Medical Policy:

Encelto (revakinagene taroretcel-lwey)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.439	August 7, 2025	August 7, 2025

Definitions

Encelto, an allogeneic encapsulated cell-based gene therapy, is indicated for the treatment of idiopathic macular telangiectasia type 2 (MacTel) in adults.1 Each Encelto implant contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (CNTF). CNTF is one of several neurotrophic factors that are produced endogenously by neurons and supporting glial cells. Although the exact mechanism of action is not completely understood, it is thought that endogenous CNTF initially targets Müller glia to trigger a cascade of signaling events that may promote photoreceptor survival.

Length of Authorization

Coverage will be provided for one dose per affected eye and may **not** be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

- 2 doses* [one single-dose implant containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF, per eye]
  (*Max units are based on administration to both eyes)

Guideline

I. INITIAL CRITERIA

Coverage is provided in the following conditions:

1. Patient is at least 18 years of age; **AND**
2. Patient is free of ocular and/or peri-ocular infections; **AND**
3. Patient does not have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM); **AND**
4. Patient's will be monitored for signs and symptoms of vision loss (e.g., BCVA, etc.) and infectious endophthalmitis at baseline and periodically during treatment; **AND**
5. Patient will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity); **AND**
6. Patient does not have evidence of other ocular disease that would preclude treatment of MacTel; **AND**
7. Patient will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery; **AND**
8. Patient has not received intravitreal steroid therapy or intravitreal anti–vascular endothelial growth factor (VEGF) therapy, for non-neovascular MacTel within the last 3 months; **AND**

Idiopathic Macular Telangiectasia (MacTel Type 2) † Φ

1. Patient has a diagnosis of macular telangiectasia, type 2, in at least one eye, as evidenced by typical fluorescein leakage and at least **one** (1) other of the following features of disease:
    a. Hyperpigmentation outside a 500-micron radius from the center of the fovea **OR**
    b. Retinal opacification **OR**
    c. Crystalline deposits **OR**
    d. Right angle vessels **OR**
    e. Inner/outer lamellar cavities; **AND**
2. Patient does NOT have neovascular macular telangiectasia; **AND**
3. Patient does not have evidence of advanced disease that would preclude treatment of MacTel (e.g., significant retinal scarring and atrophy with retinal tissue that cannot be preserved); **AND**
4. Patient has an inner segment-outer segment junction line (IS/OS) photoreceptor break and area of ellipsoid zone (EZ) loss, as measured by spectral domain optical coherence tomography (SD-OCT), at between 0.16mm^2 and 2.00m m^2; **AND**
5. Patient does not have evidence of any of the following:
    a. Intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid, or intraretinal fluid in either eye **OR**
    b. Central serous chorioretinopathy in either eye **OR**
    c. Pathologic myopia in either eye **OR**
    d. Significant media or corneal opacities in either eye **OR**
    e. History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty **OR**
    f. Any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 2, or nuclear opacity > standard 3 **OR**
    g. Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks **OR**
    h. History of ocular herpes virus in either eye **OR**
    i. Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT).

Note: Requests for use in patients with other forms of macular telangiectasia (i.e., Type 1 disease), will be reviewed on a case-by-case basis.

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Applicable Procedure Codes

Code	Description
J3590	Unclassified biologics

Applicable NDCs

Code	Description
82958-0501-xx	Encelto single-dose implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line):

ICD-10 Diagnoses

Code	Description
H35.071	Retinal telangiectasis, right eye
H35.072	Retinal telangiectasis, left eye
H35.073	Retinal telangiectasis, bilateral
H35.079	Retinal telangiectasis, unspecified eye

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	08/07/2025	New Policy

References

1. Encelto [package insert]. Cumberland, RI; Neurotech Pharm., Inc; March 2025. Accessed March 2025.
2. ClinicalTrials.gov. NCT03316300. A Phase III Multicenter Randomized, Sham Controlled, Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2. | ClinicalTrials.gov.
3. ClinicalTrials.gov. NCT03319849. A Phase III Multicenter Randomized, Sham Controlled, Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2. | ClinicalTrials.gov.
4. Kedarisetti KC, Narayanan R, Stewart MW, et al. Macular Telangiectasia Type 2: A Comprehensive Review. Clin Ophthalmol. 2022 Oct 10;16:3297-3309. doi: 10.2147/OPTH.S373538.