Encelto® (revakinagene taroretcel-lwey)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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

POLICY

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

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

Prescriber Specialties
This medication must be prescribed by or in consultation with an ophthalmologist.

Criteria for Initial Approval
Idiopathic macular telangiectasia type 2
Authorization of 3 months may be granted for treatment of idiopathic macular telangiectasia type 2 (MacTel) in members 18 years and older when all of the following criteria are met:

A. Member must have a diagnosis of MacTel type 2 in at least one eye with evidence of fluorescein leakage typical of MacTel and at least one of the following:
    i. Hyperpigmentation that is outside of a 500 micron radius from the center of the fovea
    ii. Retinal opacification
    iii. Crystalline deposits
    iv. Right-angle vessels
    v. Inner/outer lamellar cavities
B. Member must have an Inner Segment - Outer Segment Junction Line (IS/OS) Photo Receptor (PR) break in the affected eye(s) and en face ellipsoid zone (EZ) between 0.16 mm^2 and 2.00 mm^2 measured by spectral domain-optical coherence tomography (SD-OCT)
C. Member demonstrates a best corrected visual acuity (BCVA) score of 54-letters or better (20/80 or better)
D. Member has not previously received an Encelto implant

Continuation of Therapy

Repeat treatment with Encelto for any indication is considered investigational, as the safety and efficacy beyond one implant has not been studied. The evidence is insufficient to determine the effect on net health outcomes.

Other

Encelto is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

CLINICAL RATIONALE

MacTel type 2 is the more common form of macular telangiectasia, with a U.S. prevalence of about 0.1% in individuals over 40 years of age. 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. While MacTel type 2 does not usually cause total blindness, it significantly impacts quality of life due to progressive central vision loss.

Prior to Encelto, there were no FDA-approved treatments for MacTel type 2. For patients who progress to the proliferative form of MacTel type 2, the ophthalmic vascular endothelial growth factor (VEGF) inhibitors (i.e., ranibizumab, aflibercept) have demonstrated mostly positive results in terms of improvement in central macular thickness and maintenance of visual acuity. However, not all patients develop proliferative forms of MacTel type 2, and VEGF inhibitors do not help treat nor prevent progression during the earlier (nonproliferative) phases of MacTel type 2. In patients with nonproliferative MacTel type 2, carotenoid supplementation with lutein, meso-zeaxanthin, and zeaxanthin has been used to delay disease progression with mixed results in clinical studies. Studies using other medications and procedures, including laser therapy and pars plana vitrectomy, have yielded inconsistent results.

Encelto was evaluated in two identically designed Phase 3 clinical trials, each including approximately 120 patients 21–80 years of age. Patients were randomized to receive either Encelto or a placebo implant. 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.
Results for the secondary endpoint of monocular reading speed 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.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J3403 – Revakinagene taroretcel-lwey, per implant (effective 10/1/2025)
- J3490 – unclassified drugs
- J3590 – unclassified biologics

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POLICY HISTORY

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