DR.024.A Encelto (revakinagene taroretcel-lwey)

Original Implementation Date : 02/09/2026
Version [A] Date : 02/09/2026
PARP Approved Date: 12/08/2025
Last Reviewed Date: 12/17/2025

***** NOTIFICATION OF PENDING POLICY IMPLEMENTATION *****

Please note that this Policy Bulletin will be implemented on 02/09/2026

This document provides a 30-day notification of its pending implementation and is not currently implemented.

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans/Health Partners Plans lines of business unless noted below.

Gene therapy is a benefit exclusion for Individual and Family (ACA) product lines and therefore, non-covered.

POLICY STATEMENT

The plan considers **Revakinagene taroretcel-lwey (per implant)** medically necessary for its FDA approved indications when the prior authorization criteria listed in this policy are met.

FDA APPROVED INDICATIONS

Gene Therapy is the introduction, removal, or change in the content of a person's genetic code with the goal of treating or curing a disease. It includes therapies such as gene transfer, gene modified cell therapy, and gene editing.

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

OFF-LABEL USE

Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the Medical Staff will be predicated on the appropriateness of treatment and full consideration of medical necessity. For off-label use Medical Directors will review scientific literature and local practice patterns.

PRIOR AUTHORIZATION CRITERIA

Prior authorization is required for Encelto (revakinagene taroretcel-lwey).

Encelto (revakinagene taroretcel-lwey) may be considered medically necessary when **All** of the following apply:

1. FDA approved indication.

2. FDA approved age (18 years and older).

3. Must be prescribed by or in consultation with an ophthalmologist experienced in retinal diseases.

4. Confirmed diagnosis of idiopathic MacTel type 2 in at least one eye, supported by clinical documentation such as fluorescein angiography, OCT imaging, and at least one of the following features:

- Crystalline deposits
- Hyperpigmentation that is outside of the 500-micron radium from the center of the fovea
- Inner/outer lamellar cavities
- Retinal opacification
- Right-angle vessels

5. Best-corrected visual acuity (BCVA) of 54 letters or better on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, **OR** 20/80 or better on the Snellen chart.

6. Absence of neovascular (proliferative) MacTel.

7. Presence of ellipsoid zone (EZ) disruption between 0.16 mm^2 and 2.00 mm^2 as measured by spectral domain-optical coherence tomography (SD-OCT).

8. Member must have steady fixation and sufficiently clear ocular media for good quality photographs.

Coverage will not be provided for members with any of the following conditions:

- 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.
- Received intravitreal steroid therapy for non-neovascular MacTel within the past 3 months.
- 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.
- Evidence of central serous chorio-retinopathy in either eye.
- Evidence of pathologic myopia in either eye.
- Significant corneal or media opacities in either eye.
- Had a vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty.
- Member has any of the following lens opacities:
    - Cortical opacity greater than standard 3
    - Posterior subcapsular opacity greater than standard 2
    - A nuclear opacity greater than standard 3 as measured on the Age-Related Eye Disease Study (AREDS) clinical lens grading system.
- Has undergone lens removal in the previous 3 months or YAG laser within 4 weeks.
- Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT).
- Is on chemotherapy.
- History of ocular herpes virus in either eye.
- Ocular or periocular infection.
- Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM).

- Member has any of the following comorbidities:
  - Glaucoma
  - Severe nonproliferative or proliferative diabetic retinopathy
  - Uveitis

- Unable 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.

- Member has received a previous treatment course with Encelto in the affected eye(s).

Submission of the following information is necessary to initiate the prior authorization review:

- Medical records (e.g., chart notes and/or laboratory report(s) documenting the following:
  - Confirmation of the diagnosis
  - Spectral domain-optical coherence tomography (SD-OCT) results
  - Best corrected visual acuity (BCVA) results

RENEWAL CRITERIA

Encelto is a single dose, lifetime treament and not subject to renewal or reauthorization. Subsequent requests for additional implants in the same eye are non-covered.

DOSAGE AND ADMINISTRATION

ENCELTO is intended for surgical intravitreal implantation under aseptic conditions by a qualified ophthalmologist. The recommended dose is one implant per affected eye, containing 200,000–440,000 allogeneic retinal pigment epithelial cells expressing recombinant human ciliary neurotrophic factor.

ENCELTO is provided as a sterile, single-dose implant packaged in Endothelial Serum Free Media (Endo-SFM). Store between 16-37°C (61-99°F). Do not freeze or refrigerate.

