Blue Cross Blue Shield Blue Care Network of Michigan

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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.

Effective Date: 10/03/2024

Tecelra® (afamitresgene autoleucel)

HCPCS: J3590

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. Patients must have been treated with at least one of the following:
      i. An anthracycline-containing chemotherapy regimen
      ii. An ifosfamide-containing chemotherapy regimen
   d. Must be HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive
   e. 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
   f. Must have measurable disease
   g. Must not have any of the following:
      i. ECOG performance status greater than 1
      ii. Absolute neutrophil count (ANC) less than or equal to 1 x 10^9/L
      iii. Platelets less than 75,000/mm^3
      iv. Alanine transaminase (ALT) and aspartate transaminase (AST) greater than 2.5 times the upper limit of normal (ULN)
      v. Creatinine clearance less than 40 mL/min
      vi. Left ventricular ejection fraction (LVEF) less than 40%
      vii. Symptomatic central nervous system metastases
      viii. History of another primary malignancy that is not considered to be in complete remission
      ix. Infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
      x. HIV infection; hepatitis B or C virus infection permitted only if viral load undetectable; or human T-cell leukemia virus
      xi. Any primary immunodeficiency
   h. 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
   i. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM

j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list
k. 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

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: 3 months with the allowance of only one dose per lifetime
   c. 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 the 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/mm^3 and platelet count less than 75,000/mm^3. 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 2.2024). 2024 July 31. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed on August 5, 2024.
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.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date: 10/03/2024</td><td>New policy - this criteria replaces previously approved preliminary criteria</td></tr>
<tr><td>1.2</td><td>Effective Date: 10/01/2024</td><td>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></td></tr>
<tr><td>1.1</td><td>Effective Date: 08/15/2024</td><td>UM medical management system update for BCBS and BCN
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<tr><td>1.0</td><td>Effective Date: 06/06/2024</td><td>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></td></tr>
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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.*