Original Effective Date: 05/29/2019
Current Effective Date: 11/29/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
Policy Number: C16320-A

Dexycu (dexamethasone intraocular suspension)

PRODUCTS AFFECTED

Dexycu (dexamethasone intraocular suspension)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Postoperative ocular inflammation

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. OCULAR POSTOPERATIVE INFLAMMATION:
   1. Prescribed for the treatment of postoperative inflammation following ocular surgery
      AND
   2. Documentation of date of ocular surgery with notation of eye(s) being treated

AND

3. Documentation member is unable to use corticosteroid eye drops due to ONE of the following conditions [DOCUMENTATION REQUIRED]:
   a. Post-operative treatment with corticosteroid ophthalmic drops has previously failed or is contraindicated
      OR
   b. Member has cognitive issues (such as dementia or Alzheimer's disease) or dexterity issues prohibiting the member from using corticosteroid eye drops
      OR
   c. Other medical/clinical rationale supported by documentation

   AND
4. Prescriber attests the member has been informed about the potential adverse effects of Dexycu, including cataracts, increase in intraocular pressure (IOP), hypotony, endophthalmitis, and risk of need for additional surgical procedures

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: ONE time authorization, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified ophthalmologist, retinal specialist, or retinal surgeon experienced in the administration of intraocular injections. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
ONE intraocular injection 0.005 mL of 9% dexamethasone (equivalent to 517 micrograms) as a single dose per eye per surgery.

PLACE OF ADMINISTRATION:
The recommendation is that intraocular injection medications in this policy will be for pharmacy or medical benefit coverage and the intraocular injectable products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intraocular injection (intracameral)

DRUG CLASS:
Ophthalmic Steroids

FDA-APPROVED USES:
Indicated for the treatment of postoperative inflammation

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
The safety and efficacy of dexamethasone intraocular suspension 9% (Dexycu) for intracameral administration in two dosages in patients undergoing cataract surgery were evaluated in a randomized, double-masked, placebo-controlled trial. The study included 394 patients (n = 394) who received either Dexycu 342 mcg (n=158) or 517 mcg (n = 156) or a placebo (n = 80) administered by a physician at the end of the surgical procedure (Donnenfeld et al. 2018). The use of ocular, periocular, or systemic corticosteroids, immunomodulators, alkylating agents, or ocular topical non-steroidal anti-inflammatory drugs (NSAIDs) was not permitted through day 30 unless necessary; glaucoma and other ocular medications (including topical cyclosporine but excluding ocular topical NSAIDs) could be administered peri- and post-operatively as indicated. Patients who received corticosteroids or immunosuppressants for any condition (ocular or systemic) were observed for 90 days after surgery. The primary outcome measure was the AC cell clearance on post-operative day 8. Secondary outcomes in the study eyes included AC flare and AC cell plus flare clearance. Adverse events (AEs) were also evaluated.

- On post-op day eight, 57% of patients in the 342µg and 60% of patients in the 517µg Dexycu groups (n=94/156) had cleared AC cells, compared to 20% in the placebo group (n=16/80). At days 3, 8, 15 and 30, the percentage of patients receiving ocular steroid or a NSAID rescue therapy was considerably lower in the 342 and 517 mcg treatment groups compared to placebo.
- AEs were comparable across the three groups, with no serious AEs reported up to post-operative day 90. Dexycu-treated eyes had IOP increases of at least 10mmHg compared to 13% of placebo-treated eyes. IOP did not exceed 21mmHg in any measurement across the groups. Other treatment-emergent AEs that occurred in 15% of eyes included corneal edema, pain, inflammation in the AC, and dry eye. Inflammatory AEs such as macular edema, eye inflammation, and iritis were more common in placebo-treated eyes. CME as diagnosed by OCT was reported in 3.8% of placebo-treated and 3.2% of Dexycu-treated eyes.

Donnenfeld et al. (2018) compare the safety and efficacy of IBI-10090 anterior chamber intracameral dexamethasone drug-delivery suspension (Dexycu) with those of prednisolone acetate 1.0% ophthalmic drops in treating inflammation with intracameral dexamethasone after cataract surgery. The prospective, randomized, double-masked, multicenter analysis included 126 patients on dexamethasone and 55 patients on prednisolone. At the conclusion of cataract surgery, patients were randomized to either a 5µL injection of 517µg dexamethasone in the anterior eye chamber (Dexycu) or topical prednisolone 1.0% drops (1 drop 4 times daily for 3 weeks). The postoperative follow-up was 90 days. The primary outcome was safety, evaluated by the incidence and severity of AEs. Exploratory measures were AC cell, AC flare, and AC cell–flare clearing. By day 8 post-op, 51.6% of dexamethasone intraocular suspension eyes and 50.9% of prednisolone eyes had cleared AC cells, and more than 98% of eyes had cleared by 90 days. The AC flare and AC cell-flare clearing results were comparable. Of dexamethasone patients, 68.7% strongly agreed that not having to use eyedrops was very convenient; 39.2% were using prednisolone. Two serious AEs unrelated to treatment were reported. The difference in endothelial cell density between the two groups was not significant. The most common AEs were increased IOP (11.1%), iritis (6.3%) and systemic (7.9% IBI-10090 group; 10.9% prednisolone group). The safety and efficacy of dexamethasone intraocular suspension and prednisolone 1.0% were comparable; however, patients preferred intracameral dexamethasone over topical steroid drops.

