

SPECIALTY GUIDELINE MANAGEMENT

KYMRIAH (tisagenlecleucel)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication¹

A. **Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL)** Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse.

B. **Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma**

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.

Limitation of Use: Kymriah is not indicated for treatment of patients with primary central nervous system lymphoma.

All other indications are considered experimental/investigational and are not a covered benefit.

II. REQUIRED DOCUMENTATION

Testing or analysis confirming CD19 protein on the surface of the B-cell

III. CRITERIA FOR INITIAL APPROVAL

A. **Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL)¹**

Authorization of 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:

1. The disease is refractory to treatment or in second or later relapse
2. The B-cells must be CD19-positive as confirmed by testing or analysis

B. **Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma¹**

Authorization of 3 months may be granted to patients 18 years of age or older with relapsed or refractory large B-cell lymphoma (including DLBCL not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma) when all of the following criteria are met:

1. The disease is refractory to treatment or relapsed after two or more lines of systemic therapy
2. The patient does not have primary central nervous system lymphoma
3. The B-cells must be CD19-positive as confirmed by testing or analysis

Kymriah SGM P2017a

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IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.