National Institute for Health and Clinical Excellence

Health Technology Appraisal

Drugs for the primary prevention and secondary prevention of osteoporotic fragility fractures in post menopausal women

Royal College of Nursing

Comments provided by

Response to Appraisal Consultation Documents on the treatment of primary prevention and secondary prevention of osteoporotic fragility fractures in post menopausal women

Comments relating to both primary and secondary prevention

Re: Primary prevention of osteoporosis – We would like to know the rationale for stating that the individuals of all ages will require a DEXA scan in most cases. We feel this recommendation does not take into account the wider issues and disruption to healthcare with their related costs, for example insisting upon dexa scans for those who have presented or who may have a fracture as their only identified risk factor. In practical terms an elderly, disorientated or unwell patient may not receive treatment for their osteoporosis until or unless they have a DEXA scan. This seems an odd recommendation which could affect the quality of care and treatment provided to some vulnerable patients.

1.1 This section describes the thresholds at which treatment will be offered to women: aged 70-74 and aged over 75 years.

Diagnosis of osteoporosis is made by measurement of bone mineral density (BMD), with reference to the number of standard deviations (T score) from the bone mineral density in an average 25 year old woman. A woman with a BMD of -2.5 or below is said to have osteoporosis.

Under the suggested criteria, there are many women who would suffer from osteoporosis but not meet the threshold for medical intervention. To withhold treatment until the bone density becomes even more severely osteoporotic seems to go against the principles of modern drug management, which is to try and prevent bone from becoming so severely osteoporotic that fracture occurs. Given that most therapies mode of action is to prevent further bone

loss, it does not seem to be good clinical practice to wait until the thresholds described before considering intervention.

One particular group of women who would suffer is those who experience an early menopause, who may lose bone density at a particularly young age and become osteoporotic well before the age of 70. It does not make good clinical sense to withhold treatment from such women until they have a T score of -3.

It would seem appropriate to use clinical judgement as well as absolute thresholds. For example, a woman who narrowly falls outside the BMD threshold, but with recognised risk factors should not have treatment withheld simply to wait for her BMD to fall further.

1.2 Clinical Risk Factors

Clinical risk factors to be considered are parental history of hip fracture; low body mass index (in the absence of knowledge of BMD and defines as less than 19kg/m2); medical conditions independently associated with bone loss.

Whilst recognising these as major risk factors, it would be preferable to also include smoking and/or alcohol use as risk factors. These may be considered lesser risk factors but the long term impact on bone density is well recognised and their contribution to the impact on bone health should not be underestimated.

1.7 **Definition of intolerance of bisphophonates.**

Intolerance of bisphosphonates is defined as oesophageal ulceration, erosion or stricture, sufficiently severe to warrant discontinuation.

This definition is unworkable in clinical practice. If a woman appears intolerant of bisphosphonates, we do not wait until such ulceration appears or indeed send them for more costly investigative procedures to look for such ulceration. The treatment is simply changed to a more acceptable one. These criteria are too restrictive for clinical practice.

Also it seems that those who are confused or find this medication difficult to take and concord to treatment will not be eligible for other treatments as this will not be considered intolerance.

General Comments:

The appraisal reads as a guideline, mentioning ‘first and second line treatments’. With the guidelines still under development, we believe it is inappropriate for the HTA to be making treatment recommendations before the publication of the guidelines.

Finally, we consider that to move the focus of the treatment of osteoporosis from preventative treatment to treatment following fracture is a very backward step which will lead to increased pain and suffering in patients from fractures and an increased financial burden on the health and social care system. This backward step would also result in the treatment of osteoporosis in England and Wales being different and opposed to the way it is currently approached in the USA and many other countries.

We are very concerned that the figures relating to QALYS have been calculated using cost of Alendronate (Fosamax); however this drug is now available as a cheaper unbranded preparation. If the figures had been calculated on this basis, preventative treatment would be cost effective.

Secondary Prevention

In addition to the comments above, the following comments relate specifically to secondary prevention.

1.1 It appears that individuals under 65 (women only?) who have had a previously fragility fracture and have a condition known to pre-dispose to osteoporosis (e.g. Rheumatoid Arthritis +/- steroids) but have no other family risk factors will not be considered for treatment, until DXA has been performed and BMD proven to be very low. This biases treatment towards older women and penalises women who become osteoporotic at a younger age.

1.5 If patients fail bisphosphonates and have high risk factors should they also be required to have such a low BMD to qualify for treatment? This fails to protect the patient against further deterioration.

1.7 Definition of intolerance of bisphophonates.

Same comments as 1.7 above.

1.8 What is the clinician to administer to patients who are mentally impaired (or who have poor cognition) who has had one previous fragility fracture but is in the community and failing to comply with oral bisphosphonates?

What is the stance regarding patients who refuse to have a DEXA Scan? Is the physician to withhold treatment from these patients despite high risk factors?

2.1 This would be welcomed.

4.2.1 ***The Assessment Group's economic model***

We would like to ask whether the appraisal committee have undertaken calculations to estimate the cost to the NHS of these changes in relation to increasing use of DEXA scanning and estimates of additional fractures as a result of non treatment for those on the margins of what the appraisal committee see as risk (in the last 5 years physicians have been proactive in the management of individuals at risk). These guidelines if implemented would change significantly the opportunity to treat promptly. We have concerns that long waiting times for a DEXA scan would extend the time of treatment commencing to unacceptable levels.

4.3.3 Although individuals at increased risk, such as rheumatoid arthritis, are mentioned and recognised, it appears that these chronic disease groups are still going to be vulnerable to osteoporosis and should be considered as they represent a large proportion of complex clinical decision making regarding optimum management to prevent further disability (It is noted that the review considered these in the economic modelling analyses but we do not feel the

issues have been adequately reflected in the Appraisal Consultation Document).

General Comment

We believe using the proposed criteria very few people would be eligible for treatment and that as a consequence there will be an increase in the number of osteoporotic fractures. It would be interesting to see an analysis modelled on current case management and one based on the proposed guidelines and for these to be costed for quality of life issues (not simply related to being admitted to a nursing home) and the real costs of increased factures in those people who do not meet the criteria set.