

Chloroprocaine HCl ophthalmic gel) 3%

Reimbursement Guide



Comfort & confidence made simple¹²

A modern take on ocular anesthesia, IHEEZO° is designed for efficiency and comfort-delivering reliable, lasting anesthesia without adding complexity.^{1,2}

In a Phase III clinical trial evaluating IHEEZO for use in routine ophthalmic procedures, it was shown to deliver:*,2



90

second onset



Achieves full anesthesia in under 90 seconds on average-potentially minimizing prep time.²

dose process

1 step, complete coverage

A single dose-just three drops—was shown to provide sufficient anesthesia.**,1

21.5 minute duration



Confidence that carries

Sustains anesthesia for an average of 21.5 minutes outlasting most routine procedures.1,3

100% In this clinical trial, 100% of patients treated with IHEEZO maintained anathonic without sure leavest and the second sure of the second sure maintained anesthesia without supplemental treatment.**,1,2

*The Phase III clinical trial was a randomized, prospective, multicenter, active-controlled, observer-masked study in 338 patients undergoing routine cataract surgery.

**In the clinical trial, no patient undergoing routine cataract surgery receiving IHEEZO required supplemental treatment to maintain anesthesia; this was not the case for patients receiving tetracaine. Supplemental treatment was defined as general anesthesia, intraoperative systemic analgesia, or local anesthesia. Though supplemental administration was not required by any patient in the clinical trial, IHEEZO may be reapplied as needed to maintain anesthesia.¹²

APPROVED USE

IHEEZO is indicated for ocular surface anesthesia.

IMPORTANT SAFETY INFORMATION

- IHEEZO is contraindicated in patients with a history of hypersensitivity to any component of this preparation
- IHEEZO should not be injected or intraocularly administered.

Please see full Important Safety Information on page 12 and the Full Prescribing Information at www.iheezo.com/ prescribinginformation.

Novel low-viscosity gel for uniform coverage without acting as a barrier to povidone-iodine



No excessive pooling or need for redistribution^{4,5}



Reduces reliance on external applicators



Minimizes potential ocular surface irritation^{4,5}



Supports antiseptic effectiveness⁶

1975%

less viscous than other FDA-approved topical ocular anesthetic gel.^{1,2,5,6}

KEY SAFETY DATA

Sterile, single-use, and built for safety

IHEEZO is preservative-free and delivered in a sterile, single-use ampule for added patient safety.² Single-use packaging may decrease the risk of infection and medication errors.⁷

- ✓ Sterile
- ✓ Preservative-free
- ✓ Single-use ampule

TREATMENT-EMERGENT ADVERSE EVENTS BY ORGAN CLASS¹

System organ class	Chloroprocaine 3% Gel N=167	Tetracaine 0.5% N=171 (%)
Treatment emergent adverse events (TEAEs)	0	2 (1.2)
Eye disorders	0	2 (1.2)
Corneal disorder	0	1 (0.6)
Iridocele	0	1 (0.6)

Two mild TEAEs were reported in the Tetracaine 0.5% group, while none were reported in the Chloroprocaine 3% Gel group.

IMPORTANT SAFETY INFORMATION

IHEEZO is indicated for administration under the direct supervision of a healthcare provider. Do not touch the dropper tip to any surface to avoid contamination. See full Important Safety Information on page 12.

J-Code and Billing Essentials

IHEEZO is assigned a permanent, product-specific J-code:

J2403

- chloroprocaine HCI ophthalmic gel 3%
- 1 billing unit = 1mg; 1 standard 800mg ampule = 800 billing units

NDC# (11-Digit)		CPT Code	CPT Modifier
Intravitreal injection		67028	
Sub tenon injection		67515	
Panretinal Photocoagula	ation (PRP)	67228	
Selective laser trabeculo	pplasty (SLT)	65855	
Laser iridotomy		66761	RT (Right Eye)
YAG laser capsulotomy		66821	LT (Left Eye)
Complex cataract surge	ry	66982 / 66985	
Simple cataract surgery		66984	
Exchange of an intraocu	lar lens	66986	
Cataract surgery with M	IGS	66991	
HCPCS code	HCPCS modifier	Long Descriptor	NDC number
J2403	JZ [†]	chloroprocaine HCl ophthalmic gel 3%	82667-0300-01 (11-digit)

