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Dr Longson

Health Technology Appraisal

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

Appraisal Consultation Document

Thank you for inviting our comments on the above documents, which follow under NICE's suggested headings;

Primary Prevention

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

For raloxifene, however, we still maintain that the breast cancer benefit is of relevance in this patient population, and this has not been taken into account in the Appraisal.

Whilst we appreciate that it cannot be the sole reason for any recommendation, raloxifene (with breast cancer benefit taken into account) is *the only* cost effective option in younger women.

Indeed this Appraisal now fails to address the problem of primary osteoporosis in women under 70 years of age, and leaves patients and prescribers with no advice as to how to treat such patients. Whilst we also recognise that screening in the under 70s may not be

cost effective, there will be some women who will need to be treated, and options for them should be stated.

At minimum we believe that the wording from the secondary prevention ACD 1.4 (where raloxifene is an alternative treatment option in women unable to take bisphosphonates or strontium) should also be applied to primary prevention.

If, however, as we hope (see comments below on Secondary Prevention) raloxifene can be considered as joint second-line with strontium, then we would wish this to be carried through to the primary prevention guidance.

Finally, the ACD should state that women already being treated with raloxifene do not need to stop treatment unless clinically indicated.

ii. The clinical and cost effectiveness summaries are reasonable interpretations of the evidence except for the omission of inclusion of the breast cancer benefit for raloxifene in the overall result of the appraisal.

iii. On the basis of our comments on the above 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, however, since inclusion into the Appraisal of strontium ranelate, raloxifene has been "demoted" to third line position after bisphosphonates and strontium.

There is recognition in the ACD that the clinical data for strontium is not as robust as for the bisphosphonates, and it is still an unproven therapy in clinical practice. Raloxifene, in contrast, has been available for many years and has an established efficacy and safety record in clinical practice globally.

It is noted that the cost effectiveness of raloxifene is not as strong as for bisphosphonates and strontium if the breast cancer benefit is not taken into account.

However, when the breast cancer benefit is taken into account, the cost effectiveness of raloxifene is better than for strontium in almost all severities and age bands.

We therefore suggest on the balance of clinical and cost-effectiveness, that equivalent positioning be given to raloxifene and strontium- i.e. second line to bisphosphonates.

For teriparatide we note that there is now recognition (in section 4.3.21) that there are some patients under 65 years of age who may fulfil the other criteria for therapy, but that the committee did not consider that the guidance section should be changed.

We would like to suggest that this decision is reconsidered, so that prescribers are not precluded by payers from treating these women as clinically appropriate.

As it stands, we are increasingly aware that there are suitable patients in the NHS who are being denied teriparatide therapy by what amounts to age discrimination.

In addition, we do not understand why these patients need to be intolerant of bisphosphonates *and* strontium when their clinical state warrants teriparatide therapy.

Section 4.3.21 recognises that patients receiving teriparatide under this Guidance will by definition be those at high risk, and it seems inappropriate enough that it states in section 1.5 that they must already have failed on a bisphosphonate in order to receive treatment with teriparatide even if over 65 years of age.

Please also note that the statement in section 3.14 that 'Costs may differ due to locally negotiated procurement discounts' should be removed for teriparatide. We believe that all other osteoporosis therapies do have wholesaler discounts, however teriparatide is only supplied to Healthcare at Home at list price. It is then distributed to patients via Healthcare at Home nurses.

ii. The clinical and cost effectiveness summaries are reasonable interpretations of the evidence except for the omission of inclusion of the breast cancer benefit for raloxifene in the overall result of the Appraisal.

iii. On the basis of our comments on the above we <u>do not</u> consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

Should you have any queries, please do not hesitate to contact me 01256 775414.

Yours sincerely

<u>Medical Advisor and Head of HTA Strategy</u>