

National Institute for Health and Clinical Excellence

Ustekinumab for the treatment of moderate to severe psoriasis

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	British Association of Dermatologists	Appropriate.	Comment noted.
	Dorset PCT	This is an appropriate area for NICE to consider as psoriasis is a relatively common chronic condition.	Comment noted.
	Janssen-Cilag Ltd	We believe that this is an appropriate topic to refer to NICE for appraisal.	Comment noted.
	Merck Serono	We feel that this is an appropriate topic for NICE.	Comment noted.
	The Psoriasis Association	There are previous appraisals on biologic drugs for the treatment of moderate to severe psoriasis and it is entirely appropriate that new drugs in this class are also considered.	Comment noted.
	Wyeth	Given the nature of the technology it seems appropriate for NICE to appraise it.	Comment noted.
Wording	British Association of Dermatologists	Agree.	Comment noted.
	Dorset PCT	Agree.	Comment noted.
	Janssen-Cilag Ltd	The wording reflects the issues of clinical and cost effectiveness relating to ustekinumab.	Comment noted.
	Merck Serono	Agree.	Comment noted.
	The Psoriasis Association	Agree.	Comment noted.
	Wyeth	The wording reflects the decision question.	Comment noted.

Section	Consultees	Comments	Action
Timing Issues	British Association of Dermatologists	Agree.	Comment noted.
	Dorset PCT	Not urgent.	Comment noted.
	Janssen-Cilag Ltd	The suggested timing for submission of evidence is appropriate.	Comment noted.
	Merck Serono	Psoriasis is an important chronic condition where there is a current series of potential treatments. There may still be some unmet need due to intolerance therefore we feel that ustekinumab should be evaluated as per standard timelines for Single Technology Appraisals (STAs).	Comment noted.
	The Psoriasis Association	This depends on the timing of the marketing authorisation.	Comment noted.
	Wyeth	The relative urgency of the proposed appraisal is low, as already four biologic treatments are available and recommended for plaque psoriasis.	Comment noted.
Additional comments on the draft remit	British Association of Dermatologists	None.	Comment noted.
	Dorset PCT	None.	Comment noted.
	Janssen-Cilag Ltd	None.	Comment noted.
	Merck Serono	None.	Comment noted.
	The Psoriasis Association	None.	Comment noted.
	Wyeth	None.	Comment noted.

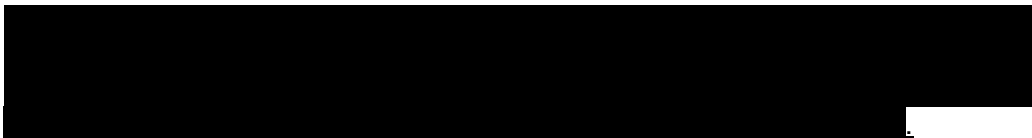

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	British Association of Dermatologists	Adequate.	Comment noted.
	Dorset PCT	Clear summary of main points.	Comment noted.
	Janssen-Cilag Ltd	<p>In order to capture the pathway of the condition and its treatment, we recommend including the following paragraph:</p> <p>'There is no cure for psoriasis, but there is a wide range of topical and systemic treatments that can potentially manage the condition. Most treatments, however, only reduce severity rather than prevent episodes, and psoriasis therefore has to be treated continuously and on a long-term basis'.</p> <p>In addition, there is evidence to suggest that psoriasis severity has a negative impact on patients ability to work (Hong et al, 2008; Horn et al, 2007), therefore we recommend including a paragraph that acknowledges this.</p> <p>References</p> <p>Hong et al. The psychosocial and occupational impact of chronic skin disease. <i>Dermatol Ther.</i> 2008 Jan-Feb;21(1):54-9</p> <p>Horn et al. Association of patient-reported psoriasis severity with income and employment. <i>J Am Acad Dermatol.</i> 2007 Dec;57(6):963-71</p>	<p>This paragraph already appears in the draft scope.</p> <p>A paragraph has been included to reflect this.</p>

Summary form

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	Merck Serono	<p>As per the 'Adalimumab for the treatment of psoriasis' scope, the following statement should be considered as an addition to the background information within the current scope:</p> <p>'A UK study of people with severe psoriasis found that 60% had taken time off work in the previous year as a direct result of their condition. People with severe disease may require a number of hospitalisations each year; the average length of a hospital stay is around 20 days.'</p>	The sentence about time off work has not been included in the scope, as NICE considers costs from an NHS and Personal Social Services perspective (not a societal perspective). The following sentence has been included in the scope 'People with severe disease may require a number of hospitalisations each year; the average number of hospital inpatient days per year is around 20 days'.
	The Psoriasis Association	Correct.	Comment noted.
The technology/ intervention	British Association of Dermatologists	Agree.	Comment noted.
	Dorset PCT	Agree.	Comment noted.
	Janssen-Cilag Ltd	Agree.	Comment noted.
	Merck Serono	To the best of our knowledge.	Comment noted.
	The Psoriasis Association	Cannot comment.	Comment noted.
Population	British Association of Dermatologists	Yes, no specific sub-groups need to be considered.	Comment noted.
	Dorset PCT	Agree.	Comment noted.

