

Royal College of General Practitioners Response to Health Technology Appraisals on the Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Post-menopausal Women.

We would like to make the following observations:

Overall, we welcome several aspects of the updated analysis:

- 1) The guidance on opportunistic osteoporosis assessment at varying ages
- 2) The guidance on who to refer for DEXA scanning
- 3) The inclusion within the cost utility assessment of GP consultations
- 4) The differential analysis of new and longer term users of bisphosphonates.

Unfortunately, the conclusions were severely limited by the (as yet unknown) likely effect on cost of generic alternatives becoming available, which greatly restricts their practical usefulness.

- The cost per QALY has been set at £20,000. This figure has not been justified.
- The assessment seems to be a combination of primary and secondary prevention, but this has been explicitly stated.
 - Acute fractures are discussed, but there is no definition of these. Those patients who have recently suffered a fracture seem to be eligible for secondary prevention, whereas those who have had a previous fracture seem to be placed alongside those to be assessed for primary prevention.
 - Patients on oral glucocorticoids are in a high risk group, but neither dose, nor timescale seem to be stated.
 - Patients with rheumatoid arthritis are placed in a high risk group, but it is not clear whether or not this is an exemplar of diseases associated with osteoporosis or is specific to those having rheumatoid arthritis.
- An opportunistic case finding strategy seems to be advocated. I feel that it is unrealistic to expect GPs to allocate three minutes from their ten minute consultation time to consider osteoporotic fracture. Osteoporosis needs a systematic approach whereby GPs focus on it as in other disease areas in the Quality of Outcomes Framework. It is anticipated that reduced fractures will lead to reduced GP consultation time. This has not been factored in.
- It seems that it is advocated that all patients will require a DXA scan before treatment. Currently in England and Wales there is a huge lack of resources for DXA provision and the cost of supplying these resources has not been included in the assessment. I feel that it would be better to initiate treatment whilst awaiting a DXA scan result as was previously advocated in the Technology Appraisal 87. In the near future we anticipate that the World Health Organisation (WHO) will advocate calculating the absolute risk of fracture. Whilst this will reduce the need for DXA scanning provision, this reduction will be small compared to the huge need of resources that is currently required.

- It seems from the analysis that patients under 70 years, whatever their high absolute risk of fracture will be denied treatment.
- The analysis suggests that Etidronate is the most cost effective treatment for osteoporosis; however, tariff prices for Alendronate have already fallen to £13.27 per four weeks. Given the price differentials between Sodium Alendronate and Risedronate, I think that NICE should be urged to separate Alendronate and Risedronate in its analysis.
- Whilst I welcome the inclusion of home help costs in the overall assessment, I would point out that there have been more recent studies indicating that the acute cost of hip fracture is in excess of £10,000.

Systematic review of Adverse Effects and Persistent with Therapy. I welcome this section, but have a few suggestions.

When GPs are faced with a patient who is suffering from dyspepsia, whilst on a Bisphosphonate they have two options: They may stop the treatment or prescribe treatment to minimise the side effects. I am not aware of any evidence that shows that prescribing neither a PPI nor an H₂RA reduces the side effects of dyspepsia caused by Bisphosphonates. The NICE guidance for dyspepsia often advocates the use of PPIs over H₂RAs and my feeling is that very few GPs now use H₂RAs. The costing of proton pump inhibitors is inaccurate and furthermore some patients presenting with dyspepsia will be referred for gastroscopy, the cost of which has not been factored in. Furthermore there is some evidence to suggest that the use of H₂RAs and PPIs reduce the effectiveness of Bisphosphonates. This has not been considered.

**On behalf: of the Royal College of General Practitioners.
22 August 2006**