BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

DURYSTA (bimatoprost implant)

Policy #: 735
Category: Pharmacy

Latest Review Date: April 2021
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **Durysta** (bimatoprost implant) as a **covered** benefit for indications approved by the FDA, including the following: open angle glaucoma or ocular hypertension.

Blue Advantage will treat **Durysta** (bimatoprost implant) as a **non-covered benefit** and **investigational** for **ALL** other indications.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE

Durysta (bimatoprost implant) is described as the first intracameral biodegradable sustained release implant designed to lower intraocular pressure in patients with conditions such as open angle glaucoma or ocular hypertension. The active ingredient involved is bimatoprost, which is a prostaglandin analog medication used to treat glaucoma and lower high eye pressure. Durysta is composed of biodegradable polymers designed to release bimatoprost in a non-pulsatile, steady-state manner over a 90-day period.

The standard of care treatment for open angle glaucoma or ocular hypertension is eye drops that are self-administered using the following technique:

- Wash your hands before use
- Take out contact lenses before using this medicine
- Do not touch the container tip to the eye, lid, or other skin
- Tilt your head back and drop drug into the eye.
- After use, keep your eyes closed. Put pressure on the inside corner of the eye. Do this for one to two minutes. This keeps the drug in your eye.

A large number of patients report non-compliance with self-administering eye drops due to either forgetfulness or side effects. Durysta, ocular implant device, has been developed to combat this non-compliance rate.

Durysta is delivered via a disposable single-use applicator that is inserted into the anterior chamber of the affected eye. Insertion is performed under magnification in an office or ambulatory surgery center. The presence of Durysta implants has been associated with corneal adverse reactions and increased risk of corneal endothelial cell loss. Per the FDA recommendation, administration of Durysta should be limited to a single implant per eye without

retreatment. Caution should be used when prescribing Durysta in patients with limited corneal endothelial cell reserve.

KEY POINTS:

This policy was developed with medical literature review through June 2, 2021.

Table 1. Clinical Outcomes of Durysta (Bimatoprost Implant) Use

ClinicalTrials.gov Identifier, study name	Author, year, country	Study Design	Population Characteristics	Interventions	Comparators	Clinical Outcomes, Length of Follow up
NCT01157364: "Safety and Efficacy of a New Ophthalmic Formulation of Bimatoprost in Patients With Open Angle Glaucoma and Ocular Hypertension"	Allergan (sponsor) Craven et al, 2020, US	Interventional Randomized Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Triple (Participant, Investigator, Outcomes Assessor); Primary Purpose: Treatment	109 participants (56 female, 53 male) with diagnosis of OAG or OCH	SR bimatoprost treatment	topical bimatoprost treatment	A single administration of bimatoprost sustained-release implant (Bimatoprost SR) lowered intraocular pressure for up to 1 year in 40% of patients and up to 2 years in 28%, with no additional treatment. Efficacy of re-administration with a second implant of Bimatoprost SR was similar to that with the first implant. The safety profile of Bimatoprost SR was favorable during the 24-month study.
NCT02247804: "Efficacy and Safety Study of Bimatoprost Sustained-Release (SR) in Participants With Open-angle	Allergan (sponsor), 2020, US	Interventional Randomized Allocation: Randomized Intervention Model: Parallel Assignment Masking: Quadruple	594 participants (288 female, 306 male) with diagnosis of either OAG or OCH in each eye and both eye require IOP lowering	Bimatoprost SR administered on Day 1, Day 16, Week 32 with timolol vehicle (placebo) administered	Timolol 0.5% administered once in morning and once in the evening for up to 20 months with sham (applicator	This study was designed to evaluate the efficacy and safety of bimatoprost SR in participants with open-angle glaucoma or ocular hypertension. The study includes a 12-month treatment period with an 8-month extended follow-up.

Glaucoma or Ocular Hypertension"		(Participant, Care Provider, Investigator, Outcomes Assessor) Primary Purpose: Treatment	treatment	once in the morning and once in the evening for up to 20 months	without needle) administered on Day 1, Day 16, and Week 32	Noninferiority is deduced with relative safety. No publication association with this study is reported.
NCT02250651: "Safety and Efficacy of Bimatoprost Sustained-Release (SR) in Patients With Open-Angle Glaucoma or Ocular Hypertension"	Allergan (sponsor), 2020, US	Interventional Randomized Allocation: Randomized Intervention Model: Parallel Assignment Masking: Triple (Participant, Investigator, Outcomes Assessor) Primary Purpose: Treatment	527 participants	Bimatoprost SR administered on Day 1, Day 16, Week 32 with timolol vehicle (placebo) administered once in the morning and once in the evening for up to 20 months	Timolol 0.5% administered once in morning and once in the evening for up to 20 months with sham (applicator without needle) administered on Day 1, Day 16, and Week 32	NR. No publication association with this study is reported.

