Subject: Dexamethasone intraocular suspension (Dexycu)	Original Effective Date: 05/29/2019
Policy Number: MCP-342	Revision Date(s):
Review Date:	
P&T Approval Date:	

DISCLAIMER

This Medical Policy is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage policy (MCP) document and provide the directive for all Medicare members.

BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Provider-administered setting, Outpatient surgical settings
	Buy/Bill
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product)
	Alternative(s) preferred: Corticosteroid ophthalmic drops
	Route of Administration: Intraocular administration
AUTHORIZATION LIMITS	Quantity Limit: One intraocular injection 0.005 mL of 9% dexamethasone (equivalent to 517 micrograms)
	Reauthorization is not allowed for this single dose, intraocular treatment. All requests must meet initial therapy criteria.
	Duration of Authorization: 1 year

This policy addresses the coverage of **dexamethasone intraocular suspension 9% (Dexycu) for intraocular administration** for the treatment of adult patients with **for the treatment of postoperative inflammation** when appropriate criteria are met.

The intent of the dexamethasone intraocular suspension 9% (Dexycu) policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. This policy is intended to address coverage criteria that are appropriate for the majority of individuals/members with a particular disease, illness, or condition. Each member's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

BACKGROUND/SUMMARY

- The consequences of postoperative inflammation are cystoid macular edema, increased intraocular pressure, posterior capsular opacification, and protein leakage from the breakdown of the blood–aqueous barrier. Postoperative visual symptoms attributed to inflammation include dryness, irritation, and pain, which may delay the postoperative recovery and affect patient satisfaction. Uncomplicated cataract surgeries may also have the inflammatory sequelae which occasionally leads to chronic uveitis and fibrin formation contributing to an undesirable surgical outcome.

  The use of multiple postoperative eye drops, despite being the current standard of care, can create a significant burden on these patients, contributing to documented and significant non-adherence to the postoperative regimen. Intracameral dexamethasone has a particular advantage over topical steroids in possibly decreasing postoperative inflammatory symptoms and objective anterior cell and flare scores. Compared to topical steroids, there may be a slightly less theoretical risk of significant intraocular pressure spikes and systemic absorption. In addition, surveys indicate patients prefer an intraoperative intracameral injection over a self-administered postoperative eye drop regimen. However, there are several adverse effects associated with intracameral dexamethasone delivery that are not seen with the noninvasive topical approach. Although it is unlikely that intracameral dexamethasone will replace topical medications as the standard management for postoperative inflammation, it is seemingly another safe and effective strategy for controlling postoperative inflammation after routine cataract surgery.

- **Dexycu (dexamethasone intraocular suspension) 9% for intraocular administration**
  Dexycu is the first long-acting intraocular product approved by the FDA for the treatment of post-operative ocular inflammation. It is an extended-release dexamethasone suspension intended for injection behind the iris and in front of the IOL at close of surgery. Dexycu treatment is applied as a single intracameral injection at the end of cataract surgery using Icon's Verisome™ (Icon Bioscience, Inc.) drug delivery technology to dispense a biodegradable extended-release formulation of dexamethasone into the posterior chamber of the eye via a single injection at the end of surgery, eliminating the burden of self-administering medicated eye drops several times a day in a primarily elderly patient population.

  Clinical efficacy was evaluated in a randomized, double-masked, placebo-controlled trial in which patients received Dexycu or placebo. The efficacy of Dexycu was demonstrated in a placebo-controlled study enrolling 394 patients. Patients received an intraocular dose of 517 mcg, 342 mcg, or placebo administered by a physician at the end of surgery. The primary endpoint was the proportion of patients with anterior chamber cell clearing on postoperative day 8.
  - The percentage of patients meeting the primary endpoint was 20% in the placebo group, and 57% (difference: 37% [97.5% CI: 24%, 50%]) and 60% (difference: 40% [97.5% CI: 27%, 54%]) in the 342 and 517 mcg treatment groups, respectively.
  - In addition, the percentage of patients receiving rescue medication of ocular steroid or a nonsteroidal anti-inflammatory drug was significantly lower at day 3, 8, 15 and 30 in the 342 and 517 mcg treatment groups vs. placebo

  Adverse events were similar between treatment groups overall; no serious adverse events were reported through post-operative day 90. Intraocular pressure (IOP) increase of at least 10mmHg from baseline was observed among 29% of Dexycu-treated eyes vs. 13% in placebo-treated eyes. IOP did not exceed 21mmHg at any measurement in any group. Other treatment-emergent adverse events, including corneal edema, pain, inflammation in the anterior chamber, and dry eye, occurred in < 15% of eyes. Inflammatory adverse events including macular edema, eye inflammation, and iritis were more common in placebo-treated eyes. CME as diagnosed by OCT was seen in 3.8% of placebo-treated and 3.2% of Dexycu-treated eyes.

