PREMERA HMO

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# PHARMACY / MEDICAL POLICY – 5.01.653

# Miscellaneous Intravitreal Drugs

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| Effective Date: | Aug. 1, 2025 | RELATED MEDICAL POLICIES: |
| Last Revised: | Jul. 8, 2025 | |
| Replaces: | N/A | |

**Select a hyperlink below to be directed to that section.**



∞ Clicking this icon returns you to the hyperlinks menu above.

## Introduction

Intravitreal drugs are medications delivered directly into the back of the eye called vitreous cavity. These drugs are used to treat a variety of eye conditions such as to help reduce swelling and/or loss of vision. This policy describes when intravitreal drugs may be considered medically necessary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

| Drug | Medical Necessity |
|---|---|
| **Encelto (revakinagene taroretcel-lwey)** | **Encelto (revakinagene taroretcel-lwey) may be considered medically necessary for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel) when all the following criteria are met:**<br>• The individual is aged 18 years or older<br>**AND** |

| Drug | Medical Necessity |
|---|---|
| | • Diagnosed with MacTel by evidence of fluorescein leakage typical of MacTel AND at least one of the following other features:<br>  ○ Hyperpigmentation outside a 500-micron radius from the fovea center<br>  ○ Retinal opacification<br>  ○ Crystalline deposits<br>  ○ Right-angle vessels<br>  ○ Inner/outer lamellar cavities<br>**AND**<br>• Has a inner segment/outer segment photoreceptor (IS/OS PR) break (loss) in ellipsoid zone (EZ) between 0.16 and 2.00 $mm^2$ measured by spectral domain-optical coherence tomography (SD-OCT)<br>**AND**<br>• Has a best corrected visual acuity (BCVA) score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart<br>**AND**<br>• Has not been diagnosed with any of the following:<br>  ○ Intraretinal neovascularization or subretinal neovascularization (SRNV)<br>  ○ Central serous chorio-retinopathy<br>  ○ Active or suspected ocular or periocular infection<br>**AND**<br>• Confirmed negative pregnancy status<br>**AND**<br>• Encelto (revakinagene taroretcel-lwey) is prescribed and administered by an ophthalmologist<br>**AND**<br>• Use is limited to a one-time surgical implantation per affected eye |

| Drug | Investigational |
|---|---|
| **As listed** | **The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.** |

| Drug | Investigational |
|---|---|
| **Encelto (revakinagene taroretcel-lwey)** | **All other uses of Encelto (revakinagene taroretcel-lwey) for conditions not outlined in this policy including macular telangiectasia type 1 are considered investigational.** |

| Length of Approval | |
|---|---|
| **Approval** | **Criteria** |
| **Initial authorization** | **Non-formulary exception reviews for Encelto (revakinagene taroretcel-lwey) may be approved for up to 12 months.**<br><br>**All other reviews for Encelto (revakinagene taroretcel-lwey) may be approved for up to 6 months as a one-time application per eye.** |
| **Re-authorization criteria** | **Re-authorization of Encelto (revakinagene taroretcel-lwey) for repeat application to the same affected eye is considered investigational.** |

| Documentation Requirements |
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| **The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:**<br>• Office visit notes that contain the diagnosis, relevant history, medication history, and physical evaluation |

## Coding

| Code | Description |
|---|---|
| **HCPCS** | |
| J3590 | Unclassified biologics (used to report: Encelto) |

**Note**: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Consideration of Age

Age limits specified in this policy are determined according to FDA-approved indications where applicable.

### Benefit Application

Encelto (revakinagene taroretcel-lwey) is managed under the medical benefit.

