

Clinical Policy: Bimatoprost Implant (Durysta)

Reference Number: ERX.SPA.395

Effective Date: 06.01.20

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Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

Bimatoprost 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Durysta is **medically necessary** when the following criteria are met:

I. 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 \geq 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

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DSAEK: Descemet's Stripping Automated Endothelial Keratoplasty	IOP: intraocular pressure
FDA: Food and Drug Administration	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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
OAG, IOH	<p>Intracameral implant containing 10 mcg of bimatoprost in a drug delivery system</p> <p><u>General Information:</u> 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.</p> <p><u>Administration:</u> 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. <u>See package insert for additional instructions.</u></p>	One implant per eye

VI. Product Availability

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

VII. References

1. Durysta Prescribing Information. Madison, NJ: Allergan USA, Inc.; March 2020. Available at https://media.allergan.com/products/durysta_pi.pdf. Accessed March 13, 2020.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 13, 2020.
3. 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.
4. 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.
5. 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. <https://aao.scientificposters.com/epsAbstractAAO.cfm?id=2>. Accessed 23 Dec 2019. ClinicalTrials.gov. NCT02250651, NCT02247804.
6. Prum BE, Rosenberg LF, Gedde SJ, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern® Guidelines. Ophthalmology; January 2016, 123(1):41-111. Available at: www.aajournal.org. Accessed March 13, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.07.20	05.20

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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