



National Coverage Determination 110.24: Chimeric Antigen Receptor T-cell Therapy

MLN Matters Number: MM12928 **Revised**

Related Change Request (CR) Number: 12928

Related CR Release Date: **December 30, 2022**

Effective Date: January 1, 2022

Related CR Transmittal Number: **R11774CP**

Implementation Date: January 31, 2023

Related CR Title: National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy

What's Changed: We revised the Article to clarify that providers shouldn't bill more than 1 unit per HCPCS code as we show in dark red on page 1.

Provider Types Affected

This MLN Matters Article is for physicians, other providers, and suppliers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

Provider Action Needed

Make sure your billing staff knows about these changes for CAR T-cell Therapy (CAR-T) billing:

- Include additional place of service (POS) codes for office and independent clinics
- Bill in 0.1-unit fractions
- **Don't bill more than 1 unit per HCPCS code**
- Use 3 modifiers, including new modifier -LU

Background

The implementing [CR 12177](#) didn't allow for processing CAR-T claims in the Part B physician office and independent clinics. In that CR, CMS only allowed CAR-T claims in Part A inpatient and hospital-affiliated POS that were Risk Evaluation and Mitigation Strategies (REMS)-approved. [CR 12928](#) allows POS codes 11 (Office) and 49 (Independent Clinic) on CAR-T claims as long as they are REMS-approved.

Additionally, we can't process CAR-T related HCPCS codes in the current Multi-Carrier System (MCS) system because the field length for the dollar amount in MCS is only 7 digits (line item or total maximum is 99999.99). CAR-T products need to bill as 1 unit with a dollar amount of 8 digits (999999.99). This isn't a problem when a single HCPCS code can be billed for multiple units or when a Part B provider is billing multiple HCPCS codes. The issue arises when, based

on the code description, you bill CAR-T products as a single unit of 1 therapeutic dose. For example, Q2041 = 1 unit = \$448,316.40.

To bill CAR-T claims correctly in the Part B setting, divide the CAR-T HCPCS codes by 10 and bill in 0.1-unit fractions. Bill a total of 10 fractional units to reach the total Medicare allowed payment amount. Depending on the Medicare allowed payment for the CAR-T HCPCS code, some providers may submit 5 separate claims for 0.2 units on each claim.

To attest that you're a REMS-approved facility, you must use 3 modifiers:

- Modifier -LU: Fractionalized payment CAR T-cell therapy
- Modifier -76: Repeat procedure or service by same physician or other qualified healthcare professional
- Modifier -KX: Requirements specified in the medical policy have been met

New HCPCS modifier -LU is in the January 2023 HCPCS Update and is effective retroactively for use on claims with dates of service on or after January 1, 2022. As we add more codes for current and future FDA-approved CAR T-cell therapies, we'll update [CMS HCPCS](#) accordingly.

Note: Part A Outpatient Prospective Payment System providers don't need to change their billing. They'll continue to bill 1 unit for the CAR T-cell products themselves.

The use of non-FDA-approved autologous T-cells with at least 1 CAR continues to be non-covered. Autologous treatment for cancer with T-cells expressing at least 1 CAR is also non-covered when the NCD criteria aren't met. We'll cover routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet requirements in [NCD 310.1](#) effective August 7, 2019.

We remind you that the use of allogenic T-cells from healthy donors aren't autologous CAR T-cell treatments and you shouldn't bill those as autologous CAR-T treatments.

See the following websites for specific REMS facility information:

- [Kymriah®](#)
- [Yescarta®](#)
- [Tecartus™](#)
- [Breyanzi®](#)
- [ABECMA®](#)
- [CARVYKTI™](#)

For complete billing details, see the revised Chapter 32, Section 400.2 of the [Medicare Claims Processing Manual](#), which is part of CR 12928.

More Information

We issued CR 12928 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
January 5, 2023	We revised the Article to clarify that providers shouldn't bill more than 1 unit per HCPCS code as we show in dark red on page 1.
December 1, 2022	Initial article released.

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