

Sent by email to: [REDACTED]

[REDACTED]
[REDACTED]
Leukaemia CARE
One Birch Court
Blackpole East
Worcester
WR3 8SG

12 September 2017

Dear [REDACTED]

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

Thank you for your letter of 25 August 2017 addressed to Andy McKeon lodging an appeal on behalf of Leukaemia CARE against the above FAD. I have taken over from Mr McKeon as the Institute's vice chair.

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

Ground 1a

1a.1 Inotuzumab ozogamicin should not have been appraised through the single technology appraisal process.

NICE's appeal guide describes ground 1(a) in these terms: *In making the assessment that preceded the recommendation, NICE has: a) failed to act fairly.* In other words, it applies to unfairness in the conduct of an appraisal. I am afraid that a decision to use the STA process to conduct an appraisal is not part of the appraisal itself and cannot be appealed.

I would not be minded to allow this appeal point to be considered.

Ground 2

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