Encelto® (Revakinagene Taroretcel-Lwey)

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➲ Instructions for Use

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Community Plan Policy

- Encelto® (Revakinagene Taroretcel-Lwey)

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Encelto is proven and medically necessary for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel) who meet all of the following:

- For **initial therapy**, **all** of the following:
  - Patient is at least 18 years of age; **and**
  - Submission of medical records (e.g., chart notes) confirming diagnosis of non-proliferative macular telangiectasia type 2 (MacTel) in at least one eye; **and**
  - Patient will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity); **and**
  - Encelto is prescribed by an ophthalmologist; **and**
  - Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; **and**
  - Authorization will be issued for no more than one treatment per eye per lifetime and for no longer than 60 days from approval

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

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HCPCS Code	Description
J3403	Revakinage taroretcel-lwey, per implant

Diagnosis Code	Description
H35.071	Retinal telangiectasis, right eye
H35.072	Retinal telangiectasis, left eye
H35.073	Retinal telangiectasis, bilateral
H35.079	Retinal telangiectasis, unspecified eye

Background

Macular telangiectasia type 2 (MacTel) is the most common type of macular telangiectasia. It is a neurodegenerative metabolic disorder linked to diabetes and coronary artery disease. In MacTel type 2, the blood vessels in the macula (the central part of the retina) become enlarged and leak fluid. This leakage causes swelling and scarring, which can lead to vision loss. Additionally, new blood vessels may grow beneath the macula, further damaging the macular photoreceptors and worsening vision loss. Type 2 MacTel happens most often in middle-aged adults. Both men and women are equally affected. In the United States, it is estimated that approximately 0.1% of the population, or around 250,000 people, have MacTel. Anti-vascular endothelial growth factor (VEGF) agents are the established standard of care for most proliferative forms of MacTel.

Encelto is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic MacTel. It involves a single surgical procedure performed by a qualified ophthalmologist, where an implant containing 200,000 to 440,000 retinal pigment epithelial cells is placed into the eye. Encelto works by secreting recombinant human ciliary neurotrophic factor (rhCNTF), which is one of several neurotrophic factors endogenously produced by neurons and supporting glial cells. Exogenous CNTF is thought to initially target Müller glia to trigger a cascade of signaling events that may promote photoreceptor survival; however, the mechanism of action for Encelto is not completely understood.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the member specific benefit plan document or in the medical or drug policy.

Clinical Evidence

Proven

The efficacy of Encelto was evaluated in two phase 3 studies involving subjects between 21 years and 80 years of age who have idiopathic macular telangiectasia type 2 (MacTel).

Study 1 was a randomized, multi-center, sham-controlled study that evaluated the efficacy of Encelto subretinal injection in MacTel patients over 24 months. To be enrolled, patients needed a photoreceptor IS/OS PR break in the ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 and a best corrected visual acuity of 20/50 or better. A total of 115 patients were randomized into two groups: Encelto (58 patients) and sham (57 patients). The primary endpoint was the rate of change in EZ area loss (IS/OS, macular PR loss) from baseline to month 24, while the secondary outcome measure was the mean change in aggregate sensitivity loss of microperimetry within the EZ break area from baseline to month 24. The mean age was 61 years (range 40 to 78 years), the majority of patients were female (69%) and white (85%). The median (min, max) baseline EZ area loss was 0.35 (0.15, 1.99) mm^2 for the Encelto group and 0.36 (0.16, 1.7) mm^2 for the sham group. The median (min, max) baseline aggregate sensitivity of microperimetry within the EZ break area 35.2 (0.75, 398.8) dB for the Encelto group and 35.5 (2, 281.3) dB for the sham group. At month 24, there was a statistically significant difference in the rate of change EZ area loss between groups: 0.075 mm^2 and 0.166 mm^2 with Encelto and sham, respectively (difference -0.091, 95% CI: -0.13, -0.06; $p < 0.0001$). This demonstrated that Encelto was superior to sham in slowing the rate of retinal disease progression over a period of 24 months. There was no statistically significant differences in the mean change in aggregate retinal sensitivity loss from baseline to 24 months: 25.27 and 43.02 with Encelto and Sham, respectively (difference -17.5, 95% CI: -32.58, -2.91; $p < 0.02$).

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Study 2 was a randomized, multi-center, sham-controlled study which enrolled adult with MacTel. For enrollment, the patients were required to have an IS/OS PR break in EZ between 0.16 and 2.00 mm^2 measured by Spectral-Domain Optical Coherence Tomography (SD-OCT) and Best Corrected Visual Acuity (BCVA) of 54-letter score or better (20/80 or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening. Patients with neovascular MacTel were excluded. Patients were randomized to receive either Encelto intravitreal implant or sham procedure under standard peri-operative procedures. The primary outcome measure was the rate of change in the area of EZ loss over 24 month, while the secondary outcome measure was the mean change in aggregate sensitivity loss of microperimetry within the EZ break area from baseline to month 24. A total of 113 patients were randomized into two groups Encelto (59 patients) and sham (44 patients).The mean age was 59 years (range: 40 to 75 years), the majority of patients were female (73%), and white (90%). The median (min, max) baseline EZ area loss was 0.48 (0.16, 1.63) mm^2 for Encelto and 0.39 (0.16, 1.38) mm^2 for the sham group. The median (min, max) baseline aggregate sensitivity of microperimetry within the EZ break area 40.07 (4.82, 291.52) dB for the Encelto group and 28.86 (0.33, 221.17) dB for the sham group. At month 24, there was a statistically significant difference in the rate of change in EZ area loss from baseline over 24 months: 0.111 mm^2 and 0.160 mm^2 with Encelto and Sham, respectively (difference -0.049, 95% CI: -0.089, -0.008; $p < 0.0186$). This demonstrated that Encelto was superior to sham in slowing the rate of retinal disease progression over a period of 24 months. There was no statistically significant differences in the mean change in aggregate retinal sensitivity loss from baseline to 24 months: 40.02 and 41.97 with Encelto and Sham, respectively (difference -1.95, 95% CI: -20.33, 16.43; $p < 0.83$).

The most common adverse reactions (≥ 2%) with Encelto use were conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, and iridocyclitis. Serious adverse reactions occurred in six patients (5%) including suture related complications (n = 5) and implant extrusion (n = 1).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Encelto (revakinagene taroretcel-lwey) is an allogeneic encapsulated cell-based gene therapy 12 indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

References

1. Encelto [package insert]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.
2. Chew EY, Gillies M, Jaffe GJ, et al. Cell-Based Ciliary Neurotrophic Factor Therapy for Macular Telangiectasia Type 2. *NEJM Evid*. 2025;4(8):EVIDoa2400481.
3. Kedarisetti KC, Narayanan R, Stewart MW, Reddy Gurram N, Khanani AM. Macular Telangiectasia Type 2: A Comprehensive Review. Clin Ophthalmol. 2022;16:3297-3309. Published 2022 Oct 10.

Policy History/Revision Information

Date	Summary of Changes

08/01/2026	**Template Update**
	• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
	• Added *Application* section to indicate this policy applies to:
	  ○ UnitedHealthcare Commercial benefit plans
	  ○ Individual Exchange benefit plans
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy versions 2025D0137B and IEXD0137.02

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Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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