Corporate Medical Policy: Afamitresgene autoleucel (Tecelra®) **"Notification"** **POLICY EFFECTIVE APRIL 1, 2026**

Restricted Product(s):

- afamitresgene autoleucel (Tecelra®) intravenous infusion for administration by a healthcare professional

FDA Approved Use:

- 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 for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient has a diagnosis of **unresectable or metastatic synovial sarcoma [medical record documentation required]**; **AND**
3. The patient is human leukocyte antigen (HLA)-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive **[medical record documentation required, including lab results]**; **AND**
4. The patient's tumor expresses the melanoma-associated antigen A4 (MAGE-A4) antigen **[medical record documentation required, including lab results]**; **AND**
5. The patient has experienced disease progression following treatment with at least one prior systemic chemotherapy (e.g., doxorubicin, ifosfamide) **[medical record documentation required]**; **AND**
6. The patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 **[medical record documentation required]**; **AND**
7. The patient is NOT heterozygous or homozygous for HLA-A*02:05P **[medical record documentation required, including lab results]**; **AND**
8. The patient has NOT had a prior allogeneic hematopoietic stem cell transplant (HSCT) **[medical record documentation required]**; **AND**
9. The patient has NOT previously received genetically modified T cell therapy or afamitresgene autoleucel (Tecelra) **[medical record documentation required]**; **AND**
10. The patient has received or will receive a lymphodepleting chemotherapy regimen of fludarabine 30 mg/m^2/day intravenously (IV) for 4 days and cyclophosphamide 600 mg/m^2/day IV for 3 days, each starting on the seventh day prior to infusion with afamitresgene autoleucel (Tecelra) **[medical record documentation required]**; **AND**

11. The patient will NOT be treated with more than 10 x 10^9 MAGE-A4 T cell receptor (TCR)-positive T cells **[medical record documentation required]**; **AND**
12. The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
13. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

Duration of Approval: 180 days (one-time, single-dose treatment per lifetime)

Please note, for certain identified gene and cellular therapies such as afamitresgene autoleucel (Tecelra®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
afamitresgene autoleucel (Tecelra®) intravenous (IV) infusion	Unresectable or metastatic synovial sarcoma in adults 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	Recommended dosing between 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T cell receptor (TCR) positive T cells, as a single IV infusion	Q2057	**1**

***Maximum units allowed for duration of approval**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

1. 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.

2. Sanderson JP, Crowley DJ, Wiedermann GE, et al. Preclinical evaluation of an affinity-enhanced MAGE-A4-specific T-cell receptor for adoptive T-cell therapy. *Oncoimmunology*. 2019 Nov;9(1):1682381.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q3 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
April 2025: Coding change: Added HCPCS code Q2057 to dosing reference table effective 4/1/2025; deleted C9399, J3490, J3590, and J9999 termed 3/31/2025.
October 2024: Original medical policy criteria issued.