NICE National Institute for Health and Care Excellence

Professional organisation submission

Baricitinib for treating moderate to severe atopic dermatitis [ID1622]

Thank you for agreeing to give us your organisation's views on this technology and its possible use in the NHS.

You can provide a unique perspective on the technology in the context of current clinical practice that is not typically available from the published literature.

To help you give your views, please use this questionnaire. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 13 pages.

About you	
1. Your name	**Dr Richard Weller**
2. Name of organisation	**British Association of Dermatologists, University of Edinburgh, NHS Lothian**

3. Job title or position	**Honorary Consultant Dermatologist, University Reader**
4. Are you (please tick all that apply):	☒ an employee or representative of a healthcare professional organisation that represents clinicians? ☒ a specialist in the treatment of people with this condition? ☐ a specialist in the clinical evidence base for this condition or technology? ☐ other (please specify):
5a. Brief description of the organisation (including who funds it).	**British Association of Dermatologists.**
4b. Has the organisation received any funding from the manufacturer(s) of the technology and/or comparator products in the last 12 months? [Relevant manufacturers are listed in the appraisal matrix.] If so, please state the name of manufacturer, amount, and	Dr Weller has participated in a Lilly advisory board on baricitinib.

purpose of funding.	
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	
The aim of treatment for this condition	
6. What is the main aim of treatment? (For example, to stop progression, to improve mobility, to cure the condition, or prevent progression or disability.)	Baricitinib is designed to ameliorate symptoms and signs of atopic dermatitis and thus improve quality of life.
7. What do you consider a clinically significant treatment response? (For example, a reduction in tumour size by x cm, or a reduction in disease activity by a certain amount.)	A reduction in EASI score of 75% or a fall in IGA of 2 points.

8. In your view, is there an unmet need for patients and healthcare professionals in this condition?	Yes. An additional oral agent for treating AD is needed.
What is the expected place of the technology in current practice?	
9. How is the condition currently treated in the NHS?	For patients with moderate to severe eczema, uncontrolled with topical agents, phototherapy or systemic treatments are generally required. Phototherapy is limited in supply and generally involves frequent time consuming visits to hospital. Existing systemic agents have a significant side effect profile, and require careful monitoring. Of the conventional systemic agents, only ciclosporin has a license for use in eczema and this only for 8 weeks, in inadequate length of time for a chronic condition such as eczema. Dupilumab has been a step change in treatment of eczema for patients not responding to, or being intolerant of, existing systemic agents. Unfortunately, not all patients respond to dupilumab, some develop problematic conjunctivitis, and others are fearful of injections.
• Are any clinical guidelines used in the treatment of the condition, and if so, which?	SIGN guidelines on Atopic Eczema in primary care (revised 2014).
• Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please	Well defined pathway of care in Scotland following SIGN guidelines, with local referral guidelines following these (e.g. Refhelp in Lothian)

state if your experience is from outside England.)	
• What impact would the technology have on the current pathway of care?	An alternative treatment to dupilumab for patients not responding to existing systemic agents and phototherapy.
10. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice?	Yes - an additional oral treatment for eczema, but probably following failure/intolerance of one or more of ciclosporin/methotrexate/azathioprine/MMF.
• How does healthcare resource use differ between the technology and current care?	No significant difference in resource use than existing systemic agents. Screening investigations will need to be performed before initiation and then occasional blood monitoring once treatment has started. This is similar to e.g. methotrexate/azathioprine use. Dupilumab does not require so much monitoring, but patients have to be taught to self-inject
• In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.)	Secondary care. Outpatient treatment. Dermatology specialist service.
• What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)	Education in safety profile and monitoring requirements for drug.

11. Do you expect the technology to provide clinically meaningful benefits compared with current care?	Yes - in that subset of patients who do not get benefit on existing systemic AD treatments.
• Do you expect the technology to increase length of life more than current care?	No.
• Do you expect the technology to increase health-related quality of life more than current care?	Yes.
12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	No, but ongoing stratification studies on eczema patients may identify factors predicting best response to different drugs.
The use of the technology	
13. Will the technology be	Easier than dupilumab (no injections) and ciclosporin (less blood monitoring). Similar to MTX and

easier or more difficult to use for patients or healthcare professionals than current care? Are there any practical implications for its use (for example, any concomitant treatments needed, additional clinical requirements, factors affecting patient acceptability or ease of use or additional tests or monitoring needed.)	azathioprine.
14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing?	Presumably this will be more expensive than existing systemic treatments and safety profile less well understood. Thus guidelines will be required for starting criteria (e.g. failure of 1+ existing systemic agents) and a stop/go decision to be made by supervising clinician at a defined time after starting treatment, based on clinical response/adverse effects.
15. Do you consider that the use of the technology will result in any substantial health-related benefits that are	No.

unlikely to be included in the quality-adjusted life year (QALY) calculation?	
16. Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how might it improve the way that current need is met?	An additional treatment option for patients wishing/needing to treat their eczema with an oral agent.
• Is the technology a 'step-change' in the management of the condition?	No - not in the way dupilumab was, but a useful additional treatment option I hope.
• Does the use of the technology address any particular unmet need of the patient population?	An oral treatment for resistant eczema and for those intolerant of dupilumab due to ocular side effects.
17. How do any side effects or adverse effects of the	Side effect profile appears different from that of existing systemic Rx. As adverse profile of systemic drugs often determines which is used (e.g. hypertension/renal impairment a C.I for ciclosporin, liver dysfunction a

technology affect the management of the condition and the patient's quality of life?	CI for MTX) a drug with a different SE profile gives more options.
Sources of evidence	
18. Do the clinical trials on the technology reflect current UK clinical practice?	Yes.
• If not, how could the results be extrapolated to the UK setting?	
• What, in your view, are the most important outcomes, and were they measured in the trials?	EASI 75, DLQI, Pruritus score and IGA. All of these were measured.
• If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?	Not relevant.
• Are there any adverse effects that were not	Not that I am aware of.

apparent in clinical trials but have come to light subsequently?	
19. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?	No.
20. How do data on real-world experience compare with the trial data?	I am not aware of any real-world data on baricitinib for atopic dermatitis.
Equality	
21a. Are there any potential equality issues that should be taken into account when considering this treatment?	Effects on different skin type (e.g. BAME skin).
21b. Consider whether these issues are different from issues with current care and why.	

Key messages
22. In up to 5 bullet points, please summarise the key messages of your submission. • First oral Jak inhibitor treatment for atopic dermatitis • First of a new class of drugs for treatment of atopic dermatitis • An alternative treatment option for patients intolerant of/not responding to conventional systemic agents • •

Thank you for your time.

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