# Encelto (revakinagene taroretcel-lwey) (Intravitreal Implant)

**Effective Date: 11/01/2025**
**Review Date: 08/20/2025**
**Scope: Medicaid, Commercial, Medicare**

## I. Length of Authorization

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

## II. Dosing Limits

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

- Max 1 dose per eye per lifetime (one single-dose implant containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF, per eye)

## III. Summary of Evidence

Encelto (revakinagene taroretcel-lwey) is the first FDA-approved treatment for MacTel type 2. It is a surgically implanted, allogeneic encapsulated cell-based gene therapy that continually delivers recombinant human ciliary neurotrophic factor (rhCNTF) to the retina to slow disease progression. The approval of Encelto was based on results from two Phase 3, randomized, multicenter studies (Study 1: NTMT-03-A [NCT03316300] and Study 2: NTMT-03-B [NCT03319849]). Of a combined 228 patients, those who were treated with Encelto (Study 1, n = 58; Study 2, n = 59) demonstrated a statistically significant reduction in the rate of change in ellipsoid zone area loss over 24 months compared with that of patients who received sham treatment. The most common adverse reactions (>15%) are conjunctival hemorrhage, delayed dark adaptation, foreign body sensation in eyes, eye pain, suture-related complications, and miosis.

## IV. Initial Approval Criteria[1]

**Coverage for is provided in the following conditions:**

- Member is between 18 and 65 years of age; AND
- Member is free of ocular and/or peri-ocular infections; AND

- Member does not have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM); AND
- Member will be monitored for signs and symptoms of vision loss [e.g., Best Corrected Visual Acuity (BCVA), etc.] and infectious endophthalmitis at baseline and periodically during treatment; AND
- Member 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
- Member does not have evidence of other ocular disease that would preclude treatment of MacTel; AND
- Member will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery; AND
- Member 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
- Encelto has been prescribed by an ophthalmologist; AND
- Implantation procedure will be completed at an authorized treatment facility by an ophthalmologist; AND
- There is no previous Encelto implant in the treatment eye; AND
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

**Idiopathic Macular Telangiectasia (MacTel Type 2)** † Φ [1-4]

- Member 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
- Member does NOT have neovascular macular telangiectasia; AND
- Member 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
- Member has a BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart; AND

- Member 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 (SDOCT), at between 0.16 $mm^2$ and 2.00 $mm^2$; AND
- Member 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)
    - Foveal involvement

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

## V. Renewal Criteria[1]

Coverage cannot be renewed.

## VI. Dosage/Administration[1]

| Indication | Dose |
|---|---|
| Idiopathic macular telangiectasia type 2 (MacTel) | The recommended dose is one Encelto implant per affected eye.<br>Each Encelto implant contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotropic 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.* | |

## VII. Billing Code/Availability information

**HCPCS Code:**

- J3590- Unclassified biologics

**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

## VIII. References

1. Encelto [package insert]. Cumberland, RI; Neurotech Pharm., Inc; March 2025. Accessed July 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.

### 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) |
| 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 |

**Policy Rationale:**

Encelto was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Encelto according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while

minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.