NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Secukinumab for treating non-radiographic axial spondyloarthritis

Final scope

Remit/appraisal objective

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

Background

Axial spondyloarthritis belongs to a clinically heterogeneous group of inflammatory rheumatologic diseases which share common genetic, histological and clinical features (also including psoriatic arthritis, arthritis associated with inflammatory bowel disease, reactive arthritis and undifferentiated spondyloarthritis). 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 radiographic axial spondyloarthritis (also known 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 limited data on the prevalence of the condition. Some people with non-radiographic axial spondyloarthritis will develop radiographic axial spondyloarthritis (about 10% of people over 2 years, and 50% over 10 years[1,2]). Around 71,000 people have been diagnosed with radiographic axial spondyloarthritis in the UK, of which 20,000 are eligible for biologic therapies but it is unclear how many people there are with non-radiographic axial spondyloarthritis or how many people are yet to be diagnosed[1].

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

NICE technology appraisal guidance 383 and 497 recommend tumour necrosis factor-alpha inhibitors adalimumab, certolizumab pegol, etanercept and golimumab as treatment options in people with disease that does not respond adequately to or cannot tolerate NSAIDs.

The technology

Secukinumab (Cosentyx, Novartis) is a fully human monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine in the inflammatory pathway, resulting in a reduction in immune response. It is administered subcutaneously.

Secukinumab does not currently have a marketing authorisation in the UK for treating non-radiographic axial spondyloarthritis. It has been studied in clinical trials compared with placebo in people with non-radiographic axial spondyloarthritis.

Secukinumab has a marketing authorisation in the UK for treating active ankylosing spondylitis (also known as radiographic axial spondyloarthritis, NICE technology guidance 407) in adults whose disease has responded inadequately to conventional therapy or TNF-alpha inhibitors.

Intervention	Secukinumab
Population	People with 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 • Golimumab • Established clinical management without biological treatments

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	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out. 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 of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar products should be taken into account.

Other considerations	If the evidence allows consideration will be given to subgroups of people who have had or have not had prior exposure to biological therapy. 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:** 'Golimumab for treating non-radiographic axial spondyloarthritis' (2018) NICE technology appraisal 497. Review date December 2020. 'TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis' (2016) NICE technology appraisal 383. Review date June 2021. 'Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors' (2016) NICE technology appraisal 407. Review date September 2019. **Related Guidelines:** 'Spondyloarthritis in over 16s: diagnosis and managment' (2017) NICE guideline 65. Review date to be confirmed. **Related Quality Standards:** 'Spondyloarthritis'. NICE quality standard 170. Review date August 2019. **Related NICE Pathways:** 'Spondyloarthritis' (2017) NICE pathway
Related National Policy	NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1,2,4 and 5.

References

[1] National Institute for Health and Clinical Excellence (2015) 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

