Gemeinsamer Bundesausschuss

Vigabatrin

Resolution of: 19 December 2019 Valid until: unlimited
Entry into force on: 19 December 2019
Federal Gazette, BAnz AT 17 01 2020 B2

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 combination with other anti-epileptic medicinal products for patients with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation, that is where all other appropriate medicinal product combinations have proved inadequate or have not been tolerated.

1. Extent of the additional benefit of the medicinal product

Infants and children from 1 month to less than 7 years of age with resistant partial epilepsy (focal onset seizures) with or without secondary generalisation in whom all other appropriate medicinal product combinations have proved inadequate or have not been tolerated.

Appropriate comparator therapy:

A patient-individual optimisation of the anti-epileptic therapy taking into account the previous therapy.

Extent and probability of the additional benefit of vigabatrin in combination with other anti-epileptics compared with the appropriate comparator therapy:

The additional benefit is deemed not to have been proven.

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

Patient population

approx. 7,300 to 14,500 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 specialists 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[1]	Annual treatment costs/patient
Medicinal product to be assessed:	
Vigabatrin TOS	€ 1,312.91 – € 5,610.34
Appropriate comparator therapy:	
Brivaracetam OSL + FCT	€ 259.59 – € 2892.28
Carbamazepin SUS + TAB	€ 18.93 – € 597.51
Clobazam OS + TAB	€ 60.14 – € 4,086.31
Gabapentin OSL + HC	€ 240.02 – € 2,145.75
Lacosamide SIR + FCT	€ 986.73 – € 3,749.58
Lamotrigine TOS + TAB	€ 18.32 – € 738.47
Levetiracetam OSL	€ 222.02 – € 1,465.89
Oxcarbazepin OSP + FCT	€ 314.59 – € 1,153.95
Phenytoin TAB	€ 14.93 – € 59.71
Primidone SUS + TAB	€ 55.41 – € 488.02
Topiramate FCT	€ 219.84 – € 491.58
Valproic acid OSL + FCT	€ 62.76 – € 198.73
Zonisamide HC	€ 953.39 – € 1077.79

1 Abbreviations in accordance with IFA GmbH guidelines (https://www.ifaffm.de/mandanten/1/documents/02_ifa_anbieter/richtlinien/IFA-Richtlinien_Darreichungsformen.pdf).
FCT: film-coated tablets; HC: hard capsules; OSL: oral solution; SIR: syrup: OSP: oral suspension; TAB: tablets; TOS: tablets for preparing an oral suspension

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