Chimeric Antigen Receptor T-Cell Therapy Setting of Care: A Retrospective Cohort Analysis of MCL and FL Patients in the US

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BACKGROUND

- The United States (US) Food and Drug Administration has recently approved chimeric antigen receptor (CAR) T-cell therapy for patients with relapsed/refractory mantle cell lymphoma (MCL) and relapsed/refractory follicular lymphoma (FL).[1]
- Although CAR T-cell therapy is commonly administered in inpatient settings, as clinicians gain experience, there is growing interest in providing infusions and follow-up care in the outpatient setting.[2]

OBJECTIVE

- To evaluate patient characteristics, treatment setting, CAR T-cell therapy-associated adverse events (CAR T-AEs), and health resource utilization (HRU) of real-world CAR T-cell therapy use for MCL and FL.

METHODS

- **Study Design and Data Source**
  - Retrospective analysis of Anlitiks All-Payor Claims (AAPC) data for services rendered from April 2017 to March 2022
    - Open-source fully adjudicated pharmacy and medical claims of patients insured through Medicare, Medicaid, or commercial plans, representing over 80% of the US population
- **Study Population**
  - Patients with MCL (ICD-9/10-CMs: 200.x, C83.1x) or FL (ICD-9/10-CMs: 202.xx, C82.xx) patients with a first claim (index date) for CAR T-cell therapy (MCL: brexucabtagene autoleucel [brexu-cel] or unspecified CAR T-cell agent; FL: lisocabtagene maraleucel [liso-cel]*, tisagenlecleucel [tisa-cel], axicabtagene ciloleucel [axi-cel] or unspecified agent) between October 2017 and December 2021, with ≥ 180 days of pre-index and ≥ 90 days of post-index follow-up
    *Grade 3B FL only (ICD-9/10-CMs 202.0x, C82.4x)
- **Exclusion Criteria**
  - Clinical trial enrollment (ICD-9/10-CMs V70.7, Z00.6) ≥ 45 days prior to their CAR T infusion date or ≥ 15 days following their CAR T infusion date
  - Concurrent MCL and FL diagnoses; concurrent diagnosis of mediastinal large B-cell lymphoma (ICD-9/10-CMs 200.7x, C85.2x), acute lymphoblastic leukemia (ALL) (ICD-9/10-CMs 204.00, 204.02, C91.00, C91.02), or diffuse large B-cell lymphoma (DLBCL) arising from FL/indolent lymphoma (ICD-9/10-CMs 200.x, C83.3x)
  - Patients with MCL with a claim for liso-cel, tisa-cel, or axi-cel; patients with FL with a claim for brexu-cel
- **Study Measures and Outcomes**
  - Demographics, clinical characteristics, and treatment (infusion) setting (inpatient/outpatient Authorized Treatment Centers [ATCs])
  - Incidence of observed CAR T-AEs assessed in claims according to components of the American Society for Transplantation and Cellular Therapy (ASTCT) cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS) consensus grading scales[3,4]
  - HRU (inpatient hospitalizations, emergency department [ED] visits, outpatient services, and medications for AE management) following the index date
- **Statistical Analyses**
  - Descriptive statistics include frequencies and percentages for categorical variables; mean, median, and range for continuous variables. Chi-square tests (categorical measures),t-tests, and Wilcoxon-Rank Sum tests (continuous measures) were used to assess group differences, where appropriate.
  - Logistic regressions were used to identify predictors of setting of CAR T-cell infusion. Cox proportional hazards models were used to analyze time from leukapheresis to CAR T-cell infusion and time to CAR T-AEs.
  - Statistical analyses were performed using R and Rapid Analyzer™ with results stratified for:
    - Patients receiving CAR T-cell therapy in inpatient versus outpatient settings
    - Patients with at least 1 observed AE-related claim* versus those without an observed AE in the follow-up period
      *For a select list of observed events related to CRS, neurological events, and infections only

RESULTS

- Majority (72%) of 151 patients with MCL were infused inpatient (**Table 1a**).
- Overall, 75% of patients were male, the mean age was 63.8 (± 8.6) years, 59% were commercially insured, 31% had Medicare, 9% had Medicaid, and 3% had unknown/other insurance types. Mean (SD) number of Elixhauser comorbidities was 2.79 (± 2.09) and 1.53 (± 1.96) for observed AE and no observed AE groups, respectively.
- Of the 113 patients with observed AE, 68% were infused inpatient and 32% were infused outputient. Of the 38 patients with no observed AE, 82% were infused inpatient and 18% were infused outpatient.

Table 1a. Baseline Characteristics of MCL Users of CAR T-cell Therapy
By Observed AE Status & Setting of CAR T-cell Infusion

Metric	Inpatient CAR T-cell Infusion (n=108; 71.5%)		Outpatient CAR T-cell Infusion (n=43; 28.5%)		All CAR T-cell Infusion (N= 151)	
	Observed AE* (n=77)	No Observed AE (n=31)	Observed AE* (n=36)	No Observed AE (n=7)	Observed AE* (n=113)	No Observed AE (n=38)
Mean Age, years (SD)	64.84 (7.79)	59.96 (8.45)	65.63 (8.93)	59.71 (11.99)	65.09 (8.14)	59.92 (9.02)
N, (%) Male	58 (75.3%)	25 (80.6%)	23 (63.9%)	7 (100%)	81 (71.7%)	32 (84.2%)
Time to CAR T-cell Infusion from Leukapheresis Date, days						
Evaluable Patients, n Mean (SD) Median (IQR)	31 29.26 (9.22) 27 (7)	7 34.37 (14.54) 27 (30)	27 26.75 (8.19) 26 (6)	3 26.0 (2.64) 25 (5)	58 28.12 (8.79) 26 (7)	10 32.09 (12.84) 25 (23)

*For a select list of observed events related to cytokine release syndrome, neurological events, and infections only, occurring from the day of CAR T-cell infusion (day 0) to day 90
MCL mantle cell lymphoma, AE(s) adverse event(s), CAR chimeric antigen receptor, SD standard deviation, IQR interquartile range

RESULTS (CONT.)

- Majority (81%) of 267 patients with FL were infused inpatient (**Table 1b**).

Table 1b. Baseline Characteristics of FL Users of CAR T-cell Therapy
By Observed AE Status & Setting of CAR T-cell Infusion

Metric	Inpatient CAR T-cell Infusion (n=216; 80.9%)		Outpatient CAR T-cell Infusion (n=51; 19.1%)		All CAR T-cell Infusion (N= 267)	
	Observed AE* (n=149)	No Observed AE (n=67)	Observed AE* (n=33)	No Observed AE (n=18)	Observed AE* (n=182)	No Observed AE (n=85)
Mean Age, years (SD)	60.61 (9.88)	62.52 (10.25)	63.21 (9.73)	59.77 (14.14)	61.08 (9.88)	61.94 (11.14)
N, (%) Male	89 (59.7%)	48 (71.6%)	25 (75.8%)	10 (55.6%)	114 (62.6%)	58 (68.2%)
Time to CAR T-cell Infusion from Leukapheresis Date, days						
Evaluable Patients, n Mean (SD) Median (IQR)	61 29.98 (9.00) 27 (8)	23 26.83 (6.35) 26 (8)	18 29 (7.18) 27 (8)	8 25.75 (11.37) 28 (4)	79 29.76 (8.60) 27 (8)	31 26.56 (7.70) 27 (8)

*For a select list of observed events related to cytokine release syndrome, neurological events, and infections only, occurring from the day of CAR T-cell infusion (day 0) to day 90
FL follicular lymphoma, AE(s) adverse event(s), CAR chimeric antigen receptor, SD standard deviation, IQR interquartile range

Table 2a. HRU* & Observed AE Status within 30 Days Post-Index,
by Setting of CAR T-cell Infusion, Patients with MCL

HRU in Days 0-3 Post-CAR T-cell Infusion	Inpatient CAR T-cell Infusion (n=108)		Outpatient CAR T-cell Infusion (n=43)		All CAR T-cell Infusion (N= 151)	
	Observed AE Status in 0-3 Days Post-CAR T-cell Infusion					
	Observed AE† (n=50)	No Observed AE (n=58)	Observed AE† (n=23)	No Observed AE (n=20)	Observed AE† (n=73)	No Observed AE (n=78)
Inpatient Hospitalization, n (%)	50 (100%)	58 (100%)	23 (100%)	11 (55%)	73 (100%)	69 (88%)
Mean LOS Among All‡,§	3.6	2.4	3.8	2.1	3.7	2.3
Mean LOS Among Those Admitted§	3.6	2.4	3.8	3.7	3.7	2.7
ICU, n (%)	12 (24%)	6 (10%)	2 (9%)	-	14 (19%)	6 (8%)
Mean LOS§	3.8	4.0	3.0	-	3.6	4.0
Non-ICU, n (%)	38 (76%)	52 (90%)	21(91%)	11 (55%)	59 (81%)	63 (81%)
ED visit, n (%)	4 (8%)	2 (3%)	-	-	4 (5%)	2 (3%)
Outpatient Services, n (%)	41 (82%)	31 (53%)	23 (100%)	20 (100%)	64 (88%)	51 (65%)
Medications, n (%)						
Tocilizumab	21 (42%)	7 (12%)	12 (52%)	4 (20%)	33 (45%)	11 (14%)
Corticosteroids	29 (58%)	14 (24%)	15 (65%)	4 (20%)	44 (60%)	18 (23%)
	Observed AE Status in 0-30 Days Post-CAR T-cell Infusion					
HRU in Days 0-30 Post-CAR T-cell Infusion	**Observed AE† (n=70)**	**No Observed AE (n=38)**	**Observed AE† (n=33)**	**No Observed AE (n=10)**	**Observed AE† (n=103)**	**No Observed AE (n=48)**
Inpatient Hospitalization, n (%)	70 (100%)	38 (100%)	33 (100%)	5 (50%)	103 (100%)	43 (90%)
Mean LOS Among All‡,††	15.5	11.1	9.4	4.4	13.5	9.7
Mean LOS Among Those Admitted††	15.5	11.1	9.4	8.8	13.5	10.9
ICU, n (%)	14 (20%)	3 (8%)	4 (12%)	-	18 (17%)	3 (6%)
Mean LOS††	18.7	6.0	13.3	-	17.5	6.0
Non-ICU, n (%)	56 (80%)	35 (92%)	29 (88%)	5 (50%)	85 (83%)	40 (83%)
ED visit, n (%)	5 (7%)	2 (5%)	-	-	5 (5%)	2 (4%)
Outpatient Services, n (%)	63 (90%)	31 (82%)	33 (100%)	10 (100%)	96 (93%)	41 (85%)
Medications, n (%)						
Tocilizumab	21 (30%)	8 (21%)	12 (36%)	4 (40%)	33 (32%)	12 (25%)
Corticosteroids	30 (43%)	16 (42%)	16 (48%)	4 (40%)	46 (45%)	20 (42%)

*Includes inpatient admission (ICU stay & non-ICU), ED visits, outpatient services (procedures/diagnostics, office visits, outpatientpharmacy) and medication use (tocilizumab and corticosteroids); †For a select list of observed events related to CRS, NEs, and infections only, occurring from the day of CAR T-cell infusion to day 3; ‡Includes patients not admitted; §LOS per patient reported in days, truncated on day 3; ¶For a select list of observed events related to CRS, NEs, and infections only, occurring from the day of CAR T-cell infusion to day 30; ††LOS per patient reported in days, truncated on day 30
HRU healthcare resource utilization, AE adverse event, CAR chimeric antigen receptor, MCL mantle cell lymphoma, ICU intensive care unit, LOS length of stay, ED emergency department, CRS cytokine release syndrome, NEs neurological events

Table 2b. HRU* & Observed AE Status within 30 Days Post-Index,
by Setting of CAR T-cell Infusion, Patients with FL

HRU in Days 0-3 Post-CAR T-cell Infusion	Inpatient CAR T-cell Infusion (n=216)		Outpatient CAR T-cell Infusion (n=51)		All CAR T-cell Infusion (N= 267)	
	Observed AE Status in 0-3 Days Post-CAR T-cell Infusion					
	Observed AE† (n=73)	No Observed AE (n=143)	Observed AE† (n=11)	No Observed AE (n=40)	Observed AE† (n=84)	No Observed AE (n=183)
Inpatient Hospitalization, n (%)	73 (100%)	143 (100%)	11 (100%)	18 (45%)	84 (100%)	161 (88%)
Mean LOS Among All‡,§	3.8	2.1	3.9	1.1	3.8	1.9
Mean LOS Among Those Admitted§	3.8	2.1	3.9	2.4	3.8	2.1
ICU, n (%)	12 (16%)	11 (8%)	3 (27%)	-	15 (18%)	11 (6%)
Mean LOS§	3.5	3.6	3.7	-	3.5	3.6
Non-ICU, n (%)	61 (84%)	132 (92%)	8 (73%)	18 (45%)	69 (82%)	150 (82%)
ED visit, n (%)	7 (10%)	3 (2%)	-	1 (3%)	7 (8%)	4 (2%)
Outpatient Services, n (%)	45 (62%)	60 (42%)	11 (100%)	40 (100%)	56 (67%)	100 (55%)
Medications, n (%)						
Tocilizumab	34 (47%)	14 (10%)	1 (9%)	7 (18%)	35 (42%)	21 (11%)
Corticosteroids	49 (67%)	35 (24%)	9 (82%)	10 (25%)	58 (69%)	45 (25%)
	Observed AE Status in 0-30 Days Post-CAR T-cell Infusion					
HRU in Days 0-30 Post-CAR T-cell Infusion	**Observed AE† (n=131)**	**No Observed AE (n=85)**	**Observed AE† (n=26)**	**No Observed AE (n=25)**	**Observed AE† (n=157)**	**No Observed AE (n=110)**
Inpatient Hospitalization, n (%)	131 (100%)	85 (100%)	26 (100%)	15 (60%)	157 (100%)	100 (91%)
Mean LOS Among All‡,††	11.0	10.8	9.5	5.3	10.8	9.5
Mean LOS Among Those Admitted††	11.0	10.8	9.5	8.8	10.8	10.5
ICU, n (%)	15 (11%)	6 (7%)	3 (12%)	2 (8%)	18 (11%)	8 (7%)
Mean LOS††	9.4	9.0	7.3	3.5	9.1	7.6
Non-ICU, n (%)	116 (89%)	79 (93%)	23 (88%)	13 (52%)	139 (89%)	92 (84%)
ED visit, n (%)	18 (14%)	3 (4%)	2 (8%)	1 (4%)	20 (13%)	4 (4%)
Outpatient Services, n (%)	126 (96%)	62 (73%)	26 (100%)	25 (100%)	152 (97%)	87 (79%)
Medications, n (%)						
Tocilizumab	38 (29%)	22 (26%)	3 (12%)	8 (32%)	41 (26%)	30 (27%)
Corticosteroids	54 (41%)	48 (56%)	10 (38%)	14 (56%)	64 (41%)	62 (56%)

*Includes inpatient admission (ICU stay & non-ICU), ED visits, outpatient services (procedures/diagnostics, office visits, outpatient pharmacy) and medication use (tocilizumab and corticosteroids); †For a select list of observed events related to CRS, NEs, and infections only, occurring from the day of CAR T-cell infusion to day 3; ‡Includes patients not admitted; §LOS per patient reported in days, truncated on day 3; ¶ For a select list of observed events related to CRS, NEs, and infections only, occurring from the day of CAR T-cell infusion to day 30; ††LOS per patient reported in days, truncated on day 30
HRU healthcare resource utilization, AE adverse event, CAR chimeric antigen receptor, FL follicular lymphoma, ICU intensive care unit, LOS length of stay, ED emergency department, CRS cytokine release syndrome, NEs neurological events

RESULTS (CONT.)

- Overall, 64% of patients were male, the mean age was 61.4 (± 10.3) years, 70% were commercially insured, 20% had Medicare, 7% had Medicaid, and 3% had unknown/other insurance types. Mean (SD) number of Elixhauser comorbidities was 1.81 (±1.79) and 1.29 (±1.35) for observed AE and no observed AE groups, respectively.
- Of the 182 patients with observed AE, 82% were infused inpatient and 18% were infused outpatient. Of the 85 patients with no observed AE, 79% were infused inpatient and 21%were infused outpatient.
- Approximately 26% of patients with FL had a particular CAR T-cell therapy specified, with axi-cel most often used (19% of full FL population).
- Median time from leukapheresis to infusion was similar for inpatient (MCL/FL: 27 days) and outpatient (MCL: 25 days; FL: 27 days) settings.
- Among patients with MCL who received T-cell therapy, 68% (n=103) had an observed AE within 30 days of infusion. Among outpatient-infused patients with MCL, 79% (n=34) and 88% (n=38) were hospitalized within 0 to 3- days and 0 to 30- day, respectively. By day 30, eighteen MCL patients with an observed AE (17%) required ICU care (**Table 2a**).
- Among patients with FL who received CAR T-cell therapy, 59% (n=157) had an observed AE within 30 days post-infusion. Among outpatient-infused patients with FL, 57% (n=29) and 80% (n=41) were hospitalized within 0 to 3- days and 0 to 30-days, respectively. By day 30, eighteen patients with an observed AE (11%) required ICU care (**Table 2b**).
- Among 43 outpatient-infused CAR T patients with MCL, 20 (47%) experienced CRS within 0-3 days; all of these patients were hospitalized in this period. Among 108 inpatient-infused CAR T patients with MCL, 45 (42%) experienced CRS within 0-3 days; all of these patients were already hospitalized (**Table 3a**).

Table 3a/3b. HRU* & Observed CRS Status within 30 Days Post-Index,
by Setting of CAR T-cell Infusion, Patients with MCL/FL

