

1 April 2008

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British Dietetic Association


Dear Sir/Madam

Final Appraisal Determination: Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (review of technology appraisal guidance 57)

Thank you for lodging the British Diabetic Association's appeal against the above Final Appraisal Determination (FAD).

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:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared guidance which is perverse in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

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 shall be referred on to the Appeal Panel.

Initial View

You have made one point of appeal under Ground 1 and one point of appeal under Ground 2.

I consider your point of appeal under Ground 1 (that because the recommendation contained in section 1.2 of the FAD was not evident in any of the preliminary drafts sent out for consultation, consultees have not been given a fair opportunity to comment on this aspect of the guidance) to be valid and I propose to refer this point of appeal to the Appeal Panel. As guidance to you, the Appeal Panel will require you to explain why you believe that the fact that the recommendation in section 1.2 of the FAD was not contained in any of the other documents has caused unfairness. I note that it is inherent in a consultation exercise that the documents under consultation may change so the simple fact that the FAD differs from the earlier documentation sent to consultees will not, of itself, establish unfairness.

I do not consider your appeal point under Ground 2 (it is perverse to suggest that a child who is well-controlled and has a good quality of life with an insulin pump should have to come off the pump) to be valid. In order to establish perversity, you must provide evidence that establishes that the recommendation in the FAD is perverse in the light of the evidence available to the Appraisal Committee; that is, that no reasonable appraisal committee could have come to that recommendation. I am afraid that it is not sufficient for the purposes of an appeal for you simply to set out the areas in which you disagree with the recommendations in the FAD, however sincerely held those views are. If, however, you wish to provide further information in support of this point of appeal, I would be happy to reconsider it.

Preliminary Conclusion

As I am minded to rule that at least one of your appeal points is valid, I will pass your appeal to the Appeal Panel for consideration.

Given the discrete and fairly limited nature of this appeal point, I do not think it is necessary for the Appeal Panel to hold an oral hearing to consider this appeal. I propose to refer your appeal to the Appeal Panel, to be determined on a review of the papers.

I suggest that the appeal should proceed as follows. Your letter will be passed to the Appraisal

Committee, which will prepare a written reply and explanation of the appraisal process which you are challenging. That reply will then be passed to you for further written comment and response (if any). Your initial letter, the Appraisal Committee's response, and your reply to that response, will then be considered by the Appeal Panel and the appeal determined on those documents and the original appraisal papers.

Should you have any comments on this proposed course of action I would be grateful to have them by **8 April 2008**, failing which I will ask the Institute to make arrangements for the appeal to proceed as outlined above. If you want to add any material in support of your complaint of unfairness at this point, I would also be grateful to receive that within seven days.

If you wish to make any further comment as to why, contrary to my initial view, your ground two appeal should also be considered, I would be grateful to receive this by **15 April 2008**.

Yours sincerely

Mark Taylor
Appeals Committee Chair
National Institute for Health and Clinical Excellence