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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 30, 2024
Subject:	Tecelra	**Page:**	1 of 4

Last Review Date: December 13, 2024

Tecelra

Description

Tecelra (afamitresgene autoleucel)

Background
Tecelra (afamitresgene autoleucel) is a genetically modified autologous T cell immunotherapy consisting of CD4 and CD8 positive T cells transduced with a self-inactivating lentiviral vector (LV) to express an affinity-enhanced T cell receptor (TCR) specific for human melanoma-associated antigen A4 (MAGE-A4) on the cell surface (1).

The TCR recognizes an HLA-A*02 restricted MAGE-A4 peptide. MAGE-A4 is an intracellular cancer-testis antigen that has restricted expression in normal tissues and is expressed in synovial sarcoma. Antigen-specific activation of Tecelra results in T cell proliferation, cytokine secretion, and killing of MAGE-A4/HLA-A*02 expressing synovial sarcoma cells (1).

Regulatory Status
FDA-approved indications: Tecelra is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices (1).

Tecelra has a boxed warning for cytokine release syndrome (CRS). CRS, which may be severe or life-threatening, may occur in patients taking Tecelra. At the first sign of CRS, immediately evaluate the patient for hospitalization and institute treatment with supportive care. Healthcare

providers administering Tecelra should have immediate access to medications and resuscitative equipment to manage CRS (1).

The safety and effectiveness of Tecelra have not been established in pediatric patients (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tecelra may be considered **medically necessary** if the conditions indicated below are met.

Tecelra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Unresectable or metastatic synovial sarcoma

AND ALL of the following:

a. Patient has received prior chemotherapy
b. Tumor contains the MAGE-A4 antigen and **ONE** of the following HLA antigens as determined by FDA-approved or cleared companion diagnostic devices:
    i. HLA-A*02:01P
    ii. HLA-A*02:02P
    iii. HLA-A*02:03P
    iv. HLA-A*02:06P
c. Prescriber agrees to monitor for signs and symptoms of cytokine release syndrome (CRS)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Quantity One infusion (only one PA approval for one infusion per lifetime)

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Tecelra is a MAGE-A4-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. Tecelra contains a boxed warning regarding cytokine release syndrome (CRS). The safety and effectiveness of Tecelra have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tecelra while maintaining optimal therapeutic outcomes.

References

1. Tecelra [package insert]. Philadelphia, PA: Adaptiummune, LLC; August 2024.
2. NCCN Drugs & Biologics Compendium® Afamitresgene autoleucel 2024. National Comprehensive Cancer Network, Inc. Accessed on October 4, 2024.

Policy History

Date	Action
August 2024	Addition to PA

December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.