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Dear Mr Burgin

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

Thank you for your response to the initial scrutiny of your appeal lodged against this FAD. This letter represents the final decision on initial scrutiny.

Ground 1

Point 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.

Thank you for drawing my attention to the comments you made on the ACD on this issue. I accept that it is not correct to say that you did not raise this issue during the appraisal.

I have noted that the relevant comments were made in an additional document, submitted in August 2011 after the closure of comment on the ACD, which NICE agreed to accept. I have also noted that your additional document was the subject of a 19 page report prepared by the ERG in September 2011 which considers its arguments in some detail. I have every confidence that this material was available to and taken into account by the committee.

However, as I commented in the initial scrutiny letter, the issue here is possible unfairness. The appraisal committee's approach does appear to have been clear, and you had (and took) the chance to make comment on it. There seems to be no evidence that those comments were not taken into account. This seems to have satisfied the requirement that the committee acts fairly. I do not think this can be a valid appeal ground.

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

Failure to follow the Secretary of State's directions and NICE's procedures is not a valid point of appeal under ground 1 (although it may contribute to a valid point of appeal). Since August 2010 NICE's first appeal ground has been that "The Institute has failed to act fairly". This is consistent with the Secretary's of State's 2005 Directions to NICE, as amended.

I do not see any unfairness raised in your appeal point. Whether or not there is a public interest in the treatment of innovation being subject to further scrutiny or reconsideration, the appeal process is not a forum for a general reconsideration of any part of NICE's role. It exists only to consider appeal points within one of the three heads set down by the Secretary of State.

The Kennedy and Cooksey reports are not documents adopted by NICE. They represent the authors' opinions only. NICE's position was as set out in the board minutes considering the Kennedy report.
http://www.nice.org.uk/media/008/77/Item1PublicBoardMeetingMarchMinutes.pdf.
http://www.nice.org.uk/media/492/A3/BoardMeetingMar10Item4NICEResponseToConsultationBoardPaper.pdf

NICE considers that innovation is an issue to explore from the scoping stage, saying in response to the Kennedy report:

" NICE proposed that where innovation is considered to be a specific and identifiable benefit of the technology, the scoping process will be used to explore the unique characteristics which support this proposition.
Where the Appraisal Committee has identified innovative characteristics during the scoping process it will investigate:

- *its potential to make a significant and substantial impact on health-related benefits*
- *how it might improve the way that a current need is met.*

This should be done either for the population for whom it is indicated or for one (or more) subgroups. The Appraisal Committee should satisfy itself that it can be regarded as a 'step-change' in the management of the condition"

In this case there is no reference in the scope to this being a possibly innovative treatment. I have also considered your submission, in which you identify as evidence of innovation an improvement in OS (which will be captured in the economic evaluation and which will therefore have been considered). The only benefit of innovation you identify which is not captured in the economic evaluation is reduced infusion time. This appears to be a minor benefit, not even equivalent to replacing an infusion with another form of administration. I cannot see that fairness would require the committee to have discussed such a benefit specifically.

It remains my view that this is not a valid appeal point.

Point 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.

You say that *"..., we should be grateful if you would please clarify your comment that "inconsistency with NICE's procedures is no longer a ground of appeal"."*

Please see NICE's appeal process guide published in August 2010, referred to above. The ground of appeal is failure to act fairly. Inconsistency with published procedures may produce unfairness in a particular case, but it is no longer per se a ground of appeal.

Conclusion

This is the final decision on initial scrutiny. The valid appeal points are Ground 1, 1.1, 1.2, 1.4, 1.6, Ground 2, 2.1, 2.2, and 2.3.

Yours sincerely

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