Abaloparatide (osteoporosis, postmenopausal women)

Resolution of: 2 October 2024/16. January 2025 Valid until: unlimited
Entry into force on: 2 October 2024/16. January 2025
Federal Gazette, BAnzAT 25 10 2024 B4/ BAnzAT 13 02 2025 B3

Therapeutic indication (according to the marketing authorisation of 12 December 2022):

Treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Therapeutic indication of the resolution (resolution of 2 October 2024):

See therapeutic indication according to marketing authorisation.

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

Postmenopausal women with osteoporosis at increased risk of fracture

Appropriate comparator therapy for abaloparatide:

Patient-individual therapy taking into account risk of fracture and previous therapy with selection of:

Alendronic acid, risedronic acid, zoledronic acid, denosumab, romosozumab (women at significantly increased risk of fracture) and teriparatide

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Postmenopausal women with osteoporosis at increased risk of fracture

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A24-41) unless otherwise indicated.

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	∅	No data available.
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

Postmenopausal women with osteoporosis at increased risk of fracture

approx. 484,000 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 Eladynos (active ingredient: abaloparatide) agreed upon in the context of the marketing authorisation at the following publicly accessible link (last access: 9 August 2024):

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

4. Treatment costs

Annual treatment costs:

Postmenopausal women with osteoporosis at increased risk of fracture

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Abaloparatide	
1st year	€ 5,509.47
Subsequent year	€ 3,100.57
Appropriate comparator therapy:	
Alendronic acid	€ 198.80
Risedronic acid	€ 216.36
Zoledronic acid	€ 246.43
Denosumab	€ 717.20
Romosozumab	€ 6,730.60
Teriparatide	
1st year	€ 5,053.90
Subsequent year	€ 5,413.91

Costs after deduction of statutory rebates (LAUER-TAXE) as last revised: 15 September 2024)

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

Postmenopausal women with osteoporosis at increased risk of fracture

No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the

medical treatment mandate, nor do they make statements about expediency or economic feasibility.