NICE National Institute for Health and Care Excellence

NICE guidance

Secukinumab for treating non-radiographic axial spondyloarthritis

Technology appraisal guidance

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Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance are at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

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.

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.

2 Information about secukinumab

Marketing authorisation indication

2.1 Secukinumab (Cosentyx, Novartis) 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) in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs)'.

Dosage in the marketing authorisation

2.2 The dosage schedule is in the summary of product characteristics.

Price

2.3 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). Annual cost of treatment for the first year is £9,750.24 and subsequent years is £7,312.68. 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.

3 Committee discussion

The appraisal committee considered evidence submitted by Novartis, a review of this submission by the evidence review group (ERG), NICE's technical report, and responses from stakeholders. See the committee papers for full details of the evidence.

The appraisal committee was aware that several issues were resolved during the technical engagement stage, and agreed that:

- In the PREVENT trial, the response criteria used to determine continuing treatment beyond 12 weeks are different from the response criteria used in the NHS, but it is appropriate to use data from this trial in the model.
- Although PREVENT assessed secukinumab with and without a loading dose, the load-dose regimen is the regimen licensed for use in the UK. Therefore, the results from the load-dose arm of PREVENT are generalisable to how secukinumab would be used in NHS clinical practice.
- Trial evidence suggests that there may be differences in efficacy in certain subgroups of the trial population. However, because PREVENT was not powered to detect differences between subgroups based on MRI or C-reactive protein status, it is not possible to conclude that there is genuine heterogeneity in treatment effect. Therefore, the cost-effectiveness results in these subgroups are not relevant for decision making.

There were remaining areas of uncertainty associated with the analyses presented, which were considered further by the committee. The appraisal committee discussed the following issues (issues 1, 2, 6, 7, 8 and 9 from the technical report), which were outstanding after the technical engagement stage.

Clinical need and current management

Non-radiographic axial spondyloarthritis causes pain, reduced mobility and affects quality of life

3.1 Axial spondyloarthritis is a chronic rheumatic condition characterised by inflammation at the sacroiliac joints and spine, although other joints can be affected. It can be associated with other conditions affecting the eyes, bowel and skin. Axial spondyloarthritis is an umbrella term encompassing both non-

radiographic axial spondyloarthritis and radiographic axial spondyloarthritis (also known as ankylosing spondylitis). Non-radiographic means that a person has symptoms but the condition cannot be identified on an X-ray. It is a painful and debilitating condition and is considered incurable with current treatments. The clinical experts explained that although the disease burden is variable, progressive spinal pain, immobility and disability experienced by people with non-radiographic axial spondyloarthritis substantially affects their quality of life and mental wellbeing. The clinical experts noted that 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. 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.

People would welcome a new treatment option that works differently to TNF-alpha inhibitors

3.2 NICE's guideline on spondyloarthritis in over 16s recommends that the first treatment for people with non-radiographic axial spondyloarthritis is physical therapy and first-line pharmacological treatment with non-steroidal anti-inflammatory drugs (NSAIDs). For disease that responds inadequately to NSAIDs, or if these are not tolerated, NICE recommends tumour necrosis factor (TNF)-alpha inhibitors (see NICE's technology appraisal guidance on TNF-alpha inhibitors and golimumab) as options for treating severe non-radiographic axial spondyloarthritis. If the first TNF-alpha inhibitor is not tolerated, or the person's condition has not responded or stops responding, NICE's technology appraisal guidance on TNF-alpha inhibitors recommends treatment with another TNF-alpha inhibitor. The committee recalled that in previous technology appraisals for axial spondyloarthritis, clinical experts stated that the response criteria used in clinical practice for deciding to continue treatment were:

- 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.

The clinical expert explained that secukinumab is an additional treatment option when TNF-alpha inhibitors are not suitable, or when the disease has not responded or stopped responding to TNF-alpha inhibitors. The clinical expert explained that if a person's disease responded to a first TNF-alpha inhibitor, it would likely respond to another TNF-alpha inhibitor. However, they noted that for disease that has had an inadequate response to TNF-alpha inhibitors, it is preferable to try a new treatment option with an alternative mechanism of action. The clinical expert also noted that some people with non-radiographic axial spondyloarthritis also have psoriasis and explained that secukinumab is more effective than TNF-alpha inhibitors for treating psoriasis. The committee concluded that people with non-radiographic axial spondyloarthritis would welcome a new treatment option with a different mechanism of action.

