

DRUG POLICY

Tecelra® (afamitresgene autoleucel)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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 human leukocyte antigen (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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Documentation of chart notes, medical record documentation or claims history supporting previous lines of therapy
2. Documentation of laboratory report confirming HLA allele and MAGE-A4 antigen status.

Criteria for Initial Approval

Synovial Sarcoma

Authorization of 3 months may be granted for treatment of unresectable or metastatic synovial sarcoma in members 18 years and older when all of the following criteria are met:

1. The member has received prior treatment with chemotherapy
2. The tumor is HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P allele positive

3. The tumor expresses the MAGE-A4 antigen
4. The member has not received previous treatment with the requested medication
5. The member is not heterozygous or homozygous for HLA-A*02:05P
6. The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
7. The member has adequate and stable cardiac and kidney function
8. The member has not had an allogeneic hematopoietic stem cell transplant
9. The member does not have a clinically significant active infection and/or inflammatory disorder

Continuation of Therapy

Repeat treatment of Tecelra for any indication is considered investigational, as the safety and efficacy beyond one dose has not been studied. The evidence is insufficient to determine the effects on net health outcomes.

Other

Tecelra is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing Limits Apply

Tecelra approvals will be limited to one treatment per lifetime.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Q2057 - Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose (effective 4/1/2025)
- J3590 - Unclassified biologics

REFERENCES

- Tecelra [package insert]. Philadelphia, PA: Adaptimmune, LLC; August 2024.

POLICY HISTORY

Policy #: 05.05.63

Original Effective Date: November 29, 2024

Reviewed: August 2026

Revised:

Current Effective Date: November 29, 2024