

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

**Review of TA 103 (part): Etanercept for the treatment of adults with psoriasis; TA 134: Infliximab for the treatment of psoriasis; TA 146: Adalimumab for the treatment of psoriasis and TA 180: Ustekinumab for the treatment of adults with moderate to severe psoriasis**

The review date for this guidance is “early 2010” (TAs 103, 134, 146); January 2010 (TA180).

Background

At the GE meeting on 13<sup>th</sup> July 2010 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	<ul style="list-style-type: none"><li>• The appraisals should be moved to the static list.</li><li>• The appraisals should be incorporated, verbatim, within the ongoing clinical guideline on the <i>diagnosis and management of psoriasis in young people and adults</i>.</li><li>• We highlight that this proposal will have the consequence of preserving the funding direction.</li><li>• That we consult on the proposal.</li></ul>
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GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

<b>Recommendation post consultation:</b>	<ul style="list-style-type: none"><li>• The appraisals should be moved to the static list.</li><li>• The appraisals should be incorporated, verbatim, within the ongoing clinical guideline on the <i>diagnosis and management of psoriasis in young people and adults</i>.</li></ul>
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	<ul style="list-style-type: none"> <li>We highlight that this proposal will have the consequence of preserving the funding direction.</li> </ul>
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Respondent	Response to proposal	Details	Comment from Technology Appraisal
NHS Quality Improvement Scotland	No comment		N/A
Royal College of Nursing	No comment		N/A
Psoriasis and Psoriatic Arthritis Alliance	Agree	<i>“The guideline development may uncover newer prescribing patterns or adverse events and this would then enable wider review and consensus, which might not be the case otherwise”</i>	Agree
Abbott Laboratories Ltd.	Agree		
British Association of Dermatologists	Agree	<p>The BAD made the following points, which would be relevant to the ongoing clinical guideline:</p> <ul style="list-style-type: none"> <li>If there are recommendations within the guideline that contradict the TAs these may need wider consultation to resolve.</li> <li>Areas that it would be useful to include in the guideline include: <ul style="list-style-type: none"> <li>What constitutes a contraindication to PUVA?</li> <li>The continuous administration of etanercept and switching between TNF inhibitors following loss of efficacy.</li> </ul> </li> </ul>	Agree

		<ul style="list-style-type: none"> <li>○ the importance of participation in disease registries (the British Association of Dermatologists Biologic Interventions Register, BADBIR)</li> </ul> <p>The BAD also note that the rapidly evolving nature of biologic therapy means that regular updates of guidance in this area, including opportunities for consultation, would be useful.</p>	
Janssen-Cilag	Agree	<p>Janssen-Cilag have confirmed that the ustekinumab Patient Access Scheme (PAS) will continue to operate, and also point out the following inaccuracies in the proposal paper:</p> <p><u>Formulation change.</u> On pages 1 and 6, reference is made to the ustekinumab vial formulation. This has now been replaced with a pre-filled syringe, which is available at the same dose and price as the original liquid in vial. The access scheme is not affected by this minor change in formulation.</p> <p><u>Psoriatic arthritis.</u> On page 8, the final clinical trial described (PSUMMIT-2, NCT01077362) relates to psoriatic arthritis and not to psoriasis. On page 9, the <i>Studies comparing systemic treatments for moderate to severe psoriasis</i> section appears to refer to the Saad <i>et al</i> publication in the May 2008 Journal of Rheumatology, which also relates to psoriatic arthritis and not to psoriasis;</p>	Agree

		<p><u>On-going clinical trials.</u> The <i>On-going clinical trials</i> section should also list the following ustekinumab studies:</p> <p>The TRANSIT study (NCT01059773), in patients who have had an inadequate response to methotrexate</p> <p>The PHOENIX-1 (NCT00267969) and PHOENIX-2 studies (NCT00307437), both of which continue to collect long-term follow-up data.</p>	
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**No response received from:**

<b>Consultees</b>	<b>Commentators (no right to submit or appeal)</b>
<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> <li>• Pfizer (etanercept)</li> <li>• Schering-Plough Ltd (infliximab)</li> </ul> <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>• Afiya Trust</li> <li>• Black Health Agency</li> <li>• Changing Faces</li> <li>• Chinese National Healthy Living Centre</li> <li>• Counsel and Care</li> <li>• Equalities National Council</li> <li>• Muslim Council of Britain</li> <li>• Muslim Health Network</li> <li>• Psoriasis Association</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• Medicines and Healthcare products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• Public Health Wales NHS Trust</li> <li>• Scottish Medicines Consortium</li> </ul>

Consultees	Commentators (no right to submit or appeal)
<ul style="list-style-type: none"> <li>• Skin Care Campaign</li> <li>• South Asian Health Foundation</li> <li>• Specialised Healthcare Alliance</li> </ul> <p><u>Professional groups</u></p> <ul style="list-style-type: none"> <li>• British Association for Services to the Elderly</li> <li>• British Dermatological Nursing Group</li> <li>• British Geriatric Society</li> <li>• British Skin Foundation</li> <li>• Primary Care Dermatology Society</li> <li>• Royal College of General Practitioners</li> <li>• Royal College of Physicians</li> <li>• Royal Pharmaceutical Society</li> <li>• Royal Society of Medicine</li> <li>• United Kingdom Clinical Pharmacy Association</li> </ul> <p><u>Others</u></p> <ul style="list-style-type: none"> <li>• Department of Health</li> <li>• Merthyr Tydfil LHB</li> <li>• NHS Hillingdon</li> <li>• Welsh Assembly Government</li> </ul>	<p><u>Possible comparator manufacturer(s)</u></p> <ul style="list-style-type: none"> <li>• none</li> </ul> <p><u>Relevant research groups</u></p> <ul style="list-style-type: none"> <li>• British Epidermo-Epidemiology Society</li> <li>• Cochrane Skin Group</li> <li>• MRC Clinical Trials Unit</li> <li>• National Institute for Health Research</li> <li>• Policy Research Institute on Ageing and Ethnicity</li> <li>• Research Institute of the Care of the Elderly</li> <li>• Skin Research Centre</li> <li>• Skin Treatment and Research Trust</li> </ul> <p><u>Assessment Group</u></p> <ul style="list-style-type: none"> <li>• National Institute for Health Research Health Technology Assessment Programme</li> </ul> <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> <li>• National Clinical Guideline Centre</li> </ul> <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> <li>• none</li> </ul>

**GE paper sign-off:** Janet Robertson 08 September 2010.

**Contributors to this paper:**

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