



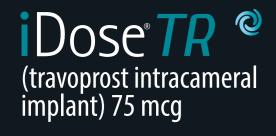
# A STEP-BY-STEP GUIDE TO COVERAGE AND REIMBURSEMENT

#### **INDICATIONS AND USAGE**

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

Please see Important Safety Information on page 15 and full Prescribing Information.





Coverage dynamics

This guide provides step-by-step guidance on claim submissions, billing and product coding, appeal processes, and Glaukos patient support.

Glaukos provides this coding guide for informational purposes only and it is subject to change without notice. This guide is not an affirmative instruction as to which codes and modifiers to use for a particular service, supply, procedure, or treatment and does not constitute advice regarding coding, coverage, or payment for Glaukos products. It is the responsibility of providers, physicians, and suppliers to determine and submit appropriate codes, charges, and modifiers for products, services, supplies, procedures, or treatment furnished or rendered. Providers, physicians, and suppliers should contact their third-party payers for specific and current information on their coding, coverage, and payment policies. For further detailed product information, including indications for use, contraindications, effects, precautions, and warnings, please consult the product's Prescribing Information prior to use. The information provided herein is without any other warranty or guarantee of any kind, expressed or implied, as to completeness, accuracy, or otherwise. This information is intended only to help estimate Medicare payment rates and product costs in the hospital outpatient department setting.

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## iDose TR coverage



iDose TR is a procedure-based treatment that is administered by a healthcare provider in an outpatient setting.1

#### Outpatient settings may include<sup>2</sup>:

- Ambulatory surgical centers (ASCs)
- Hospital outpatient departments (HOPDs)
- Office-based settings





Covered for 100% of Medicare Fee-for-Service (FFS) patients



Available for patients with Medicare Advantage (MA) plans



May also be available for patients with commercial payers

Some Medicare Advantage plans and commercial payers may require a prior authorization (PA) before covering iDose TR.<sup>3,4</sup> If appropriate, conducting a benefits verification can determine if individual plans require a PA or step therapy.

#### Medicare FFS Part B covers 80% of iDose TR cost<sup>3</sup>

The majority of FFS beneficiaries have some type of supplemental coverage<sup>5</sup>:

**Approximately 89% of Medicare FFS beneficiaries** have some form of supplemental insurance, which can help cover copays



**41% of Medicare FFS beneficiaries** have a Medigap plan that may help cover Part B coinsurance costs (20%)

Development of medical policies for treatments that are newly FDA approved, such as iDose TR, typically occur in the months following approval. Always check with the patient's payer to determine coverage rules.<sup>6</sup>

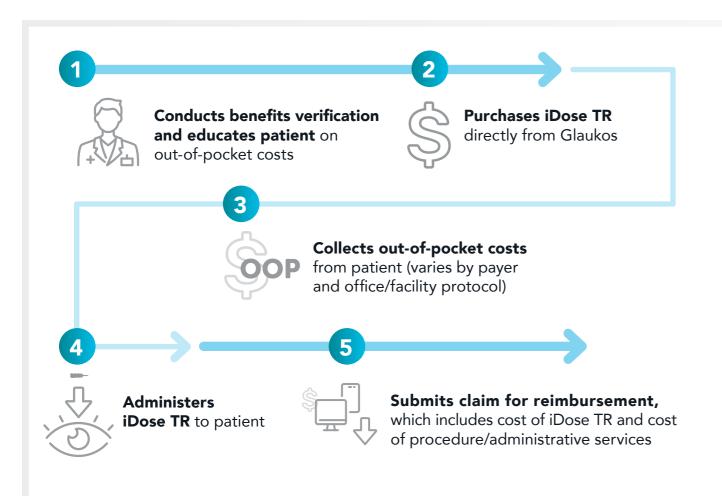
## Acquiring iDose TR through buy and bill



Many payers may allow iDose TR acquisition through the buy and bill process, where the provider purchases, stores, and then administers iDose TR to a patient.

