

Sent by email to: [REDACTED] and [REDACTED]

[REDACTED]

Royal College of Pathologists  
21 Prescott Street  
London, E1 8BB

4 October 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 14 September responding to my preliminary views on initial scrutiny.

**Ground 2**

**1 Length of stay**

I have carefully considered your additional points, and have also received an additional argument from the manufacturer on this point.

I remain unconvinced that the committee have acted unreasonably in their treatment of inpatient days. I understand your concern to know more about the committee's conclusion and whether it might yet be changed, but this is not the role of an appeal process, which can intervene (in this case) only if guidance is unreasonable, which is to say falls outside the range of conclusions that a reasonable committee could reach. I understand you take a different view and I have no doubt that view is also reasonable, but I am afraid an appeal panel cannot act on that basis.

I also note your comments on making final decisions where the evidence base may be incomplete and there exist interpretations which might change the outcome. Again I understand the concern, but NICE's decisions are only truly final once the evidence base has stopped evolving. In this case the guidance is scheduled for review after three years. Pending a definitive evidence base NICE has to do the best it can with the evidence available, it cannot not make a recommendation. I can also see you are frustrated by what you describe as picking and choosing what evidence to consider and what to reject, but the committee's role is precisely to try to make such judgements as reasonably as it can.

## **2 An incorrect assumption of the number of cycles of IO**

Already agreed to be valid.

The valid appeal point is point 2 under ground 2.

Yours sincerely

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