Drug/Drug Class: CAR T Cell Therapy Clinical Edit
First Implementation Date: June 21, 2018
Revised Date: N/A
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ Existing Criteria
☐ Revision of Existing Criteria
☐ New Criteria

Executive Summary

**Purpose:** Ensure appropriate utilization and control of CAR T Cell Therapies

**Why Issue Selected:** CAR T Cell Therapy is an emerging form of immunotherapy where a patient’s T Cells are collected and genetically engineered to produce chimeric antigen receptors (CAR) on the cell surface, allowing the modified T-cells to recognize an antigen on target cancer cells. Approved by the FDA on August 30, 2017, Kymriah™ (tisagenlecleucel) is indicated for treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse in pediatric and young adult patients (up to 25 years of age); Kymriah is also indicated for 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) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. Approved by the FDA on October 18, 2017, Yescarta® (axicabtagene ciloleucel) 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) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Neither Yescarta nor Kymriah are indicated for the treatment of primary central nervous system lymphoma. Both agents have black box warnings concerning Cytokine Release Syndrome and neurologic toxicities, and each agent has its own REMS program.

Each manufacturer certifies the facilities where CAR T cell therapy is used. MO HealthNet is treating this procedure the same way we do stem cell transplants. MO HealthNet requires all transplants to be done on an in-patient basis. Each request for CAR T Cell therapy is reviewed on a case by case basis to determine the appropriateness of treatment and a contract is put into place between MHD and the facility. This contract specifies among other things the reimbursement for the drug and for the hospital stay. This is a one-time treatment. All requests for therapy will be reviewed by a Clinical Consultant.

**Type of Criteria:**
- ☐ Increased risk of ADE
- ☒ Appropriate Indications
- ☐ Preferred Drug List
- ☒ Clinical Edit

**Data Sources:**
- ☐ Only Administrative Databases
- ☒ Databases + Prescriber-Supplied
Setting & Population

- Drug class for review: CAR T Cell Therapies
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For Kymriah:
  - Participant aged < 25 years AND documented diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse OR
  - Participant aged ≥ 18 years AND documented diagnosis of 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, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma
- For Yescarta:
  - Documented diagnosis of relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, 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
  - Participant aged ≥ 18 years
- Documentation of two or more previous lines of systemic therapy for treated diagnosis

Denial Criteria

- Therapy will be denied if no approval crieria are met
- Previous CAR T Cell Therapy
- Participant has an active infection or inflammatory disorder

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Disposition of Edit

Denial: Exception code “682” (Clinical Edit)

Default Approval Period

1 year

References

- KYMRIAH™ (tisagenlecleucel) suspension for intravenous infusion [prescribing information]. East Hanover, NJ. Novartis Pharmaceuticals Corporation May 2018
- YESCARTA® (axicabtagene ciloleucel) suspension for intravenous infusion [prescribing information]. Santa Monica, CA. Kite Pharma, Inc. May 2019.
