

Clinical Policy: Travoprost Implant (iDose TR)

Reference Number: CP.PHAR.672

Effective Date: 03.01.24

Last Review Date: 02.24

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Travoprost intracameral implant (iDose[®] TR) is a prostaglandin analog.

FDA Approved Indication(s)

iDose TR is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that iDose TR is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Open Angle Glaucoma and Ocular Hypertension (must meet all):

1. Diagnosis of OAG or OHT;
2. Prescribed by or in consultation with an ophthalmologist;
3. Age \geq 18 years;
4. Medical justification supports inability to manage regular glaucoma eye drop use (e.g., due to age or comorbidities including visual impairment);
5. The affected eye has not received prior treatment with iDose TR;
6. At the time of request, member has none of the following contraindications:
 - a. Active or suspected ocular or periocular infection;
 - b. Diagnosis of corneal endothelial cell dystrophy (e.g., Fuchs' Dystrophy, corneal guttatae);
 - c. History of corneal transplantation or endothelial cell transplant (e.g., Descemet's Stripping Automated Endothelial Keratoplasty [DSAEK]);
 - d. Hypersensitivity to travoprost or to any other component of iDose TR;
7. Dose does not exceed both of the following (a and b):
 - a. 75 mcg per eye;
 - b. One implant per eye.

Approval duration: one implant per eye (lifetime total)

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Open Angle Glaucoma and Ocular Hypertension

1. Re-authorization is not permitted. Members must meet the initial approval criteria.
Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

<p>DSAEK: Descemet’s Stripping Automated Endothelial Keratoplasty</p>	<p>IOP: intraocular pressure OAG: open-angle glaucoma OHT: ocular hypertension</p>
<p>FDA: Food and Drug Administration</p>	

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): ocular or periocular infections, corneal endothelial dystrophy, prior corneal transplantation, hypersensitivity to travoprost or to any other component of the product
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
OAG, IOH	<p>Intracameral implant containing 75 mcg of travoprost in a drug delivery system</p> <p><u>General Information:</u> iDose TR is a travoprost delivery system consisting of a travoprost releasing implant pre-loaded in a sterile, single-dose inserter. iDose TR is administered intracamerally through a small, clear corneal incision and is anchored into the sclera at the iridocorneal angle. iDose TR should not be readministered to an eye that received a prior iDose TR.</p> <p><u>Administration:</u> The procedure must be carried out under aseptic conditions which include use of sterile gloves and a sterile drape. The eye should be anesthetized using general, retrobulbar, peribulbar, or topical anesthesia per standard operating room procedures. The iDose TR implantation procedure must be performed under magnification that allows clear visualization of the anterior chamber angle and angle structures including trabecular meshwork, with the patient’s head in a stabilized position. The pupil should not be dilated prior to the procedure. <i>See package insert for additional instructions.</i></p>	One implant per eye

VI. Product Availability

Intracameral implant in a pre-loaded single-dose inserter: 75 mcg travoprost

VII. References

1. iDose TR Prescribing Information. San Clemente, CA: Glaukos Corp.; December 2023. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/218010s0001b1.pdf. Accessed December 20, 2023.
2. Gedde SJ, Vinod K, Wright MM, et al. Primary Open-Angle Glaucoma Preferred Practice Pattern[®] Guidelines. Ophthalmology; November 2020. Available at: <https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp>. Accessed December 20, 2023.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.20.23	02.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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