NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Bimekizumab for treating moderate to severe chronic plaque psoriasis

Final scope

Remit/appraisal objective

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

Background

Plaque psoriasis is an inflammatory skin condition characterised by an accelerated rate of turnover of the upper layer of the skin (epidermis). This leads to an accumulation of skin cells forming raised plaques on the skin. These plaques can be flaky, scaly, itchy and red or a darker colour to the surrounding skin. Plaque psoriasis may affect the scalp, elbows, limbs and trunk and sometimes the face, groin, nails, armpits or behind the knees. Although it is a chronic, persistent, severe condition, its course may be unpredictable, with flare-ups and remissions. In people with darker skin the appearance of psoriasis may be less obvious, and severity may be underestimated.

Psoriasis is generally graded as mild, moderate or severe and takes into account the location, surface area of skin affected and the impact of the psoriasis on the person. The Psoriasis Area and Severity Index (PASI) is an index of disease severity in adults and 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 the United Kingdom is estimated to be between 1.3% and 2.2%.[1] About 90% of people with the condition have plaque psoriasis and about 20% have moderate to severe disease (15% moderate, 5% severe),[2] equating to approximately 103,000 to 174,000 adults in England.[3]

There is no cure for psoriasis but there is a wide range of topical and systemic treatments that can manage the condition. Most treatments reduce the severity of psoriasis flares rather than prevent episodes. Psoriasis has to be treated continually and on a long-term basis. NICE clinical guideline 153 on psoriasis recommends that people with psoriasis should be offered topical therapies such as corticosteroids, vitamin D and vitamin D analogues. For people in whom topical therapy does not alleviate symptoms the guideline recommends phototherapy (broad- or narrow-band ultraviolet B light) and psoralen with ultraviolet A phototherapy (PUVA). The guideline recommends systemic non-biological therapies (such as, as ciclosporin, methotrexate and acitretin) or PUVA for people whose psoriasis:

- cannot be controlled with topical therapy **and**
- 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 appraisal guidance 103, 146, 180, 350, 419, 442, 475, 511, 521, 574, 575, and 596 recommend etanercept, adalimumab, ustekinumab, secukinumab, apremilast, ixekizumab, dimethyl fumarate, brodalumab, guselkumab, certolizumab pegol, tildrakizumab and risankizumab respectively, as treatment options for adults with severe psoriasis (as defined by a total PASI score of 10 or more and a DLQI score of more than 10) whose disease has not responded to, or who are intolerant to or contraindicated to standard systemic therapies such as ciclosporin, methotrexate, acitretin and PUVA.

Technology appraisal guidance 134 recommends infliximab as a treatment option for adults with very severe psoriasis (as defined by a total PASI score of 20 or more and a DLQI score of more than 18) whose disease has not responded to, or who are intolerant to or contraindicated to standard systemic therapies. Biosimilar products of some biological therapies are available for use in the NHS.

The technology

Bimekizumab (brand name unknown, UCB Pharma) is a monoclonal antibody which binds to and selectively neutralises IL-17A and IL-17F. It is administered by subcutaneous administration.

Bimekizumab does not currently have a UK marketing authorisation for treating moderate to severe plaque psoriasis in adults. It has been studied in clinical trials compared with placebo, adalimumab, secukinumab, or ustekinumab in adults with moderate to severe plaque psoriasis.

Intervention(s)	Bimekizumab
Population(s)	Adults with moderate to severe plaque psoriasis
Comparators	If systemic non-biological treatment or phototherapy is suitable: • Systemic non-biological therapies (including methotrexate, ciclosporin and acitretin) • Phototherapy with or without psoralen If conventional systemic non-biological treatment (including methotrexate, ciclosporin and acitretin) and phototherapy are inadequately effective, not tolerated or contraindicated: • TNF-alpha inhibitors (adalimumab, etanercept, infliximab [for very severe plaque psoriasis, as defined by a total PASI of 20 or more, and a DLQI of more than 18] and certolizumab pegol) • IL-17 family inhibitors or receptor inhibitors (brodalumab, ixekizumab and secukinumab) • IL-23 inhibitors (guselkumab, tildrakizumab and risankizumab)

	• IL-12/IL-23 inhibitors (ustekinumab) • Apremilast • Dimethyl fumarate • Best supportive care
Outcomes	The outcome measures to be considered include: • severity of psoriasis • psoriasis symptoms, such as itch on the following areas: face, scalp, nails and joints, and other difficult-to-treat areas including the hands, feet and genitals • mortality • response rate • duration of response • relapse rate • 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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. For the comparators, the availability and cost of biosimilars should be taken into account.
Other considerations	Where the evidence allows, the following subgroups will be considered: • previous use of phototherapy and systemic non-biological therapy • previous use of biological therapy • severity of psoriasis (moderate, severe). Where the evidence allows, sequencing of different drugs and the place of bimekizumab in such a sequence will be considered. The availability and cost of biosimilar products should be taken into account. 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.
Related NICE recommendations and NICE Pathways	**Related Technology Appraisals** 'Risankizumab for treating moderate to severe plaque psoriasis' NICE technology appraisals guidance 596. Review date: August 2022. 'Tildrakizumab for treating moderate to severe plaque psoriasis' NICE technology appraisals guidance 575. Review date: April 2022. 'Certolizumab pegol for treating moderate to severe plaque psoriasis' NICE technology appraisals guidance 574. Review date: April 2022. 'Guselkumab for treating moderate to severe plaque psoriasis' (2018) NICE Technology Appraisal 521. Review date: June 2021. 'Brodalumab for treating moderate to severe plaque psoriasis' (2018) NICE Technology Appraisal 511. Review date: March 2021. 'Dimethyl fumarate for treating moderate to severe plaque psoriasis' (2017) NICE Technology Appraisal 475. Review date: September 2020. 'Ixekizumab for treating moderate to severe plaque psoriasis' (2017) NICE Technology Appraisal 442. Review date: April 2020. 'Apremilast for treating moderate to severe psoriasis [rapid review of technology appraisal guidance 368]' (2016) NICE Technology Appraisal 419. Review date: November 2019. 'Secukinumab for treating moderate to severe plaque psoriasis' (2015) NICE Technology Appraisal 350. Static list. 'Ustekinumab for the treatment of adults with moderate to severe psoriasis' (2009) NICE Technology Appraisal 180. Static list. 'Adalimumab for the treatment of adults with psoriasis' (2008) NICE Technology Appraisal 146. Static list. 'Infliximab for the treatment of adults with psoriasis' (2008) NICE Technology Appraisal 134. Static list. 'Etanercept and efalizumab for the treatment of adults with psoriasis' (2006) NICE Technology Appraisal 103. Static list. Note: guidance for efalizumab has now been withdrawn. **Related Guidelines** 'Psoriasis: assessment and management' (2012) NICE guideline 153. No new evidence identified in June 2017. Review date to be confirmed.

	Related Interventional Procedures 'Grenz rays therapy for inflammatory skin conditions' (2007) NICE interventional procedures guidance 236. **Related Quality Standards** 'Psoriasis' (2013) NICE quality standard 40. **Related NICE Pathways** 'Psoriasis' (2012; updated 2019) NICE Pathway.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 61: Highly specialist dermatology services. Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1 - 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

References

1. Parisi R, Griffiths CEM, Ashcroft DM (2011) Systematic review of the incidence and prevalence of psoriasis. British Journal of Dermatology 165: e5.

2. Menter A, Korman NJ, Elmets CA et al. (2011) 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.

4. Office for National Statistics (2019) Population Estimates for UK, England and Wales, Scotland and Northern Ireland mid-2018. Accessed March 2020.

