

TO NICE: NHS QIS Comment from our nominated clinical expert on the Asssment Report for NICE Health Technology Appraisal: Strontium Ranelate for the prevention of post menopausal osteoporotic fractures

The first point which I would like to raise is with respect to the confidentiality of this Health Technology Appraisal document. As you have indicated, you already hold a signed confidentiality agreement from me in respect of this appraisal; however the document still has large parts of information missing for reasons of confidentiality. Some of this data relates specifically to hip fracture risk with respect to strontium and without access to this information, the data is less easy to interpret. I would urge QIS to look at this issue carefully from the point of view of future reviews of NICE Health Technology Appraisal documents. The full NICE document should be available to NHS Scotland reviewers.

With specific respect to this document; the overall view that strontium ranelate should be restricted to where bisphosphonates are either contraindicated or are not tolerated is appropriate and is compatible with the guidance issued by the Scottish Medicines Consortium (No 178/05). There are no major issues around the implementation of this NICE Technology Appraisal within NHS Scotland however there are two factors which require specific consideration for NHS Scotland.

Firstly consideration is needed with respect to the availability of the technology of Dual Energy X-ray Absorptiometry (DXA scanning) in NHS Scotland (at least 4 Health Board areas to my knowledge have no service provision). This NICE Technology Appraisal document acknowledges that in order to implement the guidance appropriately, access to bone densitometry measurement is required. NICE do acknowledge that the provision of this facility may not be adequate in England and Wales and similar issues will apply within NHS Scotland.

Secondly the issue relating to starting anti-osteoporosis agents in the absence of bone densitometry measurement needs to be considered again. The field of osteoporosis is quickly moving towards absolute fracture risk assessment and treatment decisions are being based upon patients reaching certain fracture risk thresholds. Whilst this is entirely appropriate, it does ignore treatment efficacy evidence base. This evidence base indicates that anti-osteoporosis therapies, in particular bisphosphonates, are only effective in reducing fracture risk where an individual patient's bone mineral density lies below a certain T-score threshold. There are no data available to support using anti-osteoporosis agents (including strontium) in situations where bone density sits within the high osteopenic range (even where the presence of multiple clinical fracture risk factors mean that a given patient has a high baseline absolute fracture risk). This has been an issue with the previous NICE Technology Appraisal on osteoporosis (No 87) and sits outwith the recommendations made in SIGN guideline 71.

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