Medicare FFS (Part B) requires iDose TR be acquired through buy and bill.7

#### In the buy and bill process, the healthcare provider8:



#### Ordering iDose TR

iDose TR can only be purchased directly from Glaukos. To place an order, contact Glaukos Customer Service:

Call: 949-367-9600 Fax: 949-367-9838

Email: CustomerService@glaukos.com

For more information, go to www.idosetrhcp.com



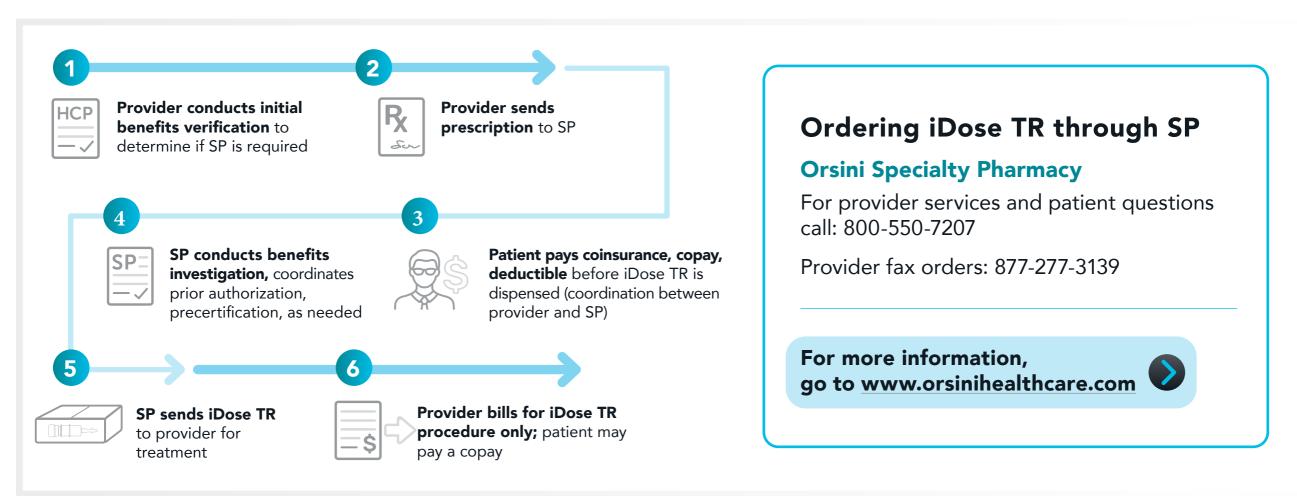
## Select commercial payers may require specialty pharmacy (SP) distribution



#### iDose TR is available exclusively through Orsini Specialty Pharmacy

Acquiring iDose TR through an SP may be required by some commercial payers.

#### In the SP distribution process<sup>9,10</sup>:



## Considerations for requesting a PA for iDose TR



Some Medicare Advantage plans and commercial payers may require a PA before covering iDose TR. Conducting a benefits verification can determine individual plan requirements.<sup>4,5</sup>



#### Tips for submitting PAs

Understand payer guidelines

Submit all required supporting documents with the PA request

Keep complete records, including a copy of everything you send to the patient's health insurance plan

#### Commonly requested information for PAs

Use the checklist below to help you navigate the approval process in the event that iDose TR requires a PA. Your Reimbursement Liaison can help you understand specific payer policies.

#### Complete and submit the PA form as required by the payer. Information required may include:

- ✓ Patient's name and date of birth
- ✓ Patient's health insurance policy number
- ✓ Patient's diagnosis/ICD-10-CM code(s)
- Provider details, specialty, contact information, and NPI number
- √ iDose TR National Drug Code (NDC)
- Medical documentation to support the treatment decision

#### If not part of the PA form, consider including the following:

- √ iDose TR full Prescribing Information
- ✓ Peer-reviewed journal articles

#### Payers may require a letter of medical necessity written on the provider's letterhead. If so, include the following:

- ✓ Patient's current symptoms or condition
- √ Rationale for treatment with iDose TR
- Patient-specific medical history related to the ICD-10-CM code(s)
- √ Diagnostic test results

✓ Previous treatment(s), duration and response or reason for discontinuation

If your patient's request for a PA is not granted, your Reimbursement Liaison can work with you to determine your next steps.

