NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Secukinumab for treating enthesitis-related arthritis or juvenile psoriatic arthritis

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of secukinumab within its marketing authorisation for treating enthesitis-related arthritis or juvenile psoriatic arthritis.

Background

Juvenile idiopathic arthritis (JIA) describes a group of conditions that involve joint inflammation which lasts for more than 6 weeks in people under 16 years of age. JIA causes pain, swelling and limitation of movement, which can change from day to day. When the condition becomes more active and the symptoms worsen, this is known as a 'flare'. In more severe cases, JIA can cause growth retardation, joint contractures, joint disease requiring joint replacements, eye problems and other extra-articular manifestations (such as inflammatory bowel disease and psoriasis), and permanent disability.

JIA can impair personal and social functioning and development. Children often miss out on schooling and other childhood activities, and as adults they may be limited in their ability to work. JIA may also have a considerable impact on the family of the child, including parents and carers who may need to miss work to take children to appointments. About 50% of children with JIA will not achieve remission from the condition, despite treatment, and will need further rheumatological care as adults[1].

A classification system for JIA has been developed by the International League of Associations for Rheumatology (ILAR)[2], with 7 categories of JIA. Enthesitis-related arthritis (ERA) is one of the ILAR categories, and is diagnosed when areas where tendons attach to the bones (entheses) are affected. Psoriatic arthritis (JPsA) is another JIA category, and is diagnosed when there is joint pain associated with psoriasis (a skin condition).

JIA has an annual incidence of 0.1 per 1,000 children in the UK[3] (equivalent to around 1,000 children diagnosed per year[4]). The prevalence of JIA is approximately 1 per 1,000 children[3]. This equates to about 10,000 children affected in the UK[4], however the condition may continue into adulthood, so there are also adults who have JIA. ERA accounts for 2 to 10% of new JIA diagnoses, and JPsA accounts for 2 to 15% of new JIA diagnoses[5].

Treatment for ERA and JPsA aims to control joint pain and inflammation; reduce joint damage, disability and loss of function; and maintain or improve quality of life. Standard treatment includes the use of the disease-modifying anti-rheumatic drugs (DMARDs), usually methotrexate, alongside intra-articular and systemic corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDS).

NICE has recommended etanercept, within its marketing authorisation, as an option for treating JPsA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate. NICE has also recommended adalimumab and etanercept, within their marketing authorisations, as options for treating ERA, that is, for people 6 years and older (adalimumab) and 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy (technology appraisal guidance 373).

The technology

Secukinumab (Cosentyx, Novartis) is a human monoclonal antibody which specifically inhibits the interleukin 17A (IL-17A) receptor. Secukinumab is administered by subcutaneous injection.

Secukinumab does not currently have a marketing authorisation in the UK for treating JPsA or ERA. It has been studied in a clinical trial as a monotherapy compared with placebo in children aged 2 to 17 who have JPsA or ERA, and whose disease has responded inadequately to, or who are intolerant of, 1 or more NSAID and 1 or more DMARD, excluding biologics.

Secukinumab has a UK marketing authorisation:

- for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.
- alone or in combination with methotrexate for the treatment of adults with active psoriatic arthritis whose disease has responded inadequately to previous DMARD therapy.

Intervention(s)	Secukinumab
Population(s)	People 2 years and older with enthesitis-related arthritis or juvenile psoriatic arthritis whose disease has responded inadequately to, or who are intolerant of, 1 or more NSAID and 1 or more DMARD
Comparators	For people eligible for currently available biologic DMARDs: • adalimumab • etanercept For people ineligible for currently available biologic DMARDs: • Best supportive care.
Outcomes	The outcome measures to be considered include: • disease activity (including disease flares and remission) • physical function • joint damage • body weight and height

	• pain • corticosteroid sparing • mortality • 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.
Other considerations	If the evidence allows the following subgroups will be considered: • People with enthesitis-related arthritis • People with juvenile psoriatic arthritis The availability and cost of biosimilar products should be taken into account. 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: Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs (2017) NICE Technology Appraisal 445. Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis' (2015). NICE Technology Appraisal 373. Appraisals in development (including suspended appraisals)

	'Anakinra for treating active Stills disease' NICE technology appraisals guidance [ID1463]. Publication date to be confirmed. Terminated appraisals: 'Canakinumab for treating systemic juvenile idiopathic arthritis' (terminated appraisal) (2013). NICE Technology Appraisal 302. Related NICE Pathways: Musculoskeletal conditions (2013) NICE pathway http://pathways.nice.org.uk/pathways/musculoskeletal-conditions
Related National Policy	NHS England (2015) Clinical Commissioning Policy Statement: Biologic Therapies for the treatment of Juvenile Idiopathic Arthritis (JIA) The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Section 138. Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2 to 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Have all relevant comparators for secukinumab been included in the scope? In particular:

- Which treatments are considered to be established clinical practice in the NHS for people with ERA or JPsA whose disease has responded inadequately to, or who are intolerant of, 1 or more NSAID and 1 or more DMARD?

- Is best supportive care a relevant comparator for secukinumab? If so, how should best supportive care be defined?

Are the outcomes listed appropriate?

Is the population listed in the scope appropriate?

Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom secukinumab is expected to be more clinically effective and cost effective, or other groups that should be examined separately?

Where do you consider secukinumab will fit into the existing NICE pathway, Musculoskeletal conditions?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected

characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which secukinumab will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider secukinumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of secukinumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Minden K, Kiessling U, Listing J, et al. (2000) Prognosis of patients with juvenile chronic arthritis and juvenile spondyloarthropathy. Journal of Rheumatology 27:2256–63

2. Petty R, et al. (2004) International League of Associations for Rheumatology Classification of Juvenile Idiopathic Arthritis: Second Revision, Edmonton, 2001. Journal of Rheumatology 31(2):390-2

3. CCAA. About Juvenile Idiopathic Arthritis (JIA). Accessed June 2020

4. Office for National Statistics. National population projections: 2018-based. Accessed June 2020

5. Patient (2018). Juvenile Idiopathic Arthritis. Accessed June 2020