Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Abaloparatide for treating osteoporosis after menopause TA991		
Available at	https://www.nice.org.uk/guidance/ta991		
Date of issue	07 August 2024	**Implementation deadline**	3 months

Medicine details[1]	
Name and brand name	Abaloparatide (Eladynos)
Manufacturer	Theramex UK Limited
Mode of action	Abaloparatide is a 34-amino acid peptide that shares 41% homology to parathyroid hormone-related peptide [PTHrP(1-34)] and is an activator of the PTH1 receptor signalling pathway. As an anabolic agent abaloparatide stimulates new growth formation on trabecular and cortical bone surfaces by stimulation of osteoblastic activity. Abaloparatide causes transient and limited increases in bone resorption and increases bone density. Stimulating bone formation before enhancing bone resorption, is the period when anabolic agents are maximally anabolic (referred to as the 'anabolic window'). The mechanism of action of abaloparatide differs to that of the PTHrP, teriparatide. Both agents act on the PTH1 receptor but in different ways. Abaloparatide is more selective for the RG conformation of the PTH1 receptor, inducing a faster and more transient signalling response, than teriparatide which is more selective for the R0 conformation of the PTH1 receptor. The major difference is a much smaller transient increase in bone resorption with abaloparatide compared with teriparatide, suggesting there is a wider anabolic window with abaloparatide that results in a greater amount of bone formation than with teriparatide.
Licenced indication	Treatment of osteoporosis in postmenopausal women at increased risk of fracture
Formulation	Solution for injection (injection). Colourless, clear solution.
Dosage	**Dosage:** • The recommended daily dose of abaloparatide is 80 µg once daily • Each prefilled pen contains 3 mg of abaloparatide in 1.5 mL of solution (corresponding to 2 mg per mL) • **The maximum total duration of treatment with abaloparatide**

	should be 18 months. It is a once in a lifetime course of treatment. • Patients should receive supplemental calcium and vitamin D if dietary intake is inadequate • Following cessation of abaloparatide therapy, patients may be continued on other osteoporosis therapies, such as bisphosphonates **Administration:** • Abaloparatide is administered as a once daily subcutaneous injection. • The first injection(s) administered by the patient or caregiver should be performed under the guidance of an appropriately qualified healthcare professional • Patients and/or caregivers should be trained in the subcutaneous administration of abaloparatide • A detailed instruction for use is included in each pack to instruct patients on the correct use of the injection pen • Abaloparatide should be injected in the lower abdomen. The site of the injection should be rotated every day • Injections should be administered at approximately the same time every day
Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	Dosage and time intervals are the same as time of NICE publication. At the time of the publication of the NICE TA, the maximum duration of use is 18 months. • The NICE TA differs from the SmPC in two ways: defining the patient group (after menopause in women, trans men and non-binary people) and limiting use to those with a very high risk of fracture. **Please note: abaloparatide is an option amongst drugs with similar modes of action and as a once in a lifetime 18 month course treatment.** This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations[2]

Recommendations

1.1 Abaloparatide is recommended as an option for treating osteoporosis after menopause in women, trans men and non-binary people, only if they have a very high risk of fracture. It is only recommended if the company provides it according to the commercial arrangement.

1.2 If people with the condition and their healthcare professional consider abaloparatide, romosozumab and teriparatide to be suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive suitable treatment should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

1.3 This recommendation is not intended to affect treatment with abaloparatide that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare

professional consider it appropriate to stop.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- This NICE TA has been assigned an implementation deadline of 3 months.
- The implementation deadline is 07 November 2024.

Clinical effectiveness

Usual treatments for osteoporosis after menopause include romosozumab or teriparatide and bisphosphonates such as alendronic acid. For this evaluation, the company asked for abaloparatide to be considered only for people who have a very high risk of fracture. This does not include everyone who abaloparatide is licensed for. It would be used as an alternative treatment to romosozumab or teriparatide.

Clinical trial evidence shows that abaloparatide followed by alendronic acid is more effective at reducing the risk of some types of fracture than placebo followed by alendronic acid. Indirect comparisons suggest that abaloparatide is likely to work at least as well as romosozumab and teriparatide.

The most likely cost-effectiveness estimates for abaloparatide are within the range that NICE considers an acceptable use of NHS resources. So, abaloparatide is recommended.

Patient safety

- The product should be used within its product licence.
- ▼ This is a Black Triangle drug – this medicinal product is subject to reporting of all suspected adverse drug reactions to the MHRA. This will allow timely identification of new safety information.

