Executive Office of Health & Human Services

Medicaid Fee for Service (FFS)

Coverage Guidelines for Modified T-Cell Therapies

November 28, 2018

General:

There are currently two FDA approved CAR-T cell therapy products, KYMRIAH® (tisagenlecleucel) and YESCARTA™ (axicabtagene ciloleucel).

Coverage requirements for KYMRIAH™:

1. The member is age 25 years or younger; and
    a. Has been diagnosed with CD19 positive B-cell precursor acute lymphoblastic leukemia (ALL); and
    b. Has failed at least two lines of treatment; or
2. The member is age 25 years or younger ; and
    a. Has been diagnosed with B-cell precursor acute lymphoblastic leukemia (ALL); and
    b. Is experiencing a second or later relapse after a minimum of two lines of treatment; or
3. The member is 18 years of age or older; and
    a. Has been diagnosed with CD-19 positive large B-cell lymphoma ; and
    b. Has failed at least two lines of systemic therapy; and
    c. Is experiencing a biopsy proven relapse after a minimum of two lines of systemic therapy;
4. AND, all of the following are met:
    a. The member has not previously had gene therapy
    b. The member does not have primary central nervous system (CNS) lymphoma
    c. The member has adequate bone marrow, cardiac, pulmonary and other organ function to tolerate the procedure
    d. If member has a history of allogeneic stem cell transplantation, there is no evidence of graft vs host disease
    e. The treating facility is certified under the KYMRIAH® Risk Evaluation and mitigation Strategy (REMS) System program.

Coverage requirements for YESCARTA™:

1. Member is age 18 or over and ONE of the following is met;
    a. Diagnosis of CD19-positive large cell lymphoma, including diffuse large cell lymphoma and has failed at least two lines of therapy; or
    b. Biopsy proven evidence of relapse of B-cell lymphoma after treatment with at least two lines of therapy; and
2. ALL of the following;
    a. No prior therapy with Yescarta™ or other gene therapy

b. No evidence of primary central nervous system lymphoma
c. Adequate bone marrow, cardiac, pulmonary and other organ function
d. If prior allogeneic stem cell transplantation, no indication of graft vs host disease
e. Treating facility must be certifies under the YESCARTA™ Risk Evaluation and Mitigation Strategy (REMS) System program.

Limitations:

1. Pregnancy
2. Member is receiving immunosuppressive therapy for an autoimmune disorder
3. Untreated underlying immune disorder
4. Additional active or metastatic malignancy outside scope of this policy
5. History of prior CAR-T therapy