NICE National Institute for Health and Care Excellence

Professional organisation submission

Mogamulizumab for treated mycosis fungoides or Sézary syndrome T-cell lymphoma [ID1405]

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	**Julia Scarisbrick**
2. Name of organisation	**British Association of Dermatologists**

3. Job title or position	**Consultant Dermatologist and Lead Cutaneous Lymphoma Service Birmingham**
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): Just to add that I now have experience prescribing mogamulizumab outside of a clinical trial and have treated 5 patients (since august 2019) on the compassionate use program and out of clinical trial it appears safe and effective
5a. Brief description of the organisation (including who funds it).	**Professional body for UK 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 stakeholder list.] If so, please state the name of	**No**

manufacturer, amount, and 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.)	Mogamulizumab is targeted against the malignant T-cells and reduces tumour burden and improves quality of life (symptom, function and emotions). It reduces tumour burden in all compartments (responses: blood 68%, skin 42% and lymph nodes 17%) and dramatically in blood. It is well tolerated and may be continued to be given until loss of clinical benefit and within the MAVORIC trial median treatment time was 170 days with mogamulizumab with lasting responses of median of 13.1months in MF and 17.3months in Sezary syndrome.
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.)	We consider responses in MF/SS as an improvement of 50% but many patients derive clinical benefit from skin symptoms, emotions and functions below 50%.

8. In your view, is there an unmet need for patients and healthcare professionals in this condition?	There is a huge unmet need for patients with cutaneous lymphoma, there are few drugs and most have limited responses (30-40%) and short duration 9-12 months. More drugs are desperately needed and immunotherapies are preferred over chemotherapy as reducing patients own innate immunity with chemotherapy appears to promote progression in some patients and is therefore recommended after failure of immunotherapies or in high grade transformed disease.
What is the expected place of the technology in current practice?	
9. How is the condition currently treated in the NHS?	The BAD guidelines referenced below were published 2019, treatments are listed as first, second or third line and for each line there are a list of therapies in no particular order of preference. Most treatments are given till loss of clinical benefit and consecutive therapies are given. British Association of Dermatologists and U.K. Cutaneous Lymphoma Group guidelines for the management of primary cutaneous lymphomas 2018. Gilson D, Whittaker SJ, Child FJ, Scarisbrick JJ, Illidge TM, Parry EJ, Mohd Mustapa MF, Exton LS, Kanfer E, Rezvani K, Dearden CE, Morris SL. Br J Dermatol. 2019 Mar;180(3):496-52
• Are any clinical guidelines used in the treatment of the condition, and if so, which?	Please see above
• Is the pathway of care well defined? Does it vary or are there differences of opinion	Our guidelines are national. As therapies are listed no order of preference there may be local preferences to therapies and patient individualised treatment approaches

between professionals across the NHS? (Please state if your experience is from outside England.)	
• What impact would the technology have on the current pathway of care?	Mogamulizumab would be a much needed addition to the choic of first line systemic therapies in cutaneous lymphoma
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?	Would add another much-needed treatment as patients live several years with disease and treatment options run out
• In what clinical setting should the technology be used? (For example, primary or secondary care, specialist clinics.)	Specialist clinic only
• What investment is needed to introduce the technology? (For	None, can be given on iv day suite

example, for facilities, equipment, or training.)	
11. Do you expect the technology to provide clinically meaningful benefits compared with current care?	Yes currently we have patients who have exhausted all available treatment options and would benefit from mogamulizumab
• Do you expect the technology to increase length of life more than current care?	This is not known yet
• Do you expect the technology to increase health-related quality of life more than current care?	Yes, MAVORIC showed this compared with vorinostat and start of trial I think we must add something on QoL in CTCL. Patients with CTCL have painful, itchy and often unsightly skin lesions and as a result suffer a reduced HRQoL [ref]. This is compounded by living with an incurable cancer with a lack of effective treatments. Most treatments result in only partial responses of short duration (<1 year) so patients consequently have active lesions throughout [ref Gilson Br J Derm Guidelines]. Those with earlier stages often exhaust the small repertoire of anti-CTCL treatments and have to be managed with supportive therapy alone. 8. Molloy K, Jonak C, Woei-A-Ji S, Guenova E, Busschots A, Bervoets A, Hauben E, Knobler R; Stefanie Porkert; ard Cowan, Evangelina Papadavid, Marie Beylot-Barry, Peng C, Howles A, Yoo J, Evison F, Scarisbrick J. Characteristics associated with significantly worse quality of life in mycosis fungoides/Sézary syndrome from the Prospective Cutaneous Lymphoma International Prognostic Index (PROCLIPI) study. Br J Dermatol epub 2019 9. Constanze Jonak, Stefanie Porkert, Simone Oerlemans, Evangelia Papadavid, Kevin Molloy, Eva Lehner-Baumgartner, Antonio Cozzio, Fabio Efficace, Julia Scarisbrick. Health-related quality of life in cutaneous

	lymphomas: past, present and prospective. Acta Derm 2019;99(7):640-646
12. Are there any groups of people for whom the technology would be more or less effective (or appropriate) than the general population?	Mogamulizumab is effective in MF and SS
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 or additional tests or monitoring needed.)	No it is straightforward, have been using on compassionate use given on a day facility and no problems encountered

14. Will any rules (informal or formal) be used to start or stop treatment with the technology? Do these include any additional testing?	No
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, reduced tumour burden, improved progression free survival (mogamulizumab therapy resulted in superior investigator-assessed progression-free survival compared with vorinostat therapy (median 7·7 months [95% CI 5·7–10·3] in the mogamulizumab group vs 3·1 months [2·9–4·1] in the vorinostat group; hazard ratio 0·53, 95% CI 0·41–0·69; stratified log-rank p<0·0001) MAVORIC). There was also improved quality of life compared to vorinostat and before trial. The pre-planned analyses of Skindex-29, FACT-G, 3-level EQ-5D, and ItchyQoL found mogamulizumab-treated patients had a greater improvement in patient-reported outcomes at the 6-month assessment than did vorinostat treated patients; these findings were statistically significant (appendix p 20).
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	Yes it provides a safe and effective therapy for MF/SS and will provide a new treatment option for patients who have no further lines of therapy available and are suffering painful itchy and disfiguring skin lesions

improve the way that current need is met?	
• Is the technology a 'step-change' in the management of the condition?	It will add another treatment for these patients where there is a dearth of available therapies
• Does the use of the technology address any particular unmet need of the patient population?	This is will be a better treatment option for our patients with efficacy, improved QOL and safety in MF/SS, and provide a therapy for those with no other options
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?	Safety profile is good, infusion reaction is common and may be safely managed with hydrocortisone / piriton and tends to settle with subsequent cycles
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?	Yes Compartmental responses, qol, progression free survival, TTNT
• If surrogate outcome measures were used, do they adequately predict long-term clinical outcomes?	n/a
• Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently?	no
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 since the publication of NICE technology appraisal guidance [TA577]?	
21. How do data on real-world experience compare with the trial data?	Mogamulizumab is available on compassionate use in UK I have personnel experience of treating 5 patients with good efficacy and tolerability similar or better than MAVORIC. I have personnel communications with US where mogamulizumab is available who report similar experiences.
Equality	
22a. Are there any potential equality issues that should be taken into account when considering this treatment?	N/A
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.

- There is an umnet need for more treatments in MF/SS may patients run out of treatment options and suffer from skin symptoms and reduced QOL
- Compared to available therapies mogamulizumab provides a safe and effective therapy with prolonged response rates > 1 year
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Thank you for your time.

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