Tecartus (brexucabtagene autoleucel)
Clinical Coverage Criteria

Overview

Chimeric antigen receptor (CAR) T-cell therapies are immunotherapies that target specific types of cancer. CAR T-cell therapies are made are made by collecting T-cells from the patient and re-engineering them in the laboratory to produce proteins on their surface called chimeric antigen receptors, or CARs. The CARs recognize and bind to specific proteins, or antigens, on the surface of cancer cells and kill them. Since 2017, six CAR T-cell therapies have been approved by the Food and Drug Administration (FDA). All are approved for the treatment of blood cancers, including lymphomas, some forms of leukemia, and, most recently, multiple myeloma. The CAR T-cell therapies approved by FDA to date target one of two antigens on B-cells, CD19 or BCMA.

Tecartus (brexucabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients 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.
- Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Full prescribing information available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/tecartus. The Tecartus (brexucabtagene autoleucel) label has a boxed warning.

Despite the therapeutic successes of CAR T-cell therapy, the intervention carries the risk of severe side effects. These include cytokine release syndrome (CRS), neurologic toxicities and B-cell aplasia, all of which can be life-threatening. On August 30, 2017, tocilizumab (Actemra) was FDA-approved to treat CAR T-cell induced CRS in in adults and in pediatric patients 2 years of age and older.

Section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) authorizes FDA to require a risk evaluation and mitigation strategy (REMS) for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. The REMS consists of elements to ensure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

The Tecartus REMS was originally approved by the FDA on July 24, 2020, and the most recent REMS modification was approved on June 12, 2024. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS. On June 26, 2025, the FDA approved Kite Pharma's request to eliminate the Tecartus REMS.

Also on June 26, 2025, the FDA announced that it was eliminating the REMS for the following BCMA- or CD19-directed autologous CAR T cell immunotherapies: Yescarta, Tecartus, Kymriah, Carvykti, Breyanzi and Abecma, noting that the approved REMS for these six products must be eliminated because a REMS is no longer necessary to ensure that the benefits of the currently

approved CAR T-cell immunotherapies outweigh their risks, and to minimize the burden on the healthcare delivery system of complying with the REMS.[1]

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization by a Fallon Health Medical Director is required for Tecartus (brexucabtagene autoleucel). 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 required.

Effective April 1, 2025, MassHealth transitioned the review and management of all APAD and APEC carve-out drugs, including Zolgensma, to the MassHealth Drug Utilization Review (DUR) Program. Effective for dates of services on or after April 1, 2025, prior authorization requests for all APAD and APEC carve-out drugs, including Zolgensma must be submitted to the DUR Program for review and approval prior to administration. NOTE: Only the prior authorization request for Zolgensma and other APAD and APEC carve out drugs will be reviewed by the MassHealth DUR Program, Fallon Health is still responsible for reviewing prior authorization requests for the member's inpatient or outpatient hospital encounter.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria for Tecartus (brexucabtagene autoleucel) apply to Community Care members. For Medicare and MassHealth members, follow the applicable criteria described in the Medicare Variation section below.

Relapsed or Refractory Mantle Cell Lymphoma
A single administration of Tecartus (brexucabtagene autoleucel) may be considered medically necessary when all of the following criteria are met:

1. The member is ≥ 18 years of age at the time of informed consent.
2. The member has mantle cell lymphoma (MCL) that is pathologically confirmed MCL, with documentation of either overexpression of cyclin D1 or presence of t(11;14).
3. At least 1 measurable lesion according to the revised IWG Response Criteria for Malignant Lymphoma (Cheson et al. 2007).
4. Relapsed or refractory disease, defined by the following:
   - Disease progression after last regimen, or
   - Refractory disease is defined as failure to achieve partial response or complete response to the last regimen.
5. Up to 5 prior regimens for MCL. Prior therapy must have included:
   - Anthracycline or bendamustine-containing chemotherapy, and
   - Anti-CD20 monoclonal antibody therapy, and
   - Ibrutinib or acalabrutinib.
6. Treatment will be administered at a healthcare facility that is enrolled in the FDA Risk Evaluation and mitigation strategies (REMS) for Tecartus.

[1] FDA Eliminates Risk Evaluation and Mitigation Strategies (REMS) for Autologous Chimeric Antigen Receptor CAR T cell Immunotherapies, https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-eliminates-risk-evaluation-and-mitigation-strategies-rems-autologous-chimeric-antigen-receptor.

Induction plus consolidation/maintenance and/or all treatments occurring between sequential complete responses was counted as 1 regimen.

Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia
A single administration of Tecartus (brexucabtagene autoleucel) may be considered medically necessary when all of the following criteria are met:

1. The member is ≥ 18 years of age at the time of informed consent.
2. The member has relapsed or refractory B-precursor acute lymphoblastic leukemia (ALL), defined as one of the following:
   a. Primary refractory disease
   b. First relapse if first remission ≤ 12 months
   c. Relapsed or refractory disease after two or more lines of systemic therapy
   d. Relapsed or refractory disease after allogeneic transplant provided subject is at least 100 days from stem cell transplant at the time of enrollment and off of immunosuppressive medications for at least 4 weeks prior to enrollment
3. Subjects with Philadelphia chromosome positive (Ph+) disease are eligible if they are intolerant to tyrosine kinase inhibitor (TKI) therapy, or if they have relapsed/refractory disease despite treatment with at least 2 different TKIs.
4. Treatment will be administered at a healthcare facility that is enrolled in the FDA Risk Evaluation and mitigation strategies (REMS) for Tecartus.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for Chimeric Antigen Receptor (CAR) T-cell therapy. Medicare has an NCD for Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24), Version Number 1, Effective Date of this Version: 08/07/2019 (Medicare Coverage Database Search 05/27/2024). Coverage criteria for CAR T-cell therapy are fully established by Medicare; therefore, the Plan's coverage criteria are not applicable.

Link: NCD Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24)

MassHealth Variation

Effective April 1, 2025, MassHealth transitioned the review and management of all APAD and APEC carve-out drugs, including Tecartus, to the MassHealth Drug Utilization Review (DUR) Program. Effective for dates of services on or after April 1, 2025, all prior authorization requests for APAD and APEC carve-out drugs, including Tecartus must be submitted to the DUR Program for review and approval before administration. Note: Only prior authorization requests for the APAD and APEC carve-out drugs themselves will be reviewed by the MassHealth DUR Program. Fallon Health will still be responsible for reviewing prior authorization requests for the member's inpatient or outpatient hospital encounter.

Additionally, also effective for dates of services on or after April 1, 2025, MassHealth will pay claims for APAD and APEC carve-out drugs for MassHealth ACO enrollees consistent with Sections 5.B.8.b and 5.C.9 of the current MassHealth Acute Hospital Request for Applications (Acute Hospital RFA) for in-state acute hospitals and regulations at 130 CMR 450.233(D) for out-of-state acute hospitals. Fallon Health will continue to pay claims for the member's inpatient or outpatient hospital encounter.

Refer to the following MassHealth Bulletins for additional information*:* MassHealth Managed Care Entity Bulletin 125 March 2025, MassHealth Acute Inpatient Hospital Bulletin 201 March 2025, and MassHealth Acute Outpatient Hospital Bulletin 41 March 2025, available at: https://www.mass.gov/masshealth-provider-bulletins.

The MassHealth Acute Hospital Carve-out Drugs List is available at: https://masshealthdruglist.ehs.state.ma.us/MHDL/.

Exclusions

- Prior treatment with any CAR T-cell therapy.

- All other indications for Tecartus (brexucabtagene autoleucel) are considered experimental/investigational and not medically necessary.

Summary of Evidence

Relapsed or Refractory Mantle Cell Lymphoma
Mantle-cell lymphoma is a B-cell non-Hodgkin's lymphoma that generally has an aggressive clinical course. Bruton's tyrosine kinase (BTK) inhibitors have greatly improved outcomes in patients with relapsed or refractory mantle-cell lymphoma, yet patients who have disease progression after the receipt of BTK inhibitor therapy have a very poor prognosis, with an objective response occurring in 25 to 42% of patients and a median overall survival of 6 to 10 months with salvage therapies. Although allogeneic stem-cell transplantation is an option for some patients with relapsed or refractory mantle-cell lymphoma, non–relapse-related mortality, even with reduced-intensity conditioning therapy, remains high at 10 to 24% (Wang et al., 2020).