Secukinumab can be used first line or second line after NSAIDs, but TNF-alpha inhibitors would likely be used first, unless unsuitable

3.3 The company noted that the marketing authorisation for secukinumab does not limit its use to a particular line of treatment. The ERG considered it unlikely that secukinumab would be the first-line biologic of choice, given the extensive clinical experience with TNF-alpha inhibitors and the lower price of biosimilar versions now available. It noted that secukinumab was more likely to be used as a second-line treatment after TNF-alpha inhibitors. The clinical experts explained that in line with NICE guidance, when more than 1 treatment is suitable, clinicians generally consider the least expensive treatment (taking into account administration costs and patient access schemes). Currently, the adalimumab biosimilar is usually the first-line biologic used when the disease has not responded to NSAIDs. The second choice is usually etanercept biosimilar when the adalimumab biosimilar is unsuitable or has failed. The committee concluded that secukinumab is licensed as a first-line or second-line treatment option after NSAIDs have not worked well enough. However, clinicians are more likely to choose a TNF-alpha inhibitor as the first biologic treatment unless these are contraindicated or unsuitable.

Clinical evidence

Secukinumab increases the proportion of people having an ASAS 40 response compared with placebo when used as first-line treatment

3.4 PREVENT is a multicentre double-blind randomised placebo-controlled trial comparing 150 mg secukinumab with a loading dose (an initial higher dose of a drug given at the beginning of a course of treatment; n=185) with placebo (n=186). It included adults with axial spondyloarthritis who fulfilled the Assessment of Spondylarthritis International Society (ASAS) classification criteria for axial spondyloarthritis, with abnormal C-reactive protein or MRI, and no radiographic evidence of changes in the sacroiliac joints. As such, the disease also fulfilled the modified New York criteria for non-radiographic axial spondyloarthritis. The primary outcome measure is the proportion of patients who have not had a TNF-alpha inhibitor before who had an ASAS 40 response (improvement of at least 40% in the ASAS, improvement in at least 2 units in 3 of the 4 main domains of ASAS and no worsening in the remaining domains) at week 16. Secukinumab increased the proportion of people who had an ASAS 40 response compared with placebo (odds ratio 1.72, $p<0.0197$; 95% confidence intervals are confidential and cannot be reported here). The proportion of patients whose BASDAI score improved by 50% from baseline (BASDAI 50), and the change in Bath Ankylosing Spondylitis Functional Index (BASFI) score from baseline, were collected as secondary endpoints. Secukinumab improved these outcomes compared with placebo. The committee concluded that, compared with placebo, secukinumab increases the proportion of people having an ASAS 40 response, BASDAI 50 response and improved function as assessed by BASFI.

There are limited clinical-effectiveness data for secukinumab used after a TNF-alpha inhibitor, but it is likely to be effective

3.5 Less than 10% of the population in PREVENT had previously had treatment with a TNF-alpha inhibitor before being randomised to the trial. The committee noted that, as a result, there is limited evidence about how effective secukinumab is when used after a TNF-alpha inhibitor has failed. The ERG acknowledged that the relative effect estimates of secukinumab compared with placebo were similar for people who had a TNF-alpha inhibitor before and those who had not. However, it noted that PREVENT was not powered to detect

differences between these subgroups. The committee concluded that there are limited data from PREVENT to measure the clinical effectiveness of secukinumab when used after a TNF-alpha inhibitor. It further concluded that secukinumab was likely to be clinically effective compared with placebo in this situation.

People in PREVENT may have more functional impairment than people in similar trials, or those who would have secukinumab in the NHS

3.6 The ERG noted that the mean baseline BASFI score (around 6) in the PREVENT trial population is higher than in other clinical trials in this disease area, and possibly higher than would be expected in clinical practice. This suggested a high functional impairment in the trial population. The company considered that, because BASFI scores are a predictor of response, treatment effect estimates for secukinumab from PREVENT can be considered conservative. This is because people with higher baseline BASFI scores (more functional impairment) may be less likely to have a good response to treatment than people with less functional impairment at baseline. The committee concluded that a higher baseline BASFI score in the trial population may affect the comparison with TNF-alpha inhibitors and the generalisability of trial results to NHS clinical practice.

No data were presented for people for whom TNF-alpha inhibitors are unsuitable, where the alternative would be conventional care

3.7 The committee noted that there will be people for whom TNF-alpha inhibitors are unsuitable for a variety of reasons, either first line or second line. According to the clinical experts, this was the group most likely to be offered secukinumab in clinical practice. The committee considered that for these people the alternative is conventional care (NSAIDs and physical therapies) without treatment with biologics. The committee noted that no data had been presented specifically for this subgroup.

The company's network meta-analysis

The company's network meta-analysis cannot exclude the

possibility that secukinumab may be less effective than TNF-alpha inhibitors

3.8 There were no trials directly comparing secukinumab with TNF-alpha inhibitors. Therefore, the company did a network meta-analysis to estimate the relative effectiveness of secukinumab compared with the relevant TNF-alpha inhibitors (etanercept, adalimumab, golimumab and certolizumab pegol). The company's base-case analysis was based on the joint modelling approach used in NICE's technology appraisal guidance on TNF-alpha inhibitors. It compared secukinumab with each individual TNF-alpha inhibitor, and with TNF-alpha inhibitors as a drug class. The committee recalled that NICE's technology appraisal guidance on TNF-alpha inhibitors concluded that, because of the lack of difference in treatment effect, TNF-alpha inhibitors should be considered as a class with broadly similar, if not identical, effects. The committee agreed that it was appropriate to consider the comparison with TNF-alpha inhibitors as a class. Numerical results from the network meta-analyses are confidential and cannot be reported here, but point estimates for secukinumab were lower for some outcomes compared with TNF-alpha inhibitors as a class. The committee noted that credible intervals around these estimates were wide and there were no statistically significant differences. Several sources of heterogeneity across the trials, such as differences in placebo response rates and baseline characteristics, were identified. These may have affected the results of the network meta-analyses, but because of a lack of data it was not possible to test whether the results were biased against secukinumab. The ERG considered that the company's network meta-analysis was appropriate but noted that because there were only a few trials included, it was not possible to check for consistency in the network or estimate heterogeneity between the studies. 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 acknowledged that this was in line with the committee conclusion in NICE's technology appraisal guidance on secukinumab for active ankylosing spondylitis. The committee concluded that the results of the company's network meta-analysis were uncertain and it could not exclude the possibility that secukinumab may be less effective than TNF-alpha inhibitors.

The company's economic model

The model structure is appropriate for decision making

3.9 The company modelled costs and quality-adjusted life years (QALYs) for secukinumab, TNF-alpha inhibitors (individually and as a class) and conventional care (NSAIDs and physical therapies) using a short-term decision tree followed by a long-term Markov model. The decision tree covered the induction period until response to treatment was assessed at 12 weeks for TNF-alpha inhibitors or at 16 weeks for secukinumab. People with disease response during the induction period continued with the same biologic therapy and entered the 3 state Markov model in the 'biologic treatment' health state. People whose disease did not respond stopped initial treatment and started in the 'conventional care' health state. The model structure and most model parameters (excluding treatment effectiveness parameters) were the same as in NICE's technology appraisal guidance on TNF-alpha inhibitors. The ERG considered the model structure to be appropriate. However, it noted that the primary analysis modelled by the company only included the population in PREVENT who had not had TNF-alpha inhibitors before, so related only to first-line use of secukinumab. The company also presented a secondary analysis, which included the small subgroup of people in PREVENT who had treatment with 1 TNF-alpha inhibitor before. No base-case analysis for the subgroup who cannot have TNF-alpha inhibitors was presented by the company. The response criterion used in the company model was the proportion of people with a BASDAI 50 response. Changes in BASDAI and BASFI after starting treatment were informed by results from the company's network meta-analysis. The committee concluded that the structure of the company's model was appropriate for decision making.

Adalimumab biosimilar costs best represent the costs for first-line use of TNF-alpha inhibitors as a class

3.10 The committee recalled that it considered the TNF-alpha inhibitors as a class because they have broadly similar clinical effectiveness (see section 3.8). However, it noted that TNF-alpha inhibitors have very different costs. The company and ERG used different assumptions to estimate the cost of TNF-alpha inhibitors. The company used confidential market share information to estimate an average cost of TNF-alpha inhibitors. The ERG considered that the

