NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Alitretinoin for the treatment of severe chronic hand eczema

Draft scope (Pre-referral)

Draft 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 associated with varying degrees of redness, thickening, dryness, lumps, blisters and weeping or crusty deposits in affected areas of the skin. Eczema is usually classified according to the primary cause in the individual, and types include atopic eczema, allergic contact eczema and pompholyx 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.

Treatment usually starts when the allergy causing agent cannot be removed. Available treatment aims to lesson the allergic inflammatory response, thereby reducing symptoms. The current standard treatments for mild hand eczema are non prescription emollient/moisturising preparations, whist moderate and severe hand eczema are usually treated with topical corticosteroids. For people who have not responded to topical steroids, treatment may include topical immunmodulatory therapies, oral corticosteroids, immunosuppressant drugs, ultraviolet light therapy, and retinoids.

The technology

Alitretinoin (Datiros, Basilea Medical) is a retinoid which works by modulating gene expression through retinoic acid receptors (RARs) and retinoic X receptors (RXRs). It is administered orally.

Alitretinoin does not currently hold a UK marketing authorisation. It has been studied as a monotherapy in clinical trials for the treatment of adults with severe chronic hand eczema that is refractory to topical corticosteroids.

Intervention(s)	Alitretinoin
Population(s)	Adults with severe chronic eczema of the hand refractory to topical corticosteroids
Standard comparators	• topical immunomodulatory therapy, such as tacrolimus and pimecrolimus • oral corticosteroids • immunosuppresive therapies, such as ciclosporin, azathioprine and mycophenolate • alternative retinoid therapies, such as isotretinoin, tretinoin, acitretin and adalapene
Outcomes	The outcome measures to be considered include: • measures of disease severity • measures of symptom control • 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.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No TA81, August 2004, Frequency of application of topical corticosteroids for eczema. Technology Appraisal No TA82, August 2004, Pimecrolimus and tacrolimus for atopic dermatitis (eczema). Related Clinical Guidelines: None Related interventional Procedures: None Related Public Health Guidance/Guidelines: None

Questions for consultation

Have the most appropriate comparators for the treatment of severe chronic hand eczema been included in the scope? Which treatments in current standard practice would alitretinoin be an alternative to? Should light therapy be included as a comparator?

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?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

Which process would be the most suitable for appraising this technology, the single technology or multiple technology process? (Information on these processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)