

Title: Tecelra (afamitresgene autoleucel)	Division: Medical Management Department: Utilization Management
Approval Date: 9/29/2026	LOB: Medicaid, SNP, HARP, CHP, QHP, EP, Gold, Goldcare, Medicare, Ultracare
Effective Date: 9/29/2026	Policy Number: UM-MP358
Review Date: 9/29/2027	Cross Reference Number:
Retired Date:	

1. POLICY DESCRIPTION:

Melanoma-Associated Antigen A4 (MAGE-A4) Directed T-Cell Immunotherapy - Tecelra (afamitresgene autoleucel)

2. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

3. DEFINITIONS:

Tecelra is a MAGE-A4 directed T-cell immunotherapy. Patients must express positive antigen results for HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P and tumor must express the MAGE-A4 antigen. The T-cell receptor has an enhanced affinity for the MAGE-A4 antigen and recognizes an HLA-A*02 restricted MAGE-A4 peptide that results in T-cell proliferation, cytokine secretion, and killing of MAGE-A4-HLA-A*02 expressing synovial sarcoma cells.

4. POLICY:

Tecelra will be considered medically necessary once the following coverage criteria is met. Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

INITIAL REQUEST:

1. Unresectable or Metastatic, Relapsed or Refractory, Synovial Sarcoma:

A. Member must be ≥ 18 years of age and ≤ 75 years of age;

AND

B. Member must have a diagnosis of ONE of the following:

a. Unresectable or metastatic synovial sarcoma;

OR

b. Relapsed or refractory synovial sarcoma;

AND

C. Prescribed by or in consultation with an board-certified oncologist;

AND

D. Tumor expresses MAGE-A4 confirmed by ONE of the following:

- a. Immunohistochemistry (IHC) that shows MAGE-A4 expression of $\geq 2+$ staining in $\geq 30\%$ of the cells;

OR

- b. Biopsy;

AND

- E. Member is positive for ONE of the following antigen results:

- a. HLA-A*02:01P;

OR

- b. HLA-A*02:02P;

OR

- c. HLA-A*02:03P;

OR

- d. HLA-A*02:06P;

AND

- F. Member must not have HLA-A*02:05P in either allele (heterozygous or homozygous);

AND

- G. Member must have received a previous treatment regimen with either an anthracycline or ifosfamide containing regimen;

AND

- H. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1;

AND

- I. Member must have left ventricular ejection fraction (LVEF) $\geq 50\%$;

AND

- J. Member must have glomerular filtration rate (GFR) ≥ 60 ml/min;

AND

- K. Member must not have received allogeneic hematopoietic stem cell transplant;

AND

- L. Member must not have received or plans on receiving the following therapy/treatments prior to leukapheresis or lymphodeleting chemotherapy;

- a. Cytotoxic chemotherapy (3 week washout period);

AND

- b. Tyrosine kinase inhibitor (e.g. pazopanib, 1 week washout period);

AND

- c. Immune therapy (e.g. monoclonal antibody therapy, checkpoint inhibitors, 4 week washout period);

AND

- d. Anti-cancer vaccine gene therapy using an integrating vector (8 week washout period);

AND

- e. Corticosteroids or any other immunosuppressive therapy (2 week washout period);

AND

- M. Member must not have ANY of the following:

- a. History of allergic reactions to similar or biologic composition to fludarabine and cyclophosphamide;

AND

- b. History of autoimmune or immune-mediated disease;
AND
 - c. Active, symptomatic central nervous system (CNS) metastases including leptomeningeal disease;
AND
 - d. Other prior malignancy that is not in complete remission;
AND
 - e. Underlying or current uncontrolled medical conditions that include but are not limited to infection, heart failure, or pulmonary hypertension that would interfere with treatment;
AND
 - f. Active infection such as human immunodeficiency virus, hepatitis B virus, hepatitis C virus, or human T-cell leukemia virus;
- AND**
- N. Member must not be pregnant or breastfeeding;
AND
 - O. Member has not received Tecelra or any other gene therapy previously.

Initial Duration of Approval: *One-time infusion per lifetime.*

RENEWAL REQUEST:

Tecelra will not be renewed for additional requests as this is a one-time therapy.

Renewal Duration of Approval: *Not Applicable*

5. LIMITATIONS/ EXCLUSIONS:

Tecelra will be considered experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C38.0	Malignant Neoplasm Of Heart
C38.1	Malignant Neoplasm Of Anterior Mediastinum
C38.2	Malignant Neoplasm Of Posterior Mediastinum
C38.3	Malignant Neoplasm Of Mediastinum, Part Unspecified
C38.4	Malignant Neoplasm Of Pleura
C38.8	Malignant Neoplasm Of Overlapping Sites Of Heart, Mediastinum And Pleura
C48.1	Malignant Neoplasm Of Specified Parts Of Peritoneum
C48.2	Malignant Neoplasm Of Peritoneum, Unspecified
C48.8	Malignant Neoplasm Of Overlapping Sites Of Retroperitoneum And Peritoneum
C49.0	Malignant Neoplasm Of Connective And Soft Tissue Of Head, Face And Neck

C49.10	Malignant Neoplasm Of Connective And Soft Tissue Of Unspecified Upper Limb, Including Shoulder
C49.11	Malignant Neoplasm Of Connective And Soft Tissue Of Right Upper Limb, Including Shoulder
C49.12	Malignant Neoplasm Of Connective And Soft Tissue Of Left Upper Limb, Including Shoulder
C49.20	Malignant Neoplasm Of Connective And Soft Tissue Of Unspecified Lower Limb, Including Hip
C49.21	Malignant Neoplasm Of Connective And Soft Tissue Of Right Lower Limb, Including Hip
C49.22	Malignant Neoplasm Of Connective And Soft Tissue Of Left Lower Limb, Including Hip
C49.3	Malignant Neoplasm Of Connective And Soft Tissue Of Thorax
C49.4	Malignant Neoplasm Of Connective And Soft Tissue Of Abdomen
C49.5	Malignant Neoplasm Of Connective And Soft Tissue Of Pelvis
C49.6	Malignant Neoplasm Of Connective And Soft Tissue Of Trunk, Unspecified
C49.8	Malignant Neoplasm Of Overlapping Sites Of Connective And Soft Tissue
C49.9	Malignant Neoplasm Of Connective And Soft Tissue, Unspecified

8. REFERENCES:

1. Tecelra intravenous infusion [prescribing information]. Philadelphia, PA: Adaptimmune; August 2024.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 17, 2026. Search term: afamitresgene.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 5.2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on August 17, 2026.
4. ClinicalTrials.gov. NCT04044768. Spearhead 1 Study in Subjects With Advanced Synovial Sarcoma or Myxoid/Round Cell Liposarcoma. Last updated August 26, 2026. Accessed September 10, 2026. <http://clinicaltrials.gov>.
5. UpToDate. Clinical presentation, diagnostic evaluation, and staging of soft tissue sarcoma. Ryan, Christopher Meyer, Janelle. Last updated July 2025. Accessed September 10, 2026. <http://www.uptodate.com>
6. IPD Analytics. ICD-10-CM CODES.

9. REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	JL	9/29/2026
Annual Review		

Approved:

Sanjiv Shah
MD
Sanjiv Shah, MD
Chief Medical Officer

Digitally signed by Sanjiv
Shah MD
Date: 2026.10.21
11:34:37 -0400

Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication. MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.