Supplementary Material

Cost-effectiveness of Lisocabtagene Maraleucel Versus Axicabtagene Ciloleucel and Tisagenlecleucel for Treatment of Relapsed or Refractory Large B-Cell Lymphoma in the United States

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Table of Contents

Supplemental Material 1 Patient characteristic used for matching in the matching-adjusted indirect comparisons

Two pairwise unanchored matching-adjusted indirect comparisons (MAIC) were conducted comparing lisocabtagene maraleucel (liso-cel) to axicabtagene ciloleucel (axi-cel) and tisagenlecleucel (tisa-cel). Each MAIC produced a set of weights that can be applied to the TRANSCEND NHL 001 (TRANSCEND) population to reflect the patient population more closely in each of the relevant comparator trials. For the purposes of economic modeling, the MAIC weights were incorporated into the statistical analyses for extrapolating progression-free survival (PFS) and overall survival (OS) to derive relative treatment effect terms based on matched populations. For safety, the odds ratios resulting from each MAIC were applied to the liso-cel–naïve adverse event (AE) rates to derive AE rates for each comparator based on matched populations.

Full details of the MAIC methods have been previously published [1, 2]. Briefly, the methods and factors adjusted were as follows. Individual patient data (IPD) from TRANSCEND were adjusted to match the marginal distribution (e.g., mean, variance) of clinical factors among patients from each comparator trial (ZUMA-1 and JULIET) individually. Patients from TRANSCEND were removed from the IPD set if they did not satisfy eligibility criteria specified in the comparator trial for each MAIC. IPD for patients who remained in the TRANSCEND data set were then weighted using a method-of-moments propensity score model. Baseline characteristic and outcome definitions were aligned with those in each trial. Clinically relevant prognostic factors (identified from literature, TRANSCEND data, and five independent clinical experts) were adjusted collectively in a stepwise fashion by ranked order.

Supplemental Table 1 Patient characteristics and clinical factors adjusted for in the MAIC

Clinical factors adjusted for/matched	Axi-cel	Tisa-cel
	ESS = 99	ESS = 49[a]
Bridging therapy	Not adjusted in matching used for economic model	No adjustment needed
Disease histology	Patients with FL3B or PMBCL were removed	Patients with FL3B were removed
ECOG PS	Patients with ECOG PS of 2 were removed	Patients with ECOG PS of 2 were removed
Secondary CNS lymphoma	Patients with secondary CNS lymphoma were removed	Patients with secondary CNS lymphoma were removed
Prior allogeneic HSCT	Patients who had received prior allogeneic HSCT were removed	Patients who had received prior allogeneic HSCT were removed
Disease histology	✓	✓
Tumor burden – sum of the products of perpendicular diameters before lymphodepleting therapy	✓	
ECOG PS score	✓	✓
Tumor burden – bulky disease	✓	
IPI score	✓	✓
R/R status to last therapy	✓	✓
Age	✓	✓
Prior auto-HSCT	✓	✓
Disease stage	✓	✓
Creatinine clearance	✓	✓[c]
Tumor burden – extranodal disease	✓	
Prior number of therapies	✓	✓
LVEF	✓	✓[c]
Sex	✓	
Pre-leukemia absolute lymphocyte count	✓	✓[b]

Axi-cel axicabtagene ciloleucel, *CNS* central nervous system, *ECOG PS* Eastern Cooperative Oncology Group performance status, *ESS* effective sample size, *FL3B* follicular lymphoma grade 3B, *HSCT* hematopoietic stem cell transplantation, *IPI* International Prognostic Index, *LVEF* left

ventricular ejection fraction, *MAIC* matching-adjusted indirect comparisons, *OS* overall survival, *PFS* progression-free survival, *PMBCL* primary mediastinal B-cell lymphoma, *R/R* relapsed or refractory, *tisa-cel* tisagenlecleucel

[a]Different ESS were used for OS (ESS = 49, rounded from 49.30) and PFS (ESS = 48, rounded from 47.52) owing to comparison with the JULIET trial involving different rank order of factors for OS and PFS

[b]Included only in the OS scenario

[c]Included only in the PFS scenario

Supplemental Material 2 Analysis of microcosting for cytokine release syndrome (CRS) and neurological events (NE)

CRS, NEs, and hypogammaglobulinemia are events of special interest for chimeric antigen receptor (CAR) T cell therapies. These events require vigilant monitoring, aggressive supportive treatments, and occasionally intensive care [3]. Accordingly, all-grade CRS, NEs, and hypogammaglobulinemia events were included in the model, irrespective of incidence. These AEs were microcosted based on drug costs in treating and managing them, along with any associated hospital or inpatient stay.

