

██████████
National Kidney Foundation
The Point, Coach Road,
Shireoaks, Worksop,
Nottinghamshire, S81 8BW

By email to: ██████████

27 January 2016

Dear ██████████

Final Appraisal Determination: immunosuppressive therapy for kidney transplantation in adults

Thank you for lodging the NKF's appeal against the above Final Appraisal Determination.

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,¹ or
- 1(b) NICE has exceeded powers;²
- (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.

¹ formerly ground 1
² Formerly ground 3

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 that it is recommendation 1.4 only that you wish to challenge. If that is not correct please will you confirm which recommendation it is that you are challenging.

Ground 2

- It is unreasonable to ignore the weight of joint clinical evidence presented by expert transplant clinicians

If an appraisal committee literally ignored relevant evidence that would be a good ground 1(a) appeal point. As you refer to the FAD being unreasonable I understand your point to be that no reasonable committee which was aware of the expert evidence submitted to it could have reached the conclusion contained in FAD 1.4. That is a valid appeal point, although if I may offer advice to assist in preparing for the appeal hearing, you will need to be specific about what evidence it is that was before the committee and why this makes it unreasonable to have concluded as they did.

- Trial results do not cover the full spectrum of clinical practice and should not be applied to the whole transplant population. Drugs should not be "not recommended", the FAD should state "no recommendation can be made".

I am presently not minded to agree this is a valid appeal point. Clinical trial populations never cover a whole patient population, because, for example, patients with co-morbidities are usually excluded. And yet trial data is used to inform clinical practice and for important decisions affecting the whole patient population, not least licensing decisions. Unless you can point to some specific reason why the trial data in this case should not have been used to make recommendations for the whole patient population I am afraid I do not think this point is arguable.

As to your second point, the committee have used "not recommended" where they are sure a drug represents a cost ineffective use of NHS resources, and have made no recommendation where they have little or no data. I would not agree that it would be reasonably open to them to record a judgement of "no recommendation" when in fact they have sufficient data in front of them to form a view. The committee are obliged to apply their judgement to the information they are given, and to make decisions where possible. They would not be entitled to decline to form a view where in fact they have the information to do so. However, other appellants have made a similar point to yours, but on the basis that their analysis of the data suggests that the committee could reasonably only have concluded that no recommendation should be made, which I have held is a valid point. As the argument will be put in any event I agree that this part of your point is a valid appeal ground.

I am not presently minded to refer the remainder of this point to an appeal panel.

- It is unreasonable to state that some drugs are not recommended while stating that there may be clinical indications where they may be of benefit. There should be a mechanism for switching drugs that is fit for purpose in a clinical timescale

I am afraid I may not fully understand the relevance of this point to an appeal against the FAD. I think that the first point refers to FAD 4.58, but it is not unreasonable (without more) to conclude both that a treatment may have benefits or specific benefits for some populations, and yet that it should not be recommended. If benefit was all that were needed for a recommendation than all license products at least would automatically be recommended, which is not the case.

Consideration of switching between therapies and how such switches should be managed would seem to be a matter for a patient's clinicians and commissioners rather than NICE.

I would particularly welcome further comment on this point but I am not presently minded to refer it to an appeal panel.

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