Policy Title:	Durysta (bimatoprost) (Implant)		
		Department:	PHA
Effective Date:	04/01/2021		
Review Date:	03/04/2021, 5/27/2021, 6/02/2022, 4/13/2023, 12/14/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Durysta (bimatoprost).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Durysta (bimatoprost) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Durysta (bimatoprost) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Durysta is an intraocular implant that is indicated for a one-time administration into each eye to reduce intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension. In controlled studies, the most common ocular adverse reactions included conjunctival hyperemia, foreign body sensation, eye pain, photophobia, conjunctival hemorrhage, dry eye, eye irritation, blurred vision, iritis, and headache. The FDA approval was based on results from two randomized, 20-month, multicenter, subject and efficacy evaluator-masked, parallel-group, phase 3 clinical studies that compared Durysta versus twice daily timolol eye drops for the treatment of glaucoma. The results showed that the baseline IOP in the 10ug bimatoprost implant (24.0mmHg) was reduced by 28.3% to 17.2mmHg while the baseline IOP in the timolol treated group (23.9mmHg) was reduced by 26.8% to 17.5mmHg after 12 weeks. All statistical tests were 2 sided with an alpha level of 0.05. The reduction in intraocular pressure that Durysta was able to produce in these studies met the predefined criteria for non-inferiority to the study comparator (timolol) for the treatment of open angle glaucoma.

Initial Criteria:

- Member is 18 years of age or older; AND
- Member has a diagnosis of open angle glaucoma or ocular hypertension; AND
- Durysta has been prescribed by or in consultation with an ophthalmologist; AND
- Intolerance or an insufficient response to at least two trials of IOP reducing eye drop agents (combination therapy should be used if warranted) from two different medication classes. For one trial, the member must have been treated with a prostaglandin analog (e.g., latanoprost, travoprost*, or bimatoprost); AND

- Member has none of the following contraindications:
  - Active or suspected ocular or periocular infection
  - Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy)
  - History of corneal transplantation or endothelial cell transplant
  - Absent or ruptured posterior lens capsule
  - Hypersensitivity to bimatoprost or to any other component of Durysta; AND
- The affected eye has not received prior treatment with Durysta (bimatoprost);
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

*ONLY applies to Medicaid and Commercial members

Continuation of Therapy Criteria:

- Re-authorization is not permitted for this medication. Durysta is only FDA approved for one single administration in each eye (lifetime limit).

Coverage durations:

- Initial coverage: One implant per eye per lifetime
- Continuation of therapy coverage: Cannot be refilled, lifetime limit of one implant per eye per lifetime

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Durysta was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Durysta according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1 mcg)
Open angle glaucoma or Ocular hypertension	Ophthalmic drug delivery system for a single intracameral administration of a biodegradable implant containing 10 mcg of bimatoprost	10 units per eye per lifetime

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J7351	Injection, bimatoprost, intracameral implant, 1 microgram

References:

1. Durysta Prescribing Information. Madison, NJ: Allergan USA, Inc.; November 2020. Available at https://media.allergan.com/products/durysta_pi.pdf. Accessed November 2023.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 15, 2021.