Patient factors

- The treatment is self-administered by the patient, which avoids the need for repeated visits to the hospital/GP practice.
- Once opened, the treatment does not need to be refrigerated (unlike teriparatide and romosozumab). This offers patients increased flexibility of travelling with their treatment.
- Daily injections are required, although this is also the case for teriparatide. For both treatments, these injections are done using an injection pen by the patient so do not require hospital/GP visits.
- Adverse events may affect a small proportion of patients
- An additional treatment option would be valued by patients. however, there are other anabolic agents already in the available pathway, so it does not constitute a novel mode of action or a new line of treatment, abaloparatide is expected to be used when teriparatide or romosuzumab are not suitable.
- This medicine is available under a homecare service so will be delivered directly to the patient. When the patient is confident in self-administering, this may reduce the number of hospital appointments to those required for review and/or monitoring.
- Patients must adhere to the storage requirements.
- Patients would need to be reviewed on a regular basis by the prescribing clinician to ensure concordance, monitor for adverse effects and efficacy.

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management.
- Homecare deliveries – patients' home (additional carbon – increase air pollution)
- Discharge into wastewater (post metabolism - unknown effect of long term exposure via water cycle)
- Sharps waste - requires safe collection and disposal

Equality & diversity

- The company noted that although the marketing authorisation for abaloparatide is for the 'treatment of osteoporosis in postmenopausal women', a person can have osteoporosis after menopause and not identify as a woman. Gender reassignment is a protected characteristic under the Equality Act 2010.
- The NICE recommendation includes women, trans men and non-binary people registered female at birth

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

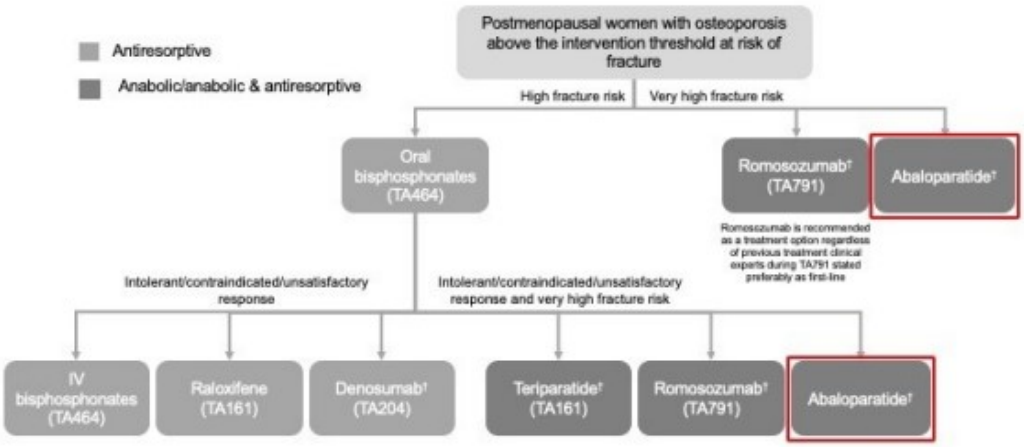
Place in therapy relative to available treatments

NICE places abaloparatide to be used in the current treatment pathway as shown below. It is proposed that this pathway is adopted as an interim measure whilst the current osteoporosis pathway is amended and reviewed.

It is recommended that the current pathway "Osteoporosis Treatment Pathway – Algorithm 1 – updated August 2022 is left as is whilst pathways are reviewed, but that a note is added to the PAD narrative that an interim pathway is in place for the box titled Specialist treatment options - RED status.

From NICE TA991 evidence papers (pg230).

Figure 1: Proposed place of abaloparatide in the current treatment pathway



† Patients stopping denosumab, teriparatide, romosozumab and abaloparatide require a sequential therapy strategy typically involving an antiresorptive drug

Abbreviations: IV, intravenous; TA, technology appraisal

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources does not exceed £100,000.

Section 1: cost of the technology

The list price of abaloparatide is £294.54 per pre-filled pen (excluding VAT, company submission). Each pre-filled pen contains 3 mg abaloparatide in 1.5 ml of solution (30 doses).

a. Annual cost per patient (or complete course if shorter)

Costs in primary care: £0
Costs in secondary care: (per 18 month course) £5,302 (list price)

b. Availability of CAP/PAS price: Yes

c. Price relative to comparable medicines:
Abaloparatide will be the 2nd most cost effective treatment available in this part of the pathway, after biosimilar teriparatide.

Section 2: NICE resource impact statement and template
Number of patients Year 1 and Year 5: 5 patients in year 1, rising to 31 by year 5.

Potential patient numbers per 100,000: 25 patients

a. NICE resource impact statement
NICE has recommended abaloparatide as an option for treating osteoporosis after menopause in women, trans men and non-binary people, only if they have a very high risk of fracture. It is only recommended if the company provides it according to the commercial arrangement.

If people with the condition and their healthcare professional consider abaloparatide, romosozumab and teriparatide to be suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive suitable treatment should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

This recommendation is not intended to affect treatment with abaloparatide that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

We expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 57. 1 million people).

This is because the technology is a further treatment option and the overall cost of treatment will be similar for this patient group.

The company has a commercial arrangement. This makes abaloparatide available to the NHS with a discount. The size of the discount is commercial in confidence.

