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)

ONE WALES INTERIM DECISION
RETIRED FEBRUARY 2023
DENOSUMAB FOR THIS INDICATION IS RECOMMENDED BY THE NATIONAL OSTEOPOROSIS GUIDELINE GROUP SEPTEMBER 2021

ONE WALES INTERIM DECISION

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

Date of original advice: March 2017
Date of review: December 2021

The following One Wales Medicines Assessment Group (OWMAG) 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 after two years or earlier if new evidence becomes available.

Advice is interim to subsequent Health Technology Assessment advice from AWMSG or 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 Medicines Assessment Group decision.

Health board responsibility
Health boards will take responsibility for implementing One Wales Medicines Assessment Group 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) has recently suspended their appraisal of denosumab for the treatment of osteoporosis as part of a multiple technology appraisal (MTA)[3]. 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 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. November 2020.

Licence status

Denosumab is licensed for the treatment of osteoporosis in men at increased risk of fractures[2].

Guidelines

NICE was due to appraise denosumab as part of a multiple technology appraisal (MTA) on non-bisphosphonates for treating osteoporosis (ID901)[3]. This was initially suspended due to the COVID-19 pandemic. However, NICE has decided to suspend this appraisal from its current work programme as they do not consider it, within the current format, will add value to the existing published guidance[3]. There is no current NICE guidance that advises on the use of denosumab for the treatment of osteoporosis in men at increased risk of fractures.

The National Osteoporosis Guideline Group (NOGG) clinical guideline for the prevention and treatment of osteoporosis has been updated (due to be published 2021)[4]. [confidential data removed].

COVID-19: Interim NICE guidance was issued in April 2020 to maximise the safety of adults with rheumatological autoimmune, inflammatory and metabolic bone disorders, with and without COVID-19, during the pandemic (NG167)[5]. The guideline was last updated in March 2021. The recommendation to continue treatment with denosumab remains[5].

The Scottish Intercollegiate Guidelines Network (SIGN) management of osteoporosis and the prevention of fragility fractures guideline, originally published in 2015, has been updated (January 2021)[6]. There has been no significant change to the guideline with regard to the treatment of osteoporosis in men[6]. In the absence of a submission from the marketing authorisation holder to the Scottish Medicines Consortium, denosumab is not recommended for use in NHS Scotland in men with osteoporosis at increased risk of fractures[6,7].

Licensed alternative medicines/Health Technology Appraisal 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.

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.

Budget impact
No information on patient numbers has been received.

Impact on health and social care services
This remains minimal.

Patient outcome data
No patient outcome data have been received.

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 September 2021.
2. European Medicines Agency. Prolia®. Procedural steps taken and scientific information after the authorisation. January 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 September 2021.
3. National Institute for Health and Care Excellence. Non-bisphosphonates for treating osteoporosis [ID901]: assessment report. January 2019. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta10072. Accessed September 2021.
4. National Osteoporosis Guideline Group. NOGG 2021: Clinical guideline for the prevention and treatment of osteoporosis. Commerical in Confidence. Due to be published in 2021.
5. National Institute for Health and Care Excellence. NICE Guideline, NG167. COVID-19 rapid guideline: rheumatological autoimmune, inflammatory and metabolic bone disorders. April 2020. Available at: https://www.nice.org.uk/guidance/ng167. Accessed September 2021.
6. Scottish Intercollegiate Guidelines Network. SIGN 142 Management of osteoporosis and the prevention of fragility fractures. June 2020. Available at: https://www.sign.ac.uk/assets/sign142.pdf. Accessed September 2021.

7. Scottish Medicines Consortium. SMC1013/14. Denosumab (Prolia®). November 2014. Available at: https://www.scottishmedicines.org.uk/medicines-advice/denosumab-prolia-nonsubmission-101314/. Accessed September 2021.