National and Specialty Organizations

Corticosteroids and NSAIDs have traditionally been used to treat inflammation prophylactically as well as post-operatively; however, currently there are no established guidelines or consensus for the treatment of inflammation induced by cataract surgery. Due to the lack of sufficient evidence from randomized controlled studies, preferred postoperative protocols for managing inflammation and pain after cataract surgery and other intraocular procedures have not been established (Aptel et al. 2017).

The American Academy of Ophthalmology (AAO) published a guideline on Cataract in the Adult Eye Preferred Practice Pattern (PPP). The PPP guidelines indicate that "medication regimens vary among practitioners. Topical corticosteroids and NSAIDs are also used for control of postoperative inflammation, but there is insufficient high-level evidence to compare these interventions (Juthani et al. 2017) making it the decision of the operating surgeon to use one or both of these medication classes. Complications of postoperative medications include elevated IOP with corticosteroids and allergic reactions to antibiotics."

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Dexycu (dexamethasone intraocular suspension) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to (dexamethasone intraocular suspension) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1095	Injection, dexamethasone 9%, intraocular, 1 mcg

AVAILABLE DOSAGE FORMS:

Dexycu SUSP 9%

REFERENCES

1. Dexycu (dexamethasone) [prescribing information]. Watertown, MA: EyePoint Pharmaceuticals US, Inc; June 2022.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS. Accessed February 2023.
3. ClinicalTrials.gov. National Library of Medicine; 2000 Feb 29 - [cited February 2019]. Available from ClinicalTrials.gov.
4. Aptel F, Colin C, Kaderli S, et al. Management of postoperative inflammation after cataract and

complex ocular surgeries: a systematic review and Delphi survey. Br J Ophthalmol. 2017;101(11):1-10. doi: 10.1136/bjophthalmol-2017-310324.
5. 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. doi: 10.1016/j.ophtha.2017.12.029. Epub 2018 Feb 13. Erratum in: Ophthalmology. 2018 Oct;125(10):1664. PMID: 29397189.
6. Donnenfeld ED, Solomon KD, Matossian C. Safety of IBI-10090 for inflammation associated with cataract surgery: Phase 3 multicenter study. Journal of Cataract & Refractive Surgery. 2018;44:1236-46. DOI: 10.1016/j.jcrs.2018.07.015
7. Juthani VV, Clearfield E, Chuck RS. Non-steroidal anti-inflammatory drugs versus corticosteroids for controlling inflammation after uncomplicated cataract surgery. Cochrane Database Syst Rev. 2017;7:CD010516. doi: 10.1002/14651858.CD010516.pub2.
8. Salinger CL, Gaynes BI, Rajpal RK. Innovations in topical ocular corticosteroid therapy for the management of postoperative ocular inflammation and pain. Am J Manag Care. 2019;25(12 Suppl):S215–S226. PMID: 31419092.
9. Shah TJ, Conway MD, Peyman GA. Intracameral dexamethasone injection in the treatment of cataract surgery induced inflammation: design, development, and place in therapy. Clin Ophthalmol. 2018;12:2223-2235. Published 2018 Nov 1. doi:10.2147/OPTH.S165722.
10. Miller KM, Oetting TA, American Academy of Ophthalmology (AAO), et al. Cataract in the adult eye preferred practice pattern. Ophthalmology. 2021 Nov. doi: https://doi.org/10.1016/j.ophtha.2021.10.006. Accessed February 2023.
11. Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Office-based cataract surgery: Population health outcomes study of more than 21,000 cases in the United States. Ophthalmology. 2016 Apr;123(4):723-8. doi: 10.1016/j.ophtha.2015.12.020. Epub 2016 Jan 22. PMID: 26804760.
12. Gollogly HE, Hodge DO, St Sauver JL, Erie JC. Increasing incidence of cataract surgery: Population-based study. J Cataract Refract Surg. 2013 Sep;39(9):1383-9. doi: 10.1016/j.jcrs.2013.03.027. Epub 2013 Jun 29.
13. 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. doi: 10.1007/s00417-017-3599-8. Epub 2017 Jan 27.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update Contraindications/Exclusions/Discontinuation	Q4 2024
MCP Conversion	Q2 2024
Policy reviewed. No changes to criteria. Updated references	4/13/2023
Policy reviewed; no changes to criteria; updated Summary of Medical Evidence and Reference sections	4/13/2022
Policy reviewed and updated, no changes in coverage criteria, updated references. Content update includes: Added information on the phase 3 prospective randomized open-label study Donnenfeld, et al. (2018) supporting criterion #4 of corticosteroid eye drops.	4/5/2021
Policy reviewed and updated, no changes in coverage criteria, updated references.	Q2 2020
New MCP	5/29/2019