Sponsor
Novartis Pharmaceuticals

Generic Drug Name
CAR-T cell therapy

Trial Indication(s)
Diffuse large B-cell lymphoma (DLBCL)

Protocol Number
CCTL019CUS08

Protocol Title
Real-world Resource Use and Costs of CAR-T Therapies in Diffuse Large B-cell Lymphoma (DLBCL): Inpatient and Outpatient Settings

Clinical Trial Phase
NA

Phase of Drug Development
NA

Study Start/End Dates
Study start date: 17/08/2020

Study Completion date: 10/05/2021

Reason for Termination

NA

Study Design/Methodology

A retrospective, non-interventional cohort study was used to address the study objectives. This study aimed to provide a better understanding of real-world HRU and healthcare reimbursement costs associated with CAR-T therapy among patients with r/r DLBCL.

Eligible adult patients with r/r DLBCL who were treated with CAR-T therapy or allo-HSCT between January 1, 2017 to September 31, 2019 were identified from the Centers for Medicare & Medicaid Services (CMS) 100% Medicare Database. The CAR-T cohort was further classified into CAR-T IP and CAR-T OP cohorts based on the infusion setting.

The index date was defined as the date of CAR-T therapy administration or allo-HSCT. Baseline period was defined as three months prior to the index date. Study period was defined from the index date to the end of health plan coverage based on insurance enrollment file or death, whichever occurred earlier.

Two sets of comparisons on HRU and healthcare reimbursement costs were conducted, one between IP vs. OP infusion of CAR-T, and the other between patients who received CAR-T therapy vs. allo-HSCT.

Centers

Novartis Investigative Site

Objectives:

Primary objective(s)

- To compare HRU and healthcare reimbursement costs between IP vs. OP infusion of CAR-T therapy among patients with r/r DLBCL

Secondary objective(s)

- To assess post-infusion IP admission/readmission and causes of IP admission/readmission among patients with r/r DLBCL who received CAR-T therapy
- To assess rate of adverse events (AEs) and cost per AE event among patients with r/r DLBCL who received CAR-T therapy
- To compare HRU and healthcare reimbursement costs of CAR-T therapy vs. allo-HSCT among patients with r/r DLBCL

Test Product (s), Dose(s), and Mode(s) of Administration

NA

Statistical Methods

Patient characteristics were described for patients in CAR-T IP, CART-T OP, CAR-T overall, and allo- HSCT cohorts. Comparisons were conducted between the CAR-T IP vs. CAR-T cohorts and between CAR-T overall vs. allo-HSCT cohorts. HRU by month during the study period was expressed as monthly incidence. Healthcare reimbursement costs by month during the study period were expressed on per patient-per-month (PPPM) basis to account for varying length of follow-up. Two sets of comparisons were conducted between the CAR-T IP vs. CAR-T OP cohorts: CAR-T IP overall (including Prospective Payment System [PPS]-exempt and non-PPS exempt) vs. CAR-T OP and CAR-T IP non-PPS exempt vs. CAR-T OP. HRU was compared between study cohorts using generalized linear models (GLMs) between patients.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion criteria

CAR-T cohort:

- Patients had at least one International Classification of Diseases, Tenth Revision (ICD- 10) diagnosis code for DLBCL.
- Patients received CAR-T therapy following DLBCL diagnosis. The administration date of CAR-T therapy was defined as the index date. Patients who received both CAR-T therapy and allo-HSCT were classified based on the first treatment that the patient received
- Patients were at least 18 years of age as of the index date
- Patients had at least three months of continuous eligibility in the Medicare Part A and Part B data before the index date. Since 2019 Part D data is not available in the current data cut, eligibility requirement in the Part D data was not required

Patients were further classified into CAR-T IP and CAR-T OP cohorts depending on where the administration occurred.

Allo-HSCT cohort:

- Patients had at least one ICD-10 diagnosis code for DLBCL.
- Patients received allo-HSCT following DLBCL diagnosis. The date of allo-HSCT procedure was defined as the index date. Patients who received both CAR-T therapy and allo-HSCT were classified based on the first treatment the patient received
- Patients were at least 18 years of age as of the index date
- Patients had at least three months of continuous eligibility in the Medicare Part A and Part B data before the index date. Since 2019 Part D data is not available in the current data cut, eligibility requirement in the Part D data was not required

Exclusion criteria

Patients had a medical claim associated with a clinical trial (ICD-9 CM code V70.7; ICD-10 CM code Z00.6) during one month before and after the index date

Participant Flow

The CAR-T cohort included 430 patients, with 380 patients receiving CAR-T treatment in the IP setting and 50 patients receiving CAR-T treatment in the OP setting. The sample size for the allo-HSCT cohort was 265.

