Guide to Reimbursement

DEXYCU™
(dexamethasone intraocular suspension) 9%

Table of Contents

The first and only FDA-approved, single-dose, sustained-release, intracameral steroid for the treatment of postoperative inflammation[1-3]

DEXYCU™
(dexamethasone intraocular suspension) 9%

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

About DEXYCU™

DEXYCU™ (dexamethasone intraocular suspension) 9%

PRODUCT INFORMATION[1]

Product Name: DEXYCU

Delivery: intraocular suspension

Active Ingredient: dexamethasone 9%

Inactive Ingredient: acetyl triethyl citrate (no antimicrobial preservative)

Description: DEXYCU (dexamethasone intraocular suspension) 9% is a corticosteroid, sterile, white to off-white opaque suspension for intraocular administration. Each vial of DEXYCU contains 0.5 mL of 9% w/w dexamethasone suspension equivalent to 51.7 mg of dexamethasone.

How Supplied: Each kit of DEXYCU contains a single dose for a single patient. The 2-mL glass vial is filled with 0.5 mL of 9% dexamethasone intraocular suspension and has a blue cap.

INDICATION AND USAGE

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

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

PACKAGING SPECIFICATIONS

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

NDC Number: 71879-0001-01

Storage Conditions: 20°C to 25°C (68°F to 77°F)

INDICATION AND USAGE

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

Reimbursement

PASS-THROUGH STATUS

Allows ASCs and HOPDs to bill Medicare and other payers for **DEXYCU** using a unique J-code—J1095. The payment is over and above the facility fees paid to ASCs or to HOPDs for cataract surgery.

HCPCS Code[4]	Short Description	Long Description
J1095	Injection, dexamethasone 9%	Injection, dexamethasone 9 percent, intraocular, 1 microgram

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.

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.

MEDICARE PART B

- Pass-through products are paid separately (ie, in addition to the packaged procedural payment) by CMS
- **DEXYCU** use in ocular surgeries (ie, cataract or lens replacement surgery) for patients with Medicare Part B coverage is separately reimbursed
- Pass-through status allows reimbursement for **DEXYCU** separate from the packaged APC reimbursement for the surgical procedure
- For pass-through drugs, CMS sets the payment rate at the WAC + 3%
  - Check the CMS website for current quarterly reimbursement rates in the Hospital OPPS or ASC Payments sections
- Payment rates are updated quarterly by CMS and will be reduced during a government sequester to 4.3%
- No copay in hospital outpatient departments (HOPDs)[5]
- 20% copay in ambulatory surgery centers (ASCs)[5]
  - Approximately 90% of Medicare Part B patients have some form of supplemental insurance, which covers copays[6]*

APC=Ambulatory Payment Classification; ASC=Ambulatory Surgery Center; ASP=Average Sales Price; CMS=Centers for Medicare & Medicaid Services; HCPCS=Healthcare Common Procedure Coding System; HOPD=Hospital Outpatient Department; OPPS=Outpatient Prospective Payment System; WAC=Wholesale Acquisition Cost.

*Based on currently available information and subject to change without notice. Individual plan coverage, policies, and procedures may vary and should be confirmed. EyePoint does not guarantee coverage or payment.

IMPORTANT SAFETY INFORMATION

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

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

MEDICARE PART C (MEDICARE ADVANTAGE)

- Medicare Advantage plans will cover **DEXYCU**, similar to traditional Medicare Part B, but the reimbursement rate may differ from traditional Part B or be subject to payer-specific facility contractual limitations. EyePoint does not guarantee payment by any payer
- The specific Medicare Advantage payer should be contacted in advance to determine the level of reimbursement

Medicare patient assistance

For government-insured patients with an uncovered out-of-pocket expense who meet certain financial criteria, EyePoint Assist℠* may enable patients to receive **DEXYCU** at no cost—a free kit will be sent to your facility prior to surgery. See page 7 for more information on EyePoint Assist.

COMMERCIAL BILLING AND REIMBURSEMENT

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.

Commercial patient reimbursement

For patients for whom **DEXYCU** is covered by commercial insurance, patients pay as little as $25 (Maximum Benefit of $100). See page 7 for more information on EyePoint Assist. Other restrictions may apply.

*To be eligible for EyePoint Assist, patients must be enrolled prior to surgery. Program is subject to change without notice. For any eligible patient, (1) the facility receives a free DEXYCU kit prior to surgery, and (2) the patient's insurance carrier(s) should not be billed for DEXYCU.

IMPORTANT SAFETY INFORMATION

Increase in Intraocular Pressure (cont'd)

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

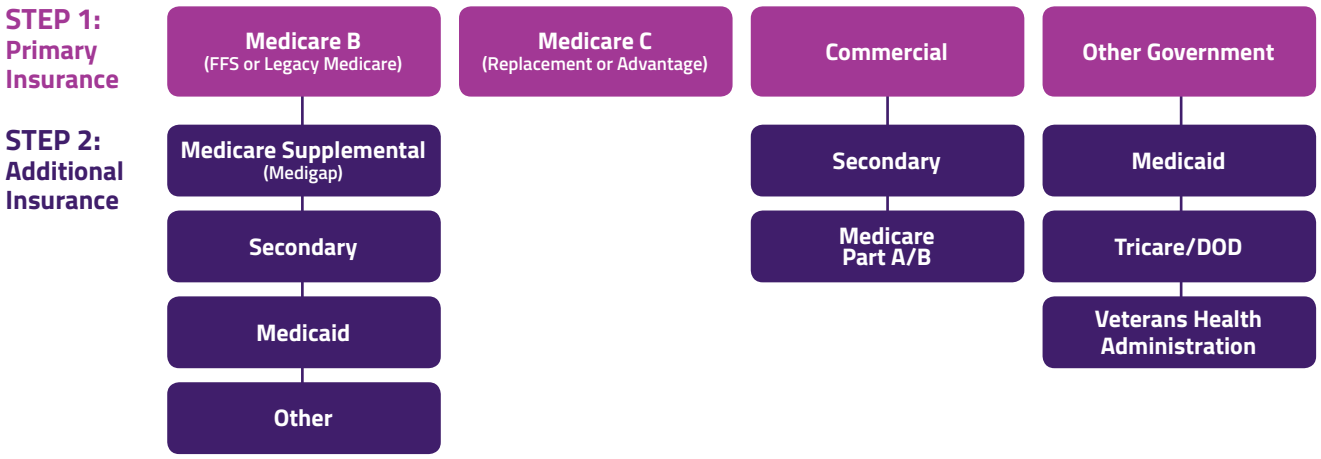
Delayed Healing

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation

Reimbursement (cont'd)

PRIMARY AND ADDITIONAL COVERAGE DETERMINES BILLABLE STATUS

Patient insurance benefits typically include primary and additional coverage that determines billable status. Work with your **DEXYCU** Reimbursement Specialist to determine billable status for your payers.



Tips for Medicare Advantage and commercial payers

- Confirm if facility-specific payer contracts allow for separate payment of drugs, new technologies, and pass-through drugs
- Double-check and verify payer payment/fee schedules for **DEXYCU**
- Confirm acceptance of J-code and payer-specific use of appropriate revenue code

DOD=Department of Defense; FFS=Fee-for-Service.

IMPORTANT SAFETY INFORMATION

Delayed Healing (cont'd)

- 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

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

EyePoint Assist℠*

Patient Assistance Program

DEXYCU™ (dexamethasone intraocular suspension) 9%

Assistance for financially eligible uninsured, government insured, and commercially insured patients

- Eligible patients may receive **DEXYCU** at no cost
- Free kit will be sent to your facility prior to surgery
- Application for free kit must be submitted at least 5 days prior to date of surgery
- Please contact your **DEXYCU** representative for more details
- If you have any questions, please call EyePoint Assist at **1-833-EYEPOINT** (1-833-393-7646), option 2. We are available Monday through Friday, 8:30 AM – 8:00 PM ET

Coverage and reimbursement vary and should be confirmed by facility. EyePoint does not guarantee reimbursement.

EyePoint ASSIST℠

Assistance for financially eligible uninsured, government insured, and commercially insured patients

Medicare patient assistance

For government-insured patients with an uncovered out-of-pocket expense who meet certain financial criteria, EyePoint Assist may enable patients to receive **DEXYCU** at no cost—a free kit will be sent to your facility prior to surgery.

