Sent by e-mail only: [XXXXXXXXXXXXXXXXXXXXXXXX](mailto:r.jones@beatson.gla.ac.uk)X

XXXXXXXXX XXX XXXXX

Consultant Medical Oncologist

On behalf of The British Uro-oncology Group

Right Angle Communications

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6 September 2021

Dear XXXXXXXXX XXXXX

**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 28 August 2021 on behalf of BUG and for explaining your involvement. This letter 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. *The opinion of patients and clinicians was ignored in the committee’s deliberations around a stopping rule*

I think you have accepted that this is not a valid appeal point.

* 1. *The failure to allow for a stopping rule was not consistent with TAs 525 and 492 (atezolizumab) or TA 692 (pembrolizumab)*

Thank you for your further elaboration of this point. It seems to me that you are saying that while the committee did give reasons for preferring not to favour a stopping rule, the committee acted unreasonably. The potential unreasonable decisions stems from the committee favouring an approach consistent with previous appraisals of avelumab rather than previous appraisals concerning locally advanced or metastatic urothelial cancer.

I do not think that can be a fairness point, which would require the appeal panel to consider the process that the committee followed. Instead, you are asking the panel to consider the substance of what the committee did. I can agree that that is a valid appeal point, but will refer it on under ground 2 rather than ground 1.

***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 police is not met.*

Already agreed to be valid.

Therefore, the valid appeal points are 1.2 (under ground 2) and 2.1.

Yours sincerely

Dr Mark Chakravarty

Lead Non-executive Director for Appeals

National Institute for Health and Care Excellence