a) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and are eligible for conventional migraine prophylactics

No data 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 | ∅ | No data available. |

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

b) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and do not respond, are ineligible or intolerant to any of the medicinal therapies/ product classes (amitriptyline, flunarizine, metoprolol, propranolol)

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-73) unless otherwise indicated.

**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

a) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and are eligible for conventional migraine prophylactics

Approx. 1,352,300 to 1,686,700 patients

b) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and do not respond, are ineligible or intolerant to any of the medicinal therapies/ product classes (amitriptyline, flunarizine, metoprolol, propranolol)

Approx. 34,600 to 39,500 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: 23 October 2025):

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

## 4. Treatment costs

**Annual treatment costs:**

a) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and are eligible for conventional migraine prophylactics

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Rimegepant | € 5,193.95 |
| Appropriate comparator therapy: | |
| Amitriptyline | € 59.31 – € 96.76 |
| Erenumab | € 3,344.99 |
| Flunarizine | € 49.37 – € 82.52 |
| Metoprolol | € 44.20 – € 62.34 |
| Propranolol | € 124.61 – € 186.92 |

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

Costs for additionally required SHI services: not applicable

b) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and do not respond, are ineligible or intolerant to any of the medicinal therapies/ product classes (amitriptyline, flunarizine, metoprolol, propranolol)

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| Rimegepant | € 5,193.95 |
| Appropriate comparator therapy: | |
| Eptinezumab | € 3,025.22 |
| Erenumab | € 3,344.99 |
| Fremanezumab | € 5,242.04 |
| Galcanezumab | € 5,532.40 |

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

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:

a) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and are eligible for conventional migraine prophylactics

- 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.

b) Adults who have at least 4 migraine attacks per month with an indication for preventive treatment of episodic migraine and do not respond, are ineligible or intolerant to any of the medicinal therapies/ product classes (amitriptyline, flunarizine, metoprolol, propranolol)

- 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.

## 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 per cent 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