CT-105

Post-infusion monitoring costs and health care resource utilization by site of care in patients with relapsed or refractory chronic lymphocytic leukemia receiving lisocabtagene maraleucel treatment in the TRANSCEND CLL 004 study

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Introduction

- Lisocabtagene maraleucel (liso-cel) is an autologous, CD19-directed, 4-1BB CAR T cell product administered at equal target doses of $CD8^+$ and $CD4^+$ chimeric antigen receptor (CAR^+) T cells[1] that is currently being evaluated for treatment of patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in the TRANSCEND CLL 004 study (NCT03331198)
- Primary analysis results from TRANSCEND CLL 004 showed durable responses and low to moderate incidence of severe cytokine release syndrome and neurological events with a single infusion of liso-cel in the R/R CLL/SLL population,[2] which could provide an opportunity for outpatient (OP) administration of liso-cel in this population
- Previous studies in other approved liso-cel indications showed lower health care resource utilization (HCRU) and costs with OP monitoring after liso-cel infusion compared with inpatient (IP)[3–5]
- Here, we estimated 1-year post-infusion HCRU and costs by site of care (IP vs OP) among patients with R/R CLL who received liso-cel in the TRANSCEND CLL 004 study

Methods

- The study was a retrospective analysis of individual patient-level case report forms of patients enrolled in the TRANSCEND CLL 004 study who received liso-cel
- A 2-step microcosting methodology was implemented to assess HCRU related to post-infusion monitoring and the associated costs as follows:
  - Key HCRU was assessed over a 1-year time frame after infusion (**Figure 1**)
    - Facility (standard IP, intensive care unit [ICU])
    - Medications (eg, tocilizumab, corticosteroids, etc)
    - Diagnostics (eg, laboratory tests, imaging, etc)
    - Procedures (eg, dialysis, mechanical ventilation, etc)
  - Unit costs were applied to each HCRU category to estimate the monthly monitoring costs over 12 months after liso-cel infusion

Table 1. Key cost inputs

Health care resource input	Source cost value or range (2023 USD)	Data source
Cost per IP day	$1542	Healthcare Cost and Utilization Project (National Inpatient Sample 2020)[a,b]
Cost per ICU day	$8659	Dasta 2005, estimated per ICU day cost without mechanical ventilation[b,a]
Diagnostic labs	($6–$163)	2023 CMS Clinical Laboratory Fee Schedule (Q1) by HCPCS code, national reimbursement rates
Diagnostic tests	($9–$1489)	2023 CMS OPPS and Physician Fee Schedule national reimbursement rates
Procedures	($63–$3453)	2023 CMS OPPS and Physician Fee Schedule national reimbursement rates and Dasta 2005[b]
Medications (per dose; excluding liso-cel)	(< $0.01–$10,720)	Merative Micromedex RED BOOK®, WAC price[c]

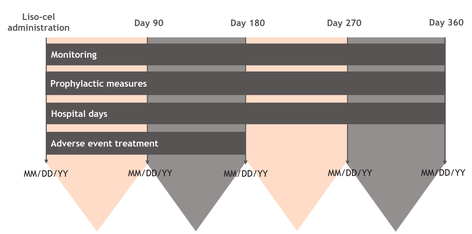
Costs were applied to any HCRU that met temporality and guideline requirements from the provider perspective. [a]Inflated to 2023 USD using the Bureau for Labor Statistics Consumer Price Index for medical care; [b]Cost value input specific to an IP stay for a patient with CLL; [c]Costed to prescribed amounts.
CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; OPPS, Outpatient Prospective Payment System; Q1, quarter 1; USD, United States dollars; WAC, wholesale acquisition cost.

- Unit costs were measured from the United States (US) health care system perspective and adjusted to 2023 USD. Cost estimates were also adjusted by site of care (**Table 1**)
- Patients were classified as "IP" if they stayed in the hospital overnight and "OP" if they were discharged the same day, after liso-cel infusion

Study populations

- TRANSCEND CLL 004 is a nonrandomized, open-label, multicenter study evaluating liso-cel in adult patients with R/R CLL/SLL
- Full population: 108 patients who received liso-cel monotherapy at the recommended dose of 100×10^6 CAR^+ T cells
- Double-class–exposed (DCE) population subgroup: 89 patients from the full population who received prior Bruton tyrosine kinase inhibitors and venetoclax

Figure 1. Study methodology



Study outcomes

- Monthly facility, medication, diagnostic, and procedure HCRU from liso-cel administration to 1-year follow-up
- Cost of care after liso-cel infusion (excluding liso-cel acquisition) for each month up to 1-year follow-up overall and stratified by site of care or HCRU category

Statistical analysis

- Descriptive statistical analyses were conducted to examine the baseline demographics and clinical characteristics, HCRU, and costs of care

Results

Full population (IP vs OP)