Summary form

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	Janssen-Cilag Ltd		The population has been amended following consultation.
	Merck Serono	Agree Not to our knowledge.	Comment noted
	The Psoriasis Association	Agree.	Comment noted
	Wyeth	The appropriate population will be defined by the marketing authorisation obtained.	Comment noted
Comparators	British Association of Dermatologists	Hydroxycarbamide is not licensed for treatment of psoriasis and is therefore not an ideal comparator. The same applies to PUVA which should probably be replaced by TLO1 phototherapy better reflecting current practice.	The comparators have been amended following consultation.
	Dorset PCT	Yes these are used in the NHS. No one treatment is the best alternative care. Some treatments are currently reserved for patients with severe disease unresponsive to first-line standard treatments and depending on licensed indication it may be appropriate to compare to these agents or to first-line standard treatments.	Comment noted.
	Janssen-Cilag Ltd		The comparators have been amended following consultation.

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	Merck Serono	<p>Yes.</p> <p>We feel that within biologicals, T-cell modulator and cytokine inhibitor products should be differentiated by their respective mode of actions. It could be argued that cytokine inhibitors should include TNF alpha inhibitors as well as interleukin inhibitors such as ustekinumab. The mode of action may have an influence on the maintenance of response rate in the long-term and the time it takes to achieve maximal response.</p> <p>In previous TAs for the use of biologicals in the treatment of psoriasis, best supportive care is used as the best alternative as patients under the remit of these guidances have already been treated with a number of systemic therapies.</p> <p>When considering the comparators, the use of infliximab in patients with a PASI \geq 20 and DLQI > 18 only and the definition of intermittent etanercept therapy should be taken into account.</p> <p>TA103/ TA134 is to be reviewed in mid 2008. Any assumptions used in this review should be taken into account in the STA process for ustekinumab.</p>	<p>The comparators have been amended following consultation.</p> <p>Comment noted.</p> <p>Comment noted.</p> <p>Comment noted.</p>
	The Psoriasis Association	Agree.	Comment noted.
	Wyeth		
	Outcomes	British Association of Dermatologists	Agree.
	Dorset PCT	Severity of psoriasis should be measured objectively using a validated score such as PASI.	Comment noted.
	Janssen-Cilag Ltd	Agree.	Comment noted.
	Merck Serono	Agree.	Comment noted.

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	The Psoriasis Association	Agree.	Comment noted.
Economic analysis	British Association of Dermatologists	None.	Comment noted.
	Dorset PCT	Appropriate time horizon difficult to ascertain because of natural fluctuations expected in disease severity over time without treatment.	Comment noted.
	Janssen-Cilag Ltd	None.	Comment noted.
	Merck Serono	A time horizon of 10 years may well reflect the chronic nature of psoriasis as has been used in the previous TAs for the use of biologicals in the treatment of psoriasis	Comment noted.
Equality	British Association of Dermatologists	None.	Comment noted.
	Dorset PCT	Nothing specific to my knowledge.	Comment noted.
	Janssen-Cilag Ltd	None.	Comment noted.
	Merck Serono	We have no comments.	Comment noted.
Other considerations	British Association of Dermatologists	None.	Comment noted.
	Dorset PCT	Sequencing of agents.	The scope states that 'where the evidence allows, sequencing of different drugs and the place of ustekinumab in such a sequence will be considered'.

Summary form

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	Janssen-Cilag Ltd	None.	Comment noted.
	Merck Serono	We feel that T-cell modulator and cytokine inhibitor products should be differentiated by their respective mode of actions. It could be argued that cytokine inhibitors should include TNF alpha inhibitors as well as interleukin inhibitors such as ustekinumab. The mode of action may have an influence on the maintenance of response rate in the long-term and the time it takes to achieve maximal response.	Comment noted.
Questions for consultation	British Association of Dermatologists	Covered above.	Comment noted.
	Dorset PCT	STA process appropriate. May be helpful in due course to have clinical guideline on psoriasis.	Comment noted.
	Janssen-Cilag Ltd	Ustekinumab is a novel treatment with a new mechanism of action and it is appropriate for it to be reviewed under the single technology appraisal process. This will minimise the delay in access of patients to a new treatment option for this devastating condition.	Comment noted.
	Merck Serono	Only one question posed which is not covered in our previous comments: Which process would be most suitable for appraisal for appraising this technology, the single or multiple technology process? The STA process would be most appropriate for ustekinumab. This should taken into account any assumptions used in the review of TA103/ TA134.	Comments noted.
	The Psoriasis Association	It is difficult to comment on whether this should be an STA or multiple TA. Both have been used for other biologic drugs for psoriasis. What is needed for patients is clarity about all available biologic drugs.	Comment noted.

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	Wyeth	<p>Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately? - The appraisal should take special consideration of overweight patients (>90kg), patients with moderate psoriasis, and such with very severe (PASI 20 and DLQI 18) psoriasis.</p> <p>Which process would be the most suitable for appraising this technology, the single technology or multiple technology process? The technology should be evaluated in the context of the planned MTA of adalimumab, efalizumab, etanercept, and infliximab.</p>	<p>The scope now states that, if the evidence allows, consideration will be given to the subgroup of people with very severe psoriasis.</p> <p>Comment noted.</p>
Additional comments on the draft scope.	Janssen-Cilag Ltd	None.	Comment noted.
	Merck Serono	None.	Comment noted.

Comment 4: Regulatory issues

Section	Consultees	Comments	Action
Remit	Janssen-Cilag Ltd	Yes, appropriate.	Comment noted.
Current or proposed marketing authorisation	Janssen-Cilag Ltd	<p>The following information is commercial in confidence:</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>All of the information provided above is not in the public domain and should therefore be treated as commercial in confidence. This can be released when marketing authorisation is obtained</p>	Comments noted.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

NHS QIS
 Royal College of Nursing
 Royal Pharmaceutical Society
 Welsh Assembly Government