

revakinogene taroretcel-lwey (Encelto)

HCPCS: J3403 Revakinogene taroretcel-lwey, per implant (Encelto)

LOB:	MCAL
Duration of Approval:	One single dose per affected eye per lifetime
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Encelto (revakinogene taroretcel-lwey) implant

****All requests must be approved by a Medical Director******PA CRITERIA FOR APPROVAL:**

1. The member has a diagnosis for an FDA approved indication (*refer to package insert under References*) OR a compendia supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed by an ophthalmologist **AND**
3. Chart notes provided confirming diagnosis of idiopathic macular telangiectasia type 2 (MacTel) with evidence of fluorescein leakage typical of MacTel AND at least one of the following:
 - a. Hyperpigmentation that is outside of 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**
4. Documentation showing a photoreceptor inner segment/outer segment 395 (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm² measured by spectral 396 domain-optical coherence tomography (SD-OCT) **AND**
5. Documentation showing best corrected visual acuity (BCVA) of 20/80 or better **AND**
6. The member does NOT have any of the following:
 - a. Neovascular macular telangiectasia (MacTel)
 - b. Ocular or periocular infections
 - c. Hypersensitivity to Endothelial Serum Free Media (endo-SFM)**AND**
7. The member has not received prior treatment with Encelto for the requested eye(s) **AND**
8. The member has not received intravitreal steroid therapy or intravitreal anti-vascular endothelial growth factor (VEGF) therapy, for non-neovascular MacTel within the last 3 months

OTHER INFORMATION:

HCPCS	Description	Brand name
J3403	Revakinogene taroretcel-lwey, per implant	Encelto
**Refer to DHCS Physician-Administered Drugs (PADs) Special Billing for (Encelto) for billing information and follow allowable number of units to approve. **		

revakinagene taroretcel-lwey (Encelto)

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REFERENCES:

1. Encelto Prescribing Information. www.neurotechpharmaceuticals.com/wp-content/uploads/ENCERTO-PRESCRIBING-INFORMATION.pdf. 03/2025.
2. Neurotech Pharmaceuticals. A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol A). clinicaltrials.gov/study/NCT03316300. NLM Identifier: NCT03316300.
3. Neurotech Pharmaceuticals. A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol B). clinicaltrials.gov/study/NCT03319849. NLM Identifier: NCT03319849.
4. DHCS Cell and Gene Therapy Overview. mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/821726E2-2EAB-4A86-AA42-4778E89A38FD/celgenover.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYlPyP5ULO. 09/2025.

UMC REVIEW:

6/2026