U.S. Food & Drug Administration (FDA) Pivotal Trial
ZUMA-2 (NCT02601313) is a single-arm, open-label, multicenter trial evaluated the efficacy and safety of a single infusion of Tecartus in adult patients (≥18 years of age) had histologically confirmed mantle cell lymphoma (MCL) with either cyclin D1 overexpression or presence of the translocation t(11;14) and had disease that was either relapsed or refractory to up to five previous regimens for mantle-cell lymphoma. Previous therapy must have included anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody, and BTK inhibitor therapy with ibrutinib or acalabrutinib. BTK inhibitor therapy was not required to be the last line of therapy before trial entry, and patients were not required to have disease that was refractory to BTK inhibitor therapy. Eligible patients had disease progression after their last regimen or refractory disease to their most recent therapy. ZUMA-2 excluded patients with active or serious infections, prior allogeneic hematopoietic stem cell transplant, detectable cerebrospinal fluid malignant cells or brain metastases, and any history of central nervous system (CNS) lymphoma or CNS disorders.

Results of ZUMA-2 are published by Wang et al., 2020. The primary end point was the percentage of patients with an objective response (complete or partial response) as assessed by the independent radiology review committee according to the Lugano classification. Bone marrow evaluation in addition to PET-CT was necessary to confirm a complete response. Secondary end points included the duration of response, progression-free survival, overall survival, the percentage of patients with an investigator-assessed objective response according to the criteria of Cheson et al., 2007[2] the incidence of adverse events, the levels of CAR T cells in blood and cytokines in serum, and changes in scores from baseline to month 6 in the five-level version of the European Quality of Life–5 Dimensions (EQ-5D) questionnaire.

From October 24, 2016, to April 16, 2019, a total of 74 patients were enrolled in the trial and underwent leukapheresis. Tecartus was successfully manufactured for 71 patients (96%) and administered to 68 (92%). The median time from leukapheresis to the delivery of Tecartus at the trial site was 16 days. A total of 3 patients for whom the manufacturing of Tecartus failed did not proceed to an additional apheresis owing to deep-vein thrombosis, death from progressive disease, or withdrawal of consent (in 1 patient each). Two patients who had successful manufacture of KTE-X19 died from progressive disease before the receipt of conditioning chemotherapy. After the receipt of conditioning chemotherapy, 1 patient with ongoing atrial fibrillation, an exclusion criterion, was deemed to be ineligible for Tecartus infusion. As of July 24, 2019, the median follow-up among the patients in the primary efficacy analysis was 12.3 months (range, 7.0 to 32.3).

High-risk features were common at baseline, and most patients had received at least three previous lines of therapy. All the patients had disease that was refractory to BTK inhibitor therapy or had disease that had progressed during or after receipt of a BTK inhibitor. A total of 42 of 68 treated patients (62%) had disease that did not respond to BTK inhibitor therapy (primary

[2] Cheson BD, Pfistner B, Juweid ME, et al. Revised response criteria for malignant lymphoma. J Clin Oncol 2007; 25: 579-86.

refractory disease), and 18 (26%) had a relapse after having an initial response while receiving BTK inhibitor therapy; therefore, 88% of the treated patients had disease that was considered to be refractory to BTK inhibitor therapy. A total of 5 patients (7%) had a relapse after stopping BTK inhibitor therapy; 3 patients (4%) were unable to take ibrutinib owing to adverse events.

Among the first 60 treated patients who had at least 7 months of follow-up (as specified in the protocol), 93% (95% confidence interval [CI], 84 to 98) had an objective response as assessed by the independent radiologic review committee, with 67% (95% CI, 53 to 78) having a complete response. High concordance (95%) was observed between rates assessed by the independent radiologic review committee and those assessed by the investigator. Among all 74 enrolled patients, 85% had an objective response, with 59% having a complete response. The percentages of patients with an objective response were consistent among key subgroups, including patients with high-risk features. The median time to an initial response was 1.0 month (range, 0.8 to 3.1), and the median time to a complete response was 3.0 months (range, 0.9 to 9.3). Among the 42 patients who initially had a partial response or stable disease, 24 patients (57%), including 21 with an initial partial response and 3 with stable disease, subsequently had a complete response after a median of 2.2 months (range, 1.8 to 8.3) after the initial response; 17 patients were continuing to have a response as of the data-cutoff date (median follow-up, 12.3 months).

