iDose TR (travoprost 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).

iDose TR (travoprost intracameral implant) is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). It consists of a microscopic, preloaded titanium intracameral implant that delivers a sustained release of travoprost directly into the anterior chamber of the 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 **iDose TR (travoprost 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 iDose TR 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 iDose TR implant; ***or***
    b. There are ocular or periocular infections present; ***or***
    c. The member has corneal endothelial dystrophy; ***or***
    d. The member has undergone prior corneal transplantation; ***or***
    e. The member has known hypersensitivity to travoprost or any other component of iDose TR; ***or***
    f. The member has previously received an iDose TR implant in the requested eye (i.e., for retreatment of the same eye with an additional iDose TR implant); ***or***
    g. The request exceeds the Plan's limit of one 75 mcg intracameral implant per affected eye.

If the above prior authorization criteria are met, iDose TR (travoprost 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

Reauthorization of iDose TR (travoprost intracameral implant) will not be approved.

- The iDose TR intracameral implant is designed as a single administration treatment to provide sustained release of travoprost over an extended period. The safety and efficacy of repeat dosing or implantation of iDose TR in the same eye has not been established in clinical trials.

The prescribing information states that iDose TR should not be readministered to an eye that received a prior iDose TR implant.

- In the pivotal Phase 3 trials that led to FDA approval (GC-010 and GC-012), iDose TR was studied as a single administration in each eye. These studies demonstrated clinically relevant IOP lowering and a favorable safety profile through 12 months post-implantation. However, data is not available on repeat administration of iDose TR to guide reauthorization criteria.

Experimental or Investigational / Not Medically Necessary

iDose TR (travoprost 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 advanced glaucoma with severe visual field loss
- Treatment of pediatric glaucoma
- Repeat administration or retreatment of the same eye with an additional iDose TR 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*
11981	Insertion, drug-delivery implant (ie, bioresorbable, biodegradable, non-biodegradable)
11982	Removal, non-biodegradable drug delivery implant
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
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

References

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Clinical Guideline Revision / History Information

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