- Among the 108 patients who met the study inclusion criteria, 94 (87%) were classified as IP and 14 (13%) as OP
- Patient demographic characteristics, including mean age, racial distribution, and ethnicity, were similar between IP and OP cohorts (**Table 2**)
- IP had higher rates of *TP53* mutation and unmutated immunoglobulin heavy-chain variable (IGHV) and OP had higher rates of del(17p) and complex karyotype mutations
- All patients (100%) in the IP cohort were hospitalized by definition
- Among OPs, 13/14 patients were hospitalized subsequently
  - Of these 13 patients, 5 were hospitalized within 96 hours after liso-cel infusion
- Patients who received a liso-cel infusion in the IP setting had higher rates of ICU stays (IP, 16.0% vs OP, 7.1%) (**Table 3**)
- The median total hospital length of stay was 4 days longer for IP (18 days) versus OP (14 days) cohorts
- Among patients who received treatment in the IP setting, there were higher utilization rates of tocilizumab and corticosteroids
- Post-infusion monitoring in the OP setting resulted in a median 1-year total post-infusion monitoring cost savings of $43,984 (IP, $82,382 vs OP, $38,398) (**Figure 2**)
  - This equates to a 53% reduction in the total post-infusion cost of care
- Median facility costs (IP, $27,752 [34%]; OP, $20,043 [52%]) and medications (IP, $27,963 [34%]; OP, $11,412 [30%]) were the primary drivers of the total cost of care in the first-year after liso-cel infusion
- A majority of the median total 1-year costs occurred within the first month after liso-cel infusion for both IP ($48,527 [59%]) and OP ($28,778 [75%])
  - Facility costs (IP, $26,210; OP, $16,960) and medication costs (IP, $15,884; OP, $9099) were the primary drivers of costs in the first month
- In a scenario analysis on the full population where OPs hospitalized within 96 hours after liso-cel infusion (n = 5) were considered IPs, the median total 1-year costs were similar to the base-case results (IP, $81,975; OP, $37,562)

Table 2. Patient baseline characteristics by site of care

Characteristic	Full population (n = 108)		DCE population (n = 89)	
	IPs (n = 94)	OPs (n = 14)	IPs (n = 78)	OPs (n = 11)
Age				
Mean (SD)	64.2 (22.9)	65.1 (22.1)	64.6 (7.8)	68 (4.2)
Median (range)	64 (49–82)	67 (50–73)	64.5 (49–82)	68 (61–73)
Male, n (%)[a]	67 (71.3)	9 (64.3)	55 (70.5)	7 (63.6)
Race, n (%)[a]				
White	80 (85.1)	12 (85.7)	65 (83.3)	10 (90.0)
Black	2 (2.1)	1 (7.1)	2 (2.6)	1 (9.1)
Asian	1 (1.1)	1 (7.1)	1 (1.3)	0
Other/unknown	11 (11.7)	0	10 (12.8)	0
Ethnicity, n (%)[a]				
Not Hispanic or Latino	86 (91.5)	12 (85.7)	70 (89.7)	9 (81.8)
Leukemia subtype, n (%)[a]				
CLL	87 (92.6)	13 (92.9)	73 (93.6)	11 (100)
SLL	7 (7.4)	1 (7.1)	5 (6.4)	0
High-risk cytogenetics				
Del(17p)	39 (41.5)	7 (50.0)	34 (43.6)	6 (54.5)
TP53 mutation	48 (51.1)	2 (14.3)	43 (55.1)	1 (9.1)
Unmutated *IGHV*	46 (48.9)	4 (28.6)	36 (46.2)	3 (27.3)
Complex karyotype	56 (59.6)	11 (78.6)	48 (61.5)	8 (72.7)
SPD, cm^2[a]				
n	86	13	70	10
Median (IQR)	35.7 (18.9–92.0)	24.7 (13.8–27.5)	39.4 (20.3–90.1)	24.7 (14.9–29.2)
LDH, U/L, median (IQR)[a]	246 (204.0–378.5)	192 (146.3–246.3)	249 (204.5–403.3)	165 (142.5–211.5)

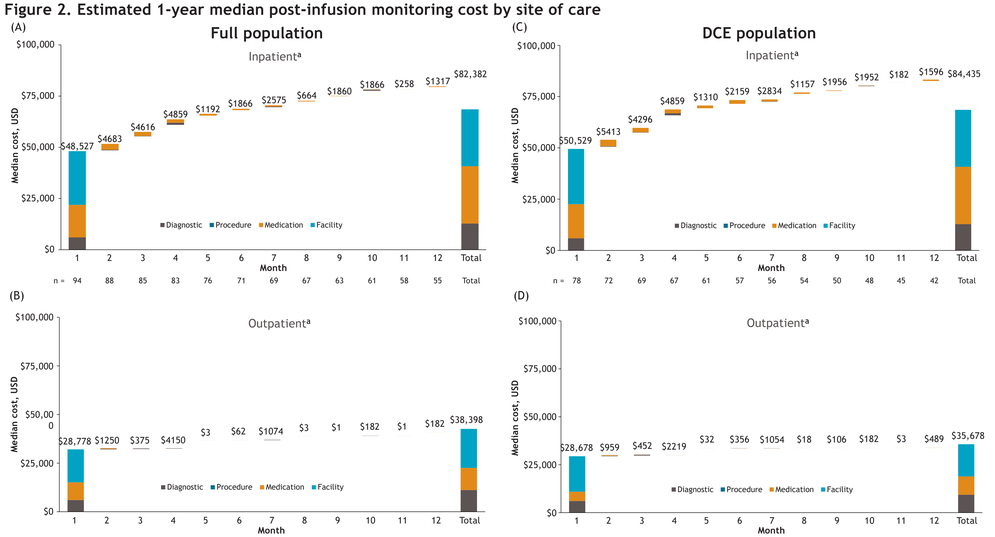
[a]The percentage was taken out of the number of patients in each site of care: full IP, n = 94; full OP, n = 14; DCE IP, n = 78; DCE OP, n = 11.
IQR, interquartile range; LDH, lactate dehydrogenase; SD, standard deviation; SPD, sum of the product of perpendicular diameters.

