

# Clinical Criteria

<u>Subject:</u>	Durysta (bimatoprost implant)
<u>Document #:</u>	ING-CC-0163
<u>Status:</u>	New
<u>Publish Date:</u>	05/28/2020
<u>Last Review Date:</u>	05/15/2020

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## Overview

This document addresses the use of Durysta (bimatoprost implant), an implantable prostaglandin analog used to reduce elevated intraocular pressure (IOP) in individuals with conditions such as open-angle glaucoma or ocular hypertension.

IOP is a measurement of the fluid pressure inside the eye. When eye pressure increases and damages the optic nerve, glaucoma results. This damage reduces vision and if not treated can lead to total blindness.

Durysta is the first intracameral (eye chamber), biodegradable, sustained-release implant that is FDA approved to reduce IOP in those with open-angle glaucoma or ocular hypertension. Previous to this approval, pharmacologic therapy consisted of topical eye-drops with varying mechanisms of action. 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. Due to an increased risk of corneal endothelial cell loss, patients should receive only one implant per eye and no retreatment.

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.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Durysta (bimatoprost implant)

Requests for Durysta (bimatoprost implant) may be approved if the following criteria are met:

- I. Individual has a diagnosis of open angle glaucoma or ocular hypertension with elevated intraocular pressure; AND Individual meets the following criteria:
  - A. Trial and insufficient response or intolerance to at least two (2) IOP eye-drop agents with different mechanisms of action, and one of which must include a prostaglandin analog (for example, bimatoprost, latanoprost, travoprost, or tafluprost); AND,
  - B. Trial and insufficient response or intolerance to combination therapy with IOP eye-drop agents (either as 2 single agent products or 1 combined agent product).

Durysta (bimatoprost implant) may not be approved for the following:

- I. Repeat administration in the same eye; OR
- II. Active or suspected ocular or periocular infections; OR
- III. Corneal endothelial cell dystrophy (for example, Fuchs' Dystrophy); OR

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IV. Prior corneal transplantation, or endothelial cell transplants (for example, Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]); OR  
 V. Absent or ruptured posterior lens capsule; OR  
 VI. When the above criteria are not met and for all other indications.

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## Quantity Limits

### Durysta (bimatoprost implant) Quantity Limits

Drug	Limit
Durysta (bimatoprost implant) 10 mcg single-use applicator	2 applicators (10 mcg) per lifetime

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS  
 J3490 Unclassified drugs (when specified as [Durysta])  
 C9399 Unclassified drugs or biologicals (when specified as [Durysta])

ICD-10 Diagnosis  
 H40.10X0-H40.1194 Open-Angle glaucoma  
 H40.051-H40.059 Ocular Hypertension

## Document History

New: 05/15/2020

### Document History:

- 05/15/2020 – Annual Review: Add new clinical criteria document for Durysta (bimatoprost implant). Coding Review: Added HCPCS codes J3490, C9399. Added ICD-10 dx H40.10X0-H40.1194, H40.051-H40.059

## References

- American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel, Hopkins 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 April 7, 2020.
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- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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