Drug Coverage Policy

Effective Date.....03/15/2025
Coverage Policy Number.....IP0699
Policy Title.....Tecelra

Oncology (Injectable) – 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 and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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 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) has not addressed Tecelra.

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.

Medical Necessity Criteria

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 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (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:

HCPCS 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

1. Tecelra intravenous infusion [prescribing information]. Philadelphia, PA: Adaptimmune; August 2024.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/1/2024
Selected Revision	**Updated HCPCS 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

The policy effective date is in force until updated or retired.