Reference number(s)
3061-A

STANDARD MEDICARE PART B 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.

A. FDA-Approved Indications

1. 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.

2. Adult Relapsed or Refractory (r/r) Diffuse 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 (NOS), 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.

B. Compendial Uses

1. Pediatric B-cell ALL first relapse post hematopoietic stem cell transplant (HSCT)
2. Diffuse large B-cell lymphoma
3. Primary mediastinal large B-cell lymphoma
4. Histologic transformation of nodal marginal zone lymphoma to DLBCL
5. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
6. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for members less than 18 years of age with B-cell lymphomas or members 26 years of age or older with B-cell precursor acute lymphoblastic leukemia.

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Pediatric and Young Adult Relapsed or Refractory (r/r) B-cell Acute Lymphoblastic Leukemia (ALL)
Authorization of 3 months may be granted for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) in members less than 26 years of age when all of the following criteria are met:

1. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
2. The B-cells must be CD19-positive as confirmed by testing or analysis
3. Member meets either of the following:
   i. Member has relapsed/refractory Philadelphia chromosome-negative disease
   ii. Member has relapsed/refractory Philadelphia chromosome-positive disease and meets any of the following:
      a. Member had an inadequate response to two tyrosine kinase inhibitors (TKIs) (e.g., bosutinib, dasatinib, imatinib, nilotinib, ponatinib) or had an intolerance to a TKI.
      b. Member has experienced a first relapse post-hematopoietic stem cell transplant (HSCT)

B. Adult B-cell Lymphomas
Authorization of 3 months may be granted as subsequent treatment of B-cell lymphomas in members 18 years of age or older when all of the following criteria are met:

1. Member has any of the following B-cell lymphoma subtypes, and has received prior treatment with two or more chemoimmunotherapy regimens (including at least one anthracycline or anthracenedione-based regimen, unless contraindicated)
   i. Diffuse large B-cell lymphoma (DLBCL) arising from follicular lymphoma (also known as histologic transformation of follicular lymphoma to DLBCL)
   ii. Histologic transformation of nodal marginal zone lymphoma to DLBCL
2. Member has any of the following B-cell lymphoma subtypes
   i. Diffuse large B-cell lymphoma (DLBCL)
   ii. Primary mediastinal large B-cell lymphoma
   iii. High-grade B-cell lymphoma (high-grade B-cell lymphoma with translocations of MYC and BCL2 and/or BCL6 [double/triple hit lymphoma], high-grade B-cell lymphoma, not otherwise specified)
   iv. Acquired immunodeficiency syndrome (AIDS)-related B-cell lymphomas (including AIDS-related diffuse large B-cell lymphoma, primary effusion lymphoma, and human herpesvirus 8 (HHV8)-positive diffuse large B-cell lymphoma, not otherwise specific)
   v. Monomorphic post-transplant lymphoproliferative disorder (B-cell type)
3. The member does not have primary central nervous system lymphoma.
4. The member has not received a previous treatment course of the requested medication or another CD19-directed chimeric antigen receptor (CAR) T-cell therapy.
5. The B-cells must be CD19-positive as confirmed by testing or analysis

V. REFERENCES

1. Kymriah [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 06, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 1.2020).© 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 30, 2020.
4. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas (Version 1.2020).© 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 06, 2020.