NICE National Institute for Health and Care Excellence

Single Technology Appraisal

Nemolizumab for treating moderate to severe atopic dermatitis in people 12 and over [ID6221]

Professional organisation submission

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 Ser-Ling Chua, Prof Carsten Flohr, Prof Michael Ardern-Jones, Prof Sara Brown on behalf of the British Association of Dermatologists
2. Name of organisation	British Association of Dermatologists (BAD)
3. Job title or position	Consultant Dermatologists
4. Are you (please select Yes or No):	An employee or representative of a healthcare professional organisation that represents clinicians? **Yes** A specialist in the treatment of people with this condition? **Yes** A specialist in the clinical evidence base for this condition or technology? **Yes** 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.
5b. 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 purpose of funding.**	No.
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 successfully treat the skin of people living with moderate-to-severe atopic dermatitis (AD).
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.)	In accordance with NICE TA814, an adequate response would be defined as at least a 50% reduction in the Eczema Activity and Severity Index (EASI) and a reduction in Dermatology Life Quality Index (DLQI) score of at least 4 points. An ideal treatment response might be reduction of EASI by 75% to 90%, Investigators' Global Assessment (IGA) score of 0 or 1 which represents clear or nearly clear skin, or a Patient-Oriented Eczema Measure (POEM) score of 0 to 2 which represents clear or nearly clear skin. All of the above would be considered clinically significant treatment responses.
8. In your view, is there an unmet need for patients and healthcare professionals in this condition?	Yes, there is an unmet need, as there are people who do not respond adequately to or are unable to tolerate existing treatments including topical corticosteroids, phototherapy and conventional systemic treatments such as ciclosporin, methotrexate and azathioprine, biologics such as dupilumab, tralokinumab, lebrikizumab and Janus kinase (JAK) inhibitors such as baricitinib, abrocitinib and upadacitinib as outlined above. They will need to have access to a range of safe and effective systemic treatments.

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

9. How is the condition currently treated in the NHS?	There is a treatment ladder or stepped-care approach to managing people with AD. 1. Emollients +/- topical corticosteroids +/- topical calcineurin inhibitors would be advised in virtually all patients. The following steps are used to reduce the need for topical corticosteroids; calcineurin inhibitors must be withdrawn before phototherapy: 2. Phototherapy (UVA and/or UVB). 3. Conventional systemic therapy such as ciclosporin, methotrexate. 4. Systemic therapy that has become available more recently such as biologics (dupilumab, tralokinumab and lebrikizumab) or Janus kinase inhibitors (baricitinib, abrocitinib and upadacitinib).
9a. Are any clinical guidelines used in the treatment of the condition, and if so, which?	• The European guideline on atopic eczema published in 2022 (https://doi.org/10.1111/jdv.18345) might be most relevant currently and includes systemic therapy appraised by NICE from 2018 to 2022 such as dupilumab, baricitinib, abrocitinib, tralokinumab and upadacitinib. • There is a NICE guideline on the diagnosis and management of eczema for under 12s published in 2007 and Scottish Intercollegiate Guidelines Network (SIGN) guidelines on the management of atopic eczema in primary care published in 2011. • Previous NICE technology appraisal guidance publications mean that the pathway for systemic treatment is defined to some extent. There is no current NICE guidance on the management of atopic eczema in adults and adolescents.
9b. 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	There is some variation in the pathway of care across England, but the variation is more marked in Scotland where Health Boards define their own policies. Therefore, according to NICE recommendations, people with moderate-to-severe AD are eligible to have treatment with newer systemic treatment options such as dupilumab, baricitinib, abrocitinib, tralokinumab, lebrikizumab and upadacitinib if their disease has not responded to at least one systemic immunosuppressant, such as ciclosporin, methotrexate, azathioprine and mycophenolate mofetil,

experience is from outside England.)	or if these are not suitable. However, in some regions of Scotland, these patients need to have failed to respond to or be unsuitable to have at least *two* immunosuppressive treatments.
9c. What impact would the technology have on the current pathway of care?	This technology would add to the treatments available for people who require biological treatment to manage their moderate-to-severe AD. It will be especially important as an alternative to other biologics available for managing people with moderate-to-severe AD and may be used in primary or secondary failure to the previously available biologics and Janus kinase inhibitors used in the management of these patients. Primary and secondary failures are well recognised to occur.
10. Will the technology be used (or is it already used) in the same way as current care in NHS clinical practice?	Yes.
10a. How does healthcare resource use differ between the technology and current care?	No significant difference – nemolizumab would be used as an alternative to previously NICE-approved biologics for managing people with moderate-to-severe AD.
10b. In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.)	Secondary and tertiary care.
10c. What investment is needed to introduce the technology? (For example, for facilities, equipment, or training.)	No significant investment as other similar drugs are already being used for AD.
11. Do you expect the technology to provide clinically meaningful	Having a variety of drugs will be useful because AD is a complex and diverse disease with different pathogenic mechanisms in different individuals. This is reflected in unpredictable inter-individual variation between people's

