

26 March 2020

Mr Tim Irish Vice Chair

National Institute for Health and Care Excellence 10 Spring Gardens

London SW1A 2BU

Dear Mr Irish,

# Re: Final Appraisal Determination – Single technology appraisal (STA) Pembrolizumab for previously treated advanced or metastatic urothelial cancer (CDF review TA519) [ID1536]

On behalf of the national Bladder Cancer patient advocacy charity, Action Bladder Cancer UK and all bladder cancer patients, I make this appeal to you with a small ’a’ rather than a formal Appeal under your strict procedure. In saying this, I recognise that we are experiencing the worst health emergency that the NHS has ever seen. Extraordinary times call for urgent and extraordinary measures, and it is in this context that I reach out to you to reconsider the decision to **not** recommend, the use of Pembrolizumab within its marketing authorisation, for treating locally advanced or metastatic urothelial carcinoma (bladder cancer) in adults who have had platinum-containing chemotherapy.

Please note that I am not appealing in terms of Grounds 1a, 1b or 2, but on compassionate grounds as a direct result of the current, Covid-19 health emergency. In brief, our arguments are as follows:

* The vast majority of bladder cancer patients are typically over 70 years old and many have significant co-morbidities, thus this population is at very high risk of contracting and being made seriously ill by Covid-19.
* Covid-19 arrangements are denying many bladder cancer patients their normal and expected Standards of Care (SOC), including: surgery, chemotherapy, surveillance and maintenance treatments.
* For this indication, patients are currently being denied their normal SOC including platinum-based chemotherapy. This will cause untold suffering and death.
* Many patients who have started their course of platinum-based chemotherapy are currently being told that they cannot continue to receive the remainder of their planned treatment. Again, this will cause suffering and death.
* So, the comparator for your HTA is **no longer valid** as the SOC is not able to be offered to this patient population.
* Patients currently have only one viable alternative in the form of the similar immunotherapy treatment, Atezolizumab.
* Although similar, it is different and acts in a subtly different way. The data for both Atezolizumab and Pembrolizumab is still immature, so we don’t know which treatment is best or for which specific patients. If you reverse the recommendation, data can quickly be generated and learning achieved, however if you maintain the recommendation, you will damage and delay the development of a potentially life saving treatment by restricting the wider gathering of data.
* During this unprecedented time, I appeal to you to **urgently** reconsider your decision and take this opportunity to examine a forced experiment where platinum-based chemotherapy will not routinely be available to these patients.

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Outside of our arguments listed above, we would also reiterate our initial arguments in the HTA consultation in the strongest possible terms:

* + We strongly believe the decision to not recommend the use of Pembrolizumab to be wrong.
	+ The lack of treatments available for bladder cancer patients is, and has been for many years, a serious health inequality resulting in the exceptionally high mortality rate for patients.
	+ Pembrolizumab is not directly replicated in any existing treatment available (see point above re comparison with Atezolizumab). It is a developing area of treatment and vital that wider use of these new treatments, and the related evidence generation, is not restricted.

Thank you for considering this appeal. I, and Action Bladder Cancer UK, will do all we can to provide written or oral information and support should you be minded to progress our appeal - as we, and all bladder cancer patients including myself, sincerely hope you will.

With very best wishes.

Yours sincerely

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**Chair, Action Bladder Cancer UK**