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 Calcifediol (secondary hyperparathyroidism in chronic kidney disease)

of 21 July 2022

At its session on 21 July 2022, 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 calcifediol as follows:

Calcifediol

Resolution of: 21 July 2022
Entry into force on: 21 July 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 18 August 2020):

Rayaldee is indicated for the treatment of secondary hyperparathyroidism (sHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D deficiency.

Therapeutic indication of the resolution (resolution of 21 July 2022):

See therapeutic indication according to marketing authorisation.

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

Adult secondary hyperparathyroidism (sHPT) patients with stage 3 or 4 chronic kidney disease and vitamin D deficiency

Appropriate comparator therapy for calcifediol:

- Paricalcitol

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adult secondary hyperparathyroidism (sHPT) patients with stage 3 or 4 chronic kidney disease and vitamin D deficiency

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-09) 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.
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
∅: 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

Adult secondary hyperparathyroidism (sHPT) patients with stage 3 or 4 chronic kidney disease and vitamin D deficiency

approx. 146,700 – 184,300 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

4. Treatment costs

Annual treatment costs:

Adult secondary hyperparathyroidism (sHPT) patients with stage 3 or 4 chronic kidney disease and vitamin D deficiency

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Calcifediol	€ 2,484.11 - € 4,968.22
Appropriate comparator therapy:	
Paricalcitol – treatment mode: 1 x daily	
Paricalcitol	€ 1,464.69 - € 4,313.91

Designation of the therapy	Annual treatment costs/ patient
Paricalcitol – treatment mode: 3 x in 7 days	
Paricalcitol	€ 1,220.28 - € 3,660.85

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 July 2022

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 21 July 2022.

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

Berlin, 21 July 2022

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

Prof. Hecken