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

Denosumab (Prolia®) for the treatment of osteoporosis in men at increased risk of fractures (OW7)

November 2020

ONE WALES INTERIM COMMISSIONING DECISION

Denosumab for the treatment of osteoporosis in men at increased risk of fractures

Date of original advice: March 2017
Date of review: November 2020

The following Interim Pathways Commissioning Group (IPCG) recommendation has been endorsed by health board Chief Executives.

Denosumab can continue to be made available within NHS Wales for the treatment of osteoporosis in men at increased risk of fractures. Denosumab should only be made available for men who fulfil the agreed criteria for treatment.

This advice will be reviewed in 12 months or earlier if new evidence becomes available.

Advice is interim to subsequent health technology assessment advice from the All Wales Medicines Strategy Group (AWMSG) or the National Institute for Health and Care Excellence (NICE) becoming available.

Clinician responsibility
Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Interim Commissioning decision.

Health board responsibility
Health boards will take responsibility for implementing One Wales Interim Commissioning decisions and ensuring that a process is in place for monitoring clinical outcomes.

One Wales advice promotes consistency of access across NHS Wales.

Criteria for treatment with denosumab for the treatment of osteoporosis in men at increased risk of fractures

These criteria have been adapted from NICE Technology Appraisal guideline TA204 Denosumab for the prevention of osteoporotic fractures in postmenopausal women[1].

Denosumab can be made available for the primary prevention of osteoporotic fractures in men at increased risk of fractures:

- Who are unable to comply with the special instructions for administering alendronate and risedronate, or have an intolerance of, or a contraindication to, those treatments,
- Who are unsuitable for treatment with intravenous (IV) zoledronic acid and
- Who have a combination of bone mineral density T-score, age and number of independent risk factors as shown in the table below:

T-scores at or below which denosumab is recommended when oral bisphosphonates are not suitable

	Number of independent clinical risk factors*		
Age (years)	**0**	**1**	**2**
65–69	Not recommended	-4.5	-4.0
70–74	-4.5	-4.0	-3.5
≥ 75	-4.0	-4.0	-3.0
*Independent clinical risk factors are: parental history of hip fracture; alcohol intake of 4 or more units per day; and rheumatoid arthritis.			

Denosumab can be made available for the secondary prevention of osteoporotic fragility fractures in men at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and risedronate, or have an intolerance of, or a contraindication to, those treatments and who are unsuitable for treatment with IV zoledronic acid.

1. National Institute for Health and Care Excellence. Technology Appraisal 204. Denosumab for the prevention of osteoporotic fractures in postmenopausal women. Oct 2010.

This is a summary of new evidence available and patient outcome data collected, to inform the review.

Background
Denosumab was first licensed in May 2010 for the treatment of osteoporosis in postmenopausal women and for the treatment of bone loss associated with hormone ablation in men with prostate cancer[1]. In June 2014 the European Medicines Agency (EMA) granted an extension to the licence of denosumab to include the treatment of osteoporosis in men at increased risk of fractures[2]. The National Institute for Health and Care Excellence (NICE) is currently in the process of appraising denosumab for the treatment of osteoporosis as part of a multiple technology appraisal (MTA)[3]. One Wales advice is interim to health technology assessment advice. Clinicians in Wales consider there is an unmet need for this medicine in men and have identified a cohort of patients who could benefit from this treatment.

Current One Wales Interim Commissioning Decision
Denosumab can continue to be made available within NHS Wales for the treatment of osteoporosis in men at increased risk of fractures. Denosumab should only be made available for men who fulfil the agreed criteria for treatment. August 2019.

Licence status
Denosumab was licensed in June 2014 for the treatment of osteoporosis in men at increased risk of fractures[2]. In June 2018, the licence was extended to include the treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture[2].

Guidelines
The NICE appraisal of denosumab is part of an MTA on non-bisphosphonates for treating osteoporosis (ID901) and has been suspended due to the COVID-19 pandemic. No new timeframe for this appraisal is available at the time of writing[3].

COVID-19: Interim NICE guidance has been issued to maximise the safety of adults with rheumatological autoimmune, inflammatory and metabolic bone disorders, with and without COVID-19, during the COVID-19 pandemic (NG167)[4]. Current advice recommends to continue treatment with denosumab as normal[4].

The Scottish Intercollegiate Guidelines Network (SIGN) management of osteoporosis and the prevention of fragility fractures guideline, originally published in 2015, has been updated (June 2020)[5]. There has been no significant change to the guideline with regards to the treatment of osteoporosis in men[5].

Health Technology Assessment advice for alternative medicines
There are no relevant new medicines or health technology assessment advice.

Efficacy/Effectiveness
No new clinical trials were identified in the repeat literature search.

NICE's assessment report for the MTA in progress has been published[6]. The clinical effectiveness data are consistent with the figures reported in the previous One Wales review (August 2019).

Safety
No relevant safety analyses were identified in the repeat literature search.

Cost effectiveness
No relevant cost-effectiveness analyses were identified in the repeat literature search.

The published cost effectiveness data from the NICE MTA assessment report are consistent with the figures reported in the August 2019 One Wales review[6].

Budget impact
No information on patient numbers has been received due to redeployment of staff during the COVID-19 pandemic.

Impact on health and social care services
This remains minimal.

Patient outcome data
Due to redeployment of staff during COVID-19 pandemic it has not been possible to provide patient outcome data at this time.

References

1. European Medicines Agency. Authorisation details: Prolia®. June 2017. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/001120/human_med_001324.jsp&mid=WC0b01ac058001d124. Accessed Jul 2020.
2. European Medicines Agency. Prolia®. Procedural steps taken and scientific information after the authorisation. Jan 2018. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Procedural_steps_taken_and_scientific_information_after_authorisation/human/001120/WC500107471.pdf. Accessed Jul 2020.
3. National Institute for Health and Care Excellence. Technology Appraisal in development GID-TA10072. Non-bisphosphonates for treating osteoporosis. Expected publication date: TBC. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta10072. Accessed Jul 2020.
4. National Institute for Health and Care Excellence. NICE Guideline, NG167. COVID-19 rapid guideline: rheumatological autoimmune, inflammatory and metabolic bone disorders. Apr 2020. Available at: https://www.nice.org.uk/guidance/ng167. Accessed Jun 2020.
5. Scottish Intercollegiate Guidelines Network. SIGN 142 Management of osteoporosis and the prevention of fragility fractures. Jun 2020. Available at: https://www.sign.ac.uk/assets/sign142.pdf. Accessed Jul 2020.
6. Davis S, Simpson E, Hamilton J et al. Denosumab, raloxifene, romosozumab and teriparatide to prevent osteoporotic fragility fractures: a systematic review and economic evaluation. *Health Technology Assessment.* 2020;24(29). Available at: https://www.journalslibrary.nihr.ac.uk/hta/hta24290/. Accessed Jul 2020.