CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Encelto® (revakinagene taroretcel-lwey)

Effective: October 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Encelto (revakinagene taroretcel-lwey) is a cell therapy from Neurotech Pharmaceuticals Inc., for the treatment of Macular Telangiectasia type 2 (Mac Tel). Mac Tel is a rare ocular disease that causes abnormalities of capillaries of the fovea or perifoveal region which leads to the loss of outer nuclear layers and ellipsoid zone. The disease causes loss of central vision and is most commonly diagnosed in people aged 40 and older. Encelto is a cell therapy designed to deliver therapeutic doses of ciliary neurotrophic factor (CNTF) to the retina to aid in slowing the proregression of the disease. Encelto is the first and only FDA-approved treatment for Mac Tel and received approval on March 6, 2025.

Food and Drug Administration (FDA) Approved Indications:

- 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). This therapy is contraindicated for people with ocular or periocular infections and known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) and MassHealth for coverage determinations for its Dual Product Eligible plan members and CMS for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals and MassHealth Medical Necessity Determinations are the basis for coverage determinations. When CMS and MassHealth do not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service. Point32Health covers Encelto in accordance with MassHealth coverage criteria.

For the therapy Encelto, evidence is sufficient for coverage. Encelto received FDA approval in March 2025 as a new implantable cell therapy that is the first and only approved treatment for adults with macular telangiectasia type 2 (MacTel). Encelto reached it primary endpoint as the change in the area of the ellipsoid zone disruption as measured on an OCTimage at 24 months from the baseline; The mean (SE) area of photoreceptor loss increased 0.27 ± 0.05 mm2 from baseline to 24 months in the sham group compared with 0.22 ± 0.05 mm2 from baseline to 24 months in the implant group.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover Encelto for Members aged 18 years or older when **ALL** the following clinical criteria is met:

1. Diagnosis of Macular Telangiectasia type 2; **and**
2. Member is ≥18 years of age; **and**
3. Prescriber is an ophthalmologist or consult notes from an ophthalmologist are provided; **and**
4. Evidence of fluorescein leakage in treatment eye; **and**
5. Inner-segment or outer-segment photoreceptor break (loss) in ellipsoid zone between 0.16 and 2.00 mm; **and**
6. BCVA score of 54 letters or better (20/80 Snellen equivalent) on ETDRS chart; **and**

7. Absence of neovascularization in the treatment eye; **and**
8. ALL of the following:
    a. No previous treatment with Encelto in treatment eye; **and**
    b. Member has not had major surgery in treatment eye or fellow eye within the last six months
    c. ONE of the following:
        i. Assuming Member is undergoing initial unilateral treatment; **or**
        ii. Member is undergoing bilateral treatment for the second eye

Limitations

Encelto is contraindicated under the following conditions:

1. Presence of ocular or periocular infection
2. Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3403	REVAKINAGENE TARORETCEL-LWEY, PER IMPLANT

References:

1. A study to determine the safety and efficacy of NT-501 in macular telangiectasia type 2 - protocol B. ClinicalTrials.gov. Updated September 24, 2024. Accessed March 24, 2025. https://clinicaltrials.gov/study/NCT03319849
2. Encelto (revakinagene taroretcel-lwey) [package insert]. Cummerland, RI. Neurotech Pharmaceuticals, March 2025

Approval And Revision History

September 17, 2025: Reviewed by the Utilization Management Committee effective October 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.