Effective July 1, 2024, the NCCI Medically Unlikely Edits (MUE) list was updated to reflect 1600 units (2 vials) of IHEEZO per day, allowing for bilateral utilization.* Billing for bilateral procedures is payer specific.**The following is a general guideline for billing on 1 or 2 lines:

- 1 Line: 1600 units, JZ modifier, 50 modifier, add NDC to box 19 and diagnosis indicators for both right & left eyes.
- 2 Lines: 800 units (each line), JZ modifier, diagnosis indicator (each line), does not require NDC in box 19.

IMPORTANT SAFETY INFORMATION

[†]JZ modifier is used to indicate no wastage

 $[*]Please\ refer\ to\ the\ CMS\ website\ at\ https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-medically-unlikely-edits$

^{**}Please refer to individual payer requirements

Coverage for IHEEZO

IHEEZO (chloroprocaine HCl ophthalmic gel) 3% is generally covered by Medicare and other payers when medically necessary with the product-specific J-Code.



Billing and Reimbursement

- IHEEZO was granted Transitional Pass-Through status, beginning April 2023.
- J2403 allows for separate reimbursement for Medicare Fee-for-Service patients in the ASC/HOPD setting and in the physician office setting.*
- Medicare reimburses 80% of the overall allowable payment amount.
 - > 20% is the responsibility of the secondary, supplemental insurance or beneficiary in the form of a co-pay or co-insurance.
 - Many patients with Fee-for-Service Medicare have a form of supplemental insurance that will cover some, if not all of the 20% co-insurance.

IMPORTANT REMINDERS

- Questions related to insurance eligibility for IHEEZO can be addressed by contacting your IHEEZO representative, emailing reimbursement@harrowinc.com, or working directly with your payer provider representative.
- Coverage and payment may vary by payer, contractual agreements, and site of service. Many
 patients with Fee-for-Service Medicare have a form of supplemental insurance that will cover
 some, if not all of the 20% co-insurance.

*It is advised that you always check in advance to determine coverage and reimbursement prior to use.

IMPORTANT SAFETY INFORMATION

Billing and Reimbursement

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, Medicare Advantage plans should cover IHEEZO®, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations.
- For a Medicare Advantage patient, the specific Medicare Advantage payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for IHEEZO.

Best practices for dealing with Medicare Advantage plans

- Before surgery, verify if patient has a Medicare Advantage plan.
- Check if your facility-specific payer contracts allow for separate payment of drugs, including IHEEZO.
- If the plan bundles payment for IHEEZO, share the CMS announcement regarding separate billable status.
- Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Harrow does not guarantee reimbursement.

YOU CAN LOOK UP A PATIENT'S MEDICARE PLAN BY ENTERING THE PATIENT'S NAME AND DATE OF BIRTH IN ANY OF THE FOLLOWING DATABASES, AMONG OTHERS:

- Secure Provider Online Tool (SPOT), provided by First Coast MAC
- Palmetto e-services

- Noridian Medicare Portal
- Availity (for BCBS, Aetna, Humana)

You do not need to pay a subscription fee to access these databases.

IMPORTANT SAFETY INFORMATION

Billing and Reimbursement

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, commercial plans should cover IHEEZO, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations.
- For a commercial patient, the specific payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for IHEEZO.

Best practices for dealing with Commercial Insurance plans

- Check if your facility-specific payer contracts allow for separate payment of drugs, new technologies, and pass-through drugs, including IHEEZO.
- Confirm if Prior Authorization (PA) is required for patient's specific commercial plan.
- Confirm and verify payer payment/fee schedules for IHEEZO.
- Verify payer-specific use of appropriate revenue code.
- Cultivate relationship with payer-provider network representative.
- Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Harrow does not guarantee reimbursement.

QUESTIONS? CONTACT OUR DEDICATED REIMBURSEMENT TEAM.

Please email **reimbursement@harrowinc.com** and you will be connected directly with one of our reimbursement team members.