Baseline Characteristics

Key baseline characteristics among CAR-T IP and CAR-T OP cohorts

Patient Characteristics	CAR-T IP N = 380	CAR-T OP N = 50	P-value
Patient Demographics			
Age (years)			
Mean ± SD	70.8 ± 6.6	68.4 ± 8.5	0.052
Median (Range)	71.0 (38.5 - 89.0)	69.1 (38.1 - 82.8)	
Gender, n (%)			
Male	237 (62.4)	35 (70.0)	0.293
Female	143 (37.6)	15 (30.0)	
Race and ethnicity, n (%)			
White	321 (84.5)	48 (96.0)	0.028*
Black	12 (3.2)	0 (0.0)	0.375
Asian	12 (3.2)	0 (0.0)	0.375
Other	22 (5.8)	<11 (<22.0)	1.000

Unknown	15 (3.9)	0 (0.0)	0.235
Year of index date, n (%)			
2015	0 (0.0)	0 (0.0)	
2016	0 (0.0)	0 (0.0)	
2017	<11 (<2.9)	0 (0.0)	0.606
2018	126 (33.2)	13 (26.0)	
2019	253 (66.6)	37 (74.0)	
CAR-T agent identifiable, n (%)	0 (0.0)	41 (82.0)	-
Yescarta users among those identifiable	0 (0.0)	<11 (<22.0)	-
Kymriah users among those identifiable	0 (0.0)	37 (74.0)	-
DLBCL-related comorbidities, n (%)			
Hypertension	225 (59.2)	26 (52.0)	0.331
Diabetes	78 (20.5)	14 (28.0)	0.226
Depression	69 (18.2)	<11 (<22.0)	0.708
Chronic pulmonary disease	68 (17.9)	<11 (<22.0)	0.495
Renal disease	63 (16.6)	<11 (<22.0)	0.231
Liver disease	53 (13.9)	<11 (<22.0)	0.116
Cerebrovascular disease	36 (9.5)	<11 (<22.0)	0.289
NCI Comorbidity Index (NCICI), mean ± SD	2.1 ± 2.0	1.6 ± 1.9	0.036*
NCI comorbidities, n (%)			
Diabetes	78 (20.5)	14 (28.0)	0.226
Peripheral vascular disease	79 (20.8)	<11 (<22.0)	0.646
Chronic obstructive pulmonary disease	78 (20.5)	<11 (<22.0)	0.931
Renal disease	63 (16.6)	<11 (<22.0)	0.231
Congestive heart failure	61 (16.1)	<11 (<22.0)	0.708
Mild liver disease	47 (12.4)	0 (0.0)	0.008*
Cerebrovascular disease	36 (9.5)	<11 (<22.0)	0.289

Baseline characteristics among CAR-T and allo-HSCT patients

	CAR-T (overall) N = 430	Allo-HSCT N = 265	P-value
Patient Demographics			
Age (years)	-		-
Mean ± SD	70.6 ± 6.9	65.6 ± 9.8	<0.001*
Median (Range)	70.8 (38.1 - 89.0)	67.9 (22.8 - 81.4)	
Gender, n (%)			
Male	272 (63.3)	163 (61.5)	0.644
Female	158 (36.7)	102 (38.5)	
Race and ethnicity, n (%)			
White	369 (85.8)	221 (83.4)	0.387
Black	12 (2.8)	17 (6.4)	0.020*
Asian	12 (2.8)	<11 (<4.2)	0.274
Other	24 (5.6)	<11 (<4.2)	0.188
Unknown	15 (3.5)	15 (5.7)	0.171
Year of index date, n (%)			
2015	0 (0.0)	23 (8.7)	
2016	0 (0.0)	62 (23.4)	
2017	<11 (<2.6)	75 (28.3)	<0.001*
2018	139 (32.3)	56 (21.1)	
2019	290 (67.4)	49 (18.5)	
DLBCL-related comorbidities, n (%)			
Hypertension	251 (58.4)	155 (58.5)	0.975
Diabetes	92 (21.4)	62 (23.4)	0.537
Depression	77 (17.9)	55 (20.8)	0.353
Chronic pulmonary disease	75 (17.4)	52 (19.6)	0.470
Renal disease	68 (15.8)	41 (15.5)	0.904
Liver disease	56 (13.0)	29 (10.9)	0.416
Cerebrovascular disease	38 (8.8)	<11 (<4.2)	0.006*
NCI Comorbidity Index (NCICI), mean ± SD	2.1 ± 2.0	1.7 ± 1.9	0.024*

