blue california
Promise Health Plan

revakinagene taroretcel-lwey (Encelto)

Medical Benefit Drug Policy

Place of Service
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Allogeneic encapsulated cell-based gene therapy
HCPCS:
J3403:Revakinagene taroretcel-lwey, per implant
How Supplied:
One single-dose implant containing 200,000 to 440,000 allogeneic 29 retinal pigment epithelial cells expressing rhCNTF

Condition(s) listed in policy *(see coverage criteria for details)*

- Idiopathic Macular Telangiectasia Type 2 (MacTel)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Idiopathic Macular Telangiectasia Type 2 (MacTel)
Meets medical necessity if all the following are met:
1. Being prescribed and administered by a retina specialist/vitreoretinal surgeon
2. Documented diagnosis of MacTel with the following: Photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm2 measured by spectral domain-optical coherence tomography (SD-OCT)
3. Best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better)
4. Patient does not have neovascular MacTel

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Covered Doses:
One implant (200,000 to 440,000 allogeneic 29 retinal pigment epithelial cells expressing rhCNTF) given intravitreally per affected eye

Coverage Period:
One implant/eye per lifetime

ICD-10:
H35.071, H35.072, H35.073, H35.079

References

1. Encelto (revakinagene taroretcel) [prescribing information]. Cumberland, RI: Neurotech Pharmaceuticals Inc; March 2025.

Review History

Date of Last Annual Review: 2Q2026
Changes from previous policy version:

- No clinical changes following routine annual review

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee