

**POLICY:** Ophthalmology – Encelto Utilization Management Medical Policy

- Encelto™ (revakinagene tarorectel-lwey intravitreal implant – Neurotech)

**EFFECTIVE DATE:** 08/01/2025

**LAST REVISION DATE:** 05/21/2025

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

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## **OVERVIEW**

Encelto, a recombinant human ciliary neurotrophic factor (rhCNTF) is indicated for the treatment of **idiopathic macular telangiectasia type 2 (MacTel)** in adults.<sup>1</sup>

In the pivotal studies, eligible patients had a best-corrected visual acuity (BCVA) of 84 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Snellen chart equivalent of 20/80 or better).<sup>1</sup>

## **Dosing**

The recommended dose is one Encelto implant per affected eye.

## **Disease Overview**

MacTel is a rare, slowly progressive, neurodegenerative disease that affects the macula.<sup>2-4</sup> MacTel develops when there are problems with the tiny blood vessels surrounding the fovea, which is the center of the macula and is essential to provide us our sharpest central vision for activities like reading.<sup>2</sup> Most patients with MacTel do not have symptoms; however, over time, patients may experience blurring, distorted vision, and loss of central vision, which progresses over a period of 10 to 20 years. In advanced cases, MacTel is characterized by outer retinal degeneration, atrophy, and scarring.<sup>3,4</sup> There are two types of MacTel.<sup>2,3</sup> In type 1 MacTel, the blood vessels dilate and tiny aneurysms form, which leak and results in macular edema, leading to damaged macular cells. Type 2 MacTel is the more common type; the blood vessels around the fovea become abnormal and may widen.

## **POLICY STATEMENT**

Prior Authorization is recommended for medical benefit coverage of Encelto. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Encelto as well as the monitoring required for adverse events and long-term efficacy, approval requires Encelto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Encelto is recommended in those who meet the following criteria:

### FDA-Approved Indication

**1. Macular Telangiectasia Type 2, Idiopathic.** Approve one implant per affected eye(s) if the patient meets ALL of the following (A, B, C, and D):

- A)** Patient is  $\geq 18$  years of age; AND
- B)** Patient does not have neovascular (or proliferative) MacTel; AND
- C)** Patient meets ONE of the following (i or ii):
  - i.** Patient has a best-corrected visual acuity (BCVA) of 54 letters or better using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; OR
  - ii.** Patient has a best-corrected visual acuity (BCVA) of 20/80 or better using the Snellen chart; AND
- D)** The medication is administered by or under the supervision of an ophthalmologist.

**Dosing.** Approve one Encelto implant per affected eye(s), administered by a single surgical intravitreal procedure.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Encelto is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## 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, Roohipoor 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.

## HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/21/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	06/17/2025