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)
Lasmiditan (migraine acute treatment)

of 5 October 2023

At its session on 5 October 2023, 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 Lasmiditan as follows:

Lasmiditan

Resolution of: 5 October 2023
Entry into force on: 5 October 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 August 2022):

Rayvow is indicated for the acute treatment of the headache phase of migraine attacks, with or without aura in adults.

Therapeutic indication of the resolution (resolution of 5 October 2023):

See therapeutic indication according to marketing authorisation.

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

Adults with migraine with or without aura who need acute treatment

Appropriate comparator therapy for lasmiditan:

- A patient-individual therapy taking into account pretreatment, the severity of the attack as well as existing concomitant diseases, selecting selective serotonin 5HT1 receptor agonists (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan) and non-steroidal antirheumatic drugs (acetylsalicylic acid, diclofenac, ibuprofen)

Extent and probability of the additional benefit of lasmiditan:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with migraine with or without aura who need acute treatment

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-35) 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

Adults with migraine with or without aura who need acute treatment

approx. 2,750,000 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 Rayvow (active ingredient: lasmiditan) at the following publicly accessible link (last access: 20 April 2023):

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

4. Treatment costs

Annual treatment costs:

Adults with migraine with or without aura who need acute treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lasmiditan	€ 21.25 - € 2,177.40[2]
Appropriate comparator therapy[3]:	
Almotriptan	€ 2.14 - € 256.37[2]
Eletriptan	€ 3.16 - € 274.60[2]
Frovatriptan	€ 4.79 - € 272.00[2]
Naratriptan	€ 6.40 - € 272.00[2]
Rizatriptan	€ 4.82 - € 237.40[2]
Sumatriptan	€ 6.27 - € 277.30[2]
Zolmitriptan	€ 6.31 - € 279.60[2]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 September 2023

Costs for additionally required SHI services: not applicable

5. 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 lasmiditan

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 need acute treatment

– 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.

[2] The annual treatment costs vary 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.
[3] The appropriate comparator therapy comprises pharmacy-only, non-prescription medicinal products. These are excluded from care according to Section 31 SGB V. An exceptional circumstance 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 illustration for these preparations is omitted in the resolution according to Section 35a paragraph 3 SGB V.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 5 October 2023.**

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

Berlin, 5 October 2023

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

Prof. Hecken