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BILLING AND CODING GUIDE

for Ambulatory Surgery Centers (ASCs)

This guide is intended to be an educational reference and for informational purposes only. It is not intended to provide medical, legal, or reimbursement advice.

Each healthcare professional and provider is responsible for determining appropriate codes, coverage, reimbursement and payment for individual patients.

Coding, coverage, and reimbursement policies vary by payer and are subject to change and may not be current when you view it. Please review and verify individual payer policies for details regarding specific requirements for ENCELTO for individual patients. All codes reported on the claim form must be supported by medical record documentation, as required by the payer.

Providing this information does not represent a guarantee of coverage, coverage levels, reimbursement or payment for ENCELTO. All such decisions are made by individual payers.
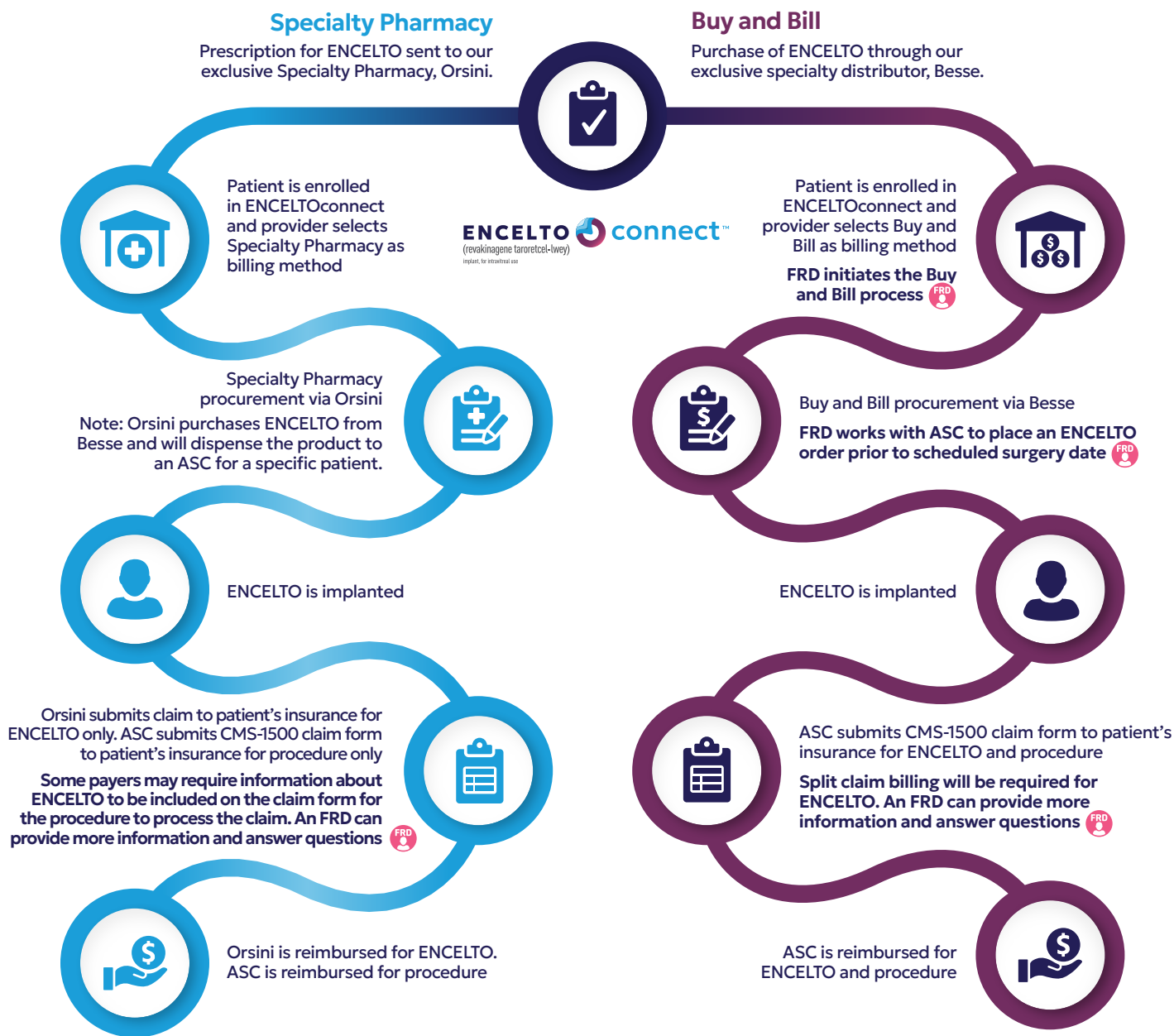
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Product Acquisition Channels

ENCELTO can be acquired one of two ways, depending on the ASC's logistical and operational needs and patient's insurance requirements. The chosen pathway determines who is purchasing and submitting a claim for the cost of ENCELTO.

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Specialty Pharmacy
Prescription for ENCELTO sent to our exclusive Specialty Pharmacy, Orsini.

Buy and Bill
Purchase of ENCELTO through our exclusive specialty distributor, Besse.

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Patient is enrolled in ENCELTOconnect and provider selects Specialty Pharmacy as billing method

Patient is enrolled in ENCELTOconnect and provider selects Buy and Bill as billing method

FRD initiates the Buy and Bill process FRD

Specialty Pharmacy procurement via Orsini

Note: Orsini purchases ENCELTO from Besse and will dispense the product to an ASC for a specific patient.

Buy and Bill procurement via Besse

FRD works with ASC to place an ENCELTO order prior to scheduled surgery date FRD

ENCELTO is implanted

ENCELTO is implanted

Orsini submits claim to patient's insurance for ENCELTO only. ASC submits CMS-1500 claim form to patient's insurance for procedure only

Some payers may require information about ENCELTO to be included on the claim form for the procedure to process the claim. An FRD can provide more information and answer questions FRD

ASC submits CMS-1500 claim form to patient's insurance for ENCELTO and procedure

Split claim billing will be required for ENCELTO. An FRD can provide more information and answer questions FRD

Orsini is reimbursed for ENCELTO. ASC is reimbursed for procedure

ASC is reimbursed for ENCELTO and procedure

FRD Field Reimbursement Director (FRD)

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Billing and Coding

This section provides general coding and appropriate use information for ENCELTO when implanted by a healthcare provider in an independent ASC.

International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Codes[1]

ICD-10-CM codes are used to identify a patient's diagnosis and support the medical necessity of treatment. The following codes may be appropriate to describe idiopathic macular telangiectasia type 2 (MacTel):

ICD-10-CM Code	Description	Appropriate Use
H35.071	Retinal telangiectasis, right eye	
H35.072	Retinal telangiectasis, left eye	
H35.073	Retinal telangiectasis, bilateral	
H35.079	Retinal telangiectasis, unspecified eye	Check payer policies for coding requirements when billing with unspecified ICD-10-CM codes.

National Drug Codes (NDCs)[2,3]

An NDC code is a unique 10-digit number that serves as a universal product identifier for drugs. Payers generally require healthcare providers to report the Health Insurance Portability and Accountability Act compliant 11-digit NDC on claims.

Payers may also require a unit of measure (UoM) qualifier and quantity. For ENCELTO, the UoM qualifier is UN (unit) and its quantity is 1. Check individual payer policies for reporting the NDC and UoM on claims.

10-digit NDC	11-digit NDC	Description
82958-501-01	82958-0501-01	Single-dose, implant that contains 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)
NDC and Unit of Measure		
N482958050101 UN1		

Healthcare Common Procedure Coding System (HCPCS) Codes[4]

HCPCS codes are used to report drugs and other procedures. Until a product specific HCPCS code is available for ENCELTO, an unclassified code should be used.

HCPCS Code	Description	Appropriate Use
J3590	Unclassified biologics	Check payer policies for coding requirements when billing for drugs/biologics reported with unclassified HCPCS codes.
J3490	Unclassified drugs	

Unclassified codes do not have associated billing units, therefore, a billing unit of 1 is entered on the claim form. Billing with unclassified codes requires additional documentation to be submitted on the claim form. On the CMS-1500 claim form, the additional information goes in Item 19.

Payer requirements may vary, but commonly reported information includes name of drug (brand and generic), strength and quantity of drug used (amount administered and discarded), NDC 11-digit format, and method of administration.

