

EXPERIENCE REPORT OF THE FIRST CAR-T IN A CELLULAR PROCESSING CENTER IN THE NORTHEAST

Marília Silveira Maia¹; Felipe Pantoja Mesquita¹; Isabel Aline Fernandes Ferreira¹; Alexsandra Nunes Pinheiro¹; Sâmya Waleska Gomes Nunes¹; Natércia Maria Moura Bruno¹; Viviane Aguiar Ferreira Gomes¹; Vanessa Fernandes Paiva¹; Weide Barbosa de Mendonça¹; Luany Elvira Mesquita Carvalho¹; Luciana Maria de Barros Carlos¹; Karine Sampaio Nunes Barroso¹; Fernando Barroso Duarte¹

¹ Centro de Hematologia e Hemoterapia do estado do Ceará

INTRODUCTION:

Immunotherapy using T cells modified with a chimeric antigen receptor (CAR-T) has gained prominence in recent years for the treatment of onco-hematological neoplasms, as it offers curative potential for patients with relapsed or refractory disease. Through genetic engineering, T cells are reprogrammed to identify and destroy cancer cells that express specific targets such as CD19 or the B-cell maturation antigen (BCMA). Unfortunately, access to this treatment remains limited to a small number of patients worldwide. The main factors contributing to this limited access include the high cost and the slow incorporation of innovative therapies into various healthcare systems. The operational management of this therapy is a complex process involving multiple stages and multidisciplinary teams to ensure that treatment is safe, effective, and compliant with regulatory standards.

AIM: To report the experience of administering CAR-T manufactured by the pharmaceutical industry from the perspective of a Cell Processing Center (CPC) located in the Northeast region of Brazil.

METHODOLOGY:

A reflective description focused on the contextualization of a professional experience.

RESULTS:

In order to obtain certification from pharmaceutical companies and become a reference center for the use of this therapy, the apheresis unit, the CPC, and the Transplant Center (TC) underwent a rigorous process of audits, documentation adjustments, technical team

training, and equipment acquisition to meet industry requirements. The first certification was granted in April 2024, and the first delivery occurred in January 2025. Through a specific online portal, we monitored the entire process from medical prescription to real-time GPS-tracked transportation. The product arrived via São Paulo but required clearance by the local finance department, which delayed its arrival. It was transported in a dry shipper, and all procedures for identity verification, quality control, and transfer to a vapor-phase nitrogen freezer at -150 °C, as outlined in the pharmaceutical manual and internal technical guidelines, were completed and reported on the portal. The existing workflow for requesting cell therapy products was maintained. The infusion took place on February 1st, 2025, at the partner TC in a patient with Acute Lymphoblastic Leukemia. The CPC team prepared the product, in a dry shipper validated by our service. Transport and delivery to the TC occurred without incident. Temperature monitoring of the dry shipper, water bath, and environment was strictly performed according to protocol. Bedside thawing by the CPC nurse and infusion by the TC team were successful. The patient was later discharged and remains under follow-up.

CONCLUSION:

In this pioneering experience in our state, we combined study, commitment, and dedication to deliver high-quality work, contributing to the implementation of CAR-T therapy, an important milestone in healthcare in the Northeast.

KEYWORDS: Cell therapy; Chimeric Antigen Receptor; T lymphocytes.