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)
Lanadelumab (new therapeutic indication: hereditary angioedema, prevention, 2 to < 12 years)

of 6 June 2024

At its session on 6 June 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 Lanadelumab in accordance with the resolution of 4 November 2021:

Lanadelumab

Resolution of: 6 June 2024
Entry into force on: 6 June 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 November 2023):

TAKHZYRO is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged 2 years and older.

Therapeutic indication of the resolution (resolution of 6 June 2024):

TAKHZYRO is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in children 2 to less than 12 years of age.

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

Children 2 to less than 12 years of age with recurrent attacks of hereditary angioedema

Appropriate comparator therapy for routine prevention:

- 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:

Children 2 to less than 12 years of age with recurrent attacks of hereditary angioedema

No suitable data versus the appropriate comparator therapy available.

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
∅: No data available.
n.a.: not assessable

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

Children 2 to less than 12 years of age with recurrent attacks of hereditary angioedema

Approx. 1 to 30 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: 28 May 2024):

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 patients with hereditary angioedema (HAE).

4. Treatment costs

Annual treatment costs:

Children 2 to less than 12 years of age with recurrent attacks of hereditary angioedema

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Lanadelumab	€ 132,419.17 - € 265,856.95

Designation of the therapy	Annual treatment costs/ patient
Appropriate comparator therapy:	
C1 esterase inhibitor	€ 88,124.13 - € 117,466.67

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2024)

Costs for additionally required SHI services: not applicable

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:

Children 2 to less than 12 years of age with recurrent attacks of hereditary angioedema

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

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 June 2024.

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

Berlin, 6 June 2024

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

Prof. Hecken