benefits compared with current care?	responses to dupilumab, tralokinumab and lebrikizumab. Nemolizumab will extend this choice and provide benefit for a greater diversity of patients.
11a. Do you expect the technology to increase length of life more than current care?	No.
11b. Do you expect the technology to increase health-related quality of life more than current care?	Yes, for people who experience primary or secondary failure to previously available biologics and Janus kinase inhibitors used in the management of moderate-to-severe AD.
12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	Evidence is not yet available to know this, but with the advent of personalised medicine and better prediction algorithms we may find such patient groups.

The use of the technology

13. Will the technology be 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	Same as current care.

or additional tests or monitoring needed.)	
14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing?	It is likely that dermatologists will adopt a process of identifying and managing people on nemolizumab that is similar to the processes identified in the NICE TA guidance published so far on dupilumab, tralokinumab and lebrikizumab such as measuring adequate EASI and DLQI responses at 16 weeks.
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 (QALY) calculation?	Yes, there is emerging evidence that nemolizumab may improve health-related quality of life outcomes (e.g. itch and sleep disturbance) in people living with moderate-to-severe AD. https://pubmed.ncbi.nlm.nih.gov/39067461/ https://pubmed.ncbi.nlm.nih.gov/31449914/ https://pubmed.ncbi.nlm.nih.gov/37522351/ https://pubmed.ncbi.nlm.nih.gov/32640132/ https://pubmed.ncbi.nlm.nih.gov/36779675/ https://pubmed.ncbi.nlm.nih.gov/29753033/
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?	It is one of several innovative novel biologic treatments for AD.
16a. Is the technology a 'step-change' in the management of the condition?	This technology will be used alongside previously identified biologics and Janus kinase inhibitors used for managing people with moderate-to-severe AD.
16b. Does the use of the technology address any	Yes, those whose AD is not controlled by other drugs.

particular unmet need of the patient population?	
17. How do any side effects or adverse effects of the technology affect the management of the condition and the patient's quality of life?	There is evidence that this new technology may have fewer and milder side effects (especially with reference to the ocular side effects of dupilumab) compared to some other agents identified above https://pubmed.ncbi.nlm.nih.gov/35412530/..

Sources of evidence

18. Do the clinical trials on the technology reflect current UK clinical practice?	Yes.
18a. If not, how could the results be extrapolated to the UK setting?	N/A
18b. What, in your view, are the most important outcomes, and were they measured in the trials?	EASI and DLQI; HOME initiative (a global initiative of patients, healthcare professionals, journal editors, regulatory authorities and the pharmaceutical industry): EASI, POEM, NRS-11, RECAP or ADCT, DLQI.
18c. If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?	No.
18d. Are there any adverse effects that were not apparent in clinical	No.

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. Are you aware of any new evidence for the comparator treatment(s) since the publication of NICE technology appraisal guidance [TA534, TA681, TA814 or TA986]?	No.
21. How do data on real-world experience compare with the trial data?	Not known yet.

Equality

22a. Are there any potential equality issues that should be taken into account when considering this treatment?	Please note, the erythema component in assessing disease severity (e.g. EASI) may be underestimated in darker skin tones. Thus, such measures may not be representative in such skin tones. Additionally, inflammatory skin disorders such as AD may have an increased impact on some people with darker skin tones due to their ethnicity – this is due to the inflammation potentially leading to longer-term effects on skin pigmentation following resolution of the inflammation. Quality of life measures such as the DLQI may not adequately capture impact in older people (question about work, studying, sport) or those who are not in a relationship (question about sexual activity). It is also known to capture anxiety and depression poorly across all groups (two parameters that are commonly negatively influenced by AD).
22b. Consider whether these issues are different from issues with current care and why.	

Key messages

23. In up to 5 bullet points, please summarise the key messages of your submission.	• This treatment which adds to systemic treatment options available for managing people with moderate-to-severe atopic dermatitis, especially for people do not respond adequately to or are unable to tolerate existing treatments. • Useful because of the heterogeneity in atopic dermatitis which is a complex disease. • Useful because of the multiple comorbidities associated with the AD population, in whom targeted biologics may be safer than other systemic immunosuppressants.

Thank you for your time.

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