Policy Name	Clinical Policy – Durysta bimatoprost implant
Policy Number	1343.00
Department	Clinical Product & Strategy
Subcategory	Medical Management
Original Approval Date	01/06/2021
Current MPC/CCO Approval Date	01/03/2024
Current Effective Date	05/01/2024

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	
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

The use of Durysta, bimatoprost SR (sustained release), implant is intended to avoid the problems with topical therapies 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. To successfully implant Durysta 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[1]. Neither rescue nor retreatment was required in 91% of patients at four months, and 71% of patients at six months. The study[2] found a large >10% had greater than 20% endothelial cell loss. FDA approval is for only one implant per year[3]. 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[4]

B. Medically Necessary

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

1. The patient has primary open angle glaucoma or ocular hypertension with grade 3 (Shaeffer) or greater angles confirmed by gonioscopy; and,
2. For patients with primary open angle glaucoma, the patient has failed to maintain acceptable intra-ocular pressure after laser trabeculoplasty; and,
3. The patient has had a satisfactory IOP lowering with a prostaglandin analogue; and,
4. The patient has ocular surface disease.

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.

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.

[1] Mederios, 2022
[2] Lewis, 2017
[3] Craven, 2019
[4] Craven, 2019

E. Procedural Detail

HCPCS/CPT Codes	
J7351	Injection, bimatoprost, intracameral implant, 10 microgram
66030	Injection, anterior chamber of eye (separate procedure); medication
Required Modifiers	
JW or JZ	Drug wastage/No drug wastage
RT	Right Side
LT	Left Side

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RELATED POLICIES AND PROCEDURES	
1317	Vascular Endothelial Growth Factor (Anti-VEGF)

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

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