

ESPRIT

6 Baldwin Crescent

London, SE5 9LQ

By email to: info@esprit.org.uk

27 January 2016

Dear [REDACTED]

**Final Appraisal Determination: immunosuppressive therapy for kidney transplantation
in Children and Young People**

Thank you for lodging the ESPRIT group's 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

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

Could you confirm that your appeal concerns all of the drugs referred to in FAD 1.4, including everolimus and belatacept?

Ground 2

I agree your appeal points are valid, with one caveat concerning your point 2.3. Drugs must be evaluated on their own merits and cost effectiveness. The clinical context of a drug's use may be relevant to that evaluation in the form of the costs and benefits of comparator therapies and treatments, and/or the alternative options open to a patient, but no further. I understand your point 2.3 to be an argument that the economic analysis is defective because a key cost of a non-treatment scenario, graft failure and subsequent dialysis or no transplant and continued dialysis has been omitted. That would be a valid point. If I have misunderstood the point please correct me.

As I agree 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 further comments within 14 days of this letter, no later than **Wednesday 10 February**.

Yours sincerely

Andy McKeon
Vice Chair
National Institute for Health and Care Excellence