This technology is commissioned by integrated care boards. Providers are NHS hospital trusts.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

b. NICE resource impact template

Surrey Heartlands ICB	Current practice - year 0	Future practice - year 1	Future practice - year 2	Future practice -year 3	Future practice - year 4	Future practice - year 5
Eligible population	**265**	**269**	**278**	**290**	**301**	**310**
Drug resource impact (cash) year on year		**£34k**	**£186k**	**£95k**	**£32k**	**£44k**

Drug costs for Surrey Heartlands: Does this exceed the £100,000 per Place threshold?
No

Commentary:

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme

Yes

Recommended traffic light status and rationale:
RED – Specialist ONLY drugs - treatment initiated and continued by specialist clinicians.

PAD definitions, available at:

FINAL April 2023
Colour classification g

Implementation

- NICE TA implementation must be within 90 days of publication.

Primary care

- This is a National Tariff excluded high-cost drug and is commissioned by ICSs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.
- Antiresorptive treatments will be started by secondary care immediately after the 18 month course of abaloparatide is completed (this is already standard procedure for other drugs in this treatment pathway). Antiresorptive treatment may be transferred to primary care, if and when appropriate and as per current PAD recommendations.

Secondary care

- Providers are NHS hospital trusts.
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- Specialists will be required to notify the ICB and pharmacy high-cost drugs teams of initiation to treatment using the Blueteq® system.
- Homecare arrangements for prescription and supply will be managed by the trust.
- This medicine is available via a homecare contract and as a subcutaneous injection so once the patient is trained and confident in self-administration will only require appointments for review and/or monitoring.
- The initiation, administration and on-going treatment is managed by secondary care.
- Antiresorptive therapy will be initiated by secondary care immediately after 18 months of treatment with abaloparatide. Antiresorptive treatment may be transferred to primary care, if and when appropriate and as per current PAD recommendations.
- An alternative prescribing option would be valued by clinicians.

ICS

- This technology is commissioned by integrated care systems and they are required to

comply with the recommendation in the NICE TA within 90 days of publication.
- Pathway to be amended to incorporate abaloparatide as indicated by NICE and discussed at the next ICB-wide Rheumatology Network for endorsement (tbc).
- Please note, abaloparatide is placed by NICE and (tbc) locally as an option and as a once in a lifetime course of treatment. It is not intended to be used sequentially, nor before or after teriparatide or romosuzumab or concomitantly with either – single agent use of abaloparatide is to be used as an ***alternative*** when teriparatide is not clinically appropriate and is more cost-effective than romosozumab.

PAD and Joint Formulary
- Remove pathway from all treatments for this condition from PAD and replace with revised pathway (temp pathway until new NICE guidance Jan-25).
- New PAD profile and JF status will be required
- No existing formulary statuses or PAD profiles will need further amendment.

Proposed tick box forms
- Blueteq® forms have been developed (see below).

References:

1 Summary of Product Characteristics. emc. Available at: Eladynos 80 microgram solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)
Accessed 9th August 2024

2 NICE Technology Appraisal Guidance: Abaloparatide for treating osteoporosis after menopause TA991. Available at: https://www.nice.org.uk/guidance/ta991
Accessed 9th August 2024

3 NICE Resource Impact Report: Tools and resources | Abaloparatide for treating osteoporosis after menopause. Available at: https://www.nice.org.uk/guidance/ta991/resources
Accessed 9th August 2024

4 NICE Resource Impact Template: Tools and resources | Abaloparatide for treating osteoporosis after menopause. Available at: https://www.nice.org.uk/guidance/ta991/resources
Accessed 9th August 2024

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	G. Randall	Senior Pharmacy Technician, Medicine Resource Unit, SHICB	21st August 2024	None
Supported by				
Reviewed by	T. Bahra	Lead Pharmacist, MRU	2.9.24	None

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	21/08/2024	G. Randall	Draft	Out for consultation
			Final	Out for clinical comment

Blueteq® form:

Please indicate whether patient meets the following NICE criteria:	Please tick
1. The patient is either a woman, trans man or a non-binary person registered as female at birth AND is postmenopausal AND has a very high risk of fracture.	○ Yes ○ No
2. NICE TA991 recommendations: The National Osteoporosis Guideline Group (NOGG) clinical guideline for the prevention and treatment of osteoporosis defines 'very high risk' as a fracture probability (based on the Fracture Risk Assessment Tool [FRAX]) that exceeds the threshold for intervention by 60% If people with the condition and their healthcare professional consider abaloparatide, romosozumab and teriparatide to be suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive suitable treatment should be used (this is currently biosimilar teriparatide). . Please give a brief explanation as to why abaloparatide had been selected over the other treatments available. :	
3. FOR INFORMATION **Abaloparatide will be funded for 18 months only, as per product licence, August 2024. Following the approved duration of treatment with abaloparatide (18 months), treatment with an antiresorptive agent should be initiated by secondary care without delay.**	