CARECONTINUUM™

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: 08/05/2026

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 adult and pediatric patients ≥ 12 years of age 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]

Dosing Information

The recommended dose of Tecelra is 1.62 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 5.2026 – July 23, 2026) guidelines recommend Tecelra as a single agent as "Useful in Certain Circumstances" 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:

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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 ≥ 12 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)** The tumor expresses melanoma-associated antigen A4 (MAGE-A4); AND
   - **F)** The medication is used as subsequent therapy; 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)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 10 x 10^9 MAGE-A4 T-cell receptor positive T-cells administered intravenously as a single dose.

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; June 2026.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 31. 2026. Search term: afamitresgene.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 5.2026 – July 23, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 31, 2026.

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
Annual Revision	**Synovial Sarcoma:** The requirement that the patient ≥ 18 years of age was modified to the patient is ≥ 12 years of age. The requirement that the patient has received prior chemotherapy was modified to the medication is used as subsequent therapy. Dosing was modified to approve up to 10 x 10^9 MAGE-A4 T-cell receptor positive T-cells administered intravenously as a single dose. Previously stated, "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."	08/05/2026

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