National Cancer Control Programme

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**28th July 2025 at 4.30pm**
Venue:	**Teleconference via MS Teams**
Assessment:	Epcoritamab-bysp (Epkinly®)

TEXT FOR REDACTION DUE TO DELIBERATIVE PROCESS HIGHLIGHTED IN YELLOW

TEXT FOR REDACTION DUE TO COMMERCIAL SENSITIVITY IS HIGHLIGHTED IN PINK

TEXT FOR REDACTION DUE TO CONFIDENTIALITY IS HIGHLIGHTED IN BLUE

Attendance:

Members present		
NCPE representative	National Centre for Pharmacoeconomics (NCPE)	By MS Teams
Dr Neil Barrett	Consultant Haematologist, Children's Health Ireland – Crumlin: IHS representative **Chair**	By MS Teams
Dr Patrick Hayden	Consultant Haematologist, St James's Hospital: HIS representative	By MS Teams
Dr Janusz Krawczyk	Consultant Haematologist, Galway: IHS representative	By MS Teams
Ms Fiona Mulligan	PCRS representative	By MS Teams
Ms Aishling McLoughlin	Chief I Pharmacist, NCCP (Deputy Chair)	By MS Teams
Dr Dearbhaile O'Donnell	Medical Oncologist, St James's Hospital: ISMO nominee	By MS Teams
Dr Derville O'Shea	Consultant Haematologist, Cork University Hospital: NCCP National Clinical Lead(s) for Haemato-oncology	By MS Teams
Non-member invited specialists present		
Apologies (members)		
Dr Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	
Dr Dearbhaile Collins	Medical Oncologist, Cork University Hospital: ISMO nominee	
Prof Maccon Keane	Medical Oncologist, Galway: NCCP National Medical Oncology Programme Clinical Advisor	
Dr Liam Smyth	Consultant Haematologist, St Vincent's Private Hospital: NCCP National Clinical Lead(s) for Haemato-oncology	
Observers present		
Ms Helena Desmond	Senior Pharmacist, NCCP	By MS Teams

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded to raise any conflicts of interest that they had in relation to any drug for discussion prior to the commencement of the discussion of that item.	
2	**Notes of previous meeting and matters arising**	
	The notes of the previous meeting on June 30th 2025 were reviewed and agreed.	
3	**Drugs/Technologies for consideration**	
	Epcoritamab-bysp (Epkinly®) (Ref. TRC 178) *As monotherapy is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy.* The clinical aspects of this indication were discussed and the current treatment options for this patient cohort were outlined. The supporting evidence for this indication comes the EPCOR NHL-1 trial, a phase I/II, open label, single-arm trial that evaluated epcoritamab as monotherapy in patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy. In the DLBCL population, at the initial data cut, the trial showed an overall response rate (ORR) of approximately 60%, of whom approximately 40% achieved a complete response (CR) and approximately 20% achieved a partial response (PR), with a median duration of response (DoR) of 15 months. At a subsequent data cut, the response was sustained, with an ORR of 60% (CR 40% PR 21%) with the median DoR of 17.3 months. The safety profile of epcoritamab was discussed, due to access to epcoritamab via a compassionate access programme (CAP), clinicians are familiar with its safety profile. Cytokine release syndrome (CRS) was reported to be relatively uncommon, with almost most patients experiencing fever. The rate of ICANs reported was much lower than that seen with CAR-T cell therapy. Epcoritamab, a Bispecific T-cell Engager (BiTE), is a non-chemotherapy treatment that may provide an alternative option to the current standard of care (SOC) chemotherapy-containing regimens such as polatuzumab in combination with riTUXimab and bendamustine (pola+BR) and other riTUXimab-based therapies (i.e.: R-GDP (rituximab, gemcitabine, dexamethasone, CISplatin) and R-GEMOX (rituximab, gemcitabine, oxaliplatin). It was noted that the use of bendamustine is declining, due to its ability to impair patient's responses to Bispecific T-cell Engaging therapy afterwards. There is a strong desire among the clinicians to have epcoritamab available to use as a bridge to CAR-T cell therapy, and as an option for elderly and less fit patients. There would also be a place in therapy for younger, fitter patients, who are not in favour of having CAR-T cell therapy, or when there are capacity constraints for CAR-T cell therapy. It was also noted that patients who respond to epcoritamab have an excellent quality of life. While epcoritamab is licensed to be continued until disease progression, the Lymphoma Clinical Advisory Group (CAG) have proposed that reassessment of ongoing benefit versus cumulative toxicity is recommended after 12 months of therapy, particularly in patients in sustained complete response (CR). Treatment discontinuation at this point may be considered in select patients who have achieved a complete molecular remission (CMR), based on clinical experience and expert opinion; however this approach is not yet supported by published data. The pharmacoeconomic aspects as outlined in the rapid review (RR) assessment carried out by the NCPE were discussed. A number concerns were highlighted by the NCPE review group, such as the relevant comparators, patients population, the single arm nature of the trial and the lack of comparator evidence for epcoritamab. The comparators used in the RR assessment were discussed, noting that the Applicant considered CAR-T cell	

