

iStent *inject*[®]W: BILLING AND CODING GUIDE



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.

CODING

PROCEDURE: The following possible Current Procedural Terminology (CPT[®]) codes may be reported when insertion of an anterior segment aqueous drainage device is performed:

CPT Code	Description	Modifiers	Revenue Codes
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion	-LT (left side) or -RT (right side)	HOPD: 0360 , Operating room services; general
+0376T	each additional device insertion (List separately in addition to code for primary procedure)		ASC: 0490 , Ambulatory surgical care; general

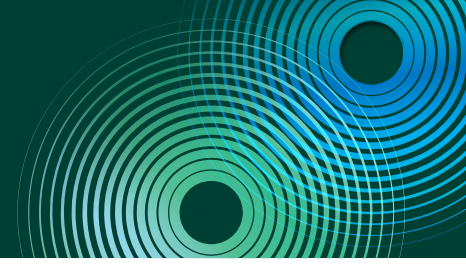
The iStent *inject*[®]W procedure must be billed on the same claim with the appropriate cataract procedure code.

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 and Medicaid Services (CMS) for the Hospital Outpatient Prospective Payment System (HOPPS) and are only valid for Medicare on claims for hospital outpatient department services and procedures. 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	Description	Revenue Code
C1783	Ocular implant; aqueous drainage assist device	0278, other implants
L8612	Aqueous shunt	

DIAGNOSIS: The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) is the coding system used to report all diagnoses, symptoms and procedures recorded in conjunction with hospital care in the United States. 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	Description
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



2020 NATIONAL AVERAGE UNADJUSTED MEDICARE PAYMENT²

PHYSICIAN: Contractor-priced. Check your local MAC fee schedule.

CPT Category III codes such as 0191T and 0376T are temporary codes that allow data collection for emerging technologies, services, procedures, and service paradigms. CPT Category III codes are not referred to the AMA-Specialty RVS Update Committee (RUC) for valuation because no relative value units (RVUs) are assigned to these codes. As a result, CMS does not establish payment levels for these services or procedures in the annual physician fee schedule, but leaves it to Medicare contractors to determine the rates.

Currently, 0191T is included in all Medicare Administrative Contractor (MAC) physician fee or carrier-priced published fee schedules. Please consult your local MAC's website for applicable physician payment rates. As utilization of iStent *inject*[®] W increases, payers will begin to incorporate 0376T into their fee schedules and coverage policies. Like all Category III CPT Codes, physician payment rates for CPT codes 0191T and 0376T will be at each MAC's discretion.

CPT Code	Descriptor	Ambulatory Surgical Center	Hospital Outpatient Department
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion	\$2,717 Device intensive procedure paid at an adjusted rate (J8)	\$3,818 Comprehensive APC 5492 (J1)
+0376T	each additional device insertion (List separately in addition to code for primary procedure)	Packaged service or item (N1)	Items and Services Packaged into APC Rates; Paid under OPPS; payment is packaged into payment for other services (N)

HOSPITAL OUTPATIENT DEPARTMENT: CPT code 0191T has a status indicator of "J1" and is assigned to a comprehensive APC, APC 5492 (Level 2 Intraocular Procedures). CPT code 0376T has a status indicator of "N" which indicates that the facility payment for this code is packaged into the APC rate for other services – in this instance, presumably APC 5492. CPT code 0376T is not a separately paid service for the facility.

Hospital outpatient departments must also report the appropriate device HCPCS code on all Medicare claims to ensure appropriate reimbursement. For more information on this, please see the "Device" paragraph in the "Coding" section above.

AMBULATORY SURGICAL CENTER: CPT code 0191T has a status indicator of "J8" and is designated as a device intensive procedure. CPT code 0376T has a status indicator of "N1" which indicates that the payment for this code is packaged.

ASCs do not report HCPCS codes to report implanted devices on claims sent to Medicare. Payment for a device is typically "packaged" into the payment for the ASC procedure. However, some commercial payer contracts may allow a carve-out for the device when a HCPCS code is reported.

iStent inject® W Sample CMS-1500 for Physicians



HEALTH INSURANCE CLAIM FORM

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

<input type="checkbox"/> PICA <input type="checkbox"/> PICA																																																																																																			
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/> <small>(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#)</small>					1a. INSURED'S I.D. NUMBER (For Program in Item 1)																																																																																														
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BOX 21A
Report the appropriate ICD-10 code specific to the patient's condition. A list of potential codes specific to Primary Open-Angle Glaucoma is included on page 1.

