Fight Bladder Cancer

Sent by email: xxxx@fightbladdercancer.co.uk

3 April 2020

Dear Sirs

**Re: Final Appraisal Document – Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum - containing chemotherapy [ID1536] (CDF guidance review of TA519)**

Thank you for your letter of 26 March 2020, lodging Fight Bladder Cancer’s appeal against the above Final Appraisal Document (FAD). I am replying as interim Vice Chair in place of Tim Irish, who is currently acting as interim Chair.

**Introduction**

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

• 1(a) NICE has failed to act fairly, or

• 1(b) NICE has exceeded powers;

• (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I will make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

**Initial View**

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

I fully understand the points you make in your letter about the value of this treatment to patients, its effect on their quality of life, and the hope it can bring. I also note that a group of patients may respond well to the treatment. I am very sympathetic to patients and to their families in what is an unenviable situation.

I can also see that it is unfair, in a colloquial sense, that any patient group cannot get any treatment that might benefit them. No one welcomes that. However, when NICE’s permitted ground for appeal use the term “unfair”, they mean “has NICE followed an unfair process” (for example, did it ignore some evidence completely, or did it not follow its own published procedures). I don’t think your letter makes a claim of that sort of unfairness and so for that reason I would not be minded to refer it to an appeal panel.

You can write to me again in the next ten days, **no later than 5pm Tuesday 21 April 2020**, to ask me to change my mind about this, and give me any further arguments you would like me to consider. I would then make my final decision.

I can tell you now that another appeal has been lodged and that there will be an appeal hearing. Ordinarily you would be entitled to attend that hearing as observers. Under the current situation I anticipate that the appeal hearing will have to be held remotely on a date to be confirmed. I am not sure what arrangements will be made for virtual attendance, but if you would like to observe, I will ask for you to be able to follow the proceedings live, technology permitting, should you wish to do so?

Yours sincerely

Dr Rima Makarem

Interim Vice-Chair

National Institute for Health and Care Excellence