

# Appeals: NICE

Dr Chakravarty

Lead Non-executive Director for Appeals NICE

2nd Floor, Redman Place London E20 1JQ

26 August 2021 Dear Dr Chakravarty

# 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 13 August in response to our letter of 05 August, which lodged ABC UK’s appeal against the decision given in the above FAD.

In response to your initial scrutiny, we would wish to make the following comments regarding whether each appeal point should be referred on to the Appeal Panel.

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

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

1. We are of the view that the explanation offered by the Committee for not considering a stopping rule in this case, does not provide a convincing rationale for departing from past practice. Evidence given by both clinicians and patient groups is consistent, and in favour of a stopping rule rather than no access. We feel that there is a failure to explain sufficiently on what basis this evidence differs from past practice. We refer you to the example raised in our letter of 05 August 2021:

***Extract from NICE Technology appraisal guidance Published: 13 June 2018 Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum chemotherapy***

***Stopping rule:*** *The committee prefers a 2-year stopping rule in the model*

*3.11 The committee understood that for other immunotherapies in the same class as atezolizumab, consideration has been given to stopping treatment after a defined period of time (a 'stopping rule'). In its additional evidence, the company included a*

*2-year treatment stopping rule in its revised economic analysis. The committee noted that the evidence for atezolizumab and its summary of product characteristics did not include a stopping rule. The company considered that there is a lack of clinical evidence to show that imposing a stopping rule is of benefit to patients in the long term.*

*However, the committee recognised that in previous NICE technology appraisals clinicians have highlighted growing concern about using immunotherapies beyond 2 years. The Cancer Drugs Fund clinical lead clarified that a 2-year stopping rule is acceptable to both patients and clinicians, and would be implementable. The*

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*committee also recognised that NICE guidance for other immunotherapies for metastatic urothelial carcinoma and other cancers include 2-year stopping rules. The committee concluded that it is appropriate to include a 2-year stopping rule in the economic model.*

1. We would question whether merely noting a view makes any subsequent judgement 'fair', particularly when it is very hard to see how that judgement can be reasonable in the light of previous judgements in very similar circumstances. We find it difficult therefore to understand whether this in fact means that the committee's judgement can never be deemed unfair and is beyond challenge.

We would question if the 'substantial paragraph' you refer to does in fact adequately explain why the committee disregarded the evidence of both patient organisations and clinical experts. The committee does in essence disregard it and presents this without what we would regard as an acceptable explanation, other than stating that the decision has been taken to that effect.

The decision regarding a stopping rule therefore appears to be made on the trial data alone and any other evidence, whether from clinical experts or patient groups, has been disregarded.

1. *The committee noted that other NICE technology appraisals of avelumab have preferred no stopping rules.*

This is the first time that avelumab has been considered by NICE for treatment of urothelial cancer. Whilst understanding that it might prove of some use to refer to other appraisals of avelumab for other conditions, the needs and requirements of those with urothelial cancer are unique and should therefore be approached as a discrete case. Other available treatment options for those with this type of cancer are severely limited, and there is an acute need. This raises the question of the actual weight given within NICE appraisals to patient evidence and need.

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

As you know, we feel that our views were not recorded accurately in the FAD and we have separately also requested that these are amended to record our actual views as expressed (we have yet to receive notification that this has been resolved). Your letter says: ‘Whether your evidence is absolutely accurately précised or not, I think it is clear that the committee were aware that patient would prefer the treatment to be available.’

We have concerns about this and consider this to be an important point. We do indeed feel that it is an extremely important requirement that our evidence **is** accurately précised. The FAD records as below:

**Ref: FAD 3.8 p8/9 Extract**: *The clinical and patient experts stated that they would accept a similar stopping rule if this would enable access to avelumab. This was confirmed by 2 patient organisations in response to consultation, although 1 group noted that the people it represented would prefer avelumab to be made available without a stopping rule.*

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This clearly gives the impression that no qualifying comment was made, which there was, (ie: we would far rather prefer avelumab available with a stopping rule than not being made available at all). If the FAD records our views as above I feel we are being entirely reasonable in considering this raises the question whether the Committee did in fact fully understand our views as clearly stated, or if this qualifying statement has been ignored, or whether NICE had selectively used only a small part of our statement on this issue to support their FAD decision.

As no patient group was allowed an opportunity at the 2nd Committee meeting to present their views on the use of a stopping rule there was no opportunity to ensure this clarity. We feel this misrepresents the view clearly stated by ABC UK both in Committee and in our letters of 05 and 12 July 2021 to XXXXXXXX XXXXXX and our letter of 05 August. We have requested that this is corrected in the FAD – we have received no response to this request.

We refer to your comment, in your initial scrutiny letter, that ‘The weight a committee gives to evidence is a question for its judgement, subject only to the requirement that the judgement is reasonable’. We are increasingly becoming concerned about what ‘weight’ is in fact given to the evidence of patient organisations and the rationale used by NICE to assess the weight and value given to such evidence.

**We therefore consider the decision regarding the rejection of a stopping rule for Avelumab to be unfair and would ask that your view of not being minded to refer this point to an appeal committee is reversed, and this point is now referred for appeal.**

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

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

We note that you have recognised this is a valid appeal point and we look forward to the Appeal.

**Conclusion**

In conclusion, we would repeat again, that urothelial cancer is extremely badly served in terms of available effective treatments. Avelumab has shown in clinical trial to be of value in treating patients with little other treatment options, and potentially of greater value if fully used in the wider clinical setting. **It is vital these new therapies and, most importantly, more than one of these new therapies (due to difference in trial data results, patient cohorts within trials, and the opportunity for vital further evidence gathering arising from wider in clinic use), are now used in this wider clinical setting to provide benefit for patients in the UK.**

We would also like to note that we are delighted the Scottish Medical Consortium have, since our letter of the 05 August 2021, confirmed that the SMC **will** be making Avelumab accessible for patients in Scotland. This positive and welcome decision was made after considering the same evidence as presented to NICE, and from a process to which we contributed. **We would find it of great concern if there was now not to be an equity of access to much-needed new therapies for urothelial cancer across the UK.**

Yours sincerely

**XXXXX** **XXXXXX**

**Chair - Action Bladder Cancer UK**

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