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** ☒ **MA Medicare Premier** ☒ **MA Medicare Value** ☒ **RI Medicare Preferred** ☒ **RI Medicare Value** ☒ **RI Medicare Maximum**	**Prior Authorization Needed?** ☒ **Yes (always required)** ☐ **Yes (only in certain situations. See this MNG for details)** ☐ **No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Benefit Type: ☒ **Medicare** ☐ **Medicaid**	**Approval Date:** 1/10/2019; 1/11/24	**Effective Date:** 4/01/2019; 1/11/24
Last Revised Date: 1/25/2019; 03/25/2020; 3/26/2021; 5/11/2022; 8/10/2023; 1/11/24	**Next Annual Review Date:** 1/10/2020; 3/25/2021; 3/26/2022; 5/11/2023; 8/10/2024	**Retire Date:**

OVERVIEW:
Cancer is a collection of related diseases of dividing cells that can start almost anywhere in or on the body, evade the immune system, and invade nearby tissues. Categories of cancer are typically organized by the location in the body and specific type of cell. These categories include carcinoma, sarcoma, leukemia, lymphoma, multiple myeloma, melanoma, and brain and spinal cord tumors. There are also changes to these cells that are not considered cancer. These changes include hyperplasia – when a cell divides faster than normal – and dysplasia – a buildup of extra cells with abnormal shape and disorganization.

A person's immune system contains cells to help fight substances that are foreign to the body, including cancer. These cells are called white blood cells, most of which are lymphocytes. The two main types of lymphocytes are B lymphocytes (B-cells) and T lymphocytes (T-cells). B-cells generate and release antibodies to fight infection, especially bacterial infections, while T-cells employ a number of other mechanisms to fight abnormal cells such as cancer. One type of therapy that leverages the immune system – immunotherapy – is *Chimeric Antigen Receptor (CAR) T-Cell therapy*.

CAR T-Cells have been genetically altered in order to improve the ability of the T-cells to fight cancer. The genetic modification creating a CAR can enhance the ability of the T-Cell to recognize and attach to a specific protein, called an antigen, on the surface of a cancer cell. Current FDA-approved CART-cell therapies include: *Kymriah (tisagenlecleucel), Yescarta (anicabtagene ciloeucel), Tecartus (brexucabtagene autleucel, KTE-X19), 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.

1. KYMRIAH: The goals of the Kymriah® (tisagenlecleucel) REMS Program are to mitigate the risks of cytokine release syndrome (CRS) and neurological toxicities by:
    a. Ensuring that hospitals and their associated clinics that dispense Kymriah are specially certified and have on-site, immediate access to tocilizumab.
    b. Ensuring those who prescribe, dispense, or administer Kymriah are aware of how to manage the risks of cytokine release syndrome and neurological toxicities.
    c. Kymriah is only available at select treatment centers. For more information, please call the REMS Call Center at 1-844-4KYMRIAH (1-844-459-6742).

2. YESCARTA: Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS
    a. Healthcare facilities that dispense and administer YESCARTA 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 YESCARTA infusion, if needed for treatment of CRS.
        i. Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer YESCARTA are trained about the management of CRS and neurologic toxicities.
    b. Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483)

3. TECARTUS: The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of TECARTUS outweigh the risks of cytokine release syndrome and neurologic toxicities.
    a. TECARTUS is available only through the YESCARTA and TECARTUS REMS Program.
    b. All hospitals and their associated clinic(s) must be certified and enrolled in the Tecartus REMS program to be able to dispense Tecartus.
    c. Relevant staff involved in the prescribing, dispensing, or administering of Tecartus are trained on Tecartus REMS requirements, and must successfully complete the Knowledge Assessment and submit it to the REMS Program to be certified.
    d. For more information, call the Tecartus REMS Center at 1-844-454-KITE (5483) or go to https://www.yescartatecartusrems.com/.

4. BREYANZI**:** is available only under a restricted program called BREYANZI REMS because of the serious risks of CRS and neurologic toxicities. The goals of the BREYANZI REMS are to mitigate the risks of CRS and neurologic toxicities by:
    a. Ensuring that hospitals and their associated clinic(s) that dispense BREYANZI are specially certified and have on-site immediate access to tocilizumab.
    b. Ensuring that those who prescribe, dispense, or administer BREYANZI are aware of how to manage the risks of CRS and neurologic toxicities.
    c. All hospitals and their associated clinic(s) must be certified and enrolled in the BREYANZI REMS to be able to infuse BREYANZI.
    d. All relevant staff involved in the prescribing, dispensing, or administering of BREYANZI are trained on the BREYANZI REMS requirements, and must successfully complete the **Knowledge Assessment** and submit it to the REMS Program.

5. ABECMA: ABECMA is only available under a restricted program called ABECMA REMS because of the serious risks of CRS and neurologic toxicities. The goals of ABECMA REMS are to mitigate the risks of CRS and neurologic toxicities by:
    a. Ensuring that hospitals and their associated clinic(s) that dispense ABECMA are specially certified and have on-site immediate access to tocilizumab.
    b. Ensuring that those who prescribe, dispense, or administer ABECMA are aware of how to manage the risks of CRS and neurologic toxicities.

