NOTE: This policy is not effective until September 1, 2025.

Medical Policy Manual Surgery, Policy No. 237

Travoprost Drug-eluting Ocular Implants for the Treatment of Glaucoma

Effective: September 1, 2025

Next Review: April 2026
Last Review: April 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The iDoseTR is a sustained-release drug (Travoprost) eluting ocular implant which is inserted intracamerally and releases medication over a prolonged period of time for the treatment of open angle glaucoma or ocular hypertension.

MEDICAL POLICY CRITERIA

Note: *This policy does not address ocular inserts such as drug eluting rings, punctual plugs or contact lenses.*

Travoprost drug eluting ocular implants (e.g. iDose®TR) are considered **investigational** for the treatment of open angle glaucoma or ocular hypertension.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Optical Coherence Tomography (OCT) of the Anterior Eye Segment, Medicine, Policy No. 133

2. Transciliary Fistulization for the Treatment of Glaucoma, Surgery, Policy No. 150
3. Laser Trabeculotomy and Trabeculostomy, Surgery, Policy No. 227

BACKGROUND

Primary open-angle glaucoma (POAG) is a chronic progressive ocular disease in which there is acquired atrophy of the optic nerve and loss of the retinal ganglion cells and their axons. Glaucoma (both open-angle and angle-closure) is a leading cause of irreversible blindness globally. A primary goal of treatment is to maintain intraocular pressure (IOP) with a range at which visual field loss is unlikely to substantially reduce a patient's health-related quality of life. Reduction of IOP is achieved by either increasing aqueous movement through the trabecular and/or uveoscleral outflow or by reducing aqueous production. The IOP can be lowered by medical treatment, laser or incisional surgery. For medical treatment, prostaglandin analogs are the most frequently prescribed eye drops for lowering IOP in patients. However, medical management is often limited by poor adherence to topical eye drops as well as local and systemic side effects.[1]

A variety of sustained-release drug eluting ocular implants are being developed as alternatives to topical delivery of IOP-lowering medications requiring daily dosing. These include travoprost (a prostaglandin analog) eluting intracameral implants (e.g., iDose®TR).

REGULATORY STATUS

The iDose®TR (Glaukos) was granted a New Drug Application (NDA) approval from the FDA in December 2023 (NDA# 218010).[2] The iDose TR is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). The iDose®TR contains 75 mcg of travoprost pre-loaded in a single-dose inserter which is administered intracamerally through a small, clear corneal incision and is anchored into the sclera at the iridocorneal angle. The iDose®TR should not be readministered to an eye that received a prior iDose®TR. The iDose®TR (travoprost intracameral implant) is contraindicated in patients with:

- active or suspected ocular or periocular infections.
- corneal Endothelial Dystrophy (e.g., Fuch's Dystrophy, corneal guttatae).
- prior corneal transplantation, or endothelial cell transplants (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]).
- hypersensitivity to travoprost or to any other components of the product.

EVIDENCE SUMMARY

IDOSE®TR (TRAVOPROST INTRACAMERAL IMPLANT)

Sarkisian (2024) published a prospective, multicenter, randomized, double-masked pivotal phase 3 trial evaluating the efficacy and safety of the travoprost intracameral SE-implant (slow-eluting implant, the intended commercial product) and FE-implant (fast-eluting implant, included primarily for masking purposes) compared to twice-daily (BID) timolol ophthalmic solution, 0.5% in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).[3] The primary efficacy endpoints were the mean change from baseline intraocular pressure (IOP) at 8 A.M. and 10 A.M. at day 10, week 6, and month 3. Non-inferiority was achieved if the upper 95% confidence interval (CI) on the difference in IOP change from baseline (implant minus timolol) was < 1.5 mmHg at all six timepoints and < 1 mmHg at three or more

timepoints. The results showed that the slow-eluting (SE) implant was non-inferior to timolol eye drops in IOP lowering over 12 months, with a significantly greater proportion of patients in the SE-implant group (83.5%) compared to the timolol group (23.9%) on fewer topical glaucoma medications at month 12 compared to screening (P < 0.0001, chi-square test). Similarly, the fast-eluting (FE) implant was non-inferior to timolol over 9 months, with 78.7% of patients in the FE-implant group on fewer topical glaucoma medications at month 12 compared to screening (P < 0.0001, chi-square test). Adverse effects were mostly mild, with treatment-emergent adverse events (TEAEs) reported in 39.5% of patients in the SE-implant group, 34.0% in the FE-implant group, and 20.1% in the timolol group. Study limitations include lack of long-term follow-up, the sham administration procedure for the timolol group and possible conflict of interest.

Sarkisian (2024) published the results of one of the phase three trials to evaluate the safety and IOP-lowering efficacy of two models of the travoprost intraocular implant (fast-eluting [FE] and slow-eluting [SE]).[4] The primary outcome was the mean change from baseline intraocular pressure (IOP) in the study eye at 8 am and 10 am, at each of day 10, week 6, and month 3. The travoprost intraocular implant (both fast-eluting [FE] and slow-eluting [SE] types) demonstrated robust IOP reduction over the 3-month primary efficacy evaluation period after a single administration. The mean IOP reduction from baseline over the six time points ranged from 6.6 to 8.4 mmHg for the FE implant group, from 6.6 to 8.5 mmHg for the SE implant group, and from 6.5 to 7.7 mmHg for the timolol group. The primary efficacy endpoint was met, with the upper limit of the 95% confidence interval of the difference between the implant groups and the timolol group being < 1 mmHg at all 6 time points, indicating noninferiority. Adverse events (AEs) were reported in 21.5% of patients in the FE implant group, 27.2% in the SE implant group, and 10.8% in the timolol group, with the most common AEs including iritis (FE implant, 0.5%; SE implant, 5.1%), ocular hyperemia (FE implant, 3.0%; SE implant, 2.6%), reduced visual acuity (FE implant, 1.0%; SE implant, 4.1%; timolol, 0.5%), and IOP increased (FE implant, 3.5%; SE implant, 2.6%; timolol, 2.1%). One serious study eye AE occurred (endophthalmitis). The study's limitations include the short follow-up period of 3 months, use of a sham administration procedure for the timolol group and possible conflict of interest.

