NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Single Technology Appraisal

Dimethyl fumarate for treating moderate to severe plaque psoriasis [ID776]

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 **Friday 26 February 2016**. 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, Project Manager on 44 (0)20 7045 2239 or at the email address above.

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. Even though the drug is routinely used in the UK in many departments, it is relatively high cost and there is probably not equal access to it.
Wording	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that*	Yes

Section	*Notes*	Your comments
	NICE should consider? If not, please suggest alternative wording.	
Timing Issues	*What is the relative urgency of this proposed appraisal to the NHS?*	Average Urgency
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.*	No comments
The technology/ intervention	*Is the description of the technology or technologies accurate?*	Yes
Population	*Is the population defined appropriately? Are there groups within this population that should be considered separately?*	Consider also children and those with psoriatic arthritis.
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'?*	Inpatient admission and bed rest is the universal standard of care in this patient group. Yes all relevant comparators have been considered. • Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis? The established treatments for moderate to severe psoriasis are: Phototherapy including UVA and a psoralen (PUVA) Standard Systemic agents such as; Methotrexate, ciclopsorin, acitretin Biological Agents; Enbrel, Humira, Stelara, Cosentyx.I have used their commercial names now to differentiate them for the biosimilars Biosimilar Agents Please note efalizumab (not "efalixumab") has now been withdrawn due to its association with progressive multifocal leukoencephalopathy.

Section	*Notes*	Your comments
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	This is debatable but they are in line with the other measures used.
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	None
Equality	*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:* • *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;* • *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;* • *could have any adverse impact on people with a particular disability or disabilities.* *Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.*	Check on the data for children and those sub-groups with psoriatic arthritis as well as psoriasis.
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	Children and young people would benefit from access to this drug. It is currently used in some centres to treat this age group
Innovation	*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)?* *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?* *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.*	No. It is not a step-change. These drugs are currently used though and are effective. It is currently, regularly in use in most Dermatology departments in the U.K. It is used for both adults and children. It provides another oral agent option in contrast to subcutaneous or intravenous therapies.

Section	*Notes*	Your comments
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).*	• Would infliximab be used as a treatment for the patient population for whom dimethyl fumarate would be a treatment option? No, dimethyl fumarate is likely to be used before biological therapies in the treatment of psoriasis. Infliximab is used for those with very severe psoriasis defined as a DLQI >18 and a PASI ≥20 or in those not responsive to any other treatment modality. • 'How should best supportive care be defined?' Inpatient admission to hospital for bed rest and topical therapies. • Are there any subgroups of people in whom dimethyl fumarate (LAS41008) is expected to be more clinically effective and cost effective or other groups that should be examined separately? Children and young people. It is not clear whether it has a place for those people with psoriatic arthritis. • Where do you consider dimethyl fumarate (LAS41008) will fit into the existing NICE pathway, Psoriasis? It would be an option in line with standard systemic agents and before biological therapies. • Do you consider that the use of dimethyl fumarate (LAS41008) can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? No
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 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: ☒

Comments on the provisional matrix of consultees and commentators

Comment 4: regulatory issues (to be completed by the company that holds the markets the technology)

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:	
	Which regulatory process are you following?	
	What is the target date (mm/yyyy) for regulatory submission?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)	
	What is the anticipated date (mm/yyyy) of regulatory approval?	
	What is the anticipated date (mm/yyyy) of UK launch?	
	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*	

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