Appendix G - professional organisation submission template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal (STA)
Apremilast for treating moderate to severe plaque psoriasis

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: Dr Ruth Murphy, Dr Pamela McHenry and Prof Catherine Smith

Name of your organisation: Nottingham University Teaching Hospitals
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, or progressing if necessary to conventional systemic therapies such as methotrexate and ciclosporin as per the recommendations in published NICE guidelines for the assessment and treatment of psoriasis CG53. In those individuals whose psoriasis cannot be controlled adequately by these means, biological therapies are prescribed subject to certain disease severity criteria. Currently, the choice for these is infliximab, adalimumab, ustekinumab or etanercept. Whilst the approach nationally may not be uniform, quality standards exist against which to audit current practice.

Sub-groups of patients who might benefit:
Approximately 60% of patients offered methotrexate will not respond; the alternative agent, ciclosporin, should not be used continuously for more than 1 year unless the disease is severe or unstable (and that other treatment options, including biological therapy, cannot be used). Only a proportion of these patients will quality for biologic therapy and there is thus a considerable unmet need for this particular sub-group of patients, specifically those who qualify for systemic therapy according to CG153 but do not meet the disease severity criteria (e.g. PASI <10 but where the impact of their disease is still very substantial, e.g. DLQI >10).

PASI has major limitations, in that the disease may be limited in extent but still affects very high-impact sites (e.g. nails, face and genitalia).

Patients who fail treatment, are intolerant of or for whom treatment with TNF-alpha inhibitors and IL-12/23 blockers are contraindicated:
At present for this group of patients, fumaric acid esters are sometimes used although these are variably effective and poorly tolerated (estimated from one tertiary centre indicate that <25% of patients are still on therapy by one year – Smith *et al.*, British Journal of Dermatology 2010 www.ncbi.nlm.nih.gov/pubmed/19519838). Additionally, the drug has to be imported from Germany, is unlicensed and expensive. Expected licensing and development of dimethylfumarate for psoriasis in 2015/16 may improve access although it is likely to be expensive.

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?

Patients who fail treatment, are intolerant of or for whom treatment with TNF-alpha inhibitors and IL-12/23 blockers are contraindicated currently do not have any other therapeutic options. Apremilast, providing inhibition of PDE4, provides an alternative pathway. This drug will probably mostly be used prior to considering biological therapy. Necessary safety data will be needed first, though.

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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, initially this would not be a usual first-line agent but instead would be used after sequential failure of systemic therapies or contraindication of 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 initially but may useful in this setting with time.

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?

Not yet available.

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.

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?

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?

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?

Any additional sources of evidence

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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.

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)?

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.