

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Single Technology Appraisal

Tocilizumab for treating systemic sclerosis ID1396

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.

Please complete this form and upload it to NICE Docs by **Wednesday 13 June 2018**. If using NICE docs is not possible please return via email to scopingta@nice.org.uk. If you have any questions please contact Michelle Adhemar, Scoping Project Manager, michelle.adhemar@nice.org.uk 020 7045 2239

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	<i>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?</i>	This topic is considered appropriate as there are currently no approved disease modifying treatments in systemic sclerosis (SSc), a condition with significant morbidity and mortality risk. A clinically important improvement in skin and pulmonary disease in SSc patients has been demonstrated with tocilizumab in clinical trials
Wording	<i>Does the wording of the remit reflect the issue(s) of clinical and</i>	The wording is appropriate

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Section	Notes	Your comments
	<i>cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.</i>	
Timing Issues	<i>What is the relative urgency of this proposed appraisal to the NHS?</i>	There are no currently approved disease modifying agents for SSc, a disease associated with significant morbidity and mortality. Tocilizumab has been shown to have a clinically important improvements in pulmonary and cutaneous aspects of disease
Any additional comments on the draft remit		

Comment 2: the draft scope

Section	Notes	Your comments
Background information	<i>Consider the accuracy and completeness of this information.</i>	The background is accurate and complete
The technology/ intervention	<i>Is the description of the technology or technologies accurate?</i>	The description of the technology is accurate
Population	<i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>	The population defined is appropriate (adult patients with SSc). The Phase II and III clinical trials only included patients with active disease within 5 years of onset. It should be clarified what inclusion criteria are proposed (eg disease duration, limited versus diffuse disease)
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>	Listed comparators are appropriate. This can be described as best alternative care
Outcomes	<i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>	Outcomes are appropriate and include physician and patient completed scores
Economic analysis	<i>Comments on aspects such as the appropriate time horizon.</i>	In the FaSScinate study clinically relevant improvements in cutaneous and pulmonary involvement were seen at week 48 with further improvement at week 96. The time point taken to assess effectiveness should reflect this.
Equality	<i>NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics</i>	No additional comments

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Section	Notes	Your comments
	<p><i>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"> <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> <i>• could lead to recommendations 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> <i>• could have any adverse impact on people with a particular disability or disabilities.</i> <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 proposed appraisal are welcome.</i></p>	No additional comments
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>	<p>There are limited treatment options for patients with SSc and no approved disease-modifying therapies. Tocilizumab has demonstrated clinically relevant improvements in cutaneous, pulmonary and functional aspects of disease in patients with severe progressive disease.</p> <p>Some current "best alternative care" options such as cyclophosphamide and stem cell transplantation are associated with significant toxicity.</p>
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>	

Section	Notes	Your comments
	<p>Any additional comments on the draft scope</p> <p>Is the aim of treatment to relieve symptoms of secondary problems caused by systemic sclerosis or to control skin thickening?</p> <p>The aim of treatment is to control (+/- improve) skin thickening with a resultant improvement in secondary problems (contractures, ulceration, impaired mobility). Tocilizumab has also been shown to improve pulmonary function. Progressive skin and pulmonary disease are predictors of mortality in SSc.</p> <p>Is the modified Rodnan Skin Score (mRSS) a suitable surrogate outcome measure for disease severity and mortality in patients with systemic sclerosis?</p> <p>Yes the mRSS is a validated measure of disease severity, progression and prognosis.</p>	

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 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:

<p>Comments on the provisional matrix of consultees and commentators</p>
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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>	
	FOR EACH PLANNED INDICATION:	
	<i>Which regulatory process are you following?</i>	

Section	Notes	Your comments
	<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>	
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>	

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