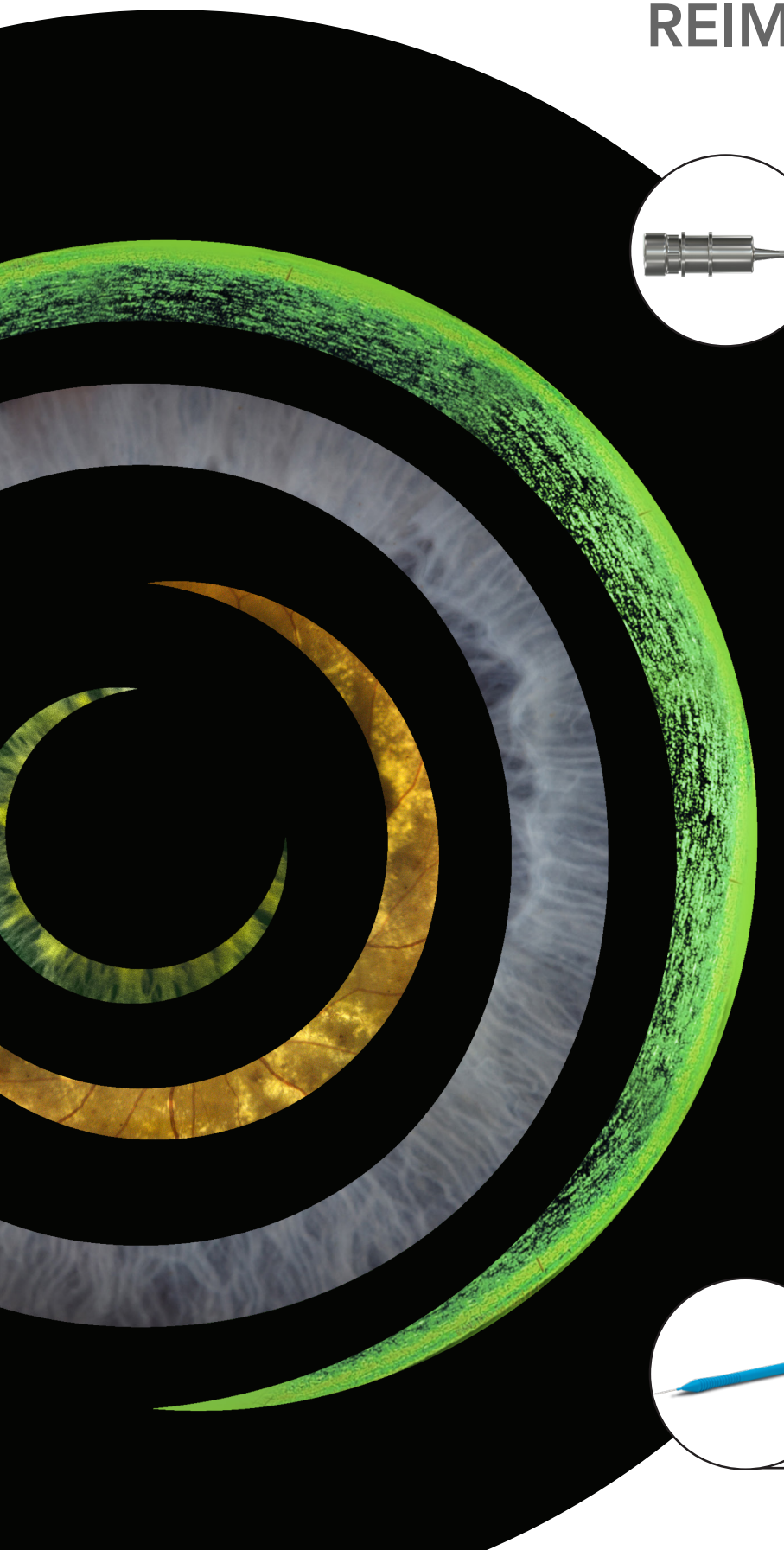
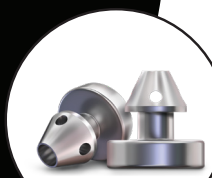
GLAUKOS®

INTERVENTIONAL GLAUCOMA REIMBURSEMENT GUIDE



iDose® *TR*
(travoprost intracameral implant) 75 mcg

iStent infinite®



iStent *inject*® *W*

iAccess®
Precision Blade

INTERVENTIONAL GLAUCOMA REIMBURSEMENT GUIDE

INDEX

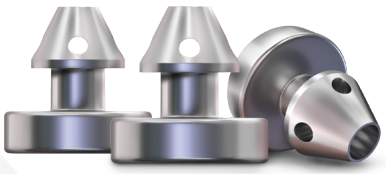
REIMBURSEMENT DISCLAIMER

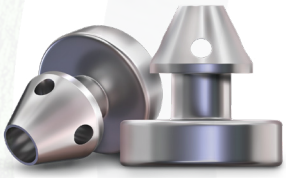
Glaukos provides this coding guide for informational purposes only and it is subject to change without notice. This guide is not an affirmative instruction as to which codes and modifiers to use for a particular service, supply, procedure, or treatment and does not constitute advice regarding coding, 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. All rates shown are national average Medicare rates and have not been adjusted for geographic variations in payment or other factors, such as sequestration. Glaukos makes no guarantee of coverage or reimbursement.

