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HTA and Health Outcomes

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23rd April 2008

Dr Carole Longson
Appraisal Programme Director
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Dr Longson

Re: **Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women**
and **Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.**

Thank you once again for the opportunity to respond to the osteoporosis appraisal consultation documents.

Teriparatide

Secondary Prevention

i. For secondary prevention we believe that all the relevant evidence was supplied and available to the Appraisal Committee. We note your comments regarding the exclusion of women on long term corticosteroid therapy (section 4.3.7) and hope that the data on teriparatide by Saag et al (N Engl J Med 2007;357:2028-39) will be considered during the development of the NICE clinical guideline.

ii. The clinical and cost effectiveness summaries are reasonable interpretations of the evidence.

In October 2004 one of the main grounds of Lilly's Appeal against the Secondary Prevention FAD (which became NICE Guidance 87) was that there was a group of patients who were younger than 65 years but who had a clinical need for teriparatide. Although this was rebutted by NICE at the time, we are pleased that this has now been recognised in the current ACD.

iii. With reference to whether the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS, we would like to understand why the recommendation for the use of teriparatide in patients who have had 'an unsatisfactory response' to bisphosphonates in TA87 has been removed; especially when section 4.3.32 of the current ACD states that 'the committee concluded that a change from the current recommendations for teriparatide (TA87) is not warranted'.

We are concerned that there is no recommendation for the use of teriparatide in patients who do not respond to or who are treatment failures on bisphosphonates – this is where the product is used in real life. Patients eligible for teriparatide treatment have had multiple fractures and the vast majority have been initially treated with bisphosphonates.

We would therefore like the recommendation for the use of teriparatide in patients who have had 'an unsatisfactory response' to bisphosphonates (in TA87) to be reinstated. Subject to such reinstatement, we believe that the recommendations would be a sound and suitable basis for the preparation of guidance to the NHS.

Raloxifene

Primary Prevention

i. For Primary prevention we consider that relevant evidence was supplied and available to the Appraisal Committee.

ii. The clinical and cost effectiveness summaries are reasonable interpretations of the evidence except once again for the omission of inclusion of the breast cancer benefit for raloxifene. We continue to maintain that the breast cancer benefit of raloxifene is of relevance in any assessment of its cost effectiveness. Raloxifene with the full economic consequences of avoided cases of breast cancer was cost effective compared to proprietary alendronate in younger women, and may remain cost effective against non-proprietary alendronate.

iii. We do not consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

Secondary Prevention

i. For secondary prevention we believe that all the relevant evidence was supplied and available to the Appraisal Committee

ii. The clinical and cost effectiveness summaries are reasonable interpretations of the evidence. We are satisfied that raloxifene is at least given equal status with strontium in the guidance.

iii. We consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

For your information, Eli Lilly and Company Limited has recently signed an agreement to transfer the marketing and distribution rights for raloxifene to Daiichi-Sankyo throughout Europe. However, the transfer of Marketing Authorisation is still pending. We will let you know when the licence has been fully transferred from Eli Lilly and Company Limited to Daiichi-Sankyo.

Yours sincerely

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