NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs [ID720]

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of secukinumab within its marketing authorisation for treating active psoriatic arthritis in adults for whom disease-modifying anti-rheumatic drugs have been inadequately effective, not tolerated or contraindicated.

Background

Psoriatic arthritis (also called psoriatic arthropathy) is an inflammatory arthritis closely associated with psoriasis. An estimated 5–7% of all people with psoriasis, and approximately 40% of those with extensive skin disease, have psoriatic arthritis. The skin symptoms of psoriatic arthritis precede the arthritis symptoms in nearly 70% of people with the disease. In some people, the diagnosis of psoriatic arthritis can be difficult if the arthritis precedes psoriasis by many years. The prevalence of psoriatic arthritis in England in 2013 was estimated to be around 53,900 to 161,600 people. Psoriatic arthritis affects men and women equally and its incidence peaks between the ages of 30 and 55 years.

Although psoriatic arthritis is a chronic condition that progresses in the joints, its course may be erratic, with flare-ups and remissions. Arthritis symptoms can range from mild inflammation of the synovial membrane surrounding a joint (synovitis) to severe progressive erosion of the joints. Skin symptoms include the presence of patchy, raised, red areas of skin inflammation with scaling, which can affect any part of the body, including changes in the appearance of finger and toe nails, but is most commonly found on the extensor surfaces of the elbows and knees, the scalp and ears, the navel, and around the genital areas or anus.

The clinical management of psoriatic arthritis aims to suppress joint, tendon and ligament inflammation, and to manage the skin symptoms of the disease. Current practice involves early diagnosis and early use of non-biological disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate, sulphasalazine, leflunomide, azathioprine and ciclosporin, in order to minimise damage to joints. Non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy and intra-articular corticosteroid injections may also be used.

In addition, biological tumour necrosis factor alpha (TNF-α) inhibitors may be used for treating people with active psoriatic arthritis. NICE technology

appraisal guidance 199 and 220 recommend etanercept, infliximab, adalimumab or golimumab when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, and the psoriatic arthritis has not responded to at least 2 other DMARDs, given on their own or together. NICE technology appraisal guidance 313 did not recommended ustekinumab for treating active psoriatic arthritis when response to previous treatment with non-biological DMARDs has been inadequate.

The technology

Secukinumab (brand name unknown, Novartis) is a high-affinity fully human monoclonal antibody antagonist of the interleukin 17A (IL-17A) receptor. It is administered by intravenous infusion.

Secukinumab does not have a marketing authorisation in the UK for treating active psoriatic arthritis. It is currently being studied in clinical trials compared with placebo for people with active psoriatic arthritis.

Intervention(s)	Secukinumab alone or in combination with methotrexate
Population(s)	Adults with active psoriatic arthritis for whom disease-modifying anti-rheumatic drugs have been inadequately effective, not tolerated or contraindicated
Comparators	For people who have only received 1 prior non-biological disease modifying anti-rheumatic drug (DMARD) • Disease modifying anti-rheumatic drugs (including methotrexate) For people whose disease has inadequately responded to at least 2 DMARDs or for whom DMARDs cannot be tolerated or are contraindicated: • Biological therapies (including etanercept, adalimumab, infliximab, golimumab and ustekinumab [subject to ongoing NICE appraisal]) For people in whom DMARDs and biological therapies (including etanercept, adalimumab, infliximab and golimumab) are not tolerated or contraindicated: • Ustekinumab [subject to ongoing NICE appraisal] • Best supportive care.

Outcomes	The outcome measures to be considered include: • disease activity • functional capacity • effect on concomitant skin condition • disease progression • other complications of psoriatic arthritis (including skin, nail and scalp outcomes) • mortality • 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 patient access schemes for the intervention or comparator technologies should be taken into account.
Other considerations	If evidence allows the following subgroups will be considered: • previous treatment (including previous treatment with DMARDs and TNF-α inhibitors) • reason for treatment failure (for example due to lack of efficacy or adverse events). 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: Technology Appraisal No. 313, May 2014, 'Ustekinumab for treating active psoriatic arthritis'. Currently undergoing rapid review.

	Technology Appraisal No. 199, August 2010, 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of technology appraisal guidance 104 and 125)'. A review proposal is currently being considered for this topic Technology Appraisal No. 220, April 2011, 'Golimumab for the treatment of psoriatic arthritis'. A review proposal is currently being considered for this topic Technology Appraisal in Preparation, 'Apremilast for treating active psoriatic arthritis'. Anticipated publication date August 2015. Related Guidelines: Clinical Guideline No. 153, October 2012. Psoriasis. Review Proposal Date TBC. Related Quality Standards: Quality Standard No. 40, August 2013, Psoriasis. Review Proposal Date TBC http://www.nice.org.uk/guidance/qs40/resources/guidance-psoriasis-pdf Related NICE Pathways: NICE Pathway: Psoriasis, Pathway created: July 2014 Psoriasis - NICE Pathways
Related National Policy	Department of Health (2013) NHS Outcomes Framework 2014-2015, Domain 2.

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 treating active psoriatic arthritis?
How should best supportive care be defined?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom secukinumab 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, psoriasis?

Are biosimilars expected to be established clinical practice for treating psoriatic arthritis within the next 12 months?

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 secukinumab 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 secukinumab 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.