Minimal residual disease was analyzed in 29 of 74 patients (39%); 24 of these 29 patients (83%) (19 patients with a complete response and 5 with a partial response) had no detectable residual disease (i.e., <1 in 100,000 cells) at week 4, and 15 of 19 patients (79%) with available data had negative results at month 6. Two patients who had disease progression after having an objective response to Tecartus received a second infusion approximately 1 year and 1.3 years after the initial infusion; analysis in these patients is ongoing.

A total of 57% of all the patients in the primary efficacy analysis and 78% of the patients who had a complete response were in remission as of the data-cutoff date. The first 28 patients who were treated had a median follow-up of 27.0 months (range, 25.3 to 32.3), with 43% having a continued remission without additional therapy. The percentages of patients with an ongoing response were also consistent across key covariates. The 3 patients who had CD19-negative tumors at baseline and were included in the primary efficacy analysis had a complete response and were in remission as of the data-cutoff date.

At 12 months, the estimated progression-free survival and overall survival were 61% and 83%, respectively. Subgroup analysis showed that progression-free survival at 6 months was consistent among patients with poor prognostic features, including pleomorphic morphologic characteristics, *TP53* mutation, or a Ki-67 proliferation index of 50% or higher.

At the time of analysis, 76% of all 68 treated patients were alive. Among the patients who had a response, progressive disease developed in 14. One patient who had a partial response underwent allogeneic stem-cell transplantation.

All 68 treated patients had at least one adverse event of any grade, with adverse events of grade 3 or higher occurring in 99% of the patients. The most common adverse events of grade 3 or higher were cytopenias (in 94% of the patients) and infections (in 32%). Grade 3 or higher cytopenias included neutropenia (in 85% of patients), thrombocytopenia (51%), and anemia (50%).

The cytokine release syndrome occurred in 91% of the patients. No patient died from cytokine release syndrome. Most cases were grade 1 or 2 (in 76% of patients), with cases of grade 3 or higher occurring in 15% of the patients. For the management of cytokine release syndrome, 59% of all treated patients received tocilizumab, 22% received glucocorticoids, and 16% received vasopressors. The median time after infusion to the onset of cytokine release syndrome of any grade was 2 days (range, 1 to 13); the corresponding interval to the onset of cytokine release syndrome of grade 3 or higher was 4 days (range, 1 to 9). All events resolved within a median of 11 days.

A total of 63% of patients had neurologic events. No patient died from a neurologic event. Neurologic events of grade 1 or 2 occurred in 32% of the patients and events of grade 3 or higher in 31%. One patient had grade 4 cerebral edema and fully recovered with aggressive multimodality therapy including ventriculostomy. For the management of neurologic events, 26% of all treated patients received tocilizumab and 38% received glucocorticoids.

A total of 68% of patients had serious adverse events. Infection of grade 3 or higher occurred in 32% of the patients, with the most common being pneumonia (in 9%).

A total of 16 patients (24%) who received Tecartus died, primarily from progressive disease (14 patients). Two patients had grade 5 adverse events, including organizing pneumonia related to conditioning chemotherapy in 1 patient and staphylococcus bacteremia related to conditioning chemotherapy and Tecartus therapy in 1 patient.

Relapsed or Refractory B-cell precursor Acute Lymphoblastic Leukemia
Acute lymphoblastic leukemia (ALL) is a heterogeneous hematologic disease characterized by the proliferation of immature lymphoid cells in the bone marrow, peripheral blood, and other organs (Jabbour et al., 2005). The age-adjusted incidence rate of ALL in the United States is 1.8 per 100,000 individuals per year, with approximately 6550 new cases and 1330 deaths estimated in 2024 (Howlader et al., 2021; Siegel et al., 2024). The median age at diagnosis for ALL is 17 years, with 53.5% of patients diagnosed at <20 years of age. In contrast, 29.6% of patients are diagnosed at ≥45 years of age and only approximately 13.7% of patients are diagnosed at ≥65 years of age (Howlader et al., 2021). ALL represents 75% to 80% of acute leukemias among children, making it the most common form of childhood leukemia; by contrast, ALL represents approximately 20% of all leukemias among adults Jabbour et al., 2005; Esparza et al., 2005).

The cure rates and survival outcomes for patients with ALL have improved dramatically over the past several decades, primarily among children. Improvements are largely owed to advances in the understanding of the molecular genetics and pathogenesis of the disease, the incorporation of minimal residual disease (MRD) testing, the refinement of risk-adapted treatment algorithms, the advent of new targeted agents, and the use of allogeneic hematopoietic cell transplantation (Ma et al., 2014).

U.S. Food & Drug Administration (FDA) Pivotal Trial
From Food and Drug Administration (FDA) Tecartus, Kite Pharmaceuticals, Inc. Package Insert (Revised: 04/2024)
The efficacy of Tecartus for the treatment of relapsed or refractory b-cell precursor acute lymphoblastic leukemia (ALL) was evaluated in ZUMA-3 (NCT02614066), an open-label, single-arm, multicenter trial. Results are published by Shah et al., 2021. Eligible patients were 18 years of age or older with Eastern Cooperative Oncology Group performance status of 0-1, and morphological disease in the bone marrow (>5% blasts), first relapse following a remission lasting ≤ 12 months, relapsed or refractory ALL after second-line or higher therapy, or relapsed or refractory ALL at least 100 days after allogeneic stem cell transplantation. The study excluded patients with active or serious infections, active graft-vs-host disease or taking immunosuppressive medications within 4 weeks prior to enrollment, and any history of CNS disorders, including CNS-2 disease with neurologic changes and CNS-3 disease irrespective of neurological changes.

The primary endpoint was the rate of overall complete remission or complete remission with incomplete hematological recovery by central assessment. Duration of remission and relapse-free survival, overall survival, minimal residual disease (MRD) negativity rate, and allogeneic stem cell transplant rate were assessed as secondary endpoints. Efficacy and safety analyses were done in the treated population (all patients who received a dose of Tecartus).

Treatment consisted of lymphodepleting chemotherapy (fludarabine 25 mg/m2 iv daily on Days -4, -3 and -2; cyclophosphamide 900 mg/m2 iv on Day -2) followed by a single intravenous infusion of Tecartus at a target dose of 1×10^6 anti-CD19 CAR T cells/kg (maximum 1×10^8 cells) on Day 0. All treated patients were hospitalized until at least Day 7.

Between Oct 1, 2018, and Oct 9, 2019, 71 patients were enrolled and underwent leukapheresis. Six of these patients did not receive Tecartus due to manufacturing failure, eight patients were not treated primarily due to adverse events following leukapheresis, two patients underwent leukapheresis and received lymphodepleting chemotherapy but were not treated with Tecartus, and one patient treated with Tecartus was unevaluable for efficacy. Among the remaining 54 efficacy-evaluable patients, the median time from leukapheresis to product delivery was 16 days (range: 11 to 39 days) and the median time from leukapheresis to Tecartus infusion was 29 days (range: 20 to 60 days).

Of the 54 patients who were efficacy evaluable, the median age was 40 years (range: 19 to 84 years), 61% were male, and 67% were White, 6% were Asian, 2% were Black or African American, and 2% were American Indian or Alaska Native. At enrollment, 46% had refractory relapse, 26% had primary refractory disease, 20% had untreated second or later relapse, and 7% had first untreated relapse.

Among prior therapies, 43% of patients were previously treated with allogeneic stem cell transplantation, 46% with blinatumomab, and 22% with inotuzumab. Twenty-six percent of patients were Philadelphia chromosome positive (Ph+). Fifty (93%) patients had received bridging therapy between leukapheresis and lymphodepleting chemotherapy to control disease burden.

The efficacy of Tecartus was established on the basis of complete remission (CR) within 3 months after infusion and the duration of CR (DOCR). Twenty-eight (51.9%) of the 54 evaluable patients achieved CR, and with a median follow-up for responders of 7.1 months, the median DOCR was not reached. The median time to CR was 56 days (range: 25 to 86 days). All efficacy evaluable patients had potential follow-up for ≥ 10 months with a median actual follow-up time of 12.3 months (range: 0.3 to 22.1 months).

