Gemeinsamer Bundesausschuss

Draft 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 Burosumab (exceeding € 50 million turnover limit: X-linked hypophosphataemia, ≥ 18 years)

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 is amended as follows:

1. **The information on burosumab in the version of the resolution of 15 April 2021 (Federal Gazette, BAnz AT 26.05.2021 B4) is repealed.**
2. **Annex XII shall be amended in alphabetical order to include burosumab as follows:**

Burosumab

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 30 September 2020):

Crysvita is indicated for the treatment of X-linked hypophosphataemia in adults.

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

Adults with X-linked hypophosphataemia (XLH)

Appropriate comparator therapy:

- a phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination

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

An additional benefit is not proven.

Study results according to endpoints:

Adults with X-linked hypophosphataemia (XLH)

No suitable data submitted.

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

Adults with X-linked hypophosphataemia (XLH)

approx. 410 - 810 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 Crysvita (active ingredient: burosumab) at the following publicly accessible link (last access: 5 May 2022):

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

Treatment with burosumab should only be initiated and monitored by doctors experienced in the therapy of metabolic bone diseases.

This medicinal product was authorised under “special conditions”. The EMA will assess new information on this medicinal product at least annually and update the product information as necessary.

4. Treatment costs

Annual treatment costs:

Adults with X-linked hypophosphataemia (XLH)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Burosumab	€ 278,090.80 - € 312,810.03
Appropriate comparator therapy:	
Phosphate replacement and active vitamin D (calcitriol or alfacalcidol) in combination	
Phosphate	€ 233.78 - € 389.64
Active vitamin D	
Calcitriol	€ 773.51 - € 1,289.18
or	
Alfacalcidol	€ 1,288.89
	Total
Phosphate + calcitriol	€ 1,007.29 - € 1,678.82
Phosphate + alfacalcidol	€ 1,522.67 - € 1,678.53

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

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Burosumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	13.0	€ 923

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