Reference number(s)
6885-A

Standard Medicare Part B Management Encelto

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Encelto	revakinagene taroretcel-lwey

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Encelto is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Idiopathic Macular Telangiectasia Type 2 (MacTel)[1-3]

Authorization of 1 month may be granted for the treatment of adult patients with idiopathic macular telangiectasia type 2 when all of the following criteria are met:

- Member has not received a previous treatment course of Encelto in affected eye(s).

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- Member has a diagnosis of idiopathic macular telangiectasia type 2 as evidenced by fluorescein leakage and at least one of the following features:
    - Hyperpigmentation outside of a 500 micron radius from the center of the fovea
    - Retinal opacification
    - Crystalline deposits
    - Right-angle vessels
    - Inner/outer lamellar cavities
- Member must have a photoreceptor inner segment/outer segment (IS/OS PR) break (loss) in ellipsoid zone (EZ) (area of IS/OS loss) between 0.16 mm2 and 2.00 mm2.
- Member has a best corrected visual acuity (BCVA) of a 54-letter score or better (20/80 or better).
- Member must have steady fixation and sufficiently clear ocular media for good quality photographs.
- Member has not previously received intravitreal steroid therapy for non-neovascular MacTel within the past 3 months.
- Member has not previously received intravitreal anti-vascular endothelial growth factor (VEGF) therapy in the affected eye(s).
- Member has not received intravitreal anti-vascular endothelial growth factor (VEGF) in the non-affected eye within the past 3 months.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Encelto.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Encelto are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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References

1. Encelto. [package insert]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.
2. Kedarisetti KC, Narayanan R, Stewart MW, Reddy Gurram N, Khanani AM. Macular Telangiectasia Type 2: A Comprehensive Review. Clin Ophthalmol. 2022 Oct 10;16:3297-3309.
3. Chew EY, Peto T, Clemons TE, Sallo FB, Pauleikhoff D, Leung I, Jaffe GJ, Heeren TFC, Egan CA, Charbel Issa P, Balaskas K, Holz FG, Gaudric A, Bird AC, Friedlander M. Macular Telangiectasia Type 2: A Classification System Using MultiModal Imaging MacTel Project Report Number 10. Ophthalmol Sci. 2022 Dec 8;3(2):100261.

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