GBA
Gemeinsamer
Bundesausschuss

Justification

for the Resolution of the Federal Joint Committee (GBA) 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

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1. Legal basis

According to Section 35a, paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (GBA) assess the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the GBA electronically, including all clinical studies the pharmaceutical company have conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The GBA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the GBA decide on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

2. Key points of the resolution

The relevant date for the start of the benefit assessment procedure was the first placing on the (German) market of the active ingredient elinzanetant on 1 April 2026 in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 of the Rules of Procedure of the GBA (VerfO). Pursuant to Section 4, paragraph 3, number 1 of the Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) in conjunction with Chapter 5, Section 8, paragraph 1, number 1 of the Rules of Procedure (VerfO), the pharmaceutical company submitted the final dossier to the GBA on 26 March 2026.

The GBA commissioned the IQWiG to carry out the assessment of the dossier. The benefit assessment was published on 1 July 2026 on the GBA website (www.g-ba.de), thus initiating the written statement procedure. In addition, an oral hearing was held.

The GBA came to a resolution on whether an additional benefit of elinzanetant compared with the appropriate comparator therapy could be determined on the basis of the dossier of the pharmaceutical company, the dossier assessment prepared by the IQWiG, and the statements

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submitted in the written statement and oral hearing procedure. In order to determine the extent of the additional benefit, the GBA have evaluated the data justifying the finding of an additional benefit on the basis of their therapeutic relevance (qualitative), in accordance with the criteria laid down in Chapter 5, Section 5, paragraph 7 VerfO. The methodology proposed by the IQWiG in accordance with the General Methods [1] was not used in the benefit assessment of elinzanetant.

In the light of the above, and taking into account the statements received and the oral hearing, the GBA have made the following assessment:

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

2.1.1 Approved therapeutic indication of Elinzanetant (Lynkuet) in accordance with the product information

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 01.10.2026):

See the approved therapeutic indication

2.1.2 Appropriate comparator therapy

The appropriate comparator therapy was determined as follows:

<u>Patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer</u>

Appropriate comparator therapy for elinzanetant:

- Monitoring wait-and-see approach

<u>Criteria according to Chapter 5, Section 6 of the Rules of Procedure of the GBA and Section 6, paragraph 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV):</u>

The appropriate comparator therapy must be an appropriate therapy in the therapeutic indication according to the generally recognised state of medical knowledge (Section 12 SGB V), preferably a therapy for which endpoint studies are available and which has proven its worth in practical application unless contradicted by the guidelines under Section 92, paragraph 1 SGB V or the principle of economic efficiency.

In determining the appropriate comparator therapy, the following criteria, in particular, must be taken into account as specified in Chapter 5, Section 6, paragraph 3 VerfO:

1. To be considered as a comparator therapy, the medicinal product must, principally, have a marketing authorisation for the therapeutic indication.
2. If a non-medicinal treatment is considered as a comparator therapy, this must be available within the framework of the SHI system.

[1] General Methods, version 8.0 from 19.12.2025. Institute for Quality and Efficiency in Health Care (IQWiG), Cologne.

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3. As comparator therapy, medicinal products or non-medicinal treatments for which the patient-relevant benefit has already been determined by the GBA shall be preferred.
4. According to the generally recognised state of medical knowledge, the comparator therapy should be part of the appropriate therapy in the therapeutic indication.

According to Section 6, paragraph 2, sentence 2 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the determination of the appropriate comparator therapy must be based on the actual medical treatment situation as it would be without the medicinal product to be assessed. According to Section 6, paragraph 2, sentence 3 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV), the GBA may exceptionally determine the off-label use of medicinal products as an appropriate comparator therapy or as part of the appropriate comparator therapy if they determine by resolution on the benefit assessment according to Section 7, paragraph 4 that, according to the generally recognised state of medical knowledge, this is considered a therapy standard in the therapeutic indication to be assessed or as part of the therapy standard in the medical treatment situation to be taken into account according to sentence 2, and

1. for the first time, a medicinal product approved in the therapeutic indication is available with the medicinal product to be assessed,
2. according to the generally recognised state of medical knowledge, the off-label use is generally preferable to the medicinal products previously approved for the therapeutic indication, or
3. according to the generally recognised state of medical knowledge, the off-label use for relevant patient groups or indication areas is generally preferable to the medicinal products previously approved for the therapeutic indication.

