Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V)
Patiromer (new therapeutic indication: hyperkalaemia, ≥ 12 to ≤ 17 years)

of 1 August 2024

At its session on 1 August 2024, 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 (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 Patiromer in accordance with the resolution of 20 September 2018:

Patiromer

Resolution of: 1 August 2024
Entry into force on: 1 August 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 5 January 2024):

Veltassa is indicated for the treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years.

Therapeutic indication of the resolution (resolution of 1 August 2024):

Treatment of hyperkalaemia in adolescents aged 12 to 17 years**.**

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

Adolescents aged 12 to 17 years with hyperkalaemia

Appropriate comparator therapy for patiromer:

- Polystyrene sulfonates (CaPSS, NaPSS)

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

An additional benefit is not proven.

Study results according to endpoints:

Adolescents aged 12 to 17 years with hyperkalaemia

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable 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 ∅: No data available. n.a.: not assessable		

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

Adolescents aged 12 to 17 years with hyperkalaemia

Approx. 370 - 790 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 Veltassa (active ingredient: patiromer) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 10 April 2024):

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

If the serum-potassium level falls below the desired target range, the patiromer dose should be reduced or treatment discontinued.

4. Treatment costs

Annual treatment costs:

Adolescents aged 12 to 17 years with hyperkalaemia

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Patiromer	€ 2,701.04- € 5,477.47
Appropriate comparator therapy:	
Calcium polystyrene sulfonate	€ 639.66- € 1,791.06
Additionally required SHI services	€ 104.29
Total	€ 743.95- € 1,895.35
Sodium polystyrene sulfonate	€ 680.95- € 1,906.67
Additionally required SHI services	€ 91.25
Total	€ 772.20- € 1,997.92

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2024)

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Adolescents aged 12 to 17 years with hyperkalaemia

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 1 August 2024.

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

Berlin, 1 August 2024

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

Prof. Hecken