Clinical Oversight Review Board (CORB) Criteria for Prescribing

Revakinagene taroretcel-lwey (Encelto)

Notes:

Non-Formulary **revakinagene taroretcel-lwey (Encelto)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:
Non-formulary **revakinagene taroretcel-lwey (Encelto)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Age >21 to <80 years old; and
- Diagnosis of MacTel type 2 with fluorescein leakage typical of MacTel type 2 and optical coherence tomography (OCT) changes consistent with MacTel type 2; and
- Have at least one of the other findings diagnostic of MacTel type 2 (hyperpigmentation that is outside of a 500 micron radius from the center of the fovea, retinal opacification, crystalline deposits, right-angle vessels, or inner/outer lamellar cavities); and
- Have an Inner Segment - Outer Segment Junction Line (IS/OS) Photo Receptor (PR) break in the eye(s) and en face EZ (area of IS/OS loss) as measured by spectral-domain optical coherence tomography (SD-OCT) between 0.16 mm^2 and 2.00 mm^2; and
- Have best corrected visual acuity (BCVA) 20/80 or better by Snellen chart; and
- Have steady fixation in the foveal or parafoveal area and sufficiently clear media for good quality photographs
- No evidence of intraretinal hyperreflectivity by OCT; or
- No evidence of ocular disease other than MacTel type 2 that, in the judgment of the physician, may confound the diagnosis, procedure, or effectiveness of the therapy (e.g. glaucoma, severe nonproliferative or proliferative diabetic retinopathy, uveitis); or
- No evidence of intraretinal neovascularization or subretinal neovascularization, as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye that would affect the visual and anatomical outcome of the implant as judged by the treating physician; or

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- No other ocular diagnosis that would reduce their visual prognosis with the therapy (severe glaucoma, vitrectomy, penetrating keratoplasty, trabeculectomy, or trabeculoplasty); or
- No significant corneal or media opacities in either eye that would limit ability to verify implant position or visual prognosis with the implant; or
- Has not undergone lens removal in the previous three months or Yttrium Aluminum Garnet (YAG) laser within four weeks; or
- No history of traumatic eye injury; or
- No history of ocular herpes virus in either eye; or
- Not a participant in any other clinical trial of an intervention (drug or device) within the last six months; or
- Not currently on chemotherapy; or
- Not pregnant or breastfeeding; or
- No life-threatening condition that may result in a significantly shortened lifespan; or
- In the opinion of the physician, has no physical or mental condition that would cause the patient to be unable to comply with surgical procedures or follow-up visits, including post-operative medications
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

Continued use criteria (12 months after initiation): Non-formulary **revakinagene taroretcel-lwey (Encelto)** will continue to be covered on the prescription drug benefit when the following criteria are met:

- Patient must have clinically meaningful benefit
- The implant is intended to last for several years, additional use beyond the initial implant is unknown and would require re-review