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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	May 2, 2025
Subject:	Encelto	**Page:**	1 of 4

Last Review Date: September 19, 2025

Encelto

Description

Encelto (revakinagene taroretcel-lwey)

Background
Encelto (revakinagene taroretcel-lwey) is an allogeneic encapsulated cell-based gene therapy. 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 initially target Müller glia to trigger a cascade of signaling events that may promote photoreceptor survival (1).

Regulatory Status
FDA-approved indication: 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) (1).

Encelto is contraindicated in ocular or periocular infections and patients with known hypersensitivity to Endothelial Serum Free Media (Endo-SFM) (1).

Encelto implantation has been associated with severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation. Additional surgical and/or medical management may be required. To reduce the risk of vitreous hemorrhages, antithrombotic medications should be temporarily discontinued prior to Encelto insertion (1).

Clinical studies of Encelto did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger patients. Use shared decision making to assess benefit in older patients (1).

Repeat dosing of Encelto is not supported by current evidence (1).

The safety and effectiveness of Encelto in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Encelto may be considered **medically necessary** if the conditions indicated below are met.

Encelto may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Idiopathic macular telangiectasia type 2 (MacTel)

AND ALL of the following:

a. Documented baseline visual acuity test
b. **NO** ocular or periocular infection

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 1 implant per eye per lifetime

Prior – Approval *Renewal* Limits

None

Rationale

Summary

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). Encelto is contraindicated in ocular or periocular infections and patients with known hypersensitivity to Endothelial Serum Free Media (Endo-SFM). Encelto implantation has been associated with severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation. The safety and effectiveness of Encelto in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Encelto while maintaining optimal therapeutic outcomes.

References

1. Encelto [package insert]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.

Policy History

Date	Action
May 2025	Addition to PA
September 2025	Annual review. Per SME, added statements in regulatory section regarding the limited support for repeat dosing and lack of evidence for use in patients aged 65 years and older.

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.