

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**Health Technology Appraisal**

**Adalimumab for the treatment of psoriasis**

**Draft scope (Pre-referral)**

**Draft remit / appraisal objective**

To appraise the clinical and cost-effectiveness of adalimumab for moderate to severe chronic plaque psoriasis.

**Background**

Psoriasis is an inflammatory skin disease that is characterised by an accelerated rate of turnover of the top layer of the skin (epidermis). Although it is a chronic progressive condition, its course may be erratic, with flare-ups and remissions.

Psoriasis is generally graded as mild, moderate or severe. The most common form (80%) of psoriasis is chronic plaque psoriasis (psoriasis vulgaris), which is characterised by well-demarcated, often symmetrically distributed, thickened, red, scaly plaques. Although the plaques can affect any part of the skin, they are typically found on the extensor surfaces of the knees and elbows, and on the scalp. It is estimated that 5–7% of all people with psoriasis, and approximately 40% of those with extensive skin disease, develop joint inflammation, which is known as psoriatic arthritis (PsA).

There are few data on the prevalence and incidence of psoriasis in the UK but estimates suggest that it affects approximately 2% of the population, although there is a higher incidence in white people than in members of other ethnic groups.

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.

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 the severity rather than stop the episodes, and the psoriasis therefore has to be treated continually and on a long-term basis. In general, the evidence base for many of these therapies is not well developed.

Mild to moderate psoriasis, particularly when a limited area of skin is involved, can be managed with topical treatments, including emollients and occlusive dressings, keratolytics (salicylic acid), coal tar, dithranol, corticosteroids, retinoids and vitamin D analogues. More severe, resistant and/or extensive psoriasis can be treated with photo(chemo)therapy, acitretin (an oral retinoid)

and oral drugs that act on the immune system, such as ciclosporin, methotrexate and hydroxycarbamide. Oral treatments can be given alone or in conjunction with topical therapies. All the oral therapies have the potential to cause severe long-term side effects, and monitoring is required. The toxic effects are cumulative and therefore many people with psoriasis require 'rotational therapy' in order to minimise the cumulative toxicity of any one treatment.

NICE has issued guidance on the use of etanercept and efalizumab for the treatment of psoriasis. Etanercept inhibits tumour necrosis factor [TNF] alpha, a naturally occurring cytokine involved in normal immune responses. Excess TNF activity can cause severe inflammation and tissue damage. Etanercept is recommended for the treatment of severe psoriasis that has failed to respond to standard systemic therapies including ciclosporin, methotrexate and PUVA (psoralen and long-wave ultraviolet radiation); or the person is intolerant to, or has a contraindication to, these treatments. Efalizumab, a T-cell modulator, is recommended for the treatment of adults with severe plaque psoriasis only if their psoriasis has failed to respond to etanercept or they are shown to be intolerant of, or have contraindications to, treatment with etanercept.

**The technology:**

Adalimumab (Humira, Abbott Laboratories Limited) inhibits the activity of TNF alpha. It is a fully human recombinant monoclonal IgG1 antibody specific for TNF alpha. Adalimumab has a marketing authorisation for the treatment of psoriatic arthritis but does not have a marketing authorisation for the treatment of psoriasis. It is currently being studied in patients with moderate to severe psoriasis. It is administered via subcutaneous injection.

<b>Intervention</b>	Adalimumab
<b>Population</b>	Adults with moderate to severe psoriasis
<b>Standard comparators</b>	<ul style="list-style-type: none"> <li>• Acitretin</li> <li>• Ciclosporin</li> <li>• Hydroxycarbamide</li> <li>• Methotrexate</li> <li>• Photo(chemo)therapy.</li> <li>• Etanercept</li> <li>• Efalizumab</li> <li>• Infliximab</li> </ul>
<b>Outcomes</b>	<p>Outcomes to be considered include:</p> <ul style="list-style-type: none"> <li>• measures of severity of psoriasis</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>

<p><b>Economic analysis</b></p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The time horizon for the economic evaluation should reflect the chronic nature of the condition.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<p><b>Other considerations</b></p>	<p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If the evidence allows, the appraisal will attempt to identify criteria for selecting patients for whom this treatment would be particularly appropriate.</p> <p>It is anticipated that individuals may also be treated with topical therapies; where the evidence permits any resulting confounding factors will be taken into consideration.</p>
<p><b>Related NICE recommendations:</b></p>	<p>NICE Appraisal Guidance No.103 – The use of etanercept and efalizumab for the treatment of psoriasis, 2006.</p> <p>NICE Appraisal Guidance No.104 – The use of Etanercept and infliximab for the treatment of psoriatic arthritis, 2006.</p>

**Questions for consultation:**

What is the most appropriate comparator for this appraisal?