



Equality and Health Impact Assessment

Teriparatide for the treatment of osteoporosis in men at increased risk for fracture

AWTTC will fill in an Equality and Health Impact Assessment in parallel with each development stage of our projects. This will help us to follow the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

Date: 06/03/2025

1.	AWTTC contact details	Tel: 02921 826900 Email: awttc@wales.nhs.uk
2.	State the objectives of the project.	<p>AWTTC will prepare an evidence summary report (ESR) for a limited AWMSG assessment for the use of teriparatide (generic) to treat osteoporosis in men at increased risk for bone fracture.</p> <p>This is a reassessment after a full submission in 2008 received a negative AWMSG recommendation for teriparatide use in men with osteoporosis due to the case for clinical and cost-effectiveness not being proven. AWTTC reviewed the recommendation in 2013 and 2016 and requested re-engagement from the company, but no submission was received. Teriparatide received a negative recommendation following appraisal by the Scottish Medicines Consortium in 2008 due to the economic analysis being insufficiently robust.</p> <p>The ESR produced by AWTTC will focus on clinical effectiveness and budget impact, as well as equity of access across Wales and the rest of the UK. The views of patient organisations relevant to this condition will also be requested. AWTTC will send the ESR to the company (marketing authorization holder)</p>



		<p>and to clinicians for comment. Clinicians, company representatives and patient organisation representatives are invited to attend the Licensed One Wales Medicines Assessment Group (LOWMAG) meeting. The LOWMAG constitution is available online.</p>
<p>3.</p>	<p>Evidence and background information considered. For example:</p> <ul style="list-style-type: none">• population data• staff and service users' data, as applicable• needs assessment• engagement and involvement findings• research• good practice guidelines• participant knowledge• list of stakeholders and how stakeholders have engaged in the development stages• comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory.</p>	<p>Osteoporosis is defined by the World Health Organization as a progressive, systemic, skeletal disease characterised by a low bone mass and micro architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. Osteoporosis is characterised by a bone mineral density (BMD) of 2.5 standard deviations or more below the mean peak mass (average of young healthy adults) reported as a T-score. It occurs as a result of increased bone breakdown by osteoclasts and decreased bone formation by osteoblasts. Age-related osteoporosis is more likely to occur as age increases and is typically observed in males over the age of 70 years. Treatments for osteoporosis include bisphosphonates (alendronate and risedronate) and denosumab (a human monoclonal antibody) which prevent bone resorption by inhibiting osteoclast activity.</p> <p>Teriparatide is indicated for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fracture. It stimulates bone formation by increasing osteoblast activity. NICE guidance TA161 (published 2008, updated 2018) recommends teriparatide for the secondary prevention of osteoporotic fractures in postmenopausal women with osteoporosis who are not responding or intolerant to the bisphosphonates, alendronate and risedronate. AWMSG advice, published in 2008, does not recommend teriparatide (Forsteo®) to treat osteoporosis in men.</p> <p>Teriparatide has been available for use in men in NHS England for many years and commissioning was formalised in August 2024 (NHSE teriparatide clinical commissioning policy). Health boards in Wales have reported that this has created inequity at the Wales/England border. Teriparatide has also been used routinely in men in some health boards in Wales but in others individual</p>



patient funding requests or specific health board decisions are required, creating the potential for geographical inequity in patient access.

Biosimilars have also been introduced since the original appraisal by AWMSG. Use in men is recommended by the [National Osteoporosis Guideline Group \(clinical guideline 2024\) \(NOGG\)](#). NOGG states teriparatide can be a first-line option in men aged 50 years and older who are at very high fracture risk (particularly in those with vertebral fractures). Teriparatide should be considered as a second-line treatment in men aged 50 years and older who are intolerant of bisphosphonates, particularly in those with vertebral fractures.

Clinicians describe teriparatide as a treatment of choice for vertebral fractures or treatment failure on antiresorptives (bisphosphonates). It would be offered to men to protect them from re-fracture or fragility fracture if they have very severe osteoporosis. Clinicians have commented that women with severe osteoporosis would qualify for teriparatide therapy and since there is evidence for efficacy in men it is difficult to justify differential treatment of men and women with the same disease and BMD.

Teriparatide is a parathyroid hormone prepared using recombinant DNA technology. It stimulates bone formation and increases bone mass and strength. Biosimilar versions are available in Wales. The recommended dose is 20 micrograms (mcg) once daily via subcutaneous injection. Patients must be trained to deliver injection into thigh or abdomen. The maximum duration should be 24 months (the 24-month course should not be repeated). Since the maximum permitted duration of treatment with teriparatide is 24 months sequential therapy with anti-resorptive drugs (bisphosphonates e.g. alendronate) is required to maintain the beneficial skeletal effects.