An appropriate comparator therapy may also be non-medicinal therapy, the best possible supportive therapy including symptomatic or palliative treatment, or monitoring wait-and-see approach.

<u>Justification based on the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO and Section 6, paragraph 2 AM-NutzenV:</u>

On 1. Apart from elinzanetant, no other medicinal products are approved for this therapeutic indication.

On 2. Non-medicinal treatment that can be provided within the SHI framework is not an option in this therapeutic indication.

On 3. In this therapeutic indication, there are no resolutions on the benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V.

On 4. The generally recognised state of medical knowledge was illustrated by a systematic search for guidelines as well as systematic reviews of clinical studies in the present indication and is presented in the "Research and synopsis of the evidence to determine the appropriate comparator therapy according to Section 35a SGB V".

The scientific-medical societies and the Drugs Commission of the German Medical Association (AkdÄ) were also involved in writing on questions relating to the comparator therapy in the present therapeutic indication according to Section 35a, paragraph 7 SGB V. However, no written feedback has been received.

No medicinal products have been approved for the treatment of moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer.

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Furthermore, on the basis of the available guidelines and the statements made by clinical experts in the written statement procedure, no off-label therapy options according to the generally recognised state of medical knowledge can be identified as standard therapy in the therapeutic indication to be assessed.

The monitoring wait-and-see approach is therefore determined as the appropriate comparator therapy for elinzanetant in patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer.

The findings in Annex XII do not restrict the scope of treatment required to fulfil the medical treatment mandate.

Any change to the appropriate comparator therapy requires a decision by the GBA based on a prior review of the criteria set out in Chapter 5, Section 6, paragraph 3 VerfO.

2.1.3 Extent and probability of the additional benefit

In summary, the additional benefit of elinzanetant is assessed as follows:

The additional benefit is not proven for patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer.

Justification:

The pharmaceutical company presented data from the OASIS-4 study for the benefit assessment of elinzanetant in the treatment of moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer. This is a study comprising a double-blind, randomised, controlled treatment phase comparing elinzanetant with placebo over 12 weeks, followed by a 40-week single-arm treatment phase in which all enrolled patients receive elinzanetant.

Patients aged 18 to 70 years with hormone receptor-positive breast cancer (stage 0 to III) or at high risk of breast cancer were enrolled. A key inclusion criterion was stable adjuvant endocrine therapy with tamoxifen or aromatase inhibitors, which was to be continued over the entire study duration. Furthermore, the patients must have experienced at least 35 moderate to severe vasomotor symptoms in the 7 days prior to the start of the study.

A total of 474 patients were enrolled in the study and randomised in a 2:1 ratio to treatment with elinzanetant (N = 316) or placebo (N = 158).

The primary endpoints of the study were the mean change in the frequency of moderate to severe vasomotor symptoms at week 4 and at week 12. Secondary endpoints comprised endpoints in the categories of morbidity, health-related quality of life and side effects.

On the duration of the present study

The treatment duration during the randomised, direct comparator phase of the OASIS-4 study was 12 weeks. A study duration of just 12 weeks is considered inadequate for the assessment of the additional benefit of elinzanetant.

According to the product information, there is no restriction on the treatment duration with elinzanetant. The advantages of symptomatic treatment should be reviewed regularly, as the need for treatment may vary from subject to subject or change over time. It is therefore assumed that elinzanetant will be taken on a long-term basis for as long as the burdensome

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symptoms persist. The recommended treatment duration of adjuvant endocrine therapy related to breast cancer is between 2 and 8 years[2,3,4,5]. Vasomotor symptoms may persist over the entire duration of adjuvant endocrine therapy, although their severity may decrease over time[6].

Overall, therefore, long-term treatment with elinzanetant is generally expected in this therapeutic indication, rather than short-term treatment lasting only a few days or weeks. Against this background, a comparative study duration of 12 weeks is considered inadequate for the assessment of the additional benefit compared with the appropriate comparator therapy.

