NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Golimumab for treating non-radiographic axial spondyloarthritis

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of golimumab within its marketing authorisation for treating non-radiographic axial spondyloarthritis.

Background

Axial spondyloarthritis belongs to a clinically heterogeneous group of inflammatory rheumatological diseases which share common genetic, histological and clinical features (also including psoriatic arthritis, arthritis associated with inflammatory bowel disease, reactive arthritis and undifferentiated spondyloarthritis). People with these diseases often have the genetic marker human leukocyte antigen (HLA)-B27. Axial spondyloarthritis involves inflammation of the sacroiliac joints and spine. If inflammation is visible on x-ray (as erosions, thickening of the bone, or fusion of joints), the disease is classified as ankylosing spondylitis. If x-rays of the sacroiliac joints and spine are normal, but there are other objective signs of inflammation (elevated C-reactive protein or evidence on magnetic resonance imaging) the disease is classified as non-radiographic axial spondyloarthritis.

The clinical symptoms of axial spondyloarthritis can vary from person to person, but usually develop slowly over several months or years. The main symptoms can include back pain, arthritis (inflammation of the joints in other parts of the body), enthesitis (inflammation where a bone is joined to a tendon), and fatigue. Extra-articular manifestations include uveitis, inflammatory bowel disease and psoriasis. The onset of symptoms typically occurs in the third decade of life, but it can be 7–10 years before a diagnosis is made.

Non-radiographic axial spondyloarthritis affects approximately equal numbers of men and women, but there are no data on the prevalence of the condition. Some people with non-radiographic axial spondyloarthritis will develop ankylosing spondylitis (about 10% of people over 2 years, and 50% over 10 years).[1,2] Around 200,000 people have been diagnosed with ankylosing spondylitis in the UK.[3,4]

Conventional therapy for non-radiographic axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy.

If a person's disease does not respond adequately to conventional therapy, or they cannot tolerate it, NICE technology appraisal 383 recommends the

tumour necrosis factor-alpha (TNF-alpha) inhibitors adalimumab, certolizumab pegol and etanercept as treatment options. The guidance makes recommendations about how to use these treatments.

The technology

Golimumab (Simponi, MSD) inhibits the pro-inflammatory cytokine TNF-alpha. Agents that inhibit the action of TNF-alpha may modify the inflammatory process of a disease. Golimumab is a monoclonal antibody and is administered by subcutaneous injection.

Golimumab has a UK marketing authorisation for treating adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation (including elevated C-reactive protein and/or evidence from magnetic resonance imaging) whose disease has responded inadequately to, or who are intolerant to, non-steroidal anti-inflammatory drugs.

Intervention(s)	Golimumab
Population(s)	People with severe active non-radiographic axial spondyloarthritis with objective signs of inflammation, whose disease has responded inadequately to, or who are intolerant to, non-steroidal anti-inflammatory drugs
Comparators	• Adalimumab • Certolizumab pegol • Etanercept
Outcomes	The outcome measures to be considered include: • disease activity • functional capacity • disease progression • pain • peripheral symptoms (including enthesitis, peripheral arthritis and dactylitis) • symptoms of extra-articular manifestations (including uveitis, inflammatory bowel disease and psoriasis) • adverse effects of treatment • health-related quality of life.

Economic analysis	A cost-comparison analysis should capture the relevant cost differences between the intervention and comparator(s) over a time horizon that is long enough to reflect materially important differences 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 should be taken into account.
Other considerations	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:** TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of technology appraisal 143 and technology appraisal 233) (2016). NICE Technology appraisal 383. Review date September 2018. **Guidelines in development:** Spondyloarthritis Publication expected February 2017 **Related NICE Pathways:** Arthritis NICE pathway (last updated June 2015)
Related National Policy	Department of Health NHS Outcomes Framework 2015-2016 (December 2014). Domains 1, 2, 4 and 5.

References

1. National Institute for Health and Clinical Excellence (2016) TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of technology appraisal 143 and technology appraisal 233) NICE technology appraisals guidance 383.

2. Siper J and Heijde van der D (2013) Non-radiographic axial spondyloarthritis. Arthritis and Rheumatism 65: 543–51

3. NHS choices website Ankylosing spondylitis. Accessed July 2015

4. Department of Health (2006) The musculoskeletal services framework. Department of Health. Accessed July 2015