

The National Osteoporosis Society
For and on behalf of the National Osteoporosis Society, the Society for Endocrinology, the British Society for Rheumatology and the Bone Research Society

Wednesday 15th August 2007
Sent by email

Dear [REDACTED]

FAD Primary prevention of osteoporotic fragility fractures in postmenopausal women
FAD Secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for your letter dated 9 July 2007. This letter is my preliminary assessment of the validity of your appeal points, as required by NICE's appeal process. I will adopt the numbering of points used in your letter. I am also annotating your referenced with the FAD I believe each point refers to, and would be grateful if you would confirm I have done so correctly.

Point 1.1 Both

A valid ground one point.

Paragraph 1.2 Primary

I am not persuaded that this is a valid ground one appeal point, although it may be a valid ground two point. Ground one appeals must be brought on the basis that "The Institute has failed to act fairly and in accordance with its procedures as set out in the Guide to the Technology Appraisal Process". The social values judgements document is not part of the technology appraisal process, nor would a failure to adhere to it be, of itself, procedurally unfair. Depending on the facts of any case, it might be procedurally unfair (if, for example, you were led to believe that certain matters would be relevant and taken into account, which were not in fact considered), but this would need to be shown to be arguable.

I would suggest that this appeal point should proceed under ground two, perversity. If you can explain how the alleged failure to adhere to the social values judgement produced unfairness in this case, I would be willing to reconsider that the point should indeed be brought under ground one.

Paragraph 1.3 Both

In light of the judgement of the High Court in *Rota Eisa v NICE*, 10/8/2007, I do not feel this is an arguable appeal point.

Paragraph 1.4 Both

I will allow these points to proceed under ground one, although for your guidance I would point out that some at least seem to belong under ground two. If you wish these points to succeed at a hearing I would suggest that you will need to explain in more detail how they have produced unfairness in the appraisal.

Paragraph 1.5 Both

I am not persuaded that these are complaints of procedural unfairness, rather than perversity, and I am minded to allow them to continue on that basis. I would also point out as guidance that, for an argument of inconsistent treatment with other appraisals to succeed, you will need to satisfy the appeal panel that the appraisals you cite are truly comparable, such that consistent treatment can be said to be a requirement.

Paragraph 1.6 Primary

I am not persuaded that this is a ground one rather than a ground two appeal point, although I would agree it should be considered under ground two.

Paragraph 1.7 Primary

I would repeat that a ground one appeal point is one which argue that " The Institute has failed to act fairly and in accordance with its procedures as set out in the Guide to the Technology Appraisal Process". Alleged failure to follow the methods guide is not a valid ground of appeal. Furthermore, the sections of the methods guide you cite refer to the justification of ICERs above £20,000 as exceptional cases. I am not sure that it is arguable that the appraisal committee is obliged, as a matter of fairness, to state why something is not an exceptional case. It seems to me it would be for those arguing that a given treatment was an exceptional case to make that point, and not vice versa. There can, by definition, be no presumption of exceptionality.

Paragraph 1.8 Both

I am not persuaded that these are complaints of procedural unfairness, rather than perversity, and I am minded to allow them to continue on that basis. I would also point out as guidance that, for an argument of inconsistent treatment with other appraisals to succeed, you will need to satisfy the appeal panel that the appraisals you cite are truly comparable, such that consistent treatment can be said to be a requirement.

Paragraph 1.9 Both

As you will be aware, a ground of appeal must be supported by evidence. Your letter gives no evidence that the FADs will limit innovation. Without that evidence I am not minded to allow this appeal point to proceed.

Paragraph 2.1 Secondary

A valid ground two appeal point.

Paragraph 2.2 Both

I am not persuaded that this is a valid appeal point. It seems to me the institute must be allowed to take a point in time for its calculations, not just for cost but for any other relevant evidence, and then produce guidance on that basis. It is obviously impossible, given the need for analysis, committee deliberations, publication of an ACD, consultation on that ACD and consideration of those comments, for an FAD published in June 2007 to include a price published in July 2007.

Paragraph 3.1 Both

A valid ground three appeal point.

Paragraph 3.2 Primary

I agree that this is a valid appeal point, although by way of guidance I would advise you to

provide the appeal panel with legal argument on whether guidance on this treatment is within the scope of Article 8.

Paragraph 3.3 Both

A valid ground three appeal point.

If you wish to make any further submissions on whether any of your disallowed points should be considered as an appeal against this guidance, I would be happy to consider them before reaching a final decision on this issues. I would also be happy to consider any comments on points which have been reallocated to different appeal grounds. I would be grateful for any such reply within three weeks of this letter (COB Wednesday 5th September 2007). As an appeal will take place in any event, the Institute will contact you to make the necessary arrangements.

Yours sincerely

Mark Taylor
Chair, Appeal Panel