National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Atezolizumab for adjuvant treatment of resected non-small-cell lung cancer ID3852

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	British Thoracic Oncology Group	Yes	Comment noted
	Roche Products Limited	The wording of the remit should be updated to reflect the expected European Medicines Agency (EMA) licenced indication: "To appraise the clinical and cost effectiveness of atezolizumab within its marketing authorisation for [redacted]."	Thank you for your comment. The remit is kept broad to cover the final marketing authorisation. No action required.
Timing Issues	British Thoracic Oncology Group	Current adjuvant therapy carries a relatively low benefit in terms of reducing risk of recurrence. Hence a therapy that can improve the curative rate should be considered for implementation urgently.	Thank you for your comment. No changes needed.

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	Roche Products Limited	Given the existing gap between marketing authorisation and access, Roche encourage this appraisal to continue in line with usual NICE scheduling to ensure there is no further delay to patient access.	Thank you for your comment. NICE tries to schedule topics in order to produce timely guidance if possible.
Additional comments on the draft remit	British Thoracic Oncology Group	No comment provided	N/A
	Roche Products Limited	No comment provided	N/A

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	British Thoracic Oncology Group	Complete and accurate	Thank you for your comment. No changes needed.
	Roche Products Limited	The information provided is accurate and provides a good overview of the disease setting.	Thank you for your comment. No changes needed.
The technology/ intervention	British Thoracic Oncology Group	Yes – but clarity on whether stage 1B is included in the appraisal ImPower 010 was stage II to IIIA	Thank you for your comment. Trial inclusion criteria for ImPower 010 was histological or

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			cytological diagnosis of Stage IB to IIIA NSCLC. The committee will discuss the presented evidence for the whole population as well as subgroups where applicable.
	Roche Products Limited	Yes	Comment noted
Population	British Thoracic Oncology Group	Same as above – need clarity on the staging the technology is aimed at ?II to IIIA	Thank you for your comment. Trial inclusion criteria for ImPower 010 was histological or cytological diagnosis of Stage IB to IIIA NSCLC. The committee will discuss the presented evidence for the whole population as well as subgroups where applicable.
	Roche Products Limited	Yes	Comment noted

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Comparators	British Thoracic Oncology Group	Yes	Comment noted
	Roche Products Limited	Roche agree that “established clinical management” represents the standard of care for United Kingdom (UK) patients in this indication. This corresponds to best supportive care (BSC) in the IMpower010 clinical trial where patients were monitored with chest x-rays and computed tomography (CT) scans.	Thank you for your comment. No changes needed.
Outcomes	British Thoracic Oncology Group	Yes Should DFS be included?	Thank you for your comment. The outcomes have been updated in the scope in line with this comment.
	Roche Products Limited	In order to more accurately reflect outcomes for adjuvant resected NSCLC patients and align with the trial primary outcome measures, we propose that “progression-free survival” (PFS) should be updated to “disease-free survival” (DFS). Further, response rates were not collected in IMpower010 and therefore will not be included as an outcome in the submission. All other outcomes are appropriate and capture the most important health-related benefits and harms.	Thank you for your comment. The outcomes have been updated in the scope in line with this comment.
Economic analysis	British Thoracic Oncology Group	n/a	Comment noted

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	Roche Products Limited	Atezolizumab has demonstrated considerable patient benefit, thus a cost-effectiveness analysis is the most appropriate economic analysis. This will be expressed in terms of incremental cost per quality-adjusted life-year. The time horizon should be sufficient to capture all health related benefits and costs of treatment. A lifetime horizon that captures the full expected overall survival of patients is the appropriate time horizon. The costs of programmed death-ligand 1 (PD-L1) testing should also be included where relevant.	Thank you for your comment. No changes to the scope required.
Equality and Diversity	British Thoracic Oncology Group	n/a	Comment noted
	Roche Products Limited	No equality issues have been identified which would affect the proposed remit and scope. However, it is worth noting that the NHS lung cancer screening pilot[1] has not been rolled out nationally yet, and this may affect how effectively early non-small cell lung cancer patients are diagnosed across the country. This may lead to equality issues if adjuvant immunotherapy becomes available for patients. [1] NHS England. NHS to rollout lung cancer scanning trucks across the country, 2019. Available: https://www.england.nhs.uk/2019/02/lung-trucks/ [Accessed 15 April 2021].	Thank you for your comment. The committee will consider equality issues during the appraisal. No changes needed.
Other considerations	British Thoracic Oncology Group	n/a	Comment noted
Innovation	British Thoracic Oncology Group	Yes Current adjuvant therapies offer modest / minimal benefit to reduce risk of recurrence.	Thank you for your comment. Innovation will be considered in more detail as part of

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		A treatment that can increase the curative rate would have a substantial and significant impact. Once a patient recurs there is clearly a huge impact on quality of life and prognosis / life expectancy for a patient. On top of this patients require on and off palliative systemic therapy, which in itself will add a cost impact on the healthcare system. Hence to be able to reduce the risk of recurrence will have patient and health economic benefit.	the full appraisal No changes needed.
	Roche Products Limited	• **Do you consider the technology 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)?** Yes, atezolizumab can be considered innovative in its potential to make a substantial impact. Atezolizumab can provide an additional treatment where currently no treatment options exist representing a step-change in the management of the condition. • **Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?** No • **Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.** IMpower010 (NCT02486718) is a phase III global, multicenter, open-label, randomized study to compare the efficacy and safety of 16 cycles (1 cycle duration=21 days) of atezolizumab (MPDL3280A) treatment compared with BSC in participants with Stage IB-Stage IIIA NSCLC following resection and adjuvant chemotherapy.[2] IMpower010 will inform the evidence base pertaining to this submission	Thank you for your comment. No changes needed. Innovation will be considered in more detail as part of the full appraisal. No action needed.

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		[2]Study to Assess Safety and Efficacy of Atezolizumab (MPDL3280A) Compared to Best Supportive Care Following Chemotherapy in Patients With Lung Cancer [IMpower010]. https://clinicaltrials.gov/ct2/show/NCT02486718	
Questions for consultation	British Thoracic Oncology Group	**Have all relevant comparators for atezolizumab for adjuvant treatment of fully resected non-small-cell lung cancer after cisplatin-based chemotherapy been included in the scope?** Yes **Are all people with fully resected stage IB, II or IIIA NSCLC suitable for adjuvant therapy?** Stage IB only if 4cm Also depends on patients fitness / co-morbidities / age **Are there any other technologies for adjuvant treatment of fully resected NSCLC after cisplatin-based chemotherapy?** For EGFR mutation positive patients – not relevant here **How should 'established clinical management without atezolizumab' be defined?** Surveillance **Is there a routine test to detect the biomarker PD-L1 in resected samples?**	Thank you for your comment. No further changes needed.

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		Yes – already established in advanced disease **Are the outcomes listed appropriate?** Yes – but should DFS be included? **Are there any subgroups of people in whom atezolizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?** PDL1 positive patients may derive greater benefit **Where do you consider atezolizumab will fit into the existing NICE pathway, Lung Cancer?** In the adjuvant setting post platinum based adjuvant chemotherapy for suitable patients	
	Roche Products Limited	• **Have all relevant comparators for atezolizumab for adjuvant treatment of fully resected non-small-cell lung cancer after cisplatin-based chemotherapy been included in the scope?** Roche have amended the proposed comparator list in order to align with standard of care for RET fusion-positive patients. Please see the Comparators row under Comment 2: the draft scope for further details. • **Are all people with fully resected stage IB, II or IIIA NSCLC suitable for adjuvant therapy?** No, Roche have engaged with UK clinical experts and understand that not all patients with fully resected stage IB, II or IIIA NSCLC are suitable for adjuvant treatment. Pre-pandemic, approximately 40% of patients would go on to receive adjuvant therapy but this would vary across centres. The main reasons a patient would not receive adjuvant therapy post surgery are:	Thank you for your comment. No further changes needed.

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		○ due to their comorbidities ○ if the surgery was extensive, and therefore led to patients not being fit enough for further systemic treatment. • **Are there any other technologies for adjuvant treatment of fully resected NSCLC after cisplatin-based chemotherapy?** No other treatments for patients at this stage of the treatment pathway are available. • **How should 'established clinical management without atezolizumab' be defined?** Established clinical management should be defined as per UK standard of care. This comprises no treatment but includes active monitoring of patients, including regular chest x-rays and CT scans. This aligns to the approach taken in the BSC population of the IMpower010 trial. • **Is there a routine test to detect the biomarker PD-L1 in resected samples?** The 22C3 and SP263 immunohistochemistry assays are PD-L1 tests routinely available across the UK (another assay available for PD-L1 testing is SP142). • **Are the outcomes listed appropriate?** Roche have suggested an update to the outcomes listed in the scope replacing PFS with DFS and the exclusion of response rates. Please see the Outcomes row for further details. • **Are there any subgroups of people in whom atezolizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?** No • **Where do you consider atezolizumab will fit into the existing NICE pathway, Lung Cancer?** [redacted]	

Section	Consultee/ Commentator	Comments [sic]	Action
		[redacted] Currently patients at this stage of the treatment pathway receive established clinical management, which includes active monitoring. • **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 atezolizumab will be licensed?** No • **Please tell us if the proposed remit and scope could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population?** No equality issues have been identified which would affect the proposed remit and scope. However, it is worth noting that the NHS lung cancer screening pilot**Error! Bookmark not defined.** has not been rolled out nationally yet, and this may affect how effectively early non-small cell lung cancer patients are diagnosed across the country. This may lead to equality issues if adjuvant immunotherapy becomes available for patients. • **Please tell us if the proposed remit and scope could have any adverse impact on people with a particular disability or disabilities?** No • **Do you consider atezolizumab 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)?** Yes, atezolizumab can be considered innovative in its potential to make a substantial impact. See the Innovation row for further details. • **Do you consider that the use of atezolizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?**	

Section	Consultee/ Commentator	Comments [sic]	Action
		No	
Additional comments on the draft scope	British Thoracic Oncology Group	No comment provided	N/A
	Roche Products Limited	No comment provided	N/A

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

Not applicable