Appendix G - professional organisation submission template

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal (MTA)

Adalimumab, etanercept and ustekinumab for treating plaque psoriasis in children and young people [ID854]

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: Ruth Murphy

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? **YES**

- 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)? **YES. Academic Vice President for the British Association of Dermatologists and President for the British Society of Paediatric Dermatology**

- other? (please specify)

Links with, or funding from the tobacco industry - please declare any direct or indirect links to, and receipt of funding from the tobacco industry:

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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?

A UK wide audit (Lam et al, BJD 2015) of the current practice in the treatment of children with moderate to severe psoriasis against the published NICE guidelines for the diagnosis and management of psoriasis (TAG 153, 2012) showed that currently there is no formally agreed disease treatment pathway for children. This is largely because none of the standard systemic therapies used to treat psoriasis in adults are licensed to treat psoriasis under 16 years of age. However, the audit showed nationwide use of both standard systemic therapies and biological therapies. These children are treated, largely in line with pathways for adult disease as the draft scope indicates.

There is limited off-license use of biological therapies in the NHS in young people with severe psoriasis who have failed standard systemic therapy. Patterns of use have followed licensing of these agents, and most clinical experience with etanercept. However, ustekinumab and adalimumab are also used. The side effect profile of these drugs compared with standard systemic agents is not known but in 2015 there was agreement to include children below 16 years of age in the UK British Association of Dermatologists biological therapies surveillance register (BADBIR).

Over time this will show whether there are any differences in the safety profiles of standard systemic when compared with biological therapies.

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?

In drugs where there is fixed dosing, patients who are heavier may be poorer responders. In the adult population there is data to support this with body weight around 85 kg being a rough watershed. There is literature to support that children with psoriasis have a higher risk of obesity. This could translate to etanercept being less effective in this patient sub-group.

Similarly if data is extrapolated from the adult population, in children with psoriatic arthritis and psoriasis, adalimumab and etanercept are more likely to be effective than ustekinumab.

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)?

These drugs should be prescribed by a paediatric dermatologist experience in their use and experienced in the management of psoriasis. This is likely to be in a secondary and tertiary care setting. These drugs should not be prescribed 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?

These drugs are being prescribed for severe disease but to date, without NICE approval in dermatology, they have often been prescribed by a paediatric rheumatologist or endocrinologist. Children with psoriasis are at an increased risk of inflammatory bowel disease and the JIA variant of psoriatic arthritis.

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 British Association of Dermatologists are just completing their review on the use of biological therapies for the treatment of psoriasis in adults and children. It should be published by December 2016 and it will have relevance to this MTA.

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.

In children with moderate to severe psoriasis who had failed standard systemic therapies, biological therapies would be prescribed. The limiting factor for their use is the necessary funding pending approval from NICE. The drugs can then be prescribed from secondary care and tertiary care settings.

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?

The clinical trial data for the use of these biological therapies in a paediatric population is short term. Most exists for etanercept which was the first to gain its license in the paediatric population. Long term safety and efficacy data for the 'real life' use of these drugs depends on registries such as BADBIR.

The published data from these trials does use PASI and life quality measures which reflects the routine assessment tools used in UK clinical practice. Apart from etanercept, drug efficacy data in this age group beyond 12 months is lacking. There is an increasing trend to look for clear or minimal disease.

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?

The long term safety data is limited with respect to the use of biological therapies to treat psoriasis in a paediatric population. The long term safety will be compared with standard systemic agents and will be available from national registry data. The UK register for the use of biological therapies is called BADBIR as explained above. Children with psoriasis treated with either standard systemic therapies or biological therapies should have the relevant safety data captured.

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.

The British Association of Dermatologists Biological Guidelines document will be available for review in December 2016. This document should be reviewed before the MTA as it will have some comments specifically about the use of these drugs in the paediatric population.

Implementation issues

The NHS is required by the Department of Health 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.

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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 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)?

Paediatric Dermatologists experienced in the treatment of moderate to severe psoriasis will be familiar with these drugs from their adult practice. No further training is required and there should be equity of access to these drugs once there is NICE approval for their use.

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.

Children with psoriasis may have inflammatory bowel disease as well as the JIA variant of psoriatic arthritis. Obviously children are more likely to prefer oral medication than an injection.