6. CARVYKTI: Carvykti is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CARVYKTI® REMS because of the risk of CRS and neurologic toxicities. The FDA has determined that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of Carvykti outweigh the risks of cytokine release syndrome and neurologic toxicities by:
    a. Ensuring that hospitals and their associated clinics that dispense CARVYKTI are specially certified and have on-site, immediate access to tocilizumab.

b. Ensuring that those who prescribe, dispense, or administer CARVYKTI are aware of how to manage the risks of CRS and neurological toxicities.

DECISION GUIDELINES:
Clinical Coverage Criteria:
Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, when available, to review prior authorization requests for medical necessity. This MNG applies to all CCA Members unless a less restrictive and applicable CMS National Coverage Determination (NCD), Local Coverage Determination (LCD), or state-specific medical necessity guideline exists.

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, 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:

2. KYMRIAH™ (Tisagenlecleucel)
Commonwealth Care Alliance may cover KYMRIAH™ (Tisagenlecleucel) when (1.) and **all** of the following criteria below 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 that is refractory* to treatment or is in its second or greater relapse after a minimum of two or more lines of treatment; and
   c. The member has one of the following:
      a. all of the following:
         a. member has Philadelphia chromosome positive ALL; and

b. member has refractory* disease or ≥ two relapses; and
c. member failed two tyrosine kinase inhibitors; or

b. both of the following:
i. member has Philadelphia chromosome negative ALL; and
ii. member has refractory* disease or ≥ two relapses.

[OR]

d. The member is age 18 years of age or older, and
e. The member has been diagnosed with relapsed or refractory* large B-cell lymphoma after two or more failed 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]

f. The member is age 18 years of age or older, and
g. The member has been diagnosed with relapsed or refractory* follicular lymphoma (FL*)* after two or more failed lines of systemic therapy.

3. YESCARTA™ (Abixcabtagene ciloleucel)
Commonwealth Care Alliance may cover YESCARTA™ (abixcabtagene ciloleucel) when (1.) and **all** of the following criteria are met:

a. The member is age 18 years of age or older, and
b. The member has been diagnosed with **one** of the following:
i. Relapsed or refractory* large B-cell lymphoma after one or more lines of failed systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma, and
a) One of the following:
- The member has primary refractory* disease or
- The member relapsed within 12 months of a completed first line chemoimmunotherapy regimen; **or**

[OR]
ii. Relapsed or refractory* follicular lymphoma after two or more failed lines of systemic therapy

4. TECARTUS™ (brexucabtagene autoleucel)
Commonwealth Care Alliance may cover TECARTUS™ (brexucabtagene autoleucel) when (1.) and **all** of the following criteria are met:

a. The member is age 18 years of age or older, and
i. The member has been diagnosed with relapsed or refractory* mantle cell lymphoma, and all of the following:
- The member had an inadequate response, adverse reaction, or contraindication to anthracycline- or bendamustine-containing chemotherapy; and
- The member had an inadequate response, adverse reaction, or contraindication to ibrutinib, acalabrutinib or Zanubrutinib

[OR]

ii. The member has relapsed or refractory* B-cell precursor acute lymphoblastic leukemia and one of the following:
    1. member experienced a first relapse following a remission lasting ≤ 12 months; or
    2. member has relapsed or refractory* ALL after second-line or higher therapy; or
    3. member has relapsed or refractory* ALL at least 100 days after allogenic stem cell transplant;
    4. if the member has Philadelphia positive ALL, inadequate response, adverse reaction, or contraindication to one tyrosine kinase inhibitor.

5. BREYANZI™ (Lisocabtagene maraleucel)
Commonwealth Care Alliance may cover BREYANZI™ (Lisocabtagene maraleucel) when (1) and **all** of the following criteria are met:

a. The member is age 18 years of age or older, and
b. The member has been diagnosed with large B-cell lymphoma and one of the following:
    i. Refractory* disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy, or
    ii. 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. The member has been diagnosed with relapsed or refractory* large B-cell lymphoma including DLBCL NOS (including DLBCL arising from indolent lymphoma), high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and FL grade 3B and has failed two or more lines of systemic therapies.

6. ABECMA™ (Idecabtagene vicleucel) and CARVYKTI™ (ciltacabtagene autoleucel)
Commonwealth Care Alliance may cover ABECMA™ (Idecabtagene vicleucel) and CARVYKTI™ (ciltacabtagene autoleucel), when (1) and **all** of the following criteria are met:

a. The member is age 18 years of age or older, and
b. The member has been diagnosed with multiple myeloma that is relapsed or refractory after four or more lines of failed systemic therapy, and
c. The member's prior treatments must have included but are not limited to all of the following:
    i. Member's disease is refractory to at least one proteasome inhibitor (e.g., bortezomib, carfilzomib, ixazomib), or has a contraindication to all proteasome inhibitors; and
    ii. Member's disease is refractory to at least one immunomodulatory agent (e.g., lenalidomide, pmalidomide) or has a contraindication to all immunomodulatory agents; and
    iii. Member's disease is refractory to at least one anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab) or has a contraindication to all anti-CD38 monoclonal antibodies

*Relapsed/Refractory 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

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.

AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. 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. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. 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).

HCPCS Code	Description
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 version 1, effective date 8/7/2019, implementation date 9/20/2021.

This Medical Necessity Guideline is not a rigid rule. As with all of 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.

RELATED REFERENCES:

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REVISION LOG:

REVISION DATE	DESCRIPTION
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]**
	1/11/2024
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Nazlim Hagmann	Chief Medical Officer
CCA CMO or Designee [Print]	**Title [Print]**
	1/11/24
Signature	**Date**