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Royal College of Pathologists
2 Carlton House Terrace
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31 March 2010

Dear ██████████

Final Appraisal Determination: Azacitidine for the treatment of Myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia

Thank you for lodging the Royal College of Pathologists and British Society for Haematology's 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 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 should be referred on to the Appeal Panel.

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

Initial View

Ground 2

Inappropriate comparator

I agree this is a valid ground of appeal.

b) End of Life Criteria and failure to indicate ICER correction

I doubt this is a valid ground of appeal, as it appears to misunderstand the EoL criteria. The effect of the criteria is that a treatment may be recommended above the normal threshold of c.£30,000 per QALY. It seems that the committee decided here that the ICER was too far above that threshold to be recommendable. The question of at what lower value it might have been recommended seems hypothetical, and I am not sure what useful purpose would have been served in the committee addressing it?

I am minded to decide this is not a valid appeal point.

Conclusion

As I am minded to rule that at least some of your appeal points are valid, I will pass your appeal to the Appeal Panel for consideration.

If you wish to make any further comment on the points that I have indicated that I do not, at this preliminary stage, view as valid, or that I have re-cast, please provide to me this within 10 working days from the date of this letter, no later than **Friday 16 April**. I will then reach a final decision on the validity of those points.

Yours sincerely



Appeals Committee Chair
National Institute for Health and Clinical Excellence