UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – T-Cell Immunotherapy – MAGE-A4) – Tecelra Utilization Management Medical Policy

- Tecelra® (afamitresgene autoleucel intravenous infusion – Adaptimmune)

REVIEW DATE: 08/06/2025

OVERVIEW

Tecelra, a melanoma-associated antigen A4 (MAGE-A4) directed genetically modified autologous T-cell immunotherapy, is indicated for the treatment of unresectable or metastatic **synovial sarcoma** in adults who have received prior chemotherapy, are human leukocyte antigen (HLA)-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive and whose tumor expresses MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.[1] This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Dosing Information

The recommended dose of Tecelra is 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T-cell receptor positive T-cells administered as a single intravenous infusion.[1] Patient should be treated with lymphodepleting chemotherapy consisting of fludarabine 30 mg/m^2/day administered intravenously (IV) on Days -7 to -4 and cyclophosphamide 600 mg/m^2/day administered IV on Days -7 to -5 prior to the administration of Tecelra.

Guidelines

The National Comprehensive Cancer Network (NCCN) Soft Tissue Sarcoma (version 1.2025 – May 2, 2025) guidelines recommend Tecelra as a single agent for the subsequent treatment of advanced/metastatic synovial sarcoma with disseminated metastases and HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive and whose tumor expresses MAGE-A4 antigen.[2,3]

Safety

Tecelra has a boxed warning for cytokine release syndrome, which may be severe or life-threatening.[1] In addition, Tecelra is contraindicated in patients who are heterozygous or homozygous for HLA-A*02:05P.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tecelra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Due to the specialized skills required for evaluation and diagnosis of patients treated with Tecelra as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecelra to be prescribed by or in consultation with a physician who specializes in the condition being treated. The approval duration is 6 months to allow for an adequate time frame to prepare and administer 1 dose of therapy.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tecelra is recommended in those who meet the following criteria:

FDA-Approved Indication

---

1. **Synovial Sarcoma.** Approve a single dose if the patient meets ALL of the following (A, B, C, D, E, F, G, H, and I):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced, unresectable or metastatic disease; AND
   - **C)** Patient is human leukocyte antigen (HLA) positive for at least ONE of the following: HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P; AND
   - **D)** Patient is NOT heterozygous or homozygous for HLA-A*02:05P; AND
   - **E)** Tumor expresses melanoma-associated antigen A4 (MAGE-A4); AND
   - **F)** Patient has received prior chemotherapy; AND
   - **G)** Patient received or plans to receive lymphodepleting chemotherapy prior to Tecelra infusion; AND
   - **H)** Patient has NOT been previously treated with Tecelra; AND
   - **I)** Medication is prescribed by or in consultation with an oncologist.

   Dosing. The dose is 2.68 x 10^9 to 10 x 10^9 MAGE-A4 T-cell receptor positive T-cells as a single intravenous infusion.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecelra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tecelra intravenous infusion [prescribing information]. Philadelphia, PA: Adaptimmune; August 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2025. Search term: afamitresgene.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 23, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/07/2024
Update	**08/25/2024**: Added National Comprehensive Cancer Network Soft Tissue Saroma (version 4.2024 – November 21, 2024) guideline recommendations to the policy.	NA
Annual Revision	The name of the policy was changed to Oncology (Injectable – T-Cell Immunotherapy – MAGE-A4) – Tecelra Utilization Management Medical Policy. Previously, it was "Oncology (Injectable) – Tecelra UM Medical Policy". **Synovial Sarcoma:** In the requirement that the patient has unresectable or metastatic disease, "advanced" was added as another option for approval.	08/06/2025