Commercial patient reimbursement

For patients for whom **DEXYCU** is covered by commercial insurance patients pay as little as $25 (Maximum Benefit of $100).

If you have any questions, please call EyePoint Assist at 1-833-EYEPOINT (1-833-393-7646), option 2, Monday through Friday, 8:30 AM – 8:00 PM ET

*To be eligible for EyePoint Assist, patients must be enrolled prior to surgery. Program is subject to change without notice. For any eligible patient, (1) the facility receives a free DEXYCU kit prior to surgery, and (2) the patient's insurance carrier(s) should not be billed for DEXYCU.

IMPORTANT SAFETY INFORMATION

Exacerbation of Infection (cont'd)

- 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

Ambulatory Surgery Center
Sample CMS-1500 Paper Claim Form

Enter all applicable patient information

When using J-code for **DEXYCU** based on instruction from payer, please include NDC on line 19

Item 21: Enter "0" if using ICD-10-CM

Item 21: Enter the Diagnosis Code(s)

Item 24B: "24" indicates an ASC

Item 24D: Enter the applicable procedure code (eg, 66984 for cataract surgery)

Item 24D: Enter the unique Billing Code for **DEXYCU**

Item 24D: Enter the Modifier for left eye (LT) or right eye (RT)

Item 24F: Enter price for **DEXYCU** from price schedule, including all applicable markups

Item 24G: Enter the number of Units (kits)

Item 33a: Entry of NPI Number is required

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE [X] (Medicare#) MEDICAID [ ] (Medicaid#) TRICARE [ ] (ID#/DoD#) CHAMPVA [ ] (Member ID#) GROUP HEALTH PLAN [ ] (ID#) FECA BLK LUNG [ ] (ID#) OTHER [ ] (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 987 65 4321A

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Taylor, Scott

3. PATIENT'S BIRTH DATE MM DD YY SEX: M [X] F [ ]

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street): 100 Broad St

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street)

CITY: Anytown STATE: NJ

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code): ( )

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) [ ] YES [ ] NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX: M [ ] F [ ]

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? [ ] YES [ ] NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? [ ] YES [ ] NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC): NDC# 71879-0001-01

20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. .XX"X" B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	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	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 12 20 2018	12 20 2018	24		66984	RT	A	XXX XX	1		NPI	3333333333
2 12 20 2018	12 20 2018	24		J1095		A	XXX XX	1		NPI	3333333333
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN [X]

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) [X] YES [ ] NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # (555) 555-5555

Any ASC
123 Cherry Street
Anytown, NJ 01234

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. EyePoint does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. If you have any questions, please call EyePoint Assist at **1-833-393-7646**.

CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code; NPI=National Provider Identifier.

CPT is a registered trademark of the American Medical Association.

Sample UB-04 Paper Claim Form

DEXYCU™ (dexamethasone intraocular suspension) 9%

Form locator 4: Enter the 4-digit code that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 013. The final digit is usually a "1," meaning one claim for the event

Enter all applicable patient information

Form locator 17: Enter Patient Status

Form locator 47: Enter price for **DEXYCU** from price schedule, including all applicable markups

