Mass General Brigham
Health Plan

Medical Policy
Tecelra (afamitresgene autoleucel)

Policy Number: 087

Contents

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.

Medicare Variation

Prior Authorization Required	Yes ☒ No ☐

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity 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 medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare had:**

- **Medicare Benefit Policy Manual Chapter 15: Covered Medical and Other Health Services**

When CMS documentation references FDA labeling, Mass General Brigham Health Plan develops coverage criteria to clarify medical necessity of the requested services. Mass General Brigham Health Plan coverage criteria align with FDA labeling without contradicting existing determinations and enhance the clarity of medical necessity requirements, documentation requirements, and clinical indications.

Criteria

1. Criteria for Initial Approval
   Authorization may be granted with ALL of the following criteria are met:
   a. Age 18 or older; and
   b. Diagnosis of advanced (metastatic or inoperable) synovial sarcoma; and
   c. Previously received chemotherapy; and
   d. 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
   e. Tumor shows melanoma-associated antigen A4 (MAGE-A4) expression.
2. Dosage and administration
   a. The recommended dose is between 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T cell receptor (TCR) positive T cells.

Exclusions

1. Hetero-/homozygous for HLA-A*02:05P
2. Previously treated with Tecelra.

Mass General Brigham ACO Variation

Prior Authorization Required	Yes ☒ No ☐

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.

One Care and Senior Care Options Variation

Prior Authorization Required	Yes ☒ No ☐

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, or the member does not meet the medical necessity criteria for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. **See Medicare Advantage criteria and exclusions, above. If Medicare Advantage criteria are not met, then MassHealth criteria are applied.**

Commercial and Qualified Health Plans Variation

Prior Authorization Required	Yes ☒ No ☐

Prior authorization for Tecelra for Commercial and Qualified Health Plan members is managed by Prime Therapeutics. See the Prime Therapeutics policy for Tecelra for more information.

Codes

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

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 Dates

May 2026: Annual review. Changed policy format. Simplified criteria, but increased age of eligibility. Clarified hierarchy of criteria in One Care and SCO variation. Updated references.
January 2026: Ad hoc review. Updated prior authorization table and added variation for One Care and SCO members. Fixed code disclaimer.
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.

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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 1.2026: January 16, 2026.
https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.

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