

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed NICE Health Technology Appraisal

Etanercept, infliximab, adalimumab (review) and golimumab for the treatment of psoriatic arthritis

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.

Enter the name of your organisation here: British Association of Dermatologists

Comments on the draft scope

The draft scope, developed from the draft remit outlines the question that the proposed appraisal would 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

Section	Notes	Your comments
Background information	<i>Consider the accuracy and completeness of this information.</i>	Adequate
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 and No

Section	Notes	Your comments
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>	Yes
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>	None
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>	None
Other considerations	<i>Suggestions for additional issues to be covered by the proposed appraisal are welcome.</i>	<p>The important matter which ought now to be considered explicitly is how to incorporate joint AND skin disease into a composite evaluation of %incremental cost per quality-adjusted life year+. This has not been achieved as yet in NICE Guidance and some thought needs to be given as to how it could be. Patients who may just fail the hurdle for eligibility when assessed by either joint or skin disease alone but who may well have more quality of life impairment than many patients with predominant skin or joint disease. This is particularly true when PASI is used for assessment of the skin as this underestimates the psychosocial and functional disability from acral, facial or flexural disease. It may not be easy to come up with a satisfactory formula. Nevertheless we shall be failing patients if we do not address this matter.</p>
Questions for consultation	<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>	Answer to both questions at the end of appendix A: No

Section	Notes	Your comments
Any additional comments on the draft scope		

Comment 2: provisional matrix of consultees and commentators

The provisional matrix of consultees and commentators 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

Comments on the provisional matrix of consultees and commentators

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>	
	FOR EACH PLANNED INDICATION:	
	<i>What is the target date (mm/yyyy) for regulatory submission?</i>	
	<i>Which regulatory process are you following?</i>	

Section	Notes	Your comments
	<p><i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?</i></p>	
	<p><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></p>	

Please return this form, preferably by e-mail, to bijal.chandarana@nice.org.uk by **24th April 2009 – 5pm.**