ENCELTO connect™
(revakinagene taroretcel-lwey)
implant, for intravitreal use

Enrollment Form

ENCELTO™
(revakinagene taroretcel-lwey)
implant, for intravitreal use

Phone: 1-877-ENCELTO (1-877-362-3586) | Fax: 1-800-670-0719

ENCELTOconnect Program Services

ENCELTOconnect is a personalized support program for patients prescribed ENCELTO™ (revakinagene taroretcel-lwey). By submitting an enrollment form, both patient and healthcare provider agree to be screened for and receive, if applicable, the following services:

Benefits Verification and Access Support
Once enrolled, patients will be paired with a Patient Access Consultant who will investigate their specific insurance coverage and eligibility requirements, serving as their guide throughout the process.

Co-pay Assistance
Eligible patients with commercial insurance can be enrolled in the co-pay assistance program to help support the out-of-pocket cost for ENCELTO.

Travel Support
Limited travel and lodging support will be provided to eligible patients in financial need to reach a treatment center.

Product Delivery Coordination
The product delivery process will be coordinated from order placement to delivery with the help of specialty couriers capable of supporting the specific temperature and delivery timing requirements for ENCELTO.

Patient enrollment into ENCELTOconnect is required prior to product acquisition.
For more information or assistance, please call ENCELTOconnect at 1-877-ENCELTO (1-877-362-3586) or visit ENCELTO.com/ecp/access-and-resources.

ENCELTOconnect Enrollment Form Instructions

If you are the prescriber:

- ☐ Ensure Patient Information and Consents in Sections 1 through 3 are complete
- ☐ Provide Prescriber and Surgery Center Information and ENCELTO Prescription Information in Sections 4 and 5
- ☐ Provide Prescriber Authorization by providing your signature in Section 6
- ☐ Fax the completed form and copies of both sides of insurance card(s) to ENCELTOconnect at 800-670-0719

If you are the patient:

- ☐ Complete all required fields in Sections 1 and 2 indicated with a red asterisk (*) to prevent delays
- ☐ Carefully read the Patient Consent and Certifications and Patient Authorization to Use and Disclose Health Information sections in Sections 7 and 8
- ☐ Provide your consent by checking the boxes and providing your signature in Section 3
- ☐ Include front and back copies of all insurance cards

Please see Important Safety Information on page 5 and full Prescribing Information and Patient Product Information for ENCELTO.

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Fields with an * are required to initiate enrollment.

Section 1: Patient Information

First name:* _____ MI: ___ **Last name:*** _____ **Gender:*** ☐ Male ☐ Female
Date of birth:* (MM/DD/YYYY) ____/____/____
Address:* _____ **City:*** _____ **State:*** ___ **ZIP Code:*** _____
Primary phone #:* _____ ☐ Home ☐ Mobile Secondary phone #: _____ ☐ Home ☐ Mobile
OK to leave a voice message? ☐ Y ☐ N
Email:* _____ Preferred language (if not English): _____

Authorized representative/Caregiver (if applicable)

First name: _____ Last name: _____
Relationship to patient: _____ Phone #: _____ Email: _____

Section 2: Patient Insurance Information

Insurance type:* ☐ Commercial/private insurance ☐ Medicare/Medicaid/Other government insurance

Primary medical insurance

Insurance carrier:* _____
Insurance phone #:* _____
Policyholder name:* _____
Relationship to patient:* _____
Policyholder date of birth:* (MM/DD/YYYY) ____/____/____
Insurance ID #:* _____
Member group #:* _____

Secondary medical insurance

Insurance carrier: _____
Insurance phone #: _____
Policyholder name: _____
Relationship to patient: _____
Policyholder date of birth: (MM/DD/YYYY) ____/____/____
Insurance ID #: _____
Member group #: _____

Section 3: Patient Consents and Signatures

☐ **Fair Credit Reporting Act (FCRA)** (Required for Travel Support program): By checking this box, I am authorizing ENCELTOconnect, under the FCRA, to obtain information from my credit profile or other information from consumer reporting agencies for the purpose of determining financial qualification for the ENCELTOconnect Travel Support program, subject to the additional terms in Section 7.

☐ **Marketing Communications** (Optional): By checking this box, I am agreeing to receive marketing communications from Neurotech and its agents (including service providers on its behalf) by mail, email, and telephone (including cell phone), including by using an automated telephone dialing system or pre-recorded voice, at the number(s) and address(es) I have provided above.

