



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

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: 04/16/2026

Encelto™ (revakinagene taroretcel-lwey)

HCPCS: J3403

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 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
 - d. The requesting physician attests to providing clinical outcome information within the appropriate provider portal as requested by BCBSM
 - 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 mm² and 2.00 mm² 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).
- A provider portal that is used to capture clinical outcome information for patients on select high-cost treatments, such as gene and cellular therapies. If a patient meets medical necessity as defined by this policy and is approved for treatment, the requesting physician must attest to providing clinical outcome information within the appropriate provider portal at the requested cadence.

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.

Policy History												
#	Date	Change Description										
1.4	Effective Date: 04/16/2026	Updated to remove the inner segment - outer segment junction line (IS/OS) photo receptor (PR) break and en face EZ measurement and to add the provider portal reporting requirement										
1.3	Effective Date: 06/01/2025	UM medical management system update for MAPPO and BCNA <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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.2	Effective Date: 04/10/2025	New policy - this criteria replaces previously approved preliminary criteria										
1.1	Effective Date: 03/20/2025	UM medical management system update for BCBS and BCN <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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 10/03/2024	Preliminary Drug Review <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>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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BCBS	No											
BCN	No											
MAPPO	No											
BCNA	No											

* 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>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021