Oscar Clinical Guideline: Durysta (bimatoprost intracameral implant) (CG116, Ver. 2)

Durysta (bimatoprost intracameral implant)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Open-angle glaucoma (OAG) is a chronic, progressive optic neuropathy characterized by irreversible damage to the optic nerve and resultant visual field loss. It is the most common form of glaucoma and a leading cause of irreversible blindness worldwide. The pathophysiology involves loss of retinal ganglion cells and their axons, leading to characteristic optic nerve head changes and corresponding visual field defects. Ocular hypertension (OHT) is a related condition in which intraocular pressure (IOP) is elevated above the normal range, but without evidence of glaucomatous optic nerve damage. However, patients with OHT are at increased risk for developing OAG.

The primary modifiable risk factor for the development and progression of OAG is elevated IOP. Treatment is aimed at lowering IOP to prevent or slow optic nerve damage and visual field loss. Current treatment options include:

1. Topical IOP-lowering medications (e.g., prostaglandin analogues, beta-blockers, alpha-agonists, carbonic anhydrase inhibitors, rho-kinase inhibitors).

2. Laser trabeculoplasty.
3. Microinvasive glaucoma surgery (MIGS).
4. Traditional incisional glaucoma surgery (e.g., trabeculectomy, tube shunt implantation).

Durysta is indicated for reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. It is administered by injection directly into the anterior chamber of the eye. Importantly, Durysta should be limited to a one-time single implant per eye. According to the FDA label, repeat administration is not recommended, due to risks of corneal endothelial cell loss that increase with successive implants. For this reason, coverage is restricted to one Durysta implant per eye, over the patient's lifetime. If the implant is used in both eyes, a maximum of 2 implants total are covered (1 per eye).

Definitions

"**Intracameral**" means within or administered into the anterior chamber of the eye.

"**Intraocular pressure (IOP)**" refers to the fluid pressure inside the eye. Elevated IOP is a major modifiable risk factor for the development and progression of glaucoma.

"**Ocular hypertension (OHT)**" is a condition in which intraocular pressure (IOP) is elevated above the normal range, but without evidence of glaucomatous optic nerve damage.

"**Open-angle glaucoma (OAG)**" refers to a chronic, progressive optic neuropathy characterized by irreversible damage to the optic nerve and resultant visual field loss in the presence of an open anterior chamber angle.

"**Prostaglandin analog**" is a class of IOP-lowering medications that increase outflow of aqueous humor through the uveoscleral pathway. Examples include latanoprost, travoprost, and bimatoprost.

"**Trabecular meshwork**" is a spongy tissue located in the anterior chamber angle of the eye that facilitates drainage of aqueous humor and helps regulate IOP.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Durysta (bimatoprost intracameral implant)** medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with trained glaucoma specialist, such as an ophthalmologist or an eye surgeon; ***AND***
2. The member is 18 years of age or older; ***AND***
3. The member has a diagnosis of open-angle glaucoma (OAG) or ocular hypertension (OHT); ***AND***
4. The member is unable to use[ɳ], or has tried and failed **ALL** of the following:
    a. at least **TWO** ophthalmic prostaglandin analogues (e.g. latanoprost, bimatoprost, travoprost); ***and***
    b. at least **ONE** of the following:
        i. An ophthalmic beta blocker (e.g. timolol); ***and/or***
        ii. An ophthalmic alpha agonist (e.g. brimonidine); ***and/or***
        iii. An ophthalmic carbonic anhydrase inhibitor (e.g. dorzolamide); ***and/or***
        iv. An ophthalmic rho kinase inhibitor (e.g. netarsudil); ***AND***

    [ɳ]*patient-specific, clinically significant reason(s) must be provided, explaining why the member requires Durysta and cannot continue to utilize ophthalmic preparations, such as solution or suspension, to treat their OAG or OHT.*
5. Information reviewed does **NOT** indicate **ANY** of the following:
    a. The member will be using other ophthalmic intraocular pressure (IOP)-lowering medications in the same eye as the Durysta implant; ***or***
    b. There are ocular or periocular infections present; ***or***
    c. The member has corneal endothelial dystrophy (e.g., Fuchs dystrophy); ***or***
    d. Absent or ruptured posterior lens capsule; ***or***
    e. The member has undergone prior corneal transplantation or endothelial cell transplants [e.g., Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)]; ***or***
    f. The member has known hypersensitivity to bimatoprost or any component of Durysta; ***or***
    g. The member has previously received a Durysta implant in the requested eye (i.e., for retreatment of the same eye with an additional Durysta implant); ***or***
    h. The request exceeds the Plan's limit of one 10 mcg intracameral implant per affected eye.