Form locator 42*: Enter the Revenue Code

Form locator 44: Enter the unique Billing Code for **DEXYCU**

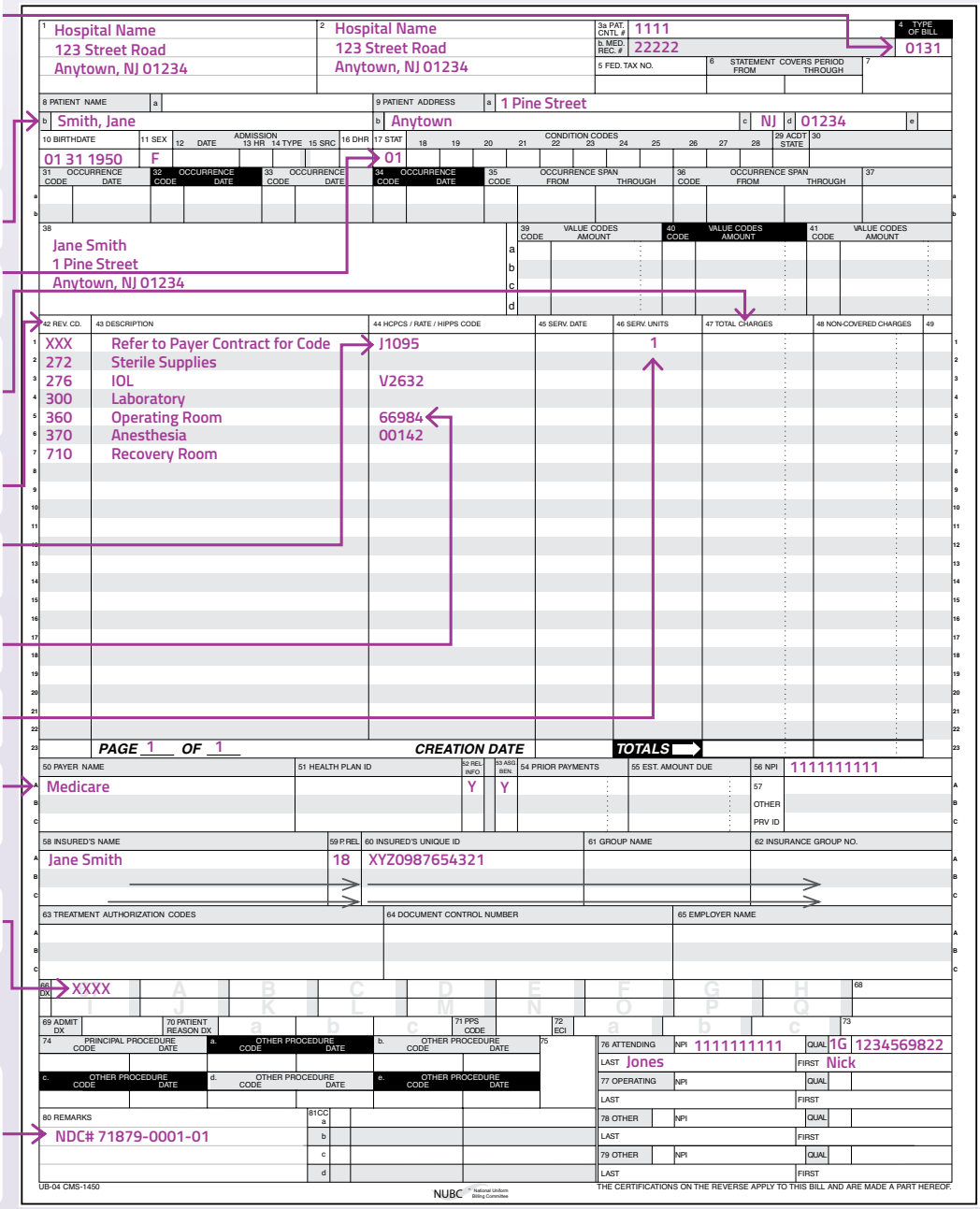
Form locator 44: Enter the Procedure Code(s)

Form locator 46: Enter the number of Units (kits)

Form locator 50A: If Medicare is the primary payer, enter "Medicare" on line A

Form locator 66: Enter the primary Diagnosis Code

Form locator 80: This is where NDC number should be placed if NOC code required or if Medicaid for 340B rebate requirement



*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.

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. EyePoint does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. If you have any questions, please call EyePoint Assist at **1-833-393-7646**.

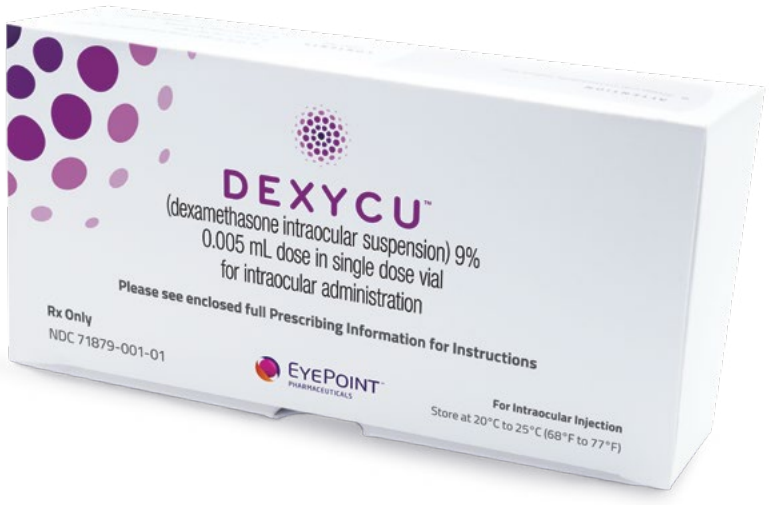
NOC=Not Otherwise Classified.

