

**The first and only FDA-approved, single-dose, sustained-release, intracameral steroid
for the treatment of postoperative inflammation¹⁻³**

DEXYCU Overview

INDICATION AND USAGE

DEXYCU™ (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

**Please see Important Safety Information throughout
and accompanying full Prescribing Information.**



DEXYCU™
(dexamethasone intraocular
suspension) 9%



About DEXYCU™ (dexamethasone intraocular suspension) 9%

What is DEXYCU?

Traditionally, post-cataract surgery eyedrop dosing regimens may include steroid, antibiotic, and nonsteroidal anti-inflammatory drug (NSAID) drops.⁴⁻⁷ This can include 70 or more steroid drops over 4 weeks with some regimens.⁴⁻⁶ Today, you and your patients have a choice. **DEXYCU** does not replace all drops, but this one-time treatment may eliminate the need for steroid drops.^{1-3,7} **DEXYCU** is the first and only FDA-approved, single-dose, sustained-release, intracameral steroid on the market.¹⁻³ Significantly fewer **DEXYCU** subjects vs placebo received ocular steroids or NSAIDs (rescue medication) on days 3, 8, 15, and 30, including 10% (n=16/156) vs 50% (n=40/80) at day 8.³ With a single injection at the end of cataract surgery, anti-inflammatory efficacy begins as early as day 1 and continues through day 30.¹ **DEXYCU** helps put control in place with a single dose.¹

What is DEXYCU indicated for?

DEXYCU is indicated for the treatment of postoperative inflammation.¹

Pass-through status:

Under the Outpatient Prospective Payment System, pass-through products are paid separately (i.e., in addition to the packaged procedural payment) by the Centers for Medicare & Medicaid Services (CMS). **DEXYCU** use for patients with Medicare Part B coverage is separately reimbursed.

J-code for DEXYCU: J1095⁸

Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs) use this unique J-code to bill CMS and other payers for separate payment.

Wholesale Acquisition Cost (WAC): \$595

Ordering DEXYCU:

DEXYCU is available through national wholesalers and specialty distributors.

Please see DEXYCU Billing & Ordering Guide for additional information.

Reimbursement FAQs



What is the cost of DEXYCU?

The WAC for **DEXYCU** is \$595. CMS sets a minimum price for drugs to qualify for pass-through status. **DEXYCU** is priced to meet those requirements. There is no effect on physician fees. Payment to the surgeon for cataract surgery under Medicare's Physician Fee Schedule will be unaffected by the use of **DEXYCU** or the pass-through payments related to **DEXYCU**, now and in the future. There is no effect on the healthcare system. The pass-through regulation is budget-neutral to the healthcare system. To the extent that ophthalmic surgeons' facilities elect not to access pass-through payments, the funds set aside will be used by other specialties. Any remaining amounts will be lost to the system.

How is DEXYCU reimbursed?

DEXYCU has been designated as a pass-through drug. This allows ASCs and HOPDs to bill Medicare and other payers for **DEXYCU** using a unique J-code: J1095.⁸ The payment is over and above the facility fees paid to ASCs or to HOPDs for cataract surgery. There is no coinsurance payment for **DEXYCU** associated with procedures performed in HOPDs, and almost all Medicare patients have some form of supplemental insurance that covers copayments. For commercial plans, coverage and reimbursement may vary by payer, contractual agreements, and site of service. Work with your **DEXYCU** representative or field reimbursement manager to determine billable status for your payers and identify which plans allow for separate payment of drugs, new technologies, and pass-through drugs.

Is patient assistance available?

EyePoint is committed to helping you access **DEXYCU** for your patients. EyePoint provides resources and helps you determine billable status for your payers and identify which plans allow for separate payment of drugs, new technologies, and pass-through drugs. EyePoint AssistSM is a program designed to help provide greater access to **DEXYCU** for more patients who need it.

