

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Tecelra Utilization Management Medical Policy

- Tecelra[®] (afamitresgene autoleucel intravenous infusion – Adaptimmune)

REVIEW DATE: 08/07/2024

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

Dosing Information

The recommended dose of Tecelra is 2.68×10^9 to 10×10^9 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/m²/day administered intravenously (IV) on Days -7 to -4 and cyclophosphamide 600 mg/m²/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 4.2024 – November 21, 2024) 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:

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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 ≥ 18 years of age; AND
 - B) Patient has 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 2.68×10^9 to 10×10^9 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.
1. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 25, 2024. Search term: afamitresgene.
2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 25, 2024.

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 Sarcoma (version 4.2024 – November 21, 2024) guideline recommendations to the policy.	NA

08/07/2024

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