Clinical Policy: Afamitresgene Autoleucel (Tecelra)

Reference Number: LA.PHAR.678
Effective Date:
Last Review Date: 02.14.25
Line of Business: Medicaid

Coding Implications
Revision Log

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

****Please note: This policy is for medical benefit****

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 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.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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 under this policy require medical director review.

It is the policy of Louisiana Healthcare Connections 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 ≥ 18 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 toLA.PMN.255.**
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 policyLA.PMN.53.**

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 toLA.PMN.255.**
   a. **o**
   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 forLA.PMN.53.

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 –LA.PMN.53 .

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 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	2.68 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: Adaptimmune; August 2024. Available at: https://www.fda.gov/media/180565/download?attachment. Accessed August 6, 2024.
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 6, 2024.
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
J3590	Unclassified biologics
C9399	Unclassified drugs or biologics

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted Corporate to LHCC policy	02.15.25	

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. LHCC 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.

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 LHCC administrative policies and procedures.

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