	therapy and pola+BR to be the most relevant comparators, and did not include other comparators such as R-GDP and R-GEMOX, therefore not reflecting real word comparators. The patient population in the supporting trial, the EPCOR NHL-1 trial, were a heavily pre-treated population in comparison to what is seen in clinical practice. Due to the single arm nature of the supporting trial, there is a lack of comparator evidence therefore, it is uncertain if epcoritamab performs better than the current SOC. In terms of the cost, the estimated cost per patient per year of epcoritamab was [redacted] based on a treatment duration of 9.1 treatment cycles (reflective of the supporting trial), The estimated cost per patient per year for tisagenlecleucel is [redacted], for axicabtagene ciloleucel is [redacted] and for pola+BR is €86K. In terms of the budget impact (BI), the Applicant estimated that [redacted] patients would be eligible for treatment per year and the net BI would be cost saving due to costs saved by displacing CAR-T cell therapy. However these estimates were made on strong assumptions that the NCPE review group consider are not correct at this time. For example the duration of treatment, the Applicant estimated that patients would be treated with epcoritamab for duration of 9.1 treatment cycles, based on the data cut after 1 year. However data published at year 2 and 3 indicate that patients were still receiving treatment 18% and 12% respectively, therefore the NCPE review group consider a treatment duration of 9.1 cycles is likely to be an underestimation. The NCPE review group highlighted concerns regarding the BI estimates with regards to the market share, the Applicant expected that the three comparators included in the RR assessment would account for equal percentage of the market share, however in reality this is not reflected, and in terms of market share this is very uncertain. Another issue with regards to the model is the assumption that epcoritamab would displace CAR-T cell therapy and pola+BR equally, however based on current clinical opinion, if capacity allows CAR-T cell therapy will continue to be the preferred option for the younger and fitter patients, therefore epcoritamab is not going to displace CAR-T therapy across the board which was estimated in the Applicants model, giving rise to uncertainty in the BI estimates. It was noted that a CIC PAS has been proposed for this indication. In terms of the NCPE recommendation, the NCPE recognise that a HTA may not be necessary, and consider that it is very important to acknowledge that there is a lack of clinical evidence for the benefit of epcoritamab compared to the current SOC, and that they are unable to make any specific recommendations without comparative evidence. Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group. *(Decision: TRC 178)*	
4	**Update on other drugs in the reimbursement process**	
	An update had been shared with the group in the documentation for the meeting	
5	**Next meeting**	
	The proposed date for the next meeting is Monday July 28th 2025	
6	**Any other business / Next meeting**	

The meeting concluded at 17.10pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
25/07	28/07/2025	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Complete

25/07	28/07/2025	Apply for CPD	NCCP	Complete