  Summary: There are approximately four million cataract surgeries performed annually in the U.S. and the current standard of care in the U.S. for treating post-operative inflammation is primarily a combination of steroid, antibiotic and non-steroidal eye drops on a tapered treatment regimen that may last up to four weeks. This eye drop treatment regimen is complicated and is estimated to result up to 100 eye drops being administered over time with up to 70 eye drops over 3-4 weeks on a tapered dosing schedule. Further, cataract surgery patients are predominantly elderly and the

high dosing burden, complex regimens, difficulty instilling drops due to osteoarthritis in their hands and poor eyesight due to the cataract surgery, compromised cognitive function and medication costs all may contribute to reduced compliance with drops.

This novel long-acting intracameral product provides the cataract surgeon the option of a single administration of a corticosteroid at the site of action which may benefit patients with dexterity issues who are prohibited from using corticosteroid eye drops and individuals who have previously failed, or has a contraindication to post-operative treatment with corticosteroid ophthalmic drops. It also eliminates any non-compliance and dosing errors associated with the current practice of relying on the patient to self-administer medicated eye drops multiple times a day.

FDA Indications

- Dexamethasone intraocular suspension 9% (Dexycu): For the treatment of inflammation associated with cataract surgery

Available As: 9% intraocular suspension equivalent to dexamethasone 103.4 mg/mL in a single-dose vial provided in a kit

FDA Approved: February 9, 2018

Black Box Warnings: None at the time of this writing

REMS: No REMS at the time of this writing

Warnings/Precautions: Increase in intraocular pressure; Delayed healing; Exacerbation of infection; Cataract progression

CLASSIFICATION: Ophthalmic-- Anti-inflammatory; Corticosteroid

Coverage Criteria for Initial Authorization

Dexamethasone intraocular suspension 9% (Dexycu) may be authorized for members who meet **ALL** of the following criteria **[ALL]**

1. - Prescriber specialty [ONE]

- ❒ Prescribed by board-certified ophthalmologists or retinal specialist, retinal surgeon experienced in the administration of intravitreal injections

2. - Diagnosis/Indication [ALL]
Prescriber submit ALL supporting documentation and clinical rationale (*includes clinical notes from the member's medical records including any applicable labs and/or tests, supporting the diagnosis*):

- ❒ Member has undergone ocular surgery and requires treatment for postoperative inflammation

3. Age/Gender/Restrictions [ALL] -

- ❒ 18 years of age or older

4. - Conventional Therapy/Concurrent Therapy/Other Requirements [ALL]
Documentation for ALL of the following must be submitted for review.

- ❒ Member is unable to use corticosteroid eye drops due to ONE (1) of the following: [ONE]
  - ❍ Post-operative treatment with corticosteroid ophthalmic drops has previously failed or is contraindicated
  - ❍ Dexterity issues prohibiting member from using corticosteroid eye drops
  - ❍ Other medical/clinical rationale supported by documentation

5. - Contraindications/Exclusions/Discontinuations
**There are no contraindications listed in the manufacturer's labeling*
Authorization for dexamethasone intraocular suspension 9% (Dexycu) will not be authorized if ANY of the following conditions apply [ANY]

- ❒ Hypersensitivity to dexamethasone, other corticosteroids, or any component of the formulation

6. - Labs/Reports/Documentation required [ALL]
All documentation for determination of medical necessity must be submitted for review. Prescriber to submit documentation as indicated in the criteria above, including but not limited to chart notes, applicable lab values and/or tests, adverse outcomes, treatment failures, or any other additional clinical information or clinical notes from the member's medical records supporting the diagnosis. Letters of support and/or explanation are often useful, but are not sufficient documentation unless ALL specific information required by this MCP is included.

NOTE: Additional documentation, rationale, and/or supporting evidence may be requested for review as deemed necessary or appropriate by Molina Medical/Pharmacy staff.

- ❒ Member has been informed about the potential adverse effects of a corticosteroid intravitreal implant, including cataracts, increased intraocular pressure, or hypotony, endophthalmitis, and risk of need for additional surgical procedures.

- ❒ Requested intravitreal implant for use in affected eye: [APPLICABLE]
  - ❍ Right eye
  - ❍ Left eye

REAUTHORIZATION/CONTINUATION OF THERAPY

Reauthorization is not allowed for this single dose, dexamethasone intraocular suspension 9% (Dexycu) treatment. All requests must meet initial therapy criteria.

