EVH Clinical Guideline 5107.CC for Encelto (Revakinagene Taroretcel-lwey)

Guideline Number: EVH_CG_5107.CC	**Applicable Codes**	
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Original Date: December 2025	**Last Revised Date:** October 2025	**Implementation Date:** December 2025

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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for Encelto (revakinagene taroretcel).

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below.

- Must be prescribed by an ophthalmologist
- Must be 21 to 80 years old
- Must submit documentation that supports a diagnosis of idiopathic macular telangiectasia (MacTel) type 2
    - Documentation should include imaging results that support the diagnosis [e.g., temporal widening of the foveal pit seen on Optical Coherence Tomography (OCT), dilated leaking capillaries seen on a Fundus Fluorescein Angiography)
- Must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 measured by spectral domain-optical coherence tomography (SD-OCT)
- Must have a best corrected visual acuity (BCVA) of 54-letter score or better (20/80 or better)
- Must have chart note documentation or an attestation from the provider of the following:
    - Must not have received intravitreal steroid therapy OR anti-vascular endothelial growth factor (VEGF) therapy in the target eye within the past 3 months
    - Must not have neovascular MacTel, central serous chorioretinopathy, pathologic myopia, significant corneal or media opacities (such as cataracts, corneal scars, and

vitreous hemorrhages) in either eye

- Must not have ocular or periocular infections
- Must not have known hypersensitivity to Endothelial Serum Free Media (SFM)
- The member has been counseled on reporting signs or symptoms that could be associated with severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation

- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved-labeling

REAUTHORIZATION CRITERIA

Encelto is not eligible for reauthorization beyond the initial implant per eye.

APPROVAL DURATIONS

Initial Authorization	Up to 6 months
Reauthorization	N/A

CODING AND STANDARDS

Codes

Code	Brand	Description
J3590	Encelto	Revakinagene taroretcel-lwey

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

Macular telangiectasia type 2 (MacTel 2) is a slowly progressive disease of the macula impairing both distant and near vision, causing loss of central vision. It is a bilateral asymmetric condition affecting people over 40 years old. The prevalence of MacTel 2 is around 0.1% of the population.

Encelto is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2. It is intended for surgical intravitreal implantation under aseptic conditions by a qualified ophthalmologist. The recommended dose is one Encelto implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotropic factor (rhCNTF). CNTF is neuroprotective and helps maintain photoreceptors and retinal ganglion cells. This therapy slows the progression of MacTel 2 but is not a cure.

POLICY HISTORY

Date	Summary
October 2025	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

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REFERENCES

1. U.S. Food and Drug Administration. (2025). ENCELTO Package Insert. Retrieved from https://www.fda.gov/media/185726/download
2. Kedarisetti, K. C., Narayanan, R., Stewart, M. W., Reddy Gurram, N., & Khanani, A. M. (2022). Macular Telangiectasia Type 2: A comprehensive review. Clinical Ophthalmology, 16 3297–3309. https://doi.org/10.2147/OPTH.S373538