# Chimeric Antigen Receptor (CAR) T-cell Therapy Medical Necessity Guideline

| Medical Necessity Guideline Title: Chimeric Antigen Receptor (CAR) T-cell Therapy | | |
|---|---|---|
| **MNG #: 001** | ☒ **SCO** ☒ **One Care**<br>☒ **MA Medicare Premier**<br>☒ **MA Medicare Value**<br>☒ **RI Medicare Preferred**<br>☒ **RI Medicare Value**<br>☒ **RI Medicare Maximum** | **Prior Authorization Needed?**<br>☒ **Yes (always required)**<br>☐ **Yes (only in certain situations. See this MNG for details)**<br>☐ **No** |
| **Benefit Type:**<br>☒ **Medicare**<br>☐ **Medicaid** | **Approval Date:**<br>1/10/2019; 1/11/24 | **Effective Date:**<br>4/01/2019; 1/11/24; 10/10/24 |
| **Last Revised Date:**<br>1/25/2019; 03/25/2020; 3/26/2021; 5/11/2022; 8/10/2023; 1/11/24; 10/10/24 | **Next Annual Review Date:**<br>1/10/2020; 3/25/2021; 3/26/2022; 5/11/2023; 8/10/2024; 10/10/25 | **Retire Date:** |

**OVERVIEW:**
Chimeric antigen receptor T cells (CAR T-cells) are a form of genetically modified autologous immunotherapy that can be directed at specific cancer antigens. T cells are taken from the patient's blood using a procedure called leukapheresis and are altered in the lab by adding a gene for a specific receptor (called a chimeric antigen receptor or CAR), which helps the T cells attach to a specific cancer cell antigen. The CAR T-cells are then given back to the patient.

Since different cancers have different antigens, each CAR is made for a specific cancer's antigen. For example, in certain kinds of leukemia or lymphoma, the cancer cells have an antigen called CD19. The CAR T-cell therapies to treat these cancers are made to attach to the CD19 antigen and will not work for a cancer that does not have the CD19 antigen.

CAR T-cell therapies are approved by the US Food and Drug Administration (FDA) to treat some kinds of lymphomas and leukemias, as well as multiple myeloma. CAR T-cell therapy is typically used after other types of treatment have been tried. Current FDA-approved CART-cell therapies include: Kymriah (tisagenlecleucel), Yescarta (anicabtagene ciloeucel), Tecartus (brexucabtagene autleucel), Breyanzi (lisocabtagene maraleucel), Abecma (idecabtagene vicleucel), and Carvykti (ciltacabtagene autoleucel).

**DEFINITIONS:**
**Chimeric Antigen Receptor (CAR) T-Cell Therapy**: Cell-based gene therapy in which T-cells are collected and genetically altered in order to improve the ability of the T-cells to fight cancer. The genetic modification enables the T-cell to express a new receptor (the chimeric antigen receptor) on the T-cell's surface to enhance its recognition and attachment to a specific antigen on the cancer cell.

**Cytokine release syndrome (CRS):** CRS is an acute systemic inflammatory syndrome characterized by fever and multiple organ dysfunction that is associated with chimeric antigen receptor (CAR)-T cell therapy, therapeutic antibodies, and

haploidentical allogeneic transplantation. Cytokine release syndrome (CRS), resulting from rapid immune activation induced by CAR-Ts, is the most significant treatment-related toxicity. CRS initially manifests with fever and can progress to life-threatening capillary leak with hypoxia and hypotension.

**Diffuse large B-cell lymphoma (DLBCL):** The most common histologic subtype of non-Hodgkin lymphoma (NHL) that includes tumors derived from germinal center B cells or post-germinal center B cells (also known as activated B cells) that resemble centroblasts or immunoblasts. The heterogeneous group of tumors consists of large, transformed B cells with prominent nucleoli and basophilic cytoplasm, a diffuse growth pattern, and a high (>40%) proliferation fraction.

**Follicular Lymphoma (FL):** The second most common subtype of non-Hodgkin lymphoma (NHL) but is regarded as the most common of the clinically indolent NHLs, defined as those lymphomas in which survival of the untreated patient is measured in years. It is a heterogenous clinicopathologic entity that includes tumors that are derived from germinal center B cells that resemble centrocytes (small cleaved follicular center cells) and centroblasts (large noncleaved follicular center cells).

**Graft versus Host Disease (GVHD)**: Multisystem disorders that are common complications of allogeneic hematopoietic cell transplant (HCT). This condition occurs when immune cells transplanted from a non-identical donor (the graft) recognize the transplant recipient (the host) as foreign, thereby initiating an immune reaction that causes disease in the transplant recipient.

