NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Risankizumab for treating moderate to severe plaque psoriasis

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of risankizumab 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, knees and lower back and sometimes the face, groin, armpits or behind the knees. Although it is a chronic, persistent, severe condition, its course may be unpredictable, with flare-ups and remissions.

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 102,000 to 172,000 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 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 and 511 recommend etanercept, adalimumab, ustekinumab, secukinumab, apremilast, ixekizumab, dimethyl fumarate and brodalumab, 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 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 the biological therapies are available for use in the NHS.

The technology

Risankizumab (brand name unknown, AbbVie and Boehringer Ingelheim) is an anti-interleukin-23 (IL-23) antibody drug that reduces inflammation by blocking the action of IL-23 protein. Risankizumab is administered by subcutaneous injection.

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

Intervention(s)	Risankizumab
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 or phototherapy are inadequately effective, not tolerated or contraindicated: • TNF-alpha inhibitors (adalimumab, etanercept and infliximab) • IL-17 inhibitors (brodalumab, ixekizumab and secukinumab) • IL-23 inhibitor (guselkumab [subject to ongoing NICE appraisal]) • IL-12/IL-23 inhibitor (ustekinumab) • Apremilast • Dimethyl fumarate • Best supportive care
Outcomes	The outcome measures to be considered include: • severity of psoriasis • psoriasis symptoms on the face, scalp, nails and joints • 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. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out. 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 patient access schemes for the intervention or comparator 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 risankizumab in such a sequence in fully incremental analysis will be considered. 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** '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. Review date: July 2018. '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. **Appraisals In Development** 'Guselkumab for treating moderate to severe plaque psoriasis' NICE technology appraisals guidance [ID1075]. Publication expected June 2018. 'Tildrakizumab for treating moderate to severe plaque psoriasis' NICE technology appraisals guidance [ID1060]. Publication date to be confirmed. **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) NICE Pathway.
Related National Policy	Department of Health (2016) NHS outcomes framework 2016 to 2017: Domains 1–5.

	NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Chapter 61: Highly specialist dermatology services. NHS England (2013) 2013/14 NHS Standard contract for specialised dermatology services (all ages).

Questions for consultation

Have all relevant comparators for risankizumab been included in the scope? Should the comparators be limited to only IL-23 inhibitors?

Which treatments are considered to be established clinical practice in the NHS for chronic plaque psoriasis?

How should best supportive care be defined?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom risankizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider risankizumab will fit into the existing NICE pathway, Psoriasis?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which risankizumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider risankizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of risankizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

NICE has published an addendum to its guide to the methods of technology appraisal (available at https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost-comparison.pdf), which states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technologies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. NICE (2017) Psoriasis: assessment and management Clinical guideline 153.

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. Office for National Statistics (2017) Population Estimates for UK, England and Wales, Scotland and Northern Ireland mid-2016. Accessed May 2018.