Drug assessment at a glance: A26-34[1]

Elinzanetant (vasomotor symptoms in menopause)

14 September 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-34. The G-BA decides on the added benefit.

Research question 1 of the benefit assessment

Population	Patients with moderate to severe vasomotor symptoms associated with the menopause for whom hormone replacement therapy is an option and who have decided in favour of hormone replacement therapy after an individual risk-benefit assessment
Intervention	elinzanetant
Comparator	Individualized treatment from a choice of ▪ oestrogen and ▪ oestrogen/progestogen combinations
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 1

	Size of the effects	Informative value of the effects
Mortality	∅	–
Morbidity	∅	–
Symptoms	∅	–
Health-related quality of life	∅	–
Side effects	∅	–
	∅ No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: no advantage or disadvantage (no suitable data)

Evidence base and noteworthy aspects – research question 1

- No relevant studies were available.

Research question 2 of the benefit assessment

Population	Patients with moderate to severe vasomotor symptoms associated with the menopause for whom hormone replacement therapy is not an option or who have decided against hormone replacement therapy after an individual risk-benefit assessment
Intervention	elinzanetant
Comparator	Watchful waiting
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects – research question 2

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity	ø	–
Symptoms	ø	–
Health-related quality of life	ø	–
Side effects	↔, ↓	–
	ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: Given the available data, it was not possible to draw any conclusions regarding the added benefit (no suitable data)

Evidence base and noteworthy aspects – research question 2

- Evidence base: subpopulation of the OASIS-3 randomized controlled trial comparing elinzanetant with placebo
- The subpopulation identified following the commenting procedure – comprising individuals with ≥35 moderate to severe vasomotor symptoms per week and various contraindications to the use of hormone replacement therapy – represented the population for research question 2 with sufficient certainty and was used for the benefit assessment.
- No data were available for the relevant subpopulation in the categories of morbidity and health-related quality of life; consequently, only data on all-cause mortality were available on the benefit side. In the given therapeutic indication, this was not considered sufficient for the derivation of conclusions on the added benefit. An added benefit of elinzanetant in comparison with watchful waiting is not proven.

References

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-34.html and https://www.iqwig.de/en/projects/a26-101.html.

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