Kymriah (tisagenlecleucel)

Document Number: 045

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

FDA-Approved Indication

- Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy. It involves reprogramming a patient's own T cells with a with a transgene encoding a chimeric antigen receptor (CAR), to identify and eliminate CD19-expressing malignant and normal cells.
- Kymriah is 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. All other indications are considered experimental/investigational.

Criteria

1. Criteria for Initial Approval
   Acute lymphoblastic leukemia
   Authorization of a single treatment within 3 months may be granted to patients less than 25 years of age for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) when **all** of the following criteria are met:
   A. The disease is refractory to treatment or in second or later relapse;
   B. The B-cells must be CD19-positive as confirmed by testing or analysis;
   C. The patient has not received prior treatment with Kymriah or any other gene therapy;
   D. The healthcare facility that dispenses and administers Kymriah must be enrolled and comply with the Risk Revaluation and Mitigation Strategy known as Kymriah 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

Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2017.