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7 December 2011

Dear Mr Burgin

Final Appraisal Determination of Eribulin for the Treatment of Locally Advanced or Metastatic Breast Cancer

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 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 should be referred on to the Appeal Panel.

I can confirm that there will be an oral hearing of the appeal.

Initial View

Ground 1

1.1. The additional data submitted by Eisai in response to the ACD were substantial and the Appraisal Committee's conclusions in relation to this material should have been subject to consultation

and

1.2. The late disclosure of the supplementary report prepared by the ERG precluded proper consideration of the report by Eisai prior to the second meeting of the Appraisal Committee.

I agree these are valid ground one appeal points

1.3. The Appraisal Committee's approach to the estimation of the overall survival benefit associated with eribulin is not consistent with standards identified by the Decision Support Unit and the choices which form the basis for the estimation are unexplained and lack transparency.

As your appeal letter notes, the methodology used was clear in the original ERG report, and the committee's acceptance of that methodology was clear before the ACD was published. I cannot find any record of your having suggested that the methodology was inappropriate when commenting on the ACD.

The appeal ground is unfairness. I doubt that it could be argued to be unfair transparently to have adopted a methodology and to have given Eisai a chance to comment on it during the appraisal process, where that chance was not taken up.

I am not presently minded to refer this point to an appeal panel.

1.4. The Appraisal Committee has failed to consider a comparison of eribulin with TPC in the population of patients previously treated with capecitabine.

A valid ground 1 appeal point.

1.5. The Appraisal Committee has not placed adequate weight on the innovative nature of eribulin in the context of this appraisal

A dispute as to the adequacy of the weight to give to a particular consideration cannot be a matter of fairness. It may go to the reasonableness of the guidance, but not to the fairness of how it was created.

I am not presently minded to refer this point to an appeal panel.

1.6. The Appraisal Committee's conclusions with respect to the costs of vinorelbine which should be used for economic modelling in this appraisal are inconsistent with the approach specified in NICE's procedures and unfair

I agree this is a valid ground one appeal point, but please note that inconsistency with NICE's procedures is no longer a ground of appeal.

1.7. The Appraisal Committee's repeated criticisms of the comparisons of eribulin with individual TPC fail to take into account that these were required by the Scope and are therefore unfair.

I believe you are not taking issue with the criticism of the comparisons. I read the committee's comments as applying to the analyses rather than the fact that you performed them. Whilst I can understand that you may feel it would be "unfair" to take you to task for a decision to perform an analysis which you did not make, the analyses themselves cannot be above criticism. I also feel that to be an appeal ground, an unfairness has to relate to the end recommendation, rather than being an unjustified criticism of a manufacturer (although, to repeat, I do not read the FAD as being critical of you).

I am not presently minded to refer this point to an appeal panel.

Ground 2

2.1. The Appraisal Committee's conclusions with the respect to the adverse events associated with eribulin do not reflect a balanced and reasonable assessment of the available evidence.

and

2.2. The Committee's decision to reject the analysis based on the data from Region 1 of the EMBRACE trial is unreasonable.

and

2.3. The Appraisal Committee's reliance on the calculation of overall survival for patients pre-treated with capecitabine, based on the ERG's methodology set out in its Addendum Report, is unreasonable

I agree these are valid ground two appeal points.

Conclusion

As I agree some of your appeal points are valid I will pass them to an appeal panel for consideration. I would be grateful for your response to the points I consider potentially not valid by 21 December 2011 so that I may take a final decision.

Yours sincerely

Dr Maggie Helliwell
Appeals Committee Chair
National Institute for Health and Clinical Excellence