NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Single Technology Appraisal

Belimumab for the treatment of active systemic lupus erythematosus

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. 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, we feel it would be appropriate.

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, we feel it does.
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?*	We do not feel that there is an undue urgency for this proposed appraisal. The suggested timing for submission of evidence seems appropriate.
Any additional comments on the draft remit None		

Comment 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	This section appears reasonable.
The technology/ intervention	*Is the description of the technology or technologies accurate?*	It appears to be.
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Perhaps consideration should be given to also including SLE patients who do not have a circulating rheumatoid factor.
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'?*	We feel this is the case. We do not feel that there is an unequivocal 'best drug'.
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	The stated outcome measures appear reasonable.
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	The terms of the economic analysis seem reasonable. An appropriate time horizon may run into years.

Section	*Notes*	Your comments
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.*	We have no comments.
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	We have no comments.
Questions for consultation	*What do you consider to be the relevant clinical outcomes and other potential health related benefits of the technology [X] in the treatment of [Y], particularly when compared with currently used treatment options?* *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.*	We feel the clinical outcomes as stated are reasonable.
	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).	We have no comments.
Any additional comments on the draft scope None.		

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?	
	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.	

Section	*Notes*	Your comments
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*	

Please return this form, preferably by e-mail, to **scopingta@nice.org.uk** by **Wednesday 01 September 2010.**

Where email is not possible, please copy this completed form onto a CD-ROM and send to: Michelle Adhemar, Acting 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 3148, fax 0207 061 9848).