## Evidence Review

### Idiopathic Macular Telangiectasia Type 2

Two primary forms of macular telangiectasia (MacTel) have been identified. Both are associated with blood vessel abnormalities in the retina. MacTel type 1 is a very rare congenital disorder that occurs unilaterally and almost exclusively in males. Type 1 is associated with the dilation of blood vessels and the formation of aneurysms in various parts of the retina, which may leak fluid, resulting in macular edema. MacTel type 2 is typically diagnosed in middle age, is more common in females, and occurs bilaterally, though each eye may be affected differently. In its early phases, MacTel type 2 is believed to be a neurodegenerative disease associated with the loss of Müller cells, which are responsible for growth factor secretion, angiogenesis/antiangiogenesis, neurotransmitter metabolism, synaptogenesis, neuroprotection, and photoreceptor survival. Over time, MacTel type 2 may progress to a proliferative form, affecting the macular vasculature and causing blood vessels surrounding the fovea (the center of the macula) to proliferate, dilate, and leak, ultimately leading to macular degeneration.

### Encelto (revakinagene taroretcel-lwey)

Encelto is a cell-based therapy delivered via an implanted drug delivery system. Genetically modified cells encapsulated in a semipermeable hollow fiber membrane are implanted

intravitreally and release recombinant human ciliary neurotrophic factor (rhCNTF) to the retina. rhCNTF has demonstrated the ability to reduce photoreceptor cell loss in animal models of retinal degeneration and may help slow disease progression.

Encelto was evaluated in two identically designed Phase 3 clinical trials, NTMT-03-A (Study 1 in the PI, NCT03316300) and NTMT-03-B (Study 2 in the PI, NCT03319849). Each trial included approximately 120 individuals aged 21 to 80 years. Individuals were randomized to receive either Encelto or sham treatment. In both trials, treatment with Encelto demonstrated a statistically significant change in the rate of ellipsoid zone (EZ) area loss from baseline through 24 months. Results for the mean change in aggregate retinal sensitivity loss from baseline to 24 months were statistically significant in Study 1 but not in Study 2. The manufacturer has evaluated pooled visual functionality data from one Phase 2 and the two Phase 3 clinical trials. Results were presented at the American Academy of Ophthalmology (AAO) 2024 annual meeting. The pooled data showed a 68% reduction in monocular reading speed loss over 2 years, favoring Encelto-treated eyes. Pooled microperimetry data showed a nearly 35% reduction in aggregate retinal sensitivity loss. Microperimetry is a noninvasive visual field test that measures retinal sensitivity by assessing how well specific areas of the retina detect light stimuli. However, best-corrected visual acuity (BCVA) was essentially the same between the Encelto-treated group and the sham-treated group.

## References


1. Neurotech Pharmaceuticals. A Phase III Multicenter Randomized, Sham Controlled, Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2. https://clinicaltrials.gov/study/NCT03316300. Accessed June 2025.
2. Neurotech Pharmaceuticals. A Phase III Multicenter Randomized, Sham Controlled, Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2. Protocol B. **https://clinicaltrials.gov/study/NCT03319849?term=NCT03319849&rank=1**. Accessed June 2025.
3. Crago, SM. AAO 2024: clinical updates on Neurotech's NT-501. Ophthalmology Times. October 18, 2024. **https://www.ophthalmologytimes.com/view/aao-2024-updates-on-neurotech-s-nt-501**. Accessed June 2025.
4. Kedarisetti KC, et al. Macular telangiectasia type 2: a comprehensive review. Clin Ophthalmol. 2022;16:3297–3309.
5. Khodabande A, et al. Management of idiopathic macular telangiectasia type 2. Ophthalmol Ther. 2019;8(2):155–175.
6. Kim SH, et al. Demographic features of idiopathic macular telangiectasia in Korean patients. Korean J Ophthalmol. 2015;29(3):155–159.
7. Yannuzzi LA, et al. Idiopathic macular telangiectasia. Arch Ophthalmol. 2006;124(4):450-60.
8. Encelto (revakinagene taroretcel-lwey) Prescribing Information. Neurotech. Cumberland, RI. Revised March 2025.

## History

| Date | Comments |
|---|---|
| 08/01/25 | New policy, approved July 8, 2025. Added coverage criteria for Encelto (revakinagene taroretcel-lwey) for the treatment of adults with idiopathic macular telangiectasia type 2. Added HCPCS code J3590 for Encelto. |



**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.