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902.HEALTH SERVICES AND QUALITY IMPROVEMENT - LYMPHOID MALIGNANCIES

Clinician and Administrator Perspectives on Chimeric Antigen Receptor (CAR) T-Cell Therapy Outpatient Administration in Relapsed or Refractory Multiple Myeloma (RRMM) in the United States (US): A Qualitative Study

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Background: The use of CAR-T cell therapy has transformed treatment paradigms in B-cell malignancies. Ciltacabtagene autoleucel (cilta-cel) was approved for use in RRMM after four or more prior lines of therapy in 2022. While the pivotal studies exclusively treated patients in an inpatient setting, robust infrastructure planning at some centers across US has fostered outpatient administration of the commercially available product. Outpatient administration of CAR-T is more desirable due to superior financial sustainability, lower healthcare resource utilization, and greater patient autonomy during the treatment. Hence, we conducted a qualitative study to evaluate clinical and administrative perspectives and trends in outpatient administration of commercialized cilta-cel with an aim to understand best practices from certified CAR-T centers in the USA.
Methods: A targeted literature review was conducted to better understand current practices around outpatient administration of CAR-T, and inform the development of primary research materials for designing subsequent interviews. Next, two 60-minute exploratory interviews were conducted with multi-stakeholder participants (n=5) from two certified cilta-cel centers, each with significant volume of outpatient administration of cilta-cel. Following the qualitative analysis of interviews, two 90-minute panels were conducted with multi-stakeholder participants (n=14) from six certified cilta-cel centers, including centers from exploratory interviews, focusing on clinical and administrative topics across the patient journey.
Results: Each center in the study treated approximately 15-30 patients with cilta-cel in the outpatient setting. Using Likert scales, participants from all centers ranked space/capacity as the most important factor in decision-making process for outpatient cilta-cel administration, and ranked reimbursement incentives as a highly (67% of participants) or a moderately (33%) important factor. All participants agreed that having a dedicated outpatient infrastructure (dedicated space such as bed availability and internal processes including standard operating procedures (SOPs)), 24/7 support, outpatient bone marrow transplant (BMT) or cell therapy experience, and robust multidisciplinary teams were key to setting-up successful outpatient centers for cilta-cel therapy.
The participants agreed that cilta-cel can be administered safely in an outpatient setting due to generally predictable, delayed onset of potential AEs, except in patients with significant comorbidities or organ dysfunction. Participants also considered caregiver support and lodging availability as factors of importance for outpatient administration. Institutionally established AE monitoring protocols are critical for safe use of cilta-cel in an outpatient setting. Over 50% of the centers interviewed have recently started to administer tocilizumab to treat mild grade 1 cytokine release syndrome (CRS) in an outpatient setting. Based on the findings across the phases of research, the patient journey for outpatient administration of cilta-cel was updated

(Figure 1). While patients may be admitted for toxicity events, 100% of centers interviewed had 24-hour coverage and bed availability for these patients if needed.
Conclusions: Overall, this study further supports the notion that centers can safely administer cilta-cel in an outpatient setting, if appropriate infrastructure is in place. Additional best practices for new outpatient sites include adequate infrastructure, SOPs, a well-trained and multidisciplinary team, and education of patients and caregivers (Table 1). Outpatient management and earlier intervention for low-grade AEs is currently evolving, with more real-world research required. Continued expert sharing of best practices can aid centers in implementing outpatient administration of CAR-T therapies.
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Figure 1: Cilta-cel administrative and clinical journey as defined by participants of the qualitative research.

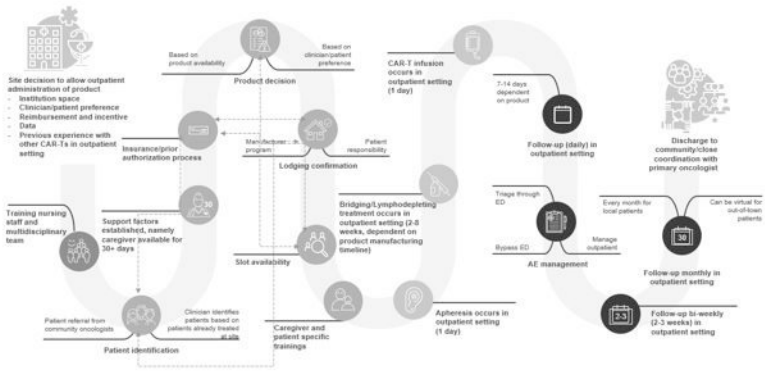

Table 1: Key participant-based recommendations for successful outpatient CAR-T administration, with focus on cilta-cel

Key recommendations	Explanations
Infrastructure	**Dedicated outpatient infrastructure is needed for patients receiving CAR-T therapy.** • Infrastructure for outpatient BMTs as a foundation for expanding their outpatient administration of CAR-T therapies. • Potential to have shared spaces with other outpatient cancer teams, such as BMT or other cell therapy teams. • Facilities for managing adverse events are needed, which can include acute cancer care centers, 24/7 cancer clinics, or day hospitals. • Adequate lodging for patients and caregivers is necessary for at least 28-days post-infusion.
SOPs and guidelines	**SOPs, and product-specific guidelines where applicable, are required to ensure proper patient care in an outpatient setting.** • Well-defined SOPs should dictate adverse event management. • These should note specific criteria for when patients should be admitted or discharged from outpatient or inpatient care. • Team structure (explained below) and capacity should be clearly laid out in terms of 24/7 access to care and AE management.
Team structure	**Multidisciplinary team in place to safely manage patient care.** • There can be separate, dedicated rounding teams for cell-therapy patients for both inpatient and outpatient services, usually split by disease area. • Centers should ensure that multidisciplinary teams consisting of medical doctors (MDs), advanced practice providers (APPs), nursing staff, pharmacy staff, social workers and many more, are in place to support the staff when patients or caregivers call if any adverse event occurs.
Education	**Education is needed for patients receiving cilta-cel, caregivers, APPs, multidisciplinary teams, and other professionals who will encounter these patients, including community-based EMS and ED staff.** • Ensure that the caregiver(s) have adequate education and are prepared to notice adverse events. They should be seen as an extension of the care team. • BMT teams and cell therapy teams experienced in previously launched products can also support trainings on best practices when managing patients in an outpatient setting. • The education around delayed neurotoxicity will need to evolve to reflect real-world evidence as it becomes available.
Safety	**Being able to identify and predict toxicities before they happen is highly important when administering cilta-cel in an outpatient setting.** This requires proper patient follow-up and monitoring post-infusion: • Medical staff should routinely follow up with patients. • The center can consider using a remote patient monitoring system. • Patients can be monitored by their caregivers.
Reimbursement	**Centers have unique reimbursement qualifications, but outpatient reimbursement structure does not hinder outpatient administration.** • A dedicated team to keep track of Medicare coding changes is needed to avoid missing potential reimbursement or incentives. • Reimbursement pre-authorization should be sought for both inpatient and outpatient care, to avoid any complications if a transition to inpatient care is needed.

Figure 1

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