RX.PA.108.MPC Encelto (revakinagene taroretcel-lwey)

The purpose of this policy is to define the prior authorization process for Encelto™ (revakinagene taroretcel-lwey), indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

PROCEDURE

A. Initial Authorization Criteria

1. Adults with Idiopathic Macular Telangiectasia Type 2 (MacTel)

- Must be prescribed by an ophthalmologist
- Must be age 21-64 years or older
- Documentation of MacTel Type 2 diagnosis confirmed with typical fluorescein leakage AND at least one other feature of the disease:
  a) Hyperpigmentation outside a 500-micron radius from the center of the fovea
  b) Retinal opacification
  c) Crystalline deposits
  d) Right angle vessels
  e) Inner/outer lamellar cavities
- 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 mm2 and 2.00 mm2
- Patient does not have a known hypersensitivity to Endothelial Serum Free Media
- Provider attest that the patient does not have evidence of advanced disease that would preclude treatment of MacTel
- Provider attests that the 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) following implantation
- Provider attests that the patient will temporarily discontinue antithrombotic medications (Ex: oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery
- Patient has not received intravitreal steroid therapy or intravitreal anti–vascular endothelial growth factor (VEGF) therapy, within the last 3 months
- Patient has not had prior treatment with Encelto in the requesting affected eye

- Documentation that the patient has been evaluated and does not have the following (evaluation completed within 60 days prior to the request):
  a) Evidence of an ocular or periocular infection
  b) Evidence of intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye
  c) Evidence of central serous chorio-retinopathy in either eye
  d) Evidence of pathologic myopia in either eye
  e) Significant media or corneal opacities in either eye
  f) History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty
  g) Any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 2, or nuclear opacity > standard 3 as measured on the Age-Related Eye Disease Study (AREDS) clinical lens grading system
  h) Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks
  i) History of ocular herpes virus in either eye
  j) Evidence of intraretinal hyperreflectivity by optical coherence tomography

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Ocular disorder treatments will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

- No reauthorization allowed

Length of Authorization (if above criteria met)	
Initial Authorization	3 Months One Encelto treatment per affected eye per lifetime
Reauthorization	No Reauthorization Allowed

APPLICABLE CODES

Code	Description
J3403	Revakinagene taroretcel-lwey, per implant

References

1. Encelto [package insert]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*01/2026*