TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Tarlatamab-dlle (Imdelltra)	**CRITERIA ID:** TX.CC.PHAR.43
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 11/01/2024	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/1/2024	
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 tarlatamab-dlle (Imdelltra).

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.

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

DEFINITIONS:
ES-SCLC - Extensive-stage small cell lung cancer
CRS – Cytokine release syndrome
ICANS - Immune effector cell-associated neurotoxicity syndrome

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of tarlatamab-dlle (Imdelltra); procedure code: C9170.

Description/Mechanism of Action:
Tarlatamab-dlle (Imdelltra) is a bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager.

FDA Approved Indications:
Tarlatamab-dlle (Imdelltra) is indicated for the treatment of adult clients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

Formulations:
Tarlatamab-dlle (Imdelltra): Lyophilized powder for injection. Available as 1mg and 10mg single-dose vials for reconstitution and further dilution.

Tarlatamab-dlle (Imdelltra) infusion must be administered by a qualified healthcare professional in a health care setting with appropriate medical support.

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. Extensive-stage small cell lung cancer (ES-SCLC):

1. The client is 18 years of age or older.
2. The client has a confirmed diagnosis of ES-SCLC:

Applicable Diagnosis Codes:							
C3400	C3401	C3402	C3410	C3411	C3412	C342	C3430
C3431	C3432	C3480	C3481	C3482	C3490	C3491	C3492

3. The client has previously received platinum-based chemotherapy (cisplatin or carboplatin).
4. The client does not have a clinically significant active systemic infection.
5. Prescriber attestation that counseling has been provided to female clients of childbearing age regarding the risk of embryo-fetal toxicity and counseling to prevent pregnancy during the treatment period and two months after the last infusion of Imdelltra by using an effective method of contraception.
6. Provider attestation that client will be monitored for:
    - Signs and symptoms of severe reactions such as cytokine release syndrome (CRS);
    - Neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome (ICANS);
    - Cytopenia, including neutropenia, thrombocytopenia, and anemia - Providers should perform complete blood counts before each Imdelltra treatment;
    - Signs and symptoms of hepatotoxicity - Providers should monitor liver enzymes and bilirubin before each Imdelltra treatment.

Approval Duration: 6 months

II. Continued Therapy

A. Extensive-stage small cell lung cancer (ES-SCLC):

1. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
2. The client continues to meet initial criteria requirements and has been previously treated with Imdelltra.
3. The client has experienced positive clinical response to treatment, as documented by stabilization of the disease, and a decrease in tumor size or spread.
4. The client has not experienced any unacceptable, clinically significant adverse reactions or toxicity (severe cytopenia, hepatotoxicity or neurotoxicity) while on Imdelltra therapy.

Approval duration: 12 months

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

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document	HHSC requires prior authorization for Imdelltra (procedure code C9170) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2024.	11/01/2024