

Medical Necessity Guidelines Encelto (revakinagene taroretcel-lwey)

Policy Number: 110

Contents

Overview.....	1
Medicare Advantage	1
Mass General Brigham ACO	2
One Care and Senior Care Options (SCO).....	2
Commercial and Qualified Health Plans.....	2
Codes	2
Summary of Evidence	3
Effective Dates.....	3
References.....	3

Overview

Encelto (revakinagene taroretcel-lwey) is an allogenic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

Medicare Advantage

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **As of Mass General Brigham Health Plan's most recent policy review, Medicare had:**

- [Medicare Benefit Policy Manual Chapter 15 - Covered Medical and Other Health Services](#)

When CMS documentation references FDA labeling, Mass General Brigham Health Plan develops coverage criteria to clarify medical necessity of the requested services. Mass General Brigham Health Plan coverage criteria align with FDA labeling without contradicting existing determinations and enhance the clarity of medical necessity requirements, documentation requirements, and clinical indications.

Criteria

1. Criteria for Initial Approval
 - Authorization may be granted to members 18 years of age or older when the following criteria are met:
 - a. The member is 18 years of age or older; and
 - b. The member has a confirmed diagnosis of MacTel.

2. Dosing and Administration
 - a. Encelto is administered by a single surgical intravitreal procedure performed by a qualified ophthalmologist.
 - b. The recommended dose of Encelto is one single implant containing 200,000 to 440,000 allogenic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF).
3. Documentation Requirements:
 - a. Tests and imaging that confirm diagnosis of MacTel; and
 - b. Encelto is prescribed by, or there are consult notes from, a qualified ophthalmologist.

Exclusions

1. Active or known ocular or periocular infections.
2. Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM).
3. The member has been previously treated with Encelto in the target eye.

Mass General Brigham ACO

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Prior authorization requests for Encelto for Mass General Brigham ACO members should be submitted to the MassHealth Drug Utilization Review Program. Criteria for Encelto are found in [Table 72: Agents Not Otherwise Classified](#).

One Care and Senior Care Options (SCO)

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its One Care and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, or the member does not meet the medical necessity criteria for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. **See Medicare Advantage criteria and exclusions above. If Medicare Advantage criteria are not met, then MassHealth criteria are applied.**

Commercial and Qualified Health Plans

Prior Authorization Required	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
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Prior authorization for Encelto for Commercial and Qualified Health Plan members is managed by Prime Therapeutics. See the Prime Therapeutics policy for Encelto for more information.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Code	Code Description
J3403	Revakinagene taroretcel-lwey, per implant



Summary of Evidence

Macular telangiectasia type 2 (MacTel type 2) is a bilateral, progressive retinal neurodegenerative disease characterized by parafoveal photoreceptor loss, ellipsoid zone (EZ) disruption, and gradual visual decline. A growing body of evidence supports the use of revakinagene tarorectel-lwey (Encelto), a cell-based therapy designed to deliver continuous intraocular ciliary neurotrophic factor (CNTF), as a treatment aimed at slowing retinal degeneration in MacTel type 2.

The pivotal randomized clinical trial conducted by the MacTel CNTF NTMT-03 Research Group demonstrated that CNTF-secreting encapsulated cell therapy significantly slowed structural disease progression compared with sham treatment (Chew et al., 2025). The primary outcome was change in EZ loss on optical coherence tomography (OCT), a validated biomarker of photoreceptor degeneration in MacTel. Over the study follow-up period, treated eyes showed a statistically significant reduction in the rate of EZ loss, with mean progression rates consistently lower than those observed in control eyes. Long-term durability of CNTF delivery has been further supported by extension and observational studies. Kauper et al. (2025) reported sustained CNTF bioactivity and structural retinal preservation over multiple years in individuals with retinal degenerative disorders, including MacTel type 2. Natural history data provide important context for these findings. A longitudinal OCT study by Raming et al. (2025) documented progression of EZ defects over time in untreated MacTel type 2 eyes, reinforcing the clinical relevance of the structural endpoints used in CNTF trials.

In aggregate, these studies indicate that Encelto provides durable, clinically meaningful slowing of retinal neurodegeneration in MacTel type 2. While improvements in visual acuity are modest, the preservation of retinal structure and function represents a substantial therapeutic advance for a disease previously managed with observation alone. Ongoing post-marketing surveillance and real-world data will be important for refining patient selection and long-term benefit-risk assessment.

Effective Dates

April 2026: Effective date.

References

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