HRU in Days 0-3 Post-CAR T-cell Infusion	Inpatient CAR T-cell Infusion (n=108)		Outpatient CAR T-cell Infusion (n=43)		All CAR T-cell Infusion (N= 151)	
	Observed CRS Status in 0-3 Days Post-CAR T-cell Infusion					
	Observed CRS† (n=45)	No Observed CRS (n=63)	Observed CRS† (n=20)	No Observed CRS (n=23)	Observed CRS† (n=65)	No Observed CRS (n=86)
Inpatient Hospitalization, n (%)	45 (100%)	63 (100%)	20 (100%)	14 (61%)	65 (100%)	77 (90%)
Mean LOS Among All‡,§	3.6	2.6	3.8	2.3	3.6	2.5
Mean LOS Among Those Admitted§	3.6	2.6	3.8	3.8	3.6	2.8
ICU, n (%)	10 (22%)	7 (11%)	2 (10%)	-	12 (18%)	7 (8%)
Mean LOS§	3.7	4.0	3.0	-	3.6	4.0
Non-ICU, n (%)	35 (78%)	56 (89%)	18 (90%)	14 (61%)	53 (82%)	70 (81%)
ED visit, n (%)	4 (9%)	2 (3%)	-	-	4 (6%)	2 (2%)
Outpatient Services, n (%)	38 (84%)	27 (43%)	20 (100%)	14 (61%)	58 (89%)	41 (48%)
Medications, n (%)						
Tocilizumab	18 (40%)	10 (16%)	12 (60%)	4 (17%)	30 (46%)	14 (16%)
Corticosteroids	25 (56%)	18 (29%)	14 (70%)	5 (22%)	39 (60%)	23 (27%)
	Observed CRS Status in 0-30 Days Post-CAR T-cell Infusion					
HRU in Days 0-30 Post-CAR T-cell Infusion	**Observed CRS† (n=65)**	**No Observed CRS (n=43)**	**Observed CRS† (n=32)**	**No Observed CRS (n=11)**	**Observed CRS† (n=97)**	**No Observed CRS (n=54)**
Inpatient Hospitalization, n (%)	65 (100%)	43 (100%)	32 (100%)	6 (55%)	97 (100%)	49 (91%)
Mean LOS Among All‡,††	15.1	12.3	9.5	4.5	13.2	10.7
Mean LOS Among Those Admitted††	15.1	12.3	9.5	8.2	13.2	11.8
ICU, n (%)	13 (20%)	4 (9%)	4 (13%)	-	17 (18%)	4 (7%)
Mean LOS††	18.2	10.8	13.3	6 (55%)	17.1	10.8
Non-ICU, n (%)	52 (80%)	39 (91%)	28 (88%)		80 (82%)	45 (83%)
ED visit, n (%)	5 (8%)	2 (5%)	-	-	5 (5%)	2 (4%)
Outpatient Services, n (%)	59 (91%)	36 (84%)	32 (100%)	11 (100%)	91 (94%)	47 (87%)
Medications, n (%)						
Tocilizumab	18 (28%)	11 (26%)	12 (38%)	4 (36%)	30 (31%)	15 (28%)
Corticosteroids	26 (40%)	20 (47%)	15 (47%)	5 (45%)	41 (42%)	25 (46%)

HRU in Days 0-3 Post-CAR T-cell Infusion	Inpatient CAR T-cell Infusion (n=216)		Outpatient CAR T-cell Infusion (n=51)		All CAR T-cell Infusion (N= 267)	
	Observed CRS Status in 0-3 Days Post-CAR T-cell Infusion					
	Observed CRS† (n=64)	No Observed CRS (n=152)	Observed CRS† (n=10)	No Observed CRS (n=41)	Observed CRS† (n=74)	No Observed CRS (n=193)
Inpatient Hospitalization, n (%)	64 (100%)	152 (100%)	10 (100%)	19 (46%)	74 (100%)	171 (89%)
Mean LOS Among All‡,§	3.9	2.1	3.9	1.2	3.9	1.9
Mean LOS Among Those Admitted§	3.9	2.1	3.9	2.5	3.9	2.2
ICU, n (%)	9 (14%)	13 (9%)	3 (30%)	-	12 (16%)	13 (7%)
Mean LOS§	3.7	3.5	3.7	-	3.7	3.5
Non-ICU, n (%)	55 (86%)	139 (91%)	7 (70%)	19 (46%)	62 (84%)	158 (82%)
ED visit, n (%)	6 (9%)	4 (3%)	-	1 (2%)	6 (8%)	5 (3%)
Outpatient Services, n (%)	43 (67%)	64 (42%)	10 (100%)	41 (100%)	53 (72%)	105 (54%)
Medications, n (%)						
Tocilizumab	30 (47%)	18 (12%)	1 (10%)	7 (17%)	31 (42%)	25 (13%)
Corticosteroids	45 (70%)	39 (26%)	8 (80%)	11 (27%)	53 (72%)	50 (26%)
	Observed CRS Status in 0-30 Days Post-CAR T-cell Infusion					
HRU in Days 0-30 Post-CAR T-cell Infusion	**Observed CRS† (n=122)**	**No Observed CRS (n=94)**	**Observed CRS† (n=25)**	**No Observed CRS (n=26)**	**Observed CRS† (n=147)**	**No Observed CRS (n=120)**
Inpatient Hospitalization, n (%)	122 (100%)	94 (100%)	22 (88%)	16 (62%)	144 (98%)	110 (92%)
Mean LOS Among All‡,††	10.7	11.2	9.6	5.2	10.5	9.9
Mean LOS Among Those Admitted††	10.7	11.2	10.9	8.4	10.8	10.8
ICU, n (%)	12 (10%)	9 (10%)	3 (12%)	2 (8%)	15 (10%)	11 (9%)
Mean LOS††	9.9	8.4	7.0	3.5	9.3	7.5
Non-ICU, n (%)	110 (90%)	85 (90%)	19 (76%)	14 (54%)	129 (88%)	99 (83%)
ED visit, n (%)	17 (14%)	3 (3%)	2 (8%)	1 (4%)	19 (13%)	4 (3%)
Outpatient Services, n (%)	114 (93%)	72 (77%)	25 (100%)	26 (100%)	139 (95%)	98 (82%)
Medications, n (%)						
Tocilizumab	34 (28%)	26 (28%)	3 (12%)	8 (31%)	37 (25%)	34 (28%)
Corticosteroids	50 (41%)	52 (55%)	9 (36%)	15 (58%)	59 (40%)	67 (56%)

