Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment on the Amendment of the Pharmaceuticals Directive: Annex XII - Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V:

Lanadelumab (reassessment of an orphan drug after exceeding the EUR 50 million turnover limit (hereditary angioedema, prevention, ≥ 12 years))

of 4 November 2021

At its session on 4 November 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 by the publication of the resolution of DD. Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII is amended as follows:

1. **The information on lanadelumab in the version of the resolution of 1 August 2019 (BAnz AT 27.08.2019 B6) is repealed.**
2. **Annex XII shall be amended in alphabetical order to include the active ingredient lanadelumab as follows:**

Lanadelumab

Resolution of: 4 November 2021
Entry into force on: 4 November 2021
BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 22 November 2018):

Takhzyro is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 12 years and older.

Therapeutic indication of the resolution (resolution of 4 November 2021):

see therapeutic indication according to marketing authorisation

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

Adolescents and adults 12 years of age and older with recurrent attacks of hereditary angioedema

Appropriate comparator therapy of lanadelumab for routine prevention:

A routine prevention with C1 esterase inhibitor

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

An additional benefit is not proven.

Study results according to endpoints: [1]

No adequate data are available to allow an assessment of the additional benefit.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A21-63) 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	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 ∅: 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

Adolescents and adults 12 years of age and older with recurrent attacks of hereditary angioedema

approx. 140 – 430 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 Takhzyro (active ingredient: lanadelumab) at the following publicly accessible link (last access: 13 October 2021):
https://www.ema.europa.eu/en/documents/product-information/takhzyro-epar-product-information_en.pdf

Treatment with lanadelumab should only be initiated and monitored by doctors experienced in treating adolescent and adult patients with hereditary angioedema (HAE).

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lanadelumab	€ 191,757.54 - € 384,990.14
Appropriate comparator therapy:	
C1 esterase inhibitor[2]	€ 160,380.32 - € 213,781.87

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 October 2021)

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 4 November 2021.

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

Berlin, 4 November 2021

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

Prof. Hecken

[2] Different dosage information is shown in the product information of the C1-esterase inhibitors. The range shown is based on an administration every 3 - 4 days.