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Dear Sir/Madam

Final Appraisal Determination: Ranibizumab and Pegaptinib for Age related Macular Degeneration

Thank you for lodging the Primary Care Trust'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 a FAD 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.

As I have understood your letter you wish to make one appeal point under each of grounds one, two and three.

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 is referred on to the Appeal

Panel.

Ground one (paras 5-8)

Unless I have misunderstood events, the reason that the PCT did not comment on the first appraisal consultation document was due to disorganisation on its part following a merger. I do not see how that can be said to show any default on the Institute's part.

I also note that in this appraisal there were two ACDs, and that you did submit comments on the second ACD (which overtook the first ACD and in due course informed the FAD). I also note that in those comments you observed that "It is noted that many of the points raised in the initial response from Derbyshire County PCT have been specifically addressed in the December 2007 ACD." Therefore it seems to me both that you had a chance to comment on the ACD which eventually led to the guidance, and that you were content that your earlier comments had been taken into account.

For all of these reasons I am minded to rule that this is not a valid ground of appeal.

Ground 2 paras 9-18

I have had some difficulty in following the argument here, and if I have misunderstood it I would be grateful for correction. The allegedly perverse conclusion is that patients with a visual acuity down to 6/96 should be treated. The PCT feels that treatment should be restricted to those with a better starting acuity. There seem to be two reasons for that argument:

- Differences in utility do not map onto differences in acuity in a linear fashion. In particular, the majority of the loss of utility is concentrated at the upper end of the acuity scale.
- Subgroup analysis has been used in other appraisals, and could have been used for Ranibizumab.

This argument is going to need further development before I can see if it is valid. I note that the Committee has found ICERs in the range of (about) £11,000-£25,000 per QALY, depending on assumption and comparators. My first concern, therefore, is that unless these findings themselves are perverse, the treatment may well be below the £20,000 level at which acceptable cost effectiveness is assumed, and if not, is at the lower end of the (roughly) £20-30,000 band where cost effectiveness is often proved. Assuming for now that restriction of treatment to those with higher starting acuity would further improve cost effectiveness, I would need to see argument as to why it would be perverse not to do this. My initial impression is that, in a case where treating the entire cohort delivers cost effectiveness which may be below the £20,000 level, far from it being perverse not to seek to improve the ICER further by restricting treatment, it would be hard to justify doing so.

My second concern is that this issue seems to have been considered by the Committee which concluded that the distribution of initial visual acuity made little difference to the ICER (FAD 4.2.3.10), (although I do note that the cohort tested ranged down only to an acuity of 6/60, and it may be your point relates to acuity below 6/60). I do not understand why their conclusion on the point is said to be perverse?

Finally, I am not sure that the underlying concern here is not affordability rather than cost effectiveness. Naturally I am well aware that affordability is a very real issue for the NHS, but it is expressly not one which NICE is allowed to consider. It would be helpful if any further elaboration on this point could focus clearly on why the guidance is perverse in terms of cost effectiveness.

As the point stands at present I am minded to rule that this is not a valid ground of appeal.

Ground 3 paras 19-24

I agree that this is a valid ground of appeal. As well as the issue of whether this amounts to co-funding, I suggest the appeal panel should consider whether or not the recommendation is sufficiently clear as to what costs the committee intended to be borne by the manufacturer.

Preliminary Conclusion

I would be happy to consider any further comments you may wish to make. Any correspondence should be sent to the Institute within two weeks of the date of this letter.

As I am minded to rule that at least one of your appeal points is valid, an appeal hearing will take place. The Institute will contact you to arrange this in due course.

Yours sincerely

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