Table 3. Health care resource utilization by site of care

HCRU	Full population (n = 108)		DCE population (n = 89)	
	IPs (n = 94)	OPs (n = 14)	IPs (n = 78)	OPs (n = 11)
Facility, n (%)[a]				
Standard IP stay	94 (100)	13 (92.9)	78 (100)	10 (90.9)
ICU stay	15 (16.0)	1 (7.1)	14 (17.9)	0
Medications, n (%)[a,b]				
Any tocilizumab	65 (69.1)	8 (57.1)	55 (70.5)	5 (45.5)
Tocilizumab only	15 (16)	2 (14.3)	12 (15.4)	1 (9.1)
Any corticosteroids	63 (67)	6 (42.9)	52 (66.7)	4 (36.4)
Corticosteroids only	13 (13.8)	0	9 (11.5)	0
Tocilizumab + corticosteroids	50 (53.2)	6 (42.9)	43 (55.1)	4 (36.4)
Procedures, n (%)[a]				
Dialysis	1 (1.1)	0	1 (1.3)	0
Intubation	4 (4.3)	1 (7.1)	4 (5.1)	0
Standard IP LOS, days[c]				
Median (range)	17 (5–122)	13 (3–119)	17.5 (5–122)	13 (3–119)
ICU LOS, days[c]				
Median (range)	5 (2–50)	14 (14–14)	5 (2–50)	0
Total LOS, days[c]				
Median (range)	18 (5–122)	14 (3–119)	18 (5–122)	13 (3–119)
Median LOS 1st month, days[c]	17	12	17	12
Median LOS 2nd month, days[c]	7	11	8	6

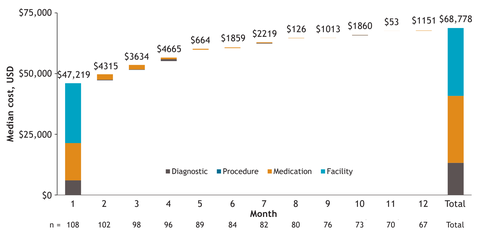
HCRU included any standard IP stay, ICU stay, diagnostic test, medication, or procedure that occurred from day of liso-cel infusion to Day 360. Only key HCRU of interest depicted above; full list of facility, diagnostic, medications (excluding liso-cel), and procedures were included in cost calculations.
[a]The percentage was taken out of the number of patients in each site of care: full IP, n = 94; full OP, n = 14; DCE IP, n = 78; DCE OP, n = 11; [b]Medication categories included oncology supportive care, prophylactic medications, drugs for adverse event management; [c]LOS calculated among hospitalized patients only.
LOS, length of stay.

Figure 2. Estimated 1-year median post-infusion monitoring cost by site of care



[a]Median costs by components and months may not add up to the total sums because they reflect the median by each component by each month.

Figure 3. Total estimated 1-year median post-infusion monitoring cost for the full population (IP + OP)[a]



[a]Median costs by components and months may not add up to the total sums because they reflect the median by each component by each month.

DCE population (IP vs OP)

- A total of 89 patients met the DCE definition, with 78 (88%) monitored as IP and 11 (12%) monitored as OP (**Table 2**)
- Median total 1-year costs (IP, $84,435; OP, $35,678), primary cost drivers (facility and medications), and HCRU were similar to the full population (**Figure 2** and **Table 3**)

Total cost of care for full population (regardless of site of care, IP + OP)

- Median total 1-year cost for the full population (ie, combining IPs and OPs) was estimated to be $68,778
- Most of the costs (69%) were incurred in the first month after infusion
- Facility (39%) and medications (38%) were the top cost drivers

Conclusions

- The study findings suggest that OP administration of liso-cel in patients with R/R CLL may have substantially lowered 1-year post-infusion monitoring costs as a result of reduced HCRU compared with IP administration
- Median post-infusion monitoring costs were 53% lower for those treated in the OP setting
- Findings support that a single infusion of liso-cel is associated with significantly less incremental monthly HCRU and costs after the initial treatment period in the first month across both IP and OP settings as demonstrated in previous studies on OP administration of CAR T cell therapy for third-line or later large B-cell lymphoma[4]
- Results provide insights into how US health care systems may optimize health care resources in the future for patients with R/R CLL who receive CAR T cell therapy by increasing adoption of OP administration

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