

## Medical Policy Manual **Approved New: Do Not Implement until 8/30/25**

### **Revakinagene Taroretcel-lwey (Encelto™)**

#### **IMPORTANT REMINDER**

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

#### **POLICY**

#### **INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

Encelto is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

All other indications are considered experimental/investigational and not medically necessary.

#### **DOCUMENTATION**

Submission of the following information is necessary to initiate the prior authorization review:

- Medical records (e.g., chart notes and/or laboratory reports) documenting following:
  - Confirmation of diagnosis
  - Spectral domain-optical coherence tomography (SD-OCT) results
  - Best corrected visual acuity (BCVA) results

#### **PRESCRIBER SPECIALITIES**

This medication must be prescribed by or in consultation with an ophthalmologist.

#### **EXCLUSIONS**

Coverage will not be provided for members with any of the following conditions:

- Evidence of intraretinal neovascularization or subretinal neovascularization (SRNV) (e.g., neovascular MacTel), as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye
- Received intravitreal steroid therapy for non-neovascular MacTel within the past 3 months
- Previously received intravitreal anti-vascular endothelial growth factor (VEGF) therapy in the affected eye(s) or has received intravitreal anti-VEGF in the non-affected eye within the past 3 months
- Evidence of central serous chorio-retinopathy in either eye
- Evidence of pathologic myopia in either eye
- Significant corneal or media opacities in either eye
- Had a vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty
- Member has any of the following lens opacities:
  - Cortical opacity greater than standard 3

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- Posterior subcapsular opacity greater than standard 2
- A nuclear opacity greater than standard 3 as measured on the Age-Related Eye Disease Study (AREDS) clinical lens grading system
- Has undergone lens removal in the previous 3 months or YAG laser within 4 weeks
- Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT)
- Is on chemotherapy
- History of ocular herpes virus in either eye
- Ocular or periocular infection
- Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)
- Member has any of the following comorbidities;
  - Glaucoma
  - Severe non-proliferative or proliferative diabetic retinopathy
  - Uveitis
- Unable to temporarily discontinue antithrombotic therapy (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) prior to insertion surgery to reduce the risk of implantation related vitreous hemorrhage
- Member has received a previous treatment course with Encelto in the affected eye(s)

### **COVERAGE CRITERIA**

#### **Idiopathic Macular Telangiectasia Type 2 (MacTel)**

Authorization of 3 months for one dose total may be granted for treatment of MacTel when all of the following criteria are met:

- Member must have at least one eye positive for the diagnosis of idiopathic macular telangiectasia type 2 (MacTel) as evidenced by fluorescein leakage and at least one of the following features:
  - Hyperpigmentation that is outside of a 500 micron radius from the center of the fovea
  - Retinal opacification
  - Crystalline deposits
  - Right-angle vessels
  - Inner/outer lamellar cavities
- Member must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) (area of IS/OS loss) between 0.16 mm<sup>2</sup> and 2.00 mm<sup>2</sup> measured by spectral domain-optical coherence tomography (SD-OCT)
- Member 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 at screening
- Member must have steady fixation and sufficiently clear ocular media for good quality photographs

### **APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS**

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

### **ADDITIONAL INFORMATION**

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice

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Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

### **REFERENCES**

1. Encelto [package insert]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.
2. Chew EY, Peto T, Clemons TE, et al. Macular telangiectasia type 2: A classification system using multimodal imaging MacTel Project Report Number 10. Ophthalmol Sci. 2022;3(2):100261. Published 2022 Dec 8.
3. Kedarisetti KC, Narayanan R, Stewart MW, et al. Macular telangiectasia type 2: A comprehensive review. Clin Ophthalmol. 2022;16:3297-3309. Published 2022 Oct 10.

### **EFFECTIVE DATE**

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