National Institute for Health and Care Excellence

Single Technology Appraisal (STA)
DCVax-L for treating newly diagnosed glioblastoma multiforme [ID836]

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

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

Section	Consultee/ Commentator	Comments [sic]	Action
Timing Issues ***What is the relative urgency of this appraisal to the NHS?***	Association of British Neurologists	Given the current absence of phase III trials for DCVaxL but the pending results of a phase III RCT trial, this NICE single technology appraisal would be better completed following publication of that study.	Comment noted. NICE aims to publish guidance on cancer drugs within 90 days of marketing authorisation. Any requirements for potential delays will be taken into account as appropriate.
Additional comments on the draft remit	Association of British Neurologists	Could/was DCVaxL for GBM (and this remit therefore) covered in the Primary brain tumours and cerebral metastases. NICE clinical guideline which is currently in development? And therefore is this separate remit required at this point?	Comment noted. This remit is specifically for a technology appraisal of DCVaxL for GBM. NICE has committed to appraising all new cancer drugs and new indications for existing

			cancer drugs. Therefore, a technology appraisal of this drug is considered necessary at this stage.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information ***Consider the accuracy and completeness of this information.***	Association of British Neurologists	1. Low grade glioma – grade II are now not referred to as "benign" as they will become more aggressive with time. 2. "Glioblastomas can be classed according how they present." I would remove this sentence.	Comments noted. The background section has been amended accordingly
Outcomes ***Will these outcome measures capture the most important health related benefits (and harms) of the technology?***	Association of British Neurologists	Yes	Comment noted. No changes to the scope are needed
Innovation ***Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it***	Association of British Neurologists	Yes – if it shown to work in a phase III clinical trial (still awaited) Data is currently awaited for phase III RCT. Data is available for phase I and II trials.	Comment noted. The committee will consider the innovative nature of the technology at the time of the appraisal. No changes to the scope are needed

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might improve the way that current need is met (is this a 'step-change' in the management of the condition)? Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.			
Questions for consultation ***Please answer any of the questions for consultation if not covered in the above sections. If appropriate, please include comments on the proposed***	Association of British Neurologists	***Which treatments are considered to be established clinical practice in the NHS for people with newly diagnosed glioblastoma who have had surgical resection and temozolomide?*** This question is being covered by the Primary brain tumours and cerebral metastases NICE clinical guideline which is currently in development. ***Are there any subgroups of people in whom DCVax-L is expected to be more clinically effective and cost effective or other groups that should***	Comments noted. No changes to the scope are needed

Section	Consultee/ Commentator	Comments [sic]	Action
process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).		***be examined separately and how are they identified in clinical practice? Should patients with a methylated MGMT gene promoter or mutations in the IHD genes be considered as a separate subgroup?*** Given the current lack of phase III studies on this this question can not currently be addressed.	

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

Department of Health, Social Services and Public Safety for Northern Ireland