SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Encelto™ (revakinagene taroretcel-lwey) **J3403 (MEDICAL)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Dosing Limits:

A. Max Units (per dose and over time) [HCPCS Unit]:

- 2 doses* [one single-dose implant containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF, per eye] (*Max units are based on administration to both eyes)

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Authorization Criteria: Coverage will be provided for one dose per affected eye and may NOT be renewed

- ❑ Member is at least 18 years of age
- ❑ Member has a diagnosis of macular telangiectasia, type 2, in at least one eye, as evidenced by typical fluorescein leakage and at least **ONE** other of the following features of disease **(check all that apply)**:
  - ❑ Hyperpigmentation outside a 500-micron radius from the center of the fovea
  - ❑ Retinal opacification
  - ❑ Crystalline deposits
  - ❑ Right angle vessels
  - ❑ Inner/outer lamellar cavities
- ❑ Member has an inner segment–outer segment junction line (IS/OS) photoreceptor break and area of ellipsoid zone (EZ) loss, as measured by spectral domain optical coherence tomography (SD-OCT), at between 0.16 mm^2 and 2.00 mm^2
- ❑ Member does **NOT** have neovascular macular telangiectasia
- ❑ Member does **NOT** have evidence of advanced disease that would preclude treatment of MacTel (e.g., significant retinal scarring and atrophy with retinal tissue that cannot be preserved)
- ❑ Member does **NOT** have evidence of any of the following:
  - Intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid, or intraretinal fluid in either eye
  - Central serous chorioretinopathy in either eye
  - Pathologic myopia in either eye
  - Significant media or corneal opacities in either eye
  - History of vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty
  - Any of the following lens opacities: cortical opacity > standard 3, posterior subcapsular opacity > standard 2, or nuclear opacity > standard 3
  - Lens removal in previous 3 months or yttrium-aluminum-garnet (YAG) laser treatment within 4 weeks
  - History of ocular herpes virus in either eye
  - Evidence of intraretinal hyperreflectivity by optical coherence tomography (OCT)
- ❑ Member does **NOT** have a known hypersensitivity to Endothelial Serum Free Media (Endo SFM)
- ❑ Member does **NOT** have evidence of other ocular disease that would preclude treatment of MacTel
- ❑ Member has **NOT** received intravitreal steroid therapy or intravitreal anti–vascular endothelial growth factor (VEGF) therapy, for non-neovascular MacTel within the last 3 months

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- ❑ Member is free of ocular and/or peri-ocular infections
- ❑ Member will be monitored for signs and symptoms of vision loss (e.g., BCVA, etc.) and infectious endophthalmitis at baseline and periodically during treatment
- ❑ Member will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity)
- ❑ Member will temporarily discontinue antithrombotic medications (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs, etc.) prior to the insertion surgery

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee: 5/22/2025**
REVISED/UPDATED/REFORMATTED: 6/9/2025