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Our reference
2025016915

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Date 15 December 2025
Re: GVS advice abaloparatide (Eladynos®) for osteoporosis in postmenopausal women

This is a rectification of the letter dated 15 December 2025 (reference 2025016915). Due to an error, the previous version of the letter and the marginal assessment included information on the standard dosage of the other products in the already existing cluster. The letter and the marginal assessment have been amended accordingly (the relevant text has been removed).

Dear Mr Bruijn,

The National Health Care Institute advises you on the inclusion in the Medicine Reimbursement System (GVS) of abaloparatide (Eladynos®) for the treatment of osteoporosis in postmenopausal women with an increased risk of fractures. This advice was prompted by your request in the letter of 10 November 2025 (CIBG-25-08921).

Clinical picture

Osteoporosis in postmenopausal women is a progressive disease in which bone density and bone quality gradually decrease. After menopause, oestrogen production in women decreases significantly, disturbing the natural balance between bone formation and bone resorption. This often accelerates bone resorption year after year, often without obvious symptoms. This leads to increasingly brittle bones and a gradually increasing risk of fractures, especially in the vertebrae, hip and wrist. In 2020, over 425,000 women with osteoporosis were registered. In 2023, 130,000 women were treated for osteoporosis. In postmenopausal women with severe osteoporosis, the preferred treatment in the Netherlands is currently a bone formation stimulating agent; teriparatide or romosozumab. Both have been previously assessed by us[1,2,3]. Abaloparatide is also a bone-forming agent. All three are administered by subcutaneous injection.

Licensed indication

Abaloparatide (Eladynos®) is indicated for the treatment of osteoporosis in postmenopausal women at increased risk of fractures. It is available in a pre-filled

[1] National Health Care Institute. GVS advice for romosozumab (Evenity®) in the treatment of severe osteoporosis. 2020. Consulted on 9-12-2025 at https://www.zorginstituutnederland.nl/documenten/2020/12/16/gvs-advies-romosozumab-evenity .

[2] Health Care Insurance Board. CFH report 03/25: teriparatide (Forsteo®). 2003.

[3] Health Care Insurance Board. CFH report 04/31 teriparatide (Forsteo®), reassessment. 2004.

pen 3 mg in 1.5 ml solution in a pack containing one or three pre-filled pens. One 40 µl dose contains 80 µg of abaloparatide.

Claim by the marketing authorisation holder
Abaloparatide has a therapeutic value comparable with that of teriparatide in women with postmenopausal osteoporosis with an increased risk of fractures. The marketing authorisation holder therefore requests inclusion in List 1A of the Health Insurance Regulation for the registered indication, in the existing cluster 0H05AAAP V, together with teriparatide and romosozumab.

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Advisory report
The National Health Care Institute advises you to include abaloparatide (Eladynos®) for osteoporosis in postmenopausal women with an increased risk of fractures in List 1A of the GVS in the 0H05AAAP V cluster.

We have explained below how we reached this advisory report.

Substantive assessment

Assessment of interchangeability
Based on the criteria for interchangeability, the National Health Care Institute concludes that abaloparatide is interchangeable with teriparatide and can therefore be included in List 1A in the Health Insurance Regulation in the 0H05AAAP V cluster. This cluster also includes romosozumab. In the absence of a WHO-defined DDD for abaloparatide, the standard dose of abaloparatide was set by the National Health Care Institute at 80 µg per day.

Therapeutic value
The National Health Care Institute concluded that abaloparatide for the mentioned indication meets the established medical science and medical practice and, as such, has a therapeutic value comparable with that of the standard treatment with teriparatide. In a randomised registration study, the ACTIVE study, abaloparatide was directly compared to teriparatide, among others. On key endpoints, the incidence of different types of fractures, they show a similar effect. The same applies to the adverse effects and the number of discontinuations due to adverse effects. Previously, the National Health Care Institute concluded that romosozumab also has a therapeutic value comparable with that of teriparatide[1].

Should you need any further information, please do not hesitate to contact us. The assessment report is attached (marginal assessment).

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board