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27 September 2017

Dear [redacted]

Appeal against Final Appraisal Determination (FAD): Intrabeam radiotherapy system for adjuvant treatment of early breast cancer

Thank you for your letter of 15 September 2017 lodging an appeal on behalf of the Royal College and others against the above FAD. I have taken over from Mr McKeon as the Vice Chair with responsibility for appeals.

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.

Initial View

Ground 1 (a)

1a.1 NICE based its judgement on incomplete evidence

I am unsure whether the issue you raise should be treated as a factual correction or a possible ground of appeal. The clinical expert in question has also contacted NICE in relation to this statement. She has asked that it be replaced with "*A clinical expert confirmed that local recurrence is not related to an increased risk of metastatic disease or mortality, for a small, highly selected group of older women (60 years or above) with very low risk breast cancer (small, low grade, oestrogen receptor positive and node negative).*"

Requests for factual correction would normally be considered by the Institute's guidance executive rather than through the appeal process.

I cannot be sure whether the requested correction would be made, but on the assumption that it is made, would this address your concern, or would you still wish to bring an appeal? I will await your comments before considering whether this would be a valid appeal point.

1a.2 NICE published misleading information about its processes around this FAD

I have read the press release you refer to. I can see that read in isolation the language it uses could suggest that NICE had reached a final decision, and in some respects the press release is incorrect (in particular in referring to a conclusion in a consultation document as "NICE recommends..."). However the release does end with the statement that "*The draft guidance is open for public consultation until 1 March*" and the hyperlink to the consultation document reads "*Intrabeam Radiotherapy System for breast cancer draft guidance*". The ACD itself opens with a substantial section that describes how the consultation will work, invited comments, and says in bold type "*Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation*."

I would agree that the wording of the press release is not ideal, and regardless of whether this appeal point progresses or not I will take this up with NICE for future appraisals. However read in the round I am not sure it can be argued that NICE appeared to have determined the outcome in advance of the consultation? At present I would not be minded to refer this point on to an appeal panel, but I will await your further comments before deciding.

Ground 2

2.1 The AC took clinical evidence out of context

This appeal point is closely related to point 1a.1 above. May I ask the same question: if the correction sought by the clinical expert is made, would you still want to press this appeal point, and if so, could you elaborate on it before I decide on the validity of the point?

2.2 A very small number of patients are treated and it is unrealistic to expect a national data set to be developed

I think it may not do justice to the committee's reasoning to focus on data collection as an end in itself. FAD 4.14 onwards seems to say that the costs and benefits of intrabeam remain uncertain, that some patients might value the choice offered by intrabeam, and that it is reasonable to continue to use existing devices but not to expand provision until new data are available (and considered). I read this as the committee concluding that to increase patient choice and pending any more definite finding as to clinical or cost effectiveness existing facilities should remain available, but there should be no expansion in the absence of new data. I do not understand them to be saying that the purpose of the recommendation is to generate data, rather, the purpose is to preserve choice and as an adjunct data should be collected. If in fact sufficient new data are not generated, then presumably the recommendation will not be reviewed.

I would welcome any further elaboration on this point, but at present I would not be minded to let it proceed.

At present I am not sure whether any of your points will proceed to an appeal or whether consideration of a factual error is the right approach. If there were to be an appeal I would be

grateful also for your comments on whether you would seek an oral hearing, or whether an appeal panel could consider your points in writing. They seem to be fairly self-contained and an appeal in writing might be the more efficient approach?

I would be grateful to receive your comments on the points above within 14 days of this letter, no later than **5pm on 11 October 2017**, whereupon I will take a final decision.

Yours sincerely

Dr Rosie Benneyworth
Vice Chair
National Institute for Health and Care Excellence