Drug Coverage Policy

Effective Date……7/15/2025
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). 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. 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.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for 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.

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

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 ≥ 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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Encelto for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 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
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	7/15/2025

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