National Institute for Health and Care Excellence

Health Technology Evaluation

Pembrolizumab for treating relapsed or refractory classical Hodgkin's lymphoma after brentuximab vedotin [review of TA540] ID5840
Response to stakeholder organisation comments on the draft remit and draft scope

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 and proposed process

Section	Stakeholder	Comments [sic]	Action
Wording	Merck Sharpe and Dohme	MSD consider the suggested wording appropriate.	Thank you for your comment.
Timing issues	Merck Sharpe and Dohme	MSD consider it important to complete the evaluation within the proposed timelines to ensure continued access to pembrolizumab for eligible patients after its exit from the Cancer Drugs Fund.	Thank you for your comment.
Additional comments on the draft remit	Merck Sharpe and Dohme		

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information		The background information is accurate and comprehensive. For clarity, we suggest amending the wording of the sentence below to reflect that TA462 specifies that brentuximab vedotin can be used as a salvage therapy either pre- or post-autologous stem cell transplant for the patient to be eligible for treatment with nivolumab: **Current wording** "NICE technology appraisal guidance 462 also recommends nivolumab as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin". **Suggested wording:** "NICE technology appraisal guidance 462 also recommends nivolumab as an option for treating relapsed or refractory classical Hodgkin lymphoma in adults after autologous stem cell transplant and treatment with brentuximab vedotin, *where brentuximab vedotin can be used as a salvage chemotherapy either pre- or post-autologous stem cell transplant*".	Thank you for your comment. The current wording used in the background information matches the wording used in the NICE TA462 recommendation. Therefore, we have kept the original wording to align with TA462; the company may include the additional detail in its submission if relevant.
The technology/intervention		Yes *(in response to: Is the description of the technology or technologies accurate?)*	No action.
Population		Yes *(in response to: Is the population defined appropriately?)*	No action.
Comparators		Yes *(in response to: Are these the standard treatment(s) currently used in the NHS with which the technology should be compared?)*	No action.
Outcomes		MSD consider the outcome measures listed to be appropriate. MSD notes that, of the outcomes listed, data from pembrolizumab's time in the Cancer Drugs Fund will be available for only overall survival. MSD suggests adding	Thank you for your comment. The scope

Section	Consultee/ Commentator	Comments [sic]	Action
		"Time to SCT" as a clinical outcome: time to SCT while on treatment with pembrolizumab was captured during the Managed Access Agreement. Evidence on other listed outcomes will be derived from the latest data cut from KEYNOTE-087.	has been updated to include time to allogeneic stem cell transplant (SCT).
Economic analysis		MSD have no comments.	No action.
Equality		None identified, MSD have no comments.	No action.
Other considerations		MSD have no comments.	No action
Innovation		MSD consider pembrolizumab to be innovative in its potential to make a significant and substantial positive impact on health-related benefits in the population of interest to this technology appraisal.	Thank you. No action.
Questions for consultation		**Where do you consider pembrolizumab will fit into the existing care pathway for relapsed or refractory classical Hodgkin lymphoma? Has the publication of NICE TA772 changed where pembrolizumab would be used in the existing care pathway, i.e. is there a population that would be offered brentuximab vedotin before pembrolizumab?** MSD response: MSD considers that clinicians would prefer to retain the option to use pembrolizumab at either the third-or fourth-line of treatment. The publication of TA772 is likely to lead to use of pembrolizumab as a third-line treatment for those with relapsed or refractory classical Hodgkin lymphoma (R/RcHL) and who are ineligible for autologous SCT. However, there are patients for whom clinicians would choose brentixumab vedotin in this setting, as indicated by applications through the Cancer Drugs Fund for use of pembrolizumab at this point in the treatment pathway.	Thank you for your comments.

Section	Consultee/ Commentator	Comments [sic]	Action
		The scope currently covers the population from TA540 that is eligible for treatment through the Cancer Drugs Fund, i.e. adults with relapsed or refractory classical Hodgkin lymphoma who have had brentuximab vedotin and cannot have autologous stem cell transplant (ASCT). Is this population appropriate, or do you consider that a full review of TA540 is needed, to include adults who have had both AHSCT and brentuximab vedotin? MSD response: MSD considers that the population listed in the draft scope is appropriate and believes it unnecessary to review again the evidence for the cohort of people with R/RcHL who have had autologous SCT and brentuximab vedotin, a population for which NICE previously did not recommend pembrolizumab. **Which treatments are considered to be established clinical practice in the NHS for people with relapsed or refractory classical Hodgkin lymphoma who have had a ASCT or for whom ASCT is not suitable?** MSD response: Based on NICE recommendations, and as detailed in the background information, established practice involves use of brentuximab vedotin and pembrolizumab for those with R/RcHL who have failed autologous SCT, or for whom autologous SCT is not suitable and who have received at least two prior lines of therapy. Additionally, for those with R/RcHL who have undergone autologous SCT and treatment with brentuximab vedotin, in any order, nivolumab is also an option. However, there is no standard of care for those who fail treatment with brentuximab vedotin without undergoing autologous SCT, or those who fail on pembrolizumab, either after autologous SCT or systemic treatment alone.	

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		How should best supportive care be defined? MSD response: In the setting of patients with R/RcHL failing on treatment with brentuximab vedotin and being ineligible for autologous SCT, MSD consider that clinical practice remains the same as at the time of the original submission. As noted in comments from stakeholders on the draft scope at that time, standard of care would likely be single-agent chemotherapy, with best supportive care predominantly comprising palliative care and pain relief. **Do you consider that the use of pembrolizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** MSD response: We do not consider that there will be substantial health-related benefits that are unlikely to be included in the QALY calculation. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** MSD response: Not applicable.	
Additional comments on the draft scope		MSD have no additional comments.	