



## 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.<sup>1</sup>

### Dosing Information

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

### Guidelines

The National Comprehensive Cancer Network (NCCN) has not addressed Tecelra.

### Safety

Tecelra has a boxed warning for cytokine release syndrome, which may be severe or life-threatening.<sup>1</sup> 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):
- 

08/07/2024

© Express Scripts Strategic Development, Inc., 2024. All Rights Reserved.

This document is confidential and proprietary to Express Scripts Strategic Development, Inc. Unauthorized use and distribution are prohibited.

- A) Patient is  $\geq 18$  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  $2.68 \times 10^9$  to  $10 \times 10^9$  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.

### HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/07/2024