Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the
Blue Cross Blue Shield Association

Title: Encelto (revakinagene taroretcel-lwey)
(Intravitreal)

Professional / Institutional
Original Effective Date: August 22, 2025
Latest Review Date:
Current Effective Date: August 22, 2025

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

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 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.*	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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]:

- 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)*

III. Initial Approval Criteria [1]

Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. 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.

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM); **AND**
- Patients 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]

Coverage cannot be renewed.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS Code(s):

- 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

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.

REVISIONS	
Posted: 07-22-2025 Effective: 08-22-2025	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.