

National Coverage Determination (NCD) Update

Benefit: Autologous treatment for cancer with chimeric antigen receptor T-cells

Effective Date: August 7, 2019

On August 7, 2019, the Centers for Medicare and Medicaid Services (CMS) announced its determination regarding:

- 1. The coverage for autologous treatment with T-cells for cancer, which have at least one chimeric antigen receptor (CAR) when:
 - a. It is administered in a healthcare facility enrolled in the Food and Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) program.
 - b. It is used for medically accepted indications, as defined in the Social Security Act, Section 1861 (t) (2).
 - c. It is used for other indications with an FDA-approved product whose use has been recognized by CMS-approved compendiums.
- 2. Maintaining coverage for routine study costs when chimeric antigen receptor therapy is used as an investigative agent in a clinical trial in accordance with the requirements in the national coverage determination established for this purpose.



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