RISK FACTORS/SIDE EFFECTS

ENCELTO

- **Adverse Reactions**: 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 formation or progression, vitreous floaters, severe vision loss, eye discharge, anterior chamber cells, and iridocyclitis.

- **Warnings and Precautions:** severe vision loss, infection, retinal tears/detachment, vitreous hemorrhage, implant extrusion, cataract, suture complications, or delayed dark adaptation.

- **Contraindications** in patients with ocular or periocular infections, or in those with a known hypersensitivity to Endothelial Serum-Free Media (Endo-SFM).

MONITORING

Immedicate post operative monoring should include:

- delayed dark adaptation
- implant extrusion
- infectious endophthalmitis
- retinal tear and detachement
- signs of severe vision loss
- suture complications,
- vitreous hemorrhage

Long term monitoring should include:

- Cataract formation
- implant positions (6 month follow up)
- Late onset complications such as implant extrusion or vitreous hemorrhage (may occur more than one year after implantation)

- MRI safety (before going under MRI imageing technician should be informed impalnt is present)

BLACK BOX WARNING

N/A

CLINICAL EVIDENCE

The efficacy and safety of ENCELTO were evaluated in two randomized, multi-center, double-masked, sham-controlled Phase 3 trials: NTMT-03-A (Study 1) and NTMT-03-B (Study 2). Both studies enrolled adult patients with non-neovascular MacTel Type 2 and an ellipsoid zone (EZ) loss area between 0.16 and 2.00 mm^2 on spectral-domain OCT. Subjects also had a best corrected visual acuity (BCVA) of 54 letters or better (20/80 or better) on the ETDRS chart. Patients were randomized 1:1 to receive either ENCELTO implantation or a sham procedure mimicking the surgical experience without actual implant placement.

In Study 1 (n=115), ENCELTO significantly reduced the progression of EZ loss over 24 months compared to sham (mean rate of EZ loss: 0.075 mm^2 vs. 0.166 mm^2; difference: -0.091 mm^2; $p<0.0001$). This represented **~55–56% reduction** in the EZ loss rate. ENCELTO also demonstrated a statistically significant preservation of retinal function, with a smaller decline in aggregate retinal sensitivity within the EZ break area (mean change: 25.27 dB vs. 43.02 dB; difference: -17.75 dB; $p=0.02$).

In Study 2 (n=113), ENCELTO showed significant slowing of structural degeneration, with a reduced rate of EZ area loss over 24 months (0.111 mm^2 vs. 0.160 mm^2; difference: -0.049 mm^2; $p=0.0186$). This represented **~30-31% reduction** in the EZ loss rate. However, the secondary endpoint of aggregate retinal sensitivity loss did not achieve statistical significance (40.02 dB vs. 41.97 dB; $p=0.83$).

Between both trials, ENCELTO proved successful as the first therapeutic option with demonstrated efficacy in slowing the neurodegenerative progression of MacTel Type 2. Its ability to preserve photoreceptor structure, and in some patients, function, represents a significant advancement in the management of this previously untreatable condition.

BACKGROUND

ENCELTO (revakinagene taroretcel-lwey) is an encapsulated cell-based gene therapy. The therapy consists of a small, surgically implanted intravitreal capsule that contains genetically modified living cells designed to continuously produce and release recombinant human ciliary neurotrophic factor (rhCNTF). The semi-permeable capsule enables localized delivery of rhCNTF directly to the retina, supporting retinal cell health and slowing the loss of photoreceptors.

ENCELTO is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel), a progressive retinal disorder associated with vision loss.

CODING

Note*:* The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that *may* be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT Code	Description
N/A	

HCPCS Code	Description
J3403	Revakinagene taroretcel-lwey, per implant

ICD-10 Codes	Description
H35.32	Macular telangiectasia

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Health Partners Plans Medicaid and Health Partners Plans Chip products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
New policy.	A	02/09/2026

REFERENCES

1. ENCELTO (revakinagene taroretcel-lwey) implant, for intravitreal use: https://www.fda.gov/media/185726/download?attachment
2. Encelto (revakinagene taroretcel-lwey: https://www.encelto.com/ecp/
3. Macular Telangiectasia: https://eyewiki.org/Macular_Telangiectasia
4. Cell-Based Ciliary Neurotrophic Factor Therapy for Macular Telangiectasia Type 2: https://pubmed.ncbi.nlm.nih.gov/40693847/
5. Encelto (revakinagene taroretcel-lwey) Prescribing Information. Neurotech Pharmaceuticals, Inc.; March 2025. Accessed October 22, 2025.