INDICATION STATEMENTS

iDose® TR (travoprost intracameral implant) 75 mcg is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT).

The iStent infinite® Trabecular Micro-Bypass System Model iS3 is an implantable device intended to reduce the intraocular pressure (IOP) of the eye. It is indicated for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed.





The iStent *inject*® W Trabecular Micro-Bypass System Model G2-W is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma.

The Glaukos iAccess® Precision Blade is intended for use in ophthalmic surgical procedures to manually cut trabecular meshwork (TM) in pediatric and adult patients.

BILLING AND CODING

iDose® TR (travoprost intracameral implant) 75 mcg

For an iDose® TR-specific reimbursement guide, please contact your Reimbursement Liaison at gps@glaukos.com

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

OUTPATIENT SETTINGS MAY INCLUDE:

- Ambulatory Surgical Centers (ASCs)
- Hospital Outpatient Departments (HOPDs)
- Office-Based Settings

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

Medicare Fee-for-service (FFS) Part B covers 80% of iDose® TR cost

The majority of FFS beneficiaries have some type of supplemental coverage:

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 U.S. Food and Drug Administration (FDA) approved, such as iDose® TR, typically occur in the months following approval. Always check with the patient's payer to determine coverage rules.

CURRENT PROCEDURAL TERMINOLOGY (CPT)®* CODES FOR DRUG ADMINISTRATION SERVICES: CPT® is the code set used to describe procedures and services performed by healthcare providers.

CPT® Category III Code	Descriptor
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach

BILLING AND CODING

iDose® TR
(travoprost intracameral implant) 75 mcg

iDose® TR Continued

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

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

ICD-10-CM	Descriptor
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.

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.

Keep in mind when billing with a miscellaneous/NOC code:

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

Always confirm payer coding and billing guidance before submitting a claim

BILLING AND CODING

iDose® TR
(travoprost intracameral implant) 75 mcg

iDose® TR Continued

The following miscellaneous/NOC HCPCS codes may be appropriate:

HCPCS Code	Description	Place of Service
J3490	Unclassified drugs	Physician office (Medicare FFS/Medicare Advantage and commercial patients)
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/commercial patients) -Confirm appropriate coding requirements with payer

ASC = ambulatory surgical center; HCPCS=Healthcare Common Procedure Coding System; HOPD = hospital outpatient department.

NATIONAL DRUG CODE:

- For drugs without a permanent HCPCS code, payers often require inclusion of the drug's National Drug Code (NDC) on the claim
- FDA-specified 10-Digit NDC (5-3-2 format) 25357-100-01
- 11-Digit NDC (5-4-2 format) 25357-0100-01
- 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

MEDICARE: For newly FDA-approved products coded as C9399, Medicare FFS reimbursement is 95% of average wholesale price (AWP).

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.

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.

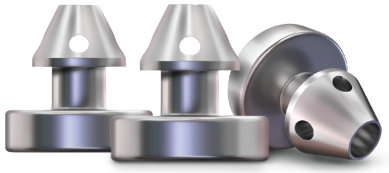
IMPORTANT SAFETY INFORMATION

CONTRADICATIONS: 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. Please see full Prescribing Information at https:// www.idosetrhcp.com/. 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.

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

BILLING AND CODING

iStent infinite®



MEDICARE COVERAGE TIP: for procedures subject to claim-by-claim consideration, the Medicare Administrative Contractor (MAC) may request medical records to assist in the evaluation and pricing. This occurs only after receipt of the claim. Therefore, providers who submit claims electronically should indicate that documentation is available upon request. For those providers that do not submit claims electronically, documentation must accompany the claim.

DIAGNOSIS: The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) is the coding system used to report patient diagnoses. Diagnosis codes are used to document the indication for the procedure and may include additional diagnoses of other clinical conditions applicable to a healthcare visit. It is up to the provider to determine the appropriate diagnosis code(s) on the claim.

ICD-10-CM Code	Descriptor
H40.XXXX	Glaucoma

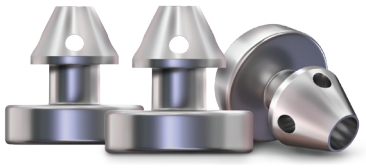
PROCEDURE: The following Current Procedural Terminology (CPT®) codes may be appropriate to describe the iStent infinite® insertion procedure.

CPT Code	Descriptor	Modifiers
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	-LT (left side) -RT (right side)
66989[1]	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), **complex**, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more.	
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more.	

[1]if iStent infinite is completed with a cataract combination procedure 66989/66991, should be used in accordance with documentation in the procedure operative note and corresponding medical documentation.

