Cenobamate

Resolution of: 19 November 2021 valid until: unlimited
Entry into force on: 19 November 2021
Federal Gazette, BAnz AT 22 12 2021 B3

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