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:

Cenobamate (epilepsy, focal seizures, after at least 2 previous therapies)

of 19 November 2021

At its session on 19 November 2021, 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 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 cenobamate as follows:

Cenobamate

Resolution of: 19 November 2021
Entry into force on: 19 November 2021
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 26 March 2021):

Ontozry is indicated for the adjunctive treatment of focal-onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite a history of treatment with at least 2 anti-epileptic medicinal products.

Therapeutic indication of the resolution (resolution of 19 November 2021):

"see therapeutic indication according to marketing authorisation"

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

Adults with epilepsy and focal-onset seizures with or without secondary generalisation who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products

Appropriate comparator therapy for cenobamate as adjunctive treatment:

- a patient-individual adjunctive anti-epileptic therapy, if medically indicated and if no pharmacoresistance (in the sense of an insufficient response), intolerance or contraindication is known, under selection of:

brivaracetam, eslicarbazepine, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, perampanel, pregabalin, topiramate, valproic acid and zonisamide

taking into account the basic and previous therapy/therapies and considering the reason for the change of therapy and any associated side effects.

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

An additional benefit is not proven.

Study results according to endpoints:

Adults with epilepsy and focal-onset seizures with or without secondary generalisation who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products

There are no suitable 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 ∅: There are no usable data for the benefit assessment. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with epilepsy and focal-onset seizures with or without secondary generalisation who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products

approx. 52,910 – 167,470 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 Ontozry (active ingredient: cenobamate) at the following publicly accessible link (last access: 4 November 2021)
https://www.ema.europa.eu/documents/product-information/ontozry-epar-product-information_en.pdf

4. Treatment costs

Annual treatment costs:

Adults with epilepsy and focal-onset seizures with or without secondary generalisation who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Cenobamate	€ 3,522.55 - € 7,045.11
Appropriate comparator therapy:	
- a patient-individual adjunctive anti-epileptic therapy, if medically indicated and if no pharmacoresistance (in the sense of an insufficient response), intolerance or contraindication is known, under selection of:	
brivaracetam	€ 1,226.05
eslicarbazepine	€ 1,616.26 - € 2,537.48
gabapentin	€ 261.54 - € 993.63
lacosamide	€ 1,929.46 - € 3,172.20
lamotrigine	€ 92.89 - € 305.54
levetiracetam	€ 201.85 - € 602.62
oxcarbazepine	€ 314.81 - € 1,027.26
perampanel	€ 1,228.34
pregabalin	€ 323.17 - € 725.69
topiramate	€ 491.80 - € 896.08
valproic acid	€ 164.14 - € 301.58
zonisamide	€ 1,617.02 - € 2,695.04

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 November 2021)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 November 2021.

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

Berlin, 19 November 2021

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

Prof. Hecken