Supplemental Table 2 Analysis of microcosting for CRS and NEs

AE	Cost, USD	Source
CRS grade ≥3	59,737	Liso-cel CRS and neurotoxicity analysis, BLA data-cut USPI AE
CRS grade 1–2	9232	
NEs grade ≥3	13,401	
NEs grade 1–2	6779	

AE adverse event, *BLA* Biologics License Application, *CRS* cytokine release syndrome, *liso-cel* lisocabtagene maraleucel, *NE* neurological event, *USD* United States dollars, *USPI* United States prescribing information

Supplemental Table 3 Microcosting inputs for hypogammaglobulinemia

Drug cost: intravenous immunoglobulins					
	Cost per unit, USD [4]	Concentration per unit	Tablet/ vial size	Administration route	Cost per mg, USD
Unit cost	47	500 mg	1 vial	IV	0.09
	Dosing	Frequency	Duration	Drug cost per episode, USD	Admin cost per episode, USD
Hypogammaglobulinemia grade ≥3	0.5 g/kg [5, 6]	Every 4 weeks	11.4 months	45,934	5304
Hypogammaglobulinemia grade 1–2	400 mg/kg [5, 6]	Every 4 weeks	4.5 months	14,505	2094
Management cost	Cost, USD	Notes			
Hypogammaglobulinemia grade ≥3	9410 [7]				
Hypogammaglobulinemia grade 1–2	84 [8]	Assume the cost of a GP visit			

GP general practitioner, *IV* intravenous, *USD* United States Dollars

Supplemental Material 3 Costing for adverse events

All other AEs were costed using data extracted from the Healthcare Cost and Utilization Project (HCUP) database. Grade ≥3 AE costs are presented below. The corresponding grade 1–2 AEs were assumed to have required a single general practitioner (GP) visit ($84) [8].

Supplemental Table 4 Unit cost for AEs

	Grade ≥3 AEs
	Average cost per episode, USD
Infections	10,507
Prolonged cytopenia	16,566
Febrile neutropenia	21,916
Anemia	7872
Fatigue	7999
Hypertension	8358
Hypotension	7042
Hypoxia	9154
Leukopenia	4040
Lymphopenia	4040
Neutropenia	12,396
Pyrexia	7592
Thrombocytopenia	11,890

AE adverse event, *USD* United States Dollars

Supplemental Material 4 Monitoring

The phases of monitoring included 28 days after CAR T-cell infusion, progression free, progression free for more than 2 years, and after progression. The types and frequencies of monitoring associated with each phase were informed based on internal Bristol Myers Squibb clinical assumption in the absence of published or long-term observational data. Resource use for patients in the third-line or later (3L+) PFS state is relatively intensive for the first few years, particularly 28 days after infusion; for patients who remain in the PFS state beyond 2 years, resource use becomes less frequent, reflecting that these patients are no longer expected to be at risk of progression or death from disease. Patients who progress require less monitoring care (vs the PFS state) until the end of the time horizon.

