NHS
National Institute for
Health and Clinical Excellence

[redacted]
Chief Executive
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Friday 24th August 2007
Sent by email

Dear [redacted]

Final Appraisal Determination: Pemetrexed for the treatment of malignant pleural mesothelioma

Thank you for lodging the Birmingham East and North PCT's appeal against the above Final Appraisal Determination (FAD).

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. The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared guidance which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain 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 is referred on to the Appeal Panel.

Initial View

You have made two points of appeal under Ground 1 (appeal points (a) and (b)), six points of appeal under Ground 2 (appeal points (ca), (c), (d), (e), (f) and (g)) and one point of appeal under Ground 3 (appeal point (h)). Note that I have adopted the lettering you have applied to your appeal points save that the first point of appeal under Ground 2 had no letter, and hence is marked as (ca).

To the extent that appeal point (a) (lack of transparency) alleges a lack of transparency within the text of the June 2007 FAD, I consider it to be a valid appeal point. The appeal panel will consider argument on the final paragraph of the appeal point, which relates to an alleged lack of clarity in relation to treatment cycles.

However, to the extent that appeal point (a) alleges a lack of transparency when the June 2007 FAD is read in comparison with the June 2006 FAD for this treatment, I do not consider it to be a valid point of appeal. To argue that there is a lack of transparency when a comparison is made between the two FADs implies that the Appraisal Committee was under a duty to give reasons for departing from its original FAD. This cannot be the case in a situation where the original FAD has been quashed by a decision of an appeal panel. It would clearly undermine the appeal process if a quashed FAD imposed any sort of presumption on the Appraisal Committee either to reaffirm its conclusions or at least to state reasons for departing from them. Having reviewed the evidence before it, the Appraisal Committee must be entitled to reach a different decision in this second FAD.

To the extent that appeal point (b) (failure to apply the Institute's values to the decision) relates to the allegation that, in reaching its decision on the treatment, the Appraisal Committee gave the patient group special consideration because malignant pleural mesothelioma (MPM) is caused by occupational exposure, I consider it to be a valid point of appeal. However, I am minded to allow it as a Ground 2 appeal point on the basis that the point relates to the Institute's *Social Value Judgments* document which is not part of the Institute's published procedures for appraisals; therefore failure to act in accordance with this document will not, of itself, trigger Ground 1. If, however, you wish to argue that you had put forward specific arguments or evidence that referred to *Social Value Judgments* and it was therefore unfair that the Appraisal Committee failed to consider it or that the Appraisal Committee's reference to occupational exposure is unfair because you did not know that the cause of MPM might be considered by the Appraisal Committee, this point of appeal could remain under Ground 1. I would be grateful for clarification on how you would like to characterise this point.

To the extent that appeal point (b) relates to the relevance of the 'rule of rescue,' I consider it to be a valid point of appeal.

For the same reasons as are given above in relation to appeal point (a), I do not consider appeal point

(ca) (essentially, that the Institute's departure from the conclusions of the June 2006 FAD is perverse given the similar nature of the assessments contained in the two FADs and the lack of new evidence given to the Appraisal Committee) to be a valid point of appeal. To the extent that you wish to make arguments alleging perversity on the part of the Appraisal Committee, these arguments must be confined to the text of the June 2007 FAD.

I consider appeal point (c) (the Institute has adopted an inappropriate ICER) to be a valid point of appeal.

In relation to appeal point (d) (the Institute has failed to demonstrate that the ICER for pemetrexed is below the £30,000 threshold), I note that the Institute's *Guide to the Methods of Technology Appraisal* document states at paragraph 6.2.6.7 that 'the Appraisal Committee does not used a fixed ICER threshold above which a technology would automatically be defined as not cost effective...'. Consistent with this, I note that the FAD did not state, as you allege, that it was ' "likely" that the ICER for pemetrexed would be below £30,000...'; rather it stated that '...the Committee agreed that the ICER for pemetrexed plus cisplatin in the fully supplemented subgroup with advanced disease and good performance status was **likely to fall within acceptable levels**' (emphasis added). However, to the extent that this appeal point considers the factors that allegedly led the committee to determine that an ICER of more than £30,000 per QALY gained was acceptable in this instance, I consider it to be valid. I would be grateful if you would reword your appeal point to reflect my comments.

I do not consider appeal point (e) (the Committee provided guidance that was divorced from the Committee's cost-effectiveness argument with respect to the use of fewer cycles of treatment) to be a valid point of appeal. The Committee's intention was not to direct NHS staff to administer less than 6 cycles; some patients will require only 4 cycles, whereas others will require more. However, it is clear that the Committee believed the evidence to show that the 'mean number of cycles in clinical practice was likely to be less than the mean of six cycles reported in the EMPHACIS trial...'. Thus, I am of the view that the fact that the FAD does not provide any direction as to the maximum number of cycles each patient may receive is not perverse.

I consider your appeal points (f) (the Committee's guidance requires use of a product that is not available within the UK) and (g) (the Committee's guidance was divorced from the Committee's cost-effectiveness argument with respect to the use of 100mg vials) to be valid points of appeal but I believe they essentially amount to the same point. I would be grateful if you would reword these arguments so that they comprise a single point of appeal.

I consider appeal point (h) (the Committee introduced a new value into its consideration that is currently at odds with NHS practice and therefore exceeded its powers) to be a valid point of appeal however I suggest that the Appeal Panel would wish particularly to hear argument on why this is unlawful given that NICE is not expressly bound to adhere to 'NHS practice'.

Preliminary Conclusion

My initial view, therefore, is that your appeal points (a) (in part), (b) (subject to your clarification of part of the point), (c), (d) (subject to your rewording of the point), (f) and (g) (to be re-worded to form one point) and (h) are valid appeal points. I regard your appeal points (a) (in part), (ca), and (e) to be invalid, however. I should be grateful to receive any further comments you may wish to make before I reach my final decision. These should be sent to NICE within three weeks of the date of this letter (COB Friday 14th September 2007).

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence