National Institute for Health and Care Excellence

Health Technology Evaluation

Epcoritamab for treating relapsed or refractory large B-cell lymphoma after 2 or more systemic treatments [ID4045]
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	No comments; AbbVie consider the proposed evaluation and evaluation route to be appropriate.	No action required
Wording	AbbVie	The license wording is anticipated to be: [redacted]	The remit is kept broad in case the marketing authorisation is not granted as anticipated. The remit includes the words 'within its marketing authorisation' so the appraisal will cover the population in

Section	Stakeholder	Comments [sic]	Action
		Therefore, please amend the wording of the remit to align with the anticipated licensed indication of epcoritamab, as follows: **"To appraise the clinical and cost effectiveness of epcoritamab within its marketing authorisation for treating adults with relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma, after two or more lines of systemic therapy."**	the final marketing authorisation. Comment noted. The population within the remit has been updated to include large B-cell lymphoma. To ensure the population is broad at this stage, diffuse large B-cell lymphoma has been removed.
Additional comments on the draft remit	AbbVie	Timing: Epcoritamab offers a highly effective and tolerable treatment option that would be available to a broad range of patients with LBCL at third line or later, who have a high unmet need for additional effective treatment options. As such, the NHS and patients would benefit from epcoritamab being prioritised for evaluation	Comment noted. Thank you for your comment. NICE aims, where possible, to produce timely guidance in line with marketing authorisation. No action needed.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
	AbbVie	The epidemiology data presented from 2017 are likely out of date; AbbVie would recommend for the epidemiology statistics to be updated based on more recent	Thank you for your comments. The

Section	Consultee/ Commentator	Comments [sic]	Action
Background information		data. Cancer Research UK provides updated data on the incidence of non-Hodgkin's lymphoma and DLBCL.[1]	population has now been altered with more recent statistics from Cancer Registration Statistics for England 2020, which was published October 2022.
	AbbVie	Under the heading "*The technology*", the phase III trial is mentioned however the phase Ib/II trial, which is investigating the efficacy and safety of epcoritamab in patients with relapsed or refractory LBCL following two or more lines of systemic therapy and will inform this evaluation, should also be mentioned. In addition, the phase III trial includes patients with LBCL, rather than DLBCL only. Please can the wording be amended as follows: "Epcoritamab is being studied in a **phase Ib/II clinical trial in people with relapsed or refractory LBCL who have received two or more lines of systemic therapy. The efficacy and safety of epcoritamab is also being studied in a** phase III clinical trial, compared to chemoimmunotherapy, in people with relapsed or refractory ~~D~~LBCL and whose disease did not respond to or who or are not eligible for autologous stem cell transplant."	Thank you for your comment. The population in the phase III trial has been altered and the phase 1b/II has been added.
Population	AbbVie	As highlighted above, the population should be adults with relapsed or refractory LBCL, including DLBCL, after two or more lines of systemic therapies, in line with the anticipated licensed indication.	Thank you for your comment. The population has been updated.

Section	Consultee/ Commentator	Comments [sic]	Action
Subgroups	AbbVie	No comments; no subgroups are considered to be relevant to the scope of this evaluation.	No action required
Comparators	AbbVie	AbbVie agree that salvage chemoimmunotherapy, polatuzumab vedotin with rituximab and bendamustine, and axicabtagene ciloleucel (subject to appraisal outcome) are relevant comparators to epcoritamab. However, based on discussions with UK clinicians, the following treatments are not relevant comparators: • Pixantrone monotherapy is not used in UK clinical practice due to a lack of efficacy and high toxicity. This is supported by the recent appraisal by NICE of tafasitamab with lenalidomide [TA10645], in which clinical experts and NHS England and NHS Improvement (NHSEI) confirmed that pixantrone is not prescribed due to a lack of efficacy.[2] Therefore, pixantrone monotherapy is no longer a relevant comparator in UK clinical practice. • Tafasitamab with lenolidamide is not (yet) recommended by NICE and is therefore not routinely used in UK clinical practice and would not be considered standard practice by the time of this evaluation. As such, it is not considered a relevant comparator in this submission. Additionally, UK clinicians have indicated that salvage chemoimmunotherapy is always given in combination with rituximab. As such, please can the scope be amended as follows: "Salvage chemo**immuno**therapy with ~~**or without**~~ rituximab"	Comment noted. At the scoping stage, the list of comparators is inclusive. Pixantrone monotherapy maybe used by some patients and is considered a relevant comparator. Comment noted. The wording has been updated in the scope to state Salvage chemoimmunotherapy with rituximab
Outcomes	AbbVie	AbbVie propose that time on treatment (ToT) is also included as an outcome measure on the scope as it captures a distinct element of treatment cost for epcoritamab.	Comment noted. The outcomes have been updated in the scope

Section	Consultee/ Commentator	Comments [sic]	Action
Equality	AbbVie	No comments; it is not anticipated that the provision (or non-provision) of epcoritamab within its marketing authorisation would exclude from consideration any people protected by equality legislation, lead to a recommendation that has a different impact on people protected by equality legislation than on the wider population, or lead to recommendations that have an adverse impact on people with a particular disability or disabilities.	No action required.
Other considerations	AbbVie	No comments	No action required.
Questions for consultation	AbbVie	Where do you consider epcoritamab will fit into the existing care pathway for DLBCL? • In line with the anticipated licensed indication, epcoritamab is expected to be a treatment for adult patients with R/R LBCL following two or more systemic therapies. Would epcoritamab be a candidate for managed access? • Epcoritamab data available at the time of submission are anticipated to be sourced from [redacted] to current NHS standard of care, and will provide evidence for the clinical and cost-effectiveness of epcoritamab as a treatment for R/R LBCL following two or more systemic therapies to support the single technology appraisal.	Thank you for your comments. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
		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? Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. AbbVie consider epcoritamab to be innovative for the management of LBCL in NHS clinical practice, [redacted] Epcoritamab is the first and only subcutaneous bispecific antibody for the treatment of adult patients with R/R LBCL after two or more line of systemic therapy. Whilst the cost-savings of the subcutaneous administration will be captured in the economic model, the benefits of greater flexibility and convenience for patients as well as reduced capacity burden for the NHS are not included in the QALY calculation.	
Additional comments on the draft scope	AbbVie	No additional comments	

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

Gilead Sciences
Lymphoma Action
Lymphoma Research Trust not taking part