Supplemental Table 5 Monitoring frequency and unit costs

Monitoring type	Unit cost, USD [8]	Unit(s) per year					
		Intensive: up to 28 days after infusion		Progression free		Patients progression free for >2 years	After progression
		CAR T cells	Salvage chemotherapy	CAR T cells	Salvage chemotherapy		
Cancer nurse	52	12	0	0	0	0	4
Oncology visit	175	12	0	4	4	2	4
Complete blood count	37	12	0	4	4	2	0
Liver function test	49	12	0	4	4	2	4
Lactate dehydrogenase	34	12	0	4	4	2	4
Coagulation panel	180	12	0	4	4	2	0
Inflammatory markers	121	12	0	4	4	2	0
Immunoglobulins	73	0	0	4	4	2	0
CT scan	622	0	0	4	4	2	2
PET scan	622	0	0	2	2	0	0
Total cost, USD		7776	0	6408	6408	2582	2484

CAR chimeric antigen receptor, *CT* computed tomography, *PET* positron emission tomography; *USD* United States Dollars

Supplemental Material 5 Deterministic sensitivity analysis (DSA) and probabilistic sensitivity analysis (PSA)

In the DSA, the lower and upper bounds of a parameter were based on the 95% confidence intervals (CI). If no CI was available, the bounds were assumed to be within ±10% of the base-case value. PSA was performed by simultaneously varying multiple parameters using a Markov chain Monte Carlo simulation with 1000 replications. Values for each parameter were sampled using statistical distributions chosen to best match the data type (e.g., beta distribution for utilities and probabilities to restrict between 0 and 1, gamma distribution for costs to restrict to 0 and positive values, Dirichlet distribution for proportions adding to 100%). Standard errors (SE) used in the PSA distributions were informed directly from the input source; if unavailable, they were calculated from the standard deviation (SD) and sample size or CIs; and, if none of those estimates were available, the SE was assumed to be 10% of the mean. Uncertainty in the survival projections and health state utilities was captured in the variance-covariance matrices from the statistical analyses and applied using the Cholesky decomposition approach.

Two key scenarios focused on differences between the CAR T-cell therapy trials. The first assumed that all patients received their CAR T-cell infusion, as this may differ in clinical practice to the trials. The second explored the impact of potential bias resulting from a difference in the ZUMA-1 and TRANSCEND designs regarding bridging therapy use. This scenario compared liso-cel with axi-cel using an MAIC that matched on bridging (i.e., excluding patients from TRANSCEND who received bridging therapy). In this scenario, PFS and OS curves for axi-cel were derived by applying hazard ratios (HR) from an update of the analysis by Maloney et al. [1] (PFS HR = 0.94; OS HR = 0.91) to the liso-cel reference curves.

Supplemental Material 6 Scenario analysis of liso-cel versus axi-cel and liso-cel versus tisa-cel

Scenario analyses were performed to assess the impact of a specific scenario or model assumption on results. Selected model parameters were varied (e.g., exploring alternative distributions), using alternative literature-based values or clinical expert assumptions versus the TRANSCEND trial, among others.

Supplemental Table 6 Top 15 scenarios: liso-cel versus axi-cel

Rank	Scenario name	Base-case value or setting	Scenario setting	INMB, USD	Percentage change from base-case INMB, %
	Base case			75,170	—
1	Comparative efficacy source for OS and PFS	MAIC-derived comparative efficacy	Naïve comparison: liso-cel: gamma (OS), loglogistic (PFS) tisa-cel: gamma (OS), loglogistic (PFS) axi-cel: gamma (OS), loglogistic (PFS) salvage chemotherapy: loglogistic (OS)	50,563	−32.7
2	Efficacy for patients receiving liso-cel out of specifications	Assume same efficacy as liso-cel	Assume same efficacy as salvage chemotherapy	57,002	−24.2
3	Pretreatment patient flow	As observed in trials	All patients receive CAR T cells	58,244	−22.5
4	Source for AE rates for all treatment	MAIC-derived AE rates	Observed AE rates	59,106	−21.4
5	AE costing approach	Microcosting	Average costs based on HCUP [7]	63,479	−15.6
6	Projection approach for axi-cel (MAIC HR vs liso-cel)	Projection with MCM fittings	HR matching on bridging vs liso-cel	85,950	14.3
7	Alternative MAIC-based OS fittings	Gamma for all treatment arms	Weibull for all treatment arms	71,998	−4.2
			Exponential for all treatment arms	66,521	−11.5
8	Health state utilities	Based on TRANSCEND NHL 001:	Based on axi-cel [9] and PV NICE [10] submissions:	73,834	−1.8

