Tecelra® (afamitresgene autoleucel)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided for one treatment course (1 dose).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit (1 dose of up to 10 billion MAGE-A4 TCR positive T-cells)

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided for the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient does not have HLA-A*02:05P in either allele (i.e., heterozygous or homozygous); **AND**
- Patient has not received systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion; **AND**
- Patient has not received a prior allogeneic stem cell transplant *(or has, but is without evidence of residual donor cells present),* and is a candidate for autologous stem cell transplantation (e.g., adequate renal and hepatic function); **AND**
- Patient does not have a history of hypersensitivity to dimethyl sulfoxide (DMSO); **AND**
- Patient does not have symptomatic brain metastases including leptomeningeal disease; **AND**
- Patient does not have a left ventricular ejection fraction (LVEF) less than 50%; **AND**
- Patient does not have a clinically significant active systemic infection; **AND**

- Patient is screened and found to be negative for Epstein-Barr Virus (EBV), Cytomegalovirus (CMV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and any other infectious agents, if clinically indicated; **AND**
- Patient is HIV negative as confirmed by a negative HIV test prior to mobilization (*Note: Patients who have received Tecelra are likely to test false-positive on some commercial HIV nucleic acid tests for HIV due to the lentiviral vector used to make Tecelra having limited, short spans of genetic material which is identical to HIV)*; **AND**
- Patient will be monitored for secondary malignancies periodically after treatment; **AND**

Synovial Sarcoma † ‡ Φ [1-4]

- Patient has a diagnosis of unresectable or advanced/metastatic synovial sarcoma; **AND**
- Tumor expresses the MAGE-A4 tumor antigen; **AND**
- Patient is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive; **AND**
- Used as subsequent therapy

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria

- Duration of authorization has not been exceeded (*refer to Section I*)

V. Dosage/Administration

Indication	Dose
Synovial Sarcoma	• Tecelra is provided as a single dose for infusion in one or more infusion bag(s). Verify the number of bags received for the indicated dose prior to preparation for infusion. • The recommended dose is between 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T cell receptor (TCR) positive T cells administered as a single intravenous infusion. Do not use a leukodepleting filter. • Plan for Tecelra to arrive prior to beginning lymphodepleting chemotherapy. Administer a lymphodepleting chemotherapy regimen of fludarabine 30 mg/m^2/day intravenously for 4 days starting on the seventh day before Tecelra infusion (Day-7 to Day -4) and cyclophosphamide 600 mg/m^2/day intravenously for 3 days starting the seventh day before Tecelra infusion (Day -7 to Day -5).
– *Administer in an inpatient hospital setting under the supervision of a physician experienced in the use of anticancer agents. An intensive care facility and specialists skilled in cardiopulmonary or intensive care medicine must be available.* – *Tecelra is for autologous use only. The patient's identity must match the patient identifiers on the drug cassette(s) and infusion bag(s).* – *Avoid prophylactic use of systemic corticosteroids which may interfere with the activity of Tecelra.* – *Ensure patients are euvolemic prior to initiating the infusions.*	

VI. Billing Code/Availability Information

HCPCS Code:

- Q2057 – Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose

NDC:

- Tecelra contains 2.68 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T-cells suspended in 1 or more patient-specific infusion bag(s): 83205-0001-xx

VII. References

1. Tecelra [package insert]. Philadelphia, PA; Adaptimmune, LLC; August 2024. Accessed September 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) afamitresgene autoleucel. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
3. Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant 2019; 25: 625-638.
4. 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 Apr 13;403(10435):1460-1471. doi: 10.1016/S0140-6736(24)00319-2. Epub 2024 Mar 27. PMID: 38554725; PMCID: PMC11419333.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma, Version 1.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion

Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
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
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC