

From: Alan Silman <[REDACTED]>
Date: Tuesday, 9 November 2021 at 11:56
To: Mark Chakravarty <[REDACTED]>, Alan Silman <[REDACTED]>
Cc: Elaine Inglesby <[REDACTED]>, Christopher Rao <[REDACTED]>, Alan M Thomas <[REDACTED]>
Subject: Re: Appeal decision avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy [ID3735]

Dear Mark,

Thank you for your email requesting clarification of our judgement on the avelumab appeal, which I have discussed with the Appeal Panel

We feel that we should not change the wording of our decision but that the opinion below can be published alongside as a clarification

The panel were very clear that this decision not to invoke the end of life (EoL) criteria was unreasonable and we gave our reasons for this. We accept that we cannot absolutely direct, as oppose to advise, an appraisal committee (AC). Conceptually it will be open for the AC, having reconsidered the question with an open mind, to come again to the view that the EoL criteria are not met. There would be a very high bar for the AC to persist in that view. They need to be left in no doubt of this, which was the intent of our wording.

Best wishes

Alan

Alan Silman

[REDACTED]

Telephone (PA) +44 (0) [REDACTED]

From: Mark Chakravarty <[REDACTED]>
Sent: 07 November 2021 10:41
To: Alan Silman <[REDACTED]>
Cc: Hocking, Stephen <[REDACTED]>; David Coombs <[REDACTED]>
Subject: Appeal decision avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy [ID3735]

Dear Alan

Many thanks for the work that you and your panel have put in on the Avelumab appeal.

Based on the outcome of the appeal, the Institute is in process of remitting the evaluation to the appraisal committee. In order to avoid any possibility of misunderstanding of the appeal panel's findings I would like to clarify one point. At paragraphs 82-94 of your decision, the panel gives its reasons for finding that the committee's conclusion that NICE's End of Life criteria did not apply were unreasonable. In those paragraphs the panel examines the judgements the committee has to make and the discretion they exercise.

At paragraph 96 of the letter you set out the consequences for the committee, and say:

"The evaluation is remitted to the appraisal committee who must now take all reasonable steps to address the following issues:

(a)...

(b) The appraisal committee should appraise the technology on the basis that the NICE end of life criteria applies"

The clarification being sought is how the discussion at paragraphs 82-94 and the reference to all reasonable steps interacts with the apparently mandatory wording at paragraph 96(b). Specifically, is the panel's view that having found it unreasonable to reject end of life criteria, based on the totality of the evidence available to the panel:

- The consideration for the application of end of life criteria is now fundamentally binary and that the only option for any reasonable committee, given the facts your panel heard in this appeal, would be limited to moving on to deciding the impact of the criteria.

Or

- The consideration for the application of end of life criteria still has the potential for deliberation and judgement by a committee based on the evidence.

There is some concern that stakeholders should not think that an appeal panel can direct a committee on specific assumptions it must adopt. For my part, I can see that if an appeal panel has reached the conclusion on a binary question that only one possible answer can be reasonable, it should say so. The consequence must be that any reappraisal that did not adopt the same conclusion would again be unreasonable and it is sensible to make that clear. On the other hand, even if an appeal panel has reached a firm view that a conclusion is unreasonable, if it considers there may be a chance, even if very limited, that a similar outcome could be reached reasonably then the correct outcome would be to refer the issue back to the committee and allow them to retake the decision taking account of the observations of the appeal panel. Their subsequent decision may again be subject to appeal.

Could I ask you to consult with your colleagues and indicate whether your conclusion was that the only reasonable view on end of life was that the criteria applied, or whether your view was that the committee should revisit that question in the light of the reasoning in your letter and the strong indication that gives?

For absolute clarity, you are not being asked to revisit your decision that the committee's position on end of life was unreasonable. That decision has been taken. It is simply whether the committee are to be allowed to look at the question themselves again or not.

Yours sincerely

Dr Mark Chakravarty

Lead non executive director for appeals

National Institute for Health and Care Excellence