



CAR T-Cell Treatment Clinical Coverage Criteria

Overview

Chimeric Antigen Receptor (CAR-T) Cell Treatment is a new cancer immunotherapy treatment which involves the patient's T-Cells to be removed from their blood and sent to a laboratory. A gene for a special receptor that binds to a certain protein on the patient's cancer cells is added in the laboratory this special receptor is called a chimeric antigen receptor (CAR). Upon return to the patient's body these genetically altered cells are used to attack the cancer cells.

Currently there are two approved CAR-T Cell treatments. Kymriah (tisagenlecleucel) which is utilized for children and young adults up to 25 years and Yescarta (axicabtagene ciloleucel) utilized in adults. Currently both treatments are approved for certain types of cancer but studies are on-going to see if it is a viable last line treatment for other types of cancer.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

CAR-T Cell therapy for any indication requires prior authorization, with Plan Medical Director review and approval. This prior authorization is separate from any prior authorization that may be required for the member's inpatient or outpatient encounter. Medical records from the providers who have diagnosed or treated the symptoms prompting this request are also required. The below requirements must be met.

Medicare Advantage plan members

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24). Effective for services performed on or after August 7, 2019, Medicare covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and 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. The NCD is the formal policy. For Medicare beneficiaries enrolled in Medicare Advantage plans, coverage determinations are to be made by the Medicare

Advantage plan (R10891CP). Effective for services performed on or after August 7, 2019, routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1 will be covered by the Medicare Administrative Contractors (MCD search 12-03-2021).

NaviCare and PACE plan members

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In situations where there is no Medicare guidance or if the plan member does not meet coverage criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members.

Each PACE plan member is assigned to an interdisciplinary team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

MassHealth ACO

Fallon Health follows MassHealth Prior Authorization Requirements for Chimeric Antigen Receptor (CAR)-T Immunotherapies for MassHealth members. Please use the following link to access the Prior Authorization Requirements:

[Table 75: Chimeric Antigen Receptor \(CAR\)-T Immunotherapies](#)

Kymriah:

1. The member is 25 years old or younger with the diagnosis of CD19 positive B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse that that has either not responded to, or relapsed after, second or greater lines of systemic therapy, OR
2. The member is 18 years old or older and has a diagnosis of diffuse large B-cell lymphoma (DLBCL) not otherwise specified that is refractory or in second or later relapse that that has either not responded to, or relapsed after, second or greater lines of systemic therapy, AND
3. The member has adequate organ function and no expectant organ deterioration during treatment, AND
4. The member does not have any of the below conditions:
 - Burkitt lymphoma/leukemia
 - Active hepatitis B, C, or any uncontrolled infection
 - Grade 2 to 4 graft-versus-host disease
 - Received allogeneic cellular therapy, such as donor lymphocyte infusion within 6 weeks prior to tisagenlecleucel infusion
 - Active central nervous system disease
5. The treatment center is certified by the manufacturer to perform treatment with Kymriah.

Yescarta:

1. The member is at least 18 years of age, AND
2. A diagnosis of DLBCL, primary mediastinal B cell lymphoma, high grade B-cell lymphoma, or DLBCL arising from follicular lymphoma that that has either not responded to, or relapsed after, second or greater lines of systemic therapy, AND
3. The member does not have diagnosed primary CNS lymphoma, AND
4. The member has sufficient functionality of organs, cardiac system, and pulmonary system, AND
5. The member lacks an active or metastatic malignancy that is unlikely to respond to treatment, AND
6. No history or diagnosis of the below:

- Active autoimmune disease requiring treatment
 - Active HIV
 - Active hepatitis B or C
7. The treatment center is certified by the manufacturer to perform treatment with Yescarta.

Though there currently are studies being performed regarding the use of CAR-T Cell treatments for other types of cancer they currently are considered experimental and investigational.

Exclusions

- Off-Label utilization of CAR-T Cell treatments.

Coding

Code	Description
C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics
J3590	Unclassified biologics
J9999	Not otherwise classified, antineoplastic drugs
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

References

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2. Hayes Inc. Yescarta (Axicabtagene Ciloleucel) Prognosis Overview. Published December 19, 2017.
3. Hayes Inc. Kymriah (Tisagenlecleucel) for Diffuse Large B-Cell Lymphoma Prognosis Overview. Published May 3, 2018.
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5. Enblad G, Karlsson H, Loskog AS. CAR T-Cell Therapy: The Role of Physical Barriers and Immunosuppression in Lymphoma. *Hum Gene Ther*. 2015 Aug;26(8):498-505.
6. Nellan A, Lee DW. Paving the road ahead for CD19 CAR T-cell therapy. *Curr Opin Hematol*. 2015 Nov;22(6):516-20.
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8. Pettitt D, Arshad Z, Smith J, et. al. CAR-T Cells: A Systematic Review and Mixed Methods Analysis of the Clinical Trial Landscape. *Mol Ther*. 2017 Nov 2. pii: S1525-0016(17)30556-7.
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13. CMS. MLN Matters®. Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions. Article Release Date: May 28, 2019. Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19009.pdf>. Accessed December 3, 2021.
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15. MassHealth Managed Care Entity Bulletin 42. Issued September 2020. Available at: <https://www.mass.gov/masshealth-provider-bulletins>.
16. MassHealth Drug List. Medication Class/Individual Agents. Table 75: Chimeric Antigen Receptor (CAR)-T Immunotherapies. Available at: <https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=1347&drugId=6404>. Accessed 12/2/2021.

Policy history

Origination date: 03/01/2018
Approval(s): Technology Assessment Committee: 02/28/2018 (introduced as a new policy), 12/05/2018 (added for indication of Diffuse Large B-Cell Lymphoma for Kymriah, added code Q2041, updated references), 02/27/2019 (clarified age for Kymriah based on diagnosis, added code Q2042 removed Q2040)

02/01/2022 (Added clarifying language related to Medicare Advantage, NaviCare, PACE and MassHealth ACO under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.