BILLING AND CODING

iStent infinite® Continued



iStent infinite®

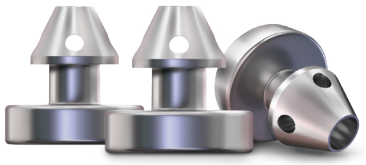
NATIONAL UNADJUSTED MEDICARE PAYMENT RATES FOR 2024*

CPT Code	Descriptor	Physician Payment*	Ambulatory Surgical Center (ASC) Payment†	Hospital Outpatient Department (HOPD) Payment‡
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more	Contractor Priced	$3,816	$4,980 APC 5493
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	$831	$3,665	$4,980 APC 5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	$664	$3,733	$4,980 APC 5493

*https://www.cms.gov/medicare/payment/fee-schedules/physician
†https://www.cms.gov/license/ama?file=/files/zip/2024-cn-addendum-aa-bb-dd1-dd2-ee-and-ff.zip
‡https://www.cms.gov/license/ama?file=/files/zip/2024-cn-opps-addendum-b-and-c.zip

BILLING AND CODING

iStent infinite® Continued



DEVICE: Healthcare Common Procedure Coding System (HCPCS) codes are used, among other things, to describe medical devices provided to patients. C-codes are HCPCS codes established by the Centers for Medicare & Medicaid Services (CMS) for the Hospital Outpatient Prospective Payment System (HOPPS) for use on Medicare claims for hospital outpatient and ambulatory surgical center items and services. The following HCPCS codes may be appropriate for reporting when iStent infinite® is used, and the number of service units for the code reported may correspond to the number of stents deployed.

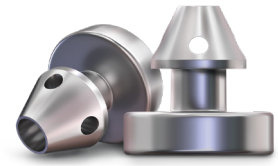
HCPCS Code	Descriptor	Revenue Codes
C1783	Ocular implant; aqueous drainage assist device	278
L8612	Aqueous shunt	278

IMPORTANT SAFETY INFORMATION

CONTRADICATIONS: The iStent infinite® is contraindicated in eyes with angle-closure glaucoma where the angle has not been surgically opened, acute traumatic, malignant, active uveitic, or active neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure.

Please see additional Important Safety Information on last page and Instructions for Use (IFU) for a complete list of contraindications, warnings, precautions, and adverse events (AEs).

BILLING AND CODING



iStent *inject*® W

COVERAGE: Prior authorization or Pre-certifications are highly recommended for commercial payers. Medical policies are a component of coverage. A published fee schedule and/or presence of codes does not guarantee coverage. For questions regarding coverage, please check with your Glaukos Reimbursement Liasion at gps@glaukos.com.

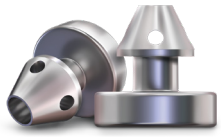
DIAGNOSIS: The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) is the coding system used to report patient diagnoses. In addition to the appropriate cataract diagnosis, the following possible ICD-10-CM diagnosis codes may describe conditions that are consistent with the FDA-labeled indication for iStent *inject*® W:

ICD-10-CM Code	Descriptor
H40.1111	Primary Open-Angle Glaucoma, Right Eye, Mild Stage
H40.1112	Primary Open-Angle Glaucoma, Right Eye, Moderate Stage
H40.1121	Primary Open-Angle Glaucoma, Left Eye, Mild Stage
H40.1122	Primary Open-Angle Glaucoma, Left Eye, Moderate Stage
H40.1131	Primary Open-Angle Glaucoma, Bilateral, Mild Stage
H40.1132	Primary Open-Angle Glaucoma, Bilateral, Moderate Stage

PROCEDURE: The following possible CPT[1] codes may be reported when insertion of an anterior segment aqueous drainage device is performed in combination with cataract or complex cataract surgery.

CPT Code	Descriptor	Modifiers
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), **complex**, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more.	-LT (left side) or -RT (right side)
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more.	

BILLING AND CODING



iStent *inject*® W

iStent *inject*® W Continued

NATIONAL UNADJUSTED MEDICARE CODING AND PAYMENT UPDATES FOR 2024*

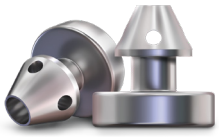
CPT Code	Descriptor	Physician Payment*	Ambulatory Surgical Center (ASC) Payment†	Hospital Outpatient Department (HOPD) Payment‡
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	$831	$3,665	$4,980 APC 5493
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	$664	$3,733	$4,980 APC 5493

DEVICE: Healthcare Common Procedure Coding System (HCPCS) codes are used, among other things, to describe medical devices provided to patients. C-codes are unique temporary HCPCS codes established by the Centers for Medicare & Medicaid Services (CMS) for the Hospital Outpatient Prospective Payment System (HOPPS) for use on claims for hospital outpatient and ambulatory surgical center items and services. Although other payers may also accept C-codes, they are not required to do so. The following HCPCS codes may be reported to describe iStent *inject*® W:

HCPCS Code	Descriptor	Revenue Code
C1783	Ocular implant; aqueous drainage assist device	**0278,** other implants
L8612	Aqueous shunt	

*https://www.cms.gov/medicare/payment/fee-schedules/physician
†https://www.cms.gov/license/ama?file=/files/zip/2024-cn-addendum-aa-bb-dd1-dd2-ee-and-ff.zip
‡https://www.cms.gov/license/ama?file=/files/zip/2024-cn-opps-addendum-b-and-c.zip

