PROVIDER POLICIES & PROCEDURES

ENCELTO™ (REVAKINAGENE TARORETCEL-LWEY)

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for ENCELTO (revakinagene taroretcel-lwey) implant. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Idiopathic macular telangiectasia type 2 (MacTel) is a gradually progressive disease that primary affects the macula impairing both distant and near vision. It had previously been considered a vascular condition, but recent evidence suggests a neurodegenerative etiology, with primary involvement of Muller cells. Retinal pigment epithelium (RPE) hyperplasia and subretinal neovascularization (SNV) are responsible for most of the vision loss in advanced cases.

ENCELTO is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2. It is intended for surgical intravitreal implantation under aseptic conditions by a qualified ophthalmologist. Encelto helps slow the progression of MacTel by promoting the survival of photoreceptors, the cells critical for vision.

CLINICAL GUIDELINE

Coverage guidelines for the use of Encelto will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage guidelines are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Initial Requests

ENCELTO (revakinagene taroretcel-lwey) may be considered medically necessary for individuals with MacTel when the following criteria are met:

A. The individual is at least 21 years of age; **AND**
B. Encelto is prescribed by and will be administered by a qualified ophthalmologist using a single surgical intravitreal procedure; **AND**
C. Submission of medical records confirming the individual has a diagnosis of idiopathic macular telangiectasia type 2 (MacTel); **AND**
D. The treating provider attests to ALL of the following:
    a. The individual has a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 measured by spectral domain-optical coherence tomography; **AND**

b. The individual has a best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart; **AND**
c. The individual does not have neovascular macular telangiectasia; **AND**
d. The individual does not have an active or suspected ocular or periocular infection; **AND**
e. The individual does not have a hypersensitivity to Endothelial Serum Free Media (Endo-SFM); **AND**
f. The individual has not received intravitreal anti-vascular endothelial growth factor (VEGF) therapy in the affected eye; **AND**
g. The individual has not received intravitreal steroid therapy within the last 3 months; **AND**
h. ONE of the following apply:
    i. The individual is not taking antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs); **OR**
    ii. If the individual is taking antithrombotic medications, they will be temporarily discontinued prior to surgical insertion of Encelto to reduce the risk of vitreous hemorrhage as directed in the FDA-approved labeling for Encelto; **AND**
i. The treating provider will follow all FDA-approved labeling for dosing, administration, and additional monitoring for Encelto.

Reauthorization Requests
N/A

Investigational and Not Medically Necessary
Encelto for all other indications is considered investigational and not medically necessary.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of Encelto is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for Encelto:
1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Encelto Prior Authorization Request form (to include physician's order and signature);
2. Clinical documentation supporting the medical necessity of treatment with Encelto should include the following:
    a. Medical record documentation confirming:
        i. Diagnosis of idiopathic macular telangiectasia type 2 (MacTel); **AND**
    b. Signed provider attestation confirming the following:
        i. The individual does not have neovascular macular telangiectasia; **AND**

ii. The individual does not have an active or suspected ocular or periocular infection; **AND**
iii. The individual does not have a hypersensitivity to Endothelial Serum Free Media (Endo-SFM); **AND**
iv. Photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2; **AND**
v. BCVA of 54-letter score or better (20/80 or better) as measured by the Early ETDRS chart; **AND**
vi. If the individual is taking antithrombotic medications, they will be temporarily discontinued prior to insertion of Encelto; **AND**
vii. The individual has not received intravitreal anti-vascular endothelial growth factor (VEGF) therapy in the affected eye; **AND**
viii. The individual has not received intravitreal steroid therapy within the last 3 months; **AND**

3. Other information as requested.

Initial Authorization
If the above criteria are met, authorization will be given for one dose per affected eye, per lifetime.

Reauthorization
N/A

EFFECTIVE DATE
This Policy for the prior authorization of Encelto for individuals covered under the HUSKY Health Program is effective August 1, 2025.

LIMITATIONS
Not Applicable

CODE:

Code	Definition
J3590	Unclassified biologics

DEFINITIONS

1. **Current Procedural Terminology (CPT):** The most recent edition of a listing, published by the American Medical Association, of descriptive terms and identifying codes for reporting medical services performed by providers.
2. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
3. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
4. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.

5. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
6. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
7. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
9. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol A. ClinicalTrials.gov identifier: NCT03316300. Updated September 24, 2024. Accessed May 27, 2025. https://clinicaltrials.gov/study/NCT03316300
- A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol B. ClinicalTrials.gov identifier: NCT03319849. Updated September 24, 2024. Accessed May 27, 2025. https://clinicaltrials.gov/study/NCT03319849
- Encelto [package insert]. Cumberland, RI; Neurotech Pharm., Inc; Revised March 2025. Accessed May 2025.
- Kedarisetti KC, Narayanan R, Stewart MW, Reddy Gurram N, Khanani AM. Macular Telangiectasia Type 2: A Comprehensive Review. *Clin Ophthalmol*. 2022;16:3297-3309. Published 2022 Oct 10. doi:10.2147/OPTH.S373538

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	May 2025	Approved at the June 11, 2025, CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on June 16, 2025. Approved by DSS on July 9, 2025.