NICE National Institute for Health and Care Excellence

Professional organisation submission

Abrocitinib for treating moderate to severe atopic dermatitis in people aged 12 and over [ID3768]

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 Bryan McDonald, Prof Carsten Flohr, and Dr Michael Ardern-Jones, on behalf of the British Association of Dermatologists' Therapy & Guidelines sub-committee**
2. Name of organisation	**British Association of Dermatologists (BAD)**

3. Job title or position	**Consultant Dermatologists**
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).	The BAD is a not-for-profit organisation whose charitable objectives are the practice, teaching, training, and research of Dermatology. It works with the Department of Health, patient bodies and commissioners across the UK, advising on best practice and the provision of Dermatology services across all service settings. It is funded by the activities of its members.
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	The BAD is a registered charity and owns various companies; one of which is the British Association of Dermatologists Eczema Register Limited (BADERL) or A-STAR (UK-Irish Atopic Eczema Systemic Therapy Register). It is still in its initial stages of growth and has now been in operation for 3 years with 14 participating sites. A-STAR is an independent observational study led by King's College London and supported by the BAD through a non-profit limited company. It was initially funded through a British Skin Foundation grant and also receives funding from Eli Lilly and Pfizer (in the form of a PI-led grant). The BAD does not receive any funding from A-STAR. For more information on A-STAR – The UK-Irish Atopic Eczema Systemic Therapy Register, please see https://astar-register.org/.

purpose of funding.	
5c. Do you have any direct or indirect links with, or funding from, the tobacco industry?	No.
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.)	To elevate symptoms and improve quality of life is those with significant atopic eczema.
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.)	50% reduction in EASI and/or quality of life score (DLQI) by 12-16 weeks into treatment.
8. In your view, is there an	Definitely. At present, we only have conventional immune-suppressive treatments, dupilumab and

unmet need for patients and healthcare professionals in this condition?	baricitinib (recently NICE-approved) and further agents are needed, as not all patients respond to these therapies and side effects limit the use in particular of the conventional treatments.
What is the expected place of the technology in current practice?	
9. How is the condition currently treated in the NHS?	Topical anti-inflammatory treatments (corticosteroids and calcineurin inhibitors) and emollients are mainstay treatments. Phototherapy is a treatment option but not suitable for everyone (e.g. those with less deeply pigmented skin that easily burns, and those with photo-aggravated atopic eczema). As for systemic treatments, conventional immune-suppressive drugs (methotrexate, ciclosporin, azathioprine, mycophenolate mofetil), dupilumab (biologic) and baricitinib (selective JAK inhibitor).
• Are any clinical guidelines used in the treatment of the condition, and if so, which?	NICE guidelines CG57 are available for children but very outdated. No NICE guidelines available for adults at present but needed.
• Is the pathway of care well defined? Does it vary or are there differences of opinion between professionals across the NHS? (Please state if your experience is from outside England.)	Yes, but availability of novel systemics is restricted to specialised centres.
• What impact would the	No fundamental changes.

technology have on the current pathway of care?	
10. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice?	Yes.
• How does healthcare resource use differ between the technology and current care?	Abrocitinib prescribing would be very similar to baricitinib use.
• In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.)	Secondary dermatology care.
• What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)	We do not yet know what the health resource use implications would be.
11. Do you expect the technology to provide clinically	Yes, broadening the treatment options, allowing switch to a medication that might be effective in those not responding to currently available treatments.

meaningful benefits compared with current care?	
• 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, certainly compared to conventional systemic medication.
12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	There is no evidence that we are aware of that there would be differences.
The use of the technology	
13. Will the technology be easier or more difficult to use for patients or healthcare	No difference. Tablets (abrocitinib, baricitinib) are preferred by some patients over subcutaneous injections (dupilumab, methotrexate can be given subcutaneously).

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.)	No anticipated practical implications.
14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing?	Safety bloods will be required at baseline and during treatment. We suspect NICE will use the same start-and-stop rules for abrocitinib, as for dupilumab and baricitinib. These are now well established.
15. Do you consider that the use of the technology will result in any substantial health-related benefits that are unlikely to be included in the quality-adjusted life year	Many atopic eczema patients have considerable psychological co-morbidities, including anxiety and depression, which are not well captured in the EQ5D. The same applies to the often substantial, well-documented impact on the whole family unit.

(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?	Novel drug belonging to the group of selective JAK inhibitors. The RCT evidence is very encouraging, suggesting superiority in treatment efficacy compared to dupilumab (Bieber, *NEJM* 2021).
• Is the technology a 'step-change' in the management of the condition?	No, as baricitinib is already in NHS clinical practice.
• Does the use of the technology address any particular unmet need of the patient population?	See above.
17. How do any side effects or adverse effects of the technology affect the management of the condition	Overall side effect profile is reassuring based on RCT data, but real-world, long-term effectiveness and safety data is required.

and the patient's quality of life?	
Sources of evidence	
18. Do the clinical trials on the technology reflect current UK clinical practice?	Most RCTs are placebo-controlled but enrolled those inadequately controlled on topical treatments alone or requiring/failing other systemic medication, representing a similar group of patients treated with systemic medication in NHS clinical care. First head-to-head trial of two novel systemic medications for atopic eczema now published, showing potential superiority of abrocitinib vs. dupilumab (Bieber, NEJM 2021).
• If not, how could the results be extrapolated to the UK setting?	A living network meta-analysis (NMA) of systemic treatments for atopic eczema is due to be published over next couple of months. Regularly updated website for this living NMA project is also available at https://eczematherapies.com/. Systemic Immunomodulatory Treatments for Patients With Atopic Dermatitis: A Systematic Review and Network Meta-analysis. Drucker AM, Ellis AG, Bohdanowicz M, Mashayekhi S, Yiu ZZN, Rochwerg B, Di Giorgio S, Arents BWM, Burton T, Spuls PI, Küster D, Siegels D, Schmitt J, Flohr C. JAMA Dermatol. 2020 Jun 1;156(6):659-667. doi: 10.1001/jamadermatol.2020.0796
• What, in your view, are the most important outcomes, and were they measured in the trials?	Systemic treatment RCTs now by and large use the same outcomes, recommended by the Harmonising Outcome Measures for Eczema (HOME) initiative. Key outcomes are disease severity (physician- and patient-assessed – EASI and POEM scores), quality of life (e.g. DLQI), and long-term disease control as well as cost-effectiveness. The last two outcomes are not addressed in short-term RCTs.

• If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?	See above.
• Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?	None of which we are aware.
19. Are you aware of any relevant evidence that might not be found by a systematic review of the trial evidence?	No.
20. Are you aware of any new evidence for comparator treatment(s) of any relevant NICE technology appraisal guidance?	See above comparison with dupilumab.
21. How do data on real-world experience compare with the	It is too early to say. There is an ongoing national register for systemic medication in atopic patients (adults and children), supported by the BAD, the UK-Irish Atopic Eczema Systemic Therapy Register (A-STAR

trial data?	https://astar-register.org/). It would be very helpful if NICE could recommend that all patients commencing novel systemic medication need to be entered into the A-STAR register.
Equality	
22a. Are there any potential equality issues that should be taken into account when considering this treatment?	No.
22b. Consider whether these issues are different from issues with current care and why.	N/A.
Key messages	

23. In up to 5 bullet points, please summarise the key messages of your submission.

- Abrocitinib is an effective and (based on current RCT evidence) safe systemic treatment for atopic eczema.
- Head-to-head RCT and NMA evidence suggests that it is superior in efficacy compared to dupilumab.
- Further assessment of the long-term (cost-)effectiveness and safety for abrocitinib is required, best addressed through the national A-STAR register.
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Thank you for your time.

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