**Multiple myeloma (MM):** Multiple myeloma is a plasma cell disorder characterized by the clonal proliferation of malignant plasma cells in the bone marrow with monoclonal protein in the serum and/or urine and associated organ dysfunction. Multiple myeloma is the second most common hematologic malignancy.

**Risk Evaluation and Mitigation Strategy (REMS)**: A strategy to ensure that benefits of using a drug outweigh its serious potential risks. This is required by the U.S. Food & Drug Administration (FDA) for currently available CAR T-cell therapies.

**DECISION GUIDELINES:**

Because of the risk of cytokine release syndrome (CRS) and neurological toxicities, CAR T-cell therapy is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Healthcare facilities that dispense and administer a CAR T-cell therapy must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after CAR T-cell infusion, if needed for treatment of cytokine release syndrome (CRS).

For the purposes of this MNG, **Relapsed/Refractory*** is defined as disease progression after last the treatment regimen or refractory/suboptimal response to the most recent therapy.
**Note:** Documentation submitted must list previous lines of treatment/systemic therapies and date of each therapy.

**Clinical Coverage Criteria:**

1. CCA may cover autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when **all** of the following criteria are met:
   a. The member has had no prior treatment with a CAR T-cell therapy; and
   b. The member does not have any of the following:
      i. HIV, active hepatitis B or C infection; and
      ii. Active uncontrolled infection; and
      iii. Autoimmune disease requiring immunosuppression; and
      iv. Primary central nervous system (CNS) lymphoma (Breyzani, Kymriah, Yescarta); and
   c. There is no evidence of active graft versus host disease (GVHD*)* requiring treatment for members with a history of an allogeneic hematopoietic stem cell transplant (HSCT); and
   d. The CAR T-cell therapy is administered in a treating facility that is certified under the appropriate Risk Evaluation and Mitigation Strategy (REMS) System program; and
   e. The CAR T-cell therapy is used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) – i.e., is used for either an FDA-approved indication (According to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia;

**AND**

Member meets Clinical Coverage Criteria for requested CAR T-cell therapy:

**KYMRIAH™ (Tisagenlecleucel)**

2. Commonwealth Care Alliance may cover KYMRIAH™ (Tisagenlecleucel) when the following criteria are met:
   a. The member is age 25 years of age or younger; **and**
   b. The member has been diagnosed with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory* to treatment or is in second or greater relapse*;
      **OR**
   c. The member is age 18 years of age or older; **and**
   d. The member has been diagnosed 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;
      **OR**
   e. The member is age 18 years of age or older; **and**
   f. The member has been diagnosed with relapsed or refractory* follicular lymphoma (FL*)* after two or more lines of systemic therapy.
      This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)

**YESCARTA™ (Abixcabtagene ciloleucel)**

3. Commonwealth Care Alliance may cover YESCARTA™ (abixcabtagene ciloleucel) when the following criteria are met:
   a. The member is age 18 years of age or older and **one** of the following:
      i. Member has been diagnosed with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy

or that relapses within 12 months of first-line chemoimmunotherapy;

**OR**

ii. Member has been diagnosed 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;

**OR**

iii. Member has been diagnosed with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

**TECARTUS™ (brexucabtagene autoleucel)**

4. Commonwealth Care Alliance may cover TECARTUS™ (brexucabtagene autoleucel) when the following criteria are met:
   a. The member is age 18 years of age or older; **and one** of the following**;**
      i. The member has been diagnosed with relapsed or refractory mantle cell lymphoma (MCL).
      This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial;
      **OR**
      ii. The member has been diagnosed with elapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

**BREYANZI™ (Lisocabtagene maraleucel)**

5. Commonwealth Care Alliance may cover BREYANZI™ (Lisocabtagene maraleucel) when the following criteria are met:
   a. The member is age 18 years of age or older **and one** of the following:
   i. The member has been diagnosed with large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, and **one** of the following:
      a) Refractory* disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, **or**
      b) Refractory* disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age, **or**
      c) Relapsed or refractory disease after two or more lines of systemic therapy;
      **OR**
   ii. The member has been diagnosed with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and has received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
   This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s);
   **OR**
   iii. The member has been diagnosed with relapsed or refractory follicular lymphoma (FL) and has received 2 or more prior lines of systemic therapy.
   This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s);
   **OR**

iv. The member has been diagnosed with relapsed or refractory mantle cell lymphoma (MCL) and has received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.