company's market share information was not representative of the expected current first-line use of TNF-alpha inhibitors in clinical practice. It explained that the cheapest TNF-alpha inhibitor was the adalimumab biosimilar. This became available in late 2018 and its use in the NHS is expected to keep increasing. The clinical expert agreed that the adalimumab biosimilar is the cheapest and most widely used TNF-alpha inhibitor in the NHS and should be considered the relevant comparator for first-line use of secukinumab. The company agreed that the adalimumab biosimilar is the most widely used TNF-alpha inhibitor in clinical practice for treating non-radiographic axial spondyloarthritis. However, it considered it inappropriate to use the cost of the adalimumab biosimilar to represent the costs for TNF-alpha inhibitors as a class, because some people do not have adalimumab first line. At the appraisal consultation stage a consultee commented that NHS England expected an uptake of less than 100% for the adalimumab biosimilar for first-line and second-line use across all of its indications. The committee noted that NICE's technology appraisal guidance on TNF-alpha inhibitors states that when more than 1 TNF-alpha inhibitor is suitable, the least expensive should be used. It agreed that this guidance is being implemented, and the lower cost of adalimumab biosimilar means that it is now the first choice TNF-alpha inhibitor for treating non-radiographic axial spondyloarthritis. It heard that if another TNF-alpha inhibitor were used (usually after failure of the first TNF-alpha inhibitor), another biosimilar, etanercept, would be second choice. The committee concluded that in clinical practice, people having a TNF-alpha inhibitor for non-radiographic axial spondyloarthritis are most likely to start taking adalimumab biosimilar. The more expensive branded agents would only be used first line if there was a specific reason relating to an individual's circumstances. It further concluded that, given NICE guidance on using the cheapest drug and expert information about the current use of TNF-alpha inhibitors in clinical practice, adalimumab biosimilar costs were representative of the costs of first-line use of TNF-alpha inhibitors as a class.

The use of common or conditional baselines in the economic model is an area of uncertainty

3.11 The company's base-case model assumed that baseline BASDAI and BASFI scores are conditional on response. This meant that people modelled to have a BASDAI 50 response had different baseline BASDAI and BASFI scores than those modelled to not have a response. This was based on observations from

clinical trials of secukinumab (PREVENT) and adalimumab (ABILITY-1), which showed that people who had a BASDAI 50 response had lower baseline BASFI and BASDAI scores than people whose disease did not respond. However, the committee recalled the preference in NICE's technology appraisal guidance on TNF-alpha inhibitors for common baselines. This was because there was no evidence showing that people with more severe disease were less likely to have a clinically meaningful benefit with TNF-alpha inhibitors than people with less severe disease. The ERG commented that, when using the measures of disease response used to decide whether to continue treatment in UK clinical practice (see section 3.2), differences in baseline BASDAI score between people with disease response and those without may be less likely. The committee concluded that the use of common or conditional baselines in the economic model was an area of substantial uncertainty.

Modelling a further line of treatment after secukinumab or a TNF-alpha inhibitor reflects the treatment pathway, but relies on common baselines

3.12 The company's base-case model did not consider further treatment with a biologic after first-line treatment with secukinumab or a TNF-alpha inhibitor. After treatment with secukinumab or a TNF-alpha inhibitor, the company initially assumed that people would have conventional care. The committee noted that this did not reflect clinical practice because people may go on to have another biologic treatment. The company did a scenario analysis in which it developed a sequence model. This compared secukinumab followed by a TNF-alpha inhibitor with a TNF-alpha inhibitor followed by a second TNF-alpha inhibitor. The ERG noted that there were errors in how the company had modelled underlying disease activity and that it was inappropriate to use conditional baselines in a sequence model. Therefore, the ERG modelled a sequence of treatments using common baselines. This assumed that if secukinumab is used first line, then adalimumab biosimilar would be the next treatment. This sequence was compared with adalimumab followed by biosimilar etanercept (the second cheapest TNF-alpha inhibitor after adalimumab). The committee concluded that a sequence model better reflects the treatment pathway. However, it noted that this relied on using common baselines, which was not favoured by the company or the ERG and is an area of uncertainty.

Results for the second-line use of both secukinumab and TNF-alpha inhibitors are uncertain because of limited evidence

3.13 The ERG highlighted that TNF-alpha inhibitors are relevant comparators for second-line secukinumab. It acknowledged that there is limited randomised data available to inform cost-effectiveness estimates. The committee noted that the baseline characteristics of people starting second-line treatment in the economic model were based on the subgroup of people who had a TNF-alpha inhibitor before in PREVENT. The ERG considered that estimates from the DANBIO registry, a registry of biologics in Denmark, were more reliable than results from this small subgroup. The company argued that the randomised data available provided more robust evidence than the DANBIO registry, which did not have a control arm. The committee concluded that because of the limited evidence available, results for second-line use of both secukinumab and TNF-alpha inhibitors are uncertain.