Rank	Scenario name	Base-case value or setting	Scenario setting	INMB, USD	Percentage change from base-case INMB, %
		pretreatment: 0.764; initial PFS: 0.831; progressed disease: 0.764	pretreatment: 0.647; initial PFS: 0.722; progressed disease: 0.647		
			Lower progressed disease value based on Whittington et al. 2019 [11] publication: 0.390 (reduction of PFS value by 0.443)	67,258	−10.5
9	Proportion receiving bridging therapy based on real-world evidence	Liso-cel: 59% Tisa-cel: 92% Axi-cel: 0%	Liso-cel: 59% Tisa-cel: 92% Axi-cel: 53%	81,276	8.1
10	AE decrements for CRS and neurotoxicity	Decrement for CRS based on Howell et al. 2022 [12]; Decrement for neurotoxicity based on TRANSCEND (0.152 for 37.2 days)	CRS assumed the same as progression-free (assumption in axi-cel NICE submission [9]) Neurotoxicity = 0.178 applied for 365 days per Howell et al. 2022 [12]	79,895	6.3
11	Discount rate for health outcomes	3%	0%	77,297	2.8
			5%	74,383	−1.0
12	Time horizon	Lifetime	10 years	73,366	−2.4
			25 years	74,918	−0.3
13	Discount rate for cost outcomes	3%	0%	74,798	−0.5
			5%	75,395	0.3
14	IVIG use	Based on incidence of hypogammaglobulinemia	Based on all IVIG use in TRANSCEND	75,763	0.8
15	Cutoff for long-term remission assumptions	2 years	5 years	75,638	0.6

AE adverse event, *axi-cel* axicabtagene ciloleucel, *CAR* chimeric antigen receptor, *CRS* cytokine release syndrome, *HCUP* Healthcare Cost and Utilization Project, *HR* hazard ratio, *INMB* incremental net monetary benefit, *IVIG* intravenous immunoglobulin, *liso-cel* lisocabtagene maraleucel, *MAIC* matching-adjusted indirect comparison, *MCM* mixture cure model, *NICE* National Institute for Health and Care Excellence, *OS* overall survival, *PFS* progression-free survival, PV Polatuzumab vedotin, *tisa*-cel tisagenlecleucel, USD United States Dollars

Supplemental Table 7 Top 15 scenario results: liso-cel versus tisa-cel

Rank	Scenario name	Base-case value or setting	Scenario setting	INMB, USD	Percentage change from base-case INMB, %
	Base case			134,125	—
1	Discount rate for health outcomes	3%	0%	222,470	65.9%
			5%	95,546	−28.8
2	Time horizon	Lifetime	10 years	49,862	−62.8
			25 years	122,371	−8.8
3	Comparative efficacy source for OS and PFS	MAIC-derived comparative efficacy	Naïve comparison: liso-cel: gamma (OS), loglogistic (PFS) tisa-cel: gamma (OS), loglogistic (PFS) axi-cel: gamma (OS), loglogistic (PFS) salvage chemotherapy: loglogistic (OS)	66,727	−50.2
4	Pretreatment patient flow	As observed in trials	All patients receive CAR T cells	186,548	39.1
5	Efficacy for patients receiving liso-cel out of specifications	Assume same efficacy as liso-cel	Assume same efficacy as salvage chemotherapy	115,957	−13.5
6	Excess mortality for cured patients vs general population	SMR 1.40 for first 2 years followed by 1.18 [13]	SMR 1.40 for the first 2 years [13]	143,819	7.2
			SMR 1.56 for the first 5 years [14]	138,880	3.5
7	Alternative MAIC-based OS fittings	Gamma for all treatment arms	OS projected using Weibull fittings for all treatment arms	132,450	−1.2
			OS projected using exponential fittings for all treatment arms	128,664	−4.1
8	Health state utilities	Based on TRANSCEND: pretreatment: 0.764; initial PFS: 0.831; progressed disease: 0.764	Based on axi-cel [9] and PV NICE [10] submissions: pretreatment: 0.647; initial PFS: 0.722; progressed disease: 0.647	129,293	−3.6
			Lower progressed disease value based on Whittington et al. 2019 [11] publication: 0.390 (reduction of PFS value by 0.443)	128,919	−3.9
9		3%	0%	130,673	−2.6

