Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

NICE Technology Appraisals: Local implementation

NICE TA Guidance name and number	Secukinumab for treating non-radiographic axial spondyloarthritis TA719		
Available at	www.nice.org.uk/guidance/ta719		
Date of issue	21 July 2021	**Implementation deadline**	21 October 2021

Medicine details[1]	
Name, brand name and manufacturer	Secukinumab (Cosentyx®) Novartis Pharmaceuticals Ltd
Mode of action	Secukinumab is a fully human IgG1/κ monoclonal antibody that selectively binds to and neutralises the proinflammatory cytokine interleukin-17A (IL-17A). Secukinumab works by targeting IL-17A and inhibiting its interaction with the IL-17 receptor.
Licensed indication	Cosentyx® is indicated for the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).
Formulation	Solution for injection in pre-filled pen and syringes.
Usual dosage	The recommended dose is 150 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing.
Comparison with NICE TA use[2]	This is the same recommended dose and schedule as the NICE TA. *This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the license following NICE publication will need to be considered by the Area Prescribing Committee and **will not be routinely funded** by local commissioners.*

Disease and potential patient group	
Brief description of disease[2,3]	Axial Spondyloarthritis - also known as axSpA or axial SpA - is a painful, chronic arthritis that mainly affects the joints of the spine. It can also affect other joints in the body, as well as tendons and ligaments. Axial Spondyloarthritis may be difficult to diagnose as it cannot always be identified on x-rays or MRI scans of the back. If arthritis of the sacroiliac joints (pelvis) or spine can be seen on x-ray, the term used is **radiographic axial Spondyloarthritis** (r-axSpA). This condition was previously called Ankylosing Spondylitis (AS) and today, both terms (r-axSpA and AS) are used interchangeably. If there are no signs of sacroiliitis on x-ray but there is evidence of inflammation in the joints on MRI, the term used is **non-radiographic axial Spondyloarthritis** (nr-axSpA). There can be a delay in diagnosis because of non-specific symptoms, an absence of visible structural damage on X-rays, and normal or ambiguous MRI results. They noted that the condition can be mistaken for other conditions such as fibromyalgia.

<table>
<tr><td></td><td>This delay in diagnosis can result in high functional impairment (difficulties doing day-to-day activities). Almost half of people with non-radiographic axial spondyloarthritis progress to the radiographic version of the disease over a period of 8 to 10 years.

People with axial spondyloarthritis report that it profoundly affects their quality of life and day-to-day activities, such as work.</td></tr>
<tr><td>Potential patient numbers per 100,000[4]</td><td>Table 1: Potential patient numbers per 100,000 adult population for NHS Surrey Heartlands CCG:
<table>
<tr><th></th><th>r-axSpA / AS</th><th>nr-axSpA</th></tr>
<tr><td>Total population, all ages</td><td colspan="2">1,049,170</td></tr>
<tr><td>Adult population</td><td colspan="2">815,884</td></tr>
<tr><td>Prevalence</td><td>1,942</td><td>1,224</td></tr>
<tr><td>Patient numbers per 100,000 adult population</td><td>238</td><td>150</td></tr>
<tr><td>People eligible for treatment with bDMARDs</td><td>777</td><td>465</td></tr>
<tr><td>Patient numbers per 100,000 adult population</td><td>95</td><td>57</td></tr>
<tr><td>People expected to continue treatment</td><td>466</td><td>140</td></tr>
<tr><td>Patient numbers per 100,000 adult population</td><td>57</td><td>17</td></tr>
</table>
Please note:
• Secukinumab is already commissioned for use in r-axSpA under TA 407, ‘Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors’, published in September 2016.</td></tr>
</table>

SUMMARY

Guidance[2]

1.1 Secukinumab is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) in adults. It is recommended only if:
- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough and
- the company provides secukinumab according to the commercial arrangement.

1.2 Assess response to secukinumab after 16 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:
- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

1.3 Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires, and make any appropriate adjustments.

1.4 These recommendations are not intended to affect treatment with secukinumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician

consider it appropriate to stop.

Please note:

- *Secukinumab was not previously licensed for use in nr-axSpA.*
- *Use in r-axSpA is already commissioned.*

Why the committee made these recommendations

Treatment for non-radiographic axial spondyloarthritis that is not controlled well enough with NSAIDs is limited to TNF-alpha inhibitors (adalimumab, certolizumab pegol, etanercept and golimumab). There are no treatment options when people cannot have TNF-alpha inhibitors, or if TNF-alpha inhibitors have not worked well enough.

Clinical trial evidence shows that secukinumab is effective compared with placebo. There are no trials directly comparing secukinumab with TNF-alpha inhibitors. But an indirect comparison suggests that secukinumab may be less effective than TNF-alpha inhibitors. However, this evidence is uncertain.

Different TNF-alpha inhibitors have different costs but similar effectiveness. When more than one TNF-alpha inhibitor is suitable, the cheapest is used, currently adalimumab biosimilar. Because of this, secukinumab is not a cost-effective use of NHS resources when compared with TNF-alpha inhibitors. Secukinumab is only considered to be cost effective for people who cannot have TNF-alpha inhibitors, or when TNF-alpha inhibitors have not worked well enough. Therefore, it is recommended in these situations.

Cost implications* [2,3,4]

Cost:
The list price is £1,218.78 for 2 pre-filled pens or syringes containing 150 mg per 1 ml solution (excluding VAT, BNF online accessed March 2021).

The company has a commercial arrangement. This makes secukinumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Annual or monthly cost per patient:
Annual cost of treatment for the first year is £9,750.24 and subsequent years is £7,312.68.

Has dose escalation been considered as part of the NICE costing template?
No.

