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24 November 2011

Dear ██████████

Final Appraisal Determination: Dabigatran etexilate for the prevention of stroke or systemic embolism in people with atrial fibrillation (AF)

Thank you for lodging your 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:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified 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 should be referred on to the Appeal Panel.

Initial View

Ground 1

1.1 The PCT is concerned that by not having access to primary care professionals neither on the Technology Appraisal Committee, nor via the professional/specialist groups or selected clinical experts, the Committee has failed to act fairly.

and

1.2 The PCT considers that by significantly changing the recommendation in the guidance following the initial ACD, it is unfair to proceed straight to the FAD. This is because had PCTs or other health care professionals identified that such a recommendation was likely, they might have responded to NICE via the ACD procedure. This is selectively unfair to commissioning stakeholders.

I agree these are valid ground one appeal points.

1.3. The PCT considers that NICE has acted unfairly by not differentiating in its recommendation in this FAD between those people for whom it has been shown that dabigatran is a cost effective use of NHS resources for this indication compared to those subgroup patients for whom the ERG has shown that the use of dabigatran is not a cost effective use of NHS resources. The implementation of this guidance is likely to adversely impact on the resources available to commission services and treatments available for the rest of population.

At present, this point seems to me to go essentially to the substance of the recommendation, rather than issues of procedural fairness, and to overlap with your point 2.1. You will note below that I agree that point 2.1 should be considered by an appeal panel. Unless you can help me by identifying some stand alone procedural weakness that might be considered under ground 1 that is over and above the arguments you will be making under point 2.1, I would not be minded to allow this point to proceed.

Ground 2

2.1. The PCT is concerned that it seems unreasonable to use a lack of evidence as the main basis for adding a subgroup of patients to a larger, significantly more cost effective patient group, to allow an averaging effect to enable the patient subgroup for which the intervention is not supported by evidence as being cost effective (QALY > £30K).

I agree this is a valid ground two appeal point. In so far as any of the issues raised under point 1.3 touch on questions of reasonableness, you may raise them in addition to the points made specifically under this heading.

2.2 The PCT is concerned that patient safety considerations were not adequately considered by the Appraisal Committee in the development of the recommendations stated in the FAD.

Lack of long term data is not uncommon in an STA, and the committee can only work within the data it has. The weight to give to data (or a lack of data) would be a matter for a committee, and a panel would only intervene if the weight (or lack of weight) was so extreme as to be unreasonable. I am not sure from your letter that this would be a possible finding here. If you could provide further argument or information explaining why the committee's approach was unreasonable, I would be happy to consider it, but at present I am not persuaded this should be referred to an appeal panel.

2.3 The PCT is concerned that the comments received from NHS Salford and other PCTs regarding cost impact were not adequately considered.

An appeal can only consider the guidance to be issued to the NHS, and implementation tools and issues around implementation are not considered in the appeal process. Additionally, NICE does not have a role in the funding of the NHS and is not empowered to take a view in guidance on cost (as opposed to cost effectiveness). If you have any further comments you would like to make on difficulties in implementation as they directly affect the reasonableness of the guidance, I would be happy to consider them, but at present I am not minded to agree this is a valid appeal point.

Ground 3: The Institute has exceeded its powers

3.1 For AF patients currently being prescribed warfarin and well controlled within target therapeutic range, as referred to in section 2 above, this FAD does not adequately justify the basis of recommending dabigatran as an alternative to warfarin as there is evidence that this is not a cost effective intervention. Therefore, the Institute has not complied with its own 'Guide to the methods of technology appraisals' in making the recommendations in this FAD.

I am not sure that I can see a ground 3 point here? If the evidence and reasoning cannot properly support the recommendation, then your appeal under ground 2.1 would succeed. If the institute has not followed its own processes, and consultees have been misled as a result, that can result in unfairness under ground 1. But ground 3 would usually address issues such as a breach of the substantive law (for example on human rights or equalities), or a failure to follow the Secretary of State's directions.

I would not be minded to refer this appeal point to a panel.

Conclusion

As I agree some of your appeal points are valid I will pass them to an appeal panel for consideration.

If you wish to make any further comment on the points that I have indicated that I do not, at this preliminary stage, view as valid, or that I have re-cast, please provide to me this by **Thursday 8 December**. I will then reach a final decision on the validity of those points.

Finally, I note that you have requested a written appeal. I do not think that an appeal panel would be able properly to consider the points you have raised without being able to question the committee directly, and so an oral hearing will be essential. However, I will ask the Institute to try to arrange that this is held at its offices in Manchester, which I hope will be more convenient for you to attend.

Yours sincerely



**For the Appeals Committee Chair
National Institute for Health and Clinical Excellence**