Sent by e-mail only: XXXXXXXXXXXXX

FAO XXXXXXXXXXXXX

Vitiligo Support UK

Thursday 8 August 2024

Dear XXXXXXXXXXXX

**Re:** **Final Draft Guidance For Ruxolitinib Cream For Treating Non-Segmental Vitiligo In People 12 Years And Over [ID 3998]**

Thank you for your letter of 30 July 2024, lodging an appeal against the above Final Draft Guidance (FDG).

Introduction

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

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

**Appeal point 1(a).1: Best Supportive Care**

I am not minded to refer this appeal point to the Appeal Panel. That is because, first, para 3.16 of the FDG shows that the Committee was aware of the numbers modelled by the company, the EAG's critique of this (see page 400 of draft guidance committee papers1) and the views of clinical experts (see page 136 of draft guidance committee papers). There therefore seems to me no arguable case that the Committee failed to take into account relevant evidence that was put to the Committee.

Importantly, you have not shown me that all of the costs listed in the final paragraph of your appeal on this point are costs that are taken into account by NICE when carrying out appraisals, and it appears to me that at least some of them are not. In particular, costs of private healthcare cannot be taken into account by NICE Committees: I refer you to paragraph 4.4 of NICE's Manual which explains that reference case costs should relate to resources that are under the control of the NHS and PSS).[[1]](#footnote-1) It appears to me that this is a key aspect of your point and that the Committee has followed NICE's procedures in this regard.

I see no arguable case of procedural unfairness (or indeed unreasonableness in light of the evidence) here.

***Ground 1(b):******NICE has exceeded its powers***

**Appeal point 1(b).1: Inequalities**

I am not minded to refer this appeal point to the Appeal Panel.

I understand your point to be that "arrangements are in place (or tolerated)" that "apply to everyone, but that put someone with a protected characteristic at an unfair disadvantage." This appears to be an argument of unlawful indirect discrimination in breach of section 19 of the Equality Act 2010 (the Act).[[2]](#footnote-2) However, your arguments do not explain with any clarity the factual or legal basis on which you say that NICE has indirectly discriminated against a protected group. I am not currently persuaded that your appeal puts an arguable case for breach of the Act. If you wish to pursue this point I invite you to explain, with reference to relevant provisions of the Act what provision, criterion or practice of NICE or the Committee puts what protected group at what particular disadvantage, and why this cannot be shown to be a proportionate means of achieving a legitimate aim. I will then consider if there is an arguable case that NICE is in breach of the Act for the Appeal Panel to consider.

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

**Appeal point 2.1: Inequalities**

I am minded to refer this appeal point to the Appeal Panel.

**Appeal point 2.2: Comparators**

I am not minded to refer this appeal point to the Appeal Panel. That is because I don't accept that the Committee's conclusions as to treatment pathway or comparator are unreasonable in light of the evidence put to the Committee, and indeed your appeal does not appear to point to evidence or make an argument that would arguably support such a case.

Rather you say that those conclusions are "confusing" or "inconsistent". I disagree. In my view the position as set out in the FDG is undoubtedly complex but is clear. In short, the committee concluded that:

"a comparison with no active treatment followed by some people having phototherapy would be most reflective of what ruxolitinib cream would displace in clinical practice."

This meant that the relevant comparator was no active treatment, and that subsequent phototherapy for a proportion of patients was taken into account when considering the treatment pathway and economic modelling.

It is not uncommon for the committee to refine its conclusions on pathway and comparators from scoping through to draft guidance and FDG, and your appeal points to nothing in the evidence that you say renders the Committee's conclusion unreasonable.

**Appeal point 2.3: Dosage**

I am not minded to refer this appeal point to the Appeal Panel.

It is clear that the Committee considered dosage in detail and was aware of patient, EAG and expert perspectives (see para 3.11 of the FDG). Mention of facial involvement does not indicate unreasonableness, given this was the relevant clinical endpoint in the trial evidence and driver of transitions in the model.

Further, it appears to me that the Committee's statement quoted in the sixth paragraph of your appeal point does reflect the 'tapering off effect' as the Committee recognises that in practice high response is likely to lead to maintenance treatment or reduced dose rather than abrupt stopping.

It appears to me that the Committee's reasoning on this issue was logical and that it was not bound to give more weight to the view of a patient expert over other evidence. However, if there is evidence that was put to the Committee that you consider renders its conclusions on dosage unreasonable, in the sense that it was obviously wrong, illogical, or 'does not add up', I invite you to set that out in your response to this letter.

Conclusion

The above sets out above my initial views on all of your appeal points.

In respect of your points which I am not minded to refer on you are entitled to submit further clarification and/or evidence to me within the next 10 working days, and I will then give a final decision on the points to put before an appeal panel. Responses must deal only with requested clarifications, or arguments or comments about the lead non-executive director for appeals' initial view that an appeal point is not valid. For the points I am already content to refer on, an oral appeal will be held which will 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 30 August 2024.

Ordinarily appeals are conducted on the basis of the appellants’ written appeal letters, and the material generated during the appraisal process. Use of additional written material is discouraged, and the panel cannot receive any new evidence. If, exceptionally, you feel there is written material that will not be before the panel that you would wish to rely on you must let the NICE Appeal team know by return of letter, indicating what the material is, why it is desirable to submit it, and when it will be available, by no later than 20 September 2024. Please note that the appeal panel cannot accept papers that are tabled late or ad hoc, as this affects the preparation of the panel and other parties for the appeal.

Yours sincerely

XXXXXXXXXXXXXXXXXXXXX

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence

1. <https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation> [↑](#footnote-ref-1)
2. <https://www.legislation.gov.uk/ukpga/2010/15/section/19> [↑](#footnote-ref-2)