October 1, 2025

PRIOR AUTHORIZATION CRITERIA FOR ENCELTO EFFECTIVE OCT. 1, 2025

BACKGROUND

On Oct. 1, 2025, Encelto, will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Encelto (procedure code J3403) for Medicaid and CHIP, effective for dates of service on or after Nov. 1, 2025.

KEY DETAILS

Encelto (revakinagene taroretcel-lwey) is an allogenic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

Prior Authorization Requirements

Prior authorization approval for an intravenous infusion of Encelto (J3403), an intravitreal implantation under aseptic conditions will be considered when the following criteria are met:

- Client is 18 years or older;
- Client has a confirmed diagnosis of retinal telangiectasis in at least one eye (diagnosis code – H35.071, H35.072, H35.073, or H35.079);
- Client has MacTel type 2 in at least one eye;
- Client does not have neovascular or proliferative MacTel;
- Client has no ocular or periocular infections;
- Client has no known hypersensitivity to Endothelial Serum Free Media (Endo-SFM);
- Client has temporarily discontinued any antithrombotic medication prior to Encelto insertion surgery; and
- Client has not received a previous Encelto insertion.

Prior authorization is limited to one Encelto treatment per eye per lifetime.

Required Monitoring Parameters

Providers are required to monitor the client for signs and symptoms of vision loss, infectious endophthalmitis and retinal tear/detachment.

Continuation Therapy

Re-authorization of Encelto is not permitted for a previously treated eye. If the request is for treatment of an eye that has not previously received an ocular implant, the client must meet the approval criteria listed in the prior authorization requirement section.

RESOURCES

Policy or Operational Documents:	TMPPM Outpatient Drug Services Handbook