Tecelra (afamitresgene autoleucel)

INDEPENDENT CARE HEALTH PLAN

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Policy Number: WI.PA-1267
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

There are no NCDs/LCDs/LCAs for **Tecelra (afamitresgene autoleucel)**.

Description

Soft tissue sarcoma (STS) is a heterogenous (varied) group of solid malignant tumors that arise from the connective tissues that support other tissues and organs in the body. These tissues include muscle, fat, blood vessels, 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.[6]

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.[6] 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] Despite initial sensitivity to chemotherapy, these aggressive tumors tend to have very poor outcomes once they metastasis with observational studies showing that 5-year survival for individuals with metastatic SS 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 solid cancers, including SS, myxoid/round cell liposarcoma, non-small-cell lung cancer, head and neck squamous cell carcinoma and ovarian, urothelial, melanoma and gastroesophageal cancers.[5] Chemotherapy regimens are used to treat metastatic disease, but new treatments are needed to improve the prognosis of individuals 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 received an expedited approval from the US Food and Drug Administration (FDA) for the treatment of SS individuals who are human leukocyte antigen (HLA) HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive, have a tumor that expresses MAGE-A4, and have previously received chemotherapy.[8] This MAGE-A4 directed genetically modified autologous T cell immunotherapy is indicated for the treatment of adults with unresectable or metastatic synovial sarcoma.[10]

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

Coverage Determination

iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

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

Tecelra will be considered medically reasonable and necessary when the following indications are met:

- Absence of limitations; **AND**
- Individual is 18 years of age and over[10]**; AND**

- Individual has unresectable or metastatic synovial sarcoma **and ALL** of the following[10]:
    - Has received prior chemotherapy; **AND**
    - HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive; **AND**
    - Whose tumor expresses the MAGE-A4 antigen; **AND**
- Individual has adequate organ function[2]**; AND**
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 with and an estimated life expectancy of greater than or equal to 6 months[2]

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to, cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, prolonged severe cytopenia and infections[10]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Tecelra will not be considered medically reasonable and necessary if the following are present:

- Individual is heterozygous or homozygous for HLA-A*02:05P[10]; **OR**
- Individual has clinically significant and active bacterial, fungal, parasitic, severe concomitant diseases or viral infection including hepatitis B or C (HBV, HCV), human immunodeficiency virus (HIV) or human T cell leukemia virus (HTLV)[2]; **OR**
- Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception[10]; **OR**
- Individual is pregnant or breastfeeding[10]; **OR**
- Other prior malignancy not in remission[2]; **OR**
- Symptomatic central nervous system (CNS) metastases including leptomeningeal disease[2]

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 (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

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**
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://www.clinicalkey.com. Updated August 21, 2024.

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. UpToDate, Inc. Clinical presentation, diagnostic evaluation, and staging of soft tissue sarcoma. https://www.uptodate.com. Updated July 2024.

7. UpToDate, Inc. Second and later lines of therapy for metastatic soft tissue sarcoma. https://www.uptodate.com. Updated August 2024.

8. UpToDate, Inc. What's new in drug therapy. https://www.uptodate.com. Updated August 2024.

9. UpToDate, Inc. What's new in oncology. https://www.uptodate.com. Updated August 2024.

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

Appendix

ECOG performance status

Grade	ECOG
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 (e.g., light housework, office work)
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

Change Summary

09/24/2024 New Policy.