Mass General Brigham
Health Plan

# Medical Policy
# Tecelra (afamitresgene autoleucel)

**Policy Number: 087**

| | Commercial and Qualified Health Plans | MassHealth | Medicare Advantage |
|---|---|---|---|
| Authorization Required | X | X | X |
| No Prior Authorization | | | |

**Overview**
Tecelra is an autologous T-cell receptor (TCR) gene therapy for treatment of metastatic or inoperable synovial sarcoma.

**FDA-Approved Indication**
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.

**Criteria**
1. Criteria for Initial Approval
   Authorization may be granted with ALL of the following criteria are met:
   a. Age 16 or older; and
   b. Diagnosis of advanced (metastatic or inoperable) synovial sarcoma; and
   c. Previously received chemotherapy; and
   d. Has measurable disease according to RECIST v1.1; and
   e. Is human leukocyte antigen (HLA) positive for HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, and/or HLA-A*06P; and
   f. Tumor shows melanoma-associated antigen A4 (MAGE-A4) expression; and
   g. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1; and
   h. Fit for leukapheresis and adequate venous access can be established for the cell collection; and
   i. Has adequate organ function.
2. Dosage and administration
   a. The recommended dose is between $2.68 \times 10^9$ to $10 \times 10^9$ MAGE-A4 T cell receptor (TCR) positive T cells.

**Exclusions**
1. Hetero-/homozygous for HLA-A*02:05P
2. Uncontrolled intercurrent illness
3. Unwilling to use effective contraception or is pregnant or breastfeeding
4. Has been previously treated with Tecelra

**MassHealth Variation**
Prior authorization requests for Tecelra for Mass General Brigham ACO members should be submitted to the MassHealth Drug Utilization Review Program. Criteria for Tecelra are found in Table 75: T-Cell Immunotherapies.

**Medicare Variation**
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare does not have any NCDs or LCDs for T-cell receptor therapy.**

**Codes**

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

**This list of codes applies to Commercial and MassHealth lines of business.**

| Authorized Code | Code Description |
|---|---|
| Q2057 | Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose |

**Summary of Evidence**
The evidence establishes afamitresgene autoleucel (Tecelra, afami-cel) as a promising therapeutic option for advanced MAGE-A4+ synovial sarcoma. Building on the foundational phase 1 study by Hong et al. (2023) that established safety and preliminary efficacy across multiple solid cancer types, the pivotal, single-arm, phase 2 SPEARHEAD-1 trial (D'Angelo 2024) evaluated afami-cel in heavily pretreated HLA-A*02+ patients with unresectable or metastatic synovial sarcoma or myxoid round cell liposarcoma that expressed MAGE-A4. In this study, overall response rate was 37% (39% for synovial sarcoma) and median overall survival was 15.4 months. Cytopenias and cytokine release syndrome were common adverse events. Afami-cel was added to the NCCN guideline on soft tissue sarcoma as a therapy that is "useful in certain circumstances" for the treatment of synovial sarcomas only. Additional phase 2 trials are ongoing to evaluate afami-cel for the treatment of head/neck cancer and for use in certain pediatric cancers, but published data on safety/efficacy are not yet available for these indications. MGB Health Plan considers afami-cel to be medically necessary for members who meet criteria based on the inclusion criteria of the pivotal SPEARHEAD-1 trial.

**Effective**
April 2025: Ad hoc review. MassHealth variation updated to include new prior authorization process. Code updated.
March 2025: Ad hoc review. Added summary of evidence.
February 18, 2025: Effective Date.

**References**
D'Angelo SP, Araujo DM, Abdul Razak AR, et al. Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD-1): an international, open-label, phase 2 trial. Lancet. 2024 Apr 13;403(10435):1460-1471. doi: 10.1016/S0140-6736(24)00319-2. Epub 2024 Mar 27. PMID: 38554725; PMCID: PMC11419333.

Dietrich J, Frigault MJ. Immune effector cell-associated neurotoxicity syndrome (ICANS). In: UpToDate, Eichler AF (Ed), Wolters Kluwer. (Accessed on December 3, 2024)

George S, Abdul Razak AR. Second and later lines of therapy for metastatic soft tissue sarcoma. In: UpToDate, Yushak M (Ed), Wolters Kluwer. (Accessed on December 3, 2024)

Hayes, Inc. Emerging Technology Report. Afamitresgene Autoleucel (Tecelra; Adaptimmune LLC) for Advanced Synovial Sarcoma. Hayes, Inc.; August 6, 2024.

Hong DS, Van Tine BA, Biswas S, et al. Autologous T cell therapy for MAGE-A4+ solid cancers in HLA-A*02+ patients: a phase 1 trial. Nat Med. 2023 Jan;29(1):104-114. doi: 10.1038/s41591-022-02128-z. Epub 2023 Jan 9. PMID: 36624315; PMCID: PMC9873554.

National Comprehensive Cancer Network (NCCN). Soft tissue sarcoma. NCCN Clinical Practice Guidelines in Oncology, Version 4.2024: November 21, 2024. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed 1/13/25.

Tecelra [package insert]. Philadelphia, PA: Adaptimmune, LLC; 2024.