Resources

Visit www.cms.gov*

- ASC and HOPD Payment Rates and Updates
- CMS Pass-Through Information
- CMS ASP Drug Pricing Files
- MLN Matters®

*This site is not controlled or endorsed by EyePoint and EyePoint is not responsible for the content provided.



Call 1-833-EYEPOINT (1-833-393-7646), option 2 for more information about DEXYCU and EyePoint Assist℠

DEXYCU™
(dexamethasone intraocular suspension) 9%

Learn more at DEXYCU.com.

IMPORTANT SAFETY INFORMATION

Exacerbation of Infection (cont'd)

- 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

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

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.** 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 November 9, 2018. **5.** Medicare program: proposed changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; requests for information on promoting interoperability and electronic health care information, price transparency, and leveraging authority for the competitive acquisition program for part B drugs and biologicals for a potential CMS innovation center model. *Fed Regist.* 2018;37046-37240. **6.** Kaiser Family Foundation analysis of the CMS Medicare Current Beneficiary Survey Cost and Use File, 2010.

Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of DEXYCU in eligible patients. EyePoint does not guarantee reimbursement. EyePoint Assist services are subject to change without notice.

MLN Matters is a registered trademark of the U.S. Centers of Medicare & Medicaid Services.

EyePoint PHARMACEUTICALS

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02/2019
US-DEX-1900009

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DEXYCU™ safely and effectively. See full prescribing information for DEXYCU.

DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration

Initial U.S. Approval: 1958

---------- INDICATIONS AND USAGE ----------

DEXYCU is a corticosteroid indicated for the treatment of postoperative inflammation (1).

---------- DOSAGE AND ADMINISTRATION ----------

- For intraocular administration (2).
- Administer 0.005 mL of DEXYCU into the posterior chamber inferiorly behind the iris at the end of ocular surgery (2).

---------- DOSAGE FORMS AND STRENGTHS ----------

Intraocular suspension: 9% equivalent to dexamethasone 103.4 mg/mL in a single-dose vial provided in a kit (3).

---------- CONTRAINDICATIONS ----------

None (4).

---------- WARNINGS AND PRECAUTIONS ----------

- Increase in intraocular pressure (IOP): Monitor for increases in IOP (5.1).
- Delayed Healing: Monitor for delayed healing (5.2).
- Infection Exacerbation: Monitor and treat for any exacerbations of bacterial, viral or fungal infections (5.3).
- Cataract Progression: Cataracts may develop or progress in phakic patients (5.4).

---------- ADVERSE REACTIONS ----------

In controlled studies, the most common adverse reactions reported by 5-15% of patients were intraocular pressure increased, corneal edema and iritis (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact EyePoint Pharmaceuticals US at 1-833-EYEPOINT (1-833-393-7646) or FDA at 1 800-FDA-1088 or www.fda.gov/medwatch.

Revised: 12/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

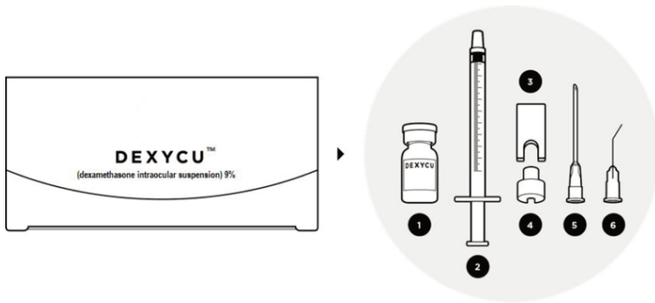
2.1 Dosing Information

DEXYCU should be administered as a single dose, intraocularly in the posterior chamber at the end of surgery. The dose is 0.005 mL of dexamethasone 9% (equivalent to 517 micrograms).