An electronic attachment may be needed to accommodate the required information due to claim form character limitations at Item 19.

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HCPCS Modifier[5]

Modifiers provide payers with additional information regarding services rendered. The following HCPCS modifier may be applicable for ENCELTO:

Modifier	Description	Appropriate Use
JZ	Zero drug amount discarded/not administered to any patient	Report modifier JZ with the HCPCS code to show that there was no amount of drug wasted on Medicare claims. Check other payer reporting requirements.

Current Procedural Terminology® (CPT) Code[6]

CPT codes describe procedures and services performed by healthcare providers. ENCELTO is intended for surgical intravitreal implantation under sterile technique by a qualified ophthalmologist. The following CPT code may be appropriate to report the intravitreal implantation:

CPT Code	Description
67027	Implantation of intravitreal drug delivery system (eg, ganciclovir implant), includes concomitant removal of vitreous

CPT Modifiers[7]

The following modifiers may be appropriate to indicate the laterality of the intravitreal implantation:

Modifier	Description
RT	Right side (used to identify procedures performed on the right side of the body)
LT	Left side (used to identify procedures performed on the left side of the body)

Place of Service Codes[8]

Place of service (POS) codes are 2-digit codes used to indicate the setting in which the service was provided. The following POS code may be appropriate when the intravitreal implantation of ENCELTO is performed in an independent ASC:

POS Code	POS Name	Description
24	Ambulatory surgical center	A freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis.

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Split Billing Considerations[9-11]

The professional electronic claim 837P (or the CMS-1500) charge field character limitations may require multiple claims to report the charge for ENCELTO.

The charge fields (24F, 28) for dollar amounts have a 7-character limitation; therefore the highest dollar value allowed on one claim form is $99,999.99.

Multiple claims may be submitted with charges split any number of ways so long as the charge on any one claim form line does not exceed $99,999.99.

Avoid same dollar amounts on the multiple claims to avoid delays/denials for duplicate claims. Payers may require specific modifiers on split claims to facilitate appropriate claims processing.

Common Modifiers That May Be Required for Split Claim Billing[10,11]

Split claim and modifier guidance varies by payer and should be verified prior to submitting a split claim.

Modifier	Description	Appropriate Use
59	Distinct procedural service	Report the payer-specified modifier with the HCPCS code to identify that multiple claims are needed due to character limitations in the charge field on claim forms. Check payer reporting requirements.
76	Repeat procedure or service by same physician or other qualified HCP	

Guidance for Filling 837P (or the CMS-1500) Fields Related to Split Claim Billing[9]

Item 19. Additional Claim Information: Use this field to indicate this is a split claim in addition to providing drug-identifying information. An electronic attachment may be needed to accommodate the required information due to claim form character limitations at Item 19. Example:

—Claim 1 of 3; Dollar amount exceeds charge line amount for ENCELTO

—Claim 2 of 3; $ amount in claim 1 exceeds charge line amt for ENCELTO

—Claim 3 of 3; Remaining $ from claim 1&2 exceed item 28 amt for ENCELTO

Item 21A-L. Diagnosis: Indicate the appropriate ICD-10-CM code based on documentation in the medical record. See page 4 for relevant codes

Item 24A. Date of Service: Enter the NDC, UoM, and quantity. Example: N482958050101 UN1

Item 24D. Procedures, Services, or Supplies: Indicate appropriate HCPCS and CPT codes. See pages 4 and 5 for codes and modifiers to use

Item 24E. Diagnosis Pointer: Enter the appropriate letter that corresponds to the diagnosis in Item 21

Item 24F. Charges: Indicate charges up to the 7-digit limit

Item 24G. Days or Units: Enter the appropriate number of units for ENCELTO. Report a billing unit of "1" when using unclassified codes

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Sample CMS-1500 Claim Form (cont'd)

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CMS-1500 Claim 1[12]

Use this field to indicate the first claim in the series, in addition to providing drug-identifying information.

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 1 of 3; Dollar amount exceeds charge line amount for ENCELTO

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)   ICD Ind.
A. H35.071   B.   C.   D.
E.   F.   G.   H.
I.   J.   K.   L.

