Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) 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 Vigabatrin (West's Syndrome)

of 19 December 2019

At its session on 19 December 2019, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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. Annex XII shall be amended in alphabetical order to include the active ingredient vigabatrin as follows:

Vigabatrin

Resolution of: 19 December 2019
Entry into force on: 19 December 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 20 September 2018):

Kigabeq is indicated in infants and children from 1 month to less than 7 years of age:
- for treatment in monotherapy of infantile spasms (West's syndrome).

1. Extent of the additional benefit of the medicinal product

Infants and children from 1 month to less than 7 years of age who suffer from infantile spasms (West's syndrome)

Appropriate comparator therapy:

Tetracosactide or glucocorticoids (prednisone, prednisolone)

Extent and probability of the additional benefit of vigabatrin in monotherapy compared with the appropriate comparator therapy:

An additional benefit is deemed not to have been proven.

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

Patient population

approx. 1000 to 2400 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 Kigabeq® (active ingredient: vigabatrin at the following publicly accessible link (last access: 25 October 2019):

https://www.ema.europa.eu/documents/product-information/kigabeq-epar-product-information_de.pdf

Treatment with vigabatrin should be initiated and monitored only by a specialist in epileptology, neurology, or neuropaediatrics.

All patients should receive an ophthalmological consultation before or shortly after starting treatment with vigabatrin.

After the start of treatment and at least every 6 weeks during therapy, the vision should be assessed. The assessment must be continued for 6 to 12 months after discontinuation of therapy.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Vigabatrin	€ 1,750.54 – € 13,090.80
Appropriate comparator therapy:	
ACTH (tetracosactide)	€ 883.57 – € 3,515.06
Prednisone	€ 25.93 – € 51.87
Prednisolone	€ 42.01 – € 86.07

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 December 2019

Costs for additionally required SHI services:

Designation of the therapy	Description of the service	Costs per unit	Number per patient per year	Costs per patient per year
Medicinal product to be assessed				
Vigabatrin	Ophthalmological examination	Non-quantifiable	different	Non-quantifiable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 19 December 2019.

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

Berlin, 19 December 2019

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

Prof. Hecken