Clinical Policy: Bimatoprost Implant (Durysta)

Reference Number: CP.PHAR.486
Effective Date: 06.01.20
Last Review Date: 05.20 Revision Log
Line of Business: Commercial, HIM, Medicaid

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.

It is the policy of health plans affiliated with Centene Corporation® 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 ≥ 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.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.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
OAG, IOH	Intracameral implant containing 10 mcg of bimatoprost in a drug delivery system <u>General Information</u>: Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant.	One implant per eye

Indication	Dosing Regimen	Maximum Dose
	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.*	

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.scien tific poste rs.com/epsAb strac tAAO. 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.aaojournal.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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.