National Institute for Health and Care Excellence

Health Technology Evaluation

Epcoritamab with rituximab and lenalidomide for treating relapsed or refractory follicular lymphoma after 1 or more systemic treatments [ID6586]

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	AbbVie	AbbVie agrees that epcoritamab with rituximab and lenalidomide for treating relapsed or refractory follicular lymphoma after 1 or more systemic treatments should be evaluated as a single technology appraisal.	Thank you for your comment.
	The Follicular Lymphoma Foundation	We are satisfied with the appropriateness of evaluation and proposed evaluation route.	Thank you for your comment.
	Royal College of Pathologists	In my opinion this is an appropriate evaluation that intends to assess the clinical efficacy and cost effectiveness of a new treatment (Rituximab-Epcoritamab-Lenalidomide) in relapsed Follicular lymphoma. It is appropriate to be assessed as a Single Technology appraisal.	Thank you for your comment.
Wording	AbbVie	The wording of the remit reflects the issue of clinical and cost-effectiveness.	Thank you for your comment.

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	The Follicular Lymphoma Foundation	We feel the wording reflects the issues.	Thank you for your comment.
	Royal College of Pathologists	Yes the wording of the remit is appropriate	Thank you for your comment.
Timing Issues	AbbVie	There is an urgent need for new therapies in relapsed/refractory (R/R) follicular lymphoma (FL). Despite periods of remission after first line treatment, FL typically recurs, and remissions after subsequent lines of therapy are generally shorter than after initial therapy. (Cancer Research UK, 2024) Epcoritamab is a humanised immunoglobulin G1 (IgG1) bispecific antibody that binds CD3 on T-cells and CD20 on B-cells (electronic medicines compendium, 2025). In this regimen, it is combined with rituximab and lenalidomide. This novel combination would introduce a new treatment option, in a therapy area where no new treatments have been reimbursed since 2020 (National Institue of Health and Care Excellence, 2025). Epcoritamab plus lenalidomide and rituximab (R2) has shown statistically significant improvement in progression free survival and overall response rate vs. R2 (Genmab, 2025), the last reimbursed treatment by NICE (National Institue of Health and Care Excellence, 2025), in the EPCORE FL-1 phase III trial.	Thank you for your comment. NICE has scheduled this topic into its work programme. No action required.

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	The Follicular Lymphoma Foundation	T cell engaging (TCE) therapies, including CART and bispecific antibodies, are active treatments for follicular lymphoma that have been available for several years. In many countries. Currently none of these are recommended for use in the UK for relapsed/refractory FL as axi-cel and mosunutuzumab were not recommended. Patients today should have access to at least one such TCE. If the pending eopcoritamab single agent recommendation is denied, then this would be an urgent matter.	Thank you for your comment. NICE has scheduled this topic into its work programme. No action required.
	Royal College of Pathologists	We anticipate additional data on this regimen to become available Dec 2025. There are very few funded treatment options for Relapsed and refractory FL in the NHS and we urgently need more effective treatment options for our patients. Accordingly I hope that this can be evaluated as a priority.	Thank you for your comment. NICE has scheduled this topic into its work programme. No action required.
Additional comments on the draft remit	AbbVie	N/A	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	AbbVie	Clarity that grade 3B does not just “grow more quickly” but behaves as an aggressive lymphoma and is treated as such. Active monitoring/watch and wait should be added as an option for patients with untreated FL before discussion of first-line treatment.	Thank you for your comment. The scope now reflects the aggressive nature of grade 3b lymphomas. The background section of the scope is intended

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			to provide a brief introduction to the disease area. No further action required.
	The Follicular Lymphoma Foundation	We are satisfied with the accuracy and completeness	Thank you for your comment.
	Royal College of Pathologists	The background information is accurate but the need for better treatments in relapsed follicular lymphoma could be made more strongly, and the poor prognosis (including inferior overall survival) for those with early progression post first-line therapy (POD24) could be added I am note sure if the details on the current marketing authorisation status of Epcoritamab in the UK are accurate, there are 2 contradictory statements. It does have an MHRA licence as a **monotherapy** in FL "*Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy*." Maybe it should say '*Epcoritamab in combination with Rituximab and Lenalidomide does not have a licence"*?	Thank you for your comment. The aim of the background is to provide a very brief summary of the disease area. Further details can be included in all submissions for this evaluation for consideration by the appraisal committee. Thank you for your comment. The wording has been updated to reflect the anticipated marketing authorisation.

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Population	AbbVie	No comment	Thank you for your comment.
	The Follicular Lymphoma Foundation	Population is defined appropriately	Thank you for your comment.
	Royal College of Pathologists	Yes	Thank you for your comment.
Subgroups	AbbVie	AbbVie does not believe that there are any subgroups that should be examined separately.	Thank you for your comment.
	The Follicular Lymphoma Foundation	No comment to add	Thank you for your comment.
	Royal College of Pathologists	Not necessarily. But depending on outcomes there could be merit in looking specifically at patients with high risk relapse (including early progression /POD24) or those who have relapsed after a certain number of prior therapies where the need for better therapies is highest.	Thank you for your comment.
Comparators	AbbVie	Of the comparators listed in the draft scope, AbbVie agree that the following are relevant comparators: - Obinutuzumab with bendamustine followed by obinutuzumab maintenance - Lenalidomide with rituximab - Rituximab alone or in combination with chemotherapy	Thank you for your comment. The comparators have been kept broad to include all potentially relevant comparators. The

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		AbbVie do not view best supportive care (BSC) to be a relevant comparator within this appraisal as people receiving BSC would not be fit enough to receive an active intervention such as epcoritamab and therefore the intervention for this appraisal is not expected to displace BSC. AbbVie do not consider epcoritamab monotherapy and tafasitamab with lenalidomide and rituximab as relevant comparators, as they are not recommended by NICE, nor are they likely to be established within current NHS practice at the time of this appraisal.	committee will discuss relevant comparators as part of its deliberations, based on available evidence and clinical opinion on current standard care in the NHS.
	The Follicular Lymphoma Foundation	We agree with the comparators used.	Thank you for your comment.
	Royal College of Pathologists	Yes the list of comparators is accurate according to the limited scope of treatments that are currently used in the NHS. There are no commissioned therapies in use in the NHS that are not included.	Thank you for your comment.
Outcomes	AbbVie	AbbVie considers the outcomes listed to be appropriate and believe these measures will capture the most important health benefits in patients treated with epcoritamab.	Thank you for your comment.
	The Follicular Lymphoma Foundation	We agree with the outcomes listed.	Thank you for your comment.
	Royal College of Pathologists	Yes, outcome measures listed are appropriate. Does not include safety (toxicity) profile though.	Thank you for your comment. Please note that the list of outcomes listed in the scope are not intended to be exhaustive and the

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			appraisal committee can consider further outcomes where relevant.
Equality	AbbVie	No further inequalities have been identified.	Thank you for your comment.
	The Follicular Lymphoma Foundation	We are satisfied with the equality.	Thank you for your comment.
	Royal College of Pathologists	Follicular lymphoma affects male and female patients almost equally, people of any ethnicity can develop FL, and although incidence increases with age it can affect people of any ago. I do not anticipate that this draft remit would lead to exclusion of any group of people with FL. It is worth considering that as the incidence of FL increases with age a proportion of patients with RR FL will fall in to older age groups and may therefore be more likely to have co-morbdities or frailty that preclude the delivery of more intensive treamtents such as multi-agent chemotherapy, stem cell transplant, or CAR-T cell therapy (where available). In my view the treatment proposed in this draft remit could be delivered to patients of any age and to patients not considered fit enough for the intensive treatment options listed above.	Thank you for your comment. Comment noted. The committee will consider any relevant equality issues during the evaluation.

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		I do not consider that any changes need making to the draft remit with regards equality of access.	
Other considerations	AbbVie	No additional comments	Thank you for your comment.
	The Follicular Lymphoma Foundation	n/a	Thank you for your comment.
	Royal College of Pathologists	None	Thank you for your comment
Questions for consultation	AbbVie	**Where do you consider epcoritamab will fit into the existing care pathway for follicular lymphoma?** **Please select from the following, will epcoritamab be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** D. Prescribed in secondary care with routine follow-up in secondary care/tertiary care via specialist cancer centres **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.**	Thank you for your comment.

