VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Tecelra Prior Authorization 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]

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 prescription benefit coverage of Tecelra. Because of 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):
   - **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.

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
Update	**08/25/2024**: Added National Comprehensive Cancer Network Soft Tissue Saroma (version 4.2024 – November 21, 2024) guideline recommendations to the policy.	NA