

British Kidney Patient Association
3 The Windmills
St Mary's Close
Turk Street
Alton GU34 1EF

By email to: [REDACTED]

27 January 2016

Dear [REDACTED]

Final Appraisal Determination: immunosuppressive therapy for kidney transplantation in adults

Thank you for lodging the BKPA appeal against the above Final Appraisal Determination. I am replying in place of Dr Helliwell as I am the new vice chair of NICE.

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

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.

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 oral hearing of the appeal.

Initial View

I have assumed your appeal relates to recommendation 1.4 only, but would be grateful if you could confirm this.

Ground 2

Where I do not refer to one of your numbered paragraphs, this means that I have accepted that it is a valid appeal point.

2.6: A NICE appraisal makes recommendations on the use of the drugs within its scope only. It cannot make recommendations as to alternatives, or as to treatment pathways, and it cannot impose requirements on commissioners as to, say, processing IFRs. The absence of an effective alternative to a treatment that is not recommended (if that is the case here) does not of itself suggest that a recommendation is unreasonable. NICE does not as a policy recommend a treatment that it would otherwise have concluded was cost ineffective on the basis that there is no alternative, because to do so diverts NHS resources away from other more cost effective treatments. I would not be minded to agree this is a valid appeal point.

2.7: I would be more optimistic than you that the recommendation would not have an effect on organ donation rates. In any event, I do not think this would be a proper point for an appraisal committee to have considered: it must evaluate a drug on its own merits. If (which with respect I doubt in this case) the effect of a recommendation is to deter people from being organ donors I do not think it can be said that a benefit of recommending the drug, which should be evaluated, is maintaining or improving donation rates. I would not be minded to agree this is a valid appeal point.

2.13: NICE's work programme is dictated by the topics referred to it. If there is any unfairness here (as to which I do not have a view) it would not undermine the conduct or recommendations of this appraisal. It would need to be taken up with those who refer topics to NICE for appraisal. I would not be minded to agree this is 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 points I am presently not minded to treat as valid within 14 days of this letter, no later than **Wednesday 10 February**, whereupon I will take a final decision.

Yours sincerely

Andy McKeon
Vice Chair
National Institute for Health and Care Excellence