

New Hampshire Medicaid Fee-for-Service Program

Encelto (revakinagene taroretcel-lwey) Criteria

Approval Date: November 17, 2025

Medications

Brand Names	Generic Names	Indication
Encelto	revakinagene taroretcel-lwey	Treatment of adults with idiopathic macular telangiectasia type 2 (MacTel)

Criteria for Approval

1. Patient is 18 years of age or older; **AND**
2. Patient has a diagnosis of macular telangiectasia type 2 (MacTel) in at least one eye, as evidenced by typical fluorescein leakage and ≥ 1 of the following additional features of 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; **AND**
3. Patient does not have neovascular MacTel; **AND**
4. 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**
5. 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), between 0.16 mm^2 and 2 mm^2 ; **AND**
6. Patient does not have evidence of any of the following:
 - a. Intraretinal neovascularization or subretinal revascularization (SRNV) as evidenced by hemorrhage, hard exudate, subretinal fluid, or intraretinal fluid in either eye
 - b. Central serous chorioretinopathy in either eye
 - c. Pathologic myopia in either eye
 - d. Significant media or corneal opacities in either eye
 - e. History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty
 - f. Any of the following lens opacities: cortical opacity $>$ standard 3, posterior subcapsular opacity $>$ standard 2 or nuclear opacity $>$ standard 3
 - g. Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks

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- h. History of ocular herpes virus in either eye
- i. Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT); **AND**
- 7. Patient does not have ocular or periocular infections; **AND**
- 8. Patient does **not** have known hypersensitivity to Endothelial Serum Free Media (Endo-SFM); **AND**
- 9. Patient will be monitored for signs and symptoms of vision loss (e.g., best corrected visual acuity [BCVA]) and infectious endophthalmitis at baseline and periodically during treatment; **AND**
- 10. Patient will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, loss of visual acuity); **AND**
- 11. Patient does not have evidence of other ocular disease that would preclude treatment of MacTel; **AND**
- 12. Patient will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) prior to the insertion surgery; **AND**
- 13. 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.

Initial approval period: 1 year

Criteria for Denial

Failure to meet approval criteria.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	09/23/2025
Commissioner Designee	Approval	11/17/2025