iStent® Trabecular Micro-Bypass Stent

Reimbursement Guide
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Overview

This guide provides coding and billing information to facilities and physicians submitting claims for procedures using the iStent Trabecular Micro-Bypass Stent (the "iStent").

Approved Indication

The iStent® Trabecular Micro-Bypass Stent (Models GTS100R and GTS100L) is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication.

Disclaimer

This reimbursement information is intended to provide health care professionals with information related to billing, coding, and reimbursement requirements that may apply to Glaukos® products. It is being provided for general informational and educational purposes only, and is not intended, and does not constitute, reimbursement or legal advice. Use of codes identified here does not guarantee coverage or payment at any specific level and is not intended to increase or maximize payment by any payer. Laws, regulations and coverage policies are complex and updated frequently. In addition, reimbursement policies vary widely from insurer to insurer and will reflect different patient conditions. You should check the current law and regulations and insurer's policies to confirm the most current coverage, coding or billing requirements. Any questions should be directed to your attorneys or reimbursement specialist. The health care professional is responsible for all aspects of reimbursement, including using codes that accurately reflect the patient's condition, procedures performed, and products used and ensuring the veracity of all claims submitted to third party payers.
Coding

Coding Overview

Medical billing codes convert a narrative description of a procedure, device, drug or disease into an alphanumeric or numeric code that health care providers use to report medical services rendered to patients to payers. When submitting claims to Medicare and other third party payers, facilities (e.g., hospitals and ASCs) and physicians list codes that describe patient condition and reflect procedures performed.

The following sections of this guide will review some of the codes that may be appropriate for billing the iStent and associated procedures. However, providers are ultimately responsible for choosing diagnosis and procedure codes that accurately describe the patient's condition, underlying disease and treatment. The key in all coding and billing to payers is to be truthful and not misleading and make full disclosures to the payer about how the product has been used and the procedures necessary to deploy and remove the product when seeking reimbursement for any product or procedure.

A table providing an overview of the types of codes that will most commonly be used when billing for the iStent and associated procedures is displayed below.

Table 1: Reimbursement Code Overview

<table>
<thead>
<tr>
<th>CODE TYPES</th>
<th>CODE DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT codes</td>
<td>Describes procedures performed and are used on claims submitted by physicians, Ambulatory Surgical Centers (ASC) and Hospital Outpatient Departments (HOPD)</td>
</tr>
<tr>
<td>Healthcare Common Procedure Coding System (HCPCS)</td>
<td>Describes items used in a patient's treatment, such as devices or drugs</td>
</tr>
<tr>
<td>ICD-9-CM diagnosis codes</td>
<td>Describes patient condition or underlying disease</td>
</tr>
<tr>
<td>Revenue codes</td>
<td>Describes the location where a procedure was performed, and the type of item, if applicable</td>
</tr>
</tbody>
</table>

Procedure Coding

Category I CPT codes are 5-digit numeric, permanent codes used to describe established procedures or services.

Category III CPT codes are temporary codes that describe emerging technologies or services. Category III CPT codes allow for data collection and tracking for these specific services/procedures and if available, Category III CPT codes must be reported instead of unlisted Category I CPT codes. Physicians and facilities need to establish a charge amount to be submitted with a Category III CPT code.

Both Category I and Category III CPT codes are eligible for coverage and reimbursement by payers.
When Category III CPT codes are submitted on claims, they are often subject to manual review by payers to make a determination on medical necessity and therefore payment. Coverage and reimbursement is not guaranteed, and the use of such codes typically requires additional documentation to be submitted to payers in order to justify the medical necessity of the procedure performed.

_iStent Procedure Coding (Physicians and Facilities)_

Table 2 below identifies the possible CPT code(s) that may be used to describe the iStent implantation procedure. Category III CPT code 0191T became effective for use July 1, 2008 and describes the insertion of glaucoma drainage devices using an _ab interno_ approach. Physicians and facilities are responsible for accurately selecting CPT procedure codes to describe the procedures performed.

**Table 2: Potential CPT Code(s)**

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0191T</td>
<td>Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork</td>
</tr>
</tbody>
</table>

The use of Category III CPT codes may require the submission of additional documentation to payers for them to assess medical necessity and determine appropriate payment levels. Such documentation may include:

- A letter of medical necessity
- Product description, including FDA approval letter
- The patient’s medical records
- A copy of the surgical/operative report with clear documentation of the procedure in question having been performed
- Clinical literature

_Cataract Procedure Coding (Physicians and Facilities)_

The iStent device is indicated for use in conjunction with cataract surgery. Standard cataract surgery with implantation of an IOL is most commonly reported with CPT code 66984, although a number of other CPT codes may apply depending on the actual services performed.

Table 3 identifies possible Category I CPT codes that may be used to describe the cataract surgery procedure(s) performed in conjunction with the iStent insertion procedure.

**Table 3: Potential CPT Code(s)**

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>66983</td>
<td>Intracapsular cataract extraction with insertion of intraocular lens prosthesis (1 stage procedure)</td>
</tr>
<tr>
<td>66984</td>
<td>Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)</td>
</tr>
</tbody>
</table>
Device Coding (Facilities Only)

Level II HCPCS codes are five-digit alphanumeric codes that include a single letter followed by four numeric digits. They are used primarily to identify a variety of medical supplies, drugs and equipment. HCPCS codes are billed by facilities and should not be included on claims for physician services only.

Table 4 below identifies the possible HCPCS code(s) that may be used by ASCs and HOPDs to report the iStent device itself.

**Table 4: Potential HCPCS Code(s)**

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8699</td>
<td>Prosthetic implant, not otherwise specified</td>
</tr>
</tbody>
</table>

Additional Coding Information

**Modifiers**

Depending on the actual procedure(s) performed with the iStent, it may be necessary to append certain modifiers to the procedure codes indicated on claim forms. Modifiers are designed to provide payers with additional information that may be necessary in order to process claims.

Modifiers are used to clarify the intent, duration, or scope of a procedure billed. Modifiers are two-digit alphanumeric codes that are appended to CPT codes when necessary to indicate that the procedure performed has been modified in some way from its original definition.

Healthcare providers may consider the coding options listed in Table 5 below and select the appropriate modifiers based on the procedure(s) performed.

**Table 5: Potential Modifiers**

<table>
<thead>
<tr>
<th>MODIFIER</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>RT</td>
<td>Used to indicate that the procedure was performed on the right side of the body</td>
</tr>
<tr>
<td>LT</td>
<td>Used to indicate that the procedure was performed on the left side of the body</td>
</tr>
<tr>
<td>-51</td>
<td>Used to indicate multiple procedures were performed during the same surgical session</td>
</tr>
</tbody>
</table>

**Revenue Codes**

Revenue codes are three-digit numeric codes reported on a UB-04 facility claim form to describe general categories of services provided and items furnished to a patient in a facility setting. Facilities are required to report revenue codes to provide a description of the specific service or item related to each revenue code reported. Revenue codes are used for tracking purposes and are not reimbursable codes.

Table 6 below identifies the possible revenue code(s) that may be used to report the iStent device in the HOPD setting of care.

**Table 6: Potential Revenue Code(s)**

<table>
<thead>
<tr>
<th>SETTING OF CARE</th>
<th>DEVICE CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Outpatient</td>
<td>278</td>
<td>Other implant</td>
</tr>
</tbody>
</table>
**Diagnosis Codes**

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes are reported on hospital and physician claims to report the patient's medical condition. Payers use this information to evaluate the episode of care and the appropriateness of the treatment the patient received. ICD-9-CM diagnosis codes are used in all settings of care.

Table 7 includes ICD-9-CM diagnosis codes that describe conditions that may be reported on iStent claim forms.

**Table 7: Potential ICD-9-CM Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>365.10</td>
<td>Open angle glaucoma, unspecified</td>
</tr>
<tr>
<td>365.11</td>
<td>Primary open angle glaucoma</td>
</tr>
<tr>
<td>365.15</td>
<td>Residual stage of open angle glaucoma</td>
</tr>
<tr>
<td>365.59</td>
<td>Glaucoma associated with other lens disorders</td>
</tr>
</tbody>
</table>

The ICD-9-CM diagnosis codes listed in this table may be commonly associated with iStent patients but are not intended to be an exhaustive list of all possible diagnosis codes. Please refer to the ICD-9-CM book for a comprehensive list of diagnosis codes.

**Note that in all cases, it is ultimately the responsibility of the provider to report the ICD-9-CM diagnosis code that most accurately describes the patient’s condition.**
Coverage

Use of the iStent must meet the requirements established by Medicare and other third party payers to be a covered service. Payer coverage policies are available in either benefit policy manuals (Medicare) or insurance contracts (private payers) which identify the products and services eligible for payment. Health insurers generally provide coverage for services when they are medically reasonable and necessary for treatment or diagnosis of illness or injury.

The iStent represents the latest technology in treating glaucoma and, like other new technologies, is in the early stages of securing widespread coverage from payers. Currently most payers have not established coverage guidelines for the iStent. Glaukos is currently working with payers to obtain specific guidance on the iStent for its customers and will provide updates when new information becomes available. In the meantime, providers are strongly encouraged to contact their local Medicare carriers and other insurers to clarify coverage guidelines specific to their patients.

In the absence of established coverage policies, payers will review claims and determine coverage on a case-by-case basis. Private payers may need to be contacted to obtain prior authorization prior to performing the procedure(s). Additionally, because Category III CPT codes are often used to identify emerging technology, insurers unfamiliar with the iStent may request additional materials to support coverage when submitting claims.

For information regarding payer coverage in your area, please consult with your Glaukos Regional Business Manager.
Payment

Payment Overview

Healthcare providers are provided payment by payers for the products and services they provide to patients during an episode of care. Two types of payments are generally made: a payment for facility resources and a payment for professional services. Facilities such as hospitals and ambulatory surgery centers are paid for the resources used in an episode of care. Physicians are paid for the services they provide in treating patients.

Medicare Payment

Physician Payment

Medicare provides payment to physicians for services based on a fee schedule called the Medicare Physician Fee Schedule (MPFS). CMS assigns national payment rates on the MPFS for Category I CPT codes. As Category III CPT codes typically reflect new and emerging technologies, CMS does not establish national payment rates on the MPFS for these types of procedures.

Payment for Category III CPT codes will be determined by individual Medicare contractors on a case-by-case basis. Physicians need to establish a charge amount to be submitted with these types of codes. Claims for professional services submitted under Category III CPT codes are often manually reviewed by payers.

The payment methodology for a procedure submitted under a Category III CPT code varies. In some instances, Medicare will calculate payment based on the amount charged on the claim. In other cases, payment will be determined by comparing work involved with the iStent to other similar procedures.

To determine the payment amount for specific codes on the MPFS, visit the Medicare MPFS Lookup feature at this website: http://www.cms.gov/PFSlookup/

Facility Payment

Medicare pays ASCs for services under a prospective payment system called the ASC Payment System. Under this payment system, Medicare assigns procedure codes, which may be performed in the ASC setting of care, to an ASC payment group. This payment group determines the amount that a facility will be paid by Medicare for services provided.

To determine the payment amount for the iStent procedure and associated cataract procedure in the ASC and to obtain additional information related to the ASC Payment System, visit the CMS website: http://www.cms.gov/center/asc.asp

Medicare pays hospitals for outpatient services under a prospective payment system Hospital Outpatient Prospective Payment System (HOPPS).

HOPPS is a payment system that groups payment for drugs and services into ambulatory payment classifications (APCs). The HOPPS provides a fixed, bundled payment for hospital outpatient procedures or services that are assigned to a particular APC (See Table 8). The system determines only the hospital payment and does not affect payment to physicians who perform services in the hospital outpatient setting.

To determine the payment amount for the iStent procedure and associated cataract procedure in the HOPD and to obtain additional information related to HOPPS, visit the CMS website: http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp
Table 8: APC assignment for CPT 0191T

<table>
<thead>
<tr>
<th>APC</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0673</td>
<td>Level V Anterior Segment Eye Procedures</td>
</tr>
</tbody>
</table>

While there is a HCPCS code that can be used to bill for the iStent device itself, Medicare does not provide separate payment for the device. Under Medicare, payment for the iStent and other implantable devices is bundled into the payment for the implantation procedure itself