Chimeric Antigen Receptor (CAR) T-cell Therapy

MPM 32.0

Disclaimer

Refer to the member’s specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.

Description

Prior Authorization is required. Benefit Certification Guide to determine when a prior authorization/benefit certification is required

https://ds.phs.org/preslogin/index.jsp

Chimeric antigen receptor (CAR) T cells and genetically engineered T-cell receptor (TCR) T cells are manufactured by collecting lymphocytes from a patient donor and modifying them ex vivo through gene transfer techniques. Viral vectors are introduced that express cell receptors that are highly specific for the individual’s tumor antigens. CAR T cells, express a hybrid receptor with an extracellular single-chain antibody fragment, a transmembrane domain, and at least 1 intracellular signaling domain. CAR T and TCR T cells are then infused back into a patient’s body, where they direct a targeted immune response to cancerous tissue. CAR T cells are most often used to treat hematological malignancies, and a common target is B-cell cluster of differentiation antigen19 (CD19).

Coverage Determinations

I. Chimeric Antigen Receptor (CAR) T-cell Therapy for Diffuse large B-cell lymphoma (DLBCL):

A. CAR T-cell therapy using Yescarta (axicabtagene ciloleucel) for Diffuse Large B-Cell Lymphoma (DLBCL):

1. Yescarta is indicated for treatment of adults patients with relapsed, or refractory large B-cell Lymphoma after two or more lines systemic therapy, including DLBCL, NOS; primary mediastinal large B-cell Lymphoma; high grade B-cell lymphoma; and DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma

2. Health care facilities that dispense and administer axicabtagene ciloleucel must be enrolled and comply with the Risk Evaluation and Mitigation Strategies (REMs) requirements. See REMS for tisagenlecleucel.
3. **Exclusion:** Chimeric Antigen Receptor (CAR) T-cell therapy, for all other indications is considered experimental, investigational and/or unproven.

B. CAR T-cell therapy using **Kymriah** TM (tisagenlecleucel) for Diffuse Large B-Cell Lymphoma:

1. Kymriah is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including Diffuse Large B-Cell Lymphoma (DLBCL), NOS and high grade B-cell Lymphoma and DLBCL arising from follicular lymphoma.

2. Health care facilities that dispense and administer Kymriah must be enrolled and comply with the Risk Evaluation and Mitigation Strategies (REMS) requirements. See **REMS for Tisagenlecleucel**.

3. **Exclusion:** Chimeric Antigen Receptor (CAR) T-cell therapy, for all other indications is considered experimental, investigational and/or unproven.

II. **Chimeric Antigen Receptor (CAR) T-cell Therapy for Acute Lymphoblastic Leukemia (ALL):**

A. CAR-T cell therapy using **Kymriah** (tisagenlecleucel) for Acute Lymphoblastic Leukemia (ALL) is indicated for the treatment of **Children**.

1. Patients <26 y/o and with refractory disease or

2. ≥2 relapses, and failure of 2 Tyrosine Kinase Inhibitor (TKI),

3. For REMS info see **FDA INDICATIONS AND USAGE- KYMRIAH**

4. **Limitation of Use:** KYMRIAH is not indicated for treatment of patients with primary central nervous system lymphoma (Adult relapsed or Refractory (r/r) Diffuse Large B-Cell Lymphoma (DLBCL)

**FDA approved**

Approved by the Food and Drug Administration (FDA) for
Chimeric Antigen Receptor (CAR) T-cell Therapy

the treatment of refractory Acute Lymphoblastic Leukemia (ALL) and Diffuse Large B-Cell Lymphoma (DLBCL)

- KYMRIAH (tisagenlecleucel) - FDA approved on August 31, 2017
- YESCARTA (axicabtagene ciloleucel) - FDA approved on October 2017

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.


<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>96365 – 96368</td>
<td>Intravenous infusion administration</td>
</tr>
<tr>
<td>96413 – 96417</td>
<td>Intravenous chemotherapy administration</td>
</tr>
<tr>
<td>Q2041</td>
<td>Axicabtagene Ciloleucel (Yescarta), up to 200 Million Autologous Anti-CD19 CAR positive T Cells, including Leukapheresis and dose preparation procedures, per therapeutic dose</td>
</tr>
<tr>
<td>Q2042</td>
<td>Tisagenlecleucel, up to 600 million CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose (Kymriah)</td>
</tr>
<tr>
<td>Q2043</td>
<td>Sipuleucel-T, minimum of 50 million autologous cd54+ cells activated with Pap-GM-CSF, including leukapheresis and all other preparatory procedures, per infusion (PROVENG)</td>
</tr>
<tr>
<td>Q2049</td>
<td>Injection, doxorubicin hydrochloride, liposomal, imported Lipodox, 10 mg</td>
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ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD10 Diagnosis Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>C83.x*</td>
<td>Non-follicular lymphoma</td>
</tr>
<tr>
<td>C85.x*</td>
<td>Other specified and unspecified types of non-Hodgkin lymphoma</td>
</tr>
<tr>
<td>C91.0x*</td>
<td>Acute lymphoblastic leukemia (ALL)</td>
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<tr>
<th>ICD10 Diagnosis Codes</th>
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<tbody>
<tr>
<td><em>The x represents a range of codes; it is dependent on the specific diagnosis</em></td>
<td></td>
</tr>
<tr>
<td>D47.x*</td>
<td>Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue (e.g., myelodysplastic syndrome)</td>
</tr>
<tr>
<td>D80.x* - D89.x*</td>
<td>Certain disorders involving the immune mechanism</td>
</tr>
</tbody>
</table>

References

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Acute Lymphoblastic Leukemia, Version 1.2018 – March 12, 2018. (See section Tisagenlecleucel (Kymriah)). Accessed 03/18/19.

Approval Signatures

Clinical Quality Committee: Norman White MD
Medical Directory: David Yu MD

Approval Dates
March 27, 2019

Publications History
1. Policy approved 03/27/2019
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This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: Click here for Medical Polices