travoprost Implant (iDose® TR)

Medicare Advantage Medical Policy # 096
Original Effective Date: 06/01/2025
Current Effective Date: 06/01/2025

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider travoprost implant (iDose® TR)‡ for the treatment of open-angle glaucoma or ocular hypertension to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for travoprost implant (iDose TR) will be considered when all of the following criteria are met:

- Patient is using the requested drug for the reduction of elevated intraocular pressure due to open angle glaucoma OR for the reduction of elevated intraocular pressure due to ocular hypertension; AND
- Patient is 18 years of age or older; AND
- Dose does NOT exceed one 75 mcg implant per eye; AND
- Patient has NOT previously received the requested drug in the requested eye; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) a GENERIC ophthalmic prostaglandin (e.g., latanoprost, bimatoprost, travoprost) after at least one month of therapy unless there is clinical evidence or patient history that suggests the required GENERIC products will be ineffective or cause an adverse reaction to the patient; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) a GENERIC ophthalmic beta-adrenergic blocker or combination product (e.g., betaxolol, carteolol, levobunolol, timolol, dorzolamide plus timolol) after at least one month of therapy unless there is clinical evidence or patient history that suggests the use of the required GENERIC products will be ineffective or cause an adverse reaction to the patient; AND
- The requested medication will NOT be used in combination with bimatoprost implant (Durysta™)‡.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Health Plan considers the use of travoprost implant (iDose TR) when the patient has NOT tried and failed the prerequisite medications for at least one month EACH to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of travoprost implant (iDose TR) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

iDose TR is a prostaglandin analog that is indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension. It is an intracameral implant that contains 75 mcg of travoprost and is believed to work by reducing intraocular pressure by increasing uveoscleral outflow, though its exact mechanism of action is unknown. The recommended dose of iDose TR is one implant per eye. iDose TR should not be readministered to an eye that has received a prior dose, and exactly how long the implant's efficacy lasts has yet to be determined. Although there are no specific recommendations on removal of the implant after it has lost its efficacy, it is recommended that the implant be surgically removed only if it becomes dislocated. iDose TR is the second intracameral prostaglandin analog, after bimatoprost implant (Durysta), to become available.

Open-angle glaucoma is an optic neuropathy characterized by progressive peripheral visual loss. The peripheral vision loss is often followed by central field loss. Open-angle glaucoma is typically accompanied by intraocular pressure increases caused by increased aqueous production and/or decreased aqueous outflow. Elevated intraocular pressure presents a major risk factor for glaucomatous field loss. The higher the level of intraocular pressure, the greater the likelihood of optic nerve damage and visual field loss. Ocular hypertension is distinguished from glaucoma in that there are no detectable changes in vision, no evidence of visual field loss, and no damage to the optic nerve. Patients diagnosed with ocular hypertension are at an increased risk of developing glaucoma. Typical treatments for open-angle glaucoma and ocular hypertension include drug classes such as ophthalmic prostaglandins (e.g. latanoprost) and ophthalmic beta blockers (e.g. timolol), both of which have generic products available in their respective classes.

The American Academy of Ophthalmology (AAO) preferred practice guidelines for the treatment of primary open-angle glaucoma note that the initial therapy choice may be influenced by cost, adverse event profile, comorbid conditions and dosing schedules. The guidelines note prostaglandins as the most frequently used initial eye drops for lowering intraocular pressure in patients with glaucoma. The AAO does not prefer one prostaglandin over another. Other ophthalmic drugs for the treatment of glaucoma include beta-adrenergic blockers, alpha2-adrenergic agonists, rho kinase inhibitors, and carbonic anhydrase inhibitors.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

iDose TR is a prostaglandin analog indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

iDose TR was evaluated in two multicenter, 12-month, randomized, parallel-group, double-masked, controlled clinical trials in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). In both trials (GC-010 and GC012), 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.

References

1. iDose TR [package insert]. Glaukos Corp. San Clemente, California. Updated December 2023.
2. iDose Drug Evaluation. Express Scripts. February 2024.
3. Open-angle glaucoma: Treatment. UpToDate. Accessed August 2024.

Policy History

Original Effective Date: 06/01/2025
Current Effective Date: 06/01/2025
03/18/2025 UM Committee Review (New Policy)
Next Scheduled Review Date: 03/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0660T, 0661T
HCPCS	J7355
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.