



MVP Health Care Medical Policy

Medicare Part B: TECELRA® (afamitresgene autoleucel)

Type of Policy:	Drug/Medical Therapy (administered by the pharmacy department)
Prior Approval Date:	N/A
Approval Date:	12/01/2024
Effective Date:	02/01/2025
Related Policies:	Experimental or Investigational Procedures, Drugs and Treatments, Clinical Trials

Drugs Requiring Prior Authorization Under the Medical Benefit

J9999 TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion

Refer to the MVP Medicare website for the Medicare Part D Formulary and Part D policies for drugs that may be covered under the Part D benefit.

Refer to the MVP website for the Medicare Part B policies for coverage criteria of drugs covered under the medical benefit.

Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.

Overview

Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy consisting of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector (LV) to express an affinity-enhanced TCR specific for human MAGE-A4 on the cell surface. MAGE-A4 is an intracellular cancer-testis antigen that has restricted expression in normal tissues and is expressed in synovial sarcoma.

Tecelra is prepared from the patient's peripheral blood mononuclear cells (PBMCs), which are obtained via a standard leukapheresis procedure. The PBMCs are enriched for T cells and are then transduced with a replication-incompetent lentiviral vector (LV) containing the MAGE-A4 TCR transgene. The transduced T cells are expanded, washed, formulated into a suspension, and cryopreserved.

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.

Tecelra has a black box warning for Cytokine Release Syndrome (CRS).

Indications/Criteria

Tecelra may be considered for coverage when all of the following are met:

- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Diagnosis of unresectable or metastatic synovial sarcoma
- Member is positive for HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P*
- Documentation that the tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices
- Documentation that the member has received prior systemic chemotherapy therapy
- Glomerular filtration rate (GFR) \geq 60 mL/min
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Provider attestation
 - To verify pregnancy status of biological females with reproductive potential prior to starting treatment
 - That the member will receive lymphodepleting chemotherapy with fludarabine for 4 days and cyclophosphamide for 3 days
 - That the member will be monitored daily at the healthcare facility for at least 7 days for signs and symptoms of cytokine release syndrome (CRS)
- Hospital administering Tecelra must be appropriately certified to do so. Please see link for treatment centers below: [Tecelra Authorized Treatment Centers](#)

Tecelra will be approved as a **one-time dose** within 6 months. Requests for replacement due to lost or damaged product will not be covered. Coverage is contingent on eligibility at the time of infusion.

Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Repeat Administration
- Adults who are heterozygous or homozygous for HLA-A*02:05P
- Pregnancy
- Members on systemic corticosteroids for at least 14 days prior to leukapheresis and lymphodepletion
- Prophylactic systemic corticosteroids
- Recipients of allogeneic hematopoietic stem cell transplants
- Active infections or active inflammatory disorders

References

1. TECELRA® (afamitresgene autoleucel) suspension, for intravenous infusion. Package Insert. Adaptimmune, LLC. Philadelphia, PA. Revised 08/2024.
2. AFAMITRESGENE AUTOLEUCEL [Contained in: Tecelra]. In: Micromedex [database on the Internet]. Greenwood Village (CO): IBM Corporation; Last Revised 8/21/2024. Available from: www.micromedexsolutions.com. Subscription required to view.