BOX 21B
Report the appropriate ICD-10 code for the cataract procedure.

BOX 24D
Report 0191T and 0376T.

BOX 24D
Report the cataract procedure using the appropriate CPT code, for example: 66984 or 66982.

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

iStent inject® W Sample CMS-1500 for Facilities



HEALTH INSURANCE CLAIM FORM

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

<input type="checkbox"/> PICA <input type="checkbox"/> PICA																																						
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/> <small>(Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#)</small>					1a. INSURED'S I.D. NUMBER (For Program in Item 1)																																	
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A. H40.XXXX			B. H25.XXX			C.			D.			E.			F.			G. DAYS OF UNUSUAL CIRCUMSTANCES			H. EPISODES			I. ID. QUAL.			J. RENDERING PROVIDER ID. #											
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BOX 21A
Report the appropriate ICD-10 code specific to the patient's condition. A list of potential codes specific to Primary Open-Angle Glaucoma is included on page 1.

BOX 21B
Report the appropriate ICD-10 code for the cataract procedure.

BOX 21D
Report 0191T and 0376T.

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
Report the cataract procedure using the appropriate CPT code, for example: 66984 or 66982.

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

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)

iStent inject® W Sample UB-04 for Facilities

BOX 44
Report 0191T and 0376T

BOX 42
This list of services is for example only and is not intended to be inclusive of all services and items that may be provided. HOPD providers should report all appropriate supplies and pharmacy items.

BOX 42
HOPDs use Rev Code 0360, ASCs use Rev Code 0490.

BOX 44
Report the cataract procedure using the appropriate CPT code, for example: 66984 or 66982.

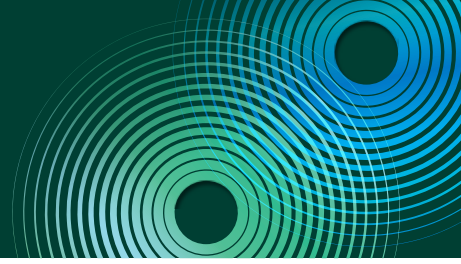
BOX 44
For Medicare claims, report the iStent inject® W device with HCPCS code C1783. Non-Medicare payers may require the use of L8612.

BOX 44
Append the appropriate modifier (-LT or -RT). Medicare no longer requires -51 to indicate multiple procedures.

BOX 66
Report the appropriate ICD-10 code specific to the patient's condition. A list of potential codes specific to Primary Open-Angle Glaucoma is included on page 1.

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

1 PATIENT NAME		2 PATIENT ADDRESS		3a PAT. CNTRL. # b. MED. REC. #		4 TYPE OF BILL	
8 PATIENT NAME		9 PATIENT ADDRESS		5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM THROUGH	
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION	
31 OCCURRENCE CODE		32 OCCURRENCE DATE		33 OCCURRENCE CODE		34 OCCURRENCE DATE	
35 OCCURRENCE SPAN FROM THROUGH		36 OCCURRENCE SPAN FROM THROUGH		37		38	
39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT		42	
43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE		46 SERV. UNITS	
47 TOTAL CHARGES		48 NON-COVERED CHARGES		49		50	
0360	Operating Room Services	0191T-RT	09/01/20	1	XXXX	XX	
0360	Operating Room Services	0376T-RT	09/01/20	1	XXX	XX	
0360	Operating Room Services	66984-RT	09/01/20	1	XXXX	XX	
0278	Other Implants	C1783	09/01/20	2	XXXX	XX	
0276	IOL Implants	XXXXX	09/01/20	1	XXXX	XX	
PAGE OF		CREATION DATE		TOTALS			
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INPC		53 ADJ. BEN.	
54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 P.PREL.		60 INSURED'S UNIQUE ID		61 GROUP NAME	
62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME	
66 DX		67		68		69	
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI	
73		74		75		76 ATTENDING	
77 OPERATING		78 OTHER		79 OTHER		80	
80 REMARKS		81CC		82		83	



INDICATION FOR USE. 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.

CONTRAINDICATIONS. 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 \geq 2 lines \geq 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.

*Observed holidays include: New Year's Day, President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and the day after, and Christmas Day.

REFERENCES:

1. CPT is a registered trademark of the American Medical Association (AMA). Copyright 2020 AMA. All rights reserved. 2. Medicare fee schedules are available at cms.gov.

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) 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. All rates shown are national average Medicare rates and have not been adjusted for geographic variations in payment or other factors, such as sequestration.

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PM-US-0XXX