NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Nivolumab with ipilimumab for adjuvant treatment of completely resected stage III or IV melanoma ID1610

Consultee and commentator comment form

Please use this form for submitting your comments on the draft remit, draft scope and provisional stakeholder list 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 remit and draft scope

The draft remit is the brief for an appraisal. Appendix B contains the draft remit. The draft scope, developed from the draft remit outlines the question that the appraisal will answer.

Please submit your comments on the draft remit and 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 appraisal, please use a separate comment form for each topic, even if the issues are similar.

Please complete this form and upload it to NICE Docs by **Friday 11 October 2019**. If using NICE Docs is not possible please return via email to scopingta@nice.org.uk If you have any questions please contact the Scoping Project Manager, Michelle Adhemar on 44 (0)20 7045 2239 or at the email address above.

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

Comment 1: the draft remit

Section	*Notes*	Your comments
Wording	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.*	Yes.
Timing Issues	*What is the relative urgency of this appraisal to the NHS?*	If trial Checkmate 915 shows significant advantage over single agent therapy ipilimumab, nivolumab, pembrolizumab then it will need to be implemented sooner rather than later. Also combination dabrafenib and

Section	*Notes*	Your comments
		trametinib can only be given in the adjuvant setting to BRAF mutated melanoma.
Any additional comments on the draft remit We do not have access to the trial results		

Comment 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	No issue.
The technology/ intervention	*Is the description of the technology or technologies accurate?*	Yes.
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Yes – the trial is for Stage IIIb,c,d and Stage 4 NED. Some wording refers to Stage III – but this is not for and not studied in Stage III A as far as I can ascertain.
Comparators	*Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as 'best alternative care'?*	Need to include single agent nivolumab, pembrolizumab and ipilimumab (latter is not used generally in UK as adjuvant treatment on its own). Can be compared to Dabrafenib and Trametinib in BRAF mutated MM.
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*	No issues.

Section	*Notes*	Your comments
	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 appraisal are welcome.*	Need to look at toxicities as we know that combination therapy increase the rate of toxicity significantly and therefore this needs to be taken into account. I note the dose of ipilimumab is reduced to 1mg/kg from the standard 3mg/kg which may help. Cost of looking after long-term toxicities may need to be considered.
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 Committee to take account of these benefits.*	Yes.
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 N/A		

Comment 3: provisional stakeholder list of consultees and commentators

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

As NICE is committed to promoting equality and eliminating unlawful discrimination Please let us know if we have missed any important organisations from the lists contained within the stakeholder list, and which organisations we should include that have a particular focus on relevant equality issues.

If you do not have any comments to make on the provisional stakeholder list of consultees and commentators, please cross this box: ☒

Comments on the provisional stakeholder list of consultees and commentators

Comment 4: regulatory issues (to be completed by the company that markets the technology)

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:	
	Which regulatory process are you following?	
	What is the target date (mm/yyyy) for regulatory submission?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)	
	What is the anticipated date (mm/yyyy) of regulatory approval?	
	What is the anticipated date (mm/yyyy) of UK launch?	

Section	*Notes*	Your comments
	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*	
Cancer Drugs Fund	*Please indicate whether this technology is likely to be a Cancer Drugs Fund candidate?*	

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