NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal

Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs [ID579]

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of certolizumab pegol and secukinumab within their marketing authorisations 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. 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 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, 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 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 other DMARDs, given on their own or together. Ustekinumab is recommended in NICE technology appraisal guidance 340 when treatment with tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered or the person has had treatment with 1 or more TNF-alpha inhibitors. Apremilast is currently undergoing a NICE appraisal for treating adults with active psoriatic arthritis that has not responded to prior DMARD therapy, or such therapy is not tolerated.

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

The technology

Certolizumab pegol (Cimzia, UCB Pharma) is an inhibitor of TNF-alpha, a pro-inflammatory mediator that is partly responsible for damage to the joints in psoriatic arthritis. It is administered subcutaneously.

Certolizumab pegol in combination with methotrexate has a marketing authorisation in the UK for treating active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Certolizumab pegol can be given as monotherapy if methotrexate cannot be tolerated or when continued treatment with methotrexate is inappropriate.

Secukinumab (Cosentyx, Novartis) is a high-affinity fully human monoclonal antibody antagonist of the interleukin 17A (IL-17A) receptor. It is administered subcutaneously.

Secukinumab alone or in combination with methotrexate has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) for treating active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate.

Intervention(s)	• Certolizumab pegol alone or in combination with methotrexate • Secukinumab alone or in combination with methotrexate
Population(s)	Adults with active psoriatic arthritis whose disease has not responded adequately to previous disease-modifying anti-rheumatic drug therapy
Comparators	The interventions listed above will be compared with

	each other. For people who have only received 1 prior non-biological disease modifying anti-rheumatic drug (DMARD) • Disease modifying anti-rheumatic drugs For people whose disease has not responded adequately to at least 2 DMARDs: • Biological therapies (with or without methotrexate including etanercept, adalimumab, infliximab, golimumab, apremilast [subject to ongoing NICE appraisal], For people whose disease has not responded adequately to DMARDs and not adequately responded to biological therapies (including etanercept, adalimumab, infliximab and golimumab) or biological therapies are contraindicated: • Ustekinumab • Apremilast [subject to ongoing NICE appraisal] • 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 and cost of biosimilars should be taken into consideration.

	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: • 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: Technology Appraisal No. 340, June 2015, 'Ustekinumab for treating active psoriatic arthritis'. Review date June 2018 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' [ID682]. Anticipated publication date TBC. Related Guidelines: Clinical Guideline No. 153, October 2012. Psoriasis: assessment and management. Review Proposal Date December 2016. 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: Musculoskeletal conditions, Pathway last updated June 2015

	Musculoskeletal conditions, - NICE Pathways
Related National Policy	Department of Health 'NHS Outcomes Framework 2015-2016', Dec 2014. Domain 2.