NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Single Technology Appraisal

Vorinostat for the second line treatment of cutaneous T-cell lymphoma

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 Dermatologists

Comments on the draft remit and draft scope

The draft remit is the brief for a proposed appraisal, given to the Institute by the Department of Health. Appendix B contains the draft remit. The draft scope, developed from the draft remit outlines the question that the proposed appraisal would 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 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 remit and draft scope, please state this in the box below.

Comment 1: the draft remit

Section	*Notes*	Your comments
Appropriateness	*It is important that appropriate topics are referred to NICE to ensure that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would it be appropriate to refer this topic to NICE for appraisal?*	yes

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 proposed appraisal to the NHS? Is the suggested timing for submission of evidence (see cover letter) appropriate?*	Appropriate
Any additional comments on the draft remit		

Comment 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	paragraph 3, last sentence, suggest " Low-grade lymphomas are currently incurable at advanced stages, and advanced stages of CTCL (IIB-IV) have a median survival of 4.0 years and 1.5 years respectively compared to 12.9 years for early stage disease (IB-IIA)." paragraph 4, suggest "Current management of early stage disease is based on skin directed therapies such as phototherapy and radiotherapy while there is no standard of care for advanced, relapsed or refractory CTCL. Therapeutic options for advanced stage disease consist of the following, used either alone or in combination: electron beam therapy (a radiotherapy that does not penetrate the skin and is applied to the whole skin surface); chemotherapy; bexarotene and interferon alpha. Responses are invariably short-lived which means that patients often have multiple sequential treatments and/or remain on maintenance therapy with palliative intent."
The technology/ intervention	*Is the description of the technology or technologies accurate?*	paragraph 2, sentence 2, suggest " It has been studied in clinical trials for the treatment of advanced, relapsed or refractory CTCL in patients who have previously been treated with at least two systemic medications."

Section	*Notes*	Your comments
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Yes No
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'?*	There is no current standard of care. Please note: chemotherapy agents listed are unlicensed. Alemtuzumab is unlicensed. Bexarotene and interferon alpha are licensed
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	*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.*	
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	
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).*	There is no current standard of care in this group of patients No specific sub-groups STA most suitable
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 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: ☒

Comments on the provisional matrix of consultees and commentators

Comment 4: 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?	
	Which regulatory process are you following?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?	

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.	

Please return this form, preferably by e-mail, to **scopingta@nice.org.uk** by **5 September 2008.**

Where email is not possible, please copy this completed form onto a CD-ROM and send to: Jenniffer Alty, Project Manager, NICE, Level 1A, City Tower, Piccadilly Plaza, Manchester, M1 4BD to arrive on or before the deadline. Further contact details are (☎ 0161 870 3155, fax 0207 061 9848).