CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Encelto (revakinagene taroretcel-lwey)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Encelto, approved by the FDA in 2025, is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).
MacTel is a macular neurodegenerative disease. The non-proliferative phase is primarily driven by neurodegenerative processes, which leads to decreased photoreceptor function and subsequent slow progressive vision loss. Patients typically present with difficulty reading, metamorphopsia (distorted vision), and paracentral scotomas (blind spots). Visual acuity is preserved until late in the disease. Fluorescein angiography (FA) is the gold standard for diagnosis.
The Encelto implant is surgically anchored with a titanium loop and secretes recombinant human ciliary neurotrophic factor (rhCNTF), an endogenously produced neurotrophic factor. CNTF has been shown to slow photoreceptor loss as measured in the area of ellipsoid zone disruption.

Encelto (revakinagene taroretcel-lwey) will be considered for coverage when the following criteria are met:

Macular telangiectasia type 2 (MacTel)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by an ophthalmologist; AND
3. Member has a diagnosis of MacTel with evidence of fluorescein leakage and at least one of the following features:
   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. Chart notes show photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 mm^2 and 2.00 mm^2 as measured by spectral-domain optical coherence tomography (SD-OCT); AND
5. Chart notes show best corrected visual acuity (BCVA) of 20/80 or better; AND
6. Chart notes show whether one or both eyes is to be treated; AND
7. Member does NOT have evidence of neovascularization; AND
8. Member does NOT have active or suspected ocular or periocular infection.
9. **Dosage allowed/Quantity limit:** One implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF), by surgical intravitreal implantation. QL: 1 implant per affected eye

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:
1. Encelto will not be reauthorized.

CareSource considers Encelto (revakinagene taroretcel-lwey) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/18/2025	New policy for Encelto created.

References:

1. Encelto [prescribing information]. Neurotech Pharmaceuticals, Inc.; 2025.
2. Chew EY, Clemons TE, Jaffe GJ, et al. Effect of Ciliary Neurotrophic Factor on Retinal Neurodegeneration in Patients with Macular Telangiectasia Type 2: A Randomized Clinical Trial. *Ophthalmology*. 2019;126(4):540-549. doi:10.1016/j.ophtha.2018.09.041
3. Kedarisetti KC, Narayanan R, Stewart MW, Reddy Gurram N, Khanani AM. Macular Telangiectasia Type 2: A Comprehensive Review. *Clin Ophthalmol*. 2022;16:3297-3309. Published 2022 Oct 10. doi:10.2147/OPTH.S373538
4. Khodabande A, Roohipoor R, Zamani J, et al. Management of Idiopathic Macular Telangiectasia Type 2. *Ophthalmol Ther*. 2019;8(2):155-175. doi:10.1007/s40123-019-0170-1

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