GBA
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
Elinzanetant (vasomotor symptoms caused by adjuvant endocrine therapy)

of 1 October 2026

At their session on 1 October 2026, the Federal Joint Committee (GBA) 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 number 4 to the information on the benefit assessment of Elinzanetant in accordance with the resolution of 1 October 2026 (vasomotor symptoms associated with menopause):

Courtesy translation – only the German version is legally binding.

Elinzanetant

Resolution of: 1 October 2026
Entry into force on: 1 October 2026
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 November 2025):

Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms (VMS):

– caused by adjuvant endocrine therapy (AET) related to breast cancer.

Therapeutic indication of the resolution (resolution of 1 October 2026):

See therapeutic indication according to marketing authorisation.

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

Patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer

Appropriate comparator therapy:

– Monitoring wait-and-see approach

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A26-35) unless otherwise indicated.

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

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

Patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer

Approximately 32,900 – 188,800 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 Lynkuet (active ingredient: elinzanetant) at the following publicly accessible link (last access: 26 May 2026):

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

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4. Treatment costs

Annual treatment costs:

Patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Elinzanetant	€ 1,131.66
Appropriate comparator therapy:	
Monitoring wait-and-see approach	Not calculable

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 July 2026)

Costs for additionally required SHI services: not applicable

II. The resolution will enter into force on the day of its publication on the GBA website on 1 October 2026.

The justification for this resolution will be published on the GBA website at www.g-ba.de.

Berlin, 1 October 2026

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Dr Optendrenk

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