18 March 2021

Mr Tim Irish

Vice Chair

2nd Floor

2 Redman Place

London E20 1JQ

Dear Mr Irish,

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

Lymphoma Action and Leukaemia Care hereby give notice to the National Institute for Health and Care Excellence (henceforth referred to as NICE) that they would like to jointly appeal against the Final Appraisal Determination (henceforth referred to as FAD) mogamulizumab for previously treated mycosis fungoides and Sézary syndrome [ID1405] on the following grounds:

**Ground one: In making the assessment that preceded the recommendation, NICE has:**

1. **failed to act fairly – 1(a)**

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

Lymphoma Action is a registered charity in England and Wales (1068395) and in Scotland (SC045850). A company limited by guarantee registered in England and Wales (number 03518755).

Leukaemia Care is a registered charity in England and Wales (1183890) and in Scotland (SC049802). A company limited by guarantee registered in England and Wales (11911752).

We submit that the decision not to recommend mogamulizumab for previously treated mycosis fungoides and Sézary syndrome [ID1405] was both unfair and unreasonable.

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

**1a. 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)”.

Lymphoma Action and Leukaemia Care jointly submit that 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).

As set out in the NICE’s guide to the methods of technology appraisal (at 6.2.16) uncertainty is a key factor underpinning the judgements of the Committee. However, it explicitly states that “the evidence base will necessarily be weaker for some technologies, such as technologies used to treat patients with very rare diseases.” 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.

**1a. End of Life**

Furthermore, 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).

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

**2.1 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.

**Conclusion**

For the reasons listed above, we believe that the appraisal of mogamulizumab was both unfair and unreasonable. It is on this basis that we wish to appeal the FAD, via a written appeal.

We urge you to make mogamulizumab available to all those who could benefit from it.

Yours Sincerely,

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