BILLING AND CODING



iStent *inject*® W

iStent *inject*® W Continued

IMPORTANT SAFETY INFORMATION

CONTRADICATIONS: The iStent inject® W is contraindicated in eyes with angle-closure glaucoma, traumatic, malignant, uveitic, or neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. WARNINGS. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization of the angle that could lead to improper placement of the stent and pose a hazard. MRI INFORMATION. The iStent inject W is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. PRECAUTIONS. The surgeon should monitor the patient postoperatively for proper maintenance of IOP. The safety and effectiveness of the iStent inject W have not been established as an alternative to the primary treatment of glaucoma with medications, in children, in eyes with significant prior trauma, abnormal anterior segment, chronic inflammation, prior glaucoma surgery (except SLT performed > 90 days preoperative), glaucoma associated with vascular disorders, pseudoexfoliative, pigmentary or other secondary open-angle glaucomas, pseudophakic eyes, phakic eyes without concomitant cataract surgery or with complicated cataract surgery, eyes with medicated IOP > 24 mmHg or unmedicated IOP < 21 mmHg or > 36 mmHg, or for implantation of more or less than two stents. ADVERSE EVENTS. Common postoperative adverse events reported in the iStent inject® randomized pivotal trial included stent obstruction (6.2%), intraocular inflammation (5.7% for iStent inject vs. 4.2% for cataract surgery only), secondary surgical intervention (5.4% vs. 5.0%) and BCVA loss ≥ 2 lines ≥ 3 months (2.6% vs. 4.2%). CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

BILLING AND CODING

iAccess® Precision Blade

INDICATION: The Glaukos iAccess® Precision Blade is intended for use in ophthalmic surgical procedures to manually cut trabecular meshwork (TM) in pediatric and adult patients.[1]

iAccess® Precision Blade

NATIONAL UNADJUSTED MEDICARE CODING AND PAYMENT UPDATES FOR 2024*

CPT® Code	Descriptor	Physician[1]	Ambulatory Surgical Center (ASC)	Hospital Outpatient Department (HOPD)
65820	Goniotomy	$803	$2,045	$3,874 APC 5492

IMPORTANT SAFETY INFORMATION

CONTRADICTIONS: The Glaukos iAccess Trabecular Trephine is contraindicated in eyes where there is poor visualization of angle structures. WARNINGS/PRECAUTIONS: Physician training is required prior to use of the iAccess Trabecular Trephine, including intraoperative gonioscopy. Do not use the Glaukos iAccess Trabecular Trephine if there is poor visualization of angle structures. Improper visualization could result in damage to adjacent eye structures. Do not re-sterilize or reuse the device as this may result in infection and/or intraocular inflammation, as well as occurrence of potential postoperative adverse events. CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of instructions, contraindications, warnings, and precautions.

*https://www.cms.gov/medicare/payment/fee-schedules/physician
[1]When performed in a facility (ASC or HOPD).

SAMPLE CLAIM FORMS

NOTE: These sample claim forms are for iStent infinite®. If support is needed for other form types, please contact the appropriate regional reimbursement liaison.

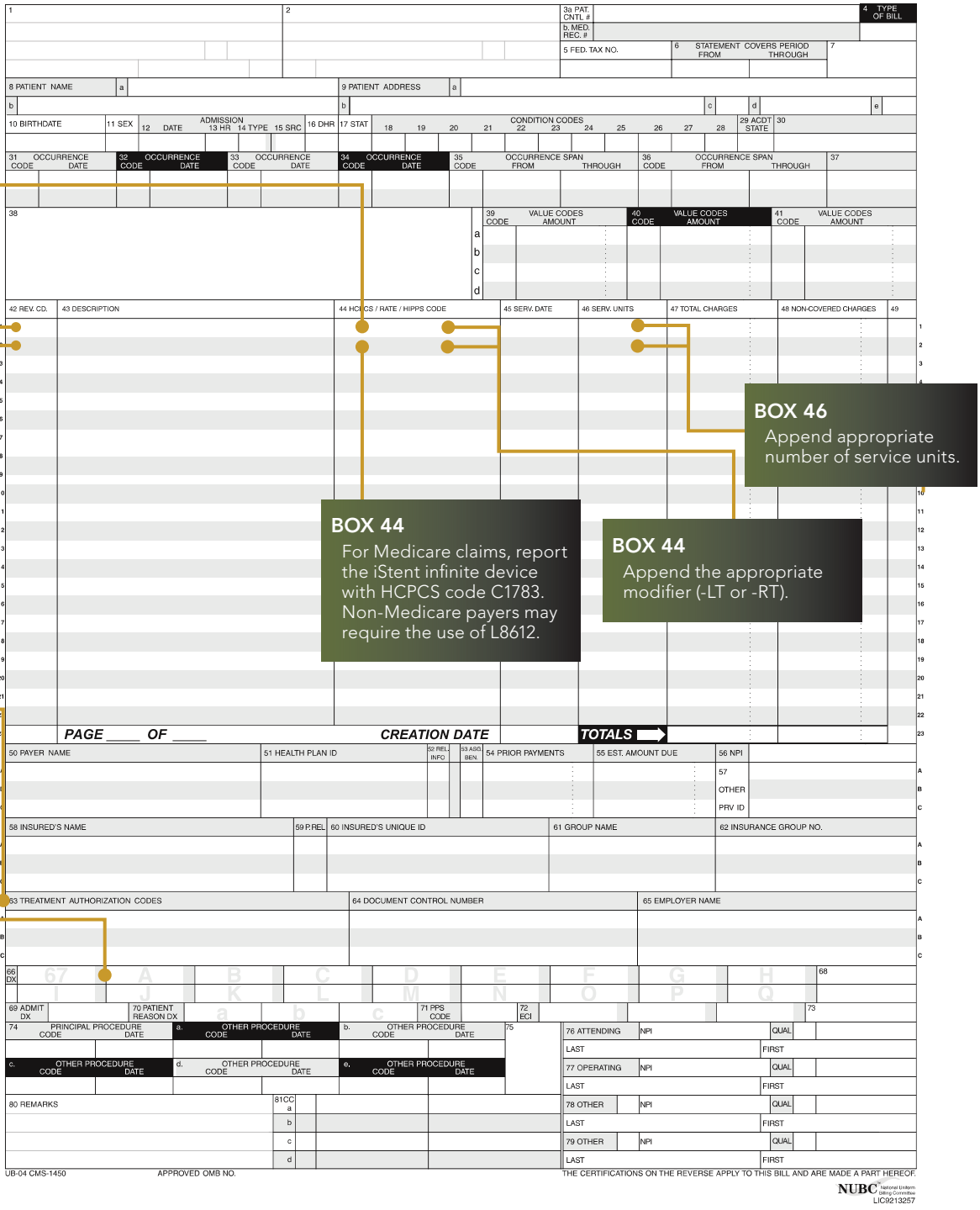
SAMPLE UB-04 FOR FACILITIES

BOX 44
Report 0671T.

BOX 42
Append appropriate revenue code per internal billing policies and procedures.

BOX 63
Coverage and coding requirements vary by payer. A benefit verification and review of the payer's medical policy prior to treatment is recommended.

BOX 66
Report the appropriate ICD-10 code for the procedure.



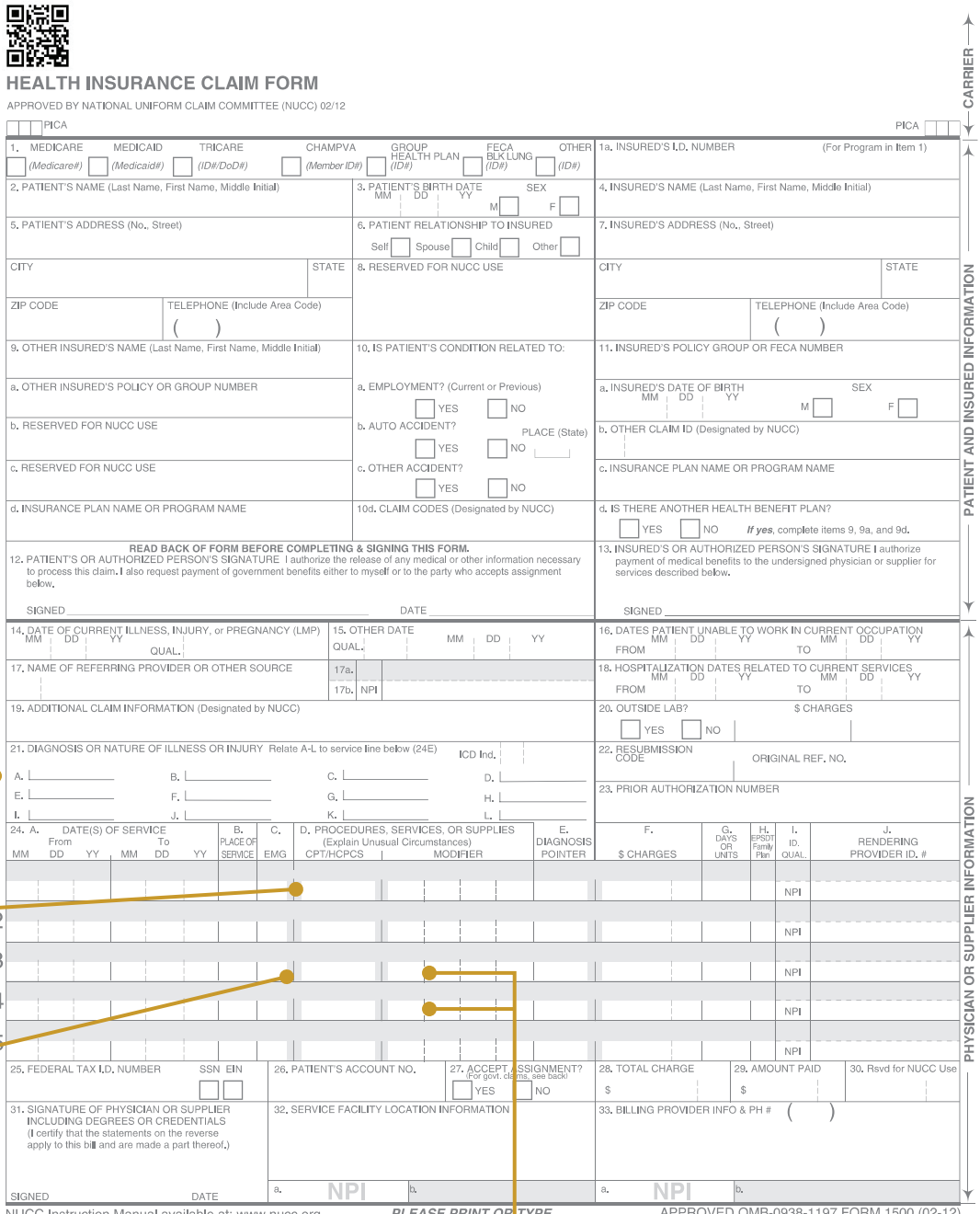
BOX 44
For Medicare claims, report the iStent infinite device with HCPCS code C1783. Non-Medicare payers may require the use of L8612.

BOX 46
Append appropriate number of service units.

BOX 44
Append the appropriate modifier (-LT or -RT).

SAMPLE CLAIM FORMS

SAMPLE CMS-1500 FOR FACILITIES



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP 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

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1										NPI	
2										NPI	
3										NPI	
4										NPI	
5										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org *PLEASE PRINT OR TYPE* APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

BOX 21B
Report the appropriate ICD-10 code specific to the patient's condition. See (A).

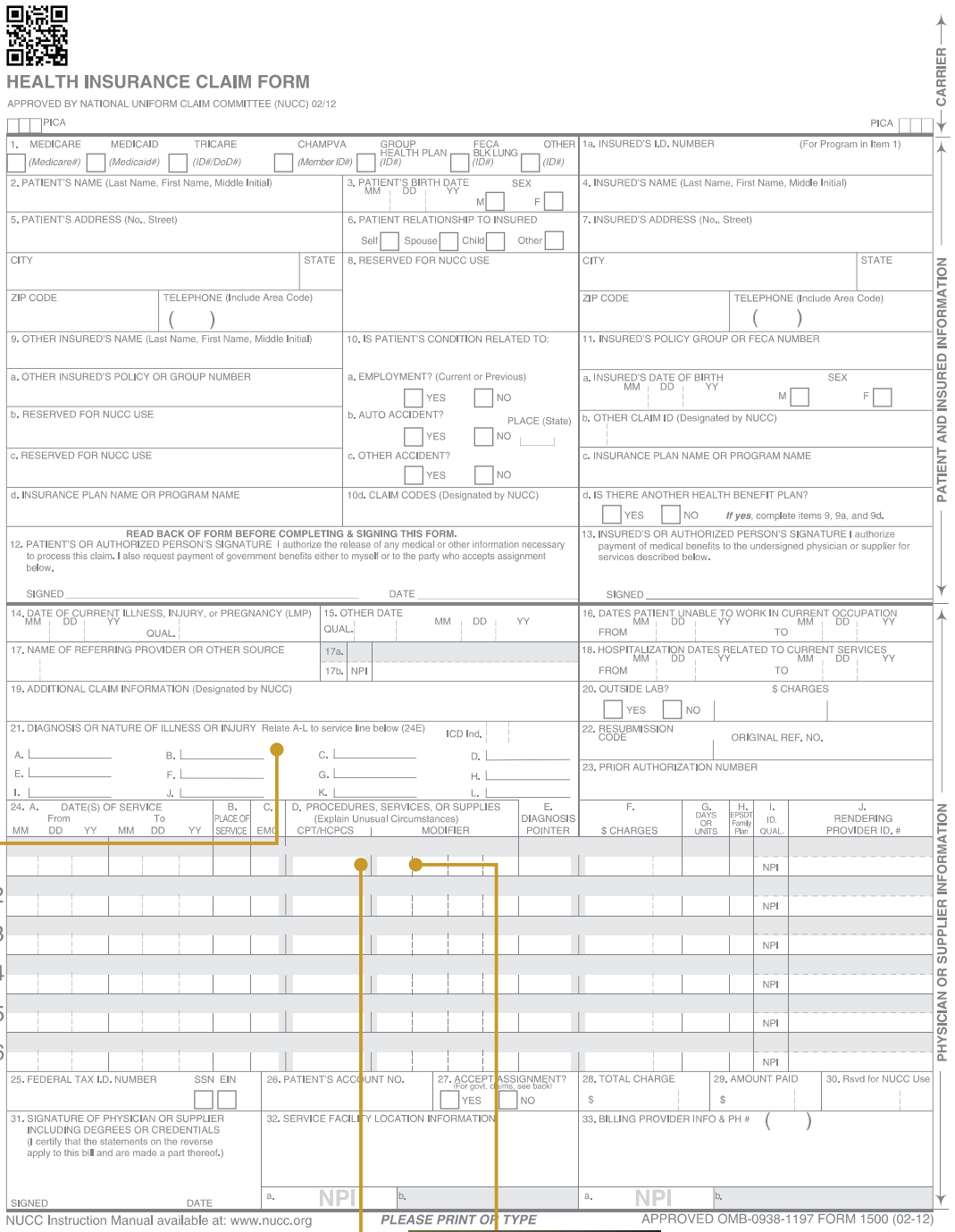
BOX 24D
Report 0671T.

