Sent by e-mail only: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

XXXXX XXXXXX

Chair

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6 September 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 26 August 2021. This is my final decision on initial scrutiny.

***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*

I note your concern that a committee’s decision on consistency may be beyond challenge provided they have noted the issue and given some reasons for departing from past practice. I can reassure you that that is not the case. Where NICE’s appeal grounds refer to something being “unfair”, they mean that the process NICE has followed to produce the guidance is defective in some way. So, for example acting inconsistently with a relevant past practice without explaining why is unfair because consultees cannot understand why the decision was taken and so cannot make a case as to why it was wrong.

Your additional material makes clear that you know why the past practice was not followed but you disagree with that decision. Such a challenge can be brought, but as a matter of reasonableness, because it looks not to how the committee acted but what it decided. Therefore, I will refer this point on, but under ground 2.

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

I understand your concern that your views are accurately represented in the FAD, and I trust the institute will engage with you to ensure that this is done. I am still of the view that the disputed wording does not evidence any material misunderstanding on the committee’s part, and this that this is not a valid ground of appeal.

***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.*

Already agreed to be valid.

Therefore, the valid appeal points are 1.1 (under ground 2) and 2.1.

Yours sincerely

Dr Mark Chakravarty

Lead Non-executive Director for Appeals

National Institute for Health and Care Excellence