*Includes inpatient admission (ICU stay & non-ICU), ED visits, outpatient services (procedures/diagnostics, office visits, outpatient pharmacy) and medication use (tocilizumab and corticosteroids); †For a select list of observed events related to CRS, occurring from the day of CAR T-cell infusion to day 3; ‡Includes patients not admitted; §LOS per patient reported in days, truncated on day 3; ¶ For a select list of observed events related to CRS, occurring from the day of CAR T-cell infusion to day 30; ††LOS per patient reported in days, truncated on day 30
HRU healthcare resource utilization, CRS cytokine release syndrome, CAR chimeric antigen receptor, MCL mantle cell lymphoma, FL follicular lymphoma, ICU intensive care unit, LOS length of stay, ED emergency department

RESULTS (CONT.)

- Among 51 outpatient-infused CAR T patients with FL, 10 (20%) experienced CRS within 0-3 days; all of these patients were hospitalized in this period. Among 216 inpatient-infused CAR T patients with FL, 64 (30%) experienced CRS within 0-3 days; all of these patients were already hospitalized (**Table 3b**).
- Four outpatient-infused CAR T patients with MCL (9%) experienced NE within 0-3 days postinfusion. This rate was slightly lower than the 10% observed in the inpatient-infused patients (n=11). Three outpatient-infused CAR T patients with FL (6%) experienced NE within 0-3 days post-infusion. This rate was slightly higher than the 5% observed in the inpatient-infused patients (n=10).

Table 4a. Logistic Regression,
Factors Associated with Setting of CAR T-cell Infusion

	Odds Ratio (95% CI)	
Inpatient vs. Outpatient (ref.)	**0-90 Days, Patients with MCL**	**0-90 Days, Patients with FL**
Age (> 65 vs. <65 years (ref.))	1.10 (0.51, 2.41)	0.60 (0.32, 1.14)
Sex (Male vs. Female (ref.))	1.38 (0.60, 3.10)	0.86 (0.43, 1.69)
Number of Elixhauser Comorbidities	0.84 (0.69, 1.01)	**1.33 (1.07, 1.69)***
Insurance Type Commercial (ref.) Medicaid Medicare Other/Unknown	- 4.55 (0.68, 92.64) 0.81 (0.37, 1.74) 0.16 (0.01, 1.80)	- 1.15 (0.41, 3.79) 1.29 (0.66, 2.57) 0.64 (0.06, 14.42)

