



Guideline	Chimeric Antigen Receptor T Cell (CAR-T) Therapy	Guideline #	UM OTH 21
		Original Effective Date	5/13/2020
Section	Other	Revised Date	4/24/2023

COVERAGE POLICY

Kymriah (tisagenlecleucel), **Yescarta** (axicabtagene ciloleucel), **Tecartus** (brexucabtagene autoleucel), **Breyanzi** (lisocabtagene maraleucel), **Abecma** (idecabtagene vicleucel), **Carvykti** (ciltacabtagene autoleucel)

Coverage criteria:

- A. All FDA-approved indications
- B. Treatment supported by National Comprehensive Cancer Network guidelines, e.g. confirmed genetic testing, prior therapy
- C. Treatment consistent with use as described by drug labeling, e.g. black box warnings, contraindications, precautions in specific populations, dosing and administration
- D. No major medical conditions that may preclude use, e.g. inadequate organ and bone marrow function at time of treatment
- E. No prior treatment with CD19-directed CAR-T cell therapy or is being considered for treatment with any other gene therapy
- F. Will be dispensed and administered at a Risk Evaluation and Mitigation Strategy (REMS) certified facility
- G. ONE (1) single-dose of CD-19-direct CAR-T cell therapy is approved per lifetime

DEFINITION OF TERMS

- A. Relapsed disease – Reappearance of leukemia cells in the bone marrow or peripheral blood after the attainment of a complete remission with chemotherapy and/or allogeneic cell transplant
- B. Refractory (resistant) disease - Failure to obtain complete response with induction therapy, i.e., failure to eradicate all detectable leukemia cells (<5% blasts) from the bone marrow and blood with subsequent restoration of normal hematopoiesis (>25% marrow cellularity and normal peripheral blood counts)
- C. Risk Evaluation and Mitigation Strategies (REMS) – Drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risk



ADDITIONAL INFORMATION

1. Kymriah-<https://www.us.kymriah.com>
2. Yescarta-<https://www.yescarta.com>
3. Tecartus-<https://www.tecartus.com>
4. Breyanzi-<https://www.breyanzi.com>
5. Abecma-<https://www.abecma.com>
6. Carvykti-<https://www.carvykti.com>

REFERENCES

1. California Department of Health Services. Medi-Cal Provider Manual: Chemotherapy. Accessed March 29, 2023.
2. The Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: CHIMERIC Antigen Receptor (CAR) T-cell access (NCD 110.24). Accessed March 29, 2023.

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