If the above prior authorization criteria are met, Durysta (bimatoprost intracameral implant) will be authorized as a one-time approval, i.e., one implant per eye (total of 2 lifetime implants if both eyes are treated, 1 per eye).

Medical Necessity Criteria for Reauthorization

Requests for continuation of therapy or reauthorization of Durysta (bimatoprost intracameral implant) will NOT be approved.

- The FDA-approved prescribing information for Durysta states that repeat administration is not recommended. Durysta should be limited to a single implant per eye without retreatment. This is due to the risk of corneal endothelial cell loss, which increases with repeated administration of Durysta implants.
- In the Phase 3 ARTEMIS clinical trials, successive Durysta implants administered every 4 months resulted in an increasing percentage of patients experiencing ≥20% loss of corneal endothelial cell density:
    - After 1st implant: 0-1.2% of patients
    - After 2nd implant: 0.6-3.9% of patients
    - After 3rd implant: 3.5-10.3% of patients
- Corneal endothelial cells are crucial for maintaining corneal clarity and visual function. Endothelial cell loss can lead to corneal edema, corneal decompensation and vision loss. The corneal endothelium has minimal regenerative capacity, so cell loss is considered irreversible. Due to this cumulative safety concern with repeat dosing of Durysta, the FDA has only approved Durysta for single administration per eye, over a patient's lifetime. Repeat treatment, even in the same eye after an extended period, is not recommended.

Experimental or Investigational / Not Medically Necessary

Durysta (bimatoprost intracameral implant) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of angle-closure glaucoma
- Treatment of secondary glaucomas (e.g., neovascular glaucoma, pigmentary glaucoma, pseudoexfoliation glaucoma, uveitic glaucoma)
- Treatment of pediatric glaucoma
- Repeat administration or retreatment of the same eye with an additional Durysta (bimatoprost intracameral implant)
- Prophylaxis of ocular hypertension in the absence of glaucomatous optic neuropathy

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
66030	Injection, anterior chamber of eye (separate procedure); medication
J7351	Injection, bimatoprost, intracameral implant, 1 microgram
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
H40.051	Ocular Hypertension, Right Eye
H40.052	Ocular Hypertension, Left Eye
H40.053	Ocular Hypertension, Bilateral
H40.059	Ocular Hypertension, Unspecified Eye
H40.10X0	Unspecified Open-Angle Glaucoma, Stage Unspecified
H40.10X1	Unspecified Open-Angle Glaucoma, Mild Stage
H40.10X2	Unspecified Open-Angle Glaucoma, Moderate Stage
H40.10X3	Unspecified Open-Angle Glaucoma, Severe Stage
H40.10X4	Unspecified Open-Angle Glaucoma, Indeterminate Stage
H40.1110	Primary Open-Angle Glaucoma, Right Eye, Stage Unspecified
H40.1111	Primary Open-Angle Glaucoma, Right Eye, Mild Stage
H40.1112	Primary Open-Angle Glaucoma, Right Eye, Moderate Stage
H40.1113	Primary Open-Angle Glaucoma, Right Eye, Severe Stage
H40.1114	Primary Open-Angle Glaucoma, Right Eye, Indeterminate Stage
H40.1120	Primary Open-Angle Glaucoma, Left Eye, Stage Unspecified
H40.1121	Primary Open-Angle Glaucoma, Left Eye, Mild Stage
H40.1122	Primary Open-Angle Glaucoma, Left Eye, Moderate Stage
H40.1123	Primary Open-Angle Glaucoma, Left Eye, Severe Stage
H40.1124	Primary Open-Angle Glaucoma, Left Eye, Indeterminate Stage

H40.1130	Primary Open-Angle Glaucoma, Bilateral, Stage Unspecified
H40.1131	Primary Open-Angle Glaucoma, Bilateral, Mild Stage
H40.1132	Primary Open-Angle Glaucoma, Bilateral, Moderate Stage
H40.1133	Primary Open-Angle Glaucoma, Bilateral, Severe Stage
H40.1134	Primary Open-Angle Glaucoma, Bilateral, Indeterminate Stage
H40.1190	Primary Open-Angle Glaucoma, Unspecified Eye, Stage Unspecified
H40.1191	Primary Open-Angle Glaucoma, Unspecified Eye, Mild Stage
H40.1192	Primary Open-Angle Glaucoma, Unspecified Eye, Moderate Stage
H40.1193	Primary Open-Angle Glaucoma, Unspecified Eye, Severe Stage
H40.1194	Primary Open-Angle Glaucoma, Unspecified Eye, Indeterminate Stage

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Clinical Guideline Revision / History Information

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