

Via email to: [appeals@nice.org.uk](mailto:appeals@nice.org.uk)

# APPEAL LETTER FROM ACTION BLADDER CANCER UK

05 August 2021

# ID3735: AVELUMAB FOR MAINTENANCE TREATMENT OF LOCALLY ADVANCED OR METASTATIC UROTHELIAL CANCER AFTER PLATINUM-BASED CHEMOTHERAPY

Action Bladder Cancer UK are submitting this appeal letter to NICE regarding the approval of Avelumab for treatment of urothelial cancer.

As a leading patient organisation representing those with bladder cancer, and their families, we feel very strongly that our views should be given full consideration as part of this Appeal process and are not rejected from this process. We are concerned that NICE have not previously given these views, and patient need, sufficient weight.

We set out below our grounds for requesting that NICE grant an appeal in this case.

# Ground 1: that Nice acted unfairly Ref: FAD 3.8 pp8-10

**Stopping rule:** We have concerns about the rejection of a stopping rule in this case and feel this is unfair action by NICE given both the precedence set within other Appraisals, and also explicit expert and patient group support for a stopping rule. We also have concerns that ABC UK’s views regarding our support for a stopping rule, as expressed in the Appraisal, have been misrepresented by NICE within the FAD:

* Stopping rules have been used within the NHS for other immunotherapies after two years;
* The NICE decision regarding a stopping rule for Avelumab is inconsistent with the methodology used in other immunotherapy appraisals – see extract from NICE guidance relating to Atezolizumab below, where a stopping rule was allowed despite not being initially included in the trial. We feel that this is directly comparable to the Avelumab appraisal and would query why there is this inconsistency:

**Extract from NICE Technology appraisal guidance Published: 13 June 2018**

**Atezolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum containing 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*

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*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 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.***

* The Committee also stated it was not in the interests of patients to implement a stopping rule. However, both clinical experts and patient groups clearly expressed views that, if faced with no access to Avelumab, they would in fact be supportive of a stopping rule to allow access in these circumstances of great patient need. These views were disregarded by NICE;

We feel that **ABC UK’s views on the stopping rule are misrepresented within the FAD** – see relevant extract 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.*

We feel this clearly misrepresents the view stated by ABC UK – see extract from our letters of 05 and 12 July 2021 to XXXXXXXX XXXXXX relating to this appraisal below. We do **not** simply say we would prefer Avelumab to be available without a stopping rule – any patient group for any type of disease would, of course, prefer no stopping rules for treatments. We stated unequivocally that we **would** prefer a stopping rule **to the alternative** of denying access to Avelumab, which is a very different statement, and that NICE had selectively used only a small part of our statement on this issue – extract from ABC UK letters:

*‘We had also stated that we would prefer to see a stopping rule in place* ***if the only alternative was to deny access to Avelumab for this very poorly served group of patients.*** *Although, of course, as a patient organisation, we would prefer that immunotherapies were made available without any stopping rule.’*

We have requested, on 05 August 2021, that this is corrected within the FAD.

* Patient Groups were not invited to present their views on the stopping rule in the 2nd Committee meeting when this was discussed in more detail.

# Ground 2: The Recommendation is unreasonable in light of evidence regarding the assessment of evidence of eol eligibility.

**Ref: FAD 3.13/3.14 pp13-16**

* ABC UK feels that the recommendation is unreasonable in this context as the majority of evidence submitted suggests Avelumab does in fact meet the eol criteria. This evidence includes real world clinical evidence, clinical expert evidence and the median average from the clinical trial;
* The only evidence modelled by NICE was mean average. The NICE committee chose to follow this model, whilst this was queried by all other parties submitting evidence. ABC UK feels that the Committee is acting unreasonably by choosing to use the outlier model despite evidence to the contrary.

# In summary:

* NICE has accepted, both in Committee and in supporting documents, that Avelumab is effective, well tolerated, and extends life for these patients;
* NICE has also accepted that there is a severe lack of available, appropriate treatments for these patients;
* There are inconsistencies in how NICE has interpreted data in this Appraisal against directly comparable Appraisals for other immunotherapies;
* A pragmatic decision would be of great benefit to patients within a therapy area where treatment options are severely lacking and patients have potentially poor outcomes;
* Real life evidence is urgently required from longer term clinical use for treatment within the NHS for those with urothelial cancer. The lack of this evidence will severely impact on further development of therapies for use in such a common cancer, with poor outcomes, high mortality and recurrence rates.

Avelumab is also currently undergoing the SMC consultation process for use in Scotland. ABC UK has participated fully in the SMC process and we have submitted our views and evidence of patient need - we await the results of this process and SMC’s decision regarding the approval of Avelumab for use in Scotland with great interest.

We look forward to confirmation that our views as expressed will be included, and considered, as part of this Appeal process.

Best wishes. Yours sincerely

**XXXXX XXXXXX**

**Chair- Action Bladder Cancer UK**