Reference number(s)
2294-A

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 Indication[1]

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 documentation confirms all of the following criteria are met:
1. The disease is refractory to treatment or in second or later relapse
2. The member has not received a previous treatment course of Kymriah.
3. The B-cells must be CD19-positive as confirmed by testing or analysis

B. **Adult Relapsed or Refractory (r/r) Large B-cell Lymphoma[1]**
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 documentation confirms 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 member has not received a previous treatment course of Kymriah.
4. The B-cells must be CD19-positive as confirmed by testing or analysis

IV. REFERENCES

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