NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Abatacept for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of abatacept within its marketing authorisation for treating active psoriatic arthritis in adults whose disease has not responded adequately to previous disease-modifying anti-rheumatic drug therapy.

Background

Psoriatic arthritis (also called psoriatic arthropathy) is an inflammatory arthritis closely associated with psoriasis. It is estimated that around 1 in 5 people with psoriasis develop psoriatic arthritis[i], although this figure may be higher in people who have severe psoriasis[i]. In around 70% of people psoriasis precedes psoriatic arthritis[i]. The prevalence of psoriatic arthritis in England in 2014 was estimated to be around 81,177 adults[ii,iii]. Men and women are equally likely to develop psoriatic arthritis with the peak onset being between the ages of 30 and 50 years[i].

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 inflammation of the synovial membrane surrounding a joint (synovitis), ligaments and tendons (enthesitis and tendonitis), and inflammation of digits (dactylitis) 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 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 aim of treatment is 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 and leflunomide, 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 (TNF)-alpha 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 standard DMARDs, given on their own or together. Ustekinumab is recommended in NICE technology appraisal guidance 340 when treatment with TNF-alpha inhibitors are contraindicated but would otherwise be considered or the person has had treatment with 1 or more TNF-alpha inhibitors. Certolizumab pegol and secukinumab are currently also being appraised by NICE.

Biosimilar products of the biological therapies are available for use in the NHS.

The technology

Abatacept (Orencia, Bristol-Myers Squibb) is a selective co-stimulation modulator which prevents T-cell activation. It is administered by intravenous infusion.

Abatacept does not currently have a marketing authorisation in the UK for treating psoriatic arthritis. It has been studied in a clinical trial (alone or with concomitant non-biological DMARDs) compared with placebo in adults with active psoriatic arthritis who have had an inadequate response to, or intolerance of, non-biological DMARDs.

Intervention(s)	Abatacept alone or in combination with non-biological disease-modifying anti-rheumatic drugs
Population(s)	Adults with active psoriatic arthritis whose disease has not responded adequately to previous disease-modifying anti-rheumatic drug therapy
Comparators	For people who have only received 1 prior non-biological disease modifying anti-rheumatic drug (DMARD) • Non-biological DMARDs For people whose disease has not responded adequately to at least 2 non-biological DMARDs: • Biological DMARDs (with or without methotrexate including etanercept, adalimumab, infliximab, golimumab, certolizumab pegol [subject to ongoing NICE appraisal], and secukinumab [subject to ongoing NICE appraisal]) For people whose disease has not responded adequately to non-biological and biological DMARDs, or biological DMARDs are contraindicated: • Ustekinumab • Best supportive care.

Outcomes	The outcome measures to be considered include: • disease activity • functional capacity • disease progression • periarticular disease (for example enthesitis, tendonitis, dactylitis) • 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 will be taken into account. For the comparators the availability and cost of biosimilars should be taken into consideration.
Other considerations	If evidence allows the following subgroups will be considered: • the reason for treatment failure (for example due to lack of efficacy, intolerance 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: 'Apremilast for treating active psoriatic arthritis' (2015). NICE Technology Appraisal 372. Review date December 2018. 'Ustekinumab for treating active psoriatic arthritis'

	(2015). NICE Technology Appraisal 340. Review date June 2018. 'Golimumab for the treatment of psoriatic arthritis' (2011). NICE Technology Appraisal 220. A review proposal is currently being considered for this topic. 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of technology appraisal guidance 104 and 125)' (2010). NICE Technology Appraisal 199. A review proposal is currently being considered for this topic. Appraisals in development (including suspended appraisals) 'Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs' NICE technology appraisals guidance [ID579]. Publication expected February 2017. Related Guidelines: 'Psoriasis: assessment and management' (2012). NICE clinical guideline 153. Review Proposal Date December 2016. Guidelines in development 'The diagnosis and management of spondyloarthritis'. Publication expected December 2016. Related Quality Standards: 'Psoriasis' (2013). Quality Standard 40. Review Proposal Date TBC Related NICE Pathways: NICE Pathway: Musculoskeletal conditions, Pathway last updated June 2015.
Related National Policy	NHS England (2016) 'Manual for Prescribed Specialised Services'. Chapter 5, Adult highly specialist rheumatology services Department of Health, NHS Outcomes Framework 2016-2017, April 2016. Domains 2 to 5.

Questions for consultation

Have all relevant comparators for abatacept been included in the scope? Which treatments are considered to be established clinical practice in the NHS for active psoriatic arthritis?

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 abatacept is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider abatacept will fit into the existing NICE pathway, musculoskeletal conditions?

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 abatacept 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 abatacept 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 abatacept 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 Technology Appraisal Process. NICE has just consulted on an additional technology appraisal process known as the Abbreviated Appraisal Process (ATA). More information on the consultation is available at https://www.nice.org.uk/about/what-we-

do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/abbreviated-technology-appraisal-process-consultation. We welcome comments on the appropriateness and suitability of considering the new ATA process for appraising this topic. Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction.

References

[i] Psoriasis Association (2014) 'Psoriatic Arthritis'
[ii] Ogdie, A., Langan, S., Love, T., Haynes, K., Shin, S., Seminara, N., Mehta, N., Troxel, A., Choi, H., Gelfand, J. (2013) 'Prevalence and treatment patterns of psoriatic arthritis in the UK'. Rheumatology (Oxford) Mar 52(3): 568-75
[iii] Office for National Statistics (2015) 'Population estimates mid-year 2014'