National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Tel: 0845 003 7780
Fax: 0845 003 7784

Email: nice@nice.org.uk
www.nice.org.uk

Sent via email

[redacted]
Chairman
UK CLL Forum

31 March 2010

Dear [redacted]

**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 a 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 all of your appeal points are made on the ground of perversity.

**1) National and International Guidelines**

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, which are not binding on NICE. Indeed, NICE is required to reach its own decision on each appraisal.

I would not be minded to allow this point to proceed.

**2) Trial data suggests CR and PR rates are no worse in patients who have received prior rituximab.**

**3) Patients who have received Rituximab as part of a clinical trial, but in a less efficacious combination, cannot receive the recommended combination**

I agree these are two valid perversity appeal points.

**4) Other second line Rituximab regimens have been approved.**

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 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 point that I have indicated that I do not, at this preliminary stage, view as valid, please provide to me this 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 grounds are 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 points that I am minded to rule inadmissible, you also have the opportunity to expand in writing on all points to give the reasoning and evidence for your appeal. The appeal panel will then pass your comments on two or more 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

[redacted]

**Appeals Committee Chair**
**National Institute for Health and Clinical Excellence**