TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Afamitresgene autoleucel (Tecelra®)	**CRITERIA ID:** TX.CC.PHAR.48
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 04/01/2025	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for afamitresgene autoleucel (Tecelra®)

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a Precision Drug. Centene's Precision Drug Action Committee (PDAC) creates a standardized approach for Centene to manage Precision Drugs and the associated costs for their administration, prior to members presenting with a request for one of these agents. All Precision Drug requests or potential requests must be reported to the PDAC for tracking, regardless of whether agents are carved out, passed through, etc. All Precision Drug medical necessity determinations will be supported by PDAC UM recommendation, utilizing specialist input as directed and allowed by turnaround times.

The procedure code Q2057 (used for Tecelra) will be limited to once per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
PDAC = Precision Drug Action Committee
HLA = Human leukocyte antigen
MAGE = Melanoma-associated antigen
CAR-T = Chimeric antigen receptor T-cell
HSCT = Hematopoietic stem cell transplant

CRS = Cytokine release syndrome
ICANS = Immune effector cell- associated neurotoxicity syndrome

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of afamitresgene autoleucel (Tecelra®); procedure code: Q2057.

Description/Mechanism of Action:
Afamitresgene autoleucel (Tecelra®) is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy.

F*DA Approved Indications:*
Afamitresgene autoleucel (Tecelra®) is indicated to treat adult clients with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A* 02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive, and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Synovial Sarcoma (unresectable or metastatic):

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. Medical necessity determinations will be supported by PDAC UM recommendation. The pharmacy clinician will review the UM recommendation with the prior authorization request for clinical appropriateness and make a recommendation to the Medical Director but will not make the ultimate determination on any case.
3. The client is 18 years of age or older.
4. The client has diagnosis of unresectable or metastatic synovial sarcoma:

Applicable Diagnosis Codes:							
C38.0	C38.1	C38.2	C38.3	C38.4	C38.8	C48.1	C48.2
C48.8	C49.0	C49.10	C49.11	C49.12	C49.20	C49.21	C49.22
C49.3	C49.4	C49.5	C49.6	C49.8	C49.9		

5. Documentation to support that the tumor is positive for human leukocyte antigen HLA-A*02:01P, HLA-A*02:02P, HLA-A* 02:03P, and/or HLA-A*02:06P.
6. Documentation to support that the tumor expresses the MAGE-A4 antigen (as determined by an FDA-approved or cleared companion diagnostic device).
7. The client is not heterozygous or homozygous for HLA-A*02:05P.
8. The client has experienced disease progression following at least one or more prior systemic chemotherapy.
9. The client has not received prior treatment with CAR-T therapy.

10. The client has not had prior hematopoietic stem cell transplant (HSCT).
11. The client does not have any active or clinically significant infections and/or inflammatory disorders.
12. Prescriber attestation that the client will be monitored for the following parameters for at least seven days following Tecelra treatment, with continued monitoring for at least four weeks:
    a. Signs and symptoms of cytokine release syndrome (CRS);
    b. Signs and symptoms of immune effector cell- associated neurotoxicity syndrome (ICANS).

Approval duration: Only 1 dose per lifetime will be provided on this drug regardless of Provider

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document	New criteria created based on MCO Notice: Prior Authorization Criteria for Tecelra Effective April 1, 2025	04/01/2025