NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SingleTechnology Appraisal

Dabrafenib and trametinib for the treatment of unresectable, advanced or metastatic BRAFV600 mutation-positive melanoma [ID605]

Consultee and commentator comment form

Please use this form for submitting your comments on the draft scope and provisional matrix of consultees and commentators. It is important that you complete and return this form even if you have no comments otherwise we may chase you for a response.

Enter the name of your organisation here: British Association of Dermatologists

Comments on the draft scope

The remit is the brief for an appraisal and has been formally referred to NICE by the Department of Health. Appendix A contains the remit. The draft scope, developed from the remit outlines the question that the appraisal will answer.

Please submit your comments on the draft scope using the table below. **Please take note of any questions that have been highlighted in the draft scope itself** (usually found at the end of the document).

If you have been asked to comment on documents for more than one proposed appraisal, please use a separate comment form for each topic, even if the issues are similar.

If you do not have any comments to make on the draft scope, please state this in the box below.

Comment 1: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	We agree with the correct use of the term “melanoma”, instead of what has been used previously, i.e. “malignant melanoma”, which is incorrect.
The technology/ intervention	*Is the description of the technology or technologies accurate?*	
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Yes.
Comparators	*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology*	

Section	*Notes*	Your comments
	should be compared? Can this (one of these) be described as 'best alternative care'?	
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	Yes.
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	
Equality	*NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:* • *could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;* • *could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;* • *could have any adverse impact on people with a particular disability or disabilities.* *Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.*	
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	
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 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*	Yes.

Section	*Notes*	Your comments
	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 process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).*	
Any additional comments on the draft scope We feel that the reference to the guidance *"Cancer Service Guidance, May 2010, 'Improving outcomes for people with skin tumours including melanoma (update): the management of low-risk basal cell carcinomas in the community' "* is inappropriate – it is not relevant to the subject matter.		

Comment 2: provisional matrix of consultees and commentators

The provisional matrix of consultees and commentators (Appendix B) is a list of organisations that we have identified as being appropriate to participate in this proposed appraisal. If you have any comments on this list, please submit them in the box below.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts. If you do not have any comments to make on the provisional matrix of consultees and commentators, please cross this box: ☐

Comments on the provisional matrix of consultees and commentators
We suggest the inclusion of BAPRAS to the list of consultees as they should be involved and will have a view.

Comment 3: regulatory issues (for manufacturers to complete)

Section	*Notes*	Your comments
Remit	*Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.*	
Current or proposed marketing authorisation	*What are the current indications for the technology?*	
	What are the planned indications for the technology?	
	FOR EACH PLANNED INDICATION:	
	What is the target date (mm/yyyy) for regulatory submission?	

Section	*Notes*	Your comments
	Which regulatory process are you following?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?	
	Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.	
Economic model software	*NICE accepts executable economic models using standard software, that is, Excel , DATA, R or WinBUGs. Please indicate which software will be used. If you plan to submit a model in a non-standard package, NICE, in association with the ERG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the ERG with temporary licences for the non –standard software for the duration of the appraisal. NICE reserves the right to reject economic models in non-standard software*	