IMPORTANT SAFETY INFORMATION

CMS-1500 CLAIM FORM (CLINIC/ASC)

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Form locator 24B:	HEALTH INSURANCE CLAIM FORM				
Example "24" indicates an ASC;	APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12 PICA PICA				
"11" indicates an office setting.					
	A A A A A A A A A A				
Formula catan 04 4D	2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Lefner, Travis 3. PATIENT'S BIRTH DATE SEX MM DD Y MX F 4. INSURED'S NAME (Last Name, First Name, Middle Initial)				
Form locator 24-1D:	5. PATIENT'S ADDRESS (No., Street) 6. PATIENT RELATIONSHIP TO INSURED 7. INSURED'S ADDRESS (No., Street)				
Enter the applicable procedure	76 Aphid Dr. Self X Spouse Child Other				
code (e.g. 66984 for cataract surgery or 67028 for an	CITY STATE 8. RESERVED FOR NUCC USE CITY STATE NJ				
intravitreal injection).Enter the	ZIP CODE TELEPHONE (Include Area Code) ZIP CODE TELEPHONE (Include Area Code)				
Modifier for left (LT) or right (RT)	07305 ()				
Widdlifer for left (E1) of right (K1)	9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) 10, IS PATIENT'S CONDITION RELATED TO: 11. INSURED'S POLICY GROUP OR FECA NUMBER				
	a. OTHER INSURED'S POLICY OR GROUP NUMBER a. EMPLOYMENT? (Current or Previous) a. INSURED'S DATE OF BIRTH MM DD YY MM DD YY				
Form locator 24-2A:	YES NO I M F				
Enter N4 qualifier 11-digit NDC	b. RESERVED FOR NUCC USE b. AUTO ACCIDENT? PLACE (State) D. OTHER CLAIM ID (Designated by NUCC)				
Number.*	c. RESERVED FOR NUCC USE . OTHER ACCIDENT? C. INSURANCE PLAN NAME OR PROGRAM NAME				
	d. INSURANCE PLAN NAME OR PROGRAM NAME Od. CLAIM CODES (Designated by NUCC) d. IS THERE ANOTHER HEALTH BENEFIT PLAN?				
	U. CLAIM CODES (Designated by NOCC) U.S. THERE AND THEN EACH THE ENERT I POWE. YES NO If yes, complete items 9, 9a, and 9d.				
Form locator 24-2D:	READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary payment of medical benefits to the undersigned physician or supplier for				
Enter the unique Billing Code	to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment services described below.				
(J2403) and modifier (JZ) -	SIGNEDDATESIGNED				
indicating no wastage.	14. DATE OF CURRE VI ILLNESS, INJURY, or PREGNANCY (LMP) 15. O HER DATE MM DD YY				
	QUAL. QUAL FROM TO				
	17b, NPI FROM TO				
Form locator 24E:	19. ADDITIONAL CLAM INFORMATION (Designated by NUCC) 20. OUTSIDE LAB? \$ CHARGES				
Enter the diagnosis code pointer	21, DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0 22, RESUBMISSION ORIGINAL REF. NO				
number from field 21 that related	A.LXX"X" B.L. C.L. D.I				
to the reason for service.	E. L F. L G. L H. L 23. PRIOR AUTHORIZATION NUMBER				
	L J. K. L L. SERVICE B. C. D. PROCEDIRES, SERVICES, OR SUPPLIES E. F. G. H. I. J. From To PLA(EOF (Explair Unusual Circumstances) DIAGNOSIS PASS PSOI D. RENDERING				
	24, A DATE(S) FSERVICE S. C. D. PROCEDURES, SERVICES, OR SUPPLIES E. F. G. H. I. J. FROM PROVIDER PROVIDER				
Form locator 24F:	1 12 20 18 12 20 23 24 66984 RT A XXX 00 1 NPI 1111111111				
Confirm charge for IHEEZO®	N482667030001UN1				
reflects per unit cost x 800	2 12 20 18 12 20 23 24 J2403 JZ A XXX 00 800 NPI 1111111111				
units according to your set fee	3				
schedule.	4				
	NPI NPI				
Form locator 24G:	5				
Enter the number of	6 ! ! ! ! ! !				
billable units. For IHEEZO ,					
1unit=800mg. Allowable billing	X				
for IHEEZO is 800 units for a	31. SIGNATURE OF PHYSICIAN OR SUPPLIER 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # (555) 555-5555				
single dose vial.	INCLUDING DERREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) Any ASC 23 Cherry St.				
9 1 222 112	Town, NJ 01234				
	SIGNED DATE a. b. a. D.				
	NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02				

The information contained within this document is provided as a reference for obtaining appropriate reimbursement. This reference is for informational purposes only. Harrow does not guarantee submitting a completed CMS-1500 form will result in reimbursement. Providers should always contact their payers directly with any questions.

