NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Abaloparatide for treating osteoporosis in postmenopausal women

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of abaloparatide within its marketing authorisation for treating osteoporosis in postmenopausal women.

Background

Osteoporosis is a progressive skeletal disorder which is characterised by low bone mass and deterioration of the structure of the bone, leading to an increase in bone fragility and risk of fracture.

Osteoporosis is asymptomatic and often remains undiagnosed in the absence of fracture. In the UK, it is estimated that around 3 million people have osteoporosis, which is defined as having a bone mineral density (BMD) that is 2.5 standard deviations or more below the average value for young healthy adults (usually referred to as a 'T-score' of -2.5 or lower). The prevalence of osteoporosis increases markedly with age. In women, decreased oestrogen levels after the menopause accelerate bone loss, increasing the risk of osteoporosis. Half of women and one-fifth of men over the age of 50 will break a bone, mostly as a result of osteoporosis.[1] Osteoporosis can also be caused by the long-term systemic use of corticosteroids.

There are approximately 536,000 new fragility fractures in the UK per year,[2] of which about 345,000 happen in women.[3] Osteoporotic fragility fractures occur most commonly in the hip, vertebrae and wrist. After a hip fracture, a high proportion of people are permanently unable to walk independently or to perform other activities of daily living and, consequently, many are unable to live independently. Vertebral fractures can be associated with curvature of the spine and height loss, and can result in chronic pain, breathing difficulties, gastrointestinal problems and difficulties in performing activities of daily living. Both hip and vertebral fractures are associated with increased mortality.

Currently, related NICE guidance includes:

- NICE clinical guideline 146, makes recommendations on the assessment of fracture risk.

- NICE technology appraisal 464, which recommends oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) and intravenous bisphosphonates (ibandronic acid and zoledronic acid) as options for treating osteoporosis in people who are eligible for risk assessment as defined in NICE clinical guideline 146 on osteoporosis, depending on the person's risk of fragility fracture. However, the risk level at which oral bisphosphonates are cost effective is not a clinical intervention threshold. This technology appraisal guidance should be applied clinically in conjunction with the NICE quality standard 149 on osteoporosis that defines the clinical intervention thresholds.

These thresholds are based on the NICE-accredited National Osteoporosis Guideline Group guideline.

- NICE technology appraisal 791, which recommends romosozumab for treating severe osteoporosis in people after menopause who are at high risk of fracture, only if they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture).

- NICE technology appraisal 204, which recommends denosumab:

    - for the primary prevention of fragility fractures in postmenopausal women at specified fracture risks, defined by age, T-score and number of independent clinical risk factors for fracture, who have osteoporosis and who cannot take alendronate and either risedronate or etidronate

    - for the secondary prevention of osteoporotic fragility fractures in postmenopausal women at increased risk of fractures who cannot take alendronate and either risedronate or etidronate.

- NICE technology appraisal 161, which recommends raloxifene, strontium ranelate and teriparatide at specified fracture risks defined by age, T-score and either number of independent clinical risk factors for fracture (raloxifene), or number of fractures (teriparatide). These recommendations are for women who have already sustained a fracture and who cannot take alendronate or risedronate.

The technology

Abaloparatide (Eladynos, Radius Health) does not currently have a marketing authorisation in the UK for treating osteoporosis. It has been studied in clinical trials compared with placebo and teriparatide in postmenopausal women with osteoporosis at increased risk of fracture defined by bone mineral density and fracture history.

Intervention(s)	Abaloparatide
Population(s)	Postmenopausal women with osteoporosis at increased risk of fracture

Subgroups	If the evidence allows the following subgroups will be considered: • subgroups based on patient characteristics that increase the risk of fracture (that is, those specified in NICE clinical guideline 146) • subgroups based on predicted risk of fracture over 10 years • subgroups based on patient characteristics that affect the impact of fracture on lifetime costs and outcomes • subgroups based on fracture history • subgroups based on history of major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture)

Comparators	• Bisphosphonates
	  ○ alendronic acid
	  ○ ibandronic acid
	  ○ risedronate sodium
	  ○ zoledronic acid
	• Non-bisphosphonates
	  ○ denosumab
	  ○ romosozumab
	  ○ strontium ranelate
	  ○ teriparatide
	  ○ raloxifene
	• No active treatment

Outcomes	The outcome measures to be considered include: • osteoporotic fragility fracture • bone mineral density • mortality • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related technology appraisals:** Romosozumab for treating severe osteoporosis (2022) NICE technology appraisal guidance 791. Bisphosphonates for treating osteoporosis (2017, updated 2019) NICE technology appraisal guidance 464. Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (2008, updated 2018) NICE technology appraisal guidance 161. Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women (2008, updated 2018) NICE technology appraisal guidance 160. Denosumab for the prevention of osteoporotic fractures in postmenopausal women (2010) NICE technology appraisal guidance 204. **Related technology appraisals in development:** Abaloparatide for treating idiopathic or hypogonadal osteoporosis in men. NICE technology appraisal guidance [ID4059] Publication date to be confirmed

	Related NICE guidelines: Osteoporosis: assessing the risk of fragility fracture (2012, updated 2017) NICE guideline CG146. **Related NICE guidelines in development:** Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update). NICE guideline. Publication expected January 2025 **Related quality standards:** Osteoporosis (2017) NICE quality standard 149
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan

Questions for consultation

How is increased risk of fracture defined in routine clinical practice?

Where do you consider abaloparatide will fit into the existing care pathway for osteoporosis?

Would abaloparatide be a candidate for managed access?

Do you consider that the use of abaloparatide can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which abaloparatide will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-tehnology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. Age UK (2022) Osteoporosis. (Accessed December 2022)

2. Compston J et al. (2017) UK clinical guideline for the prevention and treatment of osteoporosis. Archives of Osteoporosis 12(1): 43

3. Svedbom, A et al. Osteoporosis in the European Union: a compendium of country-specific reports. Archives of Osteoporosis 8(1):137.