NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal (STA)

Golimumab for the treatment of rheumatoid arthritis after failure of previous disease-modifying antirheumatic drugs

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of golimumab within its licensed indication for the treatment of rheumatoid arthritis after failure of previous disease-modifying antirheumatic drugs.

Background

Rheumatoid arthritis is a chronic, disabling autoimmune disease characterised by inflammation of the synovial tissue of the peripheral joints, which causes swelling, stiffness, pain and progressive joint destruction. For a small proportion of people, inflammatory disease outside the joints (for example, eye and lung disease, vasculitis) can also pose a significant problem. Rheumatoid arthritis is heterogeneous, it is usually a chronic relapsing condition which has a pattern of flare-ups followed by periods of lower disease activity, but for a minority of people the disease is constantly progressive. Most people develop damage to affected joints due to inflammation with the amount of damage ranging from mild to severe. Rheumatoid arthritis can have a severe impact on quality of life and it is estimated that 40% of people with RA will stop working within 5 years of diagnosis.

Rheumatoid arthritis is three times more prevalent in women than in men. It can develop at any age, but usually starts between 40 and 60 years of age. Rheumatoid arthritis affects 1% of the population, or approximately 400,000 people in England and Wales. Of these, approximately 15% have severe disease.

People with rheumatoid arthritis are usually treated in an out-patient setting and then in primary care. There is no cure for rheumatoid arthritis and treatment aims to improve quality of life and to prevent or reduce joint damage. Treatment for rheumatoid arthritis usually includes: non-steroidal anti-inflammatory agents (NSAIDs) which reduce pain, fever and joint swelling / inflammation and disease modifying anti-rheumatic drugs (DMARDS) which slow the disease process and reduce joint damage. Corticosteroids may also be used to control inflammation. DMARDs are usually started soon after diagnosis. Methotrexate and sulfasalazine are two commonly used DMARDs. NICE guidance recommends the use of a TNF-α (tumour necrosis factor) inhibitor (adalimumab, etanercept, infliximab and certolizumab pegol), a type of biologic DMARD after the failure of two conventional DMARDs such as

methotrexate and sulfasalazine. NICE guidance recommends the use of rituximab (a biologic DMARD that depletes B cells) after the failure of a TNF-α inhibitor.

Surgery to replace or resurface damaged joints is also used (for example hip replacement/ re-surfacing) and physiotherapy is also often used as an adjunct treatment to increase or maintain mobility.

The technology

Golimumab (Simponi, Schering-Plough) is a fully humanised monoclonal antibody that inhibits TNF-α. Golimumab, in combination with methotrexate, has a marketing authorization for the treatment of moderate to severe active rheumatoid arthritis in adult patients when the response to DMARD therapy including methotrexate has been inadequate. It is administered subcutaneously.

Intervention(s)	Golimumab in combination with methotrexate
Population(s)	Adults with rheumatoid arthritis who have had an inadequate response to DMARDs.
Comparators	Management strategies involving DMARDs without golimumab, including treatment with: • conventional DMARDs (for example, sulfasalazine, leflunomide) • biological agents (including adalimumab, etanercept, infliximab, rituximab, tocilizumab*, certolizumab pegol, abatacept*). *Subject to ongoing appraisal

Outcomes	The outcome measures to be considered include: • disease activity • physical function • joint damage • pain • mortality • fatigue • radiological progression • extra-articular manifestations of disease • 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	If evidence allows, the appraisal will consider subgroups of people defined by the baseline severity of their RA. If the evidence allows, the appraisal will consider the costs of joint replacement therapy and hospital admissions. Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 141, April 2008, Abatacept for the treatment of rheumatoid arthritis. Currently subject to review. Technology Appraisal No.130, October 2007, Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis. Superseded technology appraisal No. 36. Expected review date September 2010.

	Technology Appraisal No. 126, August 2007, Rituximab for the treatment of rheumatoid arthritis. Currently subject to review. Technology Appraisal No.186, Feb 2010, Certolizumab pegol for the treatment of rheumatoid arthritis. Expected review date Sept 2010. Ongoing Technology Appraisals: Technology Appraisal in Preparation, Tocilizumab for the treatment of rheumatoid arthritis. Earliest anticipated date of publication TBC. Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor (combined with a review of technology appraisal guidance 126 [rituximab] and 141 [abatacept]). Earliest anticipated date for publication June 2010. Technology Appraisal in Preparation, Golimumab for the treatment of methotrexate-naïve rheumatoid arthritis. Suspended. Related Guidelines: Clinical Guideline No 79, February 2009, Rheumatoid arthritis: the management of rheumatoid arthritis in adults. Expected review date February 2012.