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
Difelikefalin (Pruritus associated with chronic kidney disease in patients on haemodialysis)

of 6 April 2023

At its session on 6 April 2023, 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. Annex XII shall be amended in alphabetical order to include the active ingredient Difelikefalin as follows:

Difelikefalin

Resolution of: 6 April 2023
Entry into force on: 6 April 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 25 April 2022):

Kapruvia is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis.

Therapeutic indication of the resolution (resolution of 6 April 2023):

See therapeutic indication according to marketing authorisation.

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

<u>Adult patients on haemodialysis with moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)</u>

Appropriate comparator therapy for difelikefalin:

- Best supportive care

Best supportive care (BSC) is defined as the therapy that provides the best possible, patient-individual, optimised supportive treatment to alleviate symptoms and improve quality of life.

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients on haemodialysis with moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)

There are no assessable 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 assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
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

Adult patients on haemodialysis with moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)

approx. 3,500 – 22,000 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 Kapruvia (active ingredient: difelikefalin) at the following publicly accessible link (last access: 03 February 2023):

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

Treatment with difelikefalin should only be initiated and monitored in a haemodialysis centre by healthcare professionals experienced in the diagnosis and treatment of conditions for which difelikefalin is indicated. Causes of pruritus other than chronic kidney disease should be excluded before initiating treatment with difelikefalin.

4. Treatment costs

Annual treatment costs:

Adult patients on haemodialysis with moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Difelikefalin[1]	€ 6,777.82 - € 9,037.09
Appropriate comparator therapy:	
Best supportive care	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 March 2023)

Costs for additionally required SHI services: not applicable

5. 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 Difelikefalin

Medicinal products with the new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with difelikefalin for the treatment of pruritus associated with chronic kidney disease in patients on haemodialysis on the basis of the marketing authorisation granted under Medicinal Products Act:

Adult patients on haemodialysis with moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)

No active ingredient 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.

[1] For the calculation of the costs of difelikefalin, application of 3 to 4-times per week and 77 kg dry weight after dialysis are assumed.

II. Entry into force

1. **The resolution will enter into force on the day of its publication on the website of the G-BA on 6 April 2023.**

2. **The period of validity of the resolution is limited to 15 October 2023.**

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

Berlin, 6 April 2023

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

Prof. Hecken