BOX 24D
For commercial payers, include HCPCS code L8612, ocular implant, aqueous drainage assist device. For Medicare claims, do not report a HCPCS code.

BOX 24D
Append the appropriate modifier (-LT or -RT).

SAMPLE CLAIM FORMS

SAMPLE CMS-1500 FOR PHYSICIANS



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP 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

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

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SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

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E. F. G. H.

I. J. K. L.

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23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1										NPI	
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3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

BOX 21B
Report the appropriate ICD-10 code specific to the patient's condition. A list of potential codes is located on page 2.

BOX 24D
Report 0671T.

BOX 24D
Append the appropriate modifier (-LT or -RT). Medicare no longer requires -51 to indicate multiple procedures.

ISTENT INFINITE GOOD DOCUMENTATION PRACTICES & PERI-OPERATIVE DOCUMENTATION FOR MEDICAL NECESSITY

This resource packet is intended to assist providers in documenting medical necessity for iStent infinite® Trabecular Micro-Bypass System Model iS3, first standalone trabecular micro-bypass device to reduce elevated intraocular pressure (IOP) in patients with primary open-angle glaucoma uncontrolled by prior medical and surgical therapy.

DEFINING MEDICAL NECESSITY

Medicare and other third-party insurance payers provide coverage and payment of services and items used in treatment based on what is considered medically necessary and reasonable. Medicare.gov defines medical necessity as "services or supplies that are needed to diagnose or treat your medical condition and that meet accepted standards of medical practice."[1]

Upon receipt of a claim for services provided, Medicare and other payers may request additional documentation to prove the medical necessity of treatment provided. The documentation to support treatment should include:

- a history of the patient's condition,
- testing used to diagnosis the illness or injury,
- all current and previous medical and surgical interventions used to treat the condition,
- failure of current and previous medical and surgical interventions, and
- a treatment plan and expected outcomes.

Failure to comply with a payer's request for additional medical records, or records that do not demonstrate medical necessity, will likely result in non-coverage of the claim.

PRACTICE DOCUMENTATION & RESOURCES IMPORTANT TO PAYERS

To aid in supporting medical necessity for iStent infinite® this guide includes a sample operative note which may be used to support medical necessity for reasonable care. Additional documents may also support the medical documentation and claim for the beneficiary. These recommendations are for informational purposes only and must be tailored to your own practice and the patient's clinical condition.

- Sample Language for Pre-Determination/Authorization, Requests for Medical Necessity, or Claim Additional Documentation Request (ADR), Appeal and/or Denial Template Letter
- Chart Documentation Checklist, as provided by the payer correspondence
- Medical Records | Rationale to support medical necessity
  - History & Physical (H&P)
  - Pre-operative consultation report
  - Operative Report
  - Discharge/Expected Outcomes/Follow Up

[1] https://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html

ISTENT INFINITE SAMPLE OPERATIVE NOTE

Operative notes should clearly identify the patient, the date of surgery, the surgeon and assistant, the preoperative and postoperative diagnoses, the procedure(s) performed and on which eye, the implantable device used, the anesthesia and other pharmacotherapeutics used, and whether there were any intraoperative complications. In addition, the notes should include a summary of the patient's glaucoma staging, including prior medications and failed surgical treatments.

Below is a brief example of operative notes for a standalone procedure using iStent infinite® Practitioners should use their medical judgment and training to customize this sample to best reflect the patient treated and procedure(s) performed.

Date of Surgery	
Patient Name	
Surgeon	
Assistant	
Preoperative Diagnosis	
Postoperative Diagnosis	
Procedure(s) Performed	
Device(s) Implanted	
Anesthesia	
Intraoperative Complications	
Proposed target IOP (e.g., <20mmHg)	

ISTENT INFINITE OPERATIVE NOTE, CONTINUED

Indications for Surgery: The patient had a history of open angle glaucoma and has failed prior medical and surgical intervention. Additionally, report Visual Field Abnormality VF mean defect score, Optic Nerve cup to disc ratio, as well as stage of glaucoma (ICD-10) (mild, moderate, severe).

Include detail regarding current medications, including previous medical and surgical therapy (laser and incisional) [Include further detail about the medical and surgical treatments that have failed.]

Procedure: The patient was brought to the preoperative area and received topical anesthesia, then was brought to the operating room, prepped, and draped in the usual sterile ophthalmic manner. The operative eye was identified.

A lid speculum was placed. The operating microscope was placed in the proper position for ideal viewing. A clear corneal incision was made temporally. Miostat was instilled and viscoelastic was injected into the anterior chamber of the eye. The eye was examined and using a gonioscopy prism, the angle was visualized and was open with the trabecular meshwork identified.

The conjunctiva was marked for iStent infinite® placement 2 clock hours apart for a total of 3 marks in the nasal angle. The first and second devices were implanted without complication and there was immediate blood reflux from Schlemm's canal into the anterior chamber through the stents. The injector handpiece was removed from the eye. The scope was adjusted and surgeons positioning was adjusted to allow for the proper angle for injector entry into the anterior chamber. The patient's head was rotated to allow the best view upon visualizing the nasal angle with the goniolens. The superonasal angle examined, then additional viscoelastic was instilled and the third stent was then positioned with the injector in the trabecular meshwork. There was some blood reflux present. All 3 stents were visualized in the proper anatomical position.