Costing information per CCG:

1. NICE resource impact statement
No significant resource impact is anticipated.

'We do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or £9,000 per 100,000 population).

This is because the technology is a further treatment option, the overall cost of treatment will be similar and we do not think practice will change substantially as a result of this guidance'.

Availability of PAS and details (if appropriate):
Yes - the PAS price will be given to trusts which would reduce the cost price stated above.

Availability of homecare service (if appropriate): Yes

**NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.*

2. NICE resource impact template

Despite the NICE resource impact statement that no significant resource impact is anticipated, local modelling (using the NICE resource impact template) shows that for the use of **both** secukinumab and ixekizumab (same resource template) for **both** r-axSpA and nr-axSpA, the resource impact for NHS Surrey Heartlands CCG in 5 years is:

Indication	Cost	Cost/100,000 per adult CCG population
r-axSpA	£291,737	£27,806
nr-axSpA	£40,027	£3,815
axSpA	£331,764	£31,622

The cost per place of **both** secukinumab and ixekizumab for **both** r-axSpA and nr-axSpA is:

	Total population	Cost
East Surrey	188 122	£ 59,487
Guildford & Waverly	210 752	£ 66,643
North West Surrey	350 153	£ 110,724
Surrey Downs	294 255	£ 93,048
NHS Surrey Heartlands CCG	1 049 170	£ 331,764

Please note:

- *Use of secukinumab in r-axSpA is already commissioned.*
- *The costs will be mitigated by the locally agreed pathway as both are IL-17A inhibitors*

1. Accuracy of the NICE resource impact template.

This depends on the estimates of future practice and the phasing of future practice over 5 years and therefore open to huge variance.

Alternative treatments and cost per patient per year

Other NICE recommended products:

Table 2: Differences in licensing and relevant NICE TAs

Technology	Licensed for nr-axSpA	NICE TA*	Cost effectiveness choice
Adalimumab	✓	TA383	1st (biosimilar)
Certolizumab	✓	TA383	
Etanercept	✓	TA383	2nd (biosimilar)
Golimumab	✓	TA497	
Infliximab	×	×	
Ixekizumab	✓	TA718	

*NICE Technology appraisal guidance:

NICE TA	Technology	Publication date
TA383	TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis	February 2016
TA497	Golimumab for treating non-radiographic axial spondyloarthritis	January 2018
TA718	Ixekisumab for treating axial spondyloarthritis	July 2021

Options not reviewed by NICE but used in standard practice:

The first treatment is with non-steroidal anti-inflammatory drugs (NSAIDs). The current pathway states that patient has to have had adequate therapeutic trials of at least 2 NSAIDs

before bDMARDs.

Impact to patients

- An additional treatment option with a different mechanism of action would be valued by patients.
- This medicine is available under a homecare service so will be delivered directly to the patient.

Impact to primary care prescribers

- This is a National Tariff excluded high-cost drug (NTexHCD) and is commissioned by CCGs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Impact to secondary care

- The initiation, administration and on-going treatment is managed by secondary care.
- Homecare arrangements will be managed by the trust.
- This medicine is available on homecare.
- An additional treatment option with a different mechanism of action would be valued by clinicians.

Impact to CCGs

- The technology is commissioned by clinical commissioning groups (CCGs), and they are required to comply with the recommendations in a NICE TA within 3 months of its date of publication.
- Providers are NHS hospital trusts.
- Potential savings for out-patient appointments as this medicine is available on homecare.

Implementation

- NICE TA implementation must be within 90 days of publication
- Blueteq forms to be developed
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare
- Pathway to be discussed at Rheumatology Network. Points to consider:
  - Place of secukinumab in the pathway as it is only considered to be cost effective for people who cannot have TNF-alpha inhibitors (first line), or when TNF-alpha inhibitors have not worked well enough (second or subsequent lines after TNF-alpha inhibitors).
  - Choice of therapy:
    - Take into consideration that the TA states that 'different TNF-alpha inhibitors have different costs but similar effectiveness. When more than one TNF-alpha inhibitor is suitable, the cheapest is used, currently adalimumab biosimilar.'
    - The second choice is usually etanercept biosimilar when the adalimumab biosimilar is unsuitable or has failed.
    - Within the NICE TA, the company stated that the clinical efficacy of secukinumab is not expected to differ substantially from TNF-alpha inhibitors, which the clinical expert supported.
    - The committee did not consider secukinumab to be cost effective compared with TNF-alpha inhibitors for treating nr-axSpA.
  - Preference of secukinumab in people with nr-axSpA who also have psoriasis, as secukinumab is more effective than TNF-alpha inhibitors for treating psoriasis.
  - Golimumab now has a NICE TA for treating nr-axSpA.
  - Ixekizumab, another IL-17, is also available for use in nr-axSpA.

Recommendation to PCN
National Tariff excluded high-cost drug (NTexHCD): Yes **Recommended traffic light status:** Red

References:

1 Secukinumab. Specification of Product Characteristics. emc. https://www.medicines.org.uk/emc/product/3669/smpc# Available at: Accessed <2.8.21>

2 NICE Technology Appraisal Guidance: Secukinumab for treating non-radiographic axial spondyloarthritis. Available at: www.nice.org.uk/guidance/ta719 Accessed <2.8.21>

3 Axial Spondyloarthritis. The Leeds Teaching Hospitals NHS Trust. Chapel Allerton Hospital. Available at: https://www.leedsth.nhs.uk/a-z-of-services/rheumatology/specialist-spondyloarthritis-service/axial-spondyloarthritis/ Accessed <2.8.21>

4 NICE Resource impact report. Available at: https://www.nice.org.uk/guidance/ta719/resources Accessed <3.8.21>

	Name	Role	Date	Declaration of interests (please give details below table)
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Explanation of declaration of interest:
None.