PA-086

Real-world Healthcare Resource Utilization Following Outpatient or Inpatient Administration of Ciltacabtagene Autoleucel After ≥4 Prior Lines of Therapy

Murali Janakiram[1], Lin Fan[2], Victoria Alegria[2], Matthew Perciavalle[3], Bruno Emond[4], Jessica Maitland[4], Todd Bixby[2], Saurabh Nagar[2], Zaina Qureshi[2], Danai Dima[3]

[1]Judy and Bernard Briskin Center for Multiple Myeloma Research, City of Hope, Duarte, CA, USA; [2]Janssen Scientific Affairs, LLC, Horsham, PA, USA; [3]Legend Biotech USA, Inc, Somerset, NJ, USA; [4]Analysis Group ULC, Montreal, QC, Canada; [5]Fred Hutchinson Cancer Center, Seattle, WA, USA

Key Takeaway

Overall, OP administration of cilta-cel offers a patient-centric model and reduced HCRU with similar safety outcomes as IP administration in the 30 days post-infusion, and may be widely adopted

Conclusions

This real-world descriptive analysis demonstrates that OP administration of cilta-cel is feasible

Notably, nearly one-third of patients who received cilta-cel in the OP setting did not require a hospitalization within 30 days post-infusion and the mean number of hospitalization days was significantly lower at day 15, 20, and 30 post-infusion relative to patients who received cilta-cel in the IP setting

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Poster

Narrated poster video

Supplementary material

https://www.congresshub.com/Oncology/IMS2025/Cilta-cel/Janakiram

Contact the presenting author, Dr. Janakiram, at: mjanakiram@coh.org

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Disclosures

MJ reports research for Janssen, BMS; Legend, FATE Therapeutics, and advisory board with Janssen and BMS. LF, VA, TB, SN, and ZQ are employees of Janssen Scientific Affairs, LLC and own stock/stock options in Johnson & Johnson. MP is an employee of Legend Biotech USA, Inc., and owns stock options in Legend Biotech. BE and JM are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Janssen Scientific Affairs, LLC, which along with Legend Biotech USA, Inc. funded the development and conduct of this study. DD reports consulting for Karyopharm and Caribou.

Introduction

- Ciltacabtagene autoleucel (cilta-cel), a B-cell maturation antigen-directed chimeric antigen receptor T-cell (CAR-T) therapy, received initial US Food and Drug Administration (FDA) approval in February 2022 for the treatment of adults with relapsed or refractory multiple myeloma (MM) after ≥4 prior lines of therapy (5L+), based on the pivotal phase Ib/II CARTITUDE-1 trial which showed high overall response rates (97%)[1]
- While inpatient (IP) administration of cilta-cel was conducted in the pivotal trial, outpatient (OP) administration is feasible due to predictable adverse events such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS)[2]
- OP administration is becoming more common with CAR-T therapy and can expand treatment access, reduce healthcare resource utilization (HCRU) and costs, and improve patient quality of life[2,3]

Objective

- To describe real-world HCRU following cilta-cel administration in IP and OP settings

Methods

Data source

- Open claims from Komodo Research Database (1/1/2016–6/30/2024)

Study design

- A retrospective longitudinal cohort study design was used (**Figure 1**)
- The index date was defined as the date of cilta-cel infusion on or after February 28, 2022 (date of cilta-cel FDA approval)
- The baseline period was defined as the 12-month period prior to the index date
- The follow-up period was defined as the period from the index date to the earliest of 30 days post-infusion, end of clinical activity, death, or end of data availability

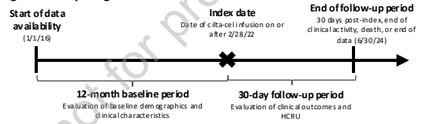
Study population

- The patient selection criteria are presented in **Figure 2**
- Patients were selected into mutually exclusive cohorts based on administration of cilta-cel in the IP or OP setting; OP administration was defined as cilta-cel infusion occurring as an outpatient

Study outcomes and statistical analyses

- Adverse events (i.e., CRS, fever, ICANS, pancytopenia) and related management strategies (i.e., tocilizumab, dexamethasone) were identified
- 30-day mortality rate and HCRU, including hospitalization days post-infusion, were reported
- Descriptive statistics were used to assess baseline patient and clinical characteristics as well as study outcomes in each cohort
- T-tests were used to perform unadjusted comparisons of study outcomes between cohorts

Figure 1: Study design



cilta-cel, ciltacabtagene autoleucel; HCRU, healthcare resource utilization.

