



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Tecelra® (afamitresgene autoleucel)

HCPCS: Q2057

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
- a. FDA approved indication
 - b. FDA approved age
 - c. Prescribed by or in consultation with an oncologist
 - d. Patients must have been treated with at least one of the following:
 - i. An anthracycline-containing chemotherapy regimen
 - ii. An ifosfamide-containing chemotherapy regimen
 - e. Must be HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive
 - f. Must not have HLA-A*02:05 in either allele
 - g. Tumor must show MAGE-A4 expression of greater than or equal to 2+ staining in greater than or equal to 30% of the cells by immunohistochemistry
 - h. Must have measurable disease
 - i. Must not have any of the following:
 - i. ECOG performance status greater than 1
 - ii. Active infection (e.g. viral, bacterial, fungal) such as HIV, active hepatitis B or active hepatitis C
 - iii. Creatinine clearance less than 40 mL/min
 - iv. Left ventricular ejection fraction (LVEF) less than 40%
 - v. Symptomatic central nervous system metastases
 - j. Only to be administered at certified bone marrow/stem cell transplant centers
 - k. Have not received prior treatment with any autologous SPEAR T-cell therapy despite indication or any other autologous SPEAR T-cell therapy or are being considered for treatment with any other autologous SPEAR T-cell therapy
 - l. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
 - m. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
 - n. If new diagnoses are FDA approved, coverage will be determined based on the FDA approved indication on a case by case basis until fully evaluated by the BCBSM Pharmacy and Therapeutics Committee

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- B. Quantity Limitations, Authorization Period and Renewal Criteria
- Quantity Limits: Align with FDA recommended dosing
 - Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time with the allowance of only one dose per lifetime
 - Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy 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.
- Specific peptide enhanced affinity receptor (SPEAR), T-cell therapy is a type of treatment that utilizes the body's own immune system to fight cancer. Autologous T-cells are transduced with a lentiviral vector to create Tecelra which expresses MAGE-A4-specific affinity-enhanced T-cell receptors (TCRs) on the surface of the cells. The engineered TCRs recognize an HLA-A*02-restricted MAGE-A4 peptide resulting in antigen-specific activation of Tecelra, T-cell proliferation, cytokine secretion, and killing of MAGE-A4/HLA-A*02-expressing synovial sarcoma cells.
- SPEAR T-cell therapy has not been studied when given following prior treatment with any SPEAR T-cell therapy or following any other genetically-modified T-cell therapy.
- Safety and efficacy were evaluated in the SPEARHEAD-1 trial, an open-label, non-randomized, phase 2 study of 44 patients with metastatic or unresectable synovial sarcoma who had received prior systemic therapy with either doxorubicin and/or ifosfamide and whose tumor expressed the MAGE-A4 tumor antigen. MAGE-A4 expression was defined as greater than or equal to 2+ staining in greater than or equal to 30% of the cells by immunohistochemistry. Patients needed to be HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, and HLA-A*02:06P allele positive. Subjects with an HLA-A*02:05P allele were not included in the trial. The study excluded patients with an ECOG score of 1 or greater, a creatinine clearance of less than or equal to 40 mL/minute, alanine aminotransferase greater than 2.5 times upper limit of normal, and left ventricular ejection fraction less than 40%. Patients were also excluded if absolute neutrophil count less than 1000 cells/mm³ and platelet count less than 75,000/mm³. Patients were required to have measurable disease. The primary endpoint was overall response rate (ORR). The ORR was 43.2% (95% CI: 28.4, 59.0) with a complete response rate of 4.5% and partial response rate of 38.6%. The median duration of response was 6 months (95% CI: 4.6, not reached). Among patients who were responsive to the treatment, 39% had a duration of response of 12 months or longer.
- A provider portal platform is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

References:

1. Tecelra [prescribing information]. Philadelphia, PA: Adaptimmune, LLC; August 2024.
2. National Comprehensive Cancer Network. Soft tissue sarcoma (Version 2.2026). 2026 Feb 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed on March 3, 2026.
3. D'Angelo SP, Araujo DM, Razak ARA, et al. Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD-1): an international, open-label, phase 2 trial. Lancet. 2024 April 13; 403 (10435): 1460 – 71.
4. Hong DS, Van Tine BA, Biswas S, et al. Autologous T-cell therapy for MAGE-A4+ solid cancers in HLA-A*02+ patients: a phase 1 trial. Nature Med. 2023 Jan 9; 29: 104 – 14.

Policy History												
#	Date	Change Description										
1.5	Effective Date: 06/01/2026 P&T Date: 04/16/2026	Updated to require drug be given in consultation with an oncologist, removed ANC, platelet, and liver function requirements, removed no HIV, hepatitis C or B infection, no uncontrollable infection or infection requiring long term antibiotics, no primary malignancy, and no primary immunodeficiency. Also added requirements of no active infection and updated the approval length to 6 months										
1.4	Effective Date: 10/09/2025	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 10/03/2024	New policy - this criteria replaces previously approved preliminary criteria										
1.2	Effective Date: 10/01/2024	UM medical management system update for MAPPO and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
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1.1	Effective Date: 08/15/2024	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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BCBS	Yes											
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1.0	Effective Date: 06/06/2024	Preliminary Drug Review <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

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Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021