Sent by e-mail only: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

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Chair

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13 August 2021

Dear XXXXX XXXXXX

**Re: Final Appraisal Document –** **avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy [ID3735]**

Thank you for your letter of 5 August 2021 addressed to Tim Irish, lodging your appeal against the above Final Appraisal Document (FAD). Mr Irish has stepped back from overseeing the NICE appeal process and I am replying as NICE’s lead non executive director for appeals.

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.

Rather than re-produce the detailed submissions in your appeal letter, which I have considered, I will refer to your appeal points in summary for convenience.

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

* 1. *Rejection of a stopping rule was unfair in light of past practice and the evidence of patients and clinicians*

Dealing first with past practice, appeal panels have been careful not to set the requirement of consistency unrealistically high. If two appraisals are truly sufficiently similar that an obligation of consistency arises, then the reason for any apparent inconsistency has to be stated, but that is the limit of the obligation.

Here it seems that the committee considered the question of a stopping rule in immunotherapies after platinum-based chemotherapy in urothelial cancer as sufficiently similar to warrant consideration. I will proceed on the basis that that is right. They have identified that in the past a stopping rule was implemented, and have given their reasons for not doing so in this case in a substantial paragraph. I note that the duration of treatment was discussed in the ACD and that consultation comments were received on it

The committee were clearly aware of past practice and that they were departing from it, and have given their reasons. It seems to me that that has discharged any obligation of consistency that past appeal panels have identified.

Dealing with the rejection of patient and expert evidence as a question of fairness, I would explain that if relevant material is ignored that would be unfair. If a committee took account of relevant material but did not agree with it, that is not unfair. The weight a committee gives to evidence is a question for its judgement, subject only to the requirement that the judgement is reasonable.

It seems to me from the FAD at paragraph 3.8 that the committee were aware that clinical and patient experts said a stopping rule would be accepted, and slides 14 and 16 of the public slide deck presented at the second committee meeting also make clear that patient groups would accept a stopping rule. That evidence was weighed alongside other evidence and overall the committee was not persuaded that a stopping rule should be included in the analysis, but I cannot see any arguable ground on which that could be said to be unfair.

I would not be minded to refer this point to an appeal committee.

* 1. *ABC’s evidence on a stopping rule was misrepresented*

I note that you have also raised this point as a factual correction. Whether your evidence is absolutely accurately précised or not, I think it is clear that the committee were aware that patients would prefer the treatment to be available, and felt that a two year stopping rule was workable. As you say I think it will be obvious that any patient group would have ordered its preferences: (1) available without stopping rule, (2) available but with stopping rule, (3) not available, and I cannot think the committee were in doubt about this.

I would not be minded to refer this point to an appeal panel.

* 1. *Patient groups were not invited to the second committee meeting.*

To be unfair this can only be on one of two related bases; either there was something that needed to be said that patients had not had the chance to say, or the committee had not properly informed itself of some relevant issue and the groups were needed at the meeting so that they could be informed.

Neither of those bases seems to apply here. The stopping rule/duration of treatment issue was in play at the ACD stage and the views of the patients and clinicians were known. The committee did not agree with those views, but fairness does not require that experts are invited to a second meeting to repeat their views to the committee. The chance to inform and persuade arises in the first meeting and through the ACD. Unless those chances have gone wrong, or some new considerations have arisen, I cannot see that a committee is required to give a further chance to repeat the same material at a second meeting. (And, for the avoidance of doubt, if it would not have been the same material but the new material could have been shared at the first meeting or in consultation, my view would be the same.)

I would not be minded to refer this point to an appeal panel.

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

*2.1 It is unreasonable to conclude that the short life expectancy criterion of the end of life policy is not met.*

A valid appeal point. So as to guide preparation for the appeal, but not to restrict the arguments you may wish to make, an appeal panel may particularly wish to consider why what appears to be a similar, but not identical, patient population was held to meet the short life expectancy criterion in TA692, but not in this appraisal.

In respect of your points which I am not minded to refer or you are entitled to submit further clarification and/or evidence to me within the next 10 working days, no later than **5pm on** **Friday 27 August 2021**, 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 7 September 2021.

Yours sincerely

Dr Mark Chakravarty

Lead Non-executive Director for Appeals

National Institute for Health and Care Excellence