An Analysis of Healthcare Plan CAR T Cell Coverage Criteria for Medicaid Beneficiaries

Landon Shupe, Pharm.D.1,2, Chuka Udeze, Pharm.D.1,2
1. Rutgers Institute for Pharmaceutical Industry Fellowship, Ernest Mario School of Pharmacy, Rutgers University, NJ, USA
2. TargenCorporation,Post-Doctoral Fellow,Summit,NJ,USA

Background
The development and commercialization of chimeric antigen receptor T-cell (CAR T) therapies have resulted in novel treatment modalities with unprecedented outcomes for patients with diffuse large B-cell lymphoma (DLBCL) and pediatric acute lymphoblastic leukemia (ALL).1-4 Since CAR T therapies involve collection, isolation, viral transduction, and reinfusion of the patient's T cells, the therapies are associated with substantial costs.2 Upon approval, the US list price for tisagenlecleucel, Kymriah®, was $475,000 for ALL and $370,000 for DLBCL, while axicabtagene ciloleucel, Yescarta®, had a price of $373,000 for DLBCL.4,5 Payers have taken different approaches thus far to managing access to CAR T cell therapies.2 In order to gain insights into how payers are managing these therapies, we collected publicly available Medicaid healthcare plan CAR T cell coverage criteria and compared these criteria to the registrational trial inclusion/exclusion criteria and FDA label indication statements for the approved products.

Objective
This study analyzed the publicly available Medicaid healthcare plan CAR T cell coverage criteria of the two currently approved CAR T products in the United States to gain a better understanding of how CAR T cell treatment access is currently being managed.

Method
A comprehensive literature review was conducted to determine state Medicaid coverage criteria for the two approved CAR T therapies, tisagenlecleucel and axicabtagene ciloleucel. Policies were compared with the registrational trial publications and FDA label indication statements.

Results
States with Collected CAR T Medical Policies

Through a public literature search, CAR T cell coverage criteria for tisagenlecleucel and axicabtagene ciloleucel on 48 different Medicaid plans in 24 different states were collected.

The number of different healthcare plan coverage criteria that were collected by product and indication:
• 20 for Kymriah in the ALL indication
• 12 for Kymriah in the DLBCL indication
• 16 for Yescarta in the DLBCL indication

Percentage of Medicaid Health Care Plan Coverage Criteria that Were Registrational Trial Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Policy Criteria</th>
<th>Kymriah ELIANA (ALL)</th>
<th>Kymriah JULIET (DLBCL)</th>
<th>Yescarta ZUMA-1 (DLBCL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>75%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>73%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>73%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Most Frequent Coverage Criteria

<table>
<thead>
<tr>
<th>Active Infection (incl. HIV &amp; HCV)</th>
<th>No Prior CAR T</th>
<th>CNS Malignancy</th>
<th>Doc. CSSIS Tumor Expression</th>
<th>Screened for Neop., Resp., C.</th>
<th>Active Inflammatory Disease</th>
<th>Performance Status</th>
<th>Life Expectancy</th>
<th>Prior Allergies</th>
<th>Transplant History</th>
<th>Vital Organ Lab Counts</th>
<th>No Live Vaccines</th>
<th>Impairment</th>
</tr>
</thead>
</table>

Medicaid CAR T Coverage Criteria

• 20 unique Medicaid CAR T coverage criteria were identified across the 48 different Medicaid healthcare plans.

• The three most frequent coverage criteria from our public literature search for both tisagenlecleucel and axicabtagene ciloleucel were: patients must not have an active infection including HIV, Hepatitis B, and Hepatitis C (54%); patients must not have had a previous CAR T cell therapy (52%); and patients must not have a malignancy involving the central nervous system (48%).

Limitations

• Medicaid healthcare plan coverage criteria were more expansive than the FDA label indication statements for both CAR T products.

• Medicaid healthcare plan coverage criteria not publicly available were not included in this analysis.

• The results are not generalizable to the commercial and Medicare populations.

• Information was collected prior to the CAR T National Coverage Analysis by CMS (may change CAR T coverage and reimbursement).

Conclusions

• There are additional Medicaid CAR T coverage criteria which are not included in the FDA labeled indication statement.

• The majority of the additional coverage criteria were associated with the registrational trial inclusion and exclusion criteria.

References