

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Single Technology Appraisal

Apremilast for treating moderate to severe plaque psoriasis ID679

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	<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>	
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>	
Timing Issues	<i>What is the relative urgency of this proposed appraisal to the NHS?</i>	

Section	Notes	Your comments
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>	<p>Page 1, bottom paragraph:</p> <p>It is important that there is reference to the NICE guideline CG153 here, which clearly sets out the pathway of care for people with psoriasis. Importantly, PUVA is no longer 'routinely offered' and there are many circumstances where this is not really appropriate to consider. This impacts potentially on HE modelling - i.e. perhaps even a majority of people with moderate to severe psoriasis will be considered 'not suitable for PUVA' (recommendations state other interventions should be actively considered, including biologics). We no longer recommend hydroxycarbamide. Combined oral and phototherapy is advised in only rare instances.</p>
The technology/ intervention	<i>Is the description of the technology or technologies accurate?</i>	
Population	<i>Is the population defined appropriately? Are there groups within this population that should be considered separately?</i>	
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>	<p>Page 2, acitretin:</p> <p>See NICE guidelines CG153 - the evidence base for this intervention is very limited and is only recommended for pustular forms of psoriasis and in chronic plaque psoriasis where ciclosporin/methotrexate failed or can't be used. It should not be used in women of childbearing age.</p> <p>Page 2, PUVA:</p> <p>For reasons stated above PUVA should not be included as a comparator.</p> <p>Page 2, "for people with severe psoriasis":</p> <p>Is this defined by PASI 10? Referencing the NICE guideline CG153 could consideration be given to including the definition used for people with psoriasis should be considered for systemic therapy?</p> <ul style="list-style-type: none"> • Offer systemic non-biological therapy

Section	Notes	Your comments
		<p>to people with any type of psoriasis if:</p> <ul style="list-style-type: none"> o it cannot be controlled with topical therapy and o it has a significant impact on physical, psychological or social wellbeing and o one or more of the following apply: <ul style="list-style-type: none"> <input type="checkbox"/> psoriasis is extensive (for example, more than 10% of body surface area affected or a Psoriasis Area and Severity Index (PASI) score of more than 10) or <input type="checkbox"/> psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example severe nail disease or involvement at high-impact sites) or <input type="checkbox"/> phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months). <p>Page 2, "has been inadequately effective": How is this being defined - PASI 75? Clear/nearly clear?</p>
Outcomes	<i>Will these outcome measures capture the most important health related benefits (and harms) of the technology?</i>	Page 2, "health-related quality of life": Psoriatic arthritis - can this be included? Nail disease?
Economic analysis	<i>Comments on aspects such as the appropriate time horizon.</i>	
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"> • <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</i> 	

Section	Notes	Your comments
	<p><i>disabilities.</i></p> <p><i>Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.</i></p>	
<p>Other considerations</p>	<p><i>Suggestions for additional issues to be covered by the proposed appraisal are welcome.</i></p>	
<p>Innovation</p>	<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>Questions for consultation</p>	<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>	
<p>Any additional comments on the draft scope</p> <p>Have all relevant comparators for apremilast been included in the scope? Yes - but would suggest that PUVA is removed - as per NICE guidelines and also clinical practice.</p> <p>Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis? As mentioned above, please see the NICE guidelines CG153 for the pathway of care for psoriasis. As indicated in this, there is a huge unmet need for moderate to severe psoriasis. It would be appropriate to consider use of apremilast in the context of the NICE recommended indication for non-biological systemic therapy, i.e.:</p> <ul style="list-style-type: none"> • Offer systemic non-biological therapy to people with any type of psoriasis if: <ul style="list-style-type: none"> o it cannot be controlled with topical therapy and o it has a significant impact on physical, psychological or social wellbeing and o one or more of the following apply: <ul style="list-style-type: none"> • psoriasis is extensive (for example, more than 10% of body surface area affected or a Psoriasis Area and Severity Index (PASI) score of more than 10) or • psoriasis is localised and associated with significant functional impairment and/or high 		

Section	Notes	Your comments
	<p>levels of distress (for example severe nail disease or involvement at high-impact sites) or</p> <ul style="list-style-type: none"> • phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months). <p>Is apremilast likely to only be used after failure of a systemic therapy, or could it be used earlier in the treatment pathway? Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately? Where do you consider apremilast will fit into the existing NICE pathway for psoriasis? Assuming the definition of 'systemic therapy' includes biologic therapy it is unlikely that aprelimast would be used before biologic therapy unless contraindication. However, there is a huge 'unmet need' in what is sometimes termed "moderate to severe" psoriasis (encompassed in the bullet points above - i.e. psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example, severe nail disease or involvement at high-impact sites) or phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months). In these patients, aprelimast would be used before biologic therapy (i.e. PASI<10); however, use of aprelimast in these categories would probably still come after failure of standard non-biologic systemic therapy (i.e. methotrexate, and as per indications in NICE guidelines, ciclosporin) given that it is a new drug/limited longer-term safety data.</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

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	<i>What are the current indications for the technology?</i>	

Section	Notes	Your comments
marketing authorisation	<i>What are the planned indications for the technology?</i>	
	<i>FOR EACH PLANNED INDICATION:</i>	
	<i>What is the target date (mm/yyyy) for regulatory submission?</i>	
	<i>Which regulatory process are you following?</i>	
	<i>What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?</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>	

Please return this form, preferably by e-mail, to scopingta@nice.org.uk by **Tuesday 10 December 2013**.

Where email is not possible, please copy this completed form onto a CD-ROM and send to: Michelle Adhemar, Project Manager, NICE, 10 Spring Gardens, London, SW1A 2BU United Kingdom to arrive on or before the deadline. Further contact details are phone: 44 (0)20 7045 2239 fax: 44 (0)20 7061 9732