Mass General Brigham
Health Plan

Yescarta
(axicabtagene ciloleucel)

Policy Number: 059

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

Yescarta 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
Yescarta is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of:

- Adults with relapsed or refractory indolent non-Hodgkin lymphoma including:
  - Follicular lymphoma (FL); and
  - Marginal zone lymphoma (MZL)
- Adults with relapsed or refractory large B-cell lymphoma including:
  - Diffuse large B-cell lymphoma (DLBCL) not otherwise specified;
  - Primary mediastinal large B-cell lymphoma;
  - High grade B-cell lymphoma; and
  - DLBCL arising from follicular lymphoma
- Yescarta is not indicated for the therapy of primary central nervous system lymphoma.

Criteria for Initial Approval

1. Patient Criteria

Authorization of a single treatment may be granted to members 18 years of age or older for treatment of FL, MZL, DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma when either A or B as seen below are met:

A. The disease is refractory to treatment or relapsed after two or more lines of systemic therapy; AND
   i. The member has not received any prior FDA approved CD19-directed therapy (e.g. Tecartus, Yescarta, or Kymriah)[1]; and
   ii. The member does not have primary central nervous system lymphoma; OR
B. The member has been diagnosed with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy; and
   i. The member has not received any prior FDA approved CD19-directed therapy (e.g. Tecartus, Yescarta, or Kymriah)[2] ; and
   ii. The member does not have primary central nervous system lymphoma.

[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.
[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.

2. Facility Criteria
    A. The healthcare facility that dispenses and administers Yescarta must be enrolled and comply with the Yescarta 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. Yescarta is prescribed by a hematologist or oncologist with demonstrated expertise in CAR-T Therapy

3. Required Documentation
    - Documentation of prior treatment to support the requirements as mentioned above in Patient Criteria section.

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

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.

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

Authorized CPT/HCPCS Codes	Code Description
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Effective

February 2024: Annual review. Indolent non-Hodgkin lymphomas added to list of indications. Removed requirement for CD19 testing.
February 2023: Annual review. Added Medicare Advantage to table. Medicare variation language added. References updated.
November 2022: Off-cycle review, to include newly added indication; adult patients with large B-cell lymphoma that is refractory to first line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
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 three months". References updated.
February 2019: Annual Review. Added introductory paragraph. Edits made to FDA-Approved indication section. Revised criteria and documentation sections.

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). 2022. Dec 12.

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