ADMINISTRATION, QUANTITY LIMITATIONS, AND AUTHORIZATION PERIOD

Consult the manufacturer's labeling for more detailed information on dosage and administration of this drug, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and monitoring.

1. - Recommended Dosage [ONE]

- ❒ Ocular postoperative inflammation (9% suspension), intraocular: One intraocular injection of 0.005 mL (517 mcg) of 9% dexamethasone (equivalent to 517 micrograms) administered into the posterior chamber inferiorly behind the iris at the end of ocular surgery.

  NOTE: Dexycu not a part of the actual ocular surgical procedure, which is complete cataract removal and placement of an intraocular lens in the capsular bag.

2. - Authorization Limit [ALL]

- ❒ Quantity limit: Treatment consists of one intraocular injection 0.005 mL of 9% dexamethasone (equivalent to 517 micrograms) as a single dose per eye per surgery

- ❒ Reauthorization is not allowed for this single dose, intraocular treatment. All requests must meet initial therapy criteria.

3. - Route of Administration [ALL]

- ❒ Dexycu should be administered by cataract surgeons and ophthalmologists in ambulatory surgery centers and other outpatient surgical settings.
  - ◆ *Refer to manufacturer's prescribing information for preparation and administration technique.*

- ❒ Intraocular administration (*record post-procedure note following the completion of treatments*). Documentation of the following information required for review and submission of requests for subsequent treatment(s):
  - ❍ Name of the intravitreal therapy
  - ❍ Dose
  - ❍ Treated eye: right eye, left eye, or both eyes

COVERAGE EXCLUSIONS

All other uses of **dexamethasone intraocular suspension 9% (Dexycu)** that are not an FDA-approved indication or not included in the 'Coverage Criteria' section of this policy are considered not medically necessary. This is subject to change based on research and medical literature, or at the discretion of Molina Healthcare. *FDA-approved indication does not, in itself, dictate coverage. Molina Clinical Policy may not recommend coverage for all FDA-approved indications. Please review this Policy in its entirety for indications covered by Molina Healthcare.*

The following are not FDA indications of dexamethasone intraocular suspension 9% (Dexycu). While it is noted that there are case series and case reports concerning the use of intravitreal dexamethasone for several disease processes, there are no long-term well conducted studies to demonstrate safety and efficacy of Dexycu for these indications at this time; therefore, this Clinical Policy recommends coverage exclusions of the following conditions:

- Non-infectious iritis/Uveitis or Panuveitis
- Cystoid macular edema not related to post-cataract surgery
- Diabetic macular edema

- Macular edema associated with retinal vein occlusion or radiation related retinopathy
- Toxoplasmic retinochoroiditis

DEFINITIONS

N/A -

APPENDIX

N/A -

CODING INFORMATION: THE CODES LISTED IN THIS CLINICAL POLICY ARE FOR INFORMATIONAL PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE AND INCLUSION OR EXCLUSION OF ANY CODES DOES NOT GUARANTEE COVERAGE. PROVIDERS SHOULD REFERENCE THE MOST UP TO DATE SOURCES OF PROFESSIONAL CODING GUIDANCE PRIOR TO THE SUBMISSION OF CLAIMS FOR REIMBURSEMENT OF COVERED SERVICES.

CPT	Description
NA	

HCPCS	Description
J1095	Injection, dexamethasone 9%, intraocular

REFERENCES

PACKAGE INSERT, FDA, DRUG COMPENDIA

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Fluocinolone Acetonide Monograph. **American Hospital Formulary Service (AHFS)** Online, Hudson, Ohio. Lexi-Comp., Inc. 2019. Accessed February 2019.

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CLINICAL TRIALS, DEFINITIONS, PEER-REVIEWED PUBLICATIONS

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Donnenfeld ED, Solomon KD, Matossian C. Safety of IBI-10090 for inflammation associated with cataract surgery: Phase 3 multicenter study. J Cataract Refract Surg. 2018;44:1236-46.

Duan P, Liu Y, Li J. The comparative efficacy and safety of topical non-steroidal anti-inflammatory drugs for the treatment of anterior chamber inflammation after cataract surgery: a systematic review and network meta-analysis. *Graefes Arch Clin Exp Ophthalmol*. 2017;255(4):639–649.

Policy History	MCPC
Policy Developed *Peer Review: AMR Peer Review Network. 5/6/2019. Practicing Physician. Board certified ophthalmologist*	5/6/2019

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