Corporate Medical Policy: Revakinagene taroretcel-lwey (Encelto®)

Restricted Product(s):

- revakinagene taroretcel-lwey (Encelto®) intravitreal implant for administration by a healthcare professional

FDA Approved Use:

- For the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel)

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient is 18 years of age or older; **AND**
2. The patient has a diagnosis of **idiopathic macular telangiectasia (MacTel) type 2** in at least one eye **[medical record documentation required]**; **AND**
3. The diagnosis has been confirmed by ALL of the following:
    a. Evidence of fluorescein leakage **[medical record documentation required]**; **AND**
    b. ONE or more of the following characteristics **[medical record documentation required]**:
        i. Hyperpigmentation outside a 500-micron radius from the fovea center; **OR**
        ii. Retinal opacification; **OR**
        iii. Crystalline deposits; **OR**
        iv. Right-angle vessels; **OR**
        v. Inner/outer lamellar cavities; **AND**
4. The patient has a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 mm^2 as measured by spectral domain-optical coherence tomography (SD-OCT) **[medical record documentation required]**; **AND**
5. The patient has a best corrected visual acuity (BCVA) score of 54 letters or better (20/80 Snellen equivalent or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart **[medical record documentation required]**; **AND**
6. The patient does NOT have evidence of neovascular MacTel **[medical record documentation required]**; **AND**
7. The patient does NOT have any active or suspected ocular and/or periocular infections **[medical record documentation required]**; **AND**
8. The patient does NOT have a known hypersensitivity to Endothelial Serum Free Media (Endo-SFM) **[medical record documentation required]**; **AND**
9. The patient does NOT have evidence of advanced disease that would preclude treatment of MacTel (e.g., significant retinal scarring and atrophy with retinal tissue that cannot be preserved) **[medical record documentation required]**; **AND**

10. The patient NOT have evidence of any of the following **[medical record documentation required]**:
    a. Intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid, or intraretinal fluid in either eye; **OR**
    b. Central serous chorioretinopathy in either eye; **OR**
    c. Pathologic myopia in either eye; **OR**
    d. Significant media or corneal opacities in either eye; **OR**
    e. History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty; **OR**
    f. Any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 2, or nuclear opacity > standard 3; **OR**
    g. Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks; **OR**
    h. History of ocular herpes virus in either eye; **OR**
    i. Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT); **AND**
11. The patient will temporarily discontinue use of any antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) prior to the insertion surgery **[medical record documentation required]**; **AND**
12. The patient has NOT received intravitreal steroid therapy or intravitreal anti-vascular endothelial growth factor (VEGF) therapy, for non-neovascular MacTel within the last 3 months **[medical record documentation required]**; **AND**
13. The patient has NOT received any previous intravitreal gene therapy for the requested indication, including the requested agent **[medical record documentation required]**; **AND**
14. The prescriber is a specialist in the area of the patient's diagnosis (e.g., ophthalmologist with experience in vitreoretinal surgery) or has consulted with a specialist in the area of the patient's diagnosis **[medical record documentation required]**; **AND**
15. The patient will NOT receive more than one implant per affected eye for surgical intravitreal insertion during a patient's lifetime **[medical record documentation required]**; **AND**
16. The requested dose is within FDA labeled dosing for the requested indication, and the requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below) **[medical record documentation required]**.

    Duration of Approval: 270 days (one single implant per eye per lifetime)

Please note, for certain identified gene and cellular therapies such as revakinagene taroretcel-lwey (Encelto®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC to coordinate this therapy.

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
revakinagene taroretcel-lwey (Encelto®) intravitreal implant	MacTel type 2 in patients ≥18 years old	One implant per affect eye, containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor (rhCNTF). Administer as a single surgical intravitreal procedure performed by a qualified ophthalmologist.	J3403	**1 (per affected eye)**

***Maximum units allowed for duration of approval**

Other revenue codes that may be applicable to this policy: 0891, 0892

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). **Policy notification given 2/1/2026 for effective date 4/1/2026**.
October 2025: Coding change: Added HCPCS code J3403 (1 unit per implant) to dosing reference table effective 10/1/2025, deleted C9399, J3490, and J3590 termed 9/30/2025.
July 2025: Original medical policy criteria issued.