BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Bimatoprost Intracameral Implant (Durysta™)

File Name:	bimatoprost_implant_durysta
Origination:	10/2020
Last CAP Review:	n/a
Next CAP Review:	6/2021
Last Review:	2/2021

Description of Procedure or Service

Bimatoprost intracameral implant (Durysta™) is an implantable, biodegradable, sustained-release prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). It was approved by the U.S. Food and Drug Administration (FDA) in March 2020 and is believed to lower IOP by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.

Elevated IOP represents a major risk factor for visual field loss related to glaucoma. The higher the IOP level, the greater the likelihood of optic nerve damage and visual field loss. Therefore, lowering IOP is the primary goal of glaucoma treatment. Randomized trials have demonstrated lowering of IOP with use of pharmacologic therapy, laser (trabeculoplasty), and/or surgery (trabeculectomy). First-line treatment for open-angle glaucoma is usually topical eye drops, with surgery reserved for patients with advanced disease who do not respond to topical medication or laser therapy or who have severe visual field loss at baseline. Topical medications work by either increasing aqueous outflow (prostaglandins, alpha adrenergic agonists, cholinergic agonists) or decreasing aqueous production (alpha adrenergic agonists, beta blockers, carbonic anhydrase inhibitors). A greater reduction in IOP may be achieved by combining drops from different classes compared to monotherapy.

Related Policies:
Aqueous Shunts and Devices for Glaucoma
Viscocanalostomy and Canaloplasty

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Bimatoprost Intracameral Implant (Durysta) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Bimatoprost Intracameral Implant (Durysta™)

When Bimatoprost Intracameral Implant (Durysta) is covered

Bimatoprost intracameral implant (Durysta) may be considered medically necessary in patients 18 years of age and older when the following criteria are met:

1. The patient has a diagnosis of open angle glaucoma or ocular hypertension; **AND**
2. ONE of the following:
    a. BOTH of the following:
        i. The patient has tried* and had an inadequate response to at least two intraocular pressure (IOP) lowering topical ophthalmic agents with different mechanisms of action, one of which must include a topical ophthalmic prostaglandin analog, after at least a one-month trial of each agent; **AND**
        ii. The patient has tried* and had an inadequate response to combination therapy with IOP lowering topical ophthalmic agents (either as two single agents or as a combination product) after at least a one-month trial; **OR**
    b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL IOP lowering topical ophthalmic agents that is not expected to occur with the requested agent; **OR**
    c. The prescriber has provided documentation indicating the patient is unable to manage instilling ophthalmic drops (e.g., due to age, visual impairment, comorbidities); **AND**
3. The patient has not been previously treated with the requested agent in the affected eye(s); **AND**
4. The bimatoprost intracameral implant is prescribed by an ophthalmologist.

*Adequate trial is defined as administering at least 75% of prescribed doses within one month

Authorization: One implant per eye per lifetime

When Bimatoprost Intracameral Implant (Durysta) is not covered

Bimatoprost intracameral implant (Durysta) is considered not medically necessary and therefore not covered when the above criteria are not met, and for all other indications not listed above.

Re-treatment with additional bimatoprost intracameral implants (Durysta) is considered **investigational**.

Policy Guidelines

Dosing and Administration

Durysta is an ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant containing 10 mcg of bimatoprost.

Due to concern for possible corneal endothelial cell loss, the FDA prescribing information warns that administration of Durysta should be limited to a single implant per eye without retreatment.

Clinical Evidence Summary

For individuals with open-angle glaucoma or ocular hypertension who receive bimatoprost intracameral implant, the evidence includes one published randomized, parallel-group, multicenter phase 3 clinical trial assessing use of bimatoprost intracameral implant compared to twice daily timolol 0.5% eye drops over 20 months in patients with OAG or OHT, including an 8-month extended follow-up (ARTEMIS 1 trial; NCT02247804). The primary outcome was change in baseline IOP through week 12. A total of 594 subjects were enrolled and randomized in a 1:1:1 ratio to receive bimatoprost 10 µg implant (n=198) or 15 µg implant (n=198) on day one with re-administration at weeks 16 and 32 or twice daily topical timolol (n=198). Both implant dose strengths met the a priori criteria for statistical and clinical noninferiority to timolol in IOP and change in IOP from baseline through 12 weeks. Implants were removed in 23 subjects in the implant groups due to treatment-emergent adverse events (TEAE). Almost 20% of the subjects in the 15-µg group did not complete the study, one of the most common reasons being TEAE. The TEAE most commonly leading to early study exit in the bimatoprost implant treatment group included corneal endothelial cell loss and corneal edema.

Several limitations were identified with the study and questions remain around the use and safety of Durysta in the treatment of glaucoma. In the ARTEMIS study, adherence to eye drop use by subjects in the timolol arm was not assessed. In each treatment group, use of non-study IOP-lowering medication in either eye was allowed during the first year. The comparator used in the study was topical timolol, not topical prostaglandin analog, and response and durability of response to previous prostaglandin topical therapy in the study participants was unknown and not assessed. Additionally, the randomized trial evaluated the efficacy of three implants at assigned dosing intervals; however, the FDA has approved use of only one implant per eye per lifetime because of safety concerns. Furthermore, as Durysta is designed to continuously release bimatoprost over 3-4 months and retreatment is not approved, it is unclear whether administration of a single implant may represent a delay in initiating subsequent lines of therapy using alternative treatments that are well-studied and with known efficacy and safety profiles. The patient population in whom this implant is intended is not well defined, nor whether it is meant to be used as replacement for topical therapy or in patients who are refractory to topical therapy. It is unclear whether one bimatoprost intracameral implant as a one-time administration will prevent deterioration of vision or lead to improved health outcomes in the treatment of glaucoma. Ongoing and unpublished studies may address safety and efficacy concerns.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *J7351*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Allergan. Durysta (bimatoprost implant) for intracameral administration. Highlights of prescribing information. March 2020. Available at: https://media.allergan.com/products/durysta_pi.pdf. Last accessed September 2020.

Medeiros FA, Walters TR, Kolko M, et al. Phase 3, randomized, 20-month study of bimatoprost implant in open-angle glaucoma and ocular hypertension (ARTEMIS 1). Ophthalmology. June 2020; 1-15. Available at: https://www.aaojournal.org/article/S0161-6420(20)30555-8/fulltext. Last accessed September 2020.

Prum BE, Rosenberg LF, Gedde SJ, et al. American Academy of Ophthalmology. Primary open-angle glaucoma preferred practice pattern guidelines. Ophthalmology. 2015;123(1):P41-P111.

Medical Director review 9/2020

Medical Director review 2/2021

Policy Implementation/Update Information

10/1/20 New policy developed. The use of bimatoprost intracameral implant (Durysta) is considered investigational for all indications including treatment of open-angle glaucoma and ocular hypertension. Added HCPCS code J7351 to Billing/Coding section. References added. Medical Director review 9/2020. (krc)

2/9/21 Added medically necessary coverage criteria for Durysta for treatment of open angle glaucoma or ocular hypertension when specific medical criteria and guidelines are met. Medical Director review 2/2021. (krc)