Please see DEXYCU Guide to Reimbursement for additional information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

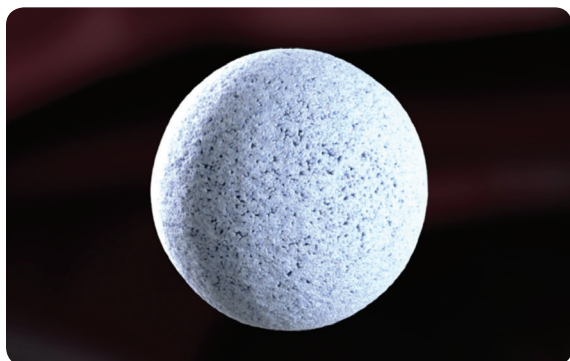
Increase in Intraocular Pressure

- Prolonged use of corticosteroids, including DEXYCU, may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision
- Steroids should be used with caution in the presence of glaucoma

How DEXYCU™ (dexamethasone intraocular suspension) 9% Works

How does DEXYCU work?

Delivers sustained release of dexamethasone from within using patented Verisome® Technology³



- DEXYCU utilizes a novel, biodegradable, sustained-release platform, Verisome Technology, to deliver the active ingredient, dexamethasone⁹
- The sphere formation is in aqueous media, which keeps the delivery system intact⁹



- Provides a controlled release of dexamethasone across the target area³
- Over time, the Verisome sphere degrades with the release of dexamethasone until the sphere is no longer visible⁹

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Delayed Healing

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

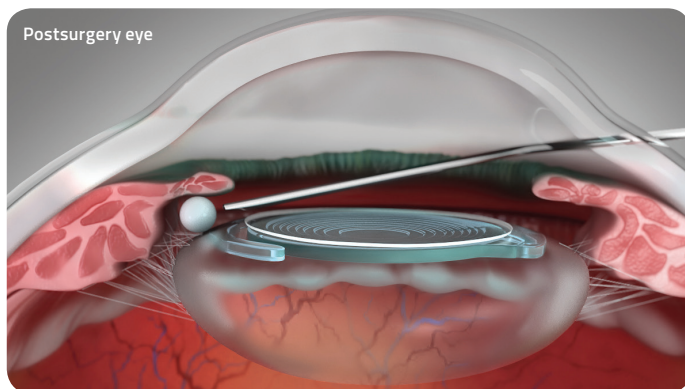
Preparation & Administration



When is DEXYCU administered?

DEXYCU helps put control in place with a single dose administered at the end of surgery¹

- In a single slow motion, inject 0.005 mL of the drug material behind the iris in the inferior portion of the posterior chamber¹
- If the sphere of administered drug after intraocular injection appears to be larger than 2 mm in diameter, excess drug material may be removed by irrigation and aspiration in the sterile surgical setting¹
- **PLEASE NOTE:** Some drug material will remain in the syringe after the injection—this is necessary for accurate dosing. Discard unused portion remaining in the syringe after administration¹



Where does DEXYCU fit into your existing surgical routine?

The scrub and circulating nurses can prepare the dose for administration toward the end of the procedure^{1,3}

- **DEXYCU** is a single-dose treatment administered at the end of surgery¹
- Each **DEXYCU** kit contains a single dose for a single patient¹

