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Sent by email to: [redacted]

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Royal College of Pathologists
21 Prescot Street
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12 September 2017

Dear [redacted]

Appeal against Final Appraisal Determination (FAD): Inotuzumab ozogamicin for treating relapsed or refractory B cell acute lyphoblastic leukaemia

Thank you for your letter lodging an appeal on behalf of the Royal College against the above FAD.

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:

- 1(a) NICE has failed to act fairly, or
- 1(b) NICE has exceeded powers;
- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

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.

Initial View

You have not allocated your points to grounds, but I suggest that they sit within ground two, as each amounts to an argument that the evidence said one thing, but the committee concluded to the contrary.

Ground 2

1 Length of stay

I read two points here, first that further investigation should have been undertaken, and second that the rejection of the 1:14 ratio of inpatient days in favour of inotuzumab was unreasonable.

On the first point: in any appraisal, and especially in an STA, the Committee relies on manufacturer(s), the ERG, and consultees and commentators to provide the material on which it can base its decision. As I expect you are aware, NICE has in the past been criticised for the time taken to prepare recommendations, and it sets weight on following a process that will terminate within a reasonable period, as well as one that gathers and considers relevant evidence robustly.

In this case the manufacturer's original submission contained one set of values for inpatient days, the ERG report suggested other values, and in response to consultation the manufacturer suggested a revised set of values. I do not think it could be said to have been unreasonable to have proceeded to take a decision on the material generated by that process, even if it would equally have been possible to make further enquiry. The Committee has followed NICE's processes. (Finally on this sub point, I note that you offer to provide length of stay data from an audit of a compassionate use programme at an appeal. I am afraid an appeal cannot receive new data that was not presented to the Committee.)

Of course that still leaves the argument that the conclusion on the number of inpatient days for each of the compared treatments was unreasonable in itself. The Committee appear to have accepted that it is likely that inotuzumab would require fewer days inpatient care than

standard care does. They concluded that the ratio was not likely to be as much as 1:14, and the result was that the manufacturer's ICER estimate was probably overstated. They preferred the ERG approach. It may be that all of the manufacturers first approach, the ERG approach, and the manufacturers second approach are open to criticism at some level (indeed it might be surprising if they were not) but I am not sure it can be said that adopting the ERG approach was unreasonable?

I would be grateful for any further comments on this point. I can tell you that the manufacturer has raised a similar point, and my initial response to them is similar to my response to you. They have also been asked for any further elaboration, so my final decision on your point may take account of any additional information they provide.

2 An incorrect assumption of the number of cycles of IO

A valid appeal point.

As I agree some of your appeal points are valid they will be passed to an appeal panel for consideration. There will be an oral hearing. I would be grateful to receive your comments on the point I am presently not minded to treat as valid within 14 days of this letter, no later than **Tuesday 26 September**, whereupon I will take a final decision.

Yours sincerely

Dr Rosie Benneyworth
Vice Chair
National Institute for Health and Care Excellence