22. RESUBMISSION CODE   ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER
XXXXXXXXXX

24. N482958050101 UN1

A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1	MM DD YY MM DD YY	24		J3590	JZ	A	XXXXX XX	1		NPI
2	MM DD YY MM DD YY	24		67027	RT	A	XXXXX XX	1		NPI

Payers may also require a unit of measure (UoM) qualifier and quantity. For ENCELTO, the UoM qualifier is UN (unit) and its quantity is 1. This will be the same across all claims.

The charge fields have a 7-character limitation; therefore, the highest dollar value allowed on one claim form is $99,999.99.

CMS-1500 Claim 2[12]

Use this field to indicate this is the second in a series of 3 claims being filed.

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 2 of 3; $ amount in claim 1 exceeds charge line amt for ENCEL

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below
A. H35.071   B.   C.
E.   F.   G.
I.   J.   K.

22. RESUBMISSION CODE   ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER
XXXXXXXXXX

24. N482958050101 UN1

	A. DATE(S) OF SERVICE	B. PLACE OF SERVICE		D. CPT/HCPCS	MODIFIER		E. DIAGNOSIS POINTER	F. $ CHARGES	G. UNITS			J.
1	MM DD YY MM DD YY	24		J3590	JZ	76	A	XXXXX XX	1		NPI	
2	MM DD YY MM DD YY	24		67027	RT		A	0 00	1		NPI	

Some payers may require a modifier for split claim billing to be used on claims subsequent to the initial one.

The dollar amount for ENCELTO on this claim should not be the same as used on claim 1 or 3.

CMS-1500 Claim 3[12]

Use this field to indicate this is the third in a series of 3 claims being filed.

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Claim 3 of 3; Remaining $ from claim 1&2 exceed item 28 amt for ENCELTO

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)   ICD Ind.
A. H35.071   B.   C.   D.
E.   F.   G.   H.
I.   J.   K.   L.

22. RESUBMISSION CODE   ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER
XXXXXXXXXX

24. N482958050101 UN1

	A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. CPT/HCPCS	MODIFIER		E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H.	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1	MM DD YY MM DD YY	24		J3590	JZ	76	A	XXXXX XX	1		NPI	
2	MM DD YY MM DD YY	24		67027	RT		A	0 00	1		NPI	

Some payers may require a modifier for split claim billing to be used on claims subsequent to the initial one.

The dollar amount for ENCELTO on this claim should not be the same as used on claim 1 or 2.

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Sample CMS-1500 Claim Form (cont'd)

Sample CMS-1500 Claim Form or Electronic Equivalent for Specialty Pharmacy Acquisition[12]

Providers who obtained ENCELTO through the specialty pharmacy will bill only for the intravitreal implantation. However, some payers may require the drug information be included on the claim form to process the claim. Please check with the individual payer for billing requirements.

The following is an example of how a physician's services may be billed using a CMS-1500 claim form and is for illustrative purposes only. It is always the provider's responsibility to submit true and accurate claims for the products and services rendered.

Item 21. Diagnosis: Enter the appropriate diagnosis code, eg,
ICD-10-CM: H35.07X (Retinal telangiectasis)
Final code depends on medical record documentation

Item 19. Additional Claim Information: Enter the drug-identifying information, method of administration and acquisition via the specialty pharmacy, eg, ENCELTO, intravitreal implantation, right eye N482958050101

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
ENCELTO, intravitreal implantation, right eye N482958050101

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
A. H35.071

20. OUTSIDE LAB?

22. RESUBMISSION CODE

23. PRIOR AUTHORIZATION NU
XXXXXXXXXX

24. A. DATE(S) OF SERVICE						B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES		G. DAYS OR UNITS
From MM	DD	YY	To MM	DD	YY								
1 N482958050101 UN1													
MM	DD	YY	MM	DD	YY	24		J3590	JZ	A	0	01	0
2													
MM	DD	YY	MM	DD	YY	24		67027	RT	A	XXXXX	XX	1

Item 24D. Procedures/Services/Supplies:
Enter the appropriate CPT/HCPCS codes and Modifiers, eg,
Drug: J3590 for ENCELTO
Modifier: JZ to show that no product was wasted
Administration: 67027 for intravitreal implantation
Modifier: RT to indicate the implantation occurred in the right eye
Add additional modifiers as appropriate

Item 24E. Diagnosis Pointer: Enter the appropriate letter (A-L) that corresponds to the diagnosis in Item 21

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Claims Submission Checklist

Coding and billing will vary based on payer-specific requirements and ASC. It is important to confirm payer-specific requirements prior to claim submission in order to avoid processing delays or denials.

