Drug Coverage Policy

Effective Date.....5/21/2026
Coverage Policy Number.....IP0744
Policy Title..... Encelto

Ophthalmology – Gene Therapy - Encelto

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

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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 typically occurs in adults > 40 years of age.[3,5] The reported prevalence of MacTel varies; one source notes that the estimated prevalence of MacTel is approximately 0.1% among 4,790 individuals 43 to 86 years of age, whereas another source cites the estimated prevalence to be 0.004% to 0.022% in 22,415 patients.[2,6] Risk factors include diabetes, coronary artery disease or hypertension, and smoking.[3,5,7] There may also be a genetic predisposition, although this is not completely understood.

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.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Encelto. Because of the specialized skills required for evaluation and diagnosis of patients treated with Encelto as well as the specialized training required for administration of Encelto, approval requires Encelto to be administered by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for one implant per affected eye(s). The approval duration is 90 days to allow for an adequate timeframe to administer Encelto. All reviews (approvals and denials) will be forwarded to the Medical Director for evaluation.

Encelto is considered medically necessary when the following criteria are met:

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, E and F):
   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; AND
   F) If criteria A through E are met, approve one Encelto implant per affected eye(s) [two implants per patient], administered by a single surgical intravitreal procedure.

   Dosing. The recommended dose of Encelto is one implant per affected eye(s) [two implants per patient], as a single surgical intravitreal procedure.

Conditions Not Covered

Encelto for any other use is considered not medically necessary including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Re-treatment 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.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J3403	Revakinagene taroretcel-lwey, per implant

References

1. Encelto™ intravitreal implant [prescribing information]. Cumberland, RI: Neurotech; March 2025.
2. 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 2, 2025.
3. Kedarisetti KC, Narayanan R, Stewart MW, et al. Macular telangiectasia type 2: a comprehensive review. *Clin Ophthalmol*. 2022;16:3297-3309.
4. 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.

5. 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 April 13, 2026.
6. 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*. 2023;9:47.
7. Khodabande A, Roohipoor R, Zamani J, et al. Management of idiopathic macular telangiectasia type 2. *Ophthalmol Ther*. 2019;8:155-175.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy	6/12/2025	7/15/2025
Coding Information: **Added HCPCS**: J3403 with a code effective date of 10/1/2025 **Updated** the description for C9399, J3490 & J3590 to include the note "Code effective until 09/30/2025"	-	10/01/2025
Updated Policy Statement **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. **Conditions Not Recommended for Approval:** Re-treatment of previously treated eye(s) was added. **Updated** policy template.	11/20/2025	11/20/2025
Policy Statement: Approval duration was changed from 1 month (30 days) to 3 months (90 days). **Coding Information:** **Removed** HCPCS codes C9399 J3490 & J3590 **Removed** "code effective date 10/1/2025" from J3403	3/26/2026	5/21/2026
Policy Statement: The statement that "approval requires Encelto to be prescribed by or in consultation with a physician who specializes in the condition being treated" was changed to "approval requires Encelto to be administered by or in consultation with a physician who specializes in the condition being treated" and approval duration was changed from "3 months (90 days)" to "90 days". **Macular Telangiectasia Type 2, Idiopathic:** Approved dosing for Encelto was added as an approval requirement, to align with the template for UM Medical policies with corresponding Embarc policies. In addition, the Dosing section was revised to align with the standard Dosing statement language.	5/14/2026	5/21/2026

The policy effective date is in force until updated or retired.