
NCD for CAR T cell Therapy: Important Considerations

Excerpt from the NCD (Effective as of August 2019)¹

“CMS covers autologous treatment for cancer with T cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.”

Medicare Coverage Implications for Sites and Settings of Care²

Healthcare facilities administering CAR T cell therapy:

- Must be enrolled with the applicable manufacturer’s REMS program
- Can include inpatient/outpatient hospitals and outpatient clinics
- Are not required to be FACT accredited

For more details on the NCD, please visit:

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAAAA>

CAR T cell = chimeric antigen receptor T cell; CMS = Centers for Medicare and Medicaid Services; FACT = Foundation for the Accreditation of Cellular Therapy; FDA = Food and Drug Administration; NCD = national coverage determination; REMS = Risk Evaluation and Mitigation Strategy.

References:

1. CMS. NCD for Chimeric Antigen Receptor T cell Therapy (110.24). <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374&bc=CAAAAAAAAAAAAA>. Accessed May 2, 2022.
2. CMS. Decision memo for chimeric antigen receptor (CAR) T cell therapy for cancers (CAG-00451N). <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=291>. Accessed May 2, 2022.