Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

**Licensed One Wales Medicines Assessment Group Recommendation**
Teriparatide solution for injection

**Date of advice**: June 2025
**AWTTC reference number**: 6561

**Teriparatide is recommended for use within NHS Wales as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in men at increased risk of fracture. Inclusion, exclusion, starting and stopping criteria are the same as those in the NHS England clinical commissioning policy for osteoporosis in men**.

This recommendation has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

This recommendation will be considered for review after three years.

This advice replaces the AWMSG recommendation previously issued in November 2008 (AWTTC reference number 306).



AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

**Licensed Medicines One Wales Medicine Assessment Group summary of decision rationale**

Medicine: **Teriparatide**
Assessment type: **Limited**
Indication: **Treatment of osteoporosis in men at increased risk of fracture**
Meeting date: **7 May 2025**

| Criteria | LOWMAG opinion |
|---|---|
| Clinical effectiveness | The AWMSG Scrutiny Panel acknowledged that clinical effectiveness is already established and therefore no clinical effectiveness evidence was required for consideration by LOWMAG. |
| Cost-effectiveness | As this is a limited assessment cost effectiveness is not considered. |
| Budget impact | LOWMAG considers the estimates of patient numbers to be reasonable.<br><br>LOWMAG considers that the ranges provided in the report are reasonable estimates of the total net cost associated with the use of teriparatide in men in NHS Wales.<br><br>LOWMAG notes that teriparatide is routinely available in some health boards and the effective net cost is therefore lower than the totals estimated. |
| Resource use | LOWMAG agrees that treatment with teriparatide is unlikely to be associated with significant additional resource use as these patients would already be routinely monitored.<br><br>LOWMAG agrees that teriparatide treatment is anticipated to result in reduced fractures in men with osteoporosis which would result in cost savings. |
| Other factors | LOWMAG noted that an AWMSG negative recommendation for the use of teriparatide in NHS Wales was issued in 2008 following a full HTA. LOWMAG noted that there is an NHSE commissioning policy recommending teriparatide use in men based on specific criteria.<br><br>LOWMAG agrees that there is an inequity of routine access to teriparatide in NHS Wales and compared to NHS England, resulting in an unmet clinical need in some areas of Wales. It is noted that NICE guidance recommends teriparatide use in menopausal women with osteoporosis therefore there is gender inequality in access. |

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| Final recommendation | LOWMAG recommends teriparatide as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in men at increased risk of fracture. LOWMAG recommends inclusion, exclusion, starting and stopping criteria as detailed in the attached appendix 1 (which are the same as those in the NHS England clinical commissioning policy for osteoporosis in men)<br>. |
| Summary of rationale | LOWMAG acknowledges that there is gender inequality of routine access to teriparatide for men in NHS Wales in comparison to women with the same disease and bone mineral density. There is also routine access to the treatment for men in NHSE and in most Welsh health boards resulting in geographical inequality.<br><br>LOWMAG recognises that conditional teriparatide use is recommended by the National Osteoporosis Guideline Group.<br><br>LOWMAG considers that making teriparatide routinely available throughout NHS Wales will have a low budget impact and service impact. |

**Appendix 1: Inclusion, exclusion, starting and stopping criteria (**NHS England clinical commissioning policy for osteoporosis in men)

**Inclusion criteria**
Teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in men.

**Exclusion criteria**
Patients are excluded if they meet any of the following criteria:
• Severe renal impairment.
• Paediatric patients (less than 18 years), or young adults with open epiphyses.
• Hypersensitivity to the active substance or to any of the excipients
• Pre-existing hypercalcaemia
• Metabolic bone diseases (including hyperparathyroidism and Paget's disease of the bone) other than primary osteoporosis or glucocorticoid-induced osteoporosis
• Unexplained elevations of alkaline phosphatase
• Prior external beam or implant radiation therapy to the skeleton
• Patients with skeletal malignancies or bone metastases should be excluded from treatment with teriparatide

In addition, caution should be exercised in moderate renal impairment**.**

**Starting criteria**
Using the criteria in NICE TA161 as a guide, teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in men:

• Who are unable to take alendronate and risedronate, or have a contraindication to or are intolerant of alendronate and risedronate (see below), or who have had an unsatisfactory response, which is defined as occurring when a man has another fragility fracture despite adhering fully to treatment for 1 year and there is evidence of a decline in BMD below his pre-treatment baseline, AND
• Who are 65 years or older and have a T-score of –4.0 SD or below, or a T- score of –3.5 SD or below plus more than two fractures, or who are aged 55– 64 years and have a T-score of –4 SD or below plus more than two fractures.

Because fracture incidence is related to absolute bone density regardless of gender it is important that this is taken into account when calculating fracture risk. Accordingly, T- scores used for fracture risk calculation in men should be based on the National Health and Nutrition Examination Survey (NHANES) female reference database. The online version of the FRAX Fracture Risk Assessment Tool does this automatically if absolute bone mineral density is entered and the manufacturer of the densitometer specified.

In line with the NICE guidance, intolerance of alendronate or risedronate is defined as persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.

**Dose**
The adult male dose is 20 micrograms daily for a maximum of 24 months.

**Stopping criteria**
Treatment may be stopped if the patient has adverse reactions. The maximum total duration of treatment with teriparatide should be 24 months. The 24-month course of teriparatide should not be repeated over a patient's lifetime**.**