Rate of Cytokine Release Syndrome in CAR-T for Medicare Fee-for-Service Beneficiaries: analysis of over 3 years of claims

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Background

Cytokine release syndrome (CRS) is the most observed CAR-T associated toxicity. CRS has been shown to lead to various negative and life-threatening outcomes. Various published works have found the rate of CRS to be from 37% to 93%. The wide range is likely due to studying on small sample sizes (e.g., <50) and dependent on the different scoring/grading of CRS symptoms. CRS received a specific ICD-10 diagnosis code in October 2020. Since then, to our knowledge, no published literature exists that summarizes system-wide occurrence of CRS over the 3+ years since the introduction of the CRS diagnosis.

Objectives

This study has three objectives:

1. Identify the rate of CRS within CAR-T Medicare FFS beneficiaries
2. Determine whether the administration of CAR-T in the inpatient or outpatient setting has higher rates of CRS.
3. Evaluate potential predictors of CRS

Methods

- This analysis used the 100% Medicare Research Identifiable Files (RIF) from Q3 2020 through Q4 2022. Beneficiaries were identified on their first occurrence of CAR-T in either the inpatient or outpatient setting.
- Beneficiaries were required to have continuous eligibility in Medicare Parts A and B for three months after discharge from their index CAR-T claim. Demographic information (age, race, dual-eligibility status, etc.) was obtained from the Master Beneficiary Summary Files (MBSF).

Figure 1: The rate of CRS was significantly lower for beneficiaries receiving CAR-T in the outpatient setting compared to inpatient (Overall - 57% vs. 69%, Fisher's exact, p<.0001).

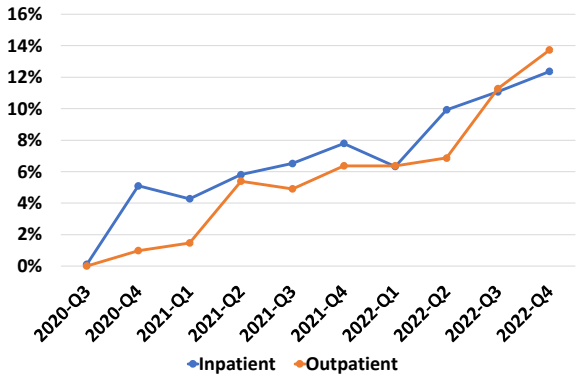
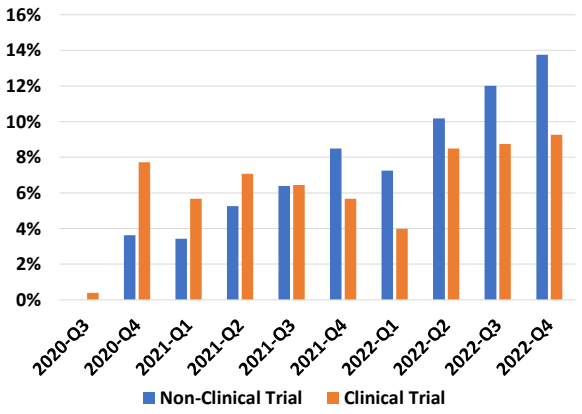


Figure 2: The rate CRS for non-clinical trials was significantly higher than for clinical trials (Overall - 70% vs. 63%, Fisher's exact, p<.0001).

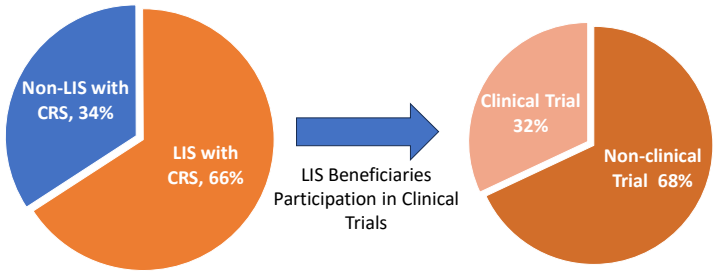


Results

Table 1: Demographics Information and sites of care for beneficiaries with CAR-T and CRS

Variable	CAR-T Case Count	CRS Count (% with CRS)	With CRS – Died in 3 Months (% among CRS Count)
Total	**2,733**	**1,870 (68%)**	**204 (11%)**
Site of Care			
Inpatient	2,529	1,753 (69%)	198 (11%)
Outpatient	204	117 (57%)	<11 (*%)
Clinical Trials			
Clinical	777	492 (63%)	71 (14%)
Non-Clinical	1,956	1,378 (70%)	133 (10%)
Mean Age	70		
Gender			
Female	1,056	737 (70%)	68 (9%)
Male	1,676	1,133 (68%)	136 (12%)
Race			
White	2,267	1,545 (68%)	171 (11%)
Black	152	105 (69%)	11 (10%)
Asian	61	42 (69%)	<11 (*%)
Hispanic	62	48 (77%)	<11 (*%)
Other	190	130 (68%)	11 (9%)
Socio-Economic			
LIS Status	337	222 (66%)	24 (11%)
Dual Eligible	318	210 (66%)	24 (11%)

Figure 3: Comparison of Non-LIS and LIS-Beneficiaries with CART and CRS by Clinical Trial Participation



Conclusions

CAR-T continues to expand into new products and indications, and CRS continues to be an important clinical variable in CAR-T treatment. Now that the CRS diagnosis code has been present for over three years, this analysis suggests that we now have the statistical power to find important predictors of CRS, which can help providers to mitigate treatment hurdles and improve patient outcomes. These factors will also become increasingly important as CAR-T administration moves into the outpatient setting.

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