National Institute for Health and Care Excellence

Single technology appraisal

Pembrolizumab for treating recurrent or metastatic squamous cell head and neck cancer

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

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
Wording	Merck, Sharp and Dohme	We suggest revision to: "To appraise the clinical and cost effectiveness of pembrolizumab within its marketing authorisation as monotherapy, or in combination with platinum and 5-fluorouracil chemotherapy, for the first-line treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults"	Comment noted. The remit/ appraisal objective is intended to be concise. The details noted in the suggested revision are noted elsewhere in the scope. No changes required.
Timing Issues	Merck, Sharp and Dohme	We anticipate that the proposed appraisal timelines will enable NICE to issue final guidance soon after regulatory approval.	Comment noted. No action required.
Additional comments on the draft remit	Merck, Sharp and Dohme	No additional comments.	Comment noted. No action required.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
The technology/ intervention	Merck, Sharp and Dohme	We suggest revision to: "Pembrolizumab within its marketing authorisation as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy"	Comment noted. 'Platinum-based' is a broad term which is intended to also cover other therapies used alongside platinum chemotherapies. This includes 5-fluorouracil. No action required.
Population	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
Comparators	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
Outcomes	Merck, Sharp and Dohme	We agree with the proposed outcome measures. In addition, we suggest inclusion of 'duration of response' as an additional outcome measure. It is known that the response to immunotherapies (immuno-oncology drugs) may be delayed, but once triggered, is likely to be durable, bringing long-term survival benefit for a subset of patients; this benefit is not captured by the proposed outcome measures, but would be captured in the duration of response outcome.	Comment noted. No change to the scope is necessary as duration of response would be covered by 'response rate'. The list of outcomes is not intended to be exhaustive.

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Economic analysis	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
Equality and Diversity	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
Other considerations	Merck, Sharp and Dohme	No comments	Comment noted. No action required.
Innovation	Merck, Sharp and Dohme	MSD considers pembrolizumab to be innovative in its potential to make a significant and substantial positive impact on health-related benefits. Pembrolizumab as a monotherapy and in combination with platinum and 5-fluorouracil chemotherapy has the potential to improve outcomes for patients receiving first line therapy for recurrent or metastatic squamous cell carcinoma of the head and neck. As a monotherapy, it provides an alternative treatment option to platinum-based chemotherapy. Pembrolizumab would be the first anti-PD-1 pathway targeting agent to be approved for the first line treatment of recurrent or metastatic squamous cell carcinoma of the head and neck, and would represent a step-change in the management of these patients	Comment noted. The extent to which the technology may or may not be innovative will be considered in any appraisal of the technology.
Questions for consultation	Merck, Sharp and Dohme	*Q: Is pembrolizumab expected to be used as monotherapy, or in combination with platinum-based chemotherapy?* A: The anticipated marketing authorisation for this indication from the EMA is for both monotherapy and combination therapy.	Comment noted. No action required.

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		Q: Is diagnostic testing for PD-L1 expression routinely available in NHS practice in England? A: MSD considers this to be the case based on feedback from UK oncologists familiar with current clinical practice for treatment of head and neck cancer.	Comment noted. No action required.
		Q: Have all relevant comparators for pembrolizumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for treating recurrent or metastatic squamous cell head and neck cancer? A: Yes, all relevant comparators have been included in the scope. Treatments that are established clinical practice in the NHS in this indication are: • Platinum-based chemotherapy regimens • Cetuximab in combination with platinum-based chemotherapy (only if the cancer started in the oral cavity)	Comment noted. No action required.
		Q: Are the outcomes listed appropriate? A: Please see our above comments against the section "Outcomes". We suggest that duration of response should be included as an outcome.	Comment noted. Please see response in the outcomes section.
		Q: Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom pembrolizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately? A: No	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		Q: Where do you consider pembrolizumab will fit into the existing NICE pathway for head and neck cancer? A: We envisage pembrolizumab would be used as a first-line treatment option for adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck. *Q: 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;* A: No *• could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;* A: No *• could have any adverse impact on people with a particular disability or disabilities.* A: No	Comment noted. No action required. Comment noted. No action required. Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts. A: Not applicable	Comment noted. No action required.
		Q: 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)? A: Yes – please see our above comments against the section "Innovation"	Comment noted. Comment noted. Please see response in the innovation section.
		Q: 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? A: No	Comment noted. No action required.
		Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits. A: We do not consider that there will be substantial health-related benefits that are unlikely to be included in the QALY calculation.	Comment noted. No action required.
		Q: 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.	

Section	Consultee/ Commentator	Comments [sic]	Action
		A: No	Comment noted. No action required.
Additional comments on the draft scope	Merck, Sharp and Dohme	No additional comments.	Comment noted. No action required.

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

None.