

revakinagene taroretcel-lwey (Encelto)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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

Covered Doses:

revakinagene taroretcel-lwey (Encelto)

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

References

1. Encelto (revakinagene taroretcel-lwey) Prescribing Information. Neurotech Pharmaceuticals, Inc., Cumberland RI: 3/2025.

Review History

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- Added HCPCS J3403, effective 10/1/2025

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee