Clinical Policy: Afamitresgene Autoleucel (Tecelra)

Reference Number: CP.PHAR.678
Effective Date: 08.01.24
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Afamitresgene autoleucel (Tecelra®) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetic modified autologous T cell immunotherapy.

FDA Approved Indication(s)

Tecelra is indicated for the treatment of adults and pediatric patients 12 years of age and older 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

All requests reviewed under this policy **require Precision Drug Action Committee (PDAC) Utilization Management Review**. Refer to CC.PHAR.21 for process details.

It is the policy of health plans affiliated with Centene Corporation® that Tecelra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Synovial Sarcoma* (must meet all)**:**

**Only for initial treatment dose; subsequent doses will not be covered.*

1. Diagnosis of unresectable or metastatic synovial sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Member is positive for one of the following (a, b, c, or d; *see Appendix D*):
   a. HLA-A*02:01P;
   b. HLA-A*02:02P;
   c. HLA-A*02:03P;
   d. HLA-A*02:06P;
5. Member is not heterozygous or homozygous for HLA-A*02:05P;
6. Documentation of MAGE-A4 antigen expression as determined by FDA-approved or cleared companion diagnostic device;
7. Member has received ≥ 1 prior systemic chemotherapy (*see Appendix B)*;
8. Member has not received prior allogenic hematopoietic stem cell transplant;
9. Member has not received prior gene therapy;

10. Dose does not exceed a single dose of 10 x 10^9 MAGE-A4 T cell receptor (TCR) positive T-cells.

Approval duration: 3 months (one time infusion per lifetime)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Synovial Sarcoma

1. Continued therapy will not be authorized as Tecelra is indicated to be dosed one time only.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HLA: human leukocyte antigen
MAGE-A4: melanoma-associated antigen A4
TCR: T cell receptor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of systemic chemotherapy regimens • AIM (doxorubicin, ifosfamide mesna) • AD (doxorubicin, dacarbazine) • Cabozantinib • Darcabazine • Doxorubicin • Liposomal doxorubicin • Epirubicin • Gemcitabine • Gemcitabine + docetaxel or dacarbazine or pazopanib or vinorelbine • Ifosfamide • Ifosfamide, eriprubicin, mesna • MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Pazopanib • Regorafenib • Temozolomide • Vinorelbine	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): adults who are heterozygous or homozygous for HLA-A*02:05P
- Boxed warning(s): cytokine release syndrome

Appendix D: General Information

- In the SPEARHEAD 1 trial, those with HLA-A*02:05 in either allele or with HLA-A*02:07 were excluded from the trial. Pre-clinical data indicate strong anti-HLA-A*02:05 alloreactivity, and decreased potency against MAGE-A44230-239 peptide when presented by HLA-A*02:07. Patients expressing these HLA should therefore not be treated with Telcera.
- The P group nomenclature represents HLA alleles that share the same protein sequence in the peptide binding domain. For example, HLA-A*01:02P includes HLA-A*01:02:01:01, HLA-A*01:02:01:02, HLA-A*01:02:01:03, HLA-A*01:02:02, and HLA-A*01:412.
- The SPEARHEAD 1 trial eligibility criteria allowed patients who had received a gene therapy using a lentiviral vector if they had persistence results below the lower limit of quantification for at least 2 samples taken at least 1 month apart. However, the study ultimately did not enroll any patients with prior lentiviral vector gene therapy; therefore, the safety and efficacy of Telcera following any prior gene therapies have not been established.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Synovial sarcoma	1.62 x 10^9 to 10 x 10^9 MAGE-A4 TCR positive T-cells as a single IV infusion	10 x 10^9 MAGE-A4 TCR positive T-cells

VI. Product Availability

Cell suspension provided in one or more infusion bag(s) containing 2.68 x10^9 to 10 x 10^9 MAGE-A4 TCR positive T-cells

VII. References

1. Tecelra Prescribing Information. Philadelphia, PA: USWM CT, LLC; June 2026. Available at: https://www.fda.gov/media/180565/download. Accessed July 10, 2026.
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 5.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 24, 2026.
3. D'Angelo SP, Araugo 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;403:1460-1471.
4. Blay JY, von Mehren M, Jones RL, et al. Synovial sarcoma: characteristics, challenges, and evolving therapeutic strategies. ESMO Open August 2023;8(5):1-14.
5. 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 2020;9(1):e1682381.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	04.09.24	05.24
Drug is now FDA approved – criteria updated per FDA labeling: clarified "unresectable and metastatic" synovial sarcoma and removed MRCLS, revised age to ≥ 18 years, added criterion "member is not heterozygous or homozygous for HLA-A*02:05P"; revised MAGE-A4 antigen expression as determined by "immunohistochemistry" to an "FDA-approved or cleared diagnostic device"; revised "member has previously received either an anthracycline or ifosfamide containing regimen" to "member has received ≥ 1 prior systemic chemotherapy"; revised prior gene therapy statement from "using a retroviral vector" to "member has not received prior gene therapy" due to no patient enrollment with prior lentiviral gene therapy; updated Appendix B and Section V; references reviewed and updated.	08.27.24	11.24
HCPCS code added [Q2057] and removed [J3590, C9399].	02.13.25	
4Q 2025 annual review: no significant changes; references reviewed and updated.	07.09.25	11.25
Updated language under Policy/Criteria to effectively redirect prior authorization reviews to Precision Drug Action Committee (PDAC) Utilization Management Review.	11.04.25	
RT4: added pediatric extension down to 12 years of age and removed accelerated approval language per updated prescribing information.	06.29.26	
4Q 2026 annual review: no significant changes; added ICHRA line of business; references reviewed and updated.	07.10.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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