Efficacy Results in Adult Patients with Relapsed/Refractory B-cell precursor ALL

	Efficacy Evaluable Patients [a] N= 54	**All Leukapheresed Patients N = 71**
OCR rate (CR + CRi), n (%) [95% CI]	35 (64.8) [51, 77]	36 (50.7) [39, 63]
CR rate, n (%) [95% CI]	28 (51.9) [37.8, 65.7]	29 (40.9) [29.3, 53.2]
Duration of Remission, Median in months [95% CI] (Range [b] in months)	13.6 [9.4, NE] (0.03+, 16.07+)	13.6 [8.7, NE] (0.03+, 16.07+)
DOR, if best response is CR, median in months [95% CI] (Range in months)	NR [9.6, NE] (0.03+, 16.07+)	13.6 [9.4, NE] (0.03+, 16.07+)
DOR, if best response is CRi, median in months [95% CI] (Range in months)	8.7 [1.0, NE] (0.03+, 10.15+)	8.7 [1.0, NE] (0.03+, 10.15+)
Median Follow-up for CR in months	7.1 (0.03+, 16.1+)	5.0 (0.03+, 16.1+)

CI, confidence interval; CR, complete remission; CRi, complete remission with incomplete blood count recovery; DOR, duration of remission; NE, not estimable; NR, not reached, OCR, overall complete remission; NE, not estimable

[a] Of the 71 patients that were enrolled (and leukapheresed), 57 patients received lymphodepleting chemotherapy, and 55 patients
received TECARTUS. 54 patients were included in the efficacy-evaluable population.

[b] A + sign indicates a censored value.

Analysis of Evidence (Rational for Determination)

The development of CAR T-cell therapy has been a decades-long journey from when the technology was first proposed in the late 1980s to the U.S. Food and Drug Administration (FDA) approval of Novartis's tisagenlecleucel in 2017. Research to further optimize CAR T-cell design and delivery raises the hope of a cure for many more people with malignancies and heralds an exciting new era in cancer treatment. Data continue to accumulate supporting the efficacy of responses to anti-CD19 CAR-T cell therapy in B-cell malignancies.

Despite promising early response rates in trials, applying this data to real-world patients is challenging, partly as inclusion criteria favor better prognosis groups. Durability of remissions and incidence of long-term adverse events are critical factors determining the utility of anti-CD19 CAR T-cell therapy, but long-term follow-up of patients treated with anti-CD19 CAR T-cells is limited.

The majority of clinical trials using CAR-T cells are early phase studies. Randomized controlled clinical trials will better establish the place for CAR-T cells in relation to existing potentially curative therapies in B-cell malignancies. The selection of suitable patients for the application of CAR T-cells is important. The factors that drive the curative potential of CAR T-cell therapy may be fundamentally different than the factors that drive outcomes with autologous stem cell transplantation, which are predominantly related to chemotherapy sensitivity.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
Q2043	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Medicare and Community Care members
Medicare has provided 3 scenarios for how to bill the services described by CPT codes 38225, 38226, and 38227. These codes may be reported for tracking purposes but are non-payable (SE19009; Medicare Claims Processing Manual, Chapter 32, Section 400 - Chimeric Antigen Receptor (CAR) T-cell Therapy).

Scenario 1: CAR-T Dosing and Preparation Services and Viable T-cells Administered in Hospital Outpatient Setting
When CAR T-cell therapies are administered in the hospital outpatient setting, outpatient hospitals should report CPT code 38228 with revenue code 0874 for the administration and HCPCS code Q2043 with revenue codes 0891 for the biological. Payment for the procedures described by CPT codes 38225 (collection/handling), 38226 (preparation for transport), and 38227 (receipt and preparation) represent the various steps required to collect and prepare the genetically modified T-cells, and these steps are not paid separately under the Outpatient Prospective Payment System (OPPS) (under OPPS these codes have status indicator “B,” not paid under OPPS). Outpatient hospitals may report the charges for these various steps to allow tracking of these services when furnished in the outpatient setting, however, these steps are not reimbursed.

Scenario 2: CAR-T Dosing and Preparation Services Administered in Hospital Outpatient Setting, but Viable T-cells Not Administered
In instances when CAR T-cell therapy is not ultimately administered to the member, but the preparation services are initiated or performed, the provider may not report the Q-code (which only applies when the T-cells are administered). Outpatient hospitals may report CPT codes 38225, 38226, and 38227, as appropriate, and the charges associated with each code under the appropriate revenue code on the outpatient hospital claim, however, these steps are not reimbursed.