#### **HCPCS** codes

Claims for drugs that are physician-administered must be submitted with a HCPCS code when billed to a payer. Until iDose TR is assigned a permanent HCPCS code, providers should submit claims using a miscellaneous/not otherwise classified (NOC) HCPCS code.<sup>11</sup>



#### Keep in mind when billing with a miscellaneous/NOC code<sup>11,12</sup>:

- These codes allow providers to begin billing at FDA approval while a product-specific code is being established
- Claims may require a manual review by payers and may result in delayed payment
- Payers may require billing with a unit of "1"

Always confirm payer coding and billing guidance before submitting a claim.

#### The following miscellaneous/NOC HCPCS codes may be used<sup>13,14</sup>:

HCPCS Code	Description	Place of Service	Payer Type
C9399	Unclassified drugs or biologicals (Medicare hospital outpatient)	ASC or HOPD	Medicare FFS only
J3490 or C9399	Unclassified drugs or biologicals	ASC or HOPD	Medicare Advantage and commercial payers (Coding requirements will vary)
J3490	Unclassified drugs	Physician office	Medicare FFS, Medicare Advantage, and commercial payers

HCPCS = Healthcare Common Procedure Coding System.

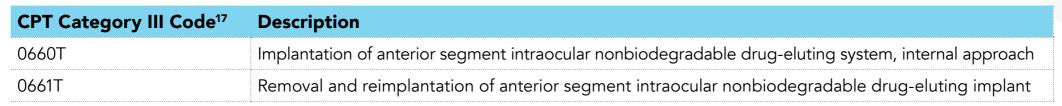
#### **National Drug Code**

- For drugs without a permanent HCPCS code, payers often require inclusion of the drug's NDC on the claim<sup>15</sup>
- While the FDA provides NDCs as 10-digit codes, some payers may require an 11-digit format<sup>15</sup>
- Converting the 10-digit NDC to an 11-digit NDC may be as simple as the payer requiring you to add a leading zero15
- Contact each payer for specific requirements, as they vary by payer<sup>15</sup>

	FDA-specified 10-Digit NDC (5-3-2 format) <sup>1</sup>	11-Digit NDC (5-4-2 format) <sup>1</sup>
iDose TR	25357-100-01	25357-0100-01

#### CPT® codes for drug administration services

CPT is the code set used to describe procedures and services performed by healthcare providers.<sup>16</sup>



CPT = Current Procedural Terminology.



CPT Category III Codes are a set of temporary (T) codes for emerging technologies, services, and procedures and are also referred to as T Codes.<sup>16</sup>

#### Diagnosis codes<sup>18</sup>

ICD-10-CM is the diagnosis code set used for all healthcare settings for medical claims reporting.

ICD-10-CM Code	Description
Open-angle glaucoma	
H40.10X	Unspecified open-angle glaucoma
H40.111	Primary open-angle glaucoma, right eye
H40.113	Primary open-angle glaucoma, bilateral
H40.119	Primary open-angle glaucoma, unspecified eye
H40.131	Pigmentary glaucoma, right eye
H40.132	Pigmentary glaucoma, left eye
H40.133	Pigmentary glaucoma, bilateral
H40.139	Pigmentary glaucoma, unspecified eye
H40.141	Capsular glaucoma with pseudoexfoliation of lens, right eye
H40.142	Capsular glaucoma with pseudoexfoliation of lens, left eye
H40.143	Capsular glaucoma with pseudoexfoliation of lens, bilateral
H40.149	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye

ICD-10-CM Code	Description
Ocular hypertension	
H40.051	Ocular hypertension, right eye
H40.052	Ocular hypertension, left eye
H40.053	Ocular hypertension, bilateral
H40.059	Ocular hypertension, unspecified eye

For open-angle glaucoma codes, please add the appropriate seventh character to reflect the stage of the patient's condition:

0 = stage unspecified

1 = mild stage

2 = moderate stage

3 = severe stage

4 = indeterminate stage

Please consult the ICD-10 Codebook for more information.

