

Encelto™ (revakinagene taroretcel-lwey)

When requesting Encelto® (revakinagene taroretcel-lwey), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Encelto is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

Coverage Guidelines

Macular Telangiectasia Type 2, Idiopathic

The individual must meet all of the following criteria for authorization:

- Is ≥ 18 years of age;
- Is not receiving re-treatment of eye(s) previously treated with Encelto;
- Does not have neovascular (or proliferative) MacTel;
- Meets one of the following:
 - Has a best-corrected visual acuity (BCVA) of 54 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR
 - Has a best-corrected visual acuity (BCVA) of 20/80 or better using the Snellen chart;
- Encelto is administered by or under the supervision of an ophthalmologist.

Approval duration: one time (per lifetime)

Dosing Recommendations

Administer one Encelto intravitreal implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF).

References

1. Encelto™ intravitreal implant [prescribing information]. Cumberland, RI: Neurotech; March 2025.
2. American Academy of Ophthalmology – What is macular telangiectasia. Available at: <https://www.aao.org/eye-health/diseases/macular-telangiectasia>. Published on September 23, 2024. Accessed on March 17, 2025.
3. Khodabande A, Roohipour R, Zamani J, et al. Management of idiopathic macular telangiectasia type 2. *Ophthalmol Ther.* 2019;8:155-175.
4. Kedariseti KC, Narayanan R, Stewart MW, et al. Macular telangiectasia type 2: a comprehensive review. *Clin Ophthalmol.* 2022;16:3297-3309.
5. Encelto – FDA Clinical Review. Available at: <https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information/encelto>. Accessed on April 13, 2026.

6. Hereen TFC, Clemons T, Scholl HPN, et al. Progression of vision loss in macular telangiectasia type 2. *Investig Ophthalmol Vis Sci*. 2015;56:3905-3912.
7. Reddy NG, Prabhu V, Sharma SV, et al. Baseline demographic, clinical and multimodal imaging features of young patients with type 2 macular telangiectasia. *Int J Retina Vitreous*. 2026;9:47.