Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/10/2025

**Encelto™** (revakinagene taroretcel-lwey)

**HCPCS:** J3590

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Must have an inner segment - outer segment junction line (IS/OS) photo receptor (PR) break and en face EZ (area of IS/OS loss) as measured by spectral-domain optical coherence tomography (SDOCT) between 0.16 $mm^2$ and 2.00 $mm^2$
   d. Must have a best corrected visual acuity (BCVA) letter score of 54 or better (greater than or equal to 20/80) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart
   e. Trial and failure, intolerance, or a contraindication to the preferred products as specified in the BCBSM/BCN medical utilization management drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: 3 months with the allowance of only one dose per eye per lifetime
   c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

**Background Information:**

- Macular telangiectasia type 2, also known as MacTel, is the most common form of macular telangiectasia. It is a neurodegenerative metabolic disorder that is correlated with diabetes and coronary artery disease. In MacTel type 2, blood vessels in the macula become dilated and leak fluid, causing swelling and scarring, which can lead to vision loss. Sometimes new blood vessels grow beneath the macula, affecting the macular photoreceptors and causing loss of vision.

- Safety and efficacy were evaluated in two phase III, randomized, multi-center, sham-controlled trials, NTMT-03-A and NTMT-03-B which included 239 patients with MacTel type 2. Participants with ellipsoid zone (EZ; inner segment/outer segment [IS/OS]) loss between 0.16 $mm^2$ and 2.00 $mm^2$ were randomly assigned 1:1 to Encelto or sham treatment in the study eye. Patients were included if they had a best corrected visual acuity (BCVA) of 54 letters or better (20/80 or better) as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at screening. The primary endpoint was rate of change in EZ area loss from baseline through 24 months. Both clinical trials demonstrated statistically significant change in EZ area loss from baseline which was 56.4% lower in the treatment group compared to the sham group in NTMT-03-A (treatment group: 0.075 mm2, 95% CI: 0.05, 0.10]; sham group: 0.166 mm2, 95% CI: 0.14, 0.19; p-value < 0.0001) and 29.2% lower in NTMT-03-B (treatment group: 0.111 mm2, 95% CI: 0.08, 0.14; sham group: 0.160 mm2, 95% CI 0.13, 0.19; p-value = 0.0186). The proportion of participants with a reduction of 15 early treatment diabetic retinopathy study (ETDRS) letters was similar between treatment groups in both NTMT-03-A (treatment group 13.8% (8/58); sham group 8.8% (5/57); p-value = 0.558) and NTMT-03-B (treatment group 3.4% (2/59); sham group 5.6% (3/54); p-value = 0.669).

**References:**


1. Encelto [prescribing information]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.
2. Clinicaltrials.gov. A study to determine the safety and efficacy of NT-501 in macular telangiectasia type 2 - protocol a (NCT03316300). Available at: https://clinicaltrials.gov/study/NCT03316300?a=22#more-information. Accessed on March 10, 2025.
3. Clinicaltrials.gov. A study to determine the safety and efficacy of NT-501 in macular telangiectasia type 2 (NCT03319849). Available at: https://clinicaltrials.gov/study/NCT03319849. Accessed on March 10, 2025.
4. American Academy of Ophthalmology. What is macular telangiectasia. 2024. Available at: https://www.aao.org/eye-health/diseases/macular-telangiectasia. Accessed on March 10, 2025.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date: 06/01/2025</td><td>UM medical management system update for MAPPO and BCNA<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date: 04/10/2025</td><td>New policy - this criteria replaces previously approved preliminary criteria</td></tr>
<tr><td>1.1</td><td>Effective Date: 03/20/2025</td><td>UM medical management system update for BCBS and BCN<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 10/03/2024</td><td>Preliminary Drug Review<br><table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm).*