My signature below certifies that I have read and agree to the Patient Consent and Certifications in Section 7.

SIGN HERE (required)

_____ ____/____/____
Patient signature* **Date*** (MM/DD/YYYY)

If signed by Legal Representative, state relationship to Patient: _____

My signature below certifies that I have read and agree to the Patient Authorization to Use and Disclose Health Information in Section 8.

SIGN HERE (required)

_____ ____/____/____
Patient signature* **Date*** (MM/DD/YYYY)

If signed by Legal Representative, state relationship to Patient: _____

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First name:* _____ MI: __ **Last name:*** _____ **Date of birth:*** (MM/DD/YYYY) ____/____/____

Please select billing method: ☐ Buy and Bill ☐ ENCELTO Specialty Pharmacy **Please note: Actual billing method may be specified by the patient's insurance.**

Section 4: Prescriber and Surgery Center Information

Prescriber first name:* _____ **Prescriber last name:*** _____
Office/Practice name:* _____ Office contact name: _____
Office phone #:* _____ Office email: _____ **Office fax #:*** _____
Mailing address:* _____
City:* _____ **State:*** ___ **ZIP Code:*** _____
Provider NPI #:* _____ Group NPI #: _____ Medicare Provider #: _____
Preferred surgical center/Hospital name: _____
Surgical center/Hospital contact name: _____ Phone #: _____ Fax #: _____
Mailing address: _____ City: _____ State: ____ ZIP Code: _____
Product Shipping/Receiving contact name: _____ Phone #: _____
Email: _____

If preferred surgical center is unknown, support may be available to identify an appropriate facility affiliated with the patient's medical insurance plan

Section 5: ENCELTO Prescription Information

Primary diagnosis code: _____ Secondary diagnosis code: _____ Eye for implantation: ☐ Left eye ☐ Right eye
Anticipated date of treatment: (MM/DD/YYYY) _____/_____/_____ (Subject to change based on medical insurance requirements)
Patient allergies: _____
Current medication(s): _____

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

Dispense: ☐ One (1) unit of ENCELTO for surgical intravitreal implantation under aseptic conditions by a qualified ophthalmologist.
NDC: 82958-501-01 Refills: None

By signing below, I certify that the above therapy is medically necessary and that I will supervise the patient's treatment accordingly.

SIGN HERE (required) _____ _____/_____/_____
Prescriber signature-Dispense as Written (No Stamp Allowed)* Date* (MM/DD/YYYY)

The Prescriber is to comply with his/her state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance with state-specific requirements may result in outreach to the Prescriber. I authorize Neurotech Pharmaceuticals and its affiliates, agents and contractors to forward the above prescription, by fax or by any means under applicable law, to the appropriate pharmacy, vendor, or partner.

Section 6: Prescriber Authorization (This section must be completed by the physician.)

By signing below, I hereby attest that I am the prescribing healthcare provider, and I have determined that the above treatment is medically necessary for my patient named above and I have prescribed the product for an FDA-approved indication. Further, I certify that, to the best of my knowledge, the information on this form is accurate and complete, and I have obtained my patient's written authorization and certification in accordance with applicable state and federal law, including the Health Insurance Portability and Accountability Act (HIPAA), to provide the health information, contact information, and other information on this form to ENCELTOconnect for the purposes set forth in this form.

With regard to any patient eligible for patient assistance through the ENCELTOconnect program, I acknowledge that EITHER no claim for reimbursement of either ENCELTO or related medical procedures and services will be submitted to Medicare, Medicaid, or any third-party payer, OR I will provide appropriate denial and appeals documentation to support requests for patients who are deemed uninsured after a claim was submitted. I certify that any ENCELTO received in response to this application is only for use for the patient named on this form and that the product will not be offered for sale, trade, or barter.

I consent to Neurotech Pharmaceuticals and its affiliates, representatives, agents, and contractors contacting me by fax, phone, mail, or email to confirm receipt of ENCELTO or provide additional information about ENCELTO or the ENCELTOconnect program. I understand that Neurotech Pharmaceuticals may revise, change, or terminate any program services at any time without notice to me.

