Tecelra (afamitresgene autoleucel)

Humana
Medicaid Medical Coverage Policy

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Line of Business: Medicaid
State(s): SC

Table of Contents

Description

Soft tissue sarcoma (STS) refers to a diverse group of malignant tumors that develop in the connective tissues responsible for supporting and connecting other structures in the body. These tissues include blood vessels, fat, muscle, lymph vessels, nerves, tendons and the lining of joints.[3] There are numerous STS histologic subtypes with distinct prognoses, treatment responses, clinical profiles and molecular alterations. A subtype of STS, synovial sarcoma (SS) typically manifests as a soft tissue tumor of the limbs in young adults and carries a high risk of lymph node metastases.[7] It accounts for 5% to 10% of STS cases diagnosed annually in the United States (US) and most frequently in adolescents and adults less than 30 years of age.[3] Although these aggressive tumors initially respond to chemotherapy, outcomes remain poor once metastasis occurs. Observational studies indicate that the 5-year survival rate for an individual with metastatic synovial sarcoma remains low.[2]

Melanoma-associated antigen A4 (MAGE-A4) is a member of the MAGE protein group of cancer/testis antigens, with expression in healthy tissue restricted to immune-privileged sites. MAGE-A4 is expressed in a range of solid tumors, including gastroesophageal, head and neck squamous cell carcinoma, melanoma, myxoid/round cell liposarcoma, non-small-cell lung cancer, ovarian, synovial sarcoma and urothelial cancers.[5] Chemotherapy regimens are used to treat metastatic disease, but new treatments are needed to improve the prognosis of an individual with metastatic or inoperable synovial sarcoma. **Tecelra (afamitresgene autoleucel)** is an engineered T-cell receptor (TCR) gene therapy proposed to address this need.[3]

Tecelra (afamitresgene autoleucel) is a MAGE-A4–directed, genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have previously received chemotherapy, human leukocyte antigen (HLA) HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P or HLA-A*02:06P positive and whose tumors express the MAGE-A4 antigen. This indication was granted accelerated approval based on overall response rate and duration of response.[9]

Requests for Tecelra (afamitresgene autoleucel) *require review by a medical director*.

Coverage Determination

Refer all requests or questions regarding Tecelra to the Corporate Transplant Department.

Phone	Fax	Email
1-866-421-5663	502-508-9300	transplant@humana.com

Humana members may be eligible under the Plan for **Tecelra (afamitresgene autoleucel), single dose** for the following indications[9]:

- Absence of limitations; **AND**
- Individual is 18 years of age and over**; AND**
- Individual has unresectable or metastatic synovial sarcoma **and ALL** the following:
  - Has received prior chemotherapy; **AND**
  - HLA-A*02:01P, -A*02:02P, -A*02:03P or -A*02:06P positive; **AND**
  - Tumor expresses the MAGE-A4 antigen; **AND**
- Individual will receive 1 dose per lifetime

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Tecelra (afamitresgene autoleucel)** for any indications other than those listed above including, but may not be limited to[9]:

- Individual is heterozygous or homozygous for HLA-A*02:05P; **OR**
- Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception; **OR**
- Individual is pregnant or breastfeeding

A review of the current medical literature shows that there is **no evidence** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
38999	Unlisted procedure, hemic or lymphatic system	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose	
ICD-10-PCS Code(s)	**Description**	**Comments**
XW03368	Introduction of Afamitresgene Autoleucel Immunotherapy into Peripheral Vein, Percutaneous Approach, New Technology Group 8	
XW04368	Introduction of Afamitresgene Autoleucel Immunotherapy into Central Vein, Percutaneous Approach, New Technology Group 8	

References

1. ClinicalKey. Drug Monograph. Afamitresgene autoleucel. https://clinicalkey.com. Updated July 10, 2025.

2. 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;403(10435):1460-1471.

3. Hayes, Inc. Emerging Technology Report. Afamitresgene autoleucel (Tecelra; Adaptimmune LLC) for advanced synovial sarcoma. https://evidence.hayesinc.com. Published August 6, 2024.

4. He K, Hong DS, Ke D, et al. Durable control of metastases in an HLA-A2+ patient with refractory melanoma after low-dose radiotherapy in combination with MAGE-A4 T cell therapy: a case report. *Melanoma Res*. 2023;33(4):332-337.

5. 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;29(1):104-114.

6. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Soft tissue sarcoma. https://nccn.org. Updated May 2, 2025.

7. UpToDate, Inc. Clinical presentation, diagnostic evaluation, and staging of soft tissue sarcoma. https://uptodate.com. Updated June 2025.

8. UpToDate, Inc. Second and later lines of therapy for metastatic soft tissue sarcoma. https://uptodate.com. Updated June 2025.

9. US Food & Drug Administration (FDA). Full prescribing information: Tecelra (afamitresgene autoleucel). https://www.fda.gov. Published August 2024.

Change Summary

01/01/2025 New Policy.
09/02/2025 Annual Review, Coverage Change.