ND

Medical Policies

Print

Policy Number:	ME-I-300		
Policy Name:	Revakinagene taroretcel-lwey (Encelto)		
Policy Type:	Medical	**Policy Subtype:**	Injections
Effective Date:	10-01-2025		

Description

Revakinagene taroretcel-lwey (Encelto™) is an allogenic encapsulated cell-base gene therapy that is indicated for the treatment of macular telangiectasia type 2 via a surgically implanted intravitreal implant. Macular telangiectasia type 2 is a rare eye disease characterized by permanent loss of macular photoreceptors, causing central vision loss. Revakinagene taroretcel-lwey (Encelto) secretes 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 trigger a cascade that may promote photoreceptor survival.

Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of service.

Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Revakinagene taroretcel-lwey (Encelto) may be considered medically necessary when **ALL** of the following criteria are met:

- Individual is 18 years of age or older; **and**
- Individual has a diagnosis of macular telangiectasia type 2 as confirmed by optical coherence tomography (OCT); **and**
  - Imaging confirms that individual has an inner segment - outer segment junction line (IS/OS) photo receptor (PR) break in the ellipsoid zone between 0.16 and 2.00 mm^2 ; **and**
- Individual's best corrected visual acuity (BVCA) is a 54-letter score or better (20/80 or better); **and**
- The medication is prescribed by an ophthalmologist with experience in vitreoretinal surgery; **and**

- Individual has not received an intravitreal anti-vascular endothelial growth factor (VEGF) injection in the affected eye within the past three (3) months; **and**
- Individual does **NOT** have any of the following:
    - Intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye; **or**
    - Central serous chorio-retinopathy in either eye; **or**
    - Pathologic myopia in either eye; **or**
    - Significant corneal or media opacities in either eye; **or**
    - Individual has undergone lens removal in the previous 3 months or YAG laser within 4 weeks; **or**
    - History of ocular herpes virus in either eye; **or**
    - Individual has any of the following lens opacities as measured on the Age Related Eye Disease Study (AREDS) clinical lens grading system:
        - Cortical opacity greater than standard 3; **or**
        - Posterior subcapsular opacity greater than standard 2; **or**
        - Nuclear opacity greater than standard 3.

Note: The safety and effectiveness of repeat administration of revakinagene taroretcel-lwey (Encelto) has not been evaluated. Therefore, coverage will be limited to once per lifetime per eye.

The use of revakinagene taroretcel-lwey (Encelto) for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

Procedure Codes

J3403

Note: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the United States Food and Drug Administration (U.S. FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines.

Professional Statements and Societal Positions Guidelines

American Vein and Lymphatic Society

In 2015, the AVLS (previously named the American College of Phlebology) published guidelines on the treatment of superficial vein disease.

AVLS gave a Grade 1 recommendation based on high quality evidence that compression is an effective method for the management of symptoms, but when individuals have a correctable source of reflux, definitive treatment should be offered unless contraindicated. AVLS recommends against a requirement for compression therapy when a definitive treatment is available. AVLS gave a strong recommendation based on moderate quality evidence that endovenous thermal ablation is the preferred treatment for saphenous and accessory saphenous vein incompetence, and gave a weak recommendation based on moderate quality evidence that mechanochemical ablation may also be used to treat venous reflux.

In 2017, AVLS published guidelines on the treatment of refluxing accessory saphenous veins. The College gave a Grade 1 recommendation based on level C evidence that individuals with symptomatic incompetence of the

accessory saphenous veins be treated with endovenous thermal ablation or sclerotherapy to reduce symptomatology. The guidelines noted that although accessory saphenous veins may drain into the great saphenous vein before it drains into the common femoral vein, they can also empty directly into the common femoral vein.

National Institute for Health and Care Excellence

In 2013, the NICE updated its guidance on ultrasound-guided foam sclerotherapy for varicose veins. NICE stated that:

'1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that individuals are warned of the small but significant risks of foam embolization (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.

1.2 During the consent process, clinicians should inform individuals that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischaemic attacks and stroke.'

In 2015, NICE published a technology assessment on the clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation, and surgery for varicose veins.

In 2016, NICE revised its guidance on endovenous mechanochemical ablation, concluding that 'Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure.

Diagnosis Codes

H35.071	H35.072	H35.073

CURRENT CODING

HCPCS:

J3590	Unclassified biologics	Medicaid Expansion

References:
I-300

1. Encelto (revakinagene taroretcel-lwey) implant, for intravitreal use [package insert]. Neurotech PharmaceuΘcals, Inc., Cumberland, RI. Revised 03/2025.

2. Clinical Pharmacology™ Compendium. 2025. Tampa FL: Gold Standard, Inc. Revakinagene taroretcel-lwey.

3. Micromedex DrugDex Compendium®. 2025. Revakinagene taroretcel-lwe

ND Committee Review

Internal Medical Policy Committee 06-10-2025 *Effective August 01, 2025*

- *Adopted* Medicaid Expansion specific policy

Internal Medical Policy Committee 09-04-2025 *Effective October 01, 2025*

- *Added* code, J3403, to policy
- *Removed* code, J3590, from policy

Disclaimer

Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.