­Sent by email only to: [XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX](mailto:XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX)X [XXXXXXXXXXXXXXXXXXXXXXXXXX](mailto:Zackpw@leukaemiacare.org.uk)X

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Lymphoma Action

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Leukaemia Care

25 March 2021

Dear XX XXXXXXXXX XXX XX XXXXXXXXX XXXXXXXX

**Re: Final Appraisal Document –** **Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome [ID1405]**

Thank you for your letter of 18 March 2021, lodging Lymphoma Action and Leukaemia Care’s joint appeal against the above Final Appraisal Document (FAD).

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

* 1(a) NICE has failed to act fairly, or
* 1(b) NICE has exceeded powers;
* (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I will make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

Initial View

I assess each of your points in turn and then summarise the appeal points that I am presently minded to refer at the end of this letter.

You make 3 appeal points, as follows.

***Ground 1(a): In making the assessment that preceded the recommendation, NICE has failed to act fairly***

1. *“Cost-effectiveness – Usage of a Lower Threshold:* *As set out in the FAD (3.14) the committee felt that “because of the uncertainty … an acceptable ICER would be no higher than the middle of the range normally considered a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained)…The explicit imposition of a lower threshold (“no higher than the middle”) than the normal range (£20,000 to £30,000) is unfair in this context, setting a dangerous precedent. To do so would create an unfair barrier to access for patients affected by rare cancers, which would be both unfair and potentially discriminatory (on the basis that cancer is a protected disability under the Equality Act 2010)...* *Given the rarity of this condition, unmet need and limited treatment options for these patients we believe the imposition of this “middle of the range” threshold to be unfair.”*

I interpret your point to be that the imposition of a maximum ICER of £25,000 per QALY gained was unfair in the sense that it was unreasonable in the circumstances. I am not persuaded that this is a valid appeal point under ground 1(a), which covers points of procedural unfairness (ie “doing things wrong”). This is however a valid appeal point under ground 2 (which deals with unreasonableness, ie “getting things wrong”) and I will refer it to the hearing on that basis.

1. “*End of Life:… NICE has criteria for end of life treatments (which if met increases the normal threshold to £50,000 per QALY gained). We submit that these criteria have been met and that a decision not to consider mogamulizumab to be a treatment ‘indicated for patients with a short life expectancy’ is unfair (and unreasonable) as set out below. In the alternative (where NICE does not consider the criteria to be met) we submit that, given the committees comments regarding the median life expectancy of this population being less than 24 months, any committee decision to utilise a lower threshold (as per 3.14 in the FAD) than the maximum available to a treatment not meeting end of life (£30,000 per QALY gained) would be unfair (and unreasonable) in the context of treatments close to end of life (but not meeting NICE’s criteria).*”

I interpret your primary point to be that it was unfair, i.e. contrary to process, for the Committee to find the end of life criteria were not met, and your alternative point to be that - because the treatment is close to (albeit not meeting) the end of life criteria - it was unfair (contrary to process) for the Committee to indicate it would accept a maximum ICER of £25,000 per QALY gained.

This is a valid appeal point.

***Ground 2: The recommendation is unreasonable in the light of the evidence submitted to NICE***

1. *“Life-extending treatment at the end of life: The end of life criteria (6.2.10) require that “the treatment is indicated for patients with a short life expectancy, normally less than 24 months”. As set out in the FAD (3.13) the median life expectancy of the patient population under consideration is normally less than 24 months, whilst the mean life expectancy falls above 24 months. The criteria make no explicit reference to use of either median or mean survival. There is precedent for using median life expectancy for the short life expectancy criterion (e.g. inotuzumab ozogamicin for treating relapsed or refractory B-cell acute lymphoblastic leukaemia [TA541]) in such a scenario. On this basis, we submit that a decision not to consider mogamulizumab to be a treatment ‘indicated for patients with a short life expectancy’ is unreasonable in the light of the evidence submitted to NICE.*

A valid appeal point.

In summary, I am presently minded to conclude that there are three valid appeal points. One is a ground 2 appeal point around the ICER threshold, and the other two are a ground 1(a) appeal point and a ground 2 appeal point regarding the application of the end of life criteria.

In respect of your point 1 (which I am minded to refer under ground 2 but not ground 1(a)), you are entitled to submit further clarification and/or evidence to me within the next 10 working days, no later than **Monday 12 April**, and I will then give a final decision on the points to put before an appeal panel. For the points I am already content to refer on, an oral appeal will be held which under current circumstances is likely to be held remotely.

Once I have made my final decision, and where there is more than one appellant, each appellant will receive the valid appeal points of the other appellants and their redacted appeal letter. This is to enable appellants to avoid duplication at the hearing where there are overlapping appeal points. If the appeal letter and/or responses to scrutiny contain confidential information please ensure you have provided a version with this information redacted by **Tuesday 20 April 2021**.

Yours sincerely

Tim Irish

Vice Chair

National Institute for Health and Care Excellence