Medical Drug Clinical Criteria

Subject:	Durysta (bimatoprost implant)		
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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. 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.

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.

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**
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).

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.

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

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

ICD-10 Diagnosis

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

Document History

Reviewed: 06/10/2024
Document History:

- 06/10/2024 – Annual Review: No changes. Coding Reviewed: Expanded code range to include H40.1310-H40.1314, H40.1320-H40.1324, H40.1330-H40.1334, H40.1390-H40.1394.
- 06/12/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 06/13/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Update criteria to require only trial of combination use of topical eye drops prior to Durysta. Coding Reviewed: No changes.
- 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. Effective 10/1/2020- Added HCPCS J7351, Delete 9/30/2020 J3490, C9399. Delete All DX pend 10/1/2020

References

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