ICD-10-CM = International Classification of Diseases, Tenth Revision, Clinical Modification.

#### Place of Service codes<sup>19</sup>

Place of service (POS) codes are 2-digit numeric codes used to indicate the setting in which a healthcare service was provided and are generally used on professional claims.



POS Code	Location
24	Ambulatory surgical center
22	On campus - outpatient hospital
19	Off campus - outpatient hospital
11	Physician office

#### **Modifiers**

Modifiers are 2-digit codes that are added to a CPT or HCPCS code and used to provide additional information about an item or service provided.<sup>20</sup>

Modifier	Description
RT	Right side (used to identify procedures performed on the right side of the body)
LT	Left side (used to identify procedures performed on the left side of the body)
JZ	For single-dose containers where there are no discarded amounts*

<sup>\*</sup>Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts.<sup>21</sup>

#### Revenue codes<sup>22,23</sup>

Revenue codes are 4-digit numeric codes used only by hospital-based facilities to indicate through what department the procedure was performed or to identify supplies used in the procedure. Revenue codes are only used on institutional claims.

Revenue Code	Description
0636	Pharmacy, drugs requiring detailed coding $^\dagger$
0360	General, operating room services

<sup>†</sup>Hospital outpatient claims for Medicare FFS should be billed using the appropriate HCPCS codes under revenue code 0636.

## **Sample CMS-1500 Claim Form**



- The CMS-1500 claim form is typically used for implant and exchange procedures in ASC and provider office settings<sup>24,25</sup>
- The CMS-1500 claim form is shown here as an example. Check with individual payers for specific coding guidance and documentation requirements<sup>26</sup>

Item 19

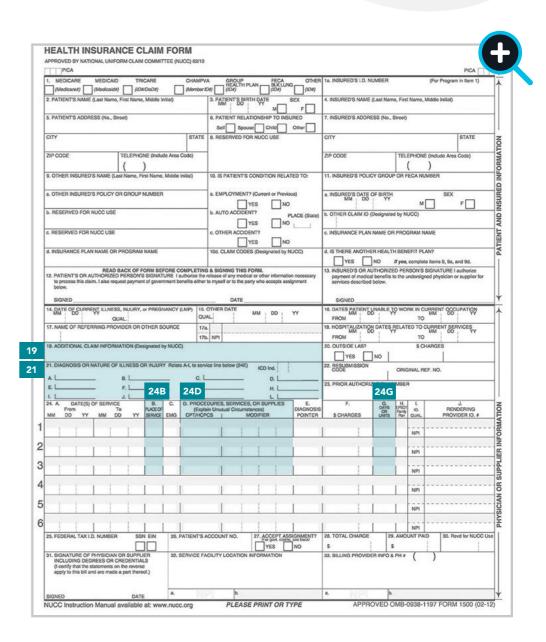
Additional Claim Information: Some payers may require additional information be provided. When billing with a miscellaneous HCPCS code, payers often require a detailed description of the drug that may include the drug name, NDC, strength, and dosage<sup>26</sup>

Diagnosis or Nature of Illness or Injury: Enter the appropriate ICD-10-CM code<sup>26</sup> Item 21

Item 24B Place of Service: Enter the appropriate POS code<sup>26</sup>

Procedures, Services, or Supplies: Enter the appropriate CPT and HCPCS codes, and modifiers if required. Document use of drug with the appropriate HCPCS (eq. J- or C-) Item 24D code and the appropriate CPT administration code(s) (eq. 0660T) on separate lines<sup>26</sup>

Days or Units: Include the number of units used for each line item. When billing Item 24G with a miscellaneous/NOC HCPCS code, bill 1 unit, regardless of dose<sup>26</sup>