2.2 Preparation and Administration

Each kit of DEXYCU is for a single administration. After preparation, 0.005 mL will be administered.

The DEXYCU administration kit contains the following items:



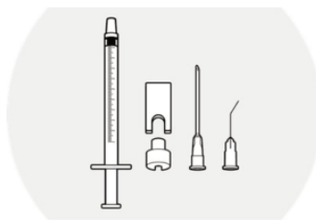
1. One glass vial: 0.5 mL of DEXYCU
2. One sterile 1-mL syringe
3. One sterile syringe guide
4. One sterile syringe ring
5. One sterile 18-gauge needle (1½ inches long), plastic cap attached
6. One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

Step 1.

Prepare a sterile field. Remove the components of the administration kit from their respective pouches:

- syringe
- syringe guide
- syringe ring
- needle
- cannula

Place onto the sterile field.

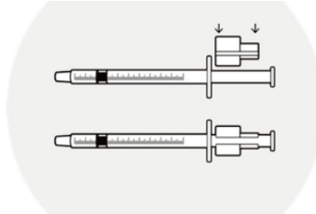


Step 2.

Withdraw the syringe plunger approximately 1 inch.

Place the syringe ring on the plunger (slit facing the plunger).

Apply slight downward pressure until the syringe ring "snaps" into place.

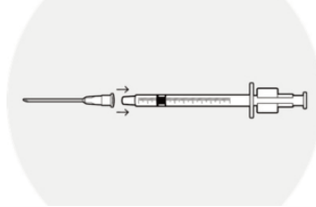


Step 3.

Place the 18-gauge needle firmly on the syringe.

Remove the cap from the needle.

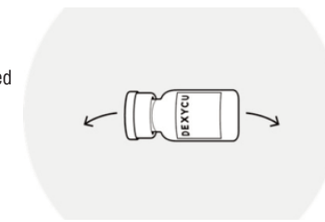
Depress the plunger completely and then withdraw the plunger to fill the syringe with air.



Step 4.

Vigorously shake the vial of DEXYCU sideways for a minimum of 30 seconds.

The suspended drug material must be used immediately after shaking.



Step 5.

Remove the blue plastic flip-cap from the vial and wipe the top of rubber stopper with an alcohol pad.

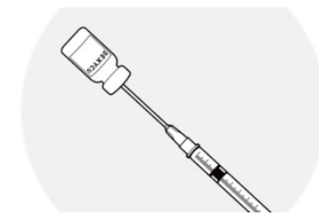
Invert the vial.

Step 6.

Insert the needle into the vial and inject the air into the vial.

Making sure the needle tip is immersed in the drug material pooled in the neck of the inverted vial, fill the syringe by slowly withdrawing the plunger approximately 0.2 mL.

Remove the needle from the vial and discard the unused portion in the vial.



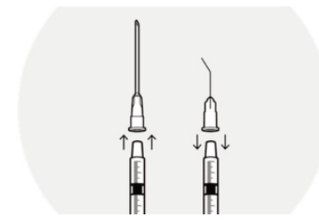
Step 7.

Remove the needle from the syringe.

Firmly place the cannula on the syringe and remove the plastic cap.

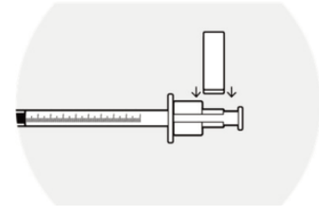
Hold the syringe vertically with the cannula pointing up.

Depress the plunger to expel air bubbles from syringe.



Step 8.

Affix the syringe guide over the syringe ring on the plunger.

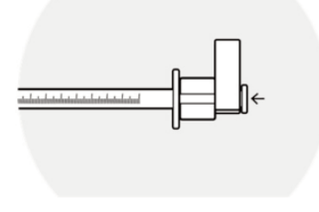


Step 9.

Depress the plunger until the syringe guide/ring mechanism comes gently into contact with the flange of the syringe.

Lightly tap/flick the barrel of the syringe to remove any excess drug from the tip of the cannula.

Do not wipe or touch the tip of the cannula to remove excess drug.

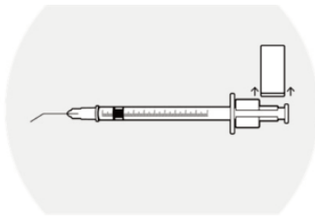


Step 10.

Remove the syringe guide, leaving the syringe ring in place.

Caution to not move the plunger. The space between the syringe ring and the top of the plunger is the medication injection volume that will be applied to the patient's eye.

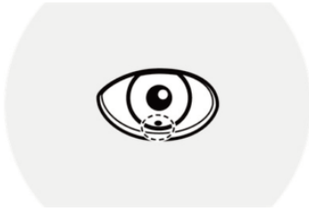
The syringe is now ready for injection.



Step 11.

In a single slow motion, inject 0.005 mL of the drug material behind the iris in the inferior portion of the posterior chamber. 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 setting.

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 administration.



3 DOSAGE FORMS AND STRENGTHS

DEXYCU contains dexamethasone 9% w/w (103.4 mg/mL) as a sterile suspension for intraocular ophthalmic administration. DEXYCU is provided as a kit for administration of a single dose of 0.005 mL of 9% dexamethasone (equivalent to 517 micrograms of dexamethasone).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 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.

5.2 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.

5.3 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.

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion 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.

5.4 Cataract Progression

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

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

- Increase in Intraocular Pressure *[see Warning and Precautions (5.1)]*
- Delayed Healing *[see Warnings and Precautions (5.2)]*
- Infection Exacerbation *[see Warnings and Precautions (5.3)]*
- Cataract Progression *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The following adverse events rates are derived from three clinical trials in which 339 patients received the 517 microgram dose of DEXYCU. The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis. Other ocular adverse reactions 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 detachment.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of DEXYCU (dexamethasone intraocular suspension) 9% in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryofetal death in mice and malformations of abdominal wall/intestines and kidneys in rabbits at doses 7 and 5 times higher than the injected recommended human ophthalmic dose (RHOD) of DEXYCU (517 micrograms dexamethasone), respectively *[see Data]*.

In the US general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in mice. A dose of 0.75 mg/kg/day in the mouse is approximately 7-times the injected RHOD of DEXYCU, on a mg/m^2 basis. In rabbits, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.20 mg/kg/day on gestational day 6, followed by 0.13 mg/kg/day on gestational days 7 – 18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A dose of 0.13 mg/kg/day in the rabbit is approximately 5-times the injected RHOD of DEXYCU, on a mg/m^2 basis. A no-observed-adverse-effect-level (NOAEL) was not identified in the mouse or rabbit studies.

8.2 Lactation

Risk Summary

Systemically administered corticosteroids are present in human milk and can suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects. There is no information regarding the presence of injected DEXYCU in human milk, the effects on breastfed infants, or the effects on milk production to inform risk of DEXYCU to an infant during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for DEXYCU and any potential adverse effects on the breastfed child from DEXYCU.

8.4 Pediatric Use

Safety and effectiveness of DEXYCU in pediatric patients have not been established.

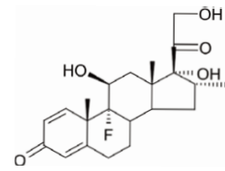
8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between older and younger patients.

11 DESCRIPTION

DEXYCU (dexamethasone intraocular suspension) 9% is a corticosteroid, sterile, white to off-white opaque suspension for intraocular administration. Each vial of DEXYCU contains 0.5 mL of 9% w/w dexamethasone suspension equivalent to 51.7 mg of dexamethasone. The inactive ingredient is acetyl triethyl citrate. DEXYCU does not contain an antimicrobial preservative.

The chemical name of dexamethasone is pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16α)-. It has a molecular formula of $C_{22}H_{29}FO_5$ and a molecular weight of 392.46 grams per mole. Its structural formula is:



12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dexamethasone is a corticosteroid. Corticosteroids have been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells.