OAG: open angle glaucoma; OHT: ocular hypertension; IOP: intraocular pressure; SR: sustained release; US: United States; NR: not reported.

Summary of Evidence

The FDA approval of Durysta is based on results from two 20-month (including 8-month extended follow up) Phase 3 ARTEMIS studies evaluating 1,122 subjects on the efficacy and safety of Durysta versus twice daily topical timolol drops, an FDA accepted comparator for registrational clinical trials, in patients with OAG or OHT. In the two Phase 3 ARTEMIS studies, Durysta reduced IOP by approximately 30 percent from baseline over the 12-week primary efficacy period, meeting the predefined criteria for non-inferiority to the study comparator. There are several ongoing studies that have not yet been completed.

Lowering of IOP is the only proven method to decrease risk of development and/or worsening glaucomatous optic neuropathy. Topical medical therapy is an effective strategy, but many patients are non-adherent to medications. Barriers to adherence are multifold and include forgetfulness, difficulty with drop instillation, need for frequent administration. Durysta could make an impact on non-compliance glaucoma management issue. There are risks to using Durysta, such as, eye pain, eye irritation, lacrimation, and conjunctival hemorrhage. Studies have shown that Durysta is an effective treatment for glaucoma, but not superior to the standard of care. The FDA clearance is for single use per each eye. In the studies reviewed, Durysta was implanted every four months for one year.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

The 2015 Primary Open-Angle Glaucoma practice guidance from the American Academy of Ophthalmology recommends switching eye-drop agents or adding on for combination therapy when target IOP is not achieved with one drug alone. The practice guidance has not been updated to include the use of Durysta in its recommendations at the time of this review.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

Durysta, bimatoprost, biodegradable implant, ocular implant, Allergan, OAG, open angle glaucoma, OHT, ocular hypertension, intracameral administration

APPROVED BY GOVERNING BODIES:

On March 4, 2020, the U.S. Food and Drug Administration (FDA) approved Allergan's Durysta (bimatoprost implant) 10 mcg for intracameral administration to treat open-angle glaucoma (OAG) or ocular hypertension (OHT). As per the FDA labeled package insert, Durysta (bimatoprost implant) is a biodegradable implant intended for a single administration and should not be re-administered to an eye that received a prior Durysta (bimatoprost implant).

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

HCPCS Codes

For dates of service 10/1/20 and after:

J7351	Injection, bimatoprost, intracameral implant, 1 microgram (Effective 10/1/2020)

PREVIOUS CODING:

Prior to 10/1/2020, there was not a specific code for Durysta.

J3490	Unclassified drugs

REFERENCES:

1. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel, Hospkins Center for Quality Eye Care. Primary Open-Angle Glaucoma 2015. Available at https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-suspect-ppp-2015. Accessed on July 16, 2020.
2. Aref, Ahmad A. Bimatoprost Implant (Durysta). https://eyewiki.org/Bimatoprost_Implant_ (Durysta) #cite_note-:0-4. Accessed July 16, 2020.
3. Craven ER, Walters T, Christie WC, Day DG, Lewis RA, Goodkin ML, Chen M, Wangsadipura V, Robinson MR, Bejanian M; Bimatoprost SR Study Group. 24-Month Phase I/II Clinical Trial of Bimatoprost Sustained-Release Implant (Bimatoprost SR) in Glaucoma Patients. Drugs. 2020 Feb; 80(2):167-179. doi: 10.1007/s40265-019-01248-0.
4. Delfaro, A. Week in review: Eye tick, acid attack, AMD style. Available at https://www.aao.org/headline/week-in-review-eye-tick-acid-attack-amd-style. Accessed July 16, 2020.
5. Gedden SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma PPP 2020. AAO PPP Glaucoma Committee, Hoskins Center for Quality Eye Care. Nov 2020. Available at https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp. Accessed April 20, 2021.
6. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
7. Kolomeyer, Natasha N. Top 7 Things to Know About First Sustained-Release Glaucoma Medication. https://www.aao.org/young-ophthalmologists/yo-info/article/top-7-things-to-know-about-first-sustained-release. Accessed July 16, 2020.
8. 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.

9. Rajan, K. Biodegradable bimatoprost implant gains FDA approval. Available at https://www.aao.org/headline/biodegradable-bimatoprost-implant-gains-fda-approv. Accessed July 16, 2020.

POLICY HISTORY

Medical Policy Panel, July 2020: New policy created.
Medical Policy Group, April 2021