Yescarta
(axicabtagene ciloleucel)

Document Number: 049

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

FDA-Approved Indication

Yescarta is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of adult patients 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;
- primary mediastinal large B-cell lymphoma;
- high grade B-cell lymphoma; and
- DLBCL arising from follicular lymphoma

Criteria

1. Criteria for Initial Approval

Authorization of a single treatment within 3 months may be granted to patients 18 years of age or older for treatment of **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) when ALL of the following criteria are met:

A. The disease is relapsed or refractory to treatment after two or more lines of systemic therapy
B. The patient has not received a previous treatment course of Yescarta;
C. The patient does not have primary central nervous system lymphoma;
D. The B-cells must be CD19-positive as confirmed by testing or analysis;
E. The healthcare facility that dispenses and administers Yescarta must be enrolled and comply with the Risk Revaluation and Mitigation Strategy known as REMS

2. Required Documentation
   - Testing or analysis confirming CD19 protein on the surface of the B-cell.

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

Effective

February 2018: Effective Date.

References

Yescarta [package insert]. Santa Monica, CA: Kite Pharma; October 2017.