



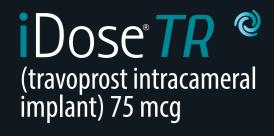
A STEP-BY-STEP GUIDE TO COVERAGE AND REIMBURSEMENT

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 16 and full Prescribing Information.





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 Instructions for Use (IFU) or prescribing information (PI) 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. Glaukos makes no guarantee of coverage or reimbursement.

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iDose® TR coverage



iDose TR is a standalone implantation procedure-based treatment that is administered by a healthcare provider in an outpatient setting.^{1,2}

Outpatient settings may include ambulatory surgical centers (ASCs), hospital outpatient departments (HOPDs), and office-based settings.²

iDose TR

Coverage



Available for patients with Medicare Advantage (MA) plans



Covered for most Medicare Fee-for-Service (FFS) patients



Available for patients with certain commercial payers

Cost and coverage for MA plans and commercial payers may vary³⁻⁶

Prior authorization (PA) may be required before covering iDose TR. Conducting a benefits verification can determine if individual plans require a PA or step therapy.

Medicare Part B covers 80% of iDose TR cost³

The majority (89%) of FFS beneficiaries have some type of supplemental coverage that can help cover copays, while 41% have a Medigap plan that may help with Part B coinsurance (20%).^{3,7}

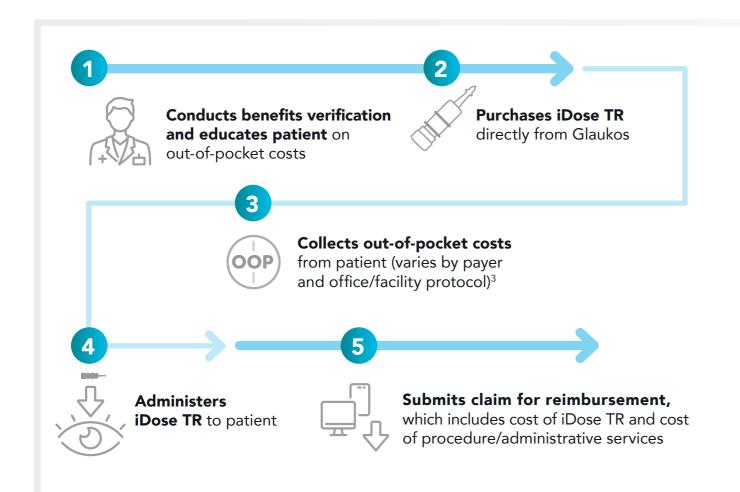
Always check with the patient's payer to determine coverage rules.

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.⁸

In the buy and bill process, the healthcare provider8:



Purchasing 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



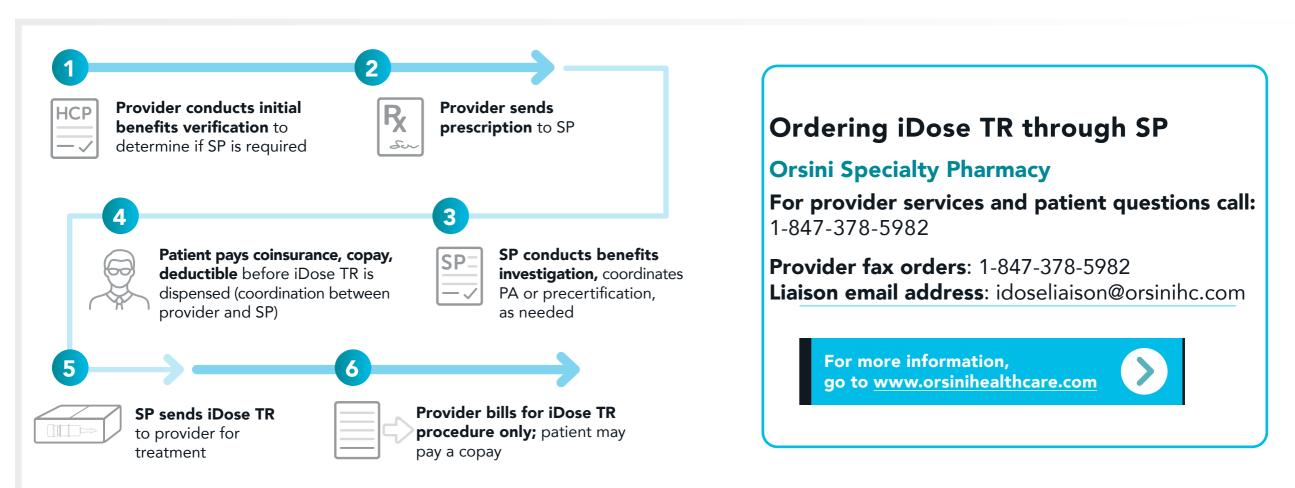
Select commercial payers may require specialty pharmacy (SP) distribution



