East Lancashire Health Economy Medicine Management Board
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Position Statement
Denosumab as a second line treatment option for the prevention of osteoporotic fragility fractures

Recommendation:

Denosumab is an LMMG Amber1 drug:

Suitable for GP prescribing following recommendation/initiation by specialist.

Denosumab is recommended as a treatment option for the **primary prevention** of osteoporotic fragility fractures in postmenopausal women and men from the age of 50 years at increased risk of fracture, 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** the patient has a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in NICE TA204

Denosumab as a treatment option for the **secondary prevention** of osteoporotic fragility fractures in postmenopausal women and men from the age of 50 years at increased risk of fracture, 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.

Background:

The National Institute for Health and Care Excellence (NICE) published technology appraisal guidance 'Denosumab for the prevention of osteoporotic fractures in postmenopausal women' (TA204)[1] in October 2010. This guidance is being updated: In development [GID-TA10072] Expected publication date: TBC

Since then the Committee for Medicinal Products for Human Use (CHMP) have published a variation assessment report (April 2014) whereby they approved the addition of a new therapeutic indication for denosumab: treatment of osteoporosis in men at increased risk of fracture [2].

In August 2017, as a result of the need for a number of IFR requests, the Lancashire Rheumatology Alliance produced for consideration, a pathway for the medical management of men and women who have (or are at risk of) osteoporosis. In response the MLCSU developed a guideline to illustrate the accepted prescribing pathway for patients with or at risk of osteoporosis in Lancashire. Within these guidelines densoumab was considered a 2nd line treatment option for those patients 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 the patient has a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in NICE TA204. For the purposes of

NICE TA204, independent clinical risk factors for fracture are parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.

However, in January 2018, the Lancashire Rheumatology Alliance decided that a guideline was no longer in the best interest and therefore a position statement for denosumab has been produced.

Denosumab may be used for up to 5 years in the first instance, then reassessed in secondary care*

To decrease the possibility of duplication of bone protection prescribing it is essential that:

- secondary care informs the patient's GP of the date denosumab therapy was initiated **and**
- primary care are advised that these details are included in the patient's repeat medication records and entered onto practice recall system for recall at 6-month intervals (see shared care guide)
- It is important that treatment with denosumab is administered on time every 6 months; timely reminders and repeat appointments will need to be arranged

Denosumab as per recent evidence from ACR does not need a drug holiday and there is no guideline on how long to use this, can continue using this drug *

Bibliography

1. National Institute for health and Care ExcellenceTA204 https://www.nice.org.uk/guidance/ta204
2. Assessment report; Prolia, International non-proprietary name: denosumab. Procedure No. EMEA/H/C/001120/II/0030 http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Assessment_Report_-_Variation/human/001120/WC500169764.pdf

Please access this guidance via the LMMG website to ensure that the correct version is in use.

Version Control

Version Number	Date	Amendments Made	Author
Version 1.0	February 2018		SA

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