Each DEXYCU kit contains all components needed for preparation and injection¹



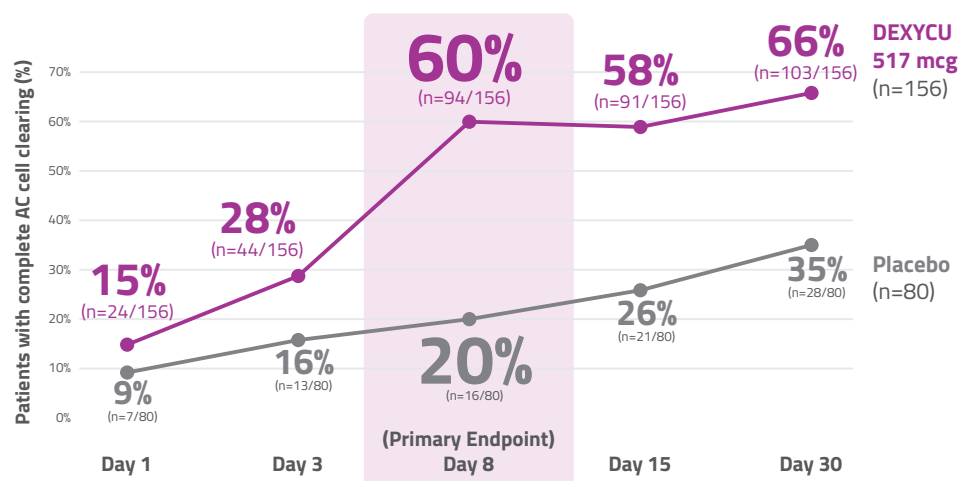
- 1 One glass vial of 0.5 mL of **DEXYCU**
- 2 One sterile 1-mL syringe
- 3 One sterile syringe guide
- 4 One sterile syringe ring
- 5 One sterile 18-gauge needle (1½ inches long), plastic cap attached
- 6 One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

Prepare the syringe for injection according to the steps described in the full Prescribing Information to ensure delivery of the 0.005 mL dose.¹

Clinical Efficacy Summary

With DEXYCU, complete anterior chamber (AC) cell clearing started as early as day 1 and continued through day 30¹

Percentage of patients with complete AC cell clearing¹



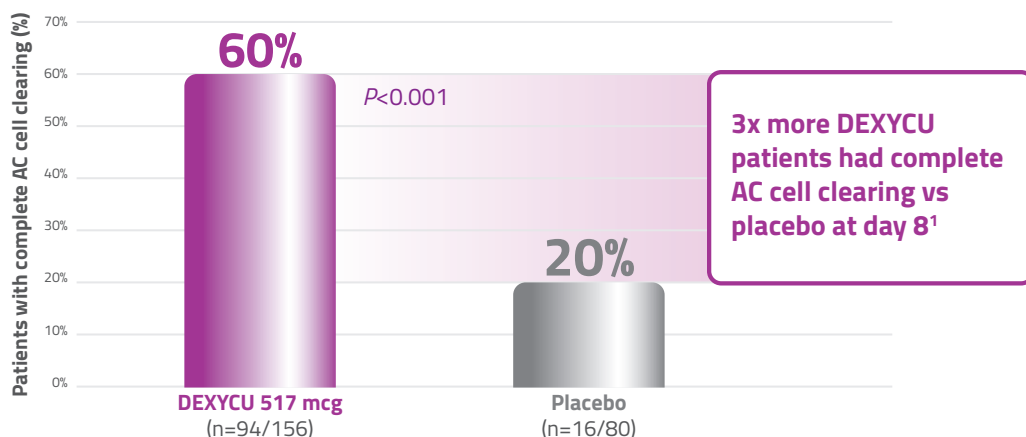
Significantly fewer DEXYCU subjects vs placebo received ocular steroids or nonsteroidal anti-inflammatory drugs (NSAIDs) (rescue medication) on days 3, 8, 15, and 30, including 10% (n=16/156) vs 50% (n=40/80) at day 8; rescue medication use=failure. Study protocol allowed for use of rescue medication only when the prespecified rescue criteria were met for AC cell grade ≥ 3 and/or AC flare grade ≥ 3 at a follow-up visit after surgery.³

Study design^{1,3}

Clinical efficacy was evaluated in a randomized, double-masked, placebo-controlled trial in patients who received either DEXYCU (342 mcg n=158; 517 mcg n=156) or a vehicle administered by a physician at the end of the surgical procedure (placebo n=80) (N=394). Use of ocular, periocular, or systemic corticosteroids, immunomodulators, alkylating agents, or ocular topical NSAIDs was not allowed through day 30 unless necessary; glaucoma and other ocular medications (including topical cyclosporine but excluding ocular topical NSAIDs) could be administered peri- and postoperatively as indicated. Patients who received corticosteroids or immunosuppressants for any condition (ocular or systemic) were followed through 90 days. The primary endpoint was the proportion of patients with complete AC cell clearing (cell score=0) on postoperative day 8.

