National Osteoporosis Society

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Dr Carole Longson, Director
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23rd August 2006

Dear 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

In response to your letter dated 31st July, please find below the National Osteoporosis Society's comments on the additional analysis prepared by the Decision Support Unit (DSU) for the above appraisals

The NOS welcomes the opportunity to review and comment on these analyses for the Technology Appraisals (TAs) addressing both the primary and secondary prevention of osteoporotic fragility fractures. The analysis has made a number of changes to the model used previously and makes a useful addition to the evidence available to the Appraisal Committee. However, the NOS believes that it still does not account for all of the possibilities that should be considered.

The analyses have made significant changes to previous work and suggest that there may be dramatic changes to the current TA87 on the secondary prevention of osteoporotic fractures during this review. In view of these changes the Society is concerned as to how the TA development process will proceed.

In particular, we would urge NICE, as its next step in this process, to produce a second ACD and not to proceed directly to a FAD on either of these TAs.

The Society has a number of concerns about the development process to date for these 2 technology appraisals:

- The circulation of these consultation documents was a week late, resulting in difficulties with resources for the Society, especially with respect to key staff being away on leave. For this reason, we have been unable to study the economic analysis in the depth that we would have wished, although we shall do so prior to receiving and commenting upon any ACD.
- The timing of this consultation has been through the period when a large number of consultees and commentators have been away on leave and has included the August Bank Holiday weekend.

- There are only 5 working days between the close of the consultation period on this analysis and the meeting of the appraisal committee on the 6th September. The Society does not believe that this can possibly allow an adequate period of time for the Appraisal Committee and the team that supports it, to properly consider all of the comments that it will have received.
- The DSU project specification letter was posted on the website in April and the NOS has received a number of calls from other organisations and members who have a strong interest in the TAs asking whether the analysis has been completed. The website has not been updated to inform people about the process.

In terms of the base case used in this analysis, we would like to make the following specific comments:

- The NOS is particularly concerned as to why an arbitrary £20,000 cut-off has been adopted for both primary and secondary prevention. This is a significant change from the previous ACDs and devalues osteoporosis as a disease compared with other conditions and puts less value on the suffering of our members compared with others.
- By including only those with "acute" fracture in the self-identification group, many women with a previous fragility fracture and at high risk of future fracture will be excluded from appropriate intervention. This is a significant step backwards from the existing NICE guidance on secondary prevention. Furthermore, most epidemiological data linking prior fracture to future fracture relates to fractures that occurred many years previously. The report suggests that it may be cost-effective to opportunistically assess women over 70 in a GP clinic, however the NOS has concerns that in practice this will not happen, particularly as osteoporosis is not included in the Quality and Outcomes Framework of the General Medical Services contract.
- The Society notes that the fracture costs used in the base case are the same as those that have been used in previous analyses. These costs are now out of date and we would urge NICE to include the costs that were calculated by Stevenson et al (in press), which are more closely aligned to the findings of other studies in clinical practice, prior to issuing any ACD. The NOS is pleased to note that NICE has included home help costs in the sensitivity analysis and would like to see these included in the fracture costs for the base case.
- The Society has noted that during the consultation period the price of alendronic acid on the Prescription Pricing Authority website has now decreased to £13.27 for 4 tablets. We are concerned that from these analyses etidronate may be considered as the most cost effective treatment for some patients and hope that that when the new price for alendronic acid is incorporated it will result in alendronate/risedronate becoming the preferred treatment option.
- In the analysis for those women who present with a self-identifying risk factor (acute fracture, rheumatoid arthritis and high dose glucocorticoids) the NOS urges NICE to ensure that a list of medical conditions, other than rheumatoid arthritis, which are known to have a significant effect on fracture risk are also included as self-identifying risk factors.
- The Society is concerned that the efficacy data for the bisphosphonates has reduced in each of the analyses that have been performed, with the decrease in this analysis being due to the pooling of the data for alendronate and risedronate. We would like to see the efficacy of alendronate being used throughout the analysis, even if this means that alendronate alone becomes the first line treatment.
- We remain concerned that the "utility multiplier" values used for all fractures may be too high. In particular, the figure used for vertebral fractures does not reflect the true impact that multiple vertebral fractures have on a woman's quality of life. The model also still fails to incorporate morphometric fractures which, if progressive, are

associated with significant morbidity for women in terms of, loss of height, kyphosis and functional impairment.

The NOS also has several more general concerns:

- As articulated in previous submissions to this process, the NOS feels that it would be unacceptable if the committee were to deny preventative treatment to women under the age of 70 years in the opportunistic group. Although the Society understands the need to include cost effectiveness arguments when considering recommendations, we would urge NICE to ensure that osteoporosis is treated in the same way as other disease areas where prevention is key. The NOS is concerned that this analysis could result in recommendations that would mean a woman younger than 70 years, who is at the same absolute risk of fracture as an older woman, would be denied treatment. This is at odds with current clinical practice.
- The Society asks that NICE ensures that a range of alternative second line treatments are available to clinicians and patients when the ACDs are developed for all patients, regardless of age. In particular, although we continue to believe that the protective effect of raloxifene should not be an over-riding factor in determining how it is used in practice, we hope that when developing the ACD, NICE does ensure that raloxifene remains available as a treatment for those women in whom bisphosphonates or strontium ranelate are not tolerated or are contra-indicated. NICE are penalising the bisphosphonates heavily for their side effects and therefore we believe that it is not consistent to make no concession for beneficial effects.
- The Society is also worried that this analysis suggests that all patients will require a DXA scan prior to receiving treatment. Our members have voiced concern about being able to access DXA services immediately after a clinical vertebral fracture, where it is not necessary to indicate the likely effectiveness of treatment, or hip fracture where frailty may inhibit the option of carrying out DXA. We would ask that patients should not be denied therapy if no immediate DXA is available but rather should be able to start therapy while DXA is awaited. Furthermore, current DXA provision, while improving, is inadequate for the additional referrals that this guidance will create and will be further stretched when the new WHO guidance is published. The NOS are also disappointed that the costs for increasing provision have not been included in this analysis.

The Society is concerned that, on publication, it will have to explain this new guidance to its members and the patients who contact the NOS. Many of these people feel that the process of developing these TAs has been overly complicated and protracted. The Society believes that the results from the current analysis do not reflect the patient population that we represent in terms of those requiring preventative treatment in particular. We urge NICE to produce guidance that does reflect the whole patient population so that we are comfortable with it and can then work with our membership (both professional and non-professional) to ensure it is smoothly implemented.

We hope that the Appraisal Committee find these comments helpful.

Yours sincerely,

Policy and Information Officer