

National Institute of Health and Clinical Excellence
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8 July 2010

Dear Kate Moore

Denosumab for the prevention of osteoporotic fractures in postmenopausal women

Thank you for the opportunity to comment on the above appraisal consultation document (ACD).

The National Osteoporosis Society welcome NICE's prompt appraisal of denosumab and the broadly supports the recommendations on its use in patients with osteoporosis. We feel that this is a positive step for people with osteoporosis who are unable to take or tolerate bisphosphonates.

In response to your specific questions, we make the following points.

Q: Has all of the relevant evidence been taken into account?

A: The evidence considered is relevant and appropriate comparators are used.

Q: Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

A: We feel that the interpretation of clinical and cost effectiveness are reasonable. We concur with the view of the Committee that the provision of denosumab in primary care will probably lie outside the General Medical Services contract and may require some additional funding via a Locally Enhanced Service (LES) payment. However, the costs of administering the treatment are likely to remain low, even under these circumstances.

Q: Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

A: The recommendations are clear, straightforward and explain how the use of denosumab should fit in with the existing Technology Appraisals for osteoporosis treatments (TA160/TA161).

It is our view that the clarity of the recommendations facilitates their adoption into NHS practice.

Q: Are there any aspects of the recommendations that need particular consideration to ensure that we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

A: We have no specific comments.

I would like to note that there are issues within this document (e.g. clinical practice moving towards fracture risk assessment rather than T-score thresholds) which are common with TA160 and TA161 and that the National Osteoporosis Society is in on-going discussions with NICE to resolve. As these matters are being dealt with via other means, I have decided not to raise these separately within this response.

I hope you have found these comments useful. Should you wish to discuss our comments further, please do not hesitate to contact me on [REDACTED]

Yours sincerely

[REDACTED]