

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Appraisal**

**Guselkumab for treating moderate to severe plaque psoriasis**

**Final scope**

**Remit/appraisal objective**

To appraise the clinical and cost effectiveness of guselkumab 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. 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% in adults<sup>1</sup>, which is about 959,000 people, of whom about 20% have moderate to severe psoriasis (15% moderate, 5% severe)<sup>2,3</sup>, equating to approximately 192,000 people. About 90% of people with the condition have plaque psoriasis<sup>3</sup>. 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 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, 419 and 442 recommend therapies for people with psoriasis for whom standard systemic therapies including ciclosporin, methotrexate and phototherapy 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**

Guselkumab (Janssen) is a fully human monoclonal antibody that inhibits interleukin-23 (IL-23), a cytokine which is believed to be involved in the body’s autoimmune response in diseases such as psoriasis. Guselkumab is administered by subcutaneous injection.

Guselkumab does not currently have a marketing authorisation in the UK for treating psoriasis. It has been studied in clinical trials, compared with placebo or adalimumab, in adults with moderate to severe plaque psoriasis for whom systemic treatment or phototherapy are appropriate options. Guselkumab has also been compared with ustekinumab in a clinical trial in adults with moderate to severe plaque psoriasis whose disease had not responded adequately to ustekinumab.

<b>Intervention(s)</b>	Guselkumab
<b>Population(s)</b>	Adults with moderate to severe plaque psoriasis

<b>Comparators</b>	<p>If non-biologic systemic treatment or phototherapy is suitable:</p> <ul style="list-style-type: none"> <li>• Systemic non-biological therapies including acitretin, ciclosporin, fumaric acid esters (including dimethyl fumarate; subject to ongoing NICE appraisal) and methotrexate</li> <li>• Phototherapy with ultraviolet (UVB) radiation</li> </ul> <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"> <li>• TNF-alpha inhibitors (etanercept, infliximab, adalimumab)</li> <li>• Ustekinumab</li> <li>• Secukinumab</li> <li>• Apremilast</li> <li>• Ixekizumab</li> <li>• Dimethyl fumarate (subject to ongoing NICE appraisal)</li> <li>• Best supportive care</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• severity of psoriasis</li> <li>• psoriasis symptoms on the face, scalp and nails</li> <li>• response and remission rate</li> <li>• relapse rate</li> <li>• mortality</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 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 should be taken into account.</p> <p>For the comparators, the availability and cost of biosimilars should be taken into consideration.</p>
<p><b>Other considerations</b></p>	<p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• previous use of phototherapy and systemic non-biological therapy</li> <li>• previous use of biological therapy</li> <li>• severity of psoriasis (moderate, severe and very severe)</li> </ul> <p>Where the evidence allows, sequencing of different drugs and the place of guselkumab 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><b>Related NICE recommendations and NICE Pathways</b></p>	<p><b>Related Technology Appraisals:</b></p> <p>Adalimumab, etanercept and ustekinumab for treating severe, chronic plaque psoriasis in children and young people (2017). NICE Technology Appraisal 455. Review proposal date: July 2020.</p> <p>Ixekizumab for treating moderate to severe plaque psoriasis (2017). NICE Technology Appraisal 442. Review proposal date: April 2020.</p> <p>Apremilast for treating moderate to severe plaque psoriasis (2016) NICE Technology Appraisal 419. Review proposal date: 2019.</p>

	<p>Secukinumab for treating moderate to severe plaque psoriasis (2015) NICE Technology Appraisal 350. Review proposal date: July 2018.</p> <p>Ustekinumab for the treatment of adults with moderate to severe psoriasis (2009) NICE Technology Appraisal 180. Static list.</p> <p>Adalimumab for the treatment of adults with psoriasis (2008) NICE Technology Appraisal 146. Static list.</p> <p>Infliximab for the treatment of adults with psoriasis (2008) Technology Appraisal 134. Static list.</p> <p>Etanercept and efalixumab for the treatment of adults with psoriasis (2006) NICE Technology Appraisal 103. Static list. Note: guidance for efalizumab has now been withdrawn.</p> <p><b>Appraisals in development (including suspended appraisals):</b></p> <p>Dimethyl fumarate for treating moderate to severe plaque psoriasis [ID776]. NICE Technology Appraisal. Publication expected August 2017.</p> <p>Brodalumab for treating moderate to severe plaque psoriasis Proposed NICE technology appraisal [ID878]. Publication date to be confirmed.</p> <p>Briakinumab for the treatment of moderate to severe chronic plaque psoriasis [ID65]. Suspended.</p> <p><b>Related Guidelines:</b></p> <p>Psoriasis: The assessment and management of psoriasis (2012) NICE guideline 153. Review proposal date to be confirmed (last review June 2017).</p> <p><b>Related Interventional Procedures:</b></p> <p>Grenz rays therapy for inflammatory skin conditions (2007) NICE interventional procedures guidance 236.</p> <p><b>Related Quality Standards:</b></p> <p>Psoriasis (2013) NICE quality standard 40.</p> <p><b>Related NICE Pathways:</b></p> <p>Psoriasis (2015) NICE pathway  <a href="http://pathways.nice.org.uk/pathways/psoriasis">http://pathways.nice.org.uk/pathways/psoriasis</a></p>
<p><b>Related National Policy</b></p>	<p>Manual for Prescribed Specialised Services for 2016/17 Chapter 61 Highly specialist dermatology services (adults and children).</p> <p><a href="https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-">https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-</a></p>

	<p><a href="#">may16.pdf</a></p> <p>Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 2-5. <a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p>
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## References

1 NICE (2015) [Psoriasis: assessment and management – costing template](#). Accessed August 2017.

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.

3 American Academy of Dermatology website. [Psoriasis](#) [accessed August 2017].