Draft New Policy: Do Not Implement

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

  - 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 radium 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 mm2 and 2.00 mm2 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

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

ID_CHS