Clinical Policy: Bimatoprost Implant (Durysta)

Reference Number: LA.PHAR.486
Effective Date:
Last Review Date: 05.01.23
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
Bimatoprost intracameral implant (Durysta™) is a prostaglandin analog.

FDA Approved Indication(s)
Durysta is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Durysta is **medically necessary** when the following criteria are met:

1. **Initial Approval Criteria**
   - **A. Open Angle Glaucoma and Ocular Hypertension** (must meet all)**:**
     1. Diagnosis of OAG or OHT;
     2. Prescribed by or in consultation with an ophthalmologist;
     3. Age ≥ 18 years;
     4. Medical justification supports inability to manage regular glaucoma eye drop use (e.g., due to age or comorbidities including visual impairment);
     5. The affected eye has not received prior treatment with Durysta;
     6. Member has none of the following contraindications:
        a. Active or suspected ocular or periocular infection;
        b. Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy);
        c. History of corneal transplantation or endothelial cell transplant (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]);
        d. Absent or ruptured posterior lens capsule;
        e. Hypersensitivity to bimatoprost or to any other component of Durysta;
     7. Dose does not exceed 10 mcg (one implant) per eye.

     Approval duration: one implant per eye (lifetime total)

   - **B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Open Angle Glaucoma and Ocular Hypertension

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DSAEK: Descemet's Stripping Automated Endothelial Keratoplasty
FDA: Food and Drug Administration
IOP: intraocular pressure
OAG: open angle glaucoma
OHT: ocular hypertension

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): ocular or periocular infections, corneal endothelial cell dystrophy, prior corneal transplantation, absent or ruptured posterior lens capsule, hypersensitivity to bimatoprost or to any other components of the product
- Boxed warning(s): none reported

3. **Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
OAG, IOH	Intracameral implant containing 10 mcg of bimatoprost in a drug delivery system General Information: Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant. Durysta should not be readministered to an eye that received a prior Durysta. Administration: The intracameral injection procedure must be performed under magnification that allows clear visualization of the anterior chamber structures and should be carried out using standard aseptic conditions for intracameral procedures, with the patient's head in a stabilized position. The eye should not be dilated prior to the procedure. Remove the foil pouch from the carton and examine for damage. Then, open the foil pouch over a sterile field and gently drop the applicator on a sterile tray. Once the foil pouch is opened, use promptly. *See package insert for additional instructions.*	One implant per eye

4. **Product Availability**
Intracameral implant in a single-use applicator that is packaged in a sealed foil pouch containing desiccant: 10 mcg bimatoprost

5. **References**

i. Durysta Prescribing Information. Madison, NJ: Allergan USA, Inc.; November 2020. Available at https://media.allergan.com/products/durysta_pi.pdf. Accessed January 13, 2022.
ii. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 13, 2022.
iii. Lewis RA, Christie WC, Day DG, et al. Bimatoprost sustained-release implants for glaucoma therapy: 6-month results from a phase I/II clinical trial. Am J Ophthalmol 2017; 175:137-147. Clinicaltrials.gov identifier: NCT01157364.
iv. Craven ER, Walters T, Christie WC, et al. 24-month phase I/II clinical trial of bimatoprost sustained-release implant (Bimatoprost SR) in glaucoma patients. Drugs 2020; 80:167-179. Clinicaltrials.gov identifier: NCT01157364.
v. Craven ER, Walters T, Christie W, Bejanian M, Goodkin ML, Guo Q, Zhang J, Robinson MR, Ahmed IK. Phase 3 evaluation of Bimatoprost sustained-release implant in patients with glaucoma or ocular hypertension: results at primary database lock [abstract no. PA054-2019]. Presented at the American Academy of Ophthalmology 2019 meeting, San Francisco, CA, 12–15 October 2019. ClinicalTrials.gov. NCT02250651, NCT02247804.

vi. Gedde SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. Ophthalmology; November 2020. Available at: https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp. Accessed January 13, 2022.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. 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.

HCPCS Codes	Description
J7351	Injection, bimatoprost, intracameral implant, 1 microgram

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or

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This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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