

Sent by email

British Uro-Oncology Group (BUG) Executive Committee
Barley Mow Centre
10 Barley Mow Passage
London W4 4 PH

3 June 2014

Dear British Uro-oncology Group (BUG) Executive Committee

Final Appraisal Determination: Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen

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 point of appeal you have raised: principally whether it falls 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 point contains the necessary information and arguably falls 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 your appeal point should be referred on to the Appeal Panel.

My initial view is that your ground of appeal is not valid and therefore that I am minded not to refer it to the Appeal Panel.

Initial View

Ground 1 (a)

1.1 Inclusion of paragraph 1.2 of the FAD is not fair

I understand your argument to be that as paragraph 1.2 of the FAD states that the use of enzalutamide for patients previously treated with abiraterone is not covered by the guidance, there will be variation in the local commissioning of treatment for such patients. This variation makes the FAD unfair.

It is apparent from the FAD that the Appraisal Committee carefully considered whether it could make a recommendation on the cost effectiveness of enzalutamide after treatment with abiraterone (see paragraph 4.23).

The logical conclusion of your argument is that the Committee should recommend a treatment about which it had insufficient evidence to make a recommendation to ensure consistency in treatment across the country. I do not think that that would be appropriate, or that the Committee can be said to have acted unfairly by not taking the course of action you suggest.

My initial view is therefore that your ground of appeal is not valid.

I would be grateful to receive your comments on my initial view on your ground of appeal within 14 days of this letter, no later than **Tuesday 17 June 2014**, whereupon I will take a final decision.

Yours sincerely

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