Overall assessment

In summary, the comparatively short study phase of the OASIS-4 study makes it unsuitable for deriving an additional benefit of elinzanetant compared with the appropriate comparator therapy. An additional benefit is therefore not proven.

2.1.4 Summary of the assessment

The present assessment concerns the benefit assessment of the new medicinal product Lynkuet with the active ingredient elinzanetant. The therapeutic indication assessed here is "Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) caused by adjuvant endocrine therapy (AET) related to breast cancer". The GBA determined the monitoring wait-and-see approach as the appropriate comparator therapy.

For the benefit assessment, the pharmaceutical company presented data from the OASIS-4 study, which compared elinzanetant with placebo over a period of 12 weeks.

As the use of elinzanetant as part of adjuvant endocrine therapy is generally expected to involve long-term treatment, a comparative study duration of 12 weeks is considered inadequate for the assessment of the additional benefit compared with the appropriate comparator therapy.

Consequently, no suitable data are available for the benefit assessment for patients with moderate to severe vasomotor symptoms caused by adjuvant endocrine therapy related to breast cancer. An additional benefit is therefore not proven.

2.2 Number of patients or demarcation of patient groups eligible for treatment

The information on the number of patients is based on the target population in statutory health insurance (SHI).

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[2] Loibl S, Andre F, Bachelot T et al. Early breast cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol 2024; 35(2): 159-182. https://doi.org/10.1016/j.annonc.2023.11.016.

[3] Guideline programme in oncology. S3 guideline on early detection, diagnosis, therapy and follow-up of breast cancer [online]. 2025 [accessed: 26.03.2026]. URL: https://www.leitlinienprogramm-onkologie.de/fileadmin/user_upload/Downloads/Leitlinien/Mammakarzinom_4_0/Version_5/LL_Mammakarzinom_Langversion_5.0.pdf.

[4] Juvisé Pharmaceuticals. Arimidex 1 mg film-coated tablets [online]. 05.2021 [accessed: 20.05.2026]. URL: https://www.fachinfo.de.

[5] AbZ-Pharma. Tamoxifen AbZ 20 mg tablets [online]. 04.2026 [accessed: 20.05.2026]. URL: https://www.fachinfo.de.

[6] Marsden J, Marsh M, Rigg A. The British Menopause Society consensus statement on the management of oestrogen deficiency symptoms, arthralgia and menopause diagnosis in women treated for early breast cancer. Post Reproductive Health. 2022 Sep;28(3):158-164. doi: 10.1177/20533691221122358

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The resolution is based on the information provided by the pharmaceutical company in the benefit assessment dossier. However, the information is uncertain overall. This is especially because the percentage of women receiving adjuvant endocrine therapy may vary, and the range cited for the presence of vasomotor symptoms resulting from oestrogen deficiency is subject to uncertainty due to the heterogeneous data basis.

2.3 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

2.4 Treatment costs

The treatment costs are based on the contents of the product information and the information listed in the LAUER-TAXE® (last revised: 15 July 2026). The calculation of treatment costs is generally based on the last revised LAUER-TAXE® version following the publication of the benefit assessment.

For the cost representation, only the dosages of the general case are considered. Patient-individual dose adjustments (e.g. because of side effects or comorbidities) are not taken into account when calculating the annual treatment costs.

If no maximum treatment duration is specified in the product information, the treatment duration is assumed to be one year (365 days), even if the actual treatment duration is different from patient to patient and/or is shorter on average. The time unit "days" is used to calculate the "number of treatments/ patient/ year", time intervals between individual treatments and for the maximum treatment duration, if specified in the product information.