[NHSE teriparatide clinical commissioning policy](#) (for osteoporosis in men) states teriparatide is recommended for people who have had several fractures despite having tried other drug treatments. Currently teriparatide is



recommended by NICE for the secondary prevention of osteoporotic fragility fractures in postmenopausal women ([TA161](#)), under specified criteria. The policy seeks to address equality issues by recommending use in men. 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:

- intolerant or not responding to alendronate and risedronate and
- who are ≥ 65 years and have a T score of -4.0 standard deviations (SD) or below, or a T score of -3.5 SD or below plus $>$ two fractures, or who are aged 55–64 years and have a T score of -4 SD or below plus more than two fractures.

[NICE quality standard \(QS149\)](#) lists teriparatide alongside other non-bisphosphonates as a medicine to prevent fragility fractures. Guidance on treatment has been focused on treating post-menopausal women because of their increased risk. Clinicians should ensure that other populations who might benefit from recommended treatments are also considered.

The clinical effectiveness of teriparatide was assessed in [2008 by AMWSG](#). The company submission included two trials in male patients with osteoporosis. A randomised controlled trial (with a follow up observational study) compared two strengths of teriparatide (20 micrograms (mcg) daily [the licensed dose] and 40 mcg daily) versus placebo ([Orwoll et al., J Bone Miner res 2003, 18, 9–17](#); [Kaufman et al., Osteoporos Int 2005, 16, 510–516](#)). A second trial compared teriparatide (40 mcg daily) versus alendronate (10 mg daily) alone and alendronate (10 mg daily) plus teriparatide (40 mcg daily) ([Finkelstein JS et al. New Engl J Med 2003, 349, 1216–1226](#)). No comparison versus risedronate or denosumab was included.

The most common adverse effects associated with teriparatide include injection-site pain and swelling, nausea, headaches, leg cramps and dizziness. These effects resulted in discontinuation rates of 6%–19% in



		<p>clinical trials.</p> <p>In the second year of use an estimated 82 men in Wales would receive teriparatide if it were available: of these, an estimated 63 men already currently receive the medicine and a further 19 men would receive it if it were approved.</p> <p>The average estimated cost to treat one patient for a year based on the list price of the medicine is £3,563 and the initial appraisal in 2008 was based on a similar cost. However the availability of biosimilars and contract pricing has now led to a significantly reduced cost of treating patients compared to this list price cost. The contract prices are confidential and are not disclosed here..</p>
4.	Who will this project affect?	People in Wales with osteoporosis who have an increased risk for bone fracture, and their families and carers.



5. EQIA - How will the project impact on people?

Questions in this section relate to the impact on people based on the 'protected characteristics' of the Equality Act 2010, and other factors.

How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
5.1 Age For most purposes, the main categories are people aged: <ul style="list-style-type: none">• under 18 years;• between 18 and 65 years;• over 65 years.	We do not expect a potential negative, or unequal, impact on people based on their age. Osteoporosis is more likely to occur as age increases and is typically observed in males over the age of 70 years. Note: For prescription medicines we expect the prescriber to have prescribed or advised their use within the terms of their UK marketing authorisations. Healthcare professionals should take note of the contraindications, warnings, safety	N/A	N/A



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	recommendations and any monitoring needs for the medicine. These are explained in the Summary of Product Characteristics (SmPC) for the medicine or the British National Formulary .		
5.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term medical conditions such as diabetes.	We do not expect a potential negative, or unequal, impact on people with a disability.	All related documents published on the AWTTC website will meet accessibility requirements. Any patient-facing materials will be also be produced as easy read booklets in Welsh and English.	N/A
5.3 People of different genders: Consider men, women, people undergoing gender reassignment. N.B. Gender-reassignment is anyone who proposes to, starts, is going through or who has	The current negative recommendation means that some men with osteoporosis are currently disadvantaged compared to women with the same condition because they	N/A	N/A