**ABECMA™ (Idecabtagene vicleucel)**

6. Commonwealth Care Alliance may cover ABECMA™ (Idecabtagene vicleucel) when the following criteria are met:
   a. The member is age 18 years of age or older; and
   b. The member has been diagnosed with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.

**CARVYKTI™ (ciltacabtagene autoleucel)**

7.Commonwealth Care Alliance may cover CARVYKTI™ (ciltacabtagene autoleucel), when the following criteria are met:
   a. The member is age 18 years of age or older, and
   b. The member has been diagnosed with relapsed or refractory multiple myeloma and has received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and is refractory to lenalidomide.

**LIMITATIONS/EXCLUSIONS:**

1. CCA will limit coverage of CAR T-cell therapies to a single dose
   a. Re-authorization of requests will require review from a CCA Medical Director to assess for medical necessity.
2. CCA will not cover and does not consider **ANY** of the following as medically necessary:
   a. The use of non-FDA-approved autologous T-cells expressing at least one CAR,
   b. The use of CAR T-cell therapy in members who:
      i. Are pregnant,
      ii. Have an untreated underlying primary immunodeficiency syndrome,
      iii. Have an active and/or metastatic malignancy that is unlikely to respond to treatment, and/or
      iv. Have demonstrated clinical decompensation from time of authorization to time of infusion and who no longer meets the clinical coverage criteria.
3. Breyzani, Kymriah and Yescarta are not indicated for treatment of members with primary central nervous system lymphoma

**CODING:**

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

| HCPCS Code | Description |
|---|---|
| 0537T | Chimeric antigen receptor T-cell (CAR-T) therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day |
| 0538T | Chimeric antigen receptor T-cell (CAR-T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage) |
| 0539T | Chimeric antigen receptor T-cell (CAR-T) therapy; receipt and preparation of CAR-T cells for administration |
| 0540T | Chimeric antigen receptor T-cell (CAR-T) therapy; CAR-T cell administration, autologous |
| Q2041 | Axicabtagene ciloleucel, up to 200 million autologous anti-CD19 CAR T Cells, including leukapheresis and dose preparation procedures, per infusion |
| Q2042 | Tisagenlecleucel, up to 600 million car-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |
| Q2053 | Brexucabtagene autoleucel, up to 200 million autologous anti-CD!9 CAR positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |
| Q2054 | Lisocabtagene maraleucel, up to 110 million autologous anti-CD19 CAR-positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |
| Q2055 | Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (BCMA) directed car-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |
| Q2056 | Ciltacabtagene autoleucel, up to 100 million autologous B-cell maturation antigen (BCMA) directed CAR-positive T cells, including leukapheresis and dose preparation procedures, per therapeutic dose |

**REGULATORY NOTES:**
Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:

1. MassHealth Drug List Table 75: Chimeric Antigen Receptor (CAR)-T Immunotherapies, Section III: Evaluation Criteria for Approval.
2. Medicare, Social Security Act (the Act) section § 1861(t) Drugs and Biologicals
3. National Coverage Determination (NCD) for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Manual section number 110.24

**Disclaimer**

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity [supporting literature (full text preferred) should be attached to the request], or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

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**REVISION LOG:**

| REVISION DATE | DESCRIPTION |
|---|---|
| 10/10/24 | Criteria updated to align with current FDA indications, REMS criteria consolidated, coding updated to include CAR-T administration codes 0537T-0540T |
| 1/11/24 | Removed Tecvayli. Added Carvykti REMS program guidance. Definitions added. |
| 12/31/23 | Utilization Management Committee approval |
| 8/10/2023 | Clinical indications added for ABECMA™ (Idecabtagene vicleucel), Carvykti™ (ciltacabtagene autoleucel), and Tecvayli (teclistamab-cqyv) and details regarding the REMS program included |
| 7/19/2022 | Clinical coverage criteria updated according to FDA approved indications for KYMRIAH, YESCARTA, and TECARTUS. HCPCS code table added. |
| 5/11/2022 | Annual review, template update, ABECMA added. |

**APPROVALS:**

| | |
|---|---|
| David Mello, | Senior Medical Director Utilization Review and Medical Policy |
| **Signature** | **Title [Print]** |
|  | 10/10/2024 |
| **CCA Senior Operational Lead [Print]** | **Date** |
| **Signature** | **Title [Print]** |
| **CCA CMO or Designee [Print]** | **Date** |
| Nazlim Hagmann | Chief Medical Officer |
|  | 10/10/24 |