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Sent via email

Gavin Lewis

Health Economics and Strategic Pricing Director

Roche Ltd

16 August 2011

Dear Gavin

Final Appraisal Determination: Lapatinib or trastuzumab in combination with an aromatase inhibitor for the first line treatment of metastatic hormone receptor positive breast cancer that over expresses HER2

Thank you for your response to the initial scrutiny of your appeal lodged against this FAD. This letter represents the final decision on initial scrutiny.

1.2 The lack of guidance issued by the Institute in relation to the calculation of small patient populations for the purposes of the End of Life advice is unclear

I have carefully considered both your original point and the further explanation you have provided. However, it still appears to me that this is not a valid ground of appeal. I have commented on the particular points that you raise below.

(a) The conclusion of the Appeal Panel in TA227

Paragraph 4.4.4 of the Guide to the Technology Appraisal Appeal Process is clear that past decisions can be relevant to the chair's decision on the initial scrutiny of appeal points. I remain of the view that this point raises issues that were dealt with by the appeal panel in TA227, where the appeal panel found that there was no unfairness caused by the absence of guidance.

I do not find your arguments for not following TA227 persuasive. The Appeal Panel decision in TA227 is clear at paragraph 38 that the formal reason for its conclusion that there was no unfairness was because the Committee had conscientiously followed the guidance confirmed in a previous appeal hearing where this had been tested. The inconsistency with purpose point was raised by Roche in the

TA227 appeal as a subsidiary argument and it is therefore covered by the appeal panel's decision on the over-arching ground of appeal that it was made in support of.

Finally, I should be clear that I do not agree with your statement that *"it is clear from the wording of the appeal decision that the Panel regarded the fact that different Committees had adopted different approaches to this issue as unsatisfactory."*

(b) The decision of the Appeal Panel in TA227 was issued too late

As the decision in TA227 was that no guidance needed to be issued in order for the appraisal to be fair, I cannot see how knowledge of that decision could require that appraisal or any other to be put on hold while guidance was produced.

(c) The uncertainty as to whether the Institute will decide to issue guidance

Similarly, as the decision in TA227 was that there was no unfairness caused by the absence of guidance, I do not see why that would require the Committee in this appraisal to seek further guidance.

2.4 The conclusion by the Appraisal Committee that estimates of progression free survival for the aromatase inhibitor monotherapy in the TAnDEM trial were likely to be too low disregards the fact that the patient population in TAnDEM was different from that in EGF30008

Thank you for your further comments.

Conclusion

This is the final decision on initial scrutiny. I have accepted all of the appeal points raised as valid, except for point 1.2.

Yours sincerely

Maggie Helliwell
Appeals Committee Chair
National Institute for Health and Clinical Excellence