

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Single Technology Appraisal**

**Cemiplimab for treating cutaneous squamous cell carcinoma ID1367**

**Consultee and commentator comment form**

Please use this form for submitting your comments on the draft remit, 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 Dermatology**

**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 **Thursday 29 March 2018**. If using NICE Docs is not possible please return via email to [scopingta@nice.org.uk](mailto: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.

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**Comment 1: the draft remit**

<b>Section</b>	<b>Notes</b>	<b>Your comments</b>
Wording	<i>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.</i>	Yes
Timing Issues	<i>What is the relative urgency of this appraisal to the NHS?</i>	This is a potentially effective new treatment for metastatic cutaneous squamous cell carcinoma where there is currently no consensus on treatment – therefore this should be considered relatively urgently

Section	Notes	Your comments
Any additional comments on the draft remit		
<p>The information on this treatment is limited to an initial Phase 1 trial of 26 patients (Kyriakos et al ascopbs.org from the 2018 annual meeting, Abstract 195) of which 3 patients at the time of the presentation were not evaluable and median PFS and OS had not been reached but it was well tolerated and only one patient had experienced PD after initial response although follow up time was short. However there is no good alternative to treatment and these initial results look promising. A phase II study is underway.</p>		

**Comment 2: the draft scope**

Section	Notes	Your comments
Background information	<i>Consider the accuracy and completeness of this information.</i>	It is accurate. It does not discuss other treatments previously used including Gefitinib, Cetuximab (EGFR inhibitors), other antiPD1 agents such as Pembrolizumab, Nivolumab (case series/case report), cisplatin as this is not a head to head trial as there is no current recommended treatment.
The technology/ intervention	<i>Is the description of the technology or technologies accurate?</i>	Yes
Population	<i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>	Yes the population is defined correctly
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>	There is no established standard care for unresectable locally advanced or metastatic cutaneous squamous cell carcinoma however other treatment options are available.
Outcomes	<i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>	Yes
Economic analysis	<i>Comments on aspects such as the appropriate time horizon.</i>	No additional comments
Equality	<p><i>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:</i></p> <ul style="list-style-type: none"> <li>• <i>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;</i></li> <li>• <i>could lead to recommendations</i></li> </ul>	No foreseeable issues

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.

Section	Notes	Your comments
	<p><i>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;</i></p> <ul style="list-style-type: none"> <li><i>• could have any adverse impact on people with a particular disability or disabilities.</i></li> </ul> <p><i>Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.</i></p>	
Other considerations	<p><i>Suggestions for additional issues to be covered by the appraisal are welcome.</i></p>	
Innovation	<p><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 condition)?</i></p> <p><i>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?</i></p> <p><i>Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.</i></p>	Yes
Questions for consultation	<p><i>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).</i></p>	
Any additional comments on the draft scope		

### Comment 3: provisional matrix of consultees and commentators

The provisional matrix 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

matrix, 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 matrix of consultees and commentators, please cross this box:

Comments on the provisional matrix of consultees and commentators

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

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>	
	<b>FOR EACH PLANNED INDICATION:</b>	
	<i>Which regulatory process are you following?</i>	
	<i>What is the target date (mm/yyyy) for regulatory submission?</i>	
	<i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)</i>	
	<i>What is the anticipated date (mm/yyyy) of regulatory approval?</i>	
	<i>What is the anticipated date (mm/yyyy) of UK launch?</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>	

Section	Notes	Your comments
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 non-standard software</i>	
Cancer Drugs Fund	<i>Please indicate whether this technology is likely to be a Cancer Drugs Fund candidate?</i>	

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