Mass General Brigham
Health Plan

Kymriah
(tisagenlecleucel)

Policy Number: 032

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X	X	X
No Prior Authorization			

Kymriah is a chimeric antigen receptor T cell therapy (CAR-T), designed to redirect the patient's immune system to recognize and attack their cancer cells. CAR-T is a type of treatment where white blood cells (T cells) are modified in a laboratory to add a gene that helps the patient's own T cells target their cancer.

FDA-Approved Indication
Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Members ("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 members with relapsed or refractory 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.
- Adult members with follicular lymphoma (FL).
- Kymriah is not indicated for the treatment of members with central nervous system lymphoma.

Criteria for Initial Approval
B-cell Precursor Acute Lymphoblastic Leukemia (ALL)

1. Patient Criteria
   Authorization of a single treatment may be granted to members less than 26 years of age for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse when **ALL** of the following criteria are met:
   A. One of the following.
      i. The member has Philadelphia chromosome positive ALL and has failed two tyrosine kinase inhibitors; **OR**
      ii. The member has Philadelphia chromosome negative ALL
   B. The patient has stable and adequate kidney, liver, pulmonary, and cardiac function as determined by the treating oncologist or hematologist.
   C. The member has not received any prior FDA approved CD19-directed therapy (e.g., Tecartus, Kymriah or Yescarta)[1].

2. Facility Criteria
   A. The healthcare facility that dispenses and administers Kymriah must be enrolled and comply with the Risk Revaluation and Mitigation Strategy known as Kymriah REMS.

[1] Exceptions for non-FDA approved CD19 therapies will be reviewed on an individual case by case basis. A detailed medical review will be required.

B. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.
C. Kymriah is prescribed by a hematologist or oncologist with demonstrated expertise in CAR-T Therapy.

Large B-cell Lymphomas or follicular lymphoma (FL)

1. Patient Criteria

   Authorization of a single treatment may be granted to members 18 years of age or older for treatment of Large B-cell lymphomas (DLBCL not otherwise specified, high grade B-cell lymphoma, or DLBCL arising from FL) or FL when **ALL** of the following criteria are met:

   A. The disease is refractory or relapsed after two or more lines of systemic therapy.
   B. The member has not received any prior FDA approved CD19-directed therapy (e.g., Kymriah or Yescarta)[2].
   C. The member does not have primary central nervous system lymphoma.

2. Facility Criteria

   A. The healthcare facility that dispenses and administers Kymriah must be enrolled and comply with the Kymriah Risk Evaluation and Mitigation Strategy known as REMS.
   B. The healthcare facility must have tocilizumab available on site for management of Cytokine Release Syndrome.
   C. Kymriah is prescribed by a hematologist or oncologist with demonstrated expertise in CAR-T Therapy.

Required Documentation

- Testing or analysis confirming CD19 protein on the surface of the B-cell.
- Documentation of refractory disease or prior lines of therapy for ALL.
- Documentation of 2 prior lines of therapy for DLBCL.

Duration of Therapy

- Single treatment course.
- Additional courses of therapy are considered experimental/investigational.

MassHealth Variation

Mass General Brigham Health Plan uses the MassHealth Drug List for coverage determinations for members of the MGB ACO. Criteria for Kymriah are found in Table 75: T-Cell Immunotherapies.

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare has an NCD for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24).**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

[2] Exceptions for non-FDA approved CD19 therapies will be reviewed on an individual case by case basis. A detailed medical review will be required.

This list of codes applies to commercial and MassHealth plans only.

Authorized CPT/HCPCS Codes	Code Description
38225	Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day
38226	Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)
38227	Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration
38228	Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Effective
February 2025: Annual review. Codes updated.
September 2024: Ad hoc update. Added MassHealth variation.
February 2024: Annual review. Added indication for follicular lymphoma. Removed requirement for CD19 testing.
February 2023: Annual review. Added Medicare Advantage to table. Under Criteria, the following changes were made to align with revised MassHealth guidelines: Changed age to 26, added Philadelphia chromosome language, and added the patient must have stable and adequate kidney, liver, pulmonary, and cardiac function. Medicare Variation language added.
February 2022: Annual review. References updated.
March 2021: Annual review. Footnotes added. Formatting changes to delineate criteria for Patient and Facility. References updated.
February 2020: Annual review. Policy Criteria clarified; removed “within 3 months”. References updated.
February 2019: Annual review. Added introduction paragraph. Revised language under FDA-Approved indication section. Added DLBCL criteria. Added language under required documentation.
February 2018: Effective Date.

References
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MassHealth Drug List. Medication Class/Individual Agents. Table 75: Chimeric Antigen Receptor (CAR)-T Immunotherapies. Prior-Authorization Requirements. Axicabtagene Ciloleucel/Yescarta. Tisagenlecleucel/Kymriah. Execute Office of Health and Human Services (EOHHS). 2020 Jun 29. Accessed at: https://masshealthdruglist.ehs.state.ma.us/MHDL/pubtheradetail.do?id=353

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