NCI comorbidities, n (%)			
Diabetes	92 (21.4)	62 (23.4)	0.537
Peripheral vascular disease	88 (20.5)	30 (11.3)	0.002*
Chronic obstructive pulmonary disease	88 (20.5)	60 (22.6)	0.496
Renal disease	68 (15.8)	41 (15.5)	0.904
Congestive heart failure	68 (15.8)	35 (13.2)	0.348
Mild liver disease	47 (10.9)	22 (8.3)	0.260
Cerebrovascular disease	38 (8.8)	<11 (<4.2)	0.006*

Primary Outcome Result(s)

HRU by CAR-T cohort and by month during the study period

Mean length of follow-up for the CAR-T IP cohort and CAR-T OP cohort was 7.7 months and 6.9 months, respectively.

In the first month following the index date (including the index encounter), 52% patients in the CAR-T OP cohort had at least one IP visit. By definition, 100% patients in the CAR-T IP cohort had at least one IP visit. Number of IP admissions was significantly lower among the CAR-T OP cohort compared to the CAR-T IP cohort during the first month following the index date (IRR [95% CI]: 0.51 [0.41, 0.63]). Number of IP admissions were nominally lower in the CART OP cohort during second, third, and fourth month following the index date and comparable between the two cohorts in subsequent months.

In the first month following the index date, number of IP days were significantly lower among the CAR-T OP cohort compared to the CAR-T IP cohort (5.2 vs. 20.4 days; IRR [95% CI]: 0.26 [0.21, 0.32]). In the second month following the index date, 34.6% of the CAR-T IP cohort and <23.9% of the CAR-T OP cohort had at least one IP visit. IP days remained significantly lower among the CAR-T OP cohort compared to the CAR-T IP cohort (1.6 vs. 4.6 days; IRR [95% CI]: 0.35 [0.13, 0.92]). IP days were nominally lower in the CAR-T OP cohort in subsequent months.

Number of ICU stays was also significant lower among the CAR-T OP cohort compared to the CAR-T IP cohort in the first month following the index date (0.1 vs. 0.3; IRR [95% CI]: 0.32 [0.14, 0.74]). Number of ICU stays were generally comparable between the two cohorts in subsequent months.

Similarly, ICU days were significantly lower among the CAR-T OP cohort compared to the CAR-T IP cohort in the first month following the index date (0.26 vs. 0.06 days; IRR [95% CI]: 0.21 [0.06, 0.70]). ICU days were generally comparable between the two cohorts in subsequent months.

In the first month following the index date, 72.1% patients in the CAR-T IP cohort had at least one OP visit and number of OP visits was significantly higher among the CAR-T OP cohort (5.2 vs. 2.1; IRR [95% CI]: 2.51 [2.08, 3.04]). Number of OP visits were generally comparable between the two cohorts in subsequent months.

Number of ER visits was significantly higher in the CAR-T OP cohort during the first month following the index date (0.32 vs. 0.03; IRR [95% CI]: 10.44 [4.23, 25.75]) and generally comparable between the two cohorts in subsequent months.

Healthcare reimbursement costs by CAR-T cohort and by month during the study period

Results below mainly focus on the comparison between the non-PPS exempt CAR-T IP cohort (N = 252) vs. the CAR-T OP cohort since healthcare reimbursement costs for inpatient admissions in the PPS-exempt hospitals were much lower compared to non PPS-exempt hospitals.

Pre-infusion costs that occurred in the OP setting during the baseline period were estimated for the CAR-T IP (including both PPS-exempt and non PPS-exempt hospitals) and OP cohorts. Leukapheresis-related costs were $2,067 for the CAR-T IP cohort and $1,967 for the CAR-T OP cohort. Lymphodepleting regimen-related costs were $3,781 for the CAR-T IP cohort and $3,427 for the CAR-T OP cohort. Additionally, CAR-T infusion-related costs for the non-PPS exempt CAR-T IP cohort and CAR-T OP cohort were $338,623 and $353,377 respectively. There were no significant differences in the pre-infusion costs between the CAR-T IP and OP cohorts and the CAR-T infusion-related costs between the non-PPS exempt CAR-T IP cohort and CAR-T OP cohort.