☐ **Confirm** that the diagnosis code is accurate and supports the medical necessity of ENCELTO

- Be sure to code to the **highest level of specificity** to avoid claim denials. Ensure the laterality of the diagnosis code matches the modifier laterality on CPT 67027

☐ **Determine with the specific payer which miscellaneous drug code** is appropriate for ENCELTO and include all required information in Item 19 of the CMS-1500 claim form

☐ **Use the appropriate 11-digit NDC** when using a not otherwise classified code. Please check payer-specific requirements

☐ **Include the charge for the drug or biologic in the physician's bill** when billing Medicare Part B for patients with traditional Medicare[13]

☐ **Check payer-specific split billing requirements** if total charges exceed the 7-character limitation on the CMS-1500 form

☐ **Append appropriate medical record documentation**, such as clinical information, imaging, and/or a letter of medical necessity

☐ **Provide PA number in Item 23 of the claim form as appropriate**

☐ Ensure **accuracy and completeness** of the **patient's information** (eg, date of birth, insurance identification number) and **provider's information** (eg, National Provider Identifier [NPI])

FRD **Reach out to your dedicated Neurotech Field Reimbursement Director (FRD), who may be able to provide certain coverage and on-label coding information. Discussions with your FRD do not replace the need to verify all information submitted for an individual patient with the payer.**

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FRD

Your FRD is available to provide support through the coverage process

General and/or plan-specific reimbursement education, including:

- Billing and coding
- Prior authorization (PA) requirements and processes
- Appeals and denials resolution

Information about Neurotech's reimbursement-related resources and programs, such as the co-pay assistance through ENCELTOconnect

Providing appropriate assistance with questions on patient coverage, access and reimbursement

Resources such as letter of medical necessity and PA appeals sample letters

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If you or your patients have questions about insurance coverage, reimbursement, or billing, ENCELTOconnect can help. For more information or assistance, please call ENCELTOconnect at 1-877-ENCELTO (1-877-362-3586) or visit ENCELTO.com/ecp/access-and-resources.

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IMPORTANT SAFETY INFORMATION

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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](#).

References: 1. National Center for Health Statistics. International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). FY2023 Full PDF April 2025. Accessed March 9, 2025. https://www.cdc.gov/nchs/icd/icd-10-cm/files.html **2.** Food and Drug Administration. Format of the national drug code. Accessed March 26, 2025. https://www.fda.gov/media/173715/download **3.** ENCELTO. Prescribing Information. Neurotech Pharmaceuticals, Inc. **4.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. Updated April 2025. Accessed March 9, 2025. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **5.** Centers for Medicare & Medicaid Services. Medicare Program. Discarded drugs and biologicals – JW modifier and JZ modifier policy: frequently asked questions. Accessed March 9, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **6.** American Medical Association. CPT 2024. Professional Edition. AMA; 2024. **7.** Centers for Medicare & Medicaid Services. Billing and Coding: Use of Laterality Modifiers. Updated December 17, 2024. Accessed March 9, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56869 **8.** Centers for Medicare & Medicaid Services. Place of service code set. Database (updated May 2, 2024). Accessed March 9, 2025. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets **9.** Centers for Medicare & Medicaid Services. MCPM Chapter 26 – Completing and processing form CMS-1500 data set. Accessed March 17, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **10.** CGS. Submitting claims when the billed amount exceeds $99,999.99. Accessed March 17, 2025. https://cgsmedicare.com/partb/pubs/news/2020/03/cope16412.html **11.** WPS. Submitting claims when the dollar amount is greater than $99,999.99. Accessed March 17, 2025. https://www.wpsgha.com/guides-resources/view/1155 **12.** Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Accessed March 9, 2025. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf **13.** CMS.gov. Incident to services & supplies. Accessed March 13, 2025. https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-practice-providers/incident-services-supplies

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