Original Effective Date: 06/27/2024
Current Effective Date: 12/11/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C27707-A

iDose TR (travoprost intracameral implant)

PRODUCTS AFFECTED

iDose TR (travoprost intracameral implant)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Open-angle glaucoma (OAG), Ocular hypertension (OHT)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. OPEN-ANGLE GLAUCOMA (OAG) OR OCULAR HYPERTENSION (OHT):
   1. Documented diagnosis of open angle glaucoma (OAG) (i.e., primary OAG, pseudoexfoliation glaucoma, pigmentary glaucoma) OR ocular hypertension (OHT) requiring intraocular pressure-

lowering treatment
AND

2. Documented inadequate response, serious side effects, contraindication, or clinical rationale supporting the inappropriateness to ALL of the following anti-glaucoma medications [DOCUMENTATION REQUIRED of ALL therapy with dates of failed therapy or clinical events]:
   a) ONE Ophthalmic prostaglandin (e.g., latanoprost, bimatoprost, travoprost)
      AND
   b) ONE Beta-adrenergic blocker or combination product (e.g., carteolol, levobunolol, metipranolol, timolol, betaxolol, dorzolamide plus timolol)
      AND
   c) ONE Alpha-2-agonist (brimonidine)

   AND
3. Documentation member has an inability to manage regular glaucoma eye drop use (e.g., due to age, dexterity, or comorbidities including visual impairment)
   AND
4. Member has not received prior iDose TR administration to the affected eye
   NOTE: iDose TR should not be readministered to an eye that received a prior iDose TR implant
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to iDose TR (travoprost intracameral implant) include: ocular or periocular infections, corneal endothelial dystrophy, prior corneal transplantation, hypersensitivity to travoprost or to any other components of the product]

CONTINUATION OF THERAPY:
N/A iDose TR should not be readministered to an eye that received a prior iDose TR implant

DURATION OF APPROVAL:
Initial authorization: 3 months, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified ophthalmologist, specialist in neuro-ophthalmology, or glaucoma specialist [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
ONE implant (75mcg) per eye per lifetime

PLACE OF ADMINISTRATION:
The recommendation is that intracameral implant medications in this policy will be for pharmacy or medical benefit coverage and the intracameral implant products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intracameral implant

DRUG CLASS:
Prostaglandins - Ophthalmic

FDA-APPROVED USES:
Indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT)

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
iDose TR efficacy was evaluated in two multicenter, 12-month, randomized, parallel-group, double-masked, controlled clinical trials in patients with OAG or OHT. In both trials (GC-010, NCT03519386, and GC012, NCT03868124), iDose TR was compared to twice-daily topical administration of timolol maleate ophthalmic solution, 0.5%. In the first 3 months following administration, iDose TR demonstrated an IOP change from baseline of -6.6 to -8.4 mmHg in the study eye of patients with a mean baseline IOP of 24 mmHg. iDose TR demonstrated non-inferiority to timolol ophthalmic solution in IOP reduction during the first 3 months. Subsequently, iDose TR did not demonstrate non-inferiority over the next 9 months, but in a previous Phase 2b study, 70% of responders were deemed well controlled on iDose TR with the same or fewer topical IOP lowering meds at 36 months.

Safety was evaluated in three randomized, double-masked clinical trials in which 868 patients with open angle glaucoma (OAG) or ocular hypertension (OHT) received an iDose TR and were followed for one year. The most commonly reported ocular adverse reactions (2% to 6%) were increases in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperaemia, and reduced visual acuity. Ocular adverse reactions reported in less than 2% of patients were conjunctival hemorrhage, photophobia, punctate keratitis, blepharitis, eye irritation, corneal abrasion, device dislocation, vitreous detachment, and foreign body sensation in eyes.

National and Specialty Organizations
American Academy of Ophthalmology (AAO)
The preferred practice guidelines (2015) for the treatment of primary OAG note that there are many considerations when choosing a target IOP, including the stage of the overall glaucoma damage as determined by the degree of structural optic nerve damage and/or functional visual field loss, the baseline IOP at which damage occurred, the age of the patient, and additional risk factors. The initial treatment choice may be influenced by potential cost, AE profile, and dosing schedule. The guidelines note prostaglandins as the most frequently used initial eye drops for lowering IOP in patients with glaucoma. The AAO does not prefer one prostaglandin over another. (Prum, 2015). Lowering the pretreatment IOP by ≥ 25% has been shown to slow the progression of primary OAG. If the target IOP is not achieved by one medication, switching, or adding medications should be considered, depending on whether the patient has responded to the first medication. The guideline recommends switching eye-drop agents or adding on for combination therapy when target IOP is not achieved with one drug alone. A more aggressive target (i.e., a lower target IOP) can be justified if there is more severe nerve damage or the damage is progressing rapidly; a less aggressive target IOP may be reasonable if the risks of treatment outweigh the benefits. The practice guidance has not been updated to include the use of iDose TR in its recommendations at the time of this review. Note: The Primary OAG guideline was corrected as of May 2021; however, the intent of the guideline

remains unchanged by the corrections.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of iDose TR (travoprost intracameral implant) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to iDose TR (travoprost intracameral implant) include: ocular or periocular infections, corneal endothelial dystrophy, prior corneal transplantation, hypersensitivity to travoprost or to any other components of the product.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J7355	Injection, travoprost, intracameral implant, 1 microgram

AVAILABLE DOSAGE FORMS:
iDose TR IMPL 75MCG single-dose inserter

REFERENCES

1. iDose® TR (travoprost intracameral implant), for intracameral administration [prescribing information]. San Clemente, CA: Glaukos Corp.; December 2023.
2. Prum BE Jr, Lim MC, Mansberger SL, Stein JD, Moroi SE, Gedde SJ, Herndon LW Jr, Rosenberg LF, Williams RD. Primary open-angle glaucoma suspect preferred practice pattern(®) guidelines. Ophthalmology. 2016 Jan;123(1):P112-51. doi: 10.1016/j.ophtha.2015.10.055. Epub 2015 Nov 12. Erratum in: Ophthalmology. 2018 Jun;125(6):949. PMID: 26581560.
3. American Academy of Ophthalmology (AAO). Primary open-angle glaucoma. Published 2020. Accessed February 2024. https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp.
4. Gedde SJ, Vinod K, Wright MM, Muir KW, Lind JT, Chen PP, Li T, Mansberger SL. American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Panel. Primary Open-Angle Glaucoma Preferred Practice Pattern®. Ophthalmology. 2021 Jan;128(1):P71-P150. doi: 10.1016/j.ophtha.2020.10.022. Epub 2020 Nov 12. PMID: 34933745.
5. Li T, Lindsley K, Rouse B, et al. Comparative effectiveness of first-line medications for primary open-angle glaucoma: A systematic review and network meta-analysis. Ophthalmology 2016; 123:129. doi: 10.1016/j.ophtha.2015.09.005.
6. National Institute for Health and Clinical Excellence (NICE). (2017). Glaucoma: diagnosis and management NICE guideline. Retrieved from

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Coding/Billing Information	Q4 2024
NEW CRITERIA CREATION	Q2 2024