Sample PA Appeal Letter for ENCELTO™ (revakinagene taroretcel-lwey)

Disclaimer: This sample letter and related information are provided for informational purposes only. It is the responsibility of the healthcare provider and/or their office staff to determine the correct diagnosis and treatment and content of all such letters and related forms for each individual patient. Neurotech does not guarantee coverage or reimbursement for the product and cannot complete or write letters of medical necessity/appeal on your patient's behalf.

INDICATIONS AND USAGE

ENCELTO is an allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ENCELTO is contraindicated in patients with active or suspected ocular or periocular infections, and in patients with known hypersensitivity to Endothelial Serum Free Media (Endo-SFM).

WARNINGS AND PRECAUTIONS

ENCELTO implantation surgery and/or implantation related procedures have been associated with the following:

Severe Vision Loss

Severe vision loss defined as three or more lines of visual acuity loss [≥15 Early Treatment Diabetic Retinopathy Study (ETDRS) letters] has occurred following ENCELTO implantation. Monitor patients for signs and symptoms of vision loss and manage as clinically indicated.

Infectious Endophthalmitis

Infectious endophthalmitis may occur following ENCELTO implantation. Signs and symptoms of infectious endophthalmitis include progressively worsening eye pain, vision loss, or scleral and conjunctival injection. To mitigate the risk of endophthalmitis, use proper aseptic surgical technique for ENCELTO implantation. Monitor patients for signs or symptoms of infectious endophthalmitis. Remove ENCELTO implant if infectious endophthalmitis occurs and manage symptoms according to clinical practice.

Retinal Tear and/or Detachment

Retinal tears and retinal detachment may occur following ENCELTO implantation. Signs and symptoms of retinal tears include acute onset of flashing lights, floaters, and/or loss of visual acuity. Signs and symptoms of retinal detachment may include progressive visual field loss and/or loss of visual acuity. Use standard vitreoretinal surgical techniques during ENCELTO implantation to minimize the risk of retinal tears and retinal detachment. Monitor for any signs or symptoms of retinal tear and/or retinal detachment. Treat rhegmatogenous retinal detachment and retinal tears promptly. Remove ENCELTO implant, if vitrectomy with a complete gas fill or silicone oil fill is required.

Please see additional Important Safety Information on the following page and accompanying full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (cont'd)

Vitreous Hemorrhage

Vitreous hemorrhage, which may result in temporary vision loss, has occurred following ENCELTO implantation. Patients receiving antithrombotic medication (e.g., oral anticoagulants, aspirin, nonsteroidal anti-inflammatory drugs) may be at increased risk of vitreous hemorrhage. To reduce the risk of vitreous hemorrhage, interrupt antithrombotic medications prior to the ENCELTO implantation. Vitrectomy surgery may be necessary to clear severe, recurrent, or non-clearing vitreous hemorrhage. If the patient has a late onset vitreous hemorrhage (greater than one year following ENCELTO implantation surgery), examine the ENCELTO implantation site for possible implant extrusion. If implant extrusion has occurred, surgically reposition ENCELTO.

Implant Extrusion

Implant extrusion through the initial scleral wound has occurred following ENCELTO implantation. Signs and symptoms of implant extrusion include recurrent uveitis, vitreous hemorrhage, eye pain more than one year after implantation, or visibility of titanium fixation loop under the conjunctiva. To reduce the risk of implant extrusion, carefully follow the specific surgical steps for ENCELTO implantation.

Evaluate patients after 6 months to confirm proper positioning of ENCELTO and then annually. If ENCELTO begins to extrude, surgically reposition ENCELTO to a proper scleral wound depth either in the same site or in the opposing inferior quadrant of the vitreous cavity.

Cataract Formation

Cataract formation, including cataract cortical, cataract nuclear, cataract subcapsular, cataract traumatic, and lenticular opacities, has occurred following ENCELTO implantation. To reduce the risk of ENCELTO-related cataract formation or progression, carefully follow the specific surgical steps for ENCELTO implantation.

Suture Related Complications

Suture related complications, including conjunctival erosions due to suture tips and suture knots, have occurred following ENCELTO implantation.

To mitigate the risk of suture related complications, carefully follow the specific surgical steps for ENCELTO implantation and manage suture-related complications as clinically indicated.

Delayed Dark Adaptation

Delayed Dark Adaptation, a delay in the ability to adjust vision from a bright lighting condition to a dim lighting, has occurred following ENCELTO administration which remained unchanged for the duration of study follow up. Advise patients to take caution while driving and navigating in the dark.

ADVERSE REACTIONS

The most common adverse reactions (≥2%) reported with ENCELTO were conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, iridocyclitis.

Please see accompanying full Prescribing Information.

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[INSERT ON PHYSICIAN LETTERHEAD]

Re: Appeal for denial of ENCELTO™ (revakinagene taroretcel-lwey)
[Date]

[Health plan name]
Attn: [Name of prior authorization department]
[Contact name (if available)]
[Health plan address 1]
[Health plan address 2]
[City, State, Zip code]

[Patient name]
[Date of birth]
[Insurance ID number]
[Insurance group number]
[Case ID number]
[PA denial reference number]
[Date of denial]

Dear [Contact Name/Medical director],

This letter is sent on behalf of [patient's name] to request an appeal of a denied prior authorization for ENCELTO™ (revakinagene taroretcel-lwey).

On March 5, 2025, the FDA approved ENCELTO for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel), the first and only approved treatment for this progressive, retinal neurodegenerative disease that leads to loss of vision and functional impairment.

According to the enclosed denial letter, [name of health plan] denied this prior authorization because [reason from denial letter].

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with MacTel (diagnosis code [H35.073, H35.079, H35.071, H35.072]) on [date] in [his/her] [left eye/right eye] and has been in my care since [date]. As an ophthalmologist [with expertise in the diagnosis and treatment of retinal diseases and MacTel specifically], I continue to believe that ENCELTO is medically appropriate and necessary for my patient.

I am asking that you reconsider your denial of coverage for ENCELTO—the only available therapy indicated for the treatment of MacTel—for [patient's name]. MacTel is a bilateral, progressive, neurodegenerative disease associated with vision loss due to loss of photoreceptors.

[Explain why you believe ENCELTO is medically appropriate and necessary for your patient. This can include but is not limited to the following information:

- Your rationale for treatment with ENCELTO for this patient
- A summary of your patient's medical and ophthalmic history, including ICD-10-CM code(s)
- Your patient's likely prognosis without treatment with ENCELTO]

To summarize, please reconsider the ENCELTO (revakinagene taroretcel-lwey) denial for [patient's name]. Given the patient's history, diagnosis of idiopathic MacTel, and the clinical data supporting the use of ENCELTO, I believe treatment of [patient's name] with ENCELTO is warranted, appropriate, and medically necessary. A copy of the most recent denial letter is included, along with medical notes and other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. I look forward to your timely approval.

Sincerely,

[Physician signature]

[Insert name]

Enclosures:

[List all enclosed documents, which may include package insert for ENCELTO (available at [neurotechpharmaceuticals.com/wp-content/uploads/ENCELTO-PRESCRIBING-INFORMATION.pdf]), copy of clinical notes/patient medical records, letter of denial (if applicable), FDA approval letter (available at [fda.gov/media/185733/download?attachment]), or other relevant supporting documentation]