NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Secukinumab for treating moderate to severe plaque psoriasis

Draft scope (pre-referral)

Draft 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 (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.

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 recommends several biologic 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, adalimumab (for people with plaque psoriasis for whom anti-tumour necrosis factor (TNF) treatment is being considered) and ustekinumab 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), and infliximab 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 anti-human interleukin-17A (IL-17A) antibody of the IgG1/kappa isotype. It 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, not tolerated or contraindicated.
Comparators	Biologic therapies (including etanercept, infliximab, adalimumab, ustekinumab and biosimilars).
Outcomes	The outcome measures to be considered include: • severity of psoriasis • remission rate • 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.
Other considerations	Where the evidence allows, sequencing of different drugs and the place of secukinumab in such a sequence will be considered. If the evidence allows, a subgroup analysis according to severity of psoriasis will be considered. Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations and NICE pathways	Related Technology Appraisals: Technology Appraisal No. 180, Sep 2009, 'Ustekinumab for the treatment of adults with moderate to severe psoriasis'. Static list. Technology Appraisal No. 146, Jun 2008, 'Adalimumab for the treatment of adults with psoriasis'. Static list. Technology Appraisal No. 134, Jan 2008, 'Infliximab for the treatment of adults with psoriasis'. Static list. Technology Appraisal No. 103, Jul 2006, 'Etanercept and efalizumab for the treatment of adults with psoriasis'. Static list. Note: guidance for efalizumab has now been withdrawn. Proposed Technology Appraisal, 'Apremilast for the treatment of moderate to severe psoriasis'. Publication TBC. Suspended Technology Appraisal 'Briakinumab for the treatment of moderate to severe chronic plaque psoriasis'. Related Guidelines: Clinical Guideline No.153, Oct 2012, 'Psoriasis: the management of psoriasis'. Review Proposal Date TBC. Related Interventional Procedures: Interventional Procedure Guidance No. 236, Nov 2007, 'Grenz rays therapy for inflammatory skin conditions'

	Review Proposal Date TBC. Related Quality Standards: Quality Standard No.40, August 2013, 'Psoriasis'. Review Proposal Date TBC. http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp Related NICE Pathways: NICE Pathway: Psoriasis, Pathway Created: Oct 2012. http://pathways.nice.org.uk/
Related NHS England Policy	None

Questions for consultation

Have all relevant comparators for secukinumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for moderate to severe psoriasis?

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

Where do you consider secukinumab will fit into the existing NICE pathway for 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 secukinumab 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 the technology 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 the technology 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.

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/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)

Subject to referral by the Department of Health, the invite for participation in this technology appraisal is anticipated for after January 2014, when new arrangements for the pricing of pharmaceuticals are expected to be in place. Consequences for this appraisal will be explored through further consultation on the scope pre-invitation.