TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Revakinagene taroretcel-lwey (Encelto)	**CRITERIA ID:** TX.CC.PHAR.53
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 10/1/2025	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):**

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for revakinagene taroretcel-lwey (Encelto)

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 J3403 (used for Encelto®) 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
UM = Utilization Management
CPS = Centene Pharmacy Service
SHP = Superior HealthPlan
MacTel = idiopathic macular telangiectasia type 2

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of revakinagene taroretcel-lwey (Encelto); procedure code: J3403.

Description/Mechanism of Action:
Revakinagene taroretcel is an allogeneic encapsulated cell-based gene therapy. It secretes recombinant human ciliary neurotrophic factor (rhCNTF), which is one of several neurotrophic factors endogenously produced by neurons and supporting glial cells. Exogenous ciliary neurotrophic factor (CNTF) is thought to initially target Muller glia to trigger a cascade of signaling events that may promote photoreceptor survival; however, the mechanism of action for revakinagene taroretcel is not completely understood.

FDA Approved Indications:
ENCELTO is an allogeneic encapsulated cell-based gene therapy 12 indicated for the treatment of adults with idiopathic macular 13 telangiectasia type 2 (MacTel)

Formulations:
One single-dose implant containing 200,000 to 440,000 allogeneic 29 retinal pigment epithelial cells expressing rhCNTF

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. Idiopathic macular telangiectasia type 2

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 CPS or SHP 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. Client is 18 years or older;
4. Client has a confirmed diagnosis of retinal telangiectasis in at least one eye (diagnosis code – H35.071, H35.072, H35.073, or H35.079);
5. Client has MacTel type 2 in at least one eye;
6. Client does not have neovascular or proliferative MacTel;
7. Client has no ocular or periocular infections;
8. Client has no known hypersensitivity to Endothelial Serum Free Media (Endo-SFM);
9. Client has temporarily discontinued any antithrombotic medication prior to Encelto insertion surgery;
10. Client has not received a previous Encelto insertion.

Approval duration: Only 1 treatment per eye 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 Policy Document	N/A	9/25/2025