

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Single Technology Appraisal**

**Ipilimumab for previously treated unresectable malignant melanoma**

**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 in collaboration with the UK Melanoma Study Group and the NCRI Melanoma Clinical Studies Group**

**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**

<b>Section</b>	<b>Notes</b>	<b>Your comments</b>
Background information	<i>Consider the accuracy and completeness of this information.</i>	We suggest including an additional sentence such as: <del>No</del> licensed systemic therapy currently available as standard care for advanced disease has been shown to impact on overall survival.+
The technology/ intervention	<i>Is the description of the technology or technologies accurate?</i>	In contrast to some of the new biologicals, the duration of treatment with ipilimumab is defined: this may be helpful when considering cost implications. Perhaps this should be mentioned in the technology

Section	Notes	Your comments
		<p>section.</p> <p>Treatment is delivered as an induction period of 4 intravenous infusions (1.5hrs every 3 weeks) over 12 weeks, before an assessment of response after an interval of 12 weeks. Only in patients who have responded at this time point is it appropriate to offer a further block of maintenance treatment comprising 4 x 3 weekly infusions.</p>
Population	<i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>	<p>Appropriate population, but limited to ECOG/WHO performance status 0 or 1.</p> <p>No subgroups.</p>
Comparators	<i>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'?</i>	<p>Perhaps treatment with dacarbazine as a single agent should be added to best supportive care as a standard comparator.</p>
Outcomes	<i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>	<p>Yes . please assess median overall survival and improvement in 1 and 2 year overall survival</p>
Economic analysis	<i>Comments on aspects such as the appropriate time horizon.</i>	<p>This is appropriate.</p>
Equality	<i>Suggestions for factors which may help promote equality and eliminate unlawful discrimination. These may include issues with the intended use of the technology (including factors relating to assessment, delivery and follow up) amongst e.g. people of different race, disability, religion and sexual orientation.</i>	<p>We are not aware of any equality issues.</p>
Other considerations	<i>Suggestions for additional issues to be covered by the proposed appraisal are welcome.</i>	<p>Toxicity can be significant for a small proportion of patients, warranting in-patient admission and supportive therapies including steroid treatment and, rarely, anti-TNF therapy. These cost implications should be considered in the economic modelling.</p>
Questions for consultation	<i>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</i>	<p>Yes. This is the first systemic therapy that has been shown to offer a survival benefit in advanced melanoma in a well-conducted randomised trial. It therefore contributes significantly to a hitherto global unmet need in melanoma patient care.</p> <p>References: Hodi FS et al, NEJM 2010; 363:711-23</p>

Section	Notes	Your comments
	<p>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.</p>	<p>Day SJ et al, Ann Oncol 2010;21:1712-7</p>
	<p>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).</p>	
<p>Any additional comments on the draft scope            None.</p>		

**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.

As NICE is committed to promoting equality and eliminating unlawful discrimination we are keen to know if we have missed any important organisations from the lists contained within the matrix and which organisations we should include who have a particular focus on relevant equality issues.

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

<p>Comments on the provisional matrix of consultees and commentators</p>
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**Comment 3: regulatory issues (for manufacturers to complete)**

Section	Notes	Your comments
Remit	<i>Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.</i>	
Current or proposed marketing authorisation	<i>What are the current indications for the technology?</i>	
	<i>What are the planned indications for the technology?</i>	
	<i>FOR EACH PLANNED INDICATION:</i>	
	<i>What is the target date (mm/yyyy) for regulatory submission?</i>	
	<i>Which regulatory process are you following?</i>	
	<i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?</i>	
	<i>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.</i>	
Economic model software	<i>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</i>	

Section	Notes	Your comments
	<i>non-standard software</i>	

Please return this form, preferably by e-mail, to [TACommA@nice.org.uk](mailto:TACommA@nice.org.uk) by **5pm on Tuesday 22<sup>nd</sup> March 2011**