



Chimeric Antigen Receptor T-Cell Therapy Claims: End of Risk Evaluation Mitigation Strategy & KX Modifier Requirement

Related CR Release Date: December 9, 2025	MLN Matters Number: MM14204
Effective Date: June 26, 2025	Related Change Request (CR) Number: CR 14204
Implementation Date: February 6, 2026	Related CR Transmittal Numbers: R13432CP & R13432CP1
Related CR Title: Removal of Chimeric Antigen Receptor (CAR) T-cell Therapy and Risk Evaluation Mitigation Strategy (REMS) – NCD 110.24 and the “KX” Modifier for CAR-T Cell Therapy Claims	

Affected Providers

- Hospitals
- Physicians
- Other providers billing Medicare Administrative Contractors (MACs) for chimeric antigen receptor (CAR) T-cell therapy services

Action Needed

As of June 26, 2025, we no longer require:

- Providers to administer CAR T-cell therapy in an FDA Risk Evaluation Mitigation Strategy (REMS)-approved facility
- The KX modifier on Medicare Part B claims for CAR T-cell therapy

Background

On August 7, 2019, CMS started covering CAR T-cell therapy through [National Coverage Determination 110.24](#). Among other criteria, we required you to administer CAR T-cell therapy at a health care facility enrolled in the FDA REMS. For many years, REMS was part of the FDA-approved indications for these therapies. We also required the use of the KX modifier on claims to acknowledge that you performed the service in an FDA REMS-participating facility.

On June 26, 2025, FDA [announced](#) the elimination of REMS and updated product labeling for CAR T-cell therapies.

Key Updates

For claims with dates of service on or after June 26, 2025, we no longer require you to perform CAR T-cell therapy services in an FDA REMS-approved facility, and you don't need to include the KX modifier on Part B claims. We updated the [Medicare Claims Processing Manual, Chapter 32](#), section 400 with these changes.

Note: Your MAC won't search their files for CAR T-cell claims; however, they'll adjust any claims that you bring to their attention.

More Information

We issued CR 14204 to your MAC as the official instruction for this change. For more information, find your [MAC's website](#).

Document History

Date of Change	Description
December 12, 2025	Initial article released.

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