NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Single Technology Appraisal

Risankizumab for treating chronic moderate to severe plaque psoriasis ID1398

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 **Tuesday 26 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, 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
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?*	Should be assessed as soon as possible
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 issue
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?*	The population is appropriate; no sub-population requires separate consideration
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'?*	As indicated in NICE guideline CG153, ciclosporin should only be used for a maximum of 1 year. Therefore, it is only ever a relatively 'short-term' option. Psoriasis is a long-term condition and no treatments are 'curative' so far. Thus, in any economic modelling, inclusion of ciclosporin is problematic. It is appropriate not to include PUVA (i.e. phototherapy with psoralen); whilst effective, it is no longer used routinely in people with psoriasis due to its propensity to cause skin cancer, particularly when followed by immunosuppression. In NICE guideline CG153 certain groups are specified as 'DO NOT USE" populations; when considering PUVA this should only be when other options – including biologic therapies – have been offered and can't be used or are inappropriate. Established clinical practice is very much in line with CG153, i.e. topicals for limited psoriasis only (not in the population being considered). Phototherapy (specifically UVB), and then systemic (non-biologic) therapy, particularly methotrexate. Where psoriatic arthritis is present, methotrexate may be used before phototherapy. Acitretin is not

Section	*Notes*	Your comments
		considered cost-effective for patients who meet NICE criteria for biologic therapy and has limited utility due to poor tolerability and teratogenicity (a risk that persists for 3 years following treatment cessation). Methotrexate is often contraindicated or is poorly tolerated due to abnormal LFTs. The population of patients with moderate disease (i.e. PASI<10) may still have significant disease with major impact (DLQI>10) and treatment options for this group are profoundly limited if methotrexate is ineffective or not tolerated, and ciclosporin cannot be used long-term. Treatments used include acitretin, fumaric acid esters/dimethyl fumarate, apremilast, biologic drugs (but only if funded under IFR route).
Outcomes	*Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	Additional outcomes that should be considered includes: 1. Other high-impact and difficult-to-treat sites: ☐Palms ☐Soles ☐Flexures ☐Genitals 2. Injection site reactions 3. Mood
Economic analysis	*Comments on aspects such as the appropriate time horizon.*	
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;*	Please note, the erythema component of psoriasis (captured as part of the PASI) may be underestimated in darker skins. Thus PASI may not be representative in brown and black skin. The DLQI may not adequately capture impact in older people (question about work, studying, sport) or those who are not in a relationship (question about sexual activity). It also is known to capture anxiety and depression poorly across all groups (two parameters that are commonly negatively influenced by psoriasis)

Section	*Notes*	Your comments
	• *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.*	
Other considerations	*Suggestions for additional issues to be covered by the proposed appraisal are welcome.*	
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.*	The p19 inhibitors are considered to be a 'step change' in terms of mechanism of action, specificity, effectiveness (particularly clearance which is very important to patients) and prolonged action. Indirect comparison of phase III studies suggest that risankizumab may be marginally better than guselkumab (PASI 90/100 rates)
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).*	
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 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.	
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*	

Section	*Notes*	Your comments
	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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