Bacharach (2024) published a post-hoc analysis study to compare the intraocular pressure (IOP) treatment effects of the slow-eluting (SE) travoprost intracameral implant and topical prostaglandin analog (PGA) monotherapy in a subgroup subjects (n = 133) who were on pre-study PGA monotherapy prior to enrollment in two pivotal phase 3 trials.[5] The primary efficacy endpoint was the IOP-lowering treatment effect. The subjects were analyzed for the IOP

treatment effects of the pre-study topical PGA monotherapy and the in-study SE

travoprost intracameral implant. The SE travoprost intracameral implant demonstrated a significantly greater IOP-lowering treatment effect (-7.07 mmHg) compared to pre-study topical PGA monotherapy (-5.76 mmHg), with a superiority margin of 1.31 mmHg (95% confidence interval: -2.01, -0.60; P = 0.0003).

Singh (2024) published a pooled 12-month analysis of two prospective, multi-center, randomized, double-masked, controlled trials to assess the efficacy and safety of the travoprost intracameral implant in subjects (n = 1150) with open-angle glaucoma (OAG) or ocular hypertension (OHT). The primary efficacy endpoints were intraocular pressure (IOP) reduction and reduction in topical IOP-lowering medications. The travoprost intracameral implant demonstrated IOP-lowering efficacy, with a reduction in mean diurnal IOP of 6.8-8.5

mmHg in the slow-eluting (SE) implant group and 6.9-8.5 mmHg in the fast-eluting (FE) implant group, which was statistically non-inferior to timolol. At month 12, 77.6% of FE and 81.4% of SE implant eyes were completely free of all topical IOP-lowering medications, and a significantly greater proportion of FE and SE implant eyes (89.9% and 93.0%) versus sham/timolol eyes (66.9%) were on the same or fewer topical IOP-lowering medications compared with pre-study ($p < 0.0001$). The most common treatment-emergent adverse events (TEAEs) related to study treatment were hyperemia (conjunctival or ocular), iritis, and increased IOP.

Summary

The evidence for the iDose®TR is limited to two phase three parallel-group randomized clinical trials. In both trials iDose TR was compared to twice-daily topical administration of timolol maleate ophthalmic solution, 0.5%. iDose TR demonstrated non-inferiority to timolol ophthalmic solution in IOP reduction during the first three months. Subsequently, iDose TR did not demonstrate non-inferiority over the next nine months. Adverse events include increase in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperemia and reduced visual acuity. The evidence is insufficient to determine that travoprost drug eluting ocular inserts (e.g., iDose®TR) result in an improvement in the net health outcome.

PRACTICE GUIDELINE SUMMARY

American Academy of Ophthalmology[1]

The 2020 American Academy of Ophthalmology (AAO) preferred practice guidelines for the treatment of primary open-angle glaucoma recognize that adherence to topical eye-drops may be a barrier to optimal therapy, and notes that multiple drug delivery systems have been developed to address this issue, including Durysta®: These guidelines do not address the iDose®TR.

SUMMARY

There is not enough research to show that travoprost drug eluting ocular implants (e.g. iDose®TR) improve health outcomes when compared to the standard of care. No clinical guidelines based on research recommend travoprost drug eluting ocular implants (e.g. iDose®TR) for the treatment of open angle glaucoma or ocular hypertension. Therefore, travoprost drug eluting ocular implants (e.g. iDose®TR) are considered investigational for treatment of open angle glaucoma or ocular hypertension.

REFERENCES

1. Gedde SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern®. *Ophthalmology.* 2021;128(1):P71-p150. PMID: 34933745
2. U.S. Food and Drug Administration (FDA) Prescribing information for iDose TR. Secondary U.S. Food and Drug Administration (FDA) Prescribing information for iDose TR [cited 1/7/2024]. 'Available from:' https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/218010s000lbl.pdf.

3. Sarkisian SR, Ang RE, Lee AM, et al. Travoprost Intracameral Implant for Open-Angle Glaucoma or Ocular Hypertension: 12-Month Results of a Randomized, Double-Masked Trial. *Ophthalmol Ther.* 2024;13(4):995-1014. PMID: 38345710
4. Sarkisian SR, Jr., Ang RE, Lee AM, et al. Phase 3 Randomized Clinical Trial of the Safety and Efficacy of Travoprost Intraocular Implant in Patients with Open-Angle Glaucoma or Ocular Hypertension. *Ophthalmology.* 2024;131(9):1021-32. PMID: 38423216
5. Bacharach J, Doan LV, Stephens KG, et al. Travoprost Intracameral Implant Demonstrates Superior IOP Lowering Versus Topical Prostaglandin Analog Monotherapy in Patients with Open-Angle Glaucoma or Ocular Hypertension. *Ophthalmol Ther.* 2024;13(9):2357-67. PMID: 38985408

CODES

Codes	Number	Description
CPT	0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach
	0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug eluting implant
HCPCS	J7355	Injection, travoprost, intracameral implant, 1 mcg

Date of Origin: *April 2025*