Medical Necessity Guideline

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<th>Medical Necessity Guideline Title: Modified T-Cell Therapy</th>
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<td>MNG #: 01</td>
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<td>Clinical: ☒</td>
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<td>Medicare Benefit: ☐</td>
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<td>Last Revised Date: 1/25/2019;</td>
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OVERVIEW:
The purpose of this Medical Necessity Guideline (MNG) is to describe the current FDA- approved CAR-T cell therapy products, KYMRIAH™ and YESCARTA™. The guidelines for each are outlined below.

DECISION GUIDELINES:
Clinical Eligibility:

1. **KYMRIAH™**

   Commonwealth Care Alliance may authorize coverage of KYMRIAH™ (tisagenlecleucel) when ONE of the following is met:

   a. The Member is age 25 years of age or younger, has been diagnosed with CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL), and has failed a minimum of two lines of treatment;

   b. The Member is age 25 years of age or younger, has been diagnosed with B-cell precursor acute lymphoblastic leukemia (ALL), and is experiencing a second or later relapse\(^1\) after a minimum of two lines of treatment;

   c. The Member is age 18 years of age or older, has been diagnosed with CD19-positive large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma, and has failed a minimum of two lines of systemic therapy;

   d. The Member is age 18 years of age or older, has been diagnosed with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma, and is experiencing a biopsy proven relapse\(^2\) after treatment with a minimum of two lines of systemic therapy;

   AND ALL of the following are met:

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\(^1\) Relapse in the context of ALL is defined as the reappearance of leukemic lymphoblasts in peripheral blood or bone marrow after there has been achievement of complete remission with other lines of treatment.

\(^2\) Relapse in the context of DLBCL is defined as **biopsy proven** return of DLBCL disease after achievement of complete remission with other lines of treatment.
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1. The Member has had no prior treatment with tisagenlecleucel or other gene therapy
2. The Member does not have primary central nervous system (CNS) lymphoma
3. The Member has adequate bone marrow, cardiac, pulmonary and organ function
4. There is no active infection, including active hepatitis B or C
5. For Members with a history of allogeneic stem cell transplantation, there is no indication of graft vs host disease
6. The treating facility is certified under the KYMRIA™ Risk Evaluation and Mitigation Strategy (REMS) System program. More information is available at https://www.us.kymriah.com/treatment-center-locator/

2. YESCARTA™

Commonwealth Care Alliance may authorize coverage of YESCARTA™ (axicabtagene ciloleucel) for the treatment of members age 18 and over when ONE of the following is met:

a. The Member has been diagnosed with CD19-positive large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma, and has failed a minimum of two lines of systemic therapy.

b. The Member has been diagnosed with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma, and is experiencing a biopsy proven relapse\(^3\) after treatment with a minimum of two lines of systemic therapy,

AND ALL of the following are met:

1. The Member has had no prior treatment with axicabtagene ciloleucel or other gene therapy.
2. The Member does not have primary central nervous system (CNS) lymphoma.
3. The Member has adequate bone marrow, cardiac, pulmonary and organ function.
4. For Members with a history of allogeneic stem cell transplantation, there is no indication of graft vs host disease.
5. There is no active infection, including active hepatitis B or C
6. The treating facility is certified under the YESCARTA™ Risk Evaluation and Mitigation Strategy (REMS) System program. More information is available at https://yescarta.com/authorized-treatment-centers/

LIMITATIONS/EXCLUSIONS:

- CAR-T cell therapy is contraindicated in pregnancy.

\(^3\) Relapse in the context of DLBCL is defined as biopsy proven return of DLBCL disease after achievement of complete remission with other lines of treatment.
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- Members receiving immunosuppressive therapy for an autoimmune disorder will not be approved for CAR-T cell therapy.
- Members with untreated underlying primary immunodeficiency syndromes will not be approved for CAR-T cell therapy.
- Members with active and/or metastatic malignancy that is unlikely to respond to treatment will not be approved for CAR-T therapy.
- Members who have had prior treatment with any form of CAR-T cell therapy will not be approved for additional CAR-T therapy.

KEY CARE PLANNING CONSIDERATIONS:
Any indications for CAR-T cell therapy other than those outlined above are considered investigational and will not be covered.

AUTHORIZATION:
N/A

REGULATORY NOTES:
N/A

RELATED REFERENCES:

ATTACHMENTS:

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