In a phase 3, randomized, double-masked, placebo-controlled trial (n=236) **DEXYCU** significantly improved the rate of complete AC cell clearing at day 8 (primary endpoint).^{1,3}

Complete AC cell clearing rates at day 8^{1,3}



Rescue medication usage

- The cumulative percentage of subjects receiving rescue medication of ocular steroid or NSAID at day 30 was significantly lower in the **DEXYCU** 517 mcg treatment group (20%; n=31/156) compared to placebo (54%; n=43/80)¹
- More than half of all **DEXYCU** patients did not require additional anti-inflammatory medication during the study (n=156)¹
 - Subjects who received rescue medication in the study eye were treated as failures¹
 - 10% (n=16/156) of **DEXYCU** patients vs 50% (n=40/80) of placebo patients required ocular corticosteroids or NSAIDs at day 8¹

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Exacerbation of Infection

- The use of **DEXYCU**, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures

Most Common Adverse Reactions

The most common adverse reactions (ARs) in $\geq 5\%$ of subjects³

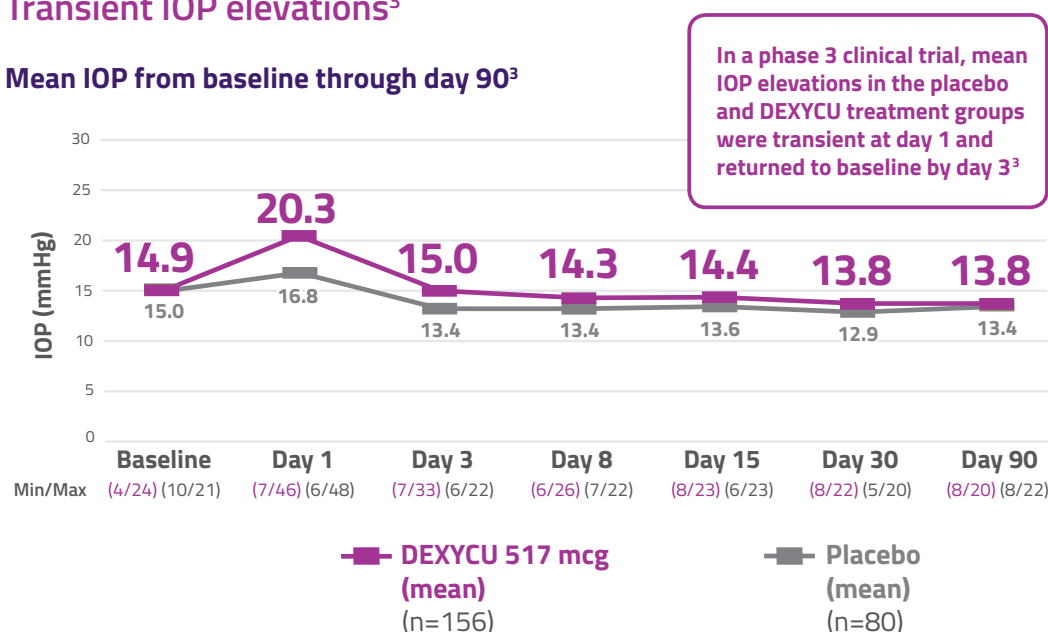
	Placebo (n=80)	DEXYCU 517 mcg (n=339)
IOP increased	7 (8.8%)	39 (11.5%)
Corneal edema	8 (10.0%)	24 (7.1%)
Iritis	11 (13.8%)	17 (5.0%)
Anterior chamber inflammation	10 (12.5%)	9 (2.7%)
Eye pain	7 (8.8%)	7 (2.1%)

IOP=intraocular pressure.

