Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive (AM-RL)

Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Perampanel (New Therapeutic Indication: Epilepsy, prim. generalised seizures, 7 to <12 years)

of 3 June 2021

At its session on 14 April 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 last amended on DD. 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 Perampanel in accordance with the resolution of 7 March 2013 last modified on 17 May 2018:

Perampanel

Resolution of: 3 June 2021
Entry into force on: 3 June 2021
BAnz AT TT. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 10 November 2020):

Fycompa (perampanel) is indicated for the adjunctive therapy of

- partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years of age and older.

- primary generalised tonic-clonic (PGTC) seizures in patients from 7 years of age and older with idiopathic generalised epilepsy (IGE).

Therapeutic indication of the resolution (resolution of 3 June 2021):

Fycompa (perampanel) is indicated for the adjunctive therapy of primary generalised tonic-clonic (PGTC) seizures in patients 7 to < 12 years of age with idiopathic generalised epilepsy (IGE).

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

Children aged 7 <12 years with idiopathic generalised epilepsy (IGE) and primary generalised tonic-clonic (PGTC) seizures in adjunctive therapy:

Appropriate comparator therapy:

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

clobazam, lamotrigine, topiramate, valproic acid[1]

taking into account the baseline and previous therapy(ies) and considering the reason for the change in therapy and any associated side effects.

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

[1] Valproic acid is not regularly considered for the adjunctive treatment of primary generalised tonic-clonic (PGTC) seizures in children 4 to 11 years of age due to potential for liver damage and teratogenicity. However, in the context of patient-individual therapy, additional treatment with valproic acid may be a possible option.

An additional benefit is not proven.

Summary of results for relevant clinical endpoints

Endpoint category	Effect direction/ Risk of bias	Summary
Mortality	n.b.	There are no evaluable data.
Morbidity	n.b.	There are no evaluable data.
Health-related quality of life	n.b.	There are no evaluable data.
Side effects	n.b.	There are no evaluable 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.b.: not assessable		

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

Children aged 7 to <12 years with idiopathic generalised epilepsy (IGE) and primary generalised tonic-clonic (PGTC) seizures in adjunctive therapy:

approx. 195 to 663 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 Fycompa (active ingredient: perampanel) at the following publicly accessible link (last access: 7 April 2021):
https://www.ema.europa.eu/en/documents/product-information/fycompa-epar-product-information_de.pdf

4. Treatment costs

Annual treatment costs:

Children aged 7 to <12 years with idiopathic generalised epilepsy (IGE) and primary generalised tonic-clonic (PGTC) seizures in adjunctive therapy:

Name of therapy2	Annual treatment costs/patient
Medicinal product to be assessed:	
Perampanel OSUS + FCT	€ 676.58 - € 1,353.16
Appropriate comparator therapy:	
Clobazam SUS + TAB	€ 125.27 - € 7,042.60
Lamotrigine TOS + TAB	€ 30.68 - € 346.75
Topiramate FCT	€ 277.07 - € 896.08
Valproic acid OS + FCT	€ 225.56- € 309.49

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 15 May 2021).

2 Abbreviations according to IFA GmbH guideline (https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/richtlinien/IFA-Richtlinien_Darreichungsformen.pdf).
FCT: Film-coated tablets; OS: Oral solution; SAE: Oral suspension; TAB: Tablets; TOS: Tablets for the preparation of oral suspension

II. The resolution will enter into force on the day of its publication on the internet on the G-BA website on 3 June 2021.

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

Berlin, 3 June 2021

Federal Joint Committee in accordance with Section 91 SGB V The chairman

Prof. Hecken