Sent by e-mail only: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxx

Breast Cancer Now and UKBCG

Ibex House

42-47 Minories

London

EC3N 1DY

Thursday 18 April 2024

Dear Breast Cancer Now and UKBCG

**Re: Final Draft Guidance — Trastuzumab deruxtecan for treating HER2-low metastatic or unresectable breast cancer after chemotherapy [ID3935]**

Thank you for your letter of 11 April 2024 responding to my initial scrutiny views. This is my final decision on initial scrutiny.

I assess your sole appeal point below.

***Ground 2:******the recommendation is unreasonable in the light of the evidence submitted to NICE***

**Appeal point 2.1: The recommendation is unreasonable in the light of the evidence submitted to NICE concerning overall survival extrapolation**

In my letter of 26 March 2024, I explained why I was not minded to refer this point to the Appeal Panel. With reference to the Committee's reasoning, I described why, from your appeal letter, I was not persuaded that the Committee's preference for the modified gamma distribution for modelling overall survival for trastuzumab deruxtecan was arguably unreasonable in light of the evidence before it. That was, at least in part, because of the Committee's concerns about the log logistic distribution, which appeared to me reasonable.

I have considered your specific argument and the evidence you have provided in your letter of 11 April 2024 but remain of the view that this appeal point should not proceed to a hearing.

I understand your letter of 11 April 2024 to argue that it was unreasonable for the Committee to conclude that a survival benefit lasting more than 10 years (as assumed by the log-logistic distribution) was clinically implausible. I accept that the Committee reached that conclusion and, at least in part, relied on it as a reason to prefer the modified gamma distribution. However, in support of your refined argument you rely solely on the report of the Lancet Breast Cancer Commission (the "**Report**") which remains under embargo at the time of writing. As explained in my initial scrutiny letter, for a recommendation to be unreasonable under ground 2, an appellant must demonstrate that it cannot reasonably be justified *in light of the evidence presented to the committee* [[1]](#footnote-1); the Committee in carrying out its task of evaluating a technology in respect of both clinical and cost effectiveness can do so only on the basis of the evidence that is presented to it. Therefore, in order to refer your refined appeal point to an appeal panel I would need to be persuaded that it is arguable that the Committee's conclusion was unreasonable *in light of the evidence that was in fact submitted to it*. It is my understanding that the Report was not made available to the Committee at the time of the appraisal (if this is incorrect, please confirm) and therefore could not be taken into account in their decision making.

Therefore, subject to confirmation from you within 7 days of this letter that the Report was in fact available and submitted to the Committee, I confirm that this point will not be referred to the Appeal Panel.

Conclusion

For the reasons set out above, I will not refer any appeal points for consideration at an appeal hearing. Subject to the above, this letter therefore brings NICE's internal appeal process to a close.

Thank you for your comments and engagement in the appeals process.

Yours sincerely

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Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence

1. See NICE's appeal process guide https://www.nice.org.uk/process/pmg41/chapter/making-an-appeal#what-is-the-scope-of-an-appeal [↑](#footnote-ref-1)