National Institute for Health and Care Excellence

Health Technology Evaluation

Bevacizumab (originator and biosimilars) with fluoropyrimidine-based chemotherapy for untreated metastatic colorectal cancer (including review of TA212) [ID6465]

Response to stakeholder organisation comments on the draft remit and draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Celltrion Healthcare UK Limited	This will likely be very helpful to NHS.	Thank you for your comment. No action required.
Wording	Celltrion Healthcare UK Limited	We believe this is appropriate.	Thank you for your comment. No action required.
Timing Issues	Celltrion Healthcare UK Limited	Certain HCPs wish for NICE guidance on this subject, so there is an undoubted need for NICE to act, although it is unclear if this is urgent.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
Additional comments on the draft remit	Celltrion Healthcare UK Limited	Questions remain on how the MTA is to be funded – as a biosimilar manufacturer, at this time Celltrion Healthcare cannot commit to funding, without further information from NICE and subsequent internal approval.	Thank you for your comment. Funding will be considered separately from the scoping consultation.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Celltrion Healthcare UK Limited	Seemingly accurate.	Thank you for your comment. No action required.
Population	Celltrion Healthcare UK Limited	Seemingly accurate.	Thank you for your comment. No action required.
Subgroups	Celltrion Healthcare UK Limited	Unable to answer.	Thank you for your comment. No action required.
Comparators	Celltrion Healthcare UK Limited	Seemingly accurate, unable to answer with authority.	Thank you for your comment. No action required.
Outcomes	Celltrion Healthcare UK Limited	Believe so.	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Equality	Celltrion Healthcare UK Limited	We do not believe this could lead to such exclusions.	Thank you for your comment. No action required.
Additional comments on the draft scope	Celltrion Healthcare UK Limited	Additional comments on the draft scope: Will the limited evaluation objective (see above) result in useful guidance for the NHS? We believe so, and look forward to comment from all other stakeholders. Where do you consider bevacizumab and bevacizumab biosimilars will fit into the existing care pathway for metastatic carcinoma of the colon or rectum? Unable to answer categorically. The belief is that a biosimilar bevacizumab should fit into any place in any pathway where originator biosimilar sits. Do you consider that the use of bevacizumab and bevacizumab biosimilars can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? Yes and No. At a patient level – potentially: yes, with respect to potentially widening access of treatments to patients; but no, with respect to specific health-related benefits (biosimilars are not designed to offer better health-related benefits). A significant point is that drug costs are very likely very much lower using biosimilars due to low and extremely competitive in-market prices, further to regional commissioning pathways.	Thank you for your comment. No action required. Thank you for your comment. No action required. Thank you for your comment. No action required. The committee will consider any relevant benefits not included in the QALY calculation as needed during its decision making.

Section	Consultee/ Commentator	Comments [sic]	Action
		Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. We offer no health-related data and make no claims. In-market pricing is available from MPSC and other Procurement Authorities. Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics. We are unable to answer this question. Please note that Celltrion biosimilar products gain approved indications to the originator product.	Thank you for your comment. No action required. Thank you for your comment. No action required.

The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope

N/A