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: Sucroferric oxyhydroxide (New Therapeutic Indication: serum phosphorus level control in chronic kidney disease, 2 to < 18 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 sucroferric oxyhydroxide in accordance with the resolution of 19 March 2015:

Sucroferric oxyhydroxide

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 16 November 2020):

Velphoro is indicated for the control of serum phosphorus levels in paediatric patients 2 years of age and older with CKD stages 4 - 5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

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

see new therapeutic indication according to marketing authorisation

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

Paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

Appropriate comparator therapy:

- Therapy according to the doctor's instructions

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

An additional benefit is not proven.

Study results according to endpoints:

Paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

There are no usable 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 evaluable data.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	n.a.	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.a.: not assessable

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

Paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.
approx. 390 to 470 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 Velphoro (active ingredient: sucroferric oxyhydroxide) at the following publicly accessible link (last access: 26 April 2021):

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

Initiation and monitoring of treatment with sucroferric oxyhydroxide should be carried out by specialists experienced in the treatment of children and adolescents with chronic kidney disease.

4. Treatment costs

Annual treatment costs:

Paediatric patients 2 years of age and older with CKD stages 4-5 (defined by a glomerular filtration rate < 30 mL/min/1.73 m²) or with CKD on dialysis.

Name of therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Sucroferric oxyhydroxide powder in sachet [a]	Incalculable
Sucroferric oxyhydroxide chewable tablets [b]	€ 1,406.22 - € 4,218.67
Appropriate comparator therapy:	
Therapy according to the doctor's instructions: - Sevelamer carbonate [c]	€ 1,795.19 - € 7,180.77

[a] Sucroferric Oxyhydroxide 125 mg Powder in sachet is currently not available on the German market, therefore a cost representation is not possible.

[b] From a daily dose of 1,000 mg or more.

[c] Costs are presented only for the active ingredient sevelamer carbonate, which is approved for paediatric and adolescent patients (> 6 years of age and with a BS > 0.75 m²) with chronic renal insufficiency and hyperphosphatemia. In addition to sevelamer carbonate, calcium-containing phosphate binders (alone or in combination) also represent suitable comparators for the present benefit assessment in the context of therapy according to the doctor's instructions. However, these medicinal products are not approved in the present therapeutic indication, and therefore no costs are presented for these medicinal products.

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

Prof. Hecken