During the first month following the index date (including the index encounter), total healthcare reimbursement cost was nominally higher in the CAR-T OP cohort compared to the CAR-T IP cohort by $13,421. Cost of IP admissions was significantly higher in the CAR-T IP cohort compared to the CAR-T OP cohort by $334,308 ($p<0.001$) and cost of OP visits was significantly higher in the CAR-T OP cohort compared to the CAR-T IP cohort by $363,607 ($p<0.001$). This is mainly driven by where the cost of CAR-T was accounted for. Costs from the second month following the index date up to the end of follow-up were largely comparable between the CAR-T IP and OP cohorts.

Secondary Outcome Result(s)

IP re-admission/admission among CAR-T IP and OP cohorts

53.7% patients in the CAR-T OP cohort were admitted to the hospital during the first month after CAR-T infusion. The trend was generally comparable when stratified by index year. Mean Length of Stay (LOS) of first IP admission was 6.8 days among the overall CAR-T OP cohort (5.1 days among patients with index year of 2018 and 7.4 days among patients with index year of 2019).

Over the entire month, the proportion of patients hospitalized at any given day was higher in CAR-T IP cohort than CAR-T OP cohort. Proportion of patients hospitalized decreased over time during first month post-infusion in the CAR-T IP cohort. 25.0% of the CAR-T IP cohort was hospitalized at Day 30 post-infusion. In the CAR-T OP cohort, proportion hospitalized was the highest at Day 7 (38%) and decreased over time starting Day 8. 14.0% of the CAR-T OP cohort was hospitalized at Day 30 post-infusion.

In the CAR-T IP cohort, the most frequent re-admitting diagnoses (i.e., IP visits after the index encounter) during 1-15 days post-infusion included encounter for antineoplastic chemotherapy and immunotherapy (36.8%), DLBCL (31.6%), and fever (6.3%). Most frequent re-admitting diagnoses during 16-30 days post-infusion also included encounter for antineoplastic chemotherapy and immunotherapy (29.4%), DLBCL (17.6%), and fever (11.8%). Most frequent re-admitting diagnoses during 31-60 days post-infusion included fever (16.7%), followed by DLBCL, dyspnea, hypercalcemia, and hypotension (11.1% each).

In the CAR-T OP cohort, the most frequent admitting diagnoses during 1-15 days post-infusion included DLBCL (55.6%), neutropenia (22.2%), and fever and pain (11.1% each). Most frequent admitting diagnosis during 16-30 days post-infusion was DLBCL (66.7%).

Main cause of readmission/admission was not presented during 61-90 days post-infusion among CAR-T IP cohort and during 31-90 days post-infusion among CAR-T OP cohort due to very limited sample size.

AE rate during the study period among CAR-T cohorts

AEs	CAR-T IP N = 380	CAR-T OP N = 50
Anemia	352 (92.6)	35 (70.0)
CRS	93 (24.5)	<11 (<22.0)
Fatigue	227 (59.7)	33 (66.0)
Febrile neutropenia	22 (5.8)	<11 (<22.0)
Hypogammaglobulinemia and B-cell aplasia	118 (31.1)	11 (22.0)
Hypokalemia	138 (36.3)	13 (26.0)
Hypophosphatemia	58 (15.3)	<11 (<22.0)
Hypotension	182 (47.9)	21 (42.0)
Neutropenia and neutrophil count decreased	290 (76.3)	28 (56.0)
Neurologic toxicity		
Encephalopathy	162 (42.6)	11 (22.0)
Mental status changes/disorientation	175 (46.1)	13 (26.0)
Disturbance in attention	0 (0.0)	0 (0.0)
Somnolence	<11 (<2.9)	0 (0.0)
Delirium	35 (9.2)	<11 (<22.0)
Abnormal motor activity	<11 (<2.9)	0 (0.0)
Aphasia	54 (14.2)	<11 (<22.0)
Speech disorder	19 (5.0)	0 (0.0)
Agitation/restlessness	<11 (<2.9)	<11 (<22.0)
Cerebral edema	12 (3.2)	0 (0.0)
Seizure	15 (3.9)	<11 (<22.0)
Thrombocytopenia and platelet count decreased	209 (55.0)	21 (42.0)
Pyrexia	303 (79.7)	30 (60.0)
White blood cell count decreased	274 (72.1)	20 (40.0)

