Appendix G - professional organisation submission template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)

Secukinumab for treating moderate to severe plaque psoriasis (ID718)

Thank you for agreeing to make a submission on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your submission, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: Drs Ruth Murphy, Pamela McHenry and Prof Catherine Smith, on behalf of the British Association of Dermatologists' Therapy & Guidelines and Biologic Interventions Register sub-committees

Name of your organisation: British Association of Dermatologists

Are you (tick all that apply):

- a specialist in the treatment of people with the condition for which NICE is considering this technology? ✓
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? ✓
- an employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc)?
- other? (please specify)

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What is the expected place of the technology in current practice?

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Moderate-to-severe psoriasis is currently treated with either phototherapy, progressing if necessary to conventional systemic therapies such as methotrexate and ciclosporin. As recognised and indicated in NICE guidance, ciclosporin and phototherapy cannot be used 'long-term' and so for those patients whose disease relapses rapidly following induction of clearance, methotrexate is the only approved intervention for long-term use. In those individuals unable to be controlled adequately by these means, biological therapies are prescribed if stipulated disease severity criteria are met (PASI 10, DLQI 10). Currently, the choice for these is TNF antagonists (infliximab, adalimumab or etanercept) and ustekinumab. The published NICE guidelines for the assessment and treatment of psoriasis CG53 and the British Association of Dermatologists' guidelines for the use of biological therapies inform this process (the latter is currently being updated). Whilst the approach nationally may not be uniform, quality standards exist against which to audit current practice.

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

Subgroups that differ from the 'typical' patient where IL-17 blockade (secukinumab) may be of benefit include:

(i) primary treatment failures to existing biologic therapies
(ii) patients who lose response to biologics (around 15% of people, year on year)
(iii) patients who are intolerant of or in whom existing biologic therapies are contra-indicated, lose response to existing biologic therapies
(iv) patients with psoriasis and psoriatic arthritis who cannot use TNFi

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

There will be very limited surveillance data on the safety and efficacy of this drug. As such, secukinumab initially would not be a usual first-line agent; instead would be used following sequential failure or contraindication of other biological therapies. The use of this agent is therefore restricted to departments used to handling severe psoriasis and biological therapies which are hospital-based secondary/ tertiary care units. It would not be suitable for use in primary care.

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

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The use of this drug is likely to be influenced by the NICE guidance and accumulated safety data going forward. At present, this drug is only available as part of a phase III trial (Signature study).

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

An evidence review for NICE guidelines for the assessment and management of psoriasis CG153 was recently published. They consider all the available evidence for the diagnosis and management of psoriasis. There is no evidence available for the efficacy and safety of secukinumab at UK national level yet. The British Association of Dermatologists' guidelines are currently being updated and will include recommendations on secukinumab (expected draft out for consultation early 2016).

The advantages and disadvantages of the technology

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

This therapy will potentially provide an alternative for those patients who do not respond or have failed therapy with anti-TNF therapies or IL-12/23 blockade. Secukinumab is a subcutaneous injection appearing as a comparator with other biological therapies. Currently though there is limited safety data which will mean in the first instance, that it is unlikely to be used as a first-line biological therapy but rather reserved for sequential use after primary or secondary failure. Accrual of long-term safety data will be essential to properly establish the place in therapy (for example, via the British Association of Dermatologists Biologics Interventions Register, BADBIR).

It is worth noting that the number of patients on secukinumab who achieve complete clearance is significantly higher.

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

Dr Murphy is a local PI on the Signature trial. The drug does appear to be efficacious to date in the two patients she had treated. Both of these have failed therapy with anti-TNF drugs.

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

There is limited available data to be able to answer this question with any good evidence. There is a theoretical risk of infection with candida if IL-17A blockade occurs but trial data to date does not appear to suggest this in clinical practice.

Any additional sources of evidence

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

There are none beyond that supplied by the manufacturers.

Implementation issues

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

The resources required to deliver this drug from secondary/tertiary care settings are already in place. Staff would not need any extra training once they were familiar with its licensing indications. A recommendation that all patients being treated with secukinumab should be entered onto a long-term safety register (i.e. BADBIR) would ensure comprehensive, high quality data including opportunity to compare efficacy and safety with existing biologic therapies is available.

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Equality

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 this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/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 lead to recommendations that 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.

We do not see any issues with respect to equality in general. For those individuals with severe psoriasis who have failed to be controlled with the biological therapies currently licensed though, excluding secukinumab means denying these individuals a possible therapy, since IL-17A blockade is not an otherwise available pharmacological intervention.