Gemeinsamer Bundesausschuss

Resolution

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:
Sodium zirconium cyclosilicate (hyperkalaemia)

of 16 September 2021

At its session on 16 September 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 by the publication of the resolution of D. month YYYY (BAnz AT TT.MM.JJJJ BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient sodium zirconium cyclosilicate as follows:

Sodium zirconium cyclosilicate

Resolution of: 16 September 2021
Entry into force on: 16 September 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 March 2018):

Lokelma is indicated for the treatment of hyperkalaemia in adult patients

Therapeutic indication of the resolution (resolution of 16 September 2021):

see therapeutic indication according to marketing authorisation.

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

Adults with hyperkalaemia

Appropriate comparator therapy:

A patient-individual therapy taking into account the aetiology, severity and symptomatology.

Optimisation of the treatment of the underlying and concomitant diseases, particularly adjustment of the medicinal therapy and dietary changes, if necessary, are measures within the framework of patient-individual treatment, which represent the standard therapy in the treatment of hyperkalaemia.

Extent and probability of the additional benefit of sodium zirconium cyclosilicate compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

There are no relevant data in comparison with the appropriate comparator therapy.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A20-40) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data for the benefit assessment.
Morbidity	n.a.	There are no assessable data for the benefit assessment.
Health-related quality of life	∅	There are no available data for the benefit assessment.
Side effects	n.a.	There are no assessable data for the benefit assessment.
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 hyperkalaemia

approx. 77,700 – 308,500 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 Lokelma (active ingredient: sodium zirconium cyclosilicate) at the following publicly accessible link (last access: 10 August 2021):

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

4. Treatment costs

Annual treatment costs:

Adults with hyperkalaemia

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	

Designation of the therapy	Annual treatment costs/ patient
Sodium zirconium cyclosilicate[2]	€ 1,914.99 – € 6,383.29
Appropriate comparator therapy:	
Patient-individual therapy[3]	patient-individual

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

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 16 September 2021.

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

Berlin, 16 September 2021

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

Prof. Hecken

[2] For the calculation of the costs of sodium zirconium cyclosilicate, both dialysis-requiring and non-dialysis-requiring dosages are considered. The annual treatment costs for patients not requiring dialysis are within the cost range of patients requiring dialysis.
[3] Elements of patient-individual therapy also apply with sodium zirconium cyclosilicate therapy.