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: Roxadustat (symptomatic anaemia in chronic kidney disease)

of 3 March 2022

At its session on 3 March 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 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 Roxadustat as follows:

Roxadustat

Resolution of: 3 March 2022
Entry into force on: 3 March 2022
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 18 August 2021):

Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).

Therapeutic indication of the resolution (resolution of 3 March 2022):

see therapeutic indication according to marketing authorisation

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

Adults with symptomatic anaemia associated with chronic kidney disease (CKD)

Appropriate comparator therapy:

- An erythropoiesis-stimulating agent (ESA) (darbepoetin alfa or epoetin (alfa, zeta) or epoetin beta or epoetin theta or methoxy-PEG-epoetin beta)

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with symptomatic anaemia associated with chronic kidney disease (CKD)

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-117) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.

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

No data available.

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

Adults with symptomatic anaemia associated with chronic kidney disease (CKD)

approx. 151,000 – 195,000 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 Evrenzo (active ingredient: roxadustat) at the following publicly accessible link (last access: 3 January 2022):

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

Treatment with roxadustat should only be initiated and monitored by doctors experienced in treating adults with symptomatic anaemia associated with chronic kidney disease.

4. Treatment costs

Annual treatment costs:

Adults with symptomatic anaemia associated with chronic kidney disease (CKD)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Roxadustat	€ 1,617.18 - € 18,292.05
Appropriate comparator therapy:	
Darbepoetin alfa	*Incalculable*
Epoetin alfa, epoetin zeta	€ 1,588.70 – € 14,073.25
Epoetin beta	€ 2,383.05 - € 23,501.27
Epoetin theta	€ 2,383.05 - € 23,501.27
Methoxy-PEG-epoetin beta	*Incalculable*

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 February 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 3 March 2022.

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

Berlin, 3 March 2022

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

Prof. Hecken