Utilization Review Policy

POLICY: Oncology (Injectable) – Tecelra Utilization Management Medical Policy

- Tecelra® (afamitresgene autoleucel intravenous infusion – Adaptimmune)

EFFECTIVE DATE: 11/15/2024
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

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.

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

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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 2.68×10^9 to 10×10^9 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
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024