Oscar Clinical Guideline: Durysta (bimatoprost intracameral implant) (CG116, Ver. 4)

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. Due to the progressive nature, those with OAG often do not experience symptoms, even as they progress to central "tunnel vision." Diagnosis is often incidental during a comprehensive ophthalmic examination, thus screening is recommended for all adults 40 and older. 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. Non-modifiable risk factors include age, race, and family history. Treatment is aimed at lowering IOP to prevent or slow optic nerve damage and visual field loss. Current treatment options include:

1. Topical (intraocular) IOP-lowering medications (e.g., prostaglandin analogs, beta-blockers, alpha-agonists, carbonic anhydrase inhibitors, rho-kinase inhibitors, cholinergic agonists, prostaglandin E2 receptor agonists).
2. Laser trabeculoplasty.
3. Microinvasive glaucoma surgery (MIGS).
4. Traditional incisional glaucoma surgery (e.g., trabeculectomy, tube shunt implantation).

Durysta (bimatoprost intracameral implant) is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in those with open-angle glaucoma or ocular hypertension. It is administered by injection directly into the anterior chamber of the eye (intracameral), under standard aseptic technique. Importantly, Durysta (bimatoprost intracameral implant) 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

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"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.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"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.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Open-Angle Glaucoma or Ocular Hypertension

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*, or has tried and failed ALL of the following[s]:
    a. At least ONE (1) ophthalmic prostaglandin analogs (e.g. latanoprost, bimatoprost, travoprost); *and*
    b. At least ONE (1) 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. Rhopressa [netarsudil]); *AND*

~patient-specific, clinically significant reason(s) must be provided, explaining why the member requires Durysta (bimatoprost intracameral implant) and cannot continue to utilize ophthalmic preparations, such as solution or suspension, to treat their OAG or OHT.

5. The member meets ALL of the following:
    a. No evidence the member will be using other ophthalmic prostaglandin analogs in the same eye as the Durysta (bimatoprost intracameral implant); *and*
    b. No evidence of ocular or periocular infections present; *and*
    c. No evidence of corneal endothelial dystrophy (e.g., Fuchs dystrophy); *and*
    d. No evidence of absent or ruptured posterior lens capsule; *and*
    e. No evidence the member has undergone prior corneal transplantation or endothelial cell transplants [e.g., Descemet's Stripping Automated Endothelial Keratoplasty (DSAEK)]; *and*
    f. No evidence the member has known hypersensitivity to bimatoprost or any component of Durysta (bimatoprost intracameral implant); *and*
    g. No evidence 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); *and*
    h. No evidence 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 up to 2 lifetime implants if both eyes are treated, 1 per eye).[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Open-Angle Glaucoma or Ocular Hypertension

Requests for continuation of therapy or reauthorization of Durysta (bimatoprost intracameral implant) will NOT be approved as it is experimental/investigational and not medically necessary.

- The FDA-approved prescribing information for Durysta (bimatoprost intracameral implant) states that repeat administration is not recommended. Durysta (bimatoprost intracameral implant) 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 (bimatoprost intracameral implant). Additionally, Durysta (bimatoprost intracameral implant)

should be used in caution in those with limited corneal endothelial cell reserve, as they are more likely to experience corneal-related adverse effects.

- 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 (bimatoprost intracameral implant), the FDA has only approved Durysta (bimatoprost intracameral implant) for single administration per eye, over an individual's lifetime. Repeat treatment, even in the same eye after an extended period, is not recommended.

Experimental or Investigational or Unproven / Not Medically Necessary[s]

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, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Treatment of angle-closure glaucoma.
- Treatment of secondary glaucomas without a primary open-angle glaucoma or ocular hypertension indication(e.g., neovascular glaucoma, pigmentary glaucoma, pseudoexfoliation glaucoma, uveitic glaucoma).
- Treatment of pediatric glaucoma. Durysta (bimatoprost intracameral implant) has not been adequately studied in the pediatric population.
- Repeat administration or retreatment of the same eye with an additional Durysta (bimatoprost intracameral implant), due to the high risk of corneal endothelial cell loss.
- Prophylaxis of ocular hypertension in the absence of glaucomatous optic neuropathy.
- Concurrent use of Durysta (bimatoprost intracameral implant) with iDose TR (travoprost intracameral implant).
- Treatment of thyroid eye diseases. While bimatoprost solution has been studied for this indication, Durysta (bimatoprost intracameral implant) is not FDA-approved or indicated for thyroid eye diseases.

