THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Encelto (revakinagene taroretcel-lwey) **Effective Date:** 10/25

Description:

Macular telangiectasia type 2 (MacTel) is a slowly progressive disease of the macula. It had previously been considered a vascular condition, but recent evidence suggests a neurodegenerative etiology, with primary involvement of Muller cells. Retinal pigment epithelium (RPE) hyperplasia and subretinal neovascularization (SNV) are responsible for most of the vision loss in advanced cases. Encelto (revakinagene taroretcel-lwey; Neurotech Pharmaceuticals) is an ocular insert that represents the first treatment for Macular Telangiectasia type 2 (MacTel).

Encelto is an encapsulated cell therapy that is implanted in the vitreous via surgical intravitreal implantation by an ophthalmologist. Encelto is designed to deliver sustained therapeutic doses of ciliary neurotrophic factor (CNTF) to the retina. This technology is designed to slow the progression of MacTel.

Applicability:

This policy applies to all OSU Health Plan (OSUHP) benefit plans.

Definitions:

Idiopathic macular telangiectasia type 2 is a bilateral, slowly progressive neurodegenerative disease of the macula.

Macula is part of the retina, and it processes what is seen in your central vision.

Neurodegenerative diseases are chronic conditions that permanently damage and destroy parts of your

nervous system over time.

Ocular inserts are sterile solid or semisolid preparations, with a thin, flexible, and multilayered structure, for insertion in the conjunctival sac.

Policy:

OSU Health Plan considers revakinagene taroretcel-lwey (Encelto) implant medically necessary for a one-time intravitreal implantation per affected eye(s) for the treatment of an adult covered person with idiopathic macular telangiectasia type 2 (MacTel) when all the following criteria are met:

- Covered person must have at least one eye positive for the diagnosis of idiopathic macular telangiectasia type 2 (MacTel) as evidenced by fluorescein leakage and at least one of the following features:
    - Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea;
    - Retinal opacification;
    - Crystalline deposits;
    - Right-angle vessels; or
    - Inner/outer lamellar cavities; and
- Covered person must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) (area of IS/OS loss) between 0.16 mm2 and 2.00 mm2 measured by spectral domain-optical coherence tomography (SD-OCT); and
- Covered person has a 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; and
- Covered person must have steady fixation and sufficiently clear ocular media for good quality photographs.

Note: OSU Health Plan considers removal of Encelto implant medically necessary, if vitrectomy with a complete gas fill or silicone oil fill is required or infectious endophthalmitis occurs.

OSU Health Plan considers Encelto for all other indications experimental, investigational, or unproven.

Procedure:

Only one implant will be approved per eye per lifetime, when criteria are met.

Prior Authorization:

Encelto requires prior authorization. Vendor restrictions apply.

Exclusions:

OSU Health Plan considers a covered person with any of the following exclusions not eligible for Encelto implant:

- Covered person has evidence of intraretinal neovascularization or subretinal neovascularization (SRNV) (e.g., neovascular MacTel), as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye;
- Covered person has received intravitreal steroid therapy for non-neovascular MacTel within the past 3 months;
- Covered person has previously received intravitreal anti-vascular endothelial growth factor (VEGF) therapy in the affected eye(s) or has received intravitreal anti-VEGF in the non-affected eye within the past 3 months;
- Covered person has evidence of central serous chorio-retinopathy in either eye;
- Covered person has evidence of pathologic myopia in either eye;
- Covered person has significant corneal or media opacities in either eye;
- Covered person has had a vitrectomy, penetrating keratoplasty, trabeculectomy,

or trabeculoplasty;

- Covered person has any of the following lens opacities:
  - Cortical opacity greater than standard 3; or
  - Posterior subcapsular opacity greater than standard 2; or
  - A nuclear opacity greater than standard 3 as measured on the Age-Related Eye Disease Study (AREDS) clinical lens grading system;
- Covered person has undergone lens removal in the previous 3 months or YAG laser within 4 weeks;
- Covered person has evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT);
- Covered person is on chemotherapy;
- Covered person with a history of ocular herpes virus in either eye;
- Covered person has an ocular or periocular infection;
- Covered person has a known hypersensitivity to Endothelial Serum Free Media (Endo-SFM);
- Covered person has any of the following comorbidities:
  - Glaucoma;
  - Severe nonproliferative or proliferative diabetic retinopathy; or
  - Uveitis;
- Covered person must be able to temporarily discontinue antithrombotic therapy (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) prior to insertion surgery to reduce the risk of implantation related vitreous hemorrhage;
- Covered person has not received a previous treatment course of Encelto in the affected eye(s).

Codes:

ICD-10 codes covered if criteria are met:

ICD-10 Code	Description

H35.071 – H35.079	Retinal telangiectasis [macular type 2 (MacTel)]

HCPCS codes covered when criteria are met:

HCPC Code	Description
J3403	Revakinagene taroretcel-lwey (Encelto) implant

References:

Aetna. (2025, July 16). Revakinagene Taroretcel-lwey (Encelto). Retrieved from https://www.aetna.com/cpb/medical/data/1000_1099/1079.html

Chew EY, Clemons TE, Jaffe GJ, et al.; Macular Telangiectasia Type 2-Phase 2 CNTF Research Group. Effect of Ciliary Neurotrophic Factor on Retinal Neurodegeneration in Patients with Macular Telangiectasia Type 2: A Randomized Clinical Trial. Ophthalmology. 2019 Apr;126(4):540-549. doi: 10.1016/j.ophtha.2018.09.041. Epub 2018 Oct 4. PMID: 30292541; PMCID: PMC8365464.

Chew EY, Clemons TE, Peto T, Sallo FB, Ingerman A, Tao W, Singerman L, Schwartz SD, Peachey NS, Bird AC; MacTel-CNTF Research Group. Ciliary neurotrophic factor for macular telangiectasia type 2: results from a phase 1 safety trial. Am J Ophthalmol. 2015 Apr;159(4):659-666.e1. doi: 10.1016/j.ajo.2014.12.013. Epub 2014 Dec 19. PMID: 25528956; PMCID: PMC4361328.

Kedarisetti KC, Narayanan R, Stewart MW, Reddy Gurram N, Khanani AM. Macular Telangiectasia Type 2: A Comprehensive Review. Clin Ophthalmol. 2022 Oct 10;16:3297-3309. doi: 10.2147/OPTH.S373538. PMID: 36237488; PMCID: PMC9553319.

Package insert Encelto (revakinagene taroretcel-lwey) United States Food and Drug Administration

(FDA Published March 2025.) Accessed September 23, 2025. https://www.fda.gov/media/185726/download?attachment

Retinal Physician. (2025, March 6). FDA Approves First Treatment for MacTel. Retrieved from https://www.retinalphysician.com/news/2025/fda-approves-first-treatment-for-mactel/