Medical Drug Clinical Criteria

Subject:	Tecelra (afamitresgene autoleucel)		
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Overview

This document addresses the use of Tecelra (afamitresgene autoleucel). Tecelra (afamitresgene autoleucel) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy FDA 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.

MAGE-A4 is an intracellular cancer-testis antigen with limited expression in normal tissues and is found in synovial sarcoma. Tecelra, when activated by the TCR-peptide-HLA-A02 complex, induces T cell proliferation, cytokine release, and the destruction of MAGE-A4/HLA-A02 expressing synovial sarcoma cells.

The recommended dose is between 2.68 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T cells administered as a single intravenous infusion per lifetime. Currently, this is the only MAGE-A4-directed autologous T-cell immunotherapy in synovial sarcoma. Prior to the approval of Tecelra, patients with synovial sarcoma only had chemotherapy as subsequent treatment options.

Tecelra has a black box warning for Cytokine Release Syndrome (CRS), which may be severe or life-threatening.

NCCN also provides a 2A recommendation for Tecelra in palliative treatment as a single agent (useful in certain circumstances) as subsequent lines of therapy for advanced/metastatic disease with disseminated metastases (synovial sarcomas only) and HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P or HLA-A*02:06P positive and whose tumor expresses the MAGE-A4 antigen.

Definitions and Measures

Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Hematopoietic stem cells: Primitive cells capable of replication and formation into mature blood cells in order to repopulate the bone marrow.

Line of Therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.

Melanoma: A type of cancer that begins in the melanocytes. Melanoma is also referred to as malignant melanoma and cutaneous melanoma.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

One line of therapy: Single line of therapy.

Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Unresectable: Unable to be removed with surgery.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tecelra (afamitresgene autoleucel)

Requests for Tecelra (afamitresgene autoleucel) may be approved if the following criteria are met:

I. Individual has a diagnosis of unresectable or Stage IV synovial sarcoma (Label, NCCN 2A); **AND**
II. Individual is 18 years of age or older; **AND**
III. Individual must be ALL of the following:
    A. Human Leukocyte Antigen (HLA)-A*02:01P, -*A02:02P, -A*02:03P, or -A02:06P positive; **AND**
    B. MAGE-A4 antigen positive; **AND**

IV. Individual must have progressed following ≥1 prior systemic chemotherapy; **AND**
V. Individual must have an Eastern Cooperative Oncology Group Performance Status of 0-1; **AND**
VI. Individual is using as a one-time, single administration dose per lifetime.

Requests for Tecelra (afamitresgene autoleucel) may not be approved for the following:

I. Repeat administration; **OR**
II. Individual is heterozygous or homozygous for HLA-A*02:05P positive; **OR**
III. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose [Tecelra]

ICD-10 Procedure

XW03368	Introduction of Afamitresgene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 8 [Tecelra]
XW04368	Introduction of Afamitresgene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 8 [Tecelra]

ICD-10 Diagnosis

C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system
C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue
Z85.831	Personal history of malignant neoplasm of soft tissue

Document History

Reviewed: 08/15/2025
Document History:

- 08/15/2025 – Annual Review: No criteria changes. Added references. Coding Reviewed: Added ICD-10-CM C47.0-C47.9.
- 03/04/2025 – Coding Update: Removed HCPCS NOC C9399, J9999, and all diagnosis pend for Tecelra. Added HCPCS Q2057 effective 4/1/25. Added ICD-10-CM C48.0-C48.8, C49.0-C49.9, Z85.831.
- 09/09/2024 – Select Review: New criteria document for Tecelra (afamitresgene autoleucel). Coding Reviewed: New criteria document. Added HCPCS C9399, J9999. Added ICD-10-PCS XW03368, XW04368. All diagnosis pend for NOC codes.

References

1. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
3. Clinicaltrials.gov. Afamitresgene. National Library of Medicine. August 5, 2024. Available at: https://clinicaltrials.gov/search?intr=afamitresgene. Accessed July 2, 2025.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 2, 2025.
    a. Soft Tissue Sarcoma. V1.2025. Revised May 2, 2025.
5. Tecelra (afamitresgene autoleucel) for intravenous infusion [prescribing information]. Philadelphia, PA. Adaptimmune; August 2024. Available at: https://www.fda.gov/media/180565/download?attachment. Accessed July 2, 2025.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.