



Drug Coverage Policy

Effective Date10/1/2025

Coverage Policy Number.....IP0699

Policy Title.....Tecelra

Oncology (Injectable – T-Cell Immunotherapy – MAGE-A4) – Tecelra

Tecelra® (afamitresgene autoleucel intravenous infusion – Adaptimmune)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 2.68×10^9 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 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.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for 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.

Tecelra is considered medically necessary when the following are met:

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 2.68×10^9 to 10×10^9 MAGE-A4 T-cell receptor positive T-cells as a single intravenous infusion.

Conditions Not Covered

Tecelra for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPSC Codes	Description
J3590	Unclassified biologics (Code effective until 3/31/2025)
Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose (Code effective 4/1/2025)

References

- Tecelra intravenous infusion [prescribing information]. Philadelphia, PA: Adaptimmune; August 2024.
- The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 23, 2025. Search term: afamitresgene.
- 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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/1/2024
Selected Revision	Updated HCPSC Coding Added new code Q2057 that will be effective on 4/1/2025 Added that J3590 will be effective until 3/31/2025	3/15/2025

Annual Revision	Policy Title: Updated from "Oncology (Injectable) – Tecelra" to "Oncology (Injectable – T-Cell Immunotherapy – MAGE-A4) – Tecelra" Synovial Sarcoma: In the requirement that the patient has unresectable or metastatic disease, "advanced" was added as another option for approval.	10/1/2025
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The policy effective date is in force until updated or retired.

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