Policy Name	Clinical Policy – Durysta bimatoprost implant
Policy Number	1343.00
Department	Clinical Product & Development
Subcategory	Medical Management
Original Approval Date	01/06/2021
Current MPC/CCO Approval Date	01/08/2025
Current Effective Date	05/01/2025

Company Entities Supported (Select All that Apply):
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company')

ACRONYM	
IOL	Intraocular
IOP	Intraocular pressure

PURPOSE

To provide the medical necessity criteria to support the indication(s) for Durysta and to render medical necessity determinations. Applicable procedure codes are also defined.

POLICY

A. BACKGROUND

Durysta, bimatoprost SR (sustained release), implant may replace complex standard topical therapies[1] while effectively reducing intraocular pressure. The implant is inserted through a stylet into the anterior chamber. This may be done either as an office-based procedure or in an operating room. Prior to Durysta implant, the eye must have open angles confirmed by gonioscopy.

Six-month results from phase I/II clinical trials documented a mean intraocular pressure reduction from baseline of 7.4 millimeters of mercury[2]. Neither rescue nor retreatment was

[1] Newman-Casey, 2015; Sleath, 2011.
[2] Mederios, 2022

required in 91% of patients at four months, and 71% of patients at six months. The primary adverse effect identified during the study[3] was that more than 10% of subjects had greater than 20% endothelial cell loss, [4] thus, the FDA approval is restricted to only one implant per eye with no retreatment.[5] The long term beneficial effects of Durysta continue to be measured. At one year follow up, a single administration of bimatoprost implant SR lowered intraocular pressure in 40% of patients to a degree comparable to bimatoprost topical therapy. At two years 28% of patients had sustained lowered intraocular pressure at a level consistent with topical bimatoprost therapy.[6]

B. Medically Necessary

Durysta (bimatoprost implant 10mcg) may be medically necessary if all the following criteria are met.

1. The patient has primary open angle glaucoma or ocular hypertension with grade 3 (Shaeffer) or greater angles confirmed by gonioscopy;[7] and,
2. The patient has failed to maintain acceptable intra-ocular pressure after laser trabeculoplasty (SLT);[8],[9] and,
3. The patient has had a satisfactory IOP lowering with a topical prostaglandin analogue;[10] and,
4. The patient has no ocular surface disease.[11]

C. Not Medically Necessary

The use of Durysta may not be medically necessary in patients who do not meet the above criteria or have any one of the following:

1. Corneal endothelial dystrophy; or,
2. Prior corneal transplantation; or,
3. Active or suspected ocular/periocular infections; or,
4. Posterior capsular tear secondary to cataract surgery.
5. Durysta is FDA approved for one implant per eye.
6. Due to Durysta' s novel status, safety outcomes for use after other drugs (e.g. iDose) are unknown. Any combination use of Durysta and iDose may not meet medical necessity.

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[3] Lewis, 2017
[4] Sirinek, 2021.
[5] Craven, 2019
[6] Craven, 2019
[7] Lim, 2022.
[8] FDA adverse events reporting system. The glaucoma experts of Versant Health MPC determined that safety profile of Durysta is not yet determined and that the less risky SLT procedure is required prior to use.
[9] Realini, 2008.
[10] Brown, 2019; Winkler, 2014
[11] Tsuge, 2019.

D. Documentation

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale for it as in the requirements above. All items must be available upon request to initiate or sustain previous payments. For any retrospective review, a full operative report is needed.

Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided/ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable.

E. Procedural Detail

HCPCS/CPT Codes	
J7351	Injection, bimatoprost, intracameral implant, 10 micrograms
66030	Injection, anterior chamber of eye (separate procedure); medication
Required Modifiers	
RT	Right Side
LT	Left Side

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RELATED POLICIES AND PROCEDURES	
1350	iDose TR

DOCUMENT HISTORY		
Approval Date	***Revisions***	***Effective Date***
01/06/2021	Initial policy	06/01/2021
01/05/2022	Annual review; no criteria changes	02/01/2022
01/04/2023	Annual review; no criteria changes	04/01/2023
09/20/2023	Administrative review for CMS 2024 final rule Medicare Part C equity: no changes.	n/a
01/03/2024	Added indication for ocular hypertension, ocular surface disease, poor compliance/intolerance to topical therapy.	05/01/2024
01/08/2025	Added FDA limitation of one implant per eye.	05/01/2025

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