Scenario 3: CAR-T Dosing and Preparation Services Administered in Hospital Outpatient Setting, but Viable T-cells Administered in the Hospital Inpatient Setting
When the CAR T-cell preparation services occur in the hospital outpatient setting, but the administration of the CAR T-cells occurs in the inpatient setting, the outpatient hospital cannot report the drug Q code (which only applies when the T-cells are administered). Per CMS instructions (SE19009), inpatient hospitals may report the charges associated with the various steps for the collection and preparation of the CAR T-cells on the inpatient claim separately using revenue codes 0871, 0872, or 0873.

Alternatively, the hospital may include the charges for these various steps in the charge reported for the CAR T-Cell therapy using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified Cell Therapy.

When the CAR T-cells are collected in the hospital outpatient setting and the CAR T-cell is administered in the hospital inpatient setting, inpatient providers should report the date that the CAR-T administration took place and not the date the cells were collected.

Sources: MLN Matters®. Chimeric Antigen Receptor (CAR) T-Cell Therapy Revenue Code and HCPCS Setup Revisions SE19009. Article Release Date: March 17, 2022. Medicare Claims Processing Manual, Chapter 32, Section 400 - Chimeric Antigen Receptor (CAR) T-cell Therapy,

Inpatient CAR T-cell therapy services

Revenue Code	Revenue Code Description
0871	Cell/Gene Therapy – Cell Collection
0872	Cell/Gene Therapy – Specialized Biologic Processing and Storage - Prior to Transport
0873	Cell/Gene Therapy – Storage and Processing after Receipt of Cells from Manufacturer
0874	Cell/Gene Therapy – Infusion of Modified Cells
0891	Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy

When CAR T-cell therapies are administered in the inpatient setting, the hospital reports CAR T-Cell therapy using revenue code 0891 – Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified Cell Therapy) with HCPCS code Q2041.

Payment for the various steps required to collect and prepare CAR T-cell is included in payment for the CAR T-Cell.

Although HCPCS codes are not typically used on inpatient claims, the National Uniform Billing Committee (NUBC) allows drug and biologic HCPCS codes on inpatient claims. Fallon Health requires HCPCS codes on claims for CAR T-cell therapy along with revenue code 0891.

Outpatient CAR T-cell Services

For Tecartus cell infusion use revenue code 0874 with CPT 38228.

For Tecartus product charges use revenue code 0891 with HCPCS code Q2043.

For cell harvesting, storage, and preparation use revenue codes 0871, 0872, or 0873, with CPT codes 38225, 38226 and 38227 respectively. These services are non-payable.

Revenue Code	Revenue Code Description	CPT/HCPCS Code	CPT/HCPCS Code Description
0871	Cell/Gene Therapy – Cell Collection	38225	Chimeric antigen receptorTt-cell (CAR T) therapy; harvest of blood-derived T lymphocytes for development of genetically modified autologous CAR T cells, per day
0872	Cell/Gene Therapy – Specialized Biologic Processing and Storage - Prior to Transport	38226	Chimeric antigen receptor T-cell (CAR T) therapy; preparation of blood-derived T lymphocytes for transportation (eg, cryopreservation, storage)

0873	Cell/Gene Therapy – Storage and Processing after Receipt of Cells from Manufacturer	38227	Chimeric antigen receptor T-cell (CAR T) therapy; receipt and preparation of CAR T cells for administration
0874	Cell/Gene Therapy – Infusion of Modified Cells	38228	Chimeric antigen receptor T-cell (CAR T) therapy; CAR T cell administration, autologous
0891	Special Processed Drugs – FDA (U.S. Food and Drug Administration) Approved Cell Therapy – Charges for Modified cell therapy	Q2043	Brexucabtagene autoleucel, up to 200 million autologous anti-CD19 car positive viable T cells, including leukapheresis and dose preparation procedures, per therapeutic dose

References

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Policy history

Origination date:	08/01/2024
Approval(s):	Technology Assessment Committee: 05/28/2024 (introduced as a new policy), 07/22/2025 (annual review, under Policy, added information about the FDA elimination of the Tecartus REMS on June 26, 2025, added new sections for Medicare and MassHealth Variation). Utilization Management Committee: 08/19/2025 (annual review, approved with no changes to coverage criteria).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity 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.

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