Guideline	Chimeric Antigen Receptor T Cell (CAR-T) Therapy	**Guideline #**	UM_OTH 21
		Original Effective Date	5/13/2020
Section	Other	**Revised Date**	4/26/2022

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 April 12, 2022.
2. The Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: CHIMERIC Antigen Receptor (CAR) T-cell access (NCD 110.24). Accessed April 12, 2022.

DISCLAIMER

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental, and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, view of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.