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10 September 2012

Dear [redacted]

Final Appraisal Determination: Denosumab for the treatment of skeletal-related events in adults with bone metastases from solid tumours

Thank you for lodging your appeal against the above Final Appraisal Determination.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the point of appeal you have raised: principally whether it falls within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your point contains the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

Initial View

You have complained that in the first draft of this appraisal, denosumab was approved for use with hormone refractory advanced prostate cancer and in the final appraisal this had been reversed, and that this was unfair.

There were two consultation documents issued in this case. After the first round of consultation, it appears that the appraisal committee were minded to change their initial view that denosumab should be recommended for these patients, and not to recommend use. They issued a further consultation document with that unfavourable recommendation. That attracted comment from a number of bodies, although not your own. (However there was a patient perspective from Prostate Action.) Therefore it seems to me you did have an opportunity to make comment on the unfavourable recommendation while it was still in draft, and that the process followed was fair.

Looking at the overall consultation exercise, and the committee's change of mind after consultation, an appeal panel considered a similar situation in the appeal concerning dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation. The panel said

> *"Whether or not the failure to issue a second consultation document in these circumstances might generate a valid appeal point would depend on the facts of the appraisal. The Appeal Panel's view is that all consultees must be taken to know that any consultation document is by definition provisional. Any consultee who does not respond or respond fully to a consultation exercise because they agree with the Appraisal Committee's preliminary conclusion, however that conclusion is expressed, does so at their peril. However, in general terms, there is a potential risk to fairness when a preliminary conclusion is reversed without further consultation. .... An Appraisal Committee needs to proceed with care."*

In fact in that appeal the panel held that a failure to reconsult on a change of mind was not unfair. Here the committee appears to have considered whether it needed to reconsult on its change of mind and to have decided that it should. I cannot see that it will be possible to argue that this was an unfair process, particularly where your organisation did not respond to either consultation.

I would not be minded to refer this appeal point to a panel.

Conclusion

If you wish to make any further comment on the point that I have indicated that I do not, at this preliminary stage, view as valid, please provide to me this within 10 working days from the date of this

letter, no later than **Monday 24 September 2012**. I will then reach a final decision on the validity of this point.

Yours sincerely

[redacted]

Appeals Committee Chair
National Institute for Health and Clinical Excellence