

Review proposal of Nivolumab for treating locally advanced unresectable or metastatic urothelial cancer after platinum-containing chemotherapy [TA530]

TA530 was published in 2018.

Decision

1. The evidence received does not indicate that an update of the existing recommendations is required at this time. The guidance will therefore remain unchanged, in its current form, unless or until NICE becomes aware of substantive information which would make it reconsider.

Rationale

2. The main uncertainty was a lack of evidence for the effect of nivolumab directly compared to current treatments. As the new evidence quoted by the stakeholder is longer term data on the 2 single-arm trials used in the appraisal, it will not address the existing clinical uncertainty.

Summary of new evidence and implications for review

Has there been any change to the price of the technology(ies) since the guidance was published?

3. The company had a PAS, which would have applied if the technology had been recommended. There have been no changes to the list price.

Are there any existing or proposed changes to the marketing authorisation that would affect the existing guidance?

4. Unknown

Were any uncertainties identified in the original guidance? Is there any new evidence that might address this?

5. Lack of evidence on comparative efficacy to current NHS treatments was considered the main clinical uncertainty. During the appraisal, the committee considered a managed access proposal from the company which included further data collection from the 2 single-arm trials used in the appraisal. However, the committee concluded that this data could not address the key clinical uncertainty, because they provided no comparative data.
6. The new evidence provided by the stakeholder is longer term follow-up from the 2 single-arm trials. As already noted in the guidance, further data from

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these single-arm trials is unlikely to address the main clinical uncertainty and result in a changed recommendation.

***Are there any related pieces of NICE guidance relevant to this appraisal?
If so, what implications might this have for the existing guidance?***

7. Avelumab for maintenance treatment of locally advanced or metastatic urothelial cancer after platinum-based chemotherapy [TA788] - published May 2022 recommended in patients who have not progressed after chemotherapy. So not a direct comparator (i.e. not in those who have progressed) but potentially changes the treatment pathway.
8. Pembrolizumab for treating locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy [TA692] – not recommended

Equality issues

9. No equality issues were identified.

Decision paper sign off

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