

# Medical Policy

## Healthcare Services Department

<b>Policy Name</b>	<b>Policy Number</b>	<b>Scope</b>
<b>Bimatoprost Implant (Durysta®)</b>	MP-RX-FP-24-23	<input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth
<b>Service Category</b>		
<div> <input type="checkbox"/> Anesthesia <input type="checkbox"/> Surgery <input type="checkbox"/> Radiology Procedures <input type="checkbox"/> Pathology and Laboratory Procedures </div> <div> <input type="checkbox"/> Medicine Services and Procedures <input type="checkbox"/> Evaluation and Management Services <input type="checkbox"/> DME/Prosthetics or Supplies <input checked="" type="checkbox"/> Part B Drugs </div>		
<b>Service Description</b>		
<p>This document addresses the use of <b>Bimatoprost Intracameral Implant (Durysta®)</b> , a prostaglandin analog approved by the Food and Drug Administration (FDA) for the treatment of open angle glaucoma or ocular hypertension.</p>		
<b>Background Information</b>		
<p>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 (OAG) or ocular hypertension (OHT).</p> <p>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.</p> <p>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. Another implant, iDose TR (travoprost) is a titanium intracameral implant, injected under magnification using standard aseptic conditions. iDose TR is only approved for use as a single implant per eye; no retreatment allowed.</p> <p>The 2020 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 recognizes that adherence to topical eye-drops may be a barrier to optimal therapy, and notes that multiple drug delivery systems have been developed to address this issue, including Durysta and iDoseTR.</p>		
<b>Approved Indications</b>		
<p>Durysta® is approved by the FDA for the following conditions:</p> <ul style="list-style-type: none"> <li>A. Ocular hypertension</li> <li>B. Open-angle glaucoma</li> </ul>		

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### Other Uses

- A. Hypotrichosis, Of the eyelashes

### Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J7351	Injection, bimatoprost, intracameral implant, 1 microgram

ICD-10	Description
H40.10X0-H40.1194	Open-Angle glaucoma
H40.051-H40.059	Ocular Hypertension
H40.1310-H40.1314	Pigmentary glaucoma, right eye
H40.1320-H40.1324	Pigmentary glaucoma, left eye
H40.1330-H40.1334	Pigmentary glaucoma, bilateral
H40.1390-H40.1394	Pigmentary glaucoma, unspecified eye

## Medical Necessity Guidelines

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.

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

## Bimatoprost Implant (Durysta®)

### A. Criteria for Initial Approval

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**
- ii. Individual has had a:
  - A. Trial and insufficient response or intolerance to two (2) IOP eye-drop agents as combination therapy with (either as 2 single agent products or 1 combined agent product), where one agent is a prostaglandin analog (for example, bimatoprost, latanoprost, travoprost, or tafluprost).

### B. Criteria for Continuation of Therapy:

- i. Durysta should not be readministered to an eye that has already received the implant.

### C. Conditions Not Covered:

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**
- 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.

### D. Authorization Duration:

- i. Initial Approval Duration: One implant per eye per lifetime.
- ii. Reauthorization Approval Duration: Not applicable, as reauthorization is not permitted.

### Limits or Restrictions

#### A. Therapeutic Alternatives

*The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.*

- i. N/A

#### B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

Drug	Limit
Durysta (bimatoprost implant) 10 mcg single-use applicator	2 applicators (10 mcg) per lifetime (One implant per eye)
Exceptions	
N/A	

### Reference Information

1. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel, Hoskins Center for Quality Eye Care. Primary Open-Angle Glaucoma 2020. Available at <https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-suspectppp-2020>. Accessed on June 1, 2022.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 1, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; 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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## Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.			
Select Review. 06/12/2024	Wording and formatting changes. Added Other uses, Authorization duration, Therapeutic Alternatives. Update background information, approved indications, and quantity limits table. Coding reviewed: Expanded code range to include H40.1310 - H40.1314, H40.1320 - H40.1324, H40.1330 - H40.1334, H40.1390 - H40.1394.	2/18/2025	3/6/2025
Policy Inception 6/12/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023