NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Golimumab for the treatment of psoriatic arthritis

Final scope

Remit/appraisal objective

To appraise the clinical and cost-effectiveness of golimumab, within its licensed indication, for the treatment of psoriatic arthritis.

Background

Psoriatic arthritis (PsA, 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 PsA. The prevalence of psoriatic arthritis in the UK is estimated to be around 0.1% to 0.3% of the total population (50,000 to 156,000 people in England and Wales). It affects men and women equally and its incidence peaks between the ages of 30 and 55 years.

Although PsA is a chronic progressive condition, 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. When the spine is affected the condition may be indistinguishable from ankylosing spondylitis.

The relationship between the skin and joint manifestations is unclear. In 60% of people with the condition the psoriasis precedes the arthritis, in 25% of people the arthritis appears first and in 15% of people the symptoms occur simultaneously. People with severe arthritis can have little or no skin disease, and vice versa. Flare-ups of symptoms do not necessarily coincide.

PsA can significantly impair a person's quality of life and cause disability; both skin and joints can be affected and people with PsA report more 'role limitation' and body pain than people with rheumatoid arthritis.

Treatment for PsA aims to improve the psoriasis, arthritis or both. Mild PsA can be managed with non-steroidal anti-inflammatory drugs (NSAIDs) and physical therapy, with intra-articular corticosteroid injections when necessary. Disease modifying anti-rheumatic drugs (DMARDs), including azathioprine, methotrexate, sulphasalazine, ciclosporin and leflunomide, are additionally used in individuals with severe or progressive disease.

In addition, a tumour necrosis factor alpha (TNF-α) inhibitor may currently be used for the treatment of people with severe active PsA. NICE technology

appraisal guidance recommended etanercept or adalimumab (TA104 and TA125 respectively) when a person has peripheral arthritis with three or more tender joints and three or more swollen joints, and the PsA has not responded to at least two other DMARDs, given on their own or together. Guidance no 104 also recommended infliximab if the person satisfies the criteria for treatment with etanercept, but is either intolerant of, or has contraindications to, treatment with etanercept, or has major difficulties with self administered injections.

The technology

Golimumab (Centocor) is a high affinity, fully humanised monoclonal antibody that inhibits TNF-α. It is being developed for intravenous and subcutaneous administration. Golimumab is intended to be used with or without methotrexate to reduce signs and symptoms of structural damage.

Golimumab does not have a marketing authorisation for the treatment of psoriatic arthritis. It has been studied in clinical trials versus placebo in people with active psoriatic arthritis despite DMARD or NSAID therapy (and permitting doses of methotrexate, low-dose corticosteroids, and NSAIDs). Golimumab is expected to be positioned in the treatment pathway for psoriatic arthritis alongside etanercept, infliximab and adalimumab.

Intervention	• Golimumab
Population(s)	People with active and progressive psoriatic arthritis who have responded inadequately to previous DMARDs
Comparators	• Alternative TNF-α inhibitors • Conventional management strategies for active and progressive psoriatic arthritis that has responded inadequately to previous DMARD therapy or NSAIDs excluding TNF inhibitors.
Outcomes	The outcome measures to be considered include: • pain and other symptoms • functional capacity • effect on concomitant skin condition • joint damage • disease progression (e.g. imaging) • 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, subgroup analysis may be carried out according to the combined severity of psoriatic arthritis and the concomitant skin condition Where the evidence allows, sequencing of different drugs may be considered. Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 104, 2006, 'Etanercept and infliximab for the treatment of psoriatic arthritis' Technology Appraisal No. 125, 2007 'Adalimumab for the treatment of psoriatic arthritis' Technology Appraisal in preparation, 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of TA104 and TA125)'. Expected date of issue: July 2010