National Institute for Health and Care Excellence

Health Technology Evaluation

Nivolumab as neoadjuvant (with chemotherapy) and adjuvant (as monotherapy) treatment for resectable non-small-cell lung cancer [ID6310]

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
Appropriateness of an evaluation and proposed evaluation route	Bristol Myers Squibb	The proposed evaluation, via the cost comparison process, is appropriate.	Thank you for your comment.
Wording	Bristol Myers Squibb	Wording is appropriate.	Thank you for your comment.

Section	Stakeholder	Comments [sic]	Action
Timing Issues	Bristol Myers Squibb	This appraisal should be evaluated with timelines for a cost comparison, given the similarity in treatment efficacy between nivolumab and pembrolizumab. Patients will receive access to nivolumab faster via the cost comparison evaluation timelines.	Thank you for your comment.
Additional comments on the draft remit	Bristol Myers Squibb	No	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Bristol Myers Squibb	Based on the comparators included in the scope (perioperative pembrolizumab and perioperative durvalumab), it would be clearer if the background was rewritten to remove the detail on those treatments that are	Thank you for your comment. The background information can be broader than the

Section	Consultee/ Commentator	Comments [sic]	Action
		not widely used or less relevant, based on the discussions at previous committee meetings[1].	comparators used for cost comparison.
	MSD UK Ltd	The adjuvant treatment options should include pembrolizumab recommended in adults with NSCLC with a high risk of recurrence after complete resection and platinum-based chemotherapy [TA1037].	Thank you for your comment. Details of TA1037 have been added to the scope.
Population	Bristol Myers Squibb	Yes.	Thank you for your comment.
Subgroups	Bristol Myers Squibb	BMS do not intend to explore subgroups for this appraisal. BMS intends to seek reimbursement for the intention-to-treat population of the CheckMate 77T trial in line with the MHRA licence wording, and in line with TA10171 (perioperative pembrolizumab) reimbursement.	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
Comparators	Bristol Myers Squibb	BMS proposes that perioperative pembrolizumab is the most relevant comparator for cost comparison decision-making for the following reasons: • Perioperative pembrolizumab1 has replaced neoadjuvant nivolumab [TA876]2 as the standard of care treatment for people with resectable NSCLC, as confirmed by 7/7 clinical experts consulted by BMS in the UK. • Nivolumab and pembrolizumab have the same mechanisms of action: both are PD-1 inhibitors, whereas durvalumab is a PD-L1 inhibitor. • A BMS indirect treatment comparison of nivolumab and pembrolizumab demonstrates a similar event-free survival (EFS) and overall survival (OS) treatment effect between nivolumab and pembrolizumab, which supports the similarity in clinical trial results for perioperative nivolumab (CheckMate-77T) and perioperative pembrolizumab (KeyNote-671). BMS propose that the most appropriate evaluation of perioperative nivolumab is via a cost comparison with perioperative pembrolizumab.	Thank you for your comment. NICE's preference is to remain inclusive of comparators at the scope stage.
Outcomes	Bristol Myers Squibb	All key outcomes are listed. Disease-free survival (DFS) may be removed as EFS is the relevant outcome for perioperative (neoadjuvant followed by adjuvant) indications.	Thank you for your comment. Disease-free survival has been

Section	Consultee/ Commentator	Comments [sic]	Action
			removed from the final scope.
Equality	Bristol Myers Squibb	No equality issues are anticipated.	Thank you for your comment.
Other considerations	Bristol Myers Squibb	No comments.	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
Questions for consultation	Bristol Myers Squibb	Are the relevant comparators for nivolumab with chemotherapy included in the scope? Based on insight from 7 consulted clinical experts, BMS consider perioperative pembrolizumab to be the new standard of care treatment for patients with resectable NSCLC in England, and thus believe that the most relevant comparator for decision making is perioperative pembrolizumab. Where do you consider nivolumab with chemotherapy will fit into the existing care pathway for resectable NSCLC? Perioperative nivolumab represents a similar treatment option to perioperative pembrolizumab for patients in the existing care pathway for resectable NSCLC, evidenced by a robust indirect treatment comparison of nivolumab and pembrolizumab. Notably, nivolumab is the only immuno-oncology agent to have demonstrated a statistically significant and clinically meaningful EFS benefit as both neoadjuvant-only and as a perioperative regimen. NICE intends to evaluate this technology through its cost comparison process. BMS agrees with NICE that cost comparison is the most appropriate routing for this appraisal. Considering the similarity in efficacy demonstrated via indirect treatment comparison for nivolumab vs. pembrolizumab, similar randomised-controlled trial results, same mechanisms of action (PD-1 inhibitors) and routine use of pembrolizumab in NHSE, BMS consider it highly appropriate to conduct this evaluation via cost comparison.	Thank you for your responses to the consultation questions.

Section	Consultee/ Commentator	Comments [sic]	Action
		Importantly, patients could achieve access to perioperative nivolumab faster via the cost comparison route compared with the standard single technology appraisal route.	
Additional comments on the draft scope	Bristol Myers Squibb	No comments.	Thank you for your comment.
	MSD UK Ltd	None	Thank you for your comment.

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

Association of Respiratory Nurses
AstraZeneca