National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Polatuzumab vedotin in combination for untreated diffuse large B-cell lymphoma [ID3901]

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.	Comment noted. No action needed.
Wording	Roche	The anticipated license is as follows: [redacted] We recommend the remit is updated to reflect this.	Comment noted. NICE will appraise the technology within its marketing authorisation. No changes required.
Timing Issues	Roche	We encourage this appraisal to continue in line with usual NICE scheduling to ensure there is no delay to patient access. [redacted]	Comment noted. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft remit	Roche	No additional comments on the draft remit received.	No action needed

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Roche	Please note the overall survival data quoted in the 4th paragraph states the following: *Overall survival rates at 5 years for DLBCL were around 55.4% in 2004-2011*[3] This has been updated on the Haematological Malignancy Research Network (HMRN) website to include data from 2004 - 2016. The reference states the OS for DLBCL (NOS) at 5 years is 59.8%. https://hmrn.org/statistics/survival Note in the 4 paragraph it states post-germinal DLBCL has a better prognosis. This should read However, diagnosis at an early stage and [redacted] DLBCL have a better prognosis.	Comment noted. Overall survival rates and survival rates by stage information updated to reflect most recent HMRN data. Germinal DLBCL is now noted as being associated with better prognosis in the draft scope.
The technology/ intervention	Roche	In the second paragraph please add the wording previously untreated to the following sentence [redacted]	Comment noted. No change required as [redacted]

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			[redacted] refer to the same population.
Population	Roche	The trial population for the POLARIX clinical trial included adults aged 18 to 80 with previously untreated DLBCL with an International Prognostic Index (IPI) of 2-5.	Comment noted. No action required.
Comparators	Roche	The draft scope includes the following comparators: Chemoimmunotherapy (including R-CHOP) R-CHOP is the current standard of care for previously untreated DLBCL.	Comment noted. No action required.
Outcomes	Roche	Yes, the listed outcomes capture the most important health-related benefits and harms. However, it is important to note that the OS is a secondary endpoint. The company suggests listing PFS first followed by OS to reflect that PFS as a primary endpoint.	The committee will consider the relevant outcomes. No action required.
Economic analysis	Roche	Pola + R-CHP has demonstrated considerable benefit over R-CHOP, 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.	Comment noted. No action needed.
Equality and Diversity	Roche	No equality issues have been identified.	Comment noted. No action needed.
Other considerations	Roche	The draft scope states:	Comment noted. The committee will consider any relevant subgroups

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		If the evidence allows, the following subgroups will be considered. These include: *germinal centre DLBCL, and* *post-germinal centre DLBCL* Patients with DLBCL comprise a heterogeneous set of patient characteristics and disease characteristics. The large sample size (N=879) of the POLARIX study represents a global and generalisable previously untreated DLBCL population and includes a diverse population with poor prognostic factors (covered in multiple subgroups) who may have suboptimal outcomes with the current standard of care therapy. The proportion of patients within various biologic subgroups in this study was also reflective of their incidence in clinical practice. [redacted] The subgroups described in the draft scope are not -appropriate to determine treatment in clinical practice, as the cell of origin biopsy results are not received back prior to treatment initiation. DLBCL is a high grade lymphoma and initiating treatment in a timely manner is critical. This was feedback from UK clinical experts attending a Roche advisory board.	if the evidence allows. No action required.
Innovation	Roche	[redacted]	Comment noted. The committee will consider if the technology is innovative. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		[redacted]	

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Questions for consultation	Roche	*Have all relevant comparators for polatuzumab vedotin been included in the scope? Which treatments are considered to be established clinical practice in the NHS for untreated diffuse large B-cell lymphoma?* Please refer to the comparator section. *Would polatuzumab vedotin only be given with R-CHP or would it be also considered in combination with other chemoimmunotherapy? If so what chemoimmunotherapy would be used?* Based on the POLARIX clinical trial, polatuzumab vedotin can only be given with R-CHP in previously untreated DLBCL. This could change in the future after conducting more clinical trials. *What tests are used to diagnose DLBCL?* There are no additional tests required to diagnose DLBCL compared with current clinical practice for the– use of polatuzumab vedotin in previously untreated DLBCL. The current diagnostic tests in clinical practice enable clinicians to calculate the patient's IPI score. *Are the outcomes listed appropriate?* Please refer to the outcomes section.	Comments noted. Please see other sections for the relevant response.

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		Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom polatuzumab vedotin with R-CHP is expected to be more clinically effective and cost effective or other groups that should be examined separately? Please see the other considerations section. *Where do you consider polatuzumab vedotin will fit into the existing NICE pathway, non-Hodgkin's lymphoma?* Polatuzumab vedotin in combination with a rituximab, cyclophosphamide, doxorubicin, and prednisone (R CHP), should be used as a first line treatment for adult patients with previously untreated DLBCL who have a IPI score of 2-5. *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 polatuzumab vedotin with R-CHP will be licensed;* *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;*	

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		could have any adverse impact on people with a particular disability or disabilities. *Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.* No equality considerations. *Do you consider polatuzumab vedotin with R-CHP 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)?* See above 'innovation section' *Do you consider that the use of polatuzumab vedotin with R-CHP can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* No comment at this stage. *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.* [redacted] [redacted]	

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		[redacted] [redacted] *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.* We don't anticipate that there will be any barriers for adoption of this technology into practice.	
Additional comments on the draft scope	Roche	No comments received.	No action needed.

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

None