Cost of AEs among CAR-T cohort during the study period

AE	Overall	Stratified by CAR-T Infusion Setting	
		CAR-T IP	CAR-T OP
	N = 430	N = 380	N = 50
Anemia, n (%)	387 (90.0)	352 (92.6)	35 (70.0)
Cost per event, mean ± SD [median]	$8,123 ± 30,915 [283]	$8,534 ± 32,520 [278]	$5,020 ± 13,277 [287]
CRS, n (%)	100 (23.3)	93 (24.5)	<11 (<22.0)
Fatigue, n (%)	260 (60.5)	227 (59.7)	33 (66.0)
Cost per event, mean ± SD [median]	$6,191 ± 24,382 [161]	$5,468 ± 22,089 [146]	$12,770 ± 39,095 [392]
Febrile neutropenia, n (%)	24 (5.6)	22 (5.8)	<11 (<22.0)
Cost per event, mean ± SD [median]	$21,756 ± 31,727 [3,843]	$28,187 ± 34,053 [17,156]	$1,747 ± 4,566 [133]
Hypogammaglobulinemia and B-cell aplasia, n (%)	129 (30.0)	118 (31.1)	11 (22.0)
Cost per event, mean ± SD [median]	$3,257 ± 8,431 [658]	$3,202 ± 8,434 [725]	$4,029 ± 8,431 [312]
Hypokalemia, n (%)	151 (35.1)	138 (36.3)	13 (26.0)
Cost per event, mean ± SD [median]	$10,235 ± 25,190 [705]	$11,003 ± 26,719 [843]	$5,139 ± 9,091 [104]
Hypophosphatemia, n (%)	62 (14.4)	58 (15.3)	<11 (<22.0)
Cost per event, mean ± SD [median]	$9,142 ± 15,072 [1,163]	$9,046 ± 15,337 [1,098]	$10,034 ± 13,347 [3,550]
Hypotension, n (%)	203 (47.2)	182 (47.9)	21 (42.0)
Cost per event, mean ± SD [median]	$10,197 ± 39,733 [285]	$10,328 ± 41,197 [271]	$8,679 ± 14,826 [395]
Neutropenia and neutrophil count decreased, n (%)	318 (74.0)	290 (76.3)	28 (56.0)
Cost per event, mean ± SD [median]	$4,759 ± 20,947 [163]	$4,430 ± 20,754 [162]	$7,082 ± 22,173 [221]
Neurologic toxicity			
Encephalopathy, n (%)	173 (40.2)	162 (42.6)	11 (22.0)
Cost per event, mean ± SD [median]	$9,599 ± 36,847 [90]	$9,405 ± 37,468 [90]	$13,177 ± 22,519 [254]
Mental status changes/disorientation, n (%)	188 (43.7)	175 (46.1)	13 (26.0)
Cost per event, mean ± SD [median]	$1,971 ± 18,484 [83]	$1,852 ± 18,624 [83]	$5,739 ± 12,993 [142]
Disturbance in attention, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Cost per event, mean ± SD [median]	-	-	-
Somnolence, n (%)	<11 (<2.6)	<11 (<2.9)	0 (0.0)
Cost per event, mean ± SD [median]	$3,301 ± 10,774 [90]	$3,301 ± 10,774 [90]	-
Delirium, n (%)	36 (8.4)	35 (9.2)	<11 (<22.0)
Cost per event, mean ± SD [median]	$24,743 ± 33,822 [803]	$23,931 ± 33,712 [344]	$62,893 ± . [62,893]
Abnormal motor activity, n (%)	<11 (<2.6)	<11 (<2.9)	0 (0.0)
Cost per event, mean ± SD [median]	$1,435 ± 2,117 [404]	$1,435 ± 2,117 [404]	-