Figure 2: Study population selection

Inclusion criteria (N=517)

- Cilta-cel after ≥4 prior lines of therapy on or after 2/28/22
- ≥1 diagnosis for MM (ICD-10-CM: C90.0) on or prior to index
- ≥18 years of age as of index
- ≥12 months of clinical activity prior to index

Exclusion criteria (N=275)

- ≥1 diagnosis of amyloidosis (ICD-10-CM: E85.x) prior to index
- Clinical trial participation on or prior to index (ICD-10-CM: Z00.6; HCPCS: S9988, S9990, S9991, S9992, S9994, S9996)
- No claims for lymphodepleting therapy agents (i.e., cyclophosphamide, fludarabine, or bendamustine) in 14 days prior to or 30 days after index

All eligible patients (N=242)

IP cilta-cel administration N=148	OP cilta-cel administration N=94

cilta-cel, ciltacabtagene autoleucel; HCPCS: Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; IP, inpatient; MM, multiple myeloma; OP, outpatient.

Results

Study population and baseline characteristics

- Among 148 patients who received cilta-cel in an IP setting and 94 patients who received cilta-cel in an OP setting, baseline patient characteristics were similar (median age [IP: 64 yrs, OP: 64 yrs], female sex [IP: 47.3%, OP: 42.6%], median Quan-Charlson Comorbidity Index [IP: 5, OP: 5], median line of therapy of cilta-cel [IP: 6, OP: 5], though there were more Black patients in the IP cohort than the OP cohort (IP: 20.9%, OP: 7.4%; **Table 1**)

Table 1: Baseline patient demographic and clinical characteristics

	IP cohort N=148	OP cohort N=94
Age at index date, mean ± SD [median], years	63.6 ± 8.2 [64.0]	63.0 ± 7.6 [64.0]
Female, n (%)	70 (47.3)	40 (42.6)
Race, n (%)		
White	80 (54.1)	52 (55.3)
Black	31 (20.9)	7 (7.4)
Hispanic	14 (9.5)	9 (9.6)
Asian	4 (2.7)	4 (4.3)
Other/Unknown	19 (12.8)	22 (23.4)
US region, n (%)		
Northeast	47 (31.8)	19 (20.2)
West	38 (25.7)	20 (21.3)
South	37 (25.0)	40 (42.6)
Midwest	26 (17.6)	15 (16.0)
Insurance plan, n (%)		
Medicare	78 (52.7)	50 (53.2)
Commercial	62 (41.9)	41 (43.6)
Medicaid	8 (5.4)	2 (2.1)
Year of index date, n (%)		
2022	29 (19.6)	14 (14.9)
2023	101 (68.2)	45 (47.9)
2024	18 (12.2)	35 (37.2)
Line of therapy, mean ± SD [median]	6.0 ± 1.1 [6.0]	5.9 ± 1.1 [5.0]
Quan-CCI, mean ± SD [median]	5.1 ± 2.8 [5.0]	5.1 ± 2.6 [5.0]
Frailty score, mean ± SD [median][1]	0.21 ± 0.11 [0.19]	0.20 ± 0.10 [0.19]
Non-frail to prefrail, n (%)	82 (55.4)	53 (56.3)
Mild-to-severe frailty, n (%)	66 (44.6)	41 (43.7)
CRAB symptoms, n (%)	122 (82.4)	75 (79.8)
Anemia	117 (79.1)	71 (75.5)
Renal impairment	30 (20.3)	22 (23.4)
Skeletal-related events	18 (12.2)	15 (16.0)
Hypercalcemia	18 (12.2)	12 (12.8)

CCI, Charlson Comorbidity Index; CRAB, calcium elevation, renal insufficiency, anemia, and bone abnormalities; IP, inpatient; OP, outpatient; SD, standard deviation; US, United States.
1. Frailty score was calculated as the sum of frailty score components identified during the 12-month baseline period divided by 31, per Patel et al.[2]

Adverse events and management strategies

- All-grade CRS (IP: 69.6%, OP: 63.8%; p=0.36), as well as CRS grades 1 and 2 (IP: 64.2%, OP: 58.5%; p=0.38) and CRS grade ≥3 (IP: 2.0%, OP: 1.1%; p=0.54) were comparable in the IP and OP cohorts
- ICANS (IP: 21.6%, OP: 20.2%; p=0.79), including grade ≥3 (IP: 2.7%, OP: 3.2%; p=0.83), and pancytopenia (IP: 79.7%, OP: 75.5%; p=0.45) were comparable between cohorts
- In the first 30 days post-infusion, use of tocilizumab (IP: 16.9%, OP: 11.7%, p=0.26) and dexamethasone (IP: 12.2%, OP: 13.8%, p=0.71) were similar between cohorts
- 30-day mortality was low in both the IP and OP cohort (IP: 1.4% [n=2], OP: 1.1% [n=1]; p=0.84; **Table 2**)

Table 2: Adverse events and management strategies post-infusion

	IP cohort N=148	OP cohort N=94	Difference in proportion (95% CI), p-value
CRS, n (%)	103 (69.6)	60 (63.8)	5.8 (-6.6; 18.1), 0.358
Grade 1-2	95 (64.2)	55 (58.5)	5.7 (-7.1; 18.4), 0.381
Grade ≥3	3 (2.0)	1 (1.1)	1.0 (-2.1; 4.1), 0.542
Grade unspecified	5 (3.4)	4 (4.3)	-0.9 (-5.9; 4.2), 0.733
Fever, n (%)	77 (52.0)	57 (60.6)	-8.6 (-21.5; 4.3), 0.189
Pancytopenia, n (%)	118 (79.7)	71 (75.5)	4.2 (-6.8; 15.2), 0.451
ICANS, n (%)	32 (21.6)	19 (20.2)	1.4 (-9.2; 12.0), 0.793
Grade 1-2	18 (12.2)	5 (5.3)	6.8 (-0.2; 13.9), 0.056
Grade ≥3	4 (2.7)	3 (3.2)	-0.5 (-4.9; 4.0), 0.829
Grade unspecified	10 (6.8)	11 (11.7)	-4.9 (-12.7; 2.8), 0.209
30-day tocilizumab use, n (%)	25 (16.9)	11 (11.7)	5.2 (-3.8; 14.1), 0.255
30-day dexamethasone use, n (%)	18 (12.2)	13 (13.8)	-1.7 (-10.5; 7.2), 0.710
30-day mortality, n (%)	2 (1.4)	1 (1.1)	0.3 (-2.5; 3.1), 0.841

CRS, cytokine release syndrome; CI, confidence interval; ICANS, immune effector cell-associated neurotoxicity syndrome; IP, inpatient; OP, outpatient.

HCRU

- Among patients in the IP cohort, 17 (11.5%) were re-admitted in the first 30 days following their initial hospitalization (**Table 3**)

Table 3: HCRU during the first 30 days post-infusion – IP cohort

	IP cohort N=148
Length of index admission (days), mean ± SD [median]	15.0 ± 5.8 [15.0]
IP re-admission[1], n (%)	17 (11.5%)

IP, inpatient; OP, outpatient; SD: standard deviation.
1. Refers to a hospitalization that occurred following discharge from the initial IP stay associated with the cilta-cel infusion.

- Among patients in the OP cohort, 64 (68.1%) were hospitalized, within a median of 6 days post-infusion (10.6% of patients were hospitalized within 3 days of infusion), and 11 (11.7) had ≥2 hospitalizations (i.e., a re-admission) in the first 30 days following cilta-cel infusion (**Table 4**)

Table 4: HCRU during the first 30 days post-infusion – OP cohort

	OP cohort N=94
IP visit, n (%)	64 (68.1%)
Time to admission (days), mean ± SD [median]	6.1 ± 2.8 [6.0]
First admission within 3 days, n (%)	10 (10.6%)
Length of first admission (days), mean ± SD [median]	6.2 ± 3.5 [6.0]
IP re-admission[1], n (%)	11 (11.7%)

IP, inpatient; OP, outpatient; SD: standard deviation.
1. Refers to having ≥2 hospitalizations that occurred during the first 30 days post-OP infusion.

- Among patients with ≥1 IP day over the first 30 days post-infusion, the mean number of hospitalization days was significantly higher in the IP cohort compared to the OP cohort (14.9 [range: 1–30] vs. 7.7 [range: 1–26] days; p<0.001; **Figure 2**)
  - At days 15 and 20 post-infusion, mean hospitalization days were significantly higher for the IP cohort compared to the OP cohort (13.0 vs. 6.1 days and 14.0 vs. 6.5 days, respectively; both p < 0.001)
- Notably, 31.9% (n=30) of patients in the OP cohort did not require hospitalization within the first 30 days post-infusion

Figure 3: Number of IP days 15-, 20-, and 30-days post-infusion among patients with ≥1 IP day[1]

CI, confidence interval; IP, inpatient; OP, outpatient.

Limitations

- The study was conducted using open claims, thus visits outside of the network may not be captured in the data
- Although the study cohorts were relatively comparable, adjusted comparisons were not conducted; hence results may be affected by residual confounding
- Risk of misclassification may exist due to possible inaccuracies in diagnosis, procedure, or drug codes as well as differences in recording of these events between cohorts

References

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Multiple Myeloma

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