National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Pembrolizumab for adjuvant treatment of resected stage 2 melanoma with high risk of recurrence [ID3908]

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	MSD	It is appropriate for NICE to appraise this topic.	Comment noted. No changes to the scope are needed.
Wording	MSD	No comment	Comment noted. No changes to the scope are needed.
Timing Issues	MSD	Patients with resected high risk stage II melanoma currently receive no active treatment. As mentioned in the background section recurrence rates are 43% and 60% for stage IIB and IIC respectively. We anticipate the proposed appraisal should be scheduled as soon as possible to enable NICE to issue final guidance soon after regulatory approval. The information on anticipated regulatory timelines presented in PharmaScan accurately reflects current expectations.	Comment noted. NICE aims to provide draft guidance to the NHS within 6 months from the date when marketing authorisation for a technology is granted. NICE has scheduled this topic into

Section	Consultee/ Commentator	Comments [sic]	Action
			its work programme. No action needed.
Additional comments on the draft remit	MSD	None	Comment noted. No changes to the scope are needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	MSD	No comment	Comment noted. No changes to the scope are needed.
The technology/ intervention	MSD	No comment	Comment noted. No changes to the scope are needed.
Population	MSD	No comment	Comment noted. No changes to the scope are needed.
Comparators	MSD	MSD agrees that in the absence of any treatments considered to be an established clinical practice in the NHS for adjuvant therapy following complete resection melanoma, we agree with the proposed comparator of 'routine surveillance'.	Comment noted. No changes to the scope are needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Outcomes	MSD	The outcomes in the draft scope are included in the trial. [redacted]	Comment noted. No changes to the scope are needed.
Economic analysis	MSD	No further comments	Comment noted. No changes to the scope are needed.
Equality and Diversity	MSD	No further comments	Comment noted. No changes to the scope are needed.
Other considerations	MSD	No additional comments	Comment noted. No changes to the scope are needed.
Innovation	MSD	MSD considers pembrolizumab to be innovative in its potential to make a significant and substantial positive impact on health-related benefits. Pembrolizumab has the potential to improve outcomes for those with resected stage 2B or 2C melanoma. Pembrolizumab would be the first licenced anti-PD-1 agent to be approved for this indication.	Comment noted. No changes to the scope are needed.

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Questions for consultation	MSD	**1. Are there any adjuvant treatments considered to be established clinical practice in the NHS for adjuvant treatment following complete resection of stage 2 melanoma?** MSD understands there are no adjuvant treatments that are established in NHS clinical practice for the treatment of Stage IIB/IIC melanoma. **2. Are the outcomes listed appropriate?** See comment above in Outcomes section. **3. Are there any subgroups of people in whom pembrolizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?** There are no subgroups that should be examined separately. **4. Where do you consider pembrolizumab will fit into the existing NICE pathway, Melanoma?** MSD anticipates pembrolizumab to be used after complete resection in stage IIB and IIC patients **5. NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:** • **could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which pembrolizumab will be licensed;** • **could lead to recommendations that have a different impact on people protected by the equality legislation than on the**	1. Comment noted. No changes to the scope are needed 2. Comment noted. No changes to the scope are needed. 3. Comment noted. No changes to the scope are needed. 4. Comment noted. No changes to the scope are needed. 5. Comment noted. No changes to the scope are needed. 6. Comment noted. No changes to the scope are needed. 7. Comment noted. No changes to the scope are needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		wider population, e.g. by making it more difficult in practice for a specific group to access the technology; • **could have any adverse impact on people with a particular disability or disabilities.** **Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.** MSD doesn't consider the proposed scope will negatively impact upon those protected by the equality legalisation. **6. Do you consider pembrolizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?** See comment above in the innovation section, **7. Do you consider that the use of pembrolizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?** All potential significant and substantial health-related benefits are captured in the QALY calculation. **8. Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.** Not applicable. **9. To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.** MSD does not anticipate any barrier to adoption of this technology.	8. Comment noted. No changes to the scope are needed. 9. Comment noted. No changes to the scope are needed. 10. Comment noted. No changes to the scope are needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		10. NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. The STA process is appropriate for this technology.	
Additional comments on the draft scope	MSD	No further comments	Comment noted. No changes to the scope are needed.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

British Association of Dermatologists