Appendix B

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Alitretinoin for the treatment of severe chronic hand eczema

Final scope

Remit/appraisal objective
To appraise the clinical and cost effectiveness of oral alitretinoin within its licensed indication for the treatment of severe chronic hand eczema.

Background
Hand eczema (also known as hand dermatitis) is an itchy inflammatory condition of the skin affecting all parts of the hands. Skin inflammation associated with hand eczema can be acute and is characterised by redness, blisters, weeping, crusting and breaks in the skin, or it may become chronic which is characterised by thickening, deep cracks (fissures) and scaling. Hand eczema is usually classified according to the primary cause in the individual, divided into endogenous (atopic) eczema and exogenous causes (allergic or irritant forms of contact eczema).

Hand eczema is estimated to affect 10% of the general population and up to 30% of high-risk occupational groups such as healthcare workers. Because of the difficulty in identifying and/or avoiding causative factors, eczema often develops into a chronic condition. Approximately 7% of people with hand eczema are estimated to have a severe, chronic form of the disease, with one third to one half of this subgroup estimated to be refractory to potent topical corticosteroids.

Available treatment aims to restore normal skin, reduce symptoms and improve hand function. The current standard treatments for mild hand eczema are non-prescription emollient/moisturising preparations. Moderate and severe hand eczema is typically treated with potent topical corticosteroids during an acute episode, and patch tests are usually performed to exclude any allergic contact factors. Potent or very potent topical corticosteroids are sometimes used with polythene occlusion during the initial phase of treatment for severe hand eczema. For people whose eczema has not responded to topical corticosteroids, the standard treatment is usually a short course of immunosuppressant drugs (such as azathioprine or ciclosporin), and/or ultraviolet light therapy.

The technology
Oral alitretinoin (Toctino, Basilea Medical) has been described as a panagonist of retinoid receptors because it activates retinoic acid receptors (RARs) and retinoic X receptors (RXRs). Binding to and activation of the various retinoid receptors might be responsible for certain biological effects of alitretinoin. The precise mechanism of action of
alitretinoin for the treatment of chronic hand eczema is unknown. It is administered orally.

Alitretinoin has a UK marketing authorisation for the treatment of severe chronic hand eczema in adults that does not respond to potent topical corticosteroid therapy.

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<tr>
<th>Intervention(s)</th>
<th>Oral alitretinoin</th>
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<td>Population(s)</td>
<td>Adults with severe chronic hand eczema refractory to potent topical corticosteroids</td>
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| Standard comparators | • ultraviolet light therapy (PUVA)  
                        • immunosuppressive therapies (ciclosporin and azathioprine) |
| Outcomes        | The outcome measures to be considered include:  
                        • measures of disease severity  
                        • measures of symptom control  
                        • disease free period/maintenance of remission  
                        • time to relapse/prevention of relapse  
                        • adverse effects of treatment  
                        • health-related quality of life |
| Economic analysis | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.  
                          The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.  
                          Costs will be considered from an NHS and Personal Social Services perspective. |
| Other considerations | Guidance will only be issued in accordance with the marketing authorisation.  
                          Consideration should be given to subgroups according to primary cause of the eczema (atopic or allergic).  
                          The economic analysis should take into account continuation rules associated with the treatment of oral alitretinoin. |
### Related NICE recommendations

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<th>Related Technology Appraisals:</th>
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<tr>
<td>Technology Appraisal No TA81, August 2004, Frequency of application of topical corticosteroids for eczema.</td>
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<tr>
<td>Technology Appraisal No TA82, August 2004, Pimecrolimus and tacrolimus for atopic dermatitis (eczema).</td>
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