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 Brivaracetam (new therapeutic indication: epilepsy with partial onset seizures, adjunctive therapy, ≥ 2 to < 4 years)

of 1 September 2022

At its session on 1 September 2022, 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. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Brivaracetam in accordance with the resolution of 17 January 2019:

Brivaracetam

Resolution of: 1 September 2022
Entry into force on: 1 September 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 24 February 2022):

Briviact is indicated as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

Therapeutic indication of the resolution (resolution of 1 September 2022):

Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in children from 2 to < 4 years with epilepsy.

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

Children aged 2 to < 4 years with partial onset epileptic seizures with or without secondary generalisation(s) on adjunctive therapy

Appropriate comparator therapy:

- a patient-individual anti-epileptic adjunctive therapy, if medically indicated and if no pharmacoresistance (in the sense of an insufficient response), intolerance or contraindication is known, taking into account the basic and previous therapy/ therapies and the reason for the change of therapy as well as any associated side effects

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

An additional benefit is not proven.

Study results according to endpoints:

Children aged 2 to < 4 years with partial onset epileptic seizures with or without secondary generalisation(s) on adjunctive therapy

There are no assessable data for the benefit assessment.

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	∅	No data available.
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

Children aged 2 to < 4 years with partial onset epileptic seizures with or without secondary generalisation(s) on adjunctive therapy

approx. 300 – 1,800 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 Briviact (active ingredient: brivaracetam) at the following publicly accessible link (last access: 27 June 2022):

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

4. Treatment costs

Annual treatment costs:

Children aged 2 to < 4 years with partial onset epileptic seizures with or without secondary generalisation(s) on adjunctive therapy

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Brivaracetam OS / FCT	€ 182.21 - € 6,726.43
Appropriate comparator therapy:	
a patient-individual anti-epileptic adjunctive therapy [a]	
Lacosamide SYR / FCT	€ 740.22 - € 2,405.72
Lamotrigine TOS + TAB	€ 15.56 - € 634.87
Levetiracetam OS	€ 303.19 - € 1,061.18
Topiramate HC / FCT	€ 195.42 - € 501.95
[a] Costs are presented only for the active ingredients lacosamide, lamotrigine, levetiracetam and topiramate. In addition to these active ingredients, the medicinal products eslicarbazepine, gabapentin and oxcarbazepine are also suitable comparators for the present benefit assessment in the context of patient-individual therapy. However, these medicinal products are not approved in the present therapeutic indication, and therefore, no costs are presented for these medicinal products.	
Abbreviations: FCT = film-coated tablets, HC = hard capsules, OS = oral solution, SYR = syrup, TAB = tablets, TOS = tablets for oral suspension	

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 August 2022)

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 1 September 2022.

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

Berlin, 1 September 2022

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

Prof. Hecken