UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Ophthalmology – Gene Therapy – Encelto Utilization Management Medical Policy
- Encelto™ (revakinagene taroretcel-lwey intravitreal implant – Neurotech)

REVIEW DATE: 05/21/2025; selected revision 11/12/2025, 03/04/2026

OVERVIEW

Encelto, an allogeneic encapsulated cell-based gene therapy, is indicated for the treatment of **idiopathic macular telangiectasia type 2 (MacTel)** in adults.[1]

Each Encelto implant contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (CNTF).[1] CNTF is one of several neurotrophic factors that are produced endogenously by neurons and supporting glial cells. Although the exact mechanism of action is not completely understood, it is thought that endogenous CNTF initially targets Müller glia to trigger a cascade of signaling events that may promote photoreceptor survival.

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).[1]

Dosing

The recommended dose is one Encelto implant per affected eye.[1] The implant is administered by a single surgical intravitreal procedure performed by a qualified ophthalmologist.

Disease Overview

MacTel is a rare, slowly progressive, neurodegenerative disease that affects the macula.[2-4] 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.[2] 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 loss of photoreceptors and consequently, visual impairment which ultimately results in loss of vision.[3,4] There are two types of MacTel.[2,3] 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. All approvals are provided for one implant per affected eye(s). Note: A 3-month (90 days) approval duration is applied to allow for the one-time treatment of the affected eye(s). 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 a one-time use in each treated eye (i.e., one implant per affected eye(s); total of two implants per patient) if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient is not receiving re-treatment of eye(s) previously treated with Encelto; AND
   - **C)** Patient does not have neovascular (or proliferative) MacTel; AND
   - **D)** 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
   - **E)** The medication is administered by or under the supervision of an ophthalmologist.

   Dosing. Approve one Encelto implant per affected eye(s) [two implants per patient], administered by a single surgical intravitreal procedure.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Encelto is not recommended in the following situations:

1. **Retreatment of Previously Treated Eye(s)**. Encelto is approved for a one-time use in each treated eye (i.e., one implant per affected eye[s]).[1] There are no data regarding re-treatment with Encelto.

2. 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. Kedarisetti 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
DEU Update	**06/02/2025.** Policy name was changed from Ophthalmology – Encelto UM Medical Policy to Ophthalmology – Gene Therapy – Encelto UM Medical Policy. Overview section was revised to include additional information.	--
Selected Revision	**Macular Telangiectasia Type 2, Idiopathic:** Policy intent was to approve one implant per affected eye(s); revised verbiage and clarified intent. In addition, a requirement that "patient is not receiving re-treatment of eye(s) previously treated with Encelto" was added. The Dosing criterion was revised to add "[two implants per patient]"; "Approve one Encelto implant per affected eyes(s) [two implants per patient], administered by a single surgical intravitreal procedure". **Conditions Not Recommended for Approval:** "Re-treatment of previously treated eye(s)" was added.	11/12/2025
Selected Revision	**Policy Statement:** Approval duration was changed from 1 month (30 days) to 3 months (90 days).	03/04/2026