Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

# Encelto® (revakinagene taroretcel-lwey)

*Effective: May 1, 2026*

| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request. | Yes ☒ No ☐ |
|---|---|

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ 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).

## Clinical Guideline Coverage Criteria

The Plan may cover revakinagene taroretcel-lwey (Encelto) implant when **ALL** the following clinical criteria is met:

1. Member is ≥18 years of age; **and**
2. Provider is a retina specialist with expertise in treating retinal disorders; ; **and**
3. The provided documentation confirms diagnosis of idiopathic macular telangiectasia type 2 (MacTel) in at least one eye with evidence of fluorescein leakage; **and**
4. Inner-segment or outer-segment photoreceptor break (loss) in ellipsoid zone between 0.16 $mm^2$ and 2.00 $mm^2$; **and**
5. BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart; **and**
6. Documentation confirms absence of neovascularization in the treatment eye; **and**

7. Provider attests that member will be monitored for signs and symptoms of retinal tears and/or retinal detachment.

**Note**: Authorization is limited to one treatment per eye per lifetime.

## Limitations

The Plan will not cover revakinagene taroretcel-lwey (Encelto) implant under any of the following conditions:

1. Member has previously been treated with Encelto in the treatment eye.
2. Member has undergone major surgery in the treatment eye within six months of the planned initiation of treatment.
3. Presence of ocular or periocular infection.
4. 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 November 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

December 17, 2025: Reviewed by the Medical Policy Approval Committee (MPAC). Effective date February 1, 2026.

Subsequent endorsement date(s) and changes made:

- March 18, 2026: Reviewed by MPAC. Revised criteria point #2. from “ophthalmologist with expertise in treating macular telangiectasia” to Retina specialist with expertise in treating retinal disorders”. 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.