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		AbbVie do not anticipate the prescribing and routine follow-up to differ for epcoritamab with rituximab and lenalidomide compared with the comparators outlined previously or for subsequent treatments. **Would epcoritamab be a candidate for managed access?** Based on currently available data from the EPCORE FL-1 trial, AbbVie expect epcoritamab with rituximab and lenalidomide to be a cost-effective use of resources for treating patients with relapsed or refractory follicular lymphoma and therefore suitable for routine commissioning. However, a managed access agreement may be considered if there is any need to address residual uncertainty. **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.** The EPCORE FL-1 trial is a phase 3 open-label interventional trial to evaluate the safety and efficacy of epcoritamab plus R2 versus R2 alone in patients with relapsed/refractory (R/R) follicular lymphoma (FL) (Genmab, 2025) and will form the basis of the data to help the committee evaluate the benefits of this combination. Within this trial, the dual primary endpoints of overall response rate and progression free survival have been achieved. These results, derived from a pre-planned interim analysis, will be submitted for presentation at the 67th Annual Meeting and Exposition of the American Society of Hematology (ASH) held from 6th-9th December, and will serve as the basis for global regulatory	

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		submissions (Genmab, 2025). The results showed that this new combination demonstrates statistically significant improvement in Overall Response Rate (ORR; 95.7%, p < 0.0001) and Progression-Free Survival (HR 0.21, p-value <0.0001) versus R2 alone in patients with relapsed/refractory (R/R) Follicular Lymphoma (FL) (Genmab, 2025). Epcoritamab plus R2 has a safety profile which is consistent with the known safety profiles of the individual regimens, with no new safety signals being observed (Genmab, 2025). As Epcoritamab plus R2 is a fixed treatment duration therapy it presents an opportunity for patients to be treatment free and provides a novel option to manage their follicular lymphoma.	
	The Follicular Lymphoma Foundation	n/a	Thank you for your comment.
	Royal College of Pathologists	Where do you consider epcoritamab will fit into the existing care pathway for follicular lymphoma? • I anticipate that this treatment would be applicable to most patients with RR FL regardless of POD24 status or number of lines of prior therapy. Most patients would have R-orO-chemo+-maintenance as first line treatment and this treatment could be considered at first or later relapse.	Thank you for your comment.

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		For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention. • Setting would be the same for comparators: most management and follow up of FL occurs in secondary care Would epcoritamab be a candidate for managed access? • If the committee consider that additional data would be helpful a managed access scheme could be considered. Do you consider that the use of epcoritamab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation? • Need to consider number and costs of subsequent treatments which will likely be lower for the treatment under consideration than for comparators. Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. • Data on the trial underpinning this draft have been presented in oral abstracts at international conferences over the last 2 years, I anticipate follow up to be presented at ASH meeting in Dec 2025 and possibly a full paper to follow at a similar time	

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Additional comments on the draft scope	AbbVie	References Cancer Research UK. (2024, March 5). Follicular lymphoma. Retrieved from Cancer Research UK: https://www.cancerresearchuk.org/about-cancer/non-hodgkin-lymphoma/types/follicular-lymphoma electronic medicines compendium. (2025, August 8). Tepkinly 4 mg/0.8 ml solution for injection. Retrieved from EMC: https://www.medicines.org.uk/emc/product/15187/smpc#gref Genmab. (2025, August 7). Genmab Announces Phase 3 EPCORE® FL-1 Clinical Trial Met Dual Primary Endpoints in Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL). Retrieved from Genmab: https://ir.genmab.com/news-releases/news-release-details/genmab-announces-phase-3-epcorer-fl-1-clinical-trial-met-dual National Institue of Health and Care Excellence. (2025, October 7). Follicular lymphoma. Retrieved from NICE: https://www.nice.org.uk/search?q=follicular%20lymphoma National Institute for Health and Care Excellence. (2020, May 13). Obinutuzumab with bendamustine for treating follicular lymphoma after rituximab. Retrieved from NICE: https://www.nice.org.uk/guidance/ta629/chapter/1-Recommendations	Thank you for your comment.
	The Follicular Lymphoma Foundation	n/a	Thank you for your comment.
	Royal College of Pathologists	n/a	

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

Incyte Biosciences, Lymphoma Action