

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Brodalumab for treating moderate to severe plaque psoriasis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of brodalumab within its marketing authorisation for treating moderate to severe plaque psoriasis.

Background

Psoriasis is an inflammatory skin disease that is characterised by an increased 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 can be psychologically distressing to people. The most common form 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.

Psoriasis can be graded as mild, moderate or severe according to the body surface area affected or by using indices such as the Psoriasis Area Severity Index (PASI), which takes into account the size of the area covered with psoriasis as well as redness, thickness and scaling. In addition, the Dermatology Life Quality Index (DLQI) is a validated tool that can be used to assess the impact of psoriasis on physical, psychological and social wellbeing.

The prevalence of psoriasis in England is estimated to be 1.75%¹, which is about 959,000 people, of whom about 20% have moderate to severe psoriasis (15% moderate, 5% severe)², equating to approximately 190,000 people. Approximately 90% of people with the condition have plaque psoriasis. 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. Psoriasis has to be treated continually and on a long-term basis.

NICE clinical guideline 153 (2012) describes the care pathway for people with psoriasis. Initially, psoriasis is managed with topical treatments, including emollients and occlusive dressings, keratolytics (salicylic acid), coal tar, dithranol, corticosteroids and vitamin D analogues. Phototherapy may be used for people with plaque psoriasis that cannot be controlled with topical treatments. Systemic non-biological therapies (such as methotrexate, ciclosporin and acitretin) should be offered to people with any type of psoriasis if:

- it cannot be controlled with topical therapy **and**
- it has a significant impact on physical, psychological or social wellbeing **and**
- one or more of the following apply:
 - psoriasis is extensive **or**
 - psoriasis is localised and associated with significant functional impairment and/or high levels of distress **or**
 - phototherapy has been ineffective, cannot be used or has resulted in rapid relapse.

NICE technology appraisals 103, 134, 146, 180, 350 and 442 recommend biological therapies 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 (technology appraisal [TA] 103), adalimumab (TA146), ustekinumab (TA180), secukinumab (TA350), apremilast (TA419) and ixekizumab (TA442) 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 (TA134) is recommended as an option for people with very severe psoriasis (PASI score of 20 or more and a DLQI score of more than 18).

The technology

Brodalumab (Kyntheum, Leo Pharma) is a monoclonal antibody which targets the interleukin (IL) 17 receptor, blocking the signalling pathway of IL-17A, IL17F and IL-25. It is administered by subcutaneous injection.

Brodalumab has a UK marketing authorisation for treating moderate to severe plaque psoriasis. It has been studied in 3 phase III clinical trials compared with placebo or ustekinumab, in adults with moderate to severe plaque psoriasis.

Intervention(s)	Brodalumab
Population(s)	Adults with moderate to severe plaque psoriasis

Comparators	<p>If non-biologic systemic treatment or phototherapy is suitable:</p> <ul style="list-style-type: none"> • Systemic non-biological therapies (including acitretin, ciclosporin, dimethyl fumarate (subject to ongoing NICE appraisal), fumaric acid esters, methotrexate) • Phototherapy with ultraviolet (UVB) radiation <p>For people with severe or very severe psoriasis for whom non-biologic systemic treatment or phototherapy is inadequately effective, not tolerated or contraindicated:</p> <ul style="list-style-type: none"> • TNF-alpha inhibitors (etanercept, infliximab, adalimumab) • Ustekinumab • Secukinumab • Apremilast • Ixekizumab • Dimethyl fumarate (subject to ongoing NICE appraisal) • Best supportive care
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • severity of psoriasis (including the Psoriasis Area Severity Index [PASI]) • psoriasis symptoms on the face, scalp and nails • mortality • response rate • relapse rate • adverse effects of treatment • health-related quality of life (including dermatology quality of life index [DLQI]).

<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>The availability of any patient access schemes for the intervention or comparator technologies will be taken into account.</p> <p>For the comparators, the availability and cost of biosimilars should be taken into consideration.</p>
<p>Other considerations</p>	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> • previous use of systemic non-biological therapy • previous use of biological therapy • severity of psoriasis (moderate, severe) <p>Where the evidence allows, sequencing of different drugs and the place of brodalumab in such a sequence will be considered.</p> <p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Etanercept and efalizumab for the treatment of adults with psoriasis' (2006) NICE Technology Appraisal 103. Note: guidance for efalizumab has now been withdrawn.</p> <p>'Infliximab for the treatment of adults with psoriasis' (2008) NICE Technology Appraisal 134. Static list.</p> <p>'Adalimumab for the treatment of adults with psoriasis' (2008) NICE Technology Appraisal 146. Static list.</p> <p>'Ustekinumab for the treatment of adults with moderate to severe psoriasis' (2009) NICE Technology Appraisal 180. Static list.</p> <p>'Secukinumab for treating moderate to severe plaque psoriasis' (2015) NICE Technology Appraisal 350.</p>

	<p>Review date: July 2018</p> <p>'Apremilast for treating moderate to severe psoriasis' (rapid review of technology appraisal guidance 368). NICE Technology Appraisals TA419. Review date: November 2019.</p> <p>'Ixekizumab for treating moderate to severe plaque psoriasis'. NICE technology appraisals guidance TA442. Review date: April 2020.</p> <p>In-development</p> <p>'Dimethyl fumarate for treating moderate to severe plaque psoriasis'. NICE technology appraisals guidance [ID776]. Publication expected: November 2017.</p> <p>'Guselkumab for treating moderate to severe plaque psoriasis'. NICE technology appraisals guidance [ID1075]. Publication expected: TBD.</p> <p>Related Guidelines:</p> <p>'Psoriasis. The assessment and management of psoriasis' (2013) NICE guideline 153. Review Proposal Date: December 2016</p> <p>Related Interventional Procedures:</p> <p>'Grenz rays therapy for inflammatory skin conditions' (2007) NICE interventional procedures guidance 236.</p> <p>Related Quality Standards:</p> <p>Quality Standard No. 40, August 2013, 'Psoriasis'. http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>Related NICE Pathways:</p> <p>'Psoriasis' (2012) NICE Pathway http://pathways.nice.org.uk/pathways/psoriasis</p>
Related National Policy	<p>NHS England Manual for Prescribed Specialised Services 2016/17. Chapter 61, Highly specialist dermatology services. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf</p> <p>NHS England standard contract for specialised dermatology services, 2013/14. https://www.england.nhs.uk/wp-content/uploads/2013/06/a12-spec-dermatology.pdf</p> <p>Department of Health, NHS Outcomes Framework 2016-2017, April 2016. Domains 2–5.</p>

	https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017
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References

1. NICE (2015) [Psoriasis: assessment and management – costing template](#). Accessed November 2016.
2. Menter A, Korman NJ, Elmets CA et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol* 2011; 65:137–74.