Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Encelto® (revakinagene taroretcel-lwey)

Effective: May 1, 2026

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products

☐ Tufts Health Plan Commercial products

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)

☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

☒ Tufts Health One Care-- A dual-eligible product; Fax 617-673-0956

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Encelto (revakinagene taroretcel-lwey) is a cell therapy from Neurotech Pharmaceuticals Inc., for the treatment of Macular Telangiectasia type 2 (Mac Tel). Mac Tel is a rare ocular disease that causes abnormalities of capillaries of the fovea or perifoveal region which leads to the loss of outer nuclear layers and ellipsoid zone. The disease causes loss of central vision and is most commonly diagnosed in people aged 40 and older. Encelto is a cell therapy designed to deliver therapeutic doses of ciliary neurotrophic factor (CNTF) to the retina to aid in slowing the proregression of the disease. Encelto is the first and only FDA-approved treatment for Mac Tel and received approval on March 6, 2025.

Food and Drug Administration (FDA) Approved Indications:

- Encelto (revakinagene taroretcel-lwey) is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel). This therapy is contraindicated for people with ocular or periocular infections and known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members and CMS for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. When CMS and MassHealth do not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service. Point32Health covers Encelto in accordance with MassHealth coverage criteria.

For the therapy Encelto, evidence is sufficient for coverage. Encelto received FDA approval in March 2025 as a new implantable cell therapy that is the first and only approved treatment for adults with macular telangiectasia type 2 (MacTel). Encelto reached it primary endpoint as the change in the area of the ellipsoid zone disruption as measured on an OCTimage at 24 months from the baseline; The mean (SE) area of photoreceptor loss increased 0.27 ± 0.05 mm2 from baseline to 24 months in the sham group compared with 0.22 ± 0.05 mm2 from baseline to 24 months in the implant group.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover Encelto for Members aged 18 years or older when **ALL** the following clinical criteria is met:

1. Diagnosis of Macular Telangiectasia type 2; **and**
2. Member is ≥18 years of age; **and**
3. Prescriber is an ophthalmologist or consult notes from an ophthalmologist are provided; **and**
4. Evidence of fluorescein leakage in treatment eye; **and**
5. Inner-segment or outer-segment photoreceptor break (loss) in ellipsoid zone between 0.16 and 2.00 mm; **and**
6. BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart; **and**
7. Absence of neovascularization in the treatment eye; **and**
8. ALL of the following:
    a. No previous treatment with Encelto in treatment eye; **and**
    b. Member has not had major surgery in treatment eye or fellow eye within the last six months
    c. ONE of the following:
        i. Assuming Member is undergoing initial unilateral treatment; **or**
        ii. Member is undergoing bilateral treatment for the second eye.

Limitations

Encelto is contraindicated under the following conditions:

1. Presence of ocular or periocular infection
2. Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3403	REVAKINAGENE TARORETCEL-LWEY, PER IMPLANT

References:

1. A study to determine the safety and efficacy of NT-501 in macular telangiectasia type 2 - protocol B. ClinicalTrials.gov. Updated September 24, 2024. Accessed March 24, 2025. https://clinicaltrials.gov/study/NCT03319849
2. Encelto (revakinagene taroretcel-lwey) [package insert]. Cumberland, RI. Neurotech Pharmaceuticals, March 2025.
3. Chew EY, Peto T, Clemons TE, et al. Macular telangiectasia type 2: A classification system using multimodal imaging MacTel Project Report Number 10. Ophthalmol Sci. 2022;3(2):100261. Published 2022 Dec 8.
4. Chew EY, Gillies M, Jaffe GJ, et. al. MacTel CNTF NTMT-03 Research investigators. Cell-Based Ciliary Neurotrophic Factor Therapy for Macular Telangiectasia Type 2. NEJM Evid. 2025 Aug;4(8):EVIDoa2400481. doi: 10.1056/EVIDoa2400481. Epub 2025 Jul 22. PMID: 40693847.
5. Kedarisetti KC, et. al. Macular Telangiectasia Type 2: A Comprehensive Review. Clin Ophthalmol. 2022 Oct 10;16:3297-3309. doi: 10.2147/OPTH.S373538. PMID: 36237488; PMCID: PMC9553319.
6. Turbert D. What is macular telangiectasia? American Academy of Ophthalmology. September 23, 2024. https://www.aao.org/eye-health/diseases/macular-telangiectasia. Accessed January 29, 2026.

Approval And Revision History

September 17, 2025: Reviewed by the Utilization Management Committee effective October 1, 2025.

Subsequent endorsement date(s) and changes made:

- March 18, 2026: Reviewed by the Medical Policy Approval Committee (MPAC), renewed without changes. References updated. Effective May 1, 2026.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.