Table 4b. Cox Proportional Hazards Model,
Factors Associated with Any Observed AE 0-3 and 0-30 Days Following CAR T-cell Infusion

	Hazard Ratio (95% CI)			
	Patients with MCL		Patients with FL	
Any Observed AE, by Follow-up Period	**0-3 Days**	**0-30 Days**	**0-3 Days**	**0-30 Days**
Age	1.00 (0.98, 1.03)	1.00 (0.97, 1.03)	1.00 (0.98, 1.02)	1.00 (0.98, 1.01)
Sex (Male vs. Female (ref.))	0.93 (0.55, 1.56)	1.44 (0.91, 2.24)	0.87 (0.58, 1.31)	0.87 (0.63, 1.21)
Number of Elixhauser Comorbidities	1.04 (0.93, 1.17)	1.09 (0.98, 1.22)	**1.16 (1.03, 1.30)***	1.08 (0.99, 1.19)
Insurance Type Commercial (ref.) Medicaid Medicare Other/Unknown	- 1.40 (0.48, 4.09) 1.26 (0.76, 2.09) **	- 0.67 (0.26, 1.74) 0.94 (0.62, 1.41) 0.14 (0.02, 1.07)	- 1.10 (0.58, 2.12) 0.95 (0.62, 1.46) 1.42 (0.19, 10.65)	- 1.72 (0.98, 3.03) 1.03 (0.74, 1.45) 1.30 (0.31, 5.47)
Diabetes with chronic complications	1.48 (0.56, 3.94)	0.80 (0.35, 1.85)	1.18 (0.46, 3.08)	1.64 (0.72, 3.74)
Liver Disease (moderate/severe)	1.11 (0.43, 2.94)	1.29 (0.54, 3.12)	0.62 (0.20, 1.96)	1.53 (0.50, 4.69)
Setting of CAR T Infusion (IP vs. OP (ref.))	0.95 (0.58, 1.54)	0.97 (0.62, 1.51)	1.23 (0.70, 2.15)	1.12 (0.74, 1.68)

*p <0.05; **Insufficient sample size
CAR chimeric antigen receptor, CI confidence interval, MCL mantle cell lymphoma, FL follicular lymphoma, AE adverse event, ref. reference, OR odds ratio

- Patients with FL with a greater number of comorbid conditions had a significantly higher likelihood of undergoing CAR T-cell infusion in the inpatient setting (OR: 1.33, 95% CI:1.07-1.69, p<0.05) (**Table 4a**).
- For patients with FL, having more comorbidities was also predictive of "any" observed AE occurrence within 3 days following CAR T-cell infusion (HR: 1.16, 95% CI:1.03-1.30; p<0.05) (**Table 4b**).

LIMITATIONS

- Data are unavailable for some characteristics that influence AE incidence and/or choice of infusion setting are not captured in claims data.
- AEs may be under-identified using a claims-based algorithm.AE identification may vary by infusion setting as patients receiving CAR T-cell therapy in the inpatient setting will have their AEs immediately observed compared to the inherent lag in outpatient AE reporting.
- Coding detail was insufficient to support product-level analysis for FL.

CONCLUSIONS

- In these real-world MCL and FL populations, 20-25% of patients received CAR T-cell therapy infusions in outpatient settings.
- Median time from leukapheresis to CAR T-cell infusion was similar for MCL and FL in both infusion settings (25-27 days).
- Adverse events were observed in 68% of patients with MCL and 59% of patients with FL within 30 days post-infusion.
- Greater comorbidity burden was associated with increased likelihood of inpatient infusion and greater risk of observed AE among patients with FL, although no similar associations were apparent among patients with MCL.

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DISCLOSURES

Seyedin: Kite/Gilead: Consultancy **Hasegawa:** Kite/Gilead: Employment
Rajagopalan: Kite/Gilead: Consultancy **Wade:** Kite/Gilead: Consultancy