### Sample CMS-1450 Claim Form



Access and

reimbursement support

- The CMS-1450 (also known as the UB-04) claim form is used to bill for services provided in the HOPD and ASC<sup>27</sup>
- Check with individual payers for specific coding guidance and documentation requirements<sup>28</sup>
- Revenue Code: Enter the appropriate code based on the cost center and service provided. In the HOPD setting, CMS requires revenue code 0636 be used when billing for a drug or biologic<sup>28</sup>
- FL 43

  Description: Enter a narrative description or standard abbreviation for each revenue code listed in FL42<sup>28</sup>
  - FL 44

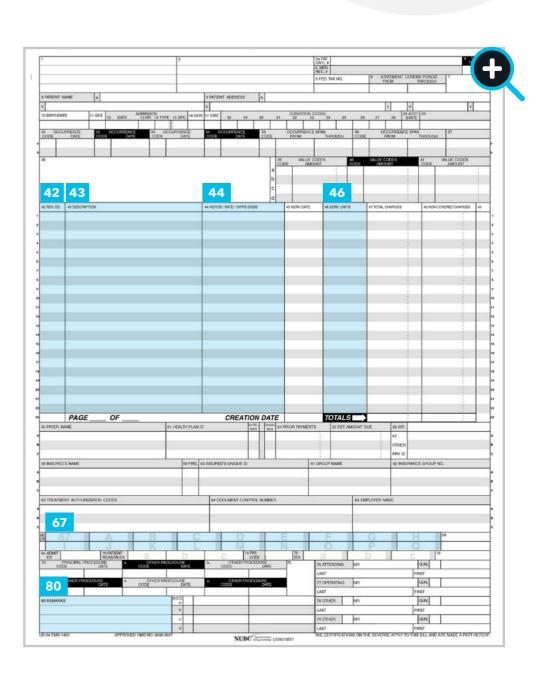
    HCPCS and Procedure Codes: Enter the appropriate CPT and HCPCS codes, and modifiers if required. Document use of drug with the appropriate HCPCS (eg, J- or C-) code and all appropriate CPT administration codes on separate lines<sup>28</sup>
  - FL 46

    Service Units: Include the number of units used for each line item. When billing with a miscellaneous HCPCS code, bill 1 unit, regardless of dose<sup>28</sup>
- FL 67

  Principal Diagnosis Code: Indicate the appropriate ICD-10-CM diagnosis code.
  FL 67A-67Q are reserved for additional diagnosis codes, if necessary<sup>28</sup>
- Remarks: Some payers may require additional information be provided. When billing with a miscellaneous/NOC HCPCS code, payers often require a detailed description of the drug, including drug name, NDC, strength, and dosage<sup>28</sup>

FI = form locator.

Coverage dynamics



#### Reimbursement for iDose TR





#### Medicare

For newly FDA approved products coded as C9399, Medicare FFS reimbursement is 95% of average wholesale price (AWP).<sup>14,29</sup>

Once iDose TR is established in the marketplace after 2 full quarters of sales, Medicare generally will reimburse based on a percentage of the average sales price (ASP)<sup>30-32</sup>

- CMS calculates ASP on a quarterly basis. The percentage may vary based on the treatment setting
- iDose TR reimbursement for ASCs, HOPDs, and physician offices will be based on ASP + 6%<sup>‡</sup> beginning October 1, 2024

<sup>‡</sup>2% sequestration (Medicare payment adjustment) continues until further notice.





#### **Commercial payers**

Commercial payer reimbursement varies and is based on the contracted rate with the provider. Review your contracts to understand your specific reimbursement rates.<sup>33</sup>



#### Medicaid

Medicaid reimbursement varies by state. Often, payment methodologies follow Medicare and are based on a percentage of ASP, wholesale acquisition cost (WAC), and AWP.<sup>34</sup>

Coverage dynamics

## Understanding denials and strategies for appeals



#### Why claims are denied<sup>35,36</sup>

Common reasons for denials include:

- New drug not yet reviewed by payer and considered nonformulary
- PA or precertification not submitted
- Missing information or data error in the coverage request
- Insurance information has changed or coverage has lapsed
- Failure to follow a step-edit (may apply to commercial payers and Medicare Advantage plans)

#### Medicare appeals process

If a patient with Medicare FFS is denied coverage for iDose TR, the decision can be appealed

- 1 Review the reason for the denial
- For Medicare FFS Part B claims, the first level of appeal is requesting a redetermination<sup>37</sup>

Complete a <u>Medicare Redetermination Request Form (CMS-20027)</u> or draft a letter that includes the patient's name, Medicare number, the service in question, the reason for appeal, and any supporting documentation.

- Send the completed form or letter, along with supporting documents, to the Medicare Administrative Contractor (MAC) that processed the claim
- 4 Track the redetermination request

The MAC is required to respond within 60 days. If there is no response within this time frame, you may request an expedited review.

- If redetermination request is unsuccessful, the appeal moves to a second-level appeal<sup>38</sup>
  - The process involves submitting a request to a Qualified Independent Contractor (QIC) within 180 days of the redetermination decision. Learn more here.

Remember that each appeal is unique. The appeal strategy needs to be based on the specific details provided in the denial notice.

## Glaukos supports patient access



Glaukos Patient Services (GPS) provides a wide array of services to help remove treatment barriers for patients so that you can focus on delivering exceptional patient care.



Coverage dynamics

## Overcome complex insurance coverage and reimbursement challenges

The GPS Reimbursement Liaison will review payer policies and help you understand coverage, documentation, and claim submission requirements.



#### Offer coding and billing guidance

The GPS Reimbursement Liaison will support your staff with education, guidance, and recommendations for the appropriate submission of claims.



#### Provide options for appeals support

The GPS Reimbursement Liaison will partner with your staff to support efficient reconciliation of claims for Glaukos products.

## iDose TR Patient Savings Program (for commercially insured patients)§

• Patients may pay as little as \$0 for one (1) iDose TR implant per eye. Subject to eligibility requirements.

§This offer applies to the iDose TR implant only and does not apply to costs for any other medication, procedure, or diagnostic service provided in conjunction with or supportive to the iDose TR treatment.

Review program eligibility and restrictions here, or contact GPS directly.



Patients can complete an online application here.





For additional support, speak to your GPS Reimbursement Liaison or contact GPS at gps@glaukos.com or 833-855-3031.



#### **IMPORTANT SAFETY INFORMATION**

#### Dosage and administration

For ophthalmic intracameral administration. The intracameral administration should be carried out under standard aseptic conditions.

#### Contraindications

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

#### Warnings and precautions

iDose TR should be used with caution in patients with narrow angles or other angle abnormalities. Monitor patients routinely to confirm the location of the iDose TR at the site of administration. Increased pigmentation of the iris can occur. Iris pigmentation is likely to be permanent.

#### Adverse reactions

In controlled studies, the most common ocular adverse reactions reported in 2% to 6% of patients were increases in intraocular pressure, iritis, dry eye, visual field defects, eye pain, ocular hyperaemia, and reduced visual acuity.

For more information, please visit www.glaukos.com.

Dose 7

implant) 75 mcg

(travoprost intracameral

#### **INDICATIONS AND USAGE**

iDose TR (travoprost intracameral implant) is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT). You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

#### Please see full Prescribing Information.

You may also call Glaukos at 1-888-404-1644.

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References 1. Dose TR. Peckage insert. Gludos Corp. 2022. 2. Singh IP. Data on the iDose intracameral traveprost sustained release implant. 3. Centers for Medicare & Medicare &

redetermination by a Medicare contractor. Accessed January 21, 2024. https://www.cms.gov/medicare/appeals-grievances/fee-for-service/first-level-appeal-redetermination-medicare-contractor. 38. Centers for Medicare & Medicaid Services.

Second level of appeal: reconsideration by a qualified independent contractor. Accessed January 21, 2024. https://www.cms.gov/medicare/appeals-grievances/fee-for-service/second-level-appeal

