

Sent by email

██████████

Consultant Clinical Oncologist, University College London Hospitals
Chair and Trustee
British Uro-Oncology Group

12 May 2014

Dear ██████████

Final Appraisal Determination: Degarelix for treating advanced hormone dependent prostate cancer

Thank you for lodging the British Uro-Oncology Group'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

¹ Formerly ground 1

² Formerly ground 3

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

Ground 1 (a)

1.1a Change in wording from ACD to FAD without due consultation

A valid ground 1(a) appeal point.

Ground 1.2(a) NICE has been inconsistent in its acceptance and review of data in the context of other technology appraisals

Although NICE accepts a broad obligation of consistency between appraisals, in practice it is very difficult to take this very far. This is because appraisals differ so widely. The quality of the evidence base for any given appraisal will vary from any other appraisal. The fact that pooled or post hoc analyses have been accepted in one appraisal cannot tell us much if anything about whether different analyses should be accepted in a subsequent appraisal. Not only will the quality of the analyses themselves inevitably vary, but the overall evidence base against which they are assessed will also vary. Where a committee feels that all the other evidence tends to one conclusion, it might feel slightly strengthened in that conclusion by, say, post hoc analyses, despite the well known limitations of those analyses. In another case where there is no overall trend to the evidence, post hoc analyses which are in themselves no worse might be rejected as a basis for a recommendation.

I am not minded to agree this is a valid appeal point.

Ground 2

Ground 2.1 The FAD recommendation by NICE is unreasonable as it fails to accept data which shows demonstrable benefits for optimum patient care

It seems to me this appeal point is a repetition of the submission made to the committee during the appraisal. The appeal panel is not able to reach its own conclusions on the detailed merits of an appraisal, only to confirm whether or not it is reasonable. I would not be minded to accept this as a valid appeal ground.

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 **Tuesday 27 May 2014**, whereupon I will take a final decision.

Yours sincerely

Dr Maggie Helliwell
Vice Chair of NICE
National Institute for Health and Care Excellence