National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Mosunetuzumab for treating relapsed or refractory follicular lymphoma [ID3931]

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	Roche	This topic is considered appropriate to be referred to NICE	Thank you for your comment. No action needed.
	Lymphoma Action	No comment	No action needed.
Wording	Roche	The licence wording is anticipated to be [redacted]	Thank you for your comment. Mosunetuzumab will be appraised for treating relapsed or refractory follicular lymphoma within its marketing authorisation. No action needed.
	Lymphoma Action	No comment	No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Timing Issues	Roche	There is an unmet clinical need perceived by experts in lymphoma treatment for patients with relapsed or refractory FL who have received at least two prior systemic therapies; cycling through anti-CD20 immuno-chemotherapy regimens (rituximab/obinutuzumab (R/O)-CHOP, R/O-bendamustine, R/O-CVP) at each relapse, represents the most common treatment pathway. Therefore, there is a need for well-tolerated, non-cytotoxic chemotherapy options delivered as monotherapy for disease management in the third line or subsequent treatment lines. We encourage this appraisal to continue in line with usual NICE scheduling to ensure there is no delay to patient access.	Thank you for your comment. NICE has scheduled this topic into its work programme and aims to provide draft guidance to the NHS as soon as possible after marketing authorisation. No action required.
	Lymphoma Action	No comment	No action needed.
Additional comments on the draft remit	Roche	No comment	No action needed.
	Lymphoma Action	No comment	No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Roche	We suggest that a statement regarding worsening prognosis with each subsequent relapse is added to provide context for this indication in multiply relapsed FL e.g. 'FL becomes more difficult and survival outcomes worsen with each subsequent relapse as patients progress through multiple lines of therapy (1). Otherwise, we consider this section accurate and complete.	Thank you for your comment. The background section has been updated to include information on

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			prognosis following relapse as suggested.
	Lymphoma Action	No comment	No action needed.
The technology/ intervention	Roche	No comment	No action needed.
	Lymphoma Action	No comment	No action needed.
Population	Roche	The appropriate population for this appraisal should be: [redacted].	Thank you for your comment. The population has been kept broad to maintain flexibility in the appraisal. No action needed.
	Lymphoma Action	No comment	No action needed.
Comparators	Roche	All relevant comparators have been identified.	Thank you for your comment. No action needed.
	Lymphoma Action	No comment	No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Outcomes	Roche	The listed outcomes capture the most important health-related benefits.	Thank you for your comment. No action needed.
	Lymphoma Action	No comment	No action needed.
Economic analysis	Roche	No comment	No action needed.
	Lymphoma Action	No comment	No action needed.
Equality and Diversity	Roche	No equity or equality issues are anticipated.	Thank you for your comment. No action needed.
	Lymphoma Action	No comment	No action needed.
Other considerations	Roche	None to consider	Thank you for your comment. No action needed.
	Lymphoma Action	No comment	No action needed.
Innovation	Roche	We consider mosunetuzumab to be an innovative technology in the context of this appraisal. We expect that mosunetuzumab will be the first CD20xCD3 bispecific antibody licensed for the treatment of any non-Hodgkin lymphoma histological subtype, having the potential to improve outcomes and health-	Thank you for your comments. The appraisal committee will consider the innovative nature of this

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		related quality of life in multiply relapsed FL as a non-chemo, monotherapy option.	technology during the appraisal. No action required.
	Lymphoma Action	Mosunetuzumab is a novel, innovative treatment that targets two different proteins, one disproportionately expressed by lymphoma cells and one by healthy T cells. This activates T cells, resulting in T-cell mediated destruction of lymphoma cells. Mosunetuzumab was granted Breakthrough Therapy Designation by the FDA in the US, recognising its potential in follicular lymphoma. This was based on clinical trial results that demonstrated high response rates and durable complete remissions in people with relapsed or refractory non-Hodgkin lymphoma. Follicular lymphoma can be difficult to get into complete remission, with many current treatments aiming for as good a partial remission as possible. Relapse is common. The ability to achieve durable complete remissions represents a breakthrough in follicular lymphoma treatment.	Thank you for your comments. The appraisal committee will consider the innovative nature of this technology during the appraisal. No action required.
Questions for consultation	Roche	Have all relevant comparators for mosunetuzumab been included in the scope? As per our comments in the comparators section, all relevant comparators have been identified. Which treatments are considered to be established clinical practice in the NHS for relapsed and refractory follicular lymphoma?	Thank you for your comments. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		Most patients considered for active treatment of FL will receive anti-CD20 (rituximab or obinutuzumab (O)) immuno-chemotherapy as first line treatment, e.g. R/O-CHOP, R/O-bendamustine, R/O-CVP. On first and second relapse, patients are likely to receive one of the above R/O-based chemotherapy regimens not received in prior treatment lines. Some patients may be eligible for a combination of rituximab and lenalidomide ('R squared') at first or second relapse <u>How would the use of mosunetuzumab change the subsequent treatments available for managing relapsed or refractory follicular lymphoma, including stem cell transplantation?</u> Use of mosunetuzumab is not expected to change subsequent treatment options, such as for instance further chemotherapy-based regimens. Instead it would result in a delay in the need for these intensive treatment options. <u>Are the outcomes listed appropriate?</u> Please see the response to the "Outcomes" section above. <u>How should best supportive care be defined?</u> Best supportive care involves regular follow-up with a lymphoma specialist and/or palliative care team, individual site radiotherapy, steroids, blood product support if required, and antibiotics to treat infection. <u>Where do you consider mosunetuzumab will fit into the existing NICE pathway, for 'treating follicular lymphoma'?</u>	

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		Aligned to the proposed licensed indication above, we expect mosunetuzumab will be used as an additional treatment option for patients requiring treatment after two or more prior systemic therapies. The clinical decision to use mosunetuzumab instead of/before existing options (e.g. rituximab-lenalidomide or autologous stem cell transplantation) may be based on patient characteristics (age, fitness) or risk of subsequent relapse (refractoriness to prior treatments, progression of disease within 24 months of first line treatment (POD24), disease stage).	
	Lymphoma Action	No comment	No action needed.
Additional comments on the draft scope	Roche	No comment	No action needed.
	Lymphoma Action	No comment	No action needed.

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

None