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██████████

On behalf of the Royal College of Pathologists and British Society for Haematology

31 March 2010

Dear ██████████

Final Appraisal Determination: Rituximab for treatment of relapsed or refractory chronic lymphocytic leukaemia

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

Your appeal was lodged shortly outside the Institute's deadline for accepting appeals. I have decided as a matter of discretion that the Institute should consider it in any event. The reasons include that the delay was very short, the Institute had in fact taken no steps in respect of publishing the guidance between the passing of the deadline and the receipt of your appeal, and that you are bringing the appeal solely in the public interest rather than to seek a benefit for your own organisation.

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 hearing of the appeal. I suggest below that it may be appropriate for the appeal to take place on the papers rather than at an oral hearing

Initial View

I assume both of your appeal points are made on the ground of perversity.

1) Guidance on retreatment in patients who have previously received rituximab is inappropriate.

You give three reasons for this statement. If I take each reason as a separate allegation of perversity, then I am minded to agree that the first two reasons are valid appeal points. I would not be minded to take the third reason as a valid appeal point, but I suspect that your point is the apparent inconsistency with, say, the patients in the Roche trial, rather than that the patients in the ofatumumab trial should per se not be treated with rituximab?

On that understanding I would be minded to allow this appeal point to go forward.

2 Relapsing patients

Although I can see reasonable people may differ on this point, I cannot currently see a ground to argue that the recommendation is perverse. It is not per se surprising or perverse for a technology appraisal to reach a different conclusion to a third party guideline. I note your comments on efficacy but it must appear that the committee was not satisfied as to cost efficacy. And I am doubtful as to whether there is very much guidance to be drawn from other illnesses, even related ones, where as a minimum the evidence base will be different and may have been more extensive.

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

Conclusion

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

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 this to me within 10 working days from the date of this letter, no later than **Monday 19 April**. I will then reach a final decision on the validity of those points.

Conduct of appeal

The proposed ground (or grounds, if I am persuaded to change my mind on your second point) is quite self contained. It seems to me it would be possible for an appeal panel to consider them fairly on the papers, and this may be the quickest and most efficient way to proceed.

I propose that, at the same time as responding to this letter on your appeal point that I am minded to rule inadmissible, you also have the opportunity to expand in writing on both points to give the reasoning and evidence for your appeal. The appeal panel will then pass your comments on one or both points (depending on my final view) to the appraisal committee, for it to draft a written reply. That written reply would be shared with you for any final written comment. Your appeal points, the committee's reply, and your final comments, would then be put before an appeal panel to consider and decide on the appeal.

I hope that seems a sensible and efficient way to manage the appeal, and look forward to your reply.

Yours sincerely



Appeals Committee Chair

National Institute for Health and Clinical Excellence