

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Secukinumab for treating moderate to severe plaque psoriasis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of secukinumab within its licensed indication for moderate to severe plaque psoriasis in people for whom other systemic therapies have been inadequately effective, not tolerated or contraindicated.

Background

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

Psoriasis is generally graded as mild, moderate or severe. The severity of the condition can be measured using indices such as the Psoriasis Area Severity Index (PASI) and the Dermatology Life Quality Index (DLQI). The most common form of psoriasis is chronic plaque psoriasis 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.

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, equating to approximately 1 million people with the condition. Moderate to severe psoriasis is estimated to affect around 20% of people with psoriasis (5% severe, 15% moderate). There is a higher incidence in white people than in members of other ethnic groups.

There is no cure for psoriasis but there are a wide range of topical and systemic treatments that can manage the condition. Most treatments reduce severity rather than prevent episodes and the psoriasis has to be treated continually and on a long-term basis.

Mild to moderate psoriasis 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 is treated with phototherapy with or without psoralen, 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 combination with topical therapies.

NICE clinical guideline 153 on the assessment and management of psoriasis incorporates verbatim recommendations from several technology appraisals for people with psoriasis for whom other systemic therapies including ciclosporin, methotrexate and phototherapy with or without psoralen have been inadequately effective, not tolerated or contraindicated. Etanercept (NICE technology appraisal 103), adalimumab (NICE technology appraisal 146) and ustekinumab (NICE technology appraisal 180) are recommended as treatment options for people with severe psoriasis (as defined by a total PASI score of 10 or more and a DLQI score of more than 10). Infliximab (NICE technology appraisal 134) is recommended for people with very severe psoriasis (PASI score of 20 or more and a DLQI score of more than 18).

The technology

Secukinumab (brand name unknown, Novartis) is a high-affinity fully human monoclonal antibody that binds to and neutralises interleukin-17A, which is believed to be involved in the body's autoimmune response in diseases such as psoriasis. Secukinumab is administered by subcutaneous injection.

Secukinumab does not currently have a UK marketing authorisation for treating moderate to severe plaque psoriasis. It has been studied in clinical trials compared with placebo or etanercept in adults with moderate to severe psoriasis for whom topical treatment, phototherapy and/or systemic therapy have been inadequately effective.

Intervention(s)	Secukinumab
Population(s)	People with moderate to severe plaque psoriasis for whom other systemic therapies including ciclosporin, methotrexate and phototherapy with or without psoralen have been inadequately effective, or are not tolerated or contraindicated.
Comparators	<ul style="list-style-type: none"> • Biologic therapies (including etanercept, infliximab, adalimumab and ustekinumab) • Best supportive care (for people in whom biologic therapies are not tolerated or contraindicated).
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • severity of psoriasis • remission rate • relapse rate • adverse effects of treatment • health-related quality of life.

<p>Economic analysis</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 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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>Biosimilars are not expected to be in established NHS practice at the time of appraisal and are not included as comparators.</p> <p>The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.</p>
<p>Other considerations</p>	<p>If the evidence allows, subgroup analyses according to severity of psoriasis and previous use of biologics will be considered.</p> <p>If the evidence allows, the place of secukinumab in a sequence of biologics will be considered.</p> <p>Guidance will only be issued in accordance with the marketing authorisation.</p>
<p>Related NICE recommendations and NICE pathways</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No. 180, Sep 2009, 'Ustekinumab for the treatment of adults with moderate to severe psoriasis'. Guidance on static list.</p> <p>Technology Appraisal No. 146, Jun 2008, 'Adalimumab for the treatment of adults with psoriasis'. Guidance on static list.</p> <p>Technology Appraisal No. 134, Jan 2008, 'Infliximab for the treatment of adults with psoriasis'. Guidance on static list.</p> <p>Technology Appraisal No. 103, Jul 2006, 'Etanercept and efalizumab for the treatment of adults with psoriasis'. Guidance on static list. Note: guidance for efalizumab has now been withdrawn.</p> <p>Technology Appraisal in preparation 'Apremilast for the treatment of moderate to severe psoriasis'. Anticipated date of publication Aug 2015.</p> <p>Related Guidelines:</p> <p>Clinical Guideline No.153, Oct 2012, 'Psoriasis: the</p>

	<p>management of psoriasis'. Review Proposal Date TBC.</p> <p>Related Interventional Procedures:</p> <p>Interventional Procedure Guidance No. 236, Nov 2007, 'Grenz rays therapy for inflammatory skin conditions' Review Proposal Date TBC.</p> <p>Related Quality Standards:</p> <p>Quality Standard No.40, August 2013, 'Psoriasis'. Review Proposal Date TBC.</p> <p>http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>Related NICE Pathways:</p> <p>NICE Pathway: Psoriasis, Pathway Created: Oct 2012.</p> <p>http://pathways.nice.org.uk/</p>
<p>Related National Policy</p>	<p>None</p>