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GlaxoSmithKline Ltd

19 July 2010

Dear [redacted]

Final Appraisal Determination: Lapatinib for the treatment of women with previously treated advanced or metastatic breast cancer

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.

1a The letter from Professor Home is unclear and does not address the issues raised by the Guidance executive

We are perhaps at cross purposes. I would accept that if the committee has not addressed the requests of the Guidance Executive that should be at least referred to an appeal panel, which I think is your point. I remain of the view that if the letter is merely arguably unclear in its response, that is not a valid matter for an appeal.

I note that your point is now that Professor Home appears to believe trastuzumab is not licensed for use prior to Lapatinib. I am afraid I cannot see how it is you say that he holds that belief? It is clear from the FAD that the committee were well aware that trastuzumab is used before lapatinib, and they must be aware that it holds a marketing authorisation for use.

I regard it as your responsibility to make a valid appeal point clear to me, and I have to say I am not sure you have done so. However in the unusual situation of a possible difference of views on the trastuzumab-lapatinib comparison between the guidance executive and the committee, and in the interests of the issue being seen to be discussed in a public forum, I am going to make an exception to what would be my normal approach and allow this point to go forward to an appeal panel.

1c the committee has not considered lapatinib for women for whom trastuzumab is unsuitable

I am afraid I still cannot understand the basis for the point being made. The FAD does discuss substitution of lapatinib for trastuzumab, and I still cannot identify any patient group who should have

been considered but who were not. "Less suitable" appears to be an unquantified, possibly unquantifiable, concept. In any event by considering lapatinib versus trastuzumab generally the committee has included these patients. I certainly cannot see any group which the committee was obliged to but did not take into account.

It remains my view that there is no valid appeal point here.

2 The committee should have considered the Lapatinib patient access scheme.

Contrary to your letter I have to note that section 4 of the FAD does indeed make reference to the patient access scheme. However, I will allow this point to go forward, so that an appeal panel can consider whether the scheme was properly included at all points where it was relevant.

3 The concern that a positive recommendation might displace capecitabine and vinorelbine is unexplained.

I agree this point should be considered by an appeal panel.

5 The conclusion that the clinical trial population may differ from the clinical practice population is not based on reliable evidence

It remains my view that the view expressed in para 4.25 of the FAD is not one which could be considered perverse by any appeal panel, even assuming that it is a view with which you reasonably disagree. Therefore it remains my view that there is no valid appeal point here

Conclusion

This is the final decision on initial scrutiny. The valid appeal points are 1(a), 1(b), 2, 3, and 4.

Yours sincerely

Maggie Helliwell

Appeal Committee Chair

National Institute for Health and Clinical Excellence