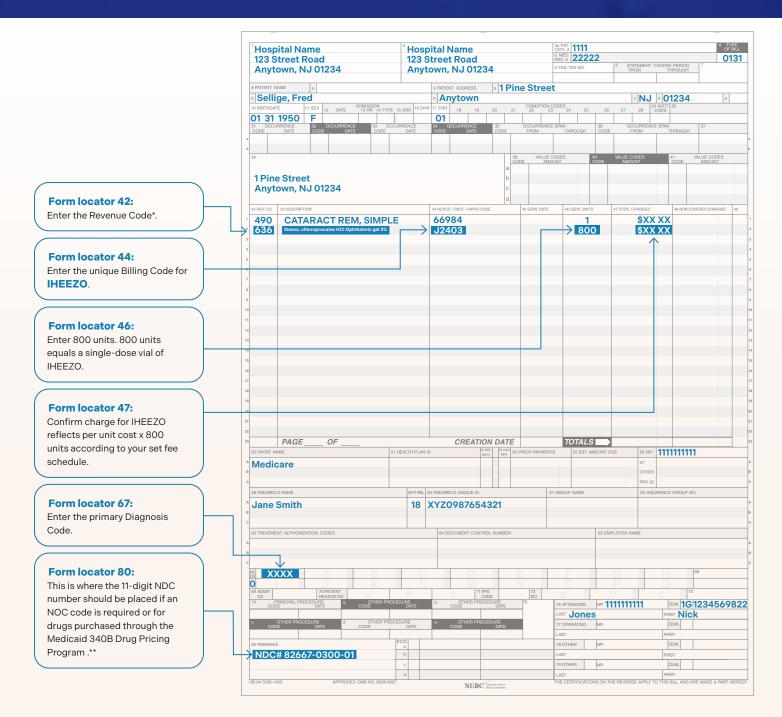
Understanding the acronyms

CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code; NPI=National Provider Identifier; HCPCS=Healthcare Common Procedure Coding System

IMPORTANT SAFETY INFORMATION

^{*}Some plans may require the 10-digit NDC #82667-300-01

UB-04 CLAIM FORM (HOPD)



^{*}Note: For hospitals and ASCs using the UB-04 form, it is best practice to confirm the correct revenue code with the payer to ensure reimbursement. The most commonly accepted revenue codes are 636, and 252.

The information contained within this document is provided as a reference for obtaining appropriate reimbursement. This reference is for informational purposes only. Harrow does not guarantee submitting a completed UB-04 form will result in reimbursement. Providers should always contact their payers directly with any questions.

Understanding the acronyms

ASC=Ambulatory Surgery Center; HOPD=Hospital Outpatient Department; ND=National Drug Code; NOC=Not Otherwise Classified

IMPORTANT SAFETY INFORMATION

^{**}Some plans may require the 10-digit NDC #82667-300-01

Appealing Denied Claims

Appealing claims

When a payer denies a claim for IHEEZO®, the first step in appealing the decision is to understand why the claim was denied.

Payers may deny claims for a number of reasons:

- Claim form contains missing or invalid information to adjudicate.
- Claim requires resubmission with invoice, operative report or injection documentation.
- Payer does not separately reimburse for use of IHEEZO.
- Missing/incomplete/invalid/deactivated/withdrawn National Drug Code (NDC).

Claims can typically be corrected through reopenings or new claim submissions depending on type of denial.

If the payer has denied the claim based on medical information:

- Utilize the payer-provider portal to review specific medical benefit coverage of IHEEZO.
- Access sample Letters of Appeal and Medical Necessity at iheezo.com/reimbursement to use in your claims appeal process.

