NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Golimumab for the treatment of rheumatoid arthritis

Draft scope (Pre-referral)

Draft remit/appraisal objective

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

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 in a minority of cases 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 has 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 inhibitor (adalimumab, etanetcept and infliximab), a type of biologic DMARD after the failure of two conventional DMARDs such as methotrexate and sulfasalazine.

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 (Centocor) is a fully humanised monoclonal antibody that inhibits TNF-α. It is being developed with both subcutaneous and intravenous formulations. It has been studied in clinical trials in adults with rheumatoid arthritis that are naive to methotrexate or who have active disease despite methotrexate therapy and/or other TNF-α inhibitor therapies.

Intervention(s)	Golimumab
Population(s)	Adults with rheumatoid arthritis
Standard comparators	Management strategies involving DMARDs without golimumab, including treatment with: • conventional DMARDs (for example methotrexate, sulfasalazine) • biologic DMARDs including adalimumab, etanercept, infliximab, rituximab
Outcomes	The outcome measures to be considered include: • disease activity • physical function • joint damage • pain • mortality • fatigue • 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	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 Technology Appraisal No.130, October 2007, Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis Technology Appraisal No. 126, August 2007, Rituximab for the treatment of rheumatoid arthritis Technology Appraisal No. 72, November 2003, The clinical effectiveness and cost effectiveness of anakinra for rheumatoid arthritis Ongoing Technology Appraisals: Technology Appraisal in Preparation, Certolizumab pegol for the treatment of rheumatoid arthritis (Earliest anticipated date of publication November 2009) Technology Appraisal in Preparation, Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis after the failure of the first TNF inhibitor (Earliest anticipated date of publication September 2008) Technology Appraisal in Preparation, Tocilizumab for the treatment of rheumatoid arthritis (Received a 'minded referral' as part of the 18th Wave in March 2008. Earliest anticipated date of publication TBC). Related Guidelines: Clinical Guideline in Preparation, Rheumatoid arthritis in adults (Earliest anticipated date of publication February 2009)

Questions for consultation

Have the most appropriate comparators for the treatment of golimumab been included in the scope?

- what is the potential place of golimumab in the pathway of care?

Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

Which process would be the most suitable for appraising this technology, the single technology or multiple technology process? (Information on these processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)