

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 2.68×10^9 to 10×10^9 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

Mass General Brigham Health Plan uses the [MassHealth Drug List](#) for coverage determinations for members of the MGB ACO. 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
J3590	Unclassified biologics

Effective

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.

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