- Derived from 3 clinical trials in which 339 patients received the DEXYCU 517-mcg dose¹
- The most commonly reported ARs in 5%-15% of subjects included increases in IOP, corneal edema, and iritis¹
- Other ocular ARs occurring in 1%-5% of subjects included corneal endothelial cell loss, blepharitis, eye pain, cystoid macular edema, dry eye, ocular inflammation, posterior capsule opacification, blurred vision, reduced visual acuity, vitreous floaters, foreign body sensation, photophobia, and vitreous detachment¹

Transient IOP elevations³

Mean IOP from baseline through day 90³





Indication/Usage and Important Safety Information

INDICATION AND USAGE

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WARNINGS AND PRECAUTIONS

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- Steroids should be used with caution in the presence of glaucoma

Delayed Healing

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

Exacerbation of Infection

- The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures
- Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections
- Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection

Cataract Progression

- The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts

ADVERSE REACTIONS

- The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis

More Information

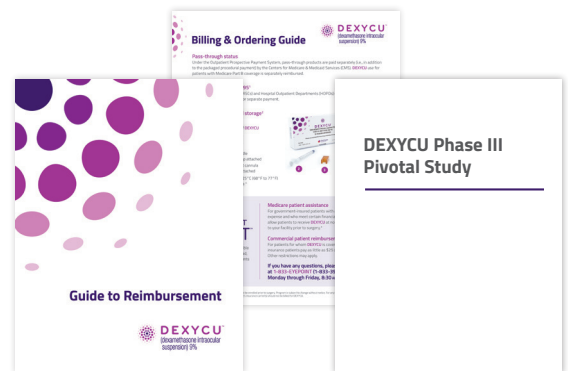
The DEXYCU Formulary Kit has helpful resources, including:

- DEXYCU Guide to Reimbursement
- DEXYCU Billing & Ordering Guide
- *Ophthalmology*, Volume 125, Number 6, June 2018 Reprint

Additional available resources include:

- DEXYCU Patient Brochure
- DEXYCU Preparation & Administration Video
- DEXYCU Preparation & Administration Guide

Learn more at **DEXYCU.com**.



References: **1.** DEXYCU™ (dexamethasone intraocular suspension) 9% full U.S. Prescribing Information. EyePoint Pharmaceuticals, Inc. December 2018. **2.** Donnenfeld E, Holland E. Dexamethasone intracameral drug-delivery suspension for inflammation associated with cataract surgery: a randomized, placebo-controlled, phase III trial. *Ophthalmology*. 2018;125(6):799-806. **3.** Data on file. EyePoint Pharmaceuticals, Inc. **4.** Durezol® (difluprednate ophthalmic emulsion) 0.05% full U.S. Prescribing Information. Alcon Laboratories, Inc. April 2017. **5.** Besivance® (besifloxacin ophthalmic suspension) 0.6% full U.S. Prescribing Information. Bausch & Lomb Incorporated. June 2016. **6.** Prolensa® (bromfenac ophthalmic solution) 0.07% full U.S. Prescribing Information. Bausch & Lomb Incorporated. June 2016. **7.** Dua HS, Attre R. Treatment of post-operative inflammation following cataract surgery – a review. *Eur Ophthalmic Rev*. 2012;6(2):98-103. **8.** U.S. Centers for Medicare & Medicaid Services. *HCPCS Quarterly Update: New Coding Action Published November 8, 2018 Effective 1-1-19*. Available at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html>. Accessed March 6, 2019. **9.** Haghjou N, Soheilian M, Abdekhodaie MJ. Sustained release intraocular drug delivery devices for treatment of uveitis. *J Ophthalmic Vis Res*. 2011;6(4):317-329.



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