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 associated with menopause)

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, information on the active ingredient Elinzanetant (vasomotor symptoms associated with menopause) shall be added in alphabetical order as follows:

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):

- associated with menopause.

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

a) Patients with moderate to severe vasomotor symptoms associated with menopause who are eligible for hormone replacement therapy and have decided in favour of hormone replacement therapy after individual risk-benefit assessment

Appropriate comparator therapy:

- Individualised therapy with selection of
  - Oestrogens
  - Oestrogen/progestogen combinations

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

An additional benefit is not proven.

b) Patients with moderate to severe vasomotor symptoms associated with menopause who are ineligible for hormone replacement therapy or have decided against hormone replacement therapy after individual risk-benefit assessment

Appropriate comparator therapy:

- Monitoring wait-and-see approach

Extent and probability of the additional benefit of elinzanetant compared to the monitoring wait-and-see approach:

An additional benefit is not proven.

Study results according to endpoints:[1]

[1] Data from the dossier assessment of the IQWiG (A26-34) and from the addendum (A26-101), unless otherwise indicated.

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a) Patients with moderate to severe vasomotor symptoms associated with menopause who are eligible for hormone replacement therapy and have decided in favour of hormone replacement therapy after individual risk-benefit assessment

No data 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		

b) Patients with moderate to severe vasomotor symptoms associated with menopause who are ineligible for hormone replacement therapy or have decided against hormone replacement therapy after individual risk-benefit assessment

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No deaths occurred.
Morbidity	↑	Advantage in the reduction of moderate and severe vasomotor symptoms.
Health-related quality of life	↔	No relevant difference for the benefit assessment.
Side effects	↓	Disadvantage in the discontinuation due to adverse events.
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		

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OASIS-3 study: elinzanetant vs monitoring wait-and-see approach (placebo); sub-population of patients who are ineligible for hormone replacement therapy (modified intention-to-treat population)

Mortality

Endpoint	Elinzanetant		Placebo		Elinzanetant vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Overall mortality[a]					
	215	0(0)	220	0(0)	-

Morbidity

Endpoint	Elinzanetant			Placebo			Elinzanetant vs placebo
	N[b]	Values at the start of the study MV (SD)	Mean change at the end of treatment MV[c] (SE)	N[b]	Values at the start of the study MV (SD)	Mean change at the end of treatment MV[c] (SE)	MD [95% CI]; p value
Daily number of moderate or severe VMS							
	215	7.06 (8.13)	−6.09 (0.48)	220	7.12 (5.51)	−3.69 (0.47)	−2.40 [−3.72; −1.08]; < 0.001
Sleep disorders (PROMIS SD SF 8b)[d]							
	188	56.76 (6.88)	−10.05 (0.95)	193	58.65 (6.85)	−6.35 (0.93)	−3.71 [−6.33; −1.09]; 0.006 SMD: −0.29 [−0.49; −0.08]

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Health-related quality of life

Endpoint Domain	Elinzanetant			Placebo			Elinzanetant vs placebo
	N[b]	Values at the start of the study MV (SD)	Mean change at the end of treatment MV[c] (SE)	N[b]	Values at the start of the study MV (SD)	Mean change at the end of treatment MV[c] (SE)	MD [95% CI]; p value
MENQOL							
Vasomotor[e]	185	5.80 (1.67)	−2.59 (0.23)	190	6.08 (1.68)	−1.79 (0.23)	−0.81 [−1.45; −0.16]; 0.015 SMD: −0.26 [−0.47; −0.05]
Psychosocial[e]	185	3.03 (1.70)	−0.81 (0.17)	190	3.49 (1.93)	−0.69 (0.17)	−0.12 [−0.59; 0.36]; 0.632
Psychological[e]	185	3.67 (1.33)	−0.76 (0.16)	190	4.00 (1.56)	−0.66 (0.15)	−0.10 [−0.54; 0.34]; 0.654
Sexual[e]	185	3.74 (2.12)	−0.75 (0.22)	188	4.09 (2.33)	−0.76 (0.22)	0.00 [−0.61; 0.62]; 0.988

Side effects

Endpoint	Elinzanetant		Placebo		Elinzanetant vs placebo
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]; p value
Total adverse events (presented additionally)					
	215	153 (71)	220	134 (61)	-
Serious adverse events (SAEs)					
	215	8 (4)	220	4 (2)	2.05 (0.63; 6.70); 0.236
Therapy discontinuation due to adverse events					
	215	30 (14)	220	10 (5)	3.07 (1.54; 6.12); 0.002
Specific adverse events: Liver-related investigations, clinical signs and symptoms (SMQ, SAEs)[x]					
	n.d.[g]				

a. The results on overall mortality are based on the data on fatal AEs.
b. Number of patients who were taken into account in the effect estimate; the values at the start of the study (and subsequently) can be based on other patient numbers.

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c. MMRM analyses
d. Lower values mean better symptomatology; negative effects (intervention minus comparison) mean an advantage for the intervention (scale range based on transformed T score values: 28.9 to 76.5).
e. Lower values mean better health-related quality of life; negative effects (intervention minus comparison) mean an advantage for the intervention (scale range: 1 to 8).
f. The following events (coded according to MedDRA) are considered: cholestasis and jaundice of hepatic origin (SMQ, AEs), drug-induced liver disorders (SMQ, severe AEs), liver-related investigations, clinical signs and symptoms (SMQ, AEs), and liver-related coagulation and bleeding disorders (SMQ, AEs), as well as confirmed liver-related adverse events of special interest (AESI).
g. No data are available for the relevant sub-population; in the total population, there were 7 (2.2%) events in the intervention arm and 12 (3.8%) events in the placebo arm.

Abbreviations used:
n.d.: no data available; CI: confidence interval; MedDRA: Medical Dictionary for Regulatory Activities; MENQOL: Menopause-specific Quality of Life Questionnaire; mITT: modified intention-to-treat population; MMRM: mixed model for repeated measures; MV: mean value; MD: mean difference; n: number of patients with (at least 1) event; N: number of patients evaluated; PROMIS-SD: Patient-Reported Outcomes Measurement Information System - Sleep Disturbance; RCT: randomised controlled trial; RR: relative risk; SD: standard deviation; SE: standard error; SF 8B: Short Form 8b; SMD: standardised mean difference; SMQ: standardised MedDRA query; SAE: serious adverse event; AE: adverse event; AESI: adverse events of special interest; VMS: vasomotor symptoms.

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

a) Patients with moderate to severe vasomotor symptoms associated with menopause who are eligible for hormone replacement therapy and have decided in favour of hormone replacement therapy after individual risk-benefit assessment

Approximately 509,500 – 593,300 patients

b) Patients with moderate to severe vasomotor symptoms associated with menopause who are ineligible for hormone replacement therapy or have decided against hormone replacement therapy after individual risk-benefit assessment

Approximately 2,037,800 – 2,373,300 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:

a) Patients with moderate to severe vasomotor symptoms associated with menopause who are eligible for hormone replacement therapy and have decided in favour of hormone replacement therapy after individual risk-benefit assessment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Elinzanetant	€ 1,131.66
Appropriate comparator therapy:	
Individualised therapy with the selection of oestrogens and oestrogen/progestogen combinations	
Oestrogen	
Estradiol	€ 76.30 - € 79.94
Oestrogen/progestogen combination	
Estradiol + drospirenone	€ 149.00

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

Costs for additionally required SHI services: not applicable

b) Patients with moderate to severe vasomotor symptoms associated with menopause who are ineligible for hormone replacement therapy or have decided against hormone replacement therapy after individual risk-benefit assessment

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

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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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