Aphasia, n (%)	55 (12.8)	54 (14.2)	<11 (<22.0)
Cost per event, mean ± SD [median]	$15,701 ± 25,889 [813]	$14,505 ± 25,277 [599]	$56,379 ± . [56,379]
Speech disorder, n (%)	19 (4.4)	19 (5.0)	0 (0.0)
Cost per event, mean ± SD [median]	$6,116 ± 8,466 [755]	$6,116 ± 8,466 [755]	-
Agitation/restlessness, n (%)	12 (2.8)	<11 (<2.9)	<11 (<22.0)
Cost per event, mean ± SD [median]	$954 ± 2,399 [84]	$1,079 ± 2,715 [73]	$517 ± 572 [278]
Cerebral edema, n (%)	12 (2.8)	12 (3.2)	0 (0.0)
Cost per event, mean ± SD [median]	$5,060 ± 14,815 [91]	$5,060 ± 14,815 [91]	-
Seizure, n (%)	16 (3.7)	15 (3.9)	<11 (<22.0)
Cost per event, mean ± SD [median]	$6,362 ± 16,353 [283]	$1,815 ± 4,610 [283]	$56,379 ± . [56,379]
Thrombocytopenia and platelet count decreased, n (%)	230 (53.5)	209 (55.0)	21 (42.0)
Cost per event, mean ± SD [median]	$5,230 ± 21,970 [386]	$5,452 ± 22,969 [416]	$3,378 ± 10,289 [286]
Pyrexia, n (%)	333 (77.4)	303 (79.7)	30 (60.0)
Cost per event, mean ± SD [median]	$6,540 ± 25,945 [90]	$6,480 ± 27,108 [90]	$6,972 ± 15,136 [99]
White blood cell count decreased, n (%)	294 (68.4)	274 (72.1)	20 (40.0)
Cost per event, mean ± SD [median]	$5,242 ± 23,238 [106]	$5,211 ± 23,761 [106]	$5,482 ± 18,795 [90]

HRU by CAR-T vs allo-HSCT cohort during the six-month follow-up period

	Monthly incidence rate		Adjusted IRR	
	CAR-T IP N = 265	CAR-T OP N = 430	CAR-T vs. Allo-HSCT (ref) IRR (95% CI)	P-value
HRU during the six-month follow-up period				
Length of follow-up in months, mean ± SD [median]	5.0 ± 1.8 [6.0]	4.5 ± 1.9 [6.0]	-	
HRU during the six-month follow-up period, including the index encounter				
IP				
Number of patients with IP visit, n (%)	251 (94.7)	416 (96.7)	-	
Number of IP admissions	0.51	0.47	0.90 (0.77, 1.04)	0.149
IP days	8.61	6.04	0.68 (0.59, 0.79)	<0.001*
ICU stay	0.09	0.08	0.94 (0.67, 1.31)	0.709
ICU days	1.02	0.58	0.59 (0.39, 0.91)	0.018*
OP				
Number of patients with OP visit, n (%)	239 (90.2)	394 (91.6)	-	
Number of OP visits	2.99	2.90	0.98 (0.90, 1.07)	0.653
ER				
Number of patients with ER visit, n (%)	71 (26.8)	128 (29.8)	-	
Number of ER visits	0.10	0.11	1.05 (0.77, 1.44)	0.747

Healthcare reimbursement costs comparing CAR-T vs. allo-HSCT cohort

Index procedure-related costs were higher in the CAR-T cohort ($266,555) compared to the allo- HSCT cohort ($89,693) by $182,337 (p<0.001).

During the first month following the index date (including the index encounter), total cost was higher in the CAR-T cohort compared to the allo-HSCT cohort by $178,895 (p<0.001). Cost of IP admissions was significantly higher in the CAR-T cohort compared to the allo-HSCT

cohort by $135,509 (p<0.001). Cost of OP visits was also significantly higher in the CAR-T cohort compared to the allo-HSCT cohort by $37,885 (p<0.001).

Total costs from the second month following the index date up to the end of follow-up were significantly higher for the allo-HSCT cohort compared to the CAR-T cohort. Difference in total cost between the two cohorts (CAR-T vs. allo-HSCT) was -$7,184 in month 2 (p<0.001), -$5,845 in month 3 (p<0.001), -$3,789 in month 4 (p<0.001), -$2,909 in month 5 (p=0.020), - $3,518 in month 6 (p<0.001), and -$2,431 in month 7 up to the end of follow-up (p=0.035). The cost differences in total healthcare reimbursement costs between cohorts were mainly contributed by healthcare reimbursement costs of IP admissions. Difference in healthcare reimbursement cost of IP admissions between the two cohorts (CAR-T vs. allo-HSCT) was - $5,145 in month 2 (p<0.001), -$3,939 in month 3 (p=0.003), -$2,296 in month 4 (p=0.091), -$2,654 in month 5 (p=0.069), -$3,105 in month 6 (p=0.012), and -$2,778 in month 7 up to the end of follow-up (p=0.005).

Healthcare reimbursement costs of OP visits in the second and third month following the index date were significantly higher among the allo-HSCT cohort and comparable between cohorts in subsequent months.

Safety Results
NA

Other Relevant Findings
None

Conclusion
In the six-month follow up period (including the index encounter), IP days and ICU days were significantly lower among the CAR-T cohort compared to the allo-HSCT cohort. Resource use of OP and ER were comparable between the two cohorts.

Date of Clinical Study Report
21 May 2021