Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Tecelra® (afamitresgene autoleucel)

Effective: January 1 ,2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Synovial sarcoma is a rare, but aggressive type of soft tissue sarcoma with a high potential for metastasis. Synovial sarcoma originally received its name from a histologic similarity to synovial cells, however its cell of origin is unknown. Although the cause of synovial sarcoma is not yet clearly defined, tumor cells in more than 90% of patients have a translocation involving chromosome 18 and chromosome X. Synovial sarcoma accounts for 5% to 10% of soft tissue sarcoma cases diagnosed annually in the United State. The incidence is estimated to be 900 new cases a year in the United States. Although synovial sarcoma can appear at any age, it appears to occur more commonly in adolescents and adults younger than forty. It is considered the most common sarcoma in the adolescent age group. The majority of synovial sarcomas are slow growing and the average duration of symptoms before diagnosis is approximately 2 years. While most patients initially present with localized disease, approximately half of these patients will progress to metastatic synovial sarcoma, which is usually incurable.

Synovial Sarcoma can occur anywhere in the body, however in many cases, synovial sarcoma begins from deep soft tissues of extremities such as the leg, arm, or foot, and near joints such as the knee and ankle. Synovial sarcoma typically appears with a mass, often deep-seated, growing with or without pain. Due to the diverse locations and symptoms of tumors, their gradual onset, and the fact that they often appear in younger patients, initial clinical misdiagnosis is possible. Treatment is dependent on the location, grade, and stage. Local tumors can typically be treated with surgery. Treatments for metastatic synovial sarcoma include chemotherapy and targeted therapy. T-cell receptor (TCR) gene therapy is an advanced form of immunotherapy designed to treat certain types of cancer. TCR gene therapy uses genetically modified lymphocytes that are directed against specific tumor markers.

Food and Drug Administration (FDA) Approved Indications:

- Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

Following treatment with Tecelra, monitor patients for at least 7 days at the healthcare facility for cytokine release syndrome (CRS). Continue to monitor patients for CRS for at least 4 weeks following treatment with Tecelra. Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, immediately evaluate patient for hospitalization and

institute treatment with supportive care. Ensure that healthcare providers administering Tecelra have immediate access to medications and resuscitative equipment to manage CRS.

NOTE: Tecelra can only be administered at a Tecelra Authorized Treatment Center (ATC). For information on locating an Authorized Treatment Center, please go to https://www.tecelra.com/atc

NOTE: Avoid prophylactic systemic corticosteroids, as it may interfere with the activity of TECELRA.

Clinical Guideline Coverage Criteria

The Plan may cover Tecelra for Members aged 18 years or over when **all** the following clinical criteria is met:

1. The Member is 18 years of age or over.

AND

2. Documentation supports that the Member has a diagnosis of inoperable or metastatic synovial sarcoma

AND

3. Documentation of Eastern Oncology Cooperative Group (ECOG) performance status of 0 or 1.

AND

4. The Member has measurable disease according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST)[8].

AND

5. Documentation of HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive tumor.

AND

6. Tumor expresses MAGE-A4 antigen as verified by an FDA-approved or cleared companion diagnostic device.

AND

7. The Member is not heterozygous or homozygous for HLA-A*02:05P positive.

AND

8. Documentation of prior chemotherapy regimen containing either anthracycline (e.g., doxorubicin, daunorubicin, epirubicin and idarubicin) or an ifosfamide.

AND

9. The Member has adequate organ function including bone marrow, cardiac, pulmonary, and neurological with no anticipated decline in organ function in close proximity to apheresis timeframe.

AND

10. The Member has no untreated active systemic infection (e.g., viral, bacterial, fungal) including HIV, active hepatitis B or active hepatitis C. Screening must be completed at the time of leukapheresis.

AND

11. Tecelra will be administered at an Authorized Treatment Center.

Limitations

- Tecelra is contraindicated in pregnancy
- If the Member is receiving systemic corticosteroids or any immunosuppressive therapy, treatment must be discontinued prior to Tecelra therapy.
- Members with untreated underlying primary immunodeficiency syndromes will not be approved for Tecelra therapy.
- Authorization of Tecelra or a genetically-modified T-cell receptor immunotherapy is limited to one single dose treatment.
- Members who have had prior treatment with Tecelra or any form of genetically-modified T-cell receptor immunotherapy, including therapies in clinical trial settings, will not be approved for an additional course of treatment with Tecelra or a genetically-modified T-cell receptor immunotherapy.
- Tecelra will not be covered if the Member demonstrates clinical decompensation from time of authorization to time of infusion and no longer meets clinical coverage criteria.
- Any indications for Tecelra other than those outlined above are considered investigational and will not be covered.

ECOG Performance Status

0: Fully active, no restrictions on activities. A performance status of 0 means no restrictions in the sense that someone is able to do everything they were able to do prior to their diagnosis.

1: Unable to do strenuous activities, but able to carry out light housework and sedentary activities. This status basically means you can't do heavy work but can do anything else. 5 Modified T-Cell Therapies

2: Able to walk and manage self-care, but unable to work. Out of bed more than 50% of waking hours. In this category, people are usually unable to carry on any work activities, including light office work.

3: Confined to bed or a chair more than 50 percent of waking hours. Capable of limited selfcare.
4: Completely disabled. Totally confined to a bed or chair. Unable to do any self-care.
5: Death

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
Q2057	Afamitresgene Autoleucel, Including Leukapheresis And Dose Preparation Procedures, Per Therapeutic Dose

References:

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3. Aytekin MN, Öztürk R, et. al. Epidemiology, incidence, and survival of synovial sarcoma subtypes: SEER database analysis. J Orthop Surg (Hong Kong). 2020 Jan-Apr;28(2):2309499020936009. doi: 10.1177/2309499020936009. PMID: 32618221.
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10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Soft Tissue Sarcoma (Version 1.2025. May 2, 2025. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf, Accessed September 25, 2025.
11. Kucharczyk M, Hatipoglu E, Jones RL, Huang PH. Adoptive T-Cell Therapy in Sarcomas. Curr Oncol Rep. 2025 Aug 14. doi: 10.1007/s11912-025-01706-x. Epub ahead of print. PMID: 40810970.
12. Parums DV. A Review of CAR T Cells and Adoptive T-Cell Therapies in Lymphoid and Solid Organ Malignancies. Med Sci Monit. 2025 Feb 2;31:e948125. doi: 10.12659/MSM.948125. PMID: 39893510; PMCID: PMC11800685.
13. Second and later lines of therapy for metastatic soft tissue sarcoma. UpToDate.com/login [via subscription only]. Published October 04, 2024. Updated August 2025. Accessed September 25, 2025.

Approval And Revision History

March 19, 2025: Reviewed by the Medical Policy Approval Committee (MPAC), effective April 1, 2025.

Subsequent endorsement date(s) and changes made:

- November 19, 2025: Reviewed by MPAC for annual review, renewed without changes, references updated, effective January 1, 2026
- December 2025: Administrative updates effective January 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better

understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.