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completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender.	do not have routine access to teriparatide. A positive recommendation would remove this inequality.		
5.4 People who are married or who have a civil partner.	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.	N/A	N/A
5.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding. They are protected for 26 weeks after having a baby whether or not they are on maternity leave.	We do not expect a potential negative, or unequal, impact on women who are expecting a baby, are breastfeeding, or are on a break from work after having a baby; this assessment of teriparatide is for its use in men with osteoporosis. Teriparatide is not to be taken during pregnancy or when breastfeeding, and women of childbearing potential should	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
	use effective methods of contraception while taking teriparatide. Please refer to the SmPC .		
5.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies and travellers, migrant workers. The Runnymede Trust	We do not expect a potential negative, or unequal, impact on people of a different race, nationality, colour, culture or ethnic origin. People of different race and ethnicities can have varying responses to medicines.	People of different race and ethnicities can have varying responses to medicines.	N/A
5.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief. Implications of religious beliefs on selection of medicines (BMJ)	We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief. Some medicines are made from certain animal products and people might not want to	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
In practice: guidance on religion, personal values and beliefs (General Pharmaceutical Council)	take them because of religion or belief.		
5.8 People who are attracted to other people of: <ul style="list-style-type: none"> the opposite sex (heterosexual); the same sex (lesbian or gay); both sexes (bisexual). Stonewall	We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.	N/A	N/A
5.9 People who communicate using the Welsh language in terms of correspondence, information leaflets, or service plans and design.	We do not expect a potential negative, or unequal, impact on people who communicate using the Welsh language. Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	Any patient-facing materials will be produced in Welsh and English, in line with the Welsh language standards, including easy read booklets.	N/A
5.10 People according to their income related group.	We do not expect a potential negative, or unequal, impact on people based on their income-related group.	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
	<p>Teriparatide is given by subcutaneous injection in the thigh or abdomen. Teriparatide is provided via the home care service. Patients are trained to use the correct injection techniques.</p> <p>In Wales, all prescription medicines are free-of-charge for patients; positive recommendations through this project will not affect people depending on their income-related group.</p>		
5.11 People according to where they live.	After receiving training in their home, patients can inject teriparatide themselves, without having to attend a treatment centre.	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
	We do not expect a potential negative, or unequal, impact on people based on where they live. There is currently a negative or unequal impact on patients in Wales, depending on whether their health board prescribes teriparatide. A positive recommendation from AWMSG would remove that and allow access for all eligible patients in Wales.		
5.12 Consider others who face health inequalities, such as: <ul style="list-style-type: none">• Looked after and accommodated children and young people• Carers: paid/unpaid, family members• People who are homeless or those who experience homelessness: people on the street; those staying	We do not expect a potential negative, or unequal, impact on people who face health inequalities.	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts	Recommendations for improvement/ mitigation <i>(What could be put in place to decrease any potential negative impacts and increase potential positive impacts?)</i>	Actions taken (and who by). <i>(Refer to where the mitigation is included in the document, as appropriate. State what action will be taken?)</i>
temporarily with friends/family; those in hostels/B&Bs <ul style="list-style-type: none">• People involved in the criminal justice system: offenders in prison or on probation, ex-offenders• People with addictions and substance misuse problems• People who have poor literacy• People living in remote, rural and island locations			
5.13 Consider any other groups and risk factors relevant to this project.	N/A	N/A	N/A

6. HIA - How will the project impact on the health and wellbeing of people in Wales and help address inequalities in health?

Questions in this section relate to the impact on the overall health of individual people, and the impact on the population in Wales.

How will the project impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i>
6.1 People being able to access the service offered.	Patients are trained to inject themselves with teriparatide by the home care service. A trained nurse visits the patient's home to train patients in administration or to administer the injection for those who are unable to self-inject. We do not expect a potential negative, or unequal, impact on people's ability to access the service offered.	N/A	N/A
6.2 People being able to improve or maintain healthy lifestyles.	We do not expect a potential negative, or unequal, impact on people's ability to improve or maintain healthy lifestyles.	N/A	N/A
6.3 People in terms of their income and employment status.	We do not expect a potential negative, or unequal, impact on people in terms of their income and employment status.	N/A	N/A
6.4 People in terms of their use of the physical environment.	We do not expect a potential negative, or unequal, impact on	N/A	N/A



How will the project impact on, or affect:	Potential positive and/or negative impacts and any particular groups affected	Recommendations for improvement/ mitigation	Actions taken (and who by) <i>Refer to where the mitigation is included in the document, as appropriate.</i>
	people's use of the physical environment.		
6.5 People in terms of social and community influences on their health.	We do not expect a potential negative, or unequal, impact on people in terms of social and community influences on their health.	N/A	N/A
6.6 People in terms of macro-economic, environmental and sustainability factors.	We do not expect a potential negative, or unequal, impact on people in terms of macroeconomic, environmental and sustainability factors.	N/A	N/A

7. Please fill in section 7.1 after completing the EqHIA, and fill in the action plan.

<p>7.1 Please summarize the potential positive and/or negative impacts of the project.</p>	<p>No potential negative impacts identified. A positive recommendation by AWMSG might remove the current inequality in access to teriparatide between England and Wales, and between different health boards in Wales.</p>
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Action plan for mitigation or improvement and implementation

	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
<p>7.2 What are the key actions identified as a result of completing the EqHIA?</p>	<ul style="list-style-type: none"> consult with clinical experts in Wales, patient organisations, patients and carers in Wales (or the UK) and invite comments through the AWTTC website or by questionnaire via email AWTTC to prepare an Evidence Summary Report (ESR) Licensed One Wales Medicines Assessment Group (LOWMAG) meet to consider and make a recommendation to AWMSG. AWMSG meet to consider and endorse the LOWMAG recommendation to Welsh Government about the use of teriparatide in Wales. 	<p>AWTTC</p>	<p>Feb–May 2025</p> <p>Feb–Apr 2025</p> <p>May 2025</p> <p>Jun 2025</p>	

	Action	Lead(s)	Timescale	Actions taken (<i>state who by</i>)
7.3 Is a more comprehensive Equalities Impact Assessment or Health Impact Assessment needed?	No			
7.4 What are the next steps?	AWTTC to write an evidence summary report for consideration by the Licensed One Wales Medicines Assessment Group (LOWMAG).	AWTTC	Mar–Apr 2025	
7.5 Review of project and EqHIA		AWTTC	[TBC]	

AWTTC's EqHIA template is adapted from the Cardiff & Vale University Health Board EHIA template.