Guide to Reimbursement
About DEXYCU®

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

PRODUCT INFORMATION

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)
DEXYCU has a 2-year shelf life.
How does DEXYCU work?

Delivers sustained release of dexamethasone at the site using patented Verisome® Technology

DEXYCU utilizes a novel, biodegradable, sustained-release platform, Verisome Technology, to deliver the active ingredient, dexamethasone.

- The sphere formation is in aqueous media, which keeps the delivery system intact.
- Provides a controlled release of dexamethasone across the target area.
- Allows for direct and immediate treatment that will self-taper over time until the sphere is no longer visible.

When is DEXYCU administered?

DEXYCU helps put control in place with a single self-tapering dose.

- 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.
- DEXYCU may be visible in the eye during a follow-up visit until its complete dissolution.

While DEXYCU does not replace all drops, this one-time treatment may replace over 70 steroid drops.

The cumulative percentage of subjects receiving rescue medication of ocular steroid or nonsteroidal anti-inflammatory drug (NSAID) by day 30 was significantly lower in the DEXYCU (517 mcg) treatment group (20%; n=31/156) compared to placebo (54%; n=43/80).

**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.
Reimbursement

PASS-THROUGH STATUS

Allows ASCs and HOPDs to bill Medicare and other payers for DEXYCU® (dexamethasone intraocular suspension) 9% using a unique J-code—J1095. The payment is over and above the facility fees paid to ASCs or to HOPDs for cataract surgery.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Description</th>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1095</td>
<td>Injection, dexamethasone 9%</td>
<td>Injection, dexamethasone 9 percent, intraocular, 1 microgram</td>
</tr>
</tbody>
</table>

CMS (Medicare) billing methodology for many specialty products is to the single unit of measure. For DEXYCU, 1 unit=1 microgram. Allowable billing for DEXYCU is 517 units.

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 ASP + 6%
  - 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 HOPDs6
- 20% copay in ASCs6
  - Approximately 90% of Medicare Part B patients have some form of supplemental insurance, which covers copays7*

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

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.

**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 the Assistance Programs tab for more information on EyePoint Assist™. Other restrictions may apply.

### 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.

*For more information about reimbursement visit DEXYCU.com*

### Merit-based Incentive Payment System (MIPS)

DEXYCU will not be included in MIPS for 2020. Contact your DEXYCU representative for more information.

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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.

†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.
Assistance programs are available through EyePoint Assist* as resources to patients. A representative can provide more background on how EyePoint Assist can help, and additional information can be found online at DEXYCU.com.†

Patient Assistance Program

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

- Eligible patients may receive DEXYCU® (dexamethasone intraocular suspension) 9% 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

Copay Assistance Program

Patients may pay as little as $25

EyePoint Assist provides commercial patient reimbursement. For patients for whom DEXYCU is covered by commercial insurance, patients may pay as little as $25 (Maximum Benefit of $100). Other restrictions may apply.

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

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

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

Please see Important Safety Information throughout and accompanying full Prescribing Information.
The DEXYCU Assurance Program process

EyePoint Pharmaceuticals will provide a discount on future orders for any unit of DEXYCU that is denied reimbursement through commercial or Medicare Advantage coverage when all program requirements are met.

- When provider follows all required steps for qualifying patients, provider is eligible to receive a discount

**STEP 1**

**Verify coverage with the payer**

To be eligible for a discount on future orders, provider must follow all requirements identified by the benefits investigation. Only patients covered under commercial or Medicare Advantage are eligible. The program is not valid for patients who are covered under Medicaid or Medicare.

- Conduct benefits investigation
- Results of benefits investigation indicate patient has coverage for DEXYCU
- If required by the payer, provider must obtain Prior Authorization, Pre-Certification, or Pre-Determination
- Administer purchased unit of DEXYCU to patient
- Provider must submit claim per payer billing and coding requirements

**STEP 2**

**Request discount**

- If the provider denies initial claim, complete the DEXYCU Assurance Program Request Form and fax it with the required documentation to the number on the form
- Receive a 16.6% discount off the next 6 orders of DEXYCU

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*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.*

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

*Discount of 16.6% off next 6 orders cannot be combined with additional rebate programs.*

*Eligibility for the 6-unit discount described herein is limited to 120 days from date of service (i.e., administration date). Claims must be received by June 30, 2020.*

*An authorization number will be issued upon approval; no paperwork will be provided during this step.*
Sample CMS-1500 Paper Claim Form

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 is a registered trademark of the American Medical Association.
**Sample UB-04 Paper Claim Form**

<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter all applicable patient information</td>
</tr>
<tr>
<td>Form locator 17: Enter Patient Status</td>
</tr>
<tr>
<td>Form locator 47: Enter price for DEXYCUC from price schedule, including all applicable markups</td>
</tr>
<tr>
<td>Form locator 42*: Enter the Revenue Code</td>
</tr>
<tr>
<td>Form locator 44: Enter the unique Billing Code for DEXYCUC</td>
</tr>
<tr>
<td>Form locator 44: Enter the Procedure Code(s)</td>
</tr>
<tr>
<td>Form locator 46: Enter the number of Units. For DEXYCUC, 1 unit=1 microgram. Allowable billing for DEXYCUC is 517 units</td>
</tr>
<tr>
<td>Form locator 50A: If Medicare is the primary payer, enter “Medicare” on line A</td>
</tr>
<tr>
<td>Form locator 66: Enter the primary Diagnosis Code</td>
</tr>
<tr>
<td>Form locator 80: This is where NDC number should be placed if NOC code required or if Medicaid for 340B rebate requirement</td>
</tr>
</tbody>
</table>

*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.*

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NOC=Not Otherwise Classified.
IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Exacerbation of Infection

- 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.


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.

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