Rank	Scenario name	Base-case value or setting	Scenario setting	INMB, USD	Percentage change from base-case INMB, %
	Discount rate for cost outcomes		5%	135,497	1.0
10	AE costing approach	Microcosting	Average costs based on HCUP [7]	131,313	−2.1
11	Source for AE rates for all treatment	MAIC-derived AE rates	Observed AE rates	136,875	2.1
12	Cutoff for long-term remission assumptions	2 years	5 years	132,623	−1.1
13	AE decrements for CRS and neurotoxicity	Decrement for CRS based on Howell et al. 2022 [12]; Decrement for neurotoxicity based on TRANSCEND (0.152 for 37.2 days)	CRS assumed the same as progression free (assumption in axi-cel NICE submission [9]) Neurotoxicity = 0.178 applied for 365 days per Howell et al. 2022 [12]	133,013	−0.8
14	Alternative MAIC-based PFS fittings	Loglogistic for all treatment arms	PFS projected using Lognormal fittings for all treatment arms	134,011	−0.1
			PFS projected using generalized gamma fittings for all treatment arms	133,679	−0.3
15	Proportion receiving liso-cel administration in an outpatient setting	9.3%	0%	133,790	−0.2

AE adverse event, *axi-cel* axicabtagene ciloleucel, *CAR* chimeric antigen receptor, *CRS* cytokine release syndrome, *HCUP* Healthcare Cost and Utilization Project, *liso-cel* lisocabtagene maraleucel, *MAIC* matching-adjusted indirect comparison, *NICE* National Institute for Health and Care Excellence, *OS* overall survival, *PFS* progression-free survival, SMR (Standardized Mortality Ratio), *tisa-cel* tisagenlecleucel; *USD* United States Dollars

Supplemental Material 7 Model results of health outcomes compared with published models

The model results were compared with results reported in relevant published studies in the United States (US) where possible. The base-case outcomes for axi-cel and tisa-cel resulting from this analysis are aligned with other published models for diffuse large B-cell lymphoma in the US. Only US studies were considered for this comparison and verification to remain consistent from a patient health perspective (e.g., patient lifestyle, characteristics, and treatment practices) and also an economic modeling perspective (e.g., discounting). The published economic analyses were identified from a systematic literature review that was performed in early 2021. The systematic literature review was performed in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* [15] and reported in alignment with the Preferred Reporting Items for Systematic Literature Reviews and Meta-Analyses (also known as PRISMA) guidelines [16]. The database searches were restricted to the publication years 1 January 2003 to 5 February 2021. An additional targeted search was conducted in March 2022 to identify any US-based economic analyses published since February 2021; two studies were identified (Qi et al. 2021 [17] and Liu et al. 2021 [18]).

Supplemental Table 8 Comparison of model results with published models

	Axi-cel		Tisa-cel	
	Discounted LYs	Discounted QALYs	Discounted LYs	Discounted QALYs
Current analysis	6.22	5.09	3.75	3.07
Roth et al. 2018 [19]	9.49	7.67	—	—
Whittington et al. 2019 [11]	9.19	7.62	—	—
ICER model for B-cell lymphoma 2008 [6]	7.35	5.87	—	—
Qi et al. 2021 [17]	—	—	—	3.35
Lin et al. 2019 [20][a]	9.11—11.80 (undiscounted)	4.28—5.50	5.9—8.25 (undiscounted)	2.82—3.92
Liu et al. 2021 [18]	9.47	7.47	6.73	5.16

ICER Institute for Clinical and Economic Review, LY life-year, *PFS* progression-free survival, *QALY* quality-adjusted life-year, *tisa-cel* tisagenlecleucel

[a]A range was reported assuming 20%, 30%, and 40% 5-year PFS. LYs were not discounted

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