12.3 Pharmacokinetics

Systemic exposure to dexamethasone was evaluated in a subgroup of patients enrolled in two studies (n=25 for the first study and n=13 for the second study). The patients received a single intraocular injection of DEXYCU containing 342 mcg or 517 mcg of dexamethasone at the end of cataract surgery and blood samples were collected prior to surgery and at several time points post-surgery between Day 1 and up to Day 30. In the first study, the dexamethasone plasma concentrations on post-surgery Day 1 ranged from 0.09 to 0.86 ng/mL and from 0.07 to 1.16 ng/mL following administration of DEXYCU 342 mcg and 517 mcg, respectively. In the second study, dexamethasone plasma concentrations on post-surgery Day 1 ranged from 0.349 to 2.79 ng/mL following administration of DEXYCU 517 mcg. In both the studies, dexamethasone plasma concentrations declined over time and very few patients had quantifiable dexamethasone plasma concentrations at the final time point of sampling (Day 15 or Day 30).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to determine whether DEXYCU has the potential for carcinogenesis or mutagenesis. Fertility studies have not been conducted in animals

14 CLINICAL STUDIES

Clinical efficacy was evaluated in a randomized, double-masked, placebo-controlled trial (NCT02006888) in which subjects received either DEXYCU or placebo (vehicle). A dose of 5 microliters of DEXYCU (equivalent to 517 micrograms of dexamethasone), a dose equivalent to 342 micrograms of dexamethasone or vehicle was administered by the physician at the end of the surgical procedure. The primary efficacy endpoint for the study was the proportion of patients with anterior chamber cell clearing (i.e., cell score=0) on postoperative day (POD) 8. The presence of anterior cells was assessed using a slit lamp binocular microscope up to 30 days post treatment. The percentage of patients with anterior chamber clearing at Day 8 was 20% in the placebo group, and 57%, and 60% in the 342 and 517 microgram treatment groups, respectively (Table 1). The percentage of subjects receiving rescue medication of ocular steroid or NSAID was significantly lower at Day 3, 8, 15 and 30 in the 342 and 517 microgram treatment groups compared to placebo (Table 2).

Table 1: Proportion of subjects with clearing of the anterior chamber cells by visit

Visits	Treatments			Difference and 97.5% CI	
	Placebo N=80	DEX342 N=158	DEX517 N=156	DEX342 vs Placebo	DEX517 vs Placebo
Day 1	7 (9%)	17 (11%)	24 (15%)	2% (-7%, 11%)	7% (-3%, 16%)
Day 3	13 (16%)	60 (38%)	44 (28%)	22% (9%, 34%)	12% (0%, 24%)
Day 8	16 (20%)	90 (57%)	94 (60%)	37% (24%, 50%)	40% (27%, 54%)
Day 15	21 (26%)	83 (52%)	91 (58%)	26% (12%, 40%)	32% (18%, 46%)
Day 30	28 (35%)	113 (72%)	103 (66%)	36% (22%, 51%)	31% (16%, 46%)

Subjects who received rescue medication were treated as failure.

Table 2: Proportion of subjects receiving rescue medications

Visits	Number (Percent) of Patients Receiving Rescue Medication, and 95% CI		
	Placebo N=80	DEX342 N=158	DEX517 N=156
Day 1	10 (13%); 6%, 22%	9 (6%); 3%, 10%	10 (6%); 3%, 12%
Day 3	30 (38%); 27%, 49%	9 (6%); 3%, 10%	16 (10%); 6%,16%
Day 8	40 (50%); 39%, 61%	12 (8%); 4%, 13%	16 (10%); 6%,16%
Day 15	43 (54%); 42%, 65%	22 (14%); 9%, 20%	26 (17%); 11%, 24%
Day 30	43 (54%); 42%, 65%	25 (16%); 10%, 22%	31 (20%); 14%, 27%

Subjects who received an ocular corticosteroid or NSAID in study eye.

16 HOW SUPPLIED/STORAGE AND HANDLING

Each kit of DEXYCU contains a single dose for a single patient. The 2-mL glass vial is filled with 0.5 mL of 9% dexamethasone intraocular suspension and has a blue cap (NDC # 71879-001-01).

Each kit also contains one sterile 18-gauge, 1.5-inch needle with a plastic cap attached, one sterile plastic 1-mL syringe for withdrawal of the vial contents, one sterile 25-gauge 8-mm cannula with a plastic cap attached for the intraocular administration, and one syringe assembly pouch containing a sterile ring and a sterile syringe guide used for measuring and injection of the 0.005 mL dose.

Store at 20°C to 25°C (68°F to 77°F).

Manufactured for: EyePoint Pharmaceuticals US, Inc. Watertown, MA 02472