Applicable Billing Codes

Table 1	
CPT/HCPCS codes for open-angle glaucoma or ocular hypertension 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

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
B73.02	Onchocerciasis with glaucoma
G93.2	Benign intracranial hypertension
H26.231	Glaucomatous flecks (subcapsular), right eye
H26.232	Glaucomatous flecks (subcapsular), left eye
H26.233	Glaucomatous flecks (subcapsular), bilateral
H26.239	Glaucomatous flecks (subcapsular), unspecified eye
H40.001	Preglaucoma, unspecified, right eye
H40.002	Preglaucoma, unspecified, left eye
H40.003	Preglaucoma, unspecified, bilateral
H40.009	Preglaucoma, unspecified, unspecified eye
H40.011	Open angle with borderline findings, low risk, right eye
H40.012	Open angle with borderline findings, low risk, left eye
H40.013	Open angle with borderline findings, low risk, bilateral
H40.019	Open angle with borderline findings, low risk, unspecified eye
H40.021	Open angle with borderline findings, high risk, right eye
H40.022	Open angle with borderline findings, high risk, left eye

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
H40.023	Open angle with borderline findings, high risk, bilateral
H40.029	Open angle with borderline findings, high risk, unspecified eye
H40.041	Steroid responder, right eye
H40.042	Steroid responder, left eye
H40.043	Steroid responder, bilateral
H40.049	Steroid responder, unspecified eye
H40.051	Ocular Hypertension, Right Eye
H40.052	Ocular Hypertension, Left Eye
H40.053	Ocular Hypertension, Bilateral
H40.059	Ocular Hypertension, Unspecified Eye
H40.061	Primary angle closure without glaucoma damage, right eye
H40.062	Primary angle closure without glaucoma damage, left eye
H40.063	Primary angle closure without glaucoma damage, bilateral
H40.069	Primary angle closure without glaucoma damage, 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

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
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
H40.1310	Pigmentary glaucoma, right eye, stage unspecified
H40.1311	Pigmentary glaucoma, right eye, mild stage
H40.1312	Pigmentary glaucoma, right eye, moderate stage
H40.1313	Pigmentary glaucoma, right eye, severe stage
H40.1314	Pigmentary glaucoma, right eye, indeterminate stage
H40.1320	Pigmentary glaucoma, left eye, stage unspecified
H40.1321	Pigmentary glaucoma, left eye, mild stage

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
H40.1322	Pigmentary glaucoma, left eye, moderate stage
H40.1323	Pigmentary glaucoma, left eye, severe stage
H40.1324	Pigmentary glaucoma, left eye, indeterminate stage
H40.1330	Pigmentary glaucoma, bilateral, stage unspecified
H40.1331	Pigmentary glaucoma, bilateral, mild stage
H40.1332	Pigmentary glaucoma, bilateral, moderate stage
H40.1333	Pigmentary glaucoma, bilateral, severe stage
H40.1334	Pigmentary glaucoma, bilateral, indeterminate stage
H40.1390	Pigmentary glaucoma, unspecified eye, stage unspecified
H40.1391	Pigmentary glaucoma, unspecified eye, mild stage
H40.1392	Pigmentary glaucoma, unspecified eye, moderate stage
H40.1393	Pigmentary glaucoma, unspecified eye, severe stage
H40.1394	Pigmentary glaucoma, unspecified eye, indeterminate stage
H40.1410	Capsular glaucoma with pseudoexfoliation of lens, right eye, stage unspecified
H40.1411	Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412	Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413	Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414	Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1420	Capsular glaucoma with pseudoexfoliation of lens, left eye, stage unspecified
H40.1421	Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422	Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
H40.1423	Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424	Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1430	Capsular glaucoma with pseudoexfoliation of lens, bilateral, stage unspecified
H40.1431	Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432	Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433	Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434	Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage
H40.1490	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, stage unspecified
H40.1491	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, mild stage
H40.1492	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, moderate stage
H40.1493	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, severe stage
H40.1494	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye, indeterminate stage
H40.831	Aqueous misdirection, right eye
H40.832	Aqueous misdirection, left eye
H40.833	Aqueous misdirection, bilateral
H40.839	Aqueous misdirection, unspecified eye
H40.841	Neovascular secondary angle closure glaucoma, right eye
H40.842	Neovascular secondary angle closure glaucoma, left eye
H40.843	Neovascular secondary angle closure glaucoma, bilateral
H40.849	Neovascular secondary angle closure glaucoma, unspecified eye

Table 2	
ICD-10 diagnosis codes considered medically necessary open-angle glaucoma or ocular hypertension with Table 1 (CPT/HCPCS) codes if criteria are met:	
Code	*Description*
H40.89	Other specified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere
H44.511	Absolute glaucoma, right eye
H44.512	Absolute glaucoma, left eye
H44.513	Absolute glaucoma, bilateral
H44.519	Absolute glaucoma, unspecified eye
H47.231	Glaucomatous optic atrophy, right eye
H47.232	Glaucomatous optic atrophy, left eye
H47.233	Glaucomatous optic atrophy, bilateral
H47.239	Glaucomatous optic atrophy, unspecified eye
Q15.0	Congenital glaucoma

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