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

Treatment period:

Designation of the therapy	Treatment mode	Number of treatments/ patient/ year	Treatment duration/ treatment (days)	Treatment days/ patient/ year
Medicinal product to be assessed				
Elinzanetant	Continuously, 1 x daily	365.0	1	365.0
Appropriate comparator therapy				
Monitoring wait-and-see approach	Not calculable			

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Consumption:

Designation of the therapy	Dosage/ application	Dosage/ patient/ treatment days	Consumption by potency/ treatment day	Treatment days/ patient/ year	Average annual consumption by potency
Medicinal product to be assessed					
Elinzanetant	120 mg	120 mg	2 x 60 mg	365.0	730.0 x 60 mg
Appropriate comparator therapy					
Monitoring wait-and-see approach	Not calculable				

Costs:

In order to improve comparability, the costs of the medicinal products were approximated both on the basis of the pharmacy sales price level and also deducting the statutory rebates in accordance with Section 130 and Section 130a SGB V. To calculate the annual treatment costs, the required number of packs of a particular potency was first determined on the basis of consumption. Having determined the number of packs of a particular potency, the costs of the medicinal products were then calculated on the basis of the costs per pack after deduction of the statutory rebates. Any reference prices shown in the cost representation may not represent the cheapest available alternative.

Costs of the medicinal products:

Designation of the therapy	Packaging size	Costs (pharmacy sales price)	Rebate Section 130 SGB V	Rebate Section 130a SGB V	Costs after deduction of statutory rebates
Medicinal product to be assessed					
Elinzanetant 60 mg	180 SC	€ 296.56	€ 1.77	€ 15.75	€ 279.04
Appropriate comparator therapy					
Monitoring wait-and-see approach	Not calculable				
Abbreviations: Abbreviations: SC = soft capsules					

LAUER-TAXE® last revised: 15 July 2026

Costs for additionally required SHI services:

Only costs directly related to the use of the medicinal product are taken into account. If there are regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, the costs incurred for this must be taken into account as costs for additionally required SHI services.

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Medical treatment costs, medical fee services, and costs incurred for routine examinations (e.g. regular laboratory services such as blood count tests) that do not exceed the standard expenditure in the course of the treatment are not shown.

Because there are no regular differences in the necessary use of medical treatment or in the prescription of other services in the use of the medicinal product to be evaluated and the appropriate comparator therapy in accordance with the product information, no costs for additionally required SHI services had to be taken into account.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 11 February 2025, the Subcommittee on Medicinal Products determined the appropriate comparator therapy.

A review of the appropriate comparator therapy took place. At their session on 25 November 2025, the Subcommittee on Medicinal Products newly determined the appropriate comparator therapy.

On 26 March 2026, the pharmaceutical company submitted a dossier for the benefit assessment of elinzanetant to the GBA in due time in accordance with Chapter 5, Section 8, paragraph 1, number 1, sentence 2 VerfO.

By letter dated 26 March 2026 in conjunction with the resolution of the GBA of 1 August 2011 concerning the commissioning of the IQWiG to assess the benefit of medicinal products with new active ingredients in accordance with Section 35a SGB V, the GBA commissioned the IQWiG to assess the dossier concerning the active ingredient elinzanetant.

The dossier assessment by the IQWiG was submitted to the GBA on 25 June 2026, and the written statement procedure was initiated with publication on the GBA website on 1 July 2026. The deadline for submitting written statements was 22 July 2026.

The oral hearing was held on 10 August 2026.

In order to prepare a recommendation for a resolution, the Subcommittee on Medicinal Products commissioned a working group (Section 35a) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and representatives of the patient organisations. Representatives of the IQWiG also participate in the sessions.

The evaluation of the written statements received and the oral hearing were discussed at the Subcommittee's session on 22 September 2026, and deliberation of the draft resolution was concluded.

At their session on 1 October 2026, the plenum adopted a resolution to amend the Pharmaceuticals Directive.

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Chronological course of consultation

Session	Date	Subject of consultation
Subcommittee on Medicinal Products	11 February 2025	Determination of the appropriate comparator therapy
Subcommittee on Medicinal Products	25 November 2025	New determination of the appropriate comparator therapy
Working group Section 35a	5 August 2026	Information on written statements received; preparation of the oral hearing
Subcommittee on Medicinal Products	10 August 2026	Conduct of the oral hearing
Working group Section 35a	19 August 2026 2 September 2026	Consultation on the dossier assessment by the IQWiG and evaluation of the written statement procedure
Subcommittee on Medicinal Products	22 September 2026	Concluding discussion of the draft resolution
Plenum	1 October 2026	Adoption of the resolution on the amendment of the Pharmaceuticals Directive

Berlin, 1 October 2026

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

Dr Optendrenk

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