BEST PRACTICES FOR CLAIM SUBMISSIONS

- Make sure submissions are timely and accurate.
- Double-check that codes and units match payer requirements.
- Check your payer contract.
- Verify
 - > Diagnosis codes and procedure codes
 - > CPT®, HCPCS, and revenue codes
 - NDC (depending on claim form)
- Stay up to date on payer coverage as well as billing and coding trends.

*It is advised that you always check in advance to determine coverage and reimbursement prior to use.

IMPORTANT SAFETY INFORMATION

Order IHEEZO with Confidence

ORDERING

IHEEZO may be ordered from any of the following wholesaler/distributors.



NDC# (11-Digit)	Unit Size	Units per Box
82667-0300-01	800 mg	1 unit
Note: In some instances required for reimbursen	s, the 10-digit code (8266 nent.	7-300-01) may be
Wholesalers & Distributors	Item Number	Contact Phone Number
Besse	#10280055	(800) 543-2111
BioCareSD	#1001474	(800) 304-3063
Cardinal Specialty (SPD)	#5851738	(877) 453-3972
McKesson Medical Surgical	#1228615	(855) 571-2100
McKesson Specialty	#5019898	(855) 477-9800
Metro Medical	#300101	(800) 768-2002

ACCESS MADE EASY

One-stop support for you, your staff, and your patients



Personalized Access Support

Connect with a specialist in under 30 seconds for access and cost support. Track patients support updates in real-time via the Provider Portal.



Seamless Enrollment & Coverage

Offers simplified enrollment for benefit investigation and coverage verification. Get alerts when a PA is required, or proceed directly—order, treat, and submit for reimbursement.





Copay & Product Assurance

Enroll in our commercial copay program, foundation research, or patient assistance based on need. Receive product replacement for breakage, spoilage, or loss—when you treat, you're covered.**

IMPORTANT SAFETY INFORMATION

^{**}It is advised that you always check in advance to determine coverage and reimbursement prior to use.

Harrow can help!



CONTACT OUR DEDICATED REIMBURSEMENT TEAM

If you need any help with denials and appeals or need detailed information about pricing, please email reimbursement@harrowinc.com and you will be connected directly with one of our reimbursement team members.

Curious about IHEEZO® coverage in your area?

Visit the link below to utilize our policy lookup tool.

- + Up-to-date policy coverage per plan
- + Local coverage determinations
- Prior authorizations forms at your fingertips



Visit IHEEZO.com/access today to learn more.



APPROVED USE

IHEEZO is indicated for ocular surface anesthesia.

IMPORTANT SAFETY INFORMATION

- IHEEZO is contraindicated in patients with a history of hypersensitivity to any component of this preparation.
- IHEEZO should not be injected or intraocularly administered.
- Patients should not touch the eye for at least 10 to 20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye.
- Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss.
- Do not touch the dropper tip to any surface as this may contaminate the gel.

- IHEEZO is indicated for administration under the direct supervision of a healthcare provider. IHEEZO is not intended for patient self-administration.
- The most common adverse reactions in studies following IHEEZO administration (incidence greater than or equal to 5%) were mydriasis, conjunctival hyperemia, and eye irritation.
- You are encouraged to report suspected adverse reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the Full Prescribing Information for IHEEZO at www.iheezo.com/prescribinginformation.

References: 1. Data on file. Harrow IP, LLC; 2023. 2. Iheezo. Prescribing information. Harrow IP, LLC; 2022. 3. Intravitreal Injections. The Foundation of the American Society of Retina Specialists. Accessed October 30, 2022. https://www.asrs.org/content/documents/fact-sheet-30-intravitreal-injections.pdf.
4. Sintetica. Chloroprocaine hydrochloride ophthalmic gel 3%. Pharmaceutical Development. Sintetica; 2002. 5. Akten. Material safety data sheet. Akorn Pharmaceuticals; 2010. 6. Costine Ilyas H, Costine R. The Effects of Low Viscosity Preservative-Free Chloroprocaine Ophthalmic Gel 3% versus BAK-Containing Tetracaine 0.5% on the Bactericidal Action of Povidone-Iodine. Clin Ophthalmol. 2024;18:825-831 https://doi.org/10.2147/OPTH.S454496. 7. Rhinehart Siegel JD, Rhinehart E, Jackson M, Chiarello L. The Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