SIGN HERE (required) _____ _____/_____/_____
Prescriber signature* **Date*** (MM/DD/YYYY)

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Section 7: Patient Consent and Certifications

Enrolling in ENCELTOconnect. By signing and submitting this form, I acknowledge that I am applying to enroll in ENCELTOconnect and I authorize Neurotech Pharmaceuticals, Inc., its affiliated companies, vendors, agents, and representatives (collectively, "Neurotech Pharmaceuticals") to assess my eligibility for and provide me services under ENCELTOconnect. Such services, as described on page 1, include: (1) benefits verification and access support, 2) co-pay assistance for eligible patients, 3) travel support for eligible patients, and 4) product delivery coordination. Further, I acknowledge that I understand and agree to the ENCELTOconnect program terms referenced above and in this form.

Privacy Policy/Use of Personal Information. I understand that my health information, contact information, and other information that I, my healthcare provider, and others share with Neurotech Pharmaceuticals is collected to assess my eligibility for and provide me services under ENCELTOconnect, for the purposes otherwise described in this form, and for other business purposes of Neurotech Pharmaceuticals, as described in the Neurotech Pharmaceuticals Privacy Policy, available at: https://www.neurotechpharmaceuticals.com/wp-content/uploads/Privacy-Policy.pdf.

Fair Credit Reporting Act (FCRA) Requirements. I understand that if I have checked the Fair Credit Reporting Act (FCRA) checkbox on page 2, the credit profile pulled as part of the financial screening process will not impact my credit score and that, upon request, ENCELTOconnect will tell me whether it requested an individual consumer report and the name and address of the agency that furnished it. I understand that I may also be required to submit proof of income documentation to determine financial eligibility for the Travel Support program.

Marketing and Other Communications. I understand that if I have checked the Marketing Communications checkbox on page 2, I authorize Neurotech Pharmaceuticals to contact me by mail, telephone, or email with information about disease states and products, promotions, services, and research studies, and to ask my opinion about such information and topics, including market research and disease-related surveys. I understand that I may opt out of these marketing communications at any time by notifying Neurotech Pharmaceuticals or by following the instructions provided.

Separately, I understand that I may be contacted by Neurotech Pharmaceuticals in connection with assessing my eligibility for and providing me services under ENCELTOconnect, as well as for other permitted purposes, such as in the event that I report an adverse event.

Section 8: Patient Authorization to Use and Disclose Health Information

I hereby authorize my treating physicians, health insurance plan(s), pharmacies, or other healthcare providers (collectively "Healthcare Providers") to use and disclose my individually identifying health information, including health insurance information, medical diagnosis and condition, prescription information, and name, address and telephone number to Neurotech Pharmaceuticals and its contractors and business partners to provide me with patient services and to administer the ENCELTOconnect program, including: 1) to contact my healthcare provider and collect, enter, and maintain my health information in a database; 2) to contact my insurers as needed to verify my insurance coverage, review reimbursement requirements, and assist with the processing of claims; 3) to determine eligibility for program offerings; 4) to contact me (or my legal representative) as described in this form; 5) to assist with prior authorization or other appeals support; 5) for the operation and administration of the ENCELTOconnect program; 6) to perform data analytics with aggregated de-identified data to assess program efficiency. I understand that once my health information has been disclosed, federal privacy laws may no longer protect the information. However, Neurotech Pharmaceuticals agrees to using and disclosing my health information only for purposes authorized in this Authorization or as required by law or regulations.

This Authorization shall remain valid for ten (10) years from the date the Authorization is signed unless earlier revoked by my written request or unless it expires earlier under applicable state law. I understand that I have a right to receive a copy of this Authorization. I understand that I have the right to revoke this Authorization at any time by mailing a letter to P.O. Box 220117, Charlotte, NC 28222 ATTN: ENCELTOconnect or by visiting ENCELTO.com/patient-support. I understand that if I revoke this Authorization, I will no longer be able to receive ENCELTOconnect services.

I understand that signing this Authorization is voluntary and that my enrollment in any of the services and/or programs described above is entirely voluntary. I further understand that my treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my authorization of this disclosure, but if I do not sign this authorization form, I will not be able to receive ENCELTOconnect services. I understand that certain parties, such as my pharmacy provider, may receive remuneration (payment) from Neurotech Pharmaceuticals in connection with the activities described in this authorization form.

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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 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.

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 the full Prescribing Information and Patient Product Information for ENCELTO.

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