iDose® TR is available exclusively through Orsini Specialty Pharmacy

Acquiring iDose TR through an SP may be required by some payers.9

In the SP distribution process⁹⁻¹²:



Considerations for requesting a PA for iDose® TR



Some MA plans and commercial payers may require a PA before covering iDose TR. Conducting a benefits investigation can determine individual plan requirements.⁴



Coverage

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 National Provider Identifier (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
- \checkmark 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
- ✓ Payer policy criteria

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

Coding for iDose® TR



HCPCS code

Claims for **drugs that are physician-administered** are submitted with a HCPCS code when billed to a payer.¹³

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

Effective July 1, 2024, the following HCPCS code may be used on claims for iDose® TR14:

HCPCS Code	Description
J7355	Injection, travoprost, intracameral implant, 1 microgram. iDose® TR is billed in 75 units

HCPCS = Healthcare Common Procedure Coding System.

CPT® codes for drug administration services

CPT is the code set used to describe procedures and services performed by healthcare providers.¹⁵

CPT Code ^{16,17}	Description
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

CPT = Current Procedural Terminology.

CPT® 2023 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

National Drug Code^{18,19}

- Payers often require inclusion of the drug's NDC on the claim
- While the FDA provides NDCs as 10-digit codes, some payers may require an 11-digit format
- Converting the 10-digit NDC to an 11-digit NDC may be as simple as the payer requiring you to add a leading zero
- Contact each payer for specific requirements, as they vary by payer

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

Diagnosis codes²⁰

ICD-10-CM is the diagnosis code set used for all healthcare settings for medical claims reporting.²¹

ICD-10-CM Code	Description
Open-angle glaucoma	
H40.10X0	Unspecified open-angle glaucoma
H40.111X	Primary open-angle glaucoma, right eye
H40.112X	Primary open-angle glaucoma, left eye
H40.113X	Primary open-angle glaucoma, bilateral
H40.131X	Pigmentary glaucoma, right eye
H40.132X	Pigmentary glaucoma, left eye
H40.133X	Pigmentary glaucoma, bilateral
H40.141X	Capsular glaucoma with pseudoexfoliation of lens, right eye
H40.142X	Capsular glaucoma with pseudoexfoliation of lens, left eye
H40.143X	Capsular glaucoma with pseudoexfoliation of lens, bilateral
H40.149X	Capsular glaucoma with pseudoexfoliation of lens, unspecified eye
Ocular hypertension	
H40.051X	Ocular hypertension, right eye
H40.052X	Ocular hypertension, left eye
H40.053X	Ocular hypertension, bilateral

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

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.



Place of Service codes²²

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.²³

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*

^{*}Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers where there are no discarded amounts.²⁴

Revenue codes^{25,26}

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
0360	General, operating room services

Reimbursement for iDose® TR





Commercial payer and MA plan reimbursement varies and is based on the contracted rate with the provider. Review your contracts to understand your specific reimbursement rates.²⁷



Medicare FFS

Reimbursement for ASCs, HOPDs, and physician offices is based on average sales price (ASP) + 6%.^{28-31†}

†2% sequestration (Medicare payment adjustment) continues until further notice.