Cost-effectiveness results

Secukinumab is more costly and less effective than TNF-alpha inhibitors

3.14 The committee noted that there is a confidential patient access scheme (PAS) for secukinumab. Some of the TNF-alpha inhibitors are available to the NHS at a confidential discount and the exact incremental costs and QALYs cannot be reported here. The committee noted that:

- Secukinumab was less costly and less effective than TNF-alpha inhibitors in the:
  - company base case, which compared secukinumab with TNF-alpha inhibitors as a class (with modelling errors corrected by the ERG). This analysis used market share estimates of TNF-alpha inhibitors to estimate an average of TNF-alpha inhibitor costs (see section 3.10)
  - ERG's exploratory base case for secukinumab as a second-line treatment. This analysis used the cost of etanercept biosimilar for the second-line TNF-alpha inhibitor (see section 3.13).

- Secukinumab was more costly and less effective in the:
  - company base case, which compared secukinumab with TNF-alpha inhibitors as a class (without modelling errors corrected by the ERG; see section 3.10)
  - ERG exploratory base case, which compared secukinumab with TNF-alpha inhibitors as a class and used the costs of adalimumab biosimilar for the TNF-alpha inhibitor costs (see section 3.10)
  - ERG sequence model with common baselines. This used the costs of adalimumab biosimilar for the first TNF-alpha inhibitor, and used the costs of etanercept biosimilar for the second TNF-alpha inhibitor. Adalimumab biosimilar was assumed to be the next treatment after secukinumab (see section 3.12).

    The committee concluded that secukinumab had fewer QALYs in all the company and ERG's analyses. The committee noted that in analyses where the cost of biosimilar adalimumab is assumed for all TNF-alpha inhibitors, the costs of secukinumab were also higher than TNF-alpha inhibitors. For the full population covered by the marketing authorisation, the committee did not consider secukinumab to be cost effective compared with TNF-alpha inhibitors for treating non-radiographic axial spondyloarthritis.

Secukinumab is cost effective for people who would otherwise have conventional care

3.15 Compared with conventional care, secukinumab gave incremental cost-effectiveness ratios (ICERs) of:

- £5,413 per QALY gained in the company base case (with modelling errors corrected by the ERG)
- £8,399 per QALY gained in the ERG exploratory base case
- £7,727 per QALY gained using the ERG exploratory base-case assumptions but assuming common baselines

- £19,421 per QALY gained in the ERG exploratory base case for second-line treatments.

  The committee noted that these estimates were for the whole population, not just people for whom TNF-alpha inhibitors were contraindicated or unsuitable. There were no data to determine if these results would be different in the subgroup of people who cannot have TNF-alpha inhibitors or whose condition had not responded to a TNF-alpha inhibitor. However, given the ICERs were lower than £20,000 compared with conventional care in the whole population, it was reasonable to consider secukinumab a cost-effective use of NHS resources for people who would otherwise have conventional care.

Conclusion

Secukinumab is likely to be cost effective only if TNF-alpha inhibitors do not work or are not suitable, so it is recommended in these situations

3.16 The committee considered the whole population who can have TNF-alpha inhibitors and noted that, considering the PAS price for secukinumab and the discounted NHS Commercial Medicines Unit prices for adalimumab biosimilar and etanercept biosimilar, secukinumab was not cost effective. It recalled that secukinumab gave fewer QALYs than biosimilar TNF-alpha inhibitors. It also noted that the costs for secukinumab were higher than biosimilar TNF-alpha inhibitors, which are used first line when 1 or more inhibitors are suitable, because of their lower cost. The committee considered the population who cannot have TNF-alpha inhibitors (for whom conventional care would be the appropriate comparator) and noted that the ICERs for secukinumab compared with conventional care were less than £20,000 per QALY gained. It was only presented with cost-effectiveness estimates for secukinumab compared with conventional care for people who could have a TNF-alpha inhibitor, but considered that secukinumab was likely to be a cost-effective use of NHS resources for people who cannot have TNF-alpha inhibitors. It would also provide an alternative biologic therapy to address the currently unmet need in this population. The committee concluded that secukinumab was recommended for people with non-radiographic axial spondyloarthritis when TNF-alpha inhibitors are not suitable or do not control the condition well enough.

4 Implementation

4.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

4.2 Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

4.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has non-radiographic axial spondyloarthritis and the doctor responsible for their care thinks that secukinumab is the right treatment, it should be available for use, in line with NICE's recommendations.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee A.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

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Accreditation