Viscoelastic and residual blood were removed from the eye with irrigation. BSS was injected into the corneal incisions for hydration, and they were confirmed to be sealed with a Weck-cel sponge with a well-formed anterior chamber and a reasonable intraocular pressure determined by palpation. The patient received [postoperative medication regimen]. The patient left the operating room in satisfactory condition with no complications noted.

GLAUCOMA FAQs

HOW DO YOU CODE FOR THE REMOVAL OF AN ISTENT *INJECT*® & INFINITE®?
When an iStent is explanted, code 65920, Removal of implanted material, anterior segment of eye, may be appropriate. Diagnosis code T85.698A, mechanical complication of implanted material, may be appropriate.

HOW SHOULD PROVIDERS SET CHARGES FOR ISTENT INFINITE®?
Providers should use a charge setting methodology consistent across all payers.

Physicians should set charges taking into consideration the time, intensity, and resources utilized to provide care.

Hospital outpatient departments should also set charges consistent with their usual and customary protocol. All device costs should be accounted for when charges are set

ARE THERE ADDITIONAL DOCUMENTATION REQUIREMENTS FOR ISTENT INFINITE®?
Providers must always satisfy the payer's medical necessity requirements. Accurate and complete documentation is essential. Our Glaukos Reimbursement Liaison staff can assist you with obtaining our Documenting to Support Medical Necessity Guide.

When payers begin to see claims for a new procedure, it is common for records to be requested. First and foremost, there must be proper documentation, medical justification, and submission of complete records to justify the procedure.

GLAUCOMA FAQs

IN THE RARE INSTANCE THAT AN ISTENT INFINITE PROCEDURE IS DISCONTINUED, WHAT ARE THE BILLING OPTIONS FOR THE PHYSICIAN AND THE ASC?

Medicare and non-Medicare payers may have differing policies for billing discontinued procedures. Each payer's guidelines should be reviewed and followed. Typically, Medicare billing would follow the scenarios outlined in the chart below.

iStent infinite Procedure	Physician Billing Options	ASC Billing Options
Attempted, no stents placed	Provider decision…. Bill 0671T, modifier -53 (discontinued procedure) Carefully document the procedure steps completed and reason for discontinuing the procedure Payer may adjust the procedure payment	Bill 0671T -74 (discontinued procedure) Carefully document the procedure steps completed and reason for discontinuing the procedure Payer may adjust the procedure payment
Only one of two stents placed	Bill 0671T as usual, no modifier	Bill 0671T, no modifier

NOTE: If a procedure is aborted or if a stent is unable to be implanted/surgery unable to be completed for any reason, you are required to notify Medical Safety of the event—even if the event is unrelated to the device.

WHAT IF ISTENT INFINITE® IS PERFORMED AT THE SAME TIME AS CATARACT SURGERY?

If infinite is used with cataract surgery, CPT code 66989 or 66991 is appropriate with sufficient documentation and medical necessity. Coding is not product specific; it's based on anatomical approach, structure, and the work involved to perform a procedure. Stent coding structure is based on whether cataract surgery is performed or not. If stenting is performed standalone (i.e.,without cataract) the code 0671T is appropriate with sufficient documentation and medical necessity. National Correct Coding Initiative (NCCI) edits exist disallowing coding 66989/66991 with cataract 66982/66984 codes.

Physician claims are subject to the multiple procedure payment reduction (MPPR). The highest paying procedure would be paid at 100% and each lower valued service would be reduced by 50%.

GLAUCOMA FAQs

MULTIPLE PROCEDURE PAYMENT REDUCTION

The MPPR means that if a healthcare provider performs multiple procedures during a single patient encounter, Medicare (and many commercial insurers) typically will pay "full price" for only the highest-valued procedure. The reason is explained in Chapter 1 of the National Correct Coding Initiative (NCCI)* Policy Manual: most medical and surgical procedures include pre-procedure, intra-procedure, and post-procedure work. When multiple procedures are performed at the same patient encounter, there is often overlap of the pre-procedure and post-procedure work. Payment methodologies for surgical procedures account for the overlap of the pre-procedure and post-procedure work.

*https://www.cms.gov/files/document/medicare-ncci-policy-manual-2024-chapter-1.pdf

Email: gps@glaukos.com **Phone:** 833-855-3031 **Fax:** 949-876-8729

GPS
Glaukos Patient Services

Glaukos Patient Services (GPS) provides a wide array of services to help remove treatment barriers for patients so that you can focus on providing the very best healthcare possible for those with glaucoma.

GPS Support

Overcome complex insurance coverage and reimbursement challenges

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

Offer coding and billing guidance

The GPS Reimbursement Liaison supports your staff with guidance, education, and recommendations related to the appropriate submission of claims.

Provide appeals support

The GPS Reimbursement Liaison partners with your staff on efficiently resolving claim denials for Glaukos products.

For additional support, please contact GPS at gps@glaukos.com or 833-855-3031