Medicaid reimbursement varies by state. Often, payment methodologies follow Medicare and may be based on wholesale acquisition cost (WAC) and average wholesale price (AWP).³²

Ambulatory Payment Classification (APC) is the government's method for paying facilities for outpatient services through the Medicare program.³³

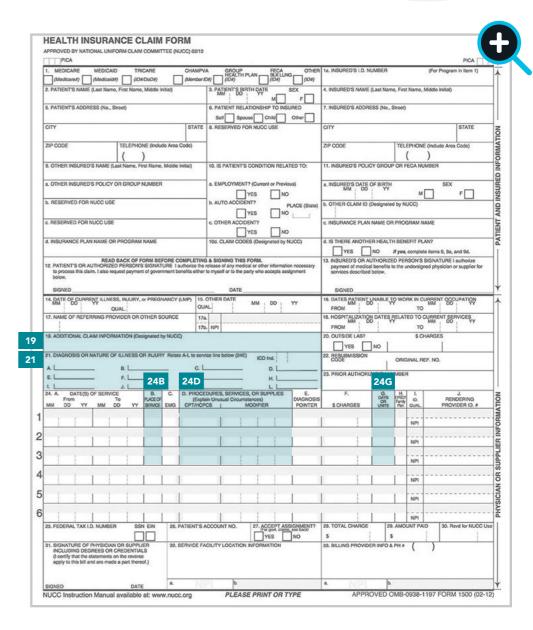
National unadjusted Medicare payments

CPT Code	Description
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

Coverage



- The CMS-1500 claim form is typically used for implant and exchange procedures in ASC and provider office settings^{36,37}
- The CMS-1500 claim form is shown here as an example. Check with individual payers for specific coding guidance and documentation requirements³⁸



Coverage



- The CMS-1450 (also known as the UB-04) claim form is used to bill for services provided in the HOPD and ASC³⁹
- Check with individual payers for specific coding guidance and documentation requirements⁴⁰

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^{1,26}

Description: Enter a narrative description or standard abbreviation for each revenue code listed in FL42

HCPCS and Procedure Codes: Enter the appropriate CPT and HCPCS codes and modifiers, if required. Document use of drug with the appropriate HCPCS code (eg, J-code) and all appropriate CPT administration codes on separate lines

FL 46 Service Units: Include the number of units used for each line item. iDose® TR is billed in 75 units¹

FL 67 Principal Diagnosis Code: Indicate the appropriate ICD-10-CM diagnosis code. FL 67A-67Q are reserved for additional diagnosis codes, if necessary

Remarks: Some payers may require additional information

42 43 TOTALS OUAL CUAL CUNL

FL = form locator.

FL 80

Understanding denials and appeals



Why claims are denied

Common reasons for denials include⁴¹⁻⁴³:

- Coding inaccuracies and missing or incorrect information, including unit dosing
- PA or precertification not submitted

- Failure to fulfill payer requirement to include letter of medical necessity
- Change in insurance
- Failure to follow policy requirements (eg, intolerance or an insufficient response to other ophthalmic prostaglandin analogs)
- For Medicare FFS, failure to respond to a Medicare <u>additional</u> documentation request (ADR)

Appealing a denial⁴⁴

If a patient is denied coverage for iDose® TR, the decision can be appealed.

	Medicare FFS ^{44,46}	Commercial ^{47,48}
REVIEW) the reason for the denial		
FILE an internal appeal		
 Level 1: REQUEST for reconsideration Standard requests must be made in writing, unless the enrollee's plan accepts verbal requests Requests must be made within 60 days of denial notification by the MA plan 	Level 1: REQUEST a redetermination Complete a Medicare Redetermination Request Form (CMS-20027) or draft a letter that includes the patient's name, Medicare number, specific date(s) of service, the service in question, the reason for appeal, and any supporting documentation	 SUBMIT a written appeal to the health planted requesting they reconsider the denial Typically allowed 180 days from receiving the der to file an internal appeal
SEND (MAC) that processed the claim		
The insurer must respond within specific timef	rames	
 The insurer must respond within specific timef 30 calendar days for standard pre-service requests No later than 72 hours for expedited pre-service benefit or Part B drug requests 7 calendar days for standard Part B drug requests 60 calendar days for payment requests 	• Within 60 days	30 days for standard appeals72 hours for expedited claims
 30 calendar days for standard pre-service requests No later than 72 hours for expedited pre-service benefit or Part B drug requests 7 calendar days for standard Part B drug requests 	• Within 60 days	30 days for standard appeals 72 hours for expedited claims

Managing additional documentation requests (ADRs) for Medicare claims





What is an ADR?

An ADR is generated when documentation is necessary to support a Medicare claim. **An ADR is not a denial,** but an interim step for Medicare to ensure that payment is made only for services that meet all Medicare coverage, coding, billing, and medical necessity requirements.⁴⁹

A timely response to ADRs is important. The claim will automatically be denied if a response has not been received by the specified date on the ADR.⁵⁰

How to respond to an ADR^{49,50}

- Prepare the requested documentation and use a copy of the ADR letter as the first page/cover sheet to ensure the documentation is matched to the appropriate patient and claim
- ✓ **Providers should submit the necessary documentation** to support the services for the billing period being reviewed. This may include documentation that is prior to the review period
- ✓ **Documentation may be received by** the MAC either via US Mail; esMD; the MAC-designated provider portal; fax; or on CD, DVD, or USB
- ✓ You have a set number of days from the date of the letter to provide documentation. For example, 30 days from the date on the ADR letter. Refer to the request letter for the specific time frame

Avoid these common mistakes⁵⁰

- X Never use your own cover sheet instead of the ADR letter. Forms you create to use as a cover sheet are not recognized by our system
 - If you are missing the ADR letter and cannot provide it as the cover sheet, indicate "ADR Response" and include the following critical information on your cover sheet: Medicare number, claim number, and dates of service on the claim
- X Never omit requested information. All information requested must be returned, otherwise the response may be incomplete and result in a denial
- × Never combine multiple requests into a single response. Combining documents for multiple requests delays the review and may result in a denial
- × **Never send original documents.** Always send a clear copy of the requested information. Medicare contractors will not return your documents following review of your information
- × Do not send your response to the attention of a person or department as you might not have the most up-to-date information, and delays could occur
- × **Never miss your deadline.** Claims will be automatically denied if a timely response is not received. Medicare contractors may decide to reopen your claim, but are not required to

CD = compact disc; DVD = digital video disc; esMD = Electronic Submission of Medical Documentation; MAC = Medicare Administrative Contractor; USB = Universal Serial Bus.



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



Coverage

Overcome complex insurance coverage and reimbursement challenges

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



Offer coding and billing guidance

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



Provide options for appeals support

The Glaukos 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 Glaukos directly.



Patients can complete an online application here.





For additional support, speak to your Glaukos Reimbursement Liaison or email marketaccess@glaukos.com.

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

Please see full Prescribing Information.

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- The CMS-1500 claim fo procedures in ASC and
- The CMS-1500 claim for payers for specific cod

Item 19

Additional Claim
When billing with
description of the o

Item 21

Diagnosis or Natu

Item 24

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Item 24D

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Item 24G

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	MEDICARE MEDICAID TRICARE CHAMPV	A GROUP FECA OTHER HEALTH PLAN (ID#) (ID#)	1a, INSURED'S I.D. NUMBER	(For Program in Item 1)	
	(Medicare#) (Medicaid#) (ID#/DoD#) (Member IL	Oil) (IDil) (IDil) (IDil)			
-	PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name	, First Name, Middle Initial)	
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Z	IP CODE TELEPHONE (Include Area Code)		ZIP CODE	TELEPHONE (Include Area Code)	
9	OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP	OR FECA NUMBER	
	OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous)	a. INSURED'S DATE OF BIRTH	SEX	_
	OTHER INSORES OF SECTION STORES FROM SER	YES NO	MM DD YY	M F	
5	RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated	by NUCC)	
C	RESERVED FOR NUCC USE	c. OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR	PROGRAM NAME	
d	INSURANCE PLAN NAME OR PROGRAM NAME	YES NO 10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH	BENEFIT PLAN?	-
		and the same of the same of		f yes, complete items 9, 9a, and 9d.	
12	READ BACK OF FORM BEFORE COMPLETING 2. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE 1 authorize the to process this claim. I also request payment of government benefits either below.	release of any medical or other information necessary		D PERSON'S SIGNATURE I authorize the undersigned physician or supplier for	
	SIGNED	DATE	SIGNED		
	MM DD YY QUAL QUAL QUAL 7. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a		FROM DD YY 18. HOSPITALIZATION DATES R MM DD YY	TO DELATED TO CURRENT SERVICES	_
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	9. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? YES NO	то	
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Coverage Acquiring iDose TR Prior authorization Coding for Reimbursement considerations Sample claim forms for iDose TR Understanding denials Access and requests iDose TR considerations for iDose TR and appeals reimbursement support

Sample CMS-

- The CMS-1450 (also know for services provided in th
- Check with individual pay documentation requirement

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