CADTH

Table 3: Level 2 Checklist for Screening Full-Text Articles and Clinical Effectiveness Study Reports

Reviewer: Date:					
Ref Aut Pul	Ref ID: Author: Publication Year:				
Did the study include:		Yes (Include)	No (Exclude)		
Α.	The population of interest:				
	 Adults (mean age of 18 years or older) with any of the following types of histologically confirmed relapsed or refractory large B-cell lymphoma:^a DLBCL, primary mediastinal B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma 				
	Mixed population, including adults with eligible types of relapsed or refractory large B-cell lymphoma, and results are reported separately for the eligible population				
	 Mixed population, including adults with eligible types of relapsed or refractory large B-cell lymphoma, but results are not reported separately. There are sufficient numbers of eligible patients (66% or more) to include in the study, but results will be reported and discussed separately. 				
В.	The intervention of interest:				
	Axicabtagene ciloleucel ^b				
C.	A comparator of interest:				
	Other CAR T-cell therapies (e.g., tisagenlecleucel)				
	Salvage chemotherapy				
	No comparator				
	No additional therapy				
D.	Outcome(s) of interest:				
•	Clinical effectiveness outcomes (e.g., response rate, survival, persistence of CAR T cells, health-related quality of life, patient-reported outcomes, and the need for subsequent treatment)				
•	Safety/harms outcomes (e.g., mortality, AEs, CRS, febrile neutropenia, B-cell aplasia, neurological effects including hallucination and dysphasia, infections, development of secondary malignancy, hospitalization)				
•	Other outcomes (frequency of manufacturing failure, management of AEs)				
Е.	A study design of interest:				
	• RCTs				
	Non-randomized controlled trialsSingle-arm studies				
	Cohort studies				
	Case-control studies				
	Case series				
	Indirect treatment comparisons, network meta-analyses				
F.	Notes:				
G.	Selected for inclusion in the review ^c	Yes 🗆	No 🗆		
Н.	Reason for exclusion	Irrelevant populationIrrelevant intervention			



Reviewer:	Date:		
Ref ID: Author: Publication Year:			
Did the study include:		Yes (Include)	No (Exclude)
		Irrelevant comparator Irrelevant outcomes Irrelevant study design Other (specify):	

AE= adverse event; CAR = chimeric antigen receptor; CRS = cytokine release syndrome; DLBCL = diffuse large B-cell lymphoma; RCT = randomized controlled trial. ^a Eligible indications include patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy.

^c Both reviewers must answer "yes" to all questions for inclusion at the full-text level. If there is a discrepancy between the reviewers, disagreements will be resolved by discussion or with the involvement of a third reviewer, if necessary.

^b Prescribing information indicates that the dose of axicabtagene ciloleucel is 2 × 10⁶ CAR-positive viable T cells per kg body weight, with a maximum of 2 × 10⁸ CAR-positive viable T cells in approximately 68 mL.¹⁵ Studies in which axicabtagene ciloleucel was administered at a different dose will also be eligible for inclusion, but the evidence will be considered separately.