Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Kymriah® (tisagenlecleucel)

Effective: September 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ Tufts Health One Care -- A dual-eligible product; Fax 617-673-0956

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Chimeric antigen receptor T-cell therapy (CAR T-cell therapy), a type of immunotherapy which may also be referred to as adoptive T-cell therapy, attempts to program patients' own immune systems to recognize and attack cancer cells. The first step in this therapy is to remove T-cells from the patient via apheresis, a process that removes blood from the body and removes one or more blood components (such as white blood cells, plasma, or platelets). The remaining blood is then returned to the body. The T-cells are then sent to a drug manufacturing facility or laboratory where they are genetically engineered to produce chimeric antigen receptors (CARs) on their surface. These CARs are what allow the T-cells to recognize an antigen on targeted tumor cells. The genetically modified T-cells are grown in the lab until there are enough of them (many millions) to freeze and return to the center treating the patient. There they are infused into the recipient with the expectation that the CAR T-cells will recognize and kill cancerous cells that have the targeted antigen on their surface. Since the CAR T-cells may remain in the body long after the infusion, it is possible the treatment can bring about long-term remission. CAR T-cell therapy can be used to treat certain hematologic malignancies when the disease is relapsed or refractory to standard line(s) of treatment.

Food and Drug Administration (FDA) Approved Indications:

Kymriah (tisagenlecleucel) is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of:

- Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.
- Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.
- Limitations of Use: KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma.
- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication

is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

- **NOTE**: According to recent updated guidance from the FDA, the REMS Program requirement is no longer required.[1]
- **NOTE**: Tocilizumab must be available to treat potential serious adverse reactions as needed.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members, and Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations where available. For the Plan's members, the following criteria is used: Chimeric Antigen Receptor (CAR) T- cell Therapy NCD 110.24

Clinical Guideline Coverage Criteria

The Plan may cover Kymriah for Members, when **all** the following clinical criteria are met:

1. The Member meets ONE (1) of the following criteria:
    a. The Member is 25 years of age or younger and has been diagnosed with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory* or in second or later relapse*.

    OR

    b. The Member is 18 years of age or older and has been diagnosed with one of the following:
        i. Relapsed or refractory* (r/r) large B-cell lymphoma after two (2) or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

        OR

        ii. Relapsed* or refractory* follicular lymphoma (FL) after two or more lines of systemic therapy.

*Relapsed/Refractory defined as disease progression after the last treatment regimen or refractory/ suboptimal response to the most recent therapy.

NOTE: Documentation submitted must list previous lines of treatment/systemic therapies and date of each therapy.

In addition to the above criteria, the Plan may cover Kymriah in an outpatient setting when the provider attests that they have assessed the Member and determined that outpatient administration is clinically appropriate.

NOTE: Prior authorization for Kymriah is required regardless of hospital inpatient or outpatient setting.

Limitations

- Authorization for Kymriah is limited to a one-time infusion.
- Members who have had prior treatment with any form of CAR T-cell therapy, including therapies in clinical trial settings, will not be approved for additional CAR-T therapy.
- All other indications other than those listed above are considered experimental/investigational and not medically necessary.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
Q2042	Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Table 2: CPT Codes

CPT Codes	Description
	none

References:

1. FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor (CAR) T cell Immunotherapies. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor. Published June 26, 2025. Accessed June 26, 2025.
2. Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2020.
3. Center for Medicare and Medicaid National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy. https://www.cms.gov/medicare-coverage-database/ .
4. United States Food and Drug Administration. Package Insert-KYMRIAH. Available at fda.gov. https://www.fda.gov/media/107296/download.
5. Leukemia & Lymphoma Society. Chimeric Antigen Receptor (CAR) T-Cell Therapy Facts. Available at lls.org. Last accessed October 20, 2017.
6. Hansen, D. K., Liu, Y. H., Ranjan, S., Bhandari, H., Potluri, R., McFarland, L., De Braganca, K. C., & Huo, S. (2023). The Impact of Outpatient versus Inpatient Administration of CAR-T Therapies on Clinical, Economic, and Humanistic Outcomes in Patients with Hematological Cancer: A Systematic Literature Review. Cancers, 15(24), 5746. https://doi.org/10.3390/cancers15245746
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11. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic (Version 1.2026). August 11, 2025. https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed May 5, 2026.
12. Treatment of relapsed or refractory acute lymphoblastic leukemia in adults. UpToDate.com/login [via subscription only]. Published March 3, 2025. Updated April 1, 2026. Accessed May 6, 2026
13. Relapsed or refractory acute lymphoblastic leukemia/lymphoblastic lymphoma in children and adolescents. .com/login [via subscription only]. Published August 22, 2025. Updated April 1, 2026. Accessed May 6, 2026
14. Ludwig H, et. al. Prevention and management of adverse events during treatment with bispecific antibodies and CAR T cells in multiple myeloma: a consensus report of the European Myeloma Network. Lancet Oncol. 2023 Jun;24(6):e255-e269. doi: 10.1016/S1470-2045(23)00159-6. PMID: 37269857.
15. Rampotas A, Roddie C. The present and future of CAR T-cell therapy for adult B-cell ALL. Blood. 2025 Apr 3;145(14):1485-1497. doi: 10.1182/blood.2023022922. PMID: 39316713.
16. John S, et. al.. Real-world data for tisagenlecleucel in patients with R/R B-ALL: subgroup analyses from the CIBMTR registry. Blood Adv. 2025 Oct 28;9(20):5249-5262. doi: 10.1182/bloodadvances.2025015881. PMID: 40554426; PMCID: PMC12552949.
17. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 1.2026). April 8, 2026. Available at: nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed May 5, 2026.

Approval And Revision History

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- Originally approved at September 21, 2022 MPAC effective January 1, 2023
- Administrative update: November 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939, changed Unify name to One Care, and clarified NCD language effective January 1, 2024
- November 16, 2023: Reviewed by MPAC, renewed without changes effective January 1, 2024
- January 17, 2024: Reviewed by MPAC, added criteria for allow for outpatient administration and updated references effective March 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes. Effective January 1, 2025.
- December 13, 2024: Reviewed by UM Committee; Coding updated: Removal of prior authorization from 0537T, 0538T, 0539T, and 0540T. Effective January 1, 2025.
- December 18, 2024: Reviewed by MPAC; Coding updated: Removal of prior authorization from 0537T, 0538T, 0539T, and 0540T. Effective January 1, 2025.

- June 18, 2025: Reviewed by MPAC. Annual review.
- July 16, 2025: Reviewed by MPAC. REMS language removed from both Overview and Criteria sections. Two notes were added in the Overview section. References updated. Effective date September 1, 2025.
- July 15, 2026: Reviewed by MPAC. Annual Review. References updated. Effective September 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment, or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.