Encelto™ (revakinagene taroretcel-lwey)
(Intravitreal)

Document Number: OHSU HEALTHSERVICES-0793

Last Review Date: 10/02/2025
Date of Origin: 04/07/2025
Dates Reviewed: 04/2025, 10/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one dose per affected eye.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

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

- 2 billable units* *[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)*

III. Initial Approval Criteria [1]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax**.** Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines.

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or periocular infections; **AND**
- Patient does not have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM); **AND**
- Patient will be monitored for signs and symptoms of vision loss (e.g., BCVA, etc.) and infectious endophthalmitis at baseline and periodically during treatment**; AND**

- 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**
- Patient does not have evidence of other ocular disease that would preclude treatment of MacTel; **AND**
- Patient will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery; **AND**
- 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 [1-4]

- 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:
  - hyperpigmentation outside a 500-micron radius from the center of the fovea
  - retinal opacification
  - crystalline deposits
  - right angle vessels
  - inner/outer lamellar cavities; **AND**
- Patient does NOT have neovascular macular telangiectasia; **AND**
- 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**
- 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 0.16 mm^2 and 2.00 mm^2; **AND**
- Patient does not have evidence of any of the following:
  - Intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid, or intraretinal fluid in either eye
  - Central serous chorioretinopathy in either eye
  - Pathologic myopia in either eye
  - Significant media or corneal opacities in either eye
  - History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty
  - Any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 2, or nuclear opacity > standard 3
  - Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks
  - History of ocular herpes virus in either eye
  - 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

IV. Renewal Criteria [1]

- Duration of authorization has not been exceeded *(refer to Section I).*

V. Dosage/Administration [1]

Indication	Dose
Idiopathic macular telangiectasia type 2 (MacTel)	The recommended dose is one Encelto implant per affected eye. Each Encelto implant contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF) (NTC-201-6A cell line), a neurotrophic factor.
– *For surgical intravitreal implantation performed in an operating room under aseptic conditions by a qualified ophthalmologist.*	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3403 – Revakinagene taroretcel-lwey, per implant; 1 billable unit = 1 implant

NDC(s):

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

VII. References

1. Encelto [package insert]. Cumberland, RI; Neurotech Pharmaceuticals, Inc.; March 2025. Accessed August 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.
5. Chew EY, Gillies M, Jaffe GJ, et al; MacTel CNTF NTMT-03 Research investigators. Cell-Based Ciliary Neurotrophic Factor Therapy for Macular Telangiectasia Type 2. NEJM Evid. 2025 Aug;4(8):EVIDoa2400481. doi: 10.1056/EVIDoa2400481. Epub 2025 Jul 22. PMID: 40693847.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
H35.071	Retinal telangiectasis, right eye
H35.072	Retinal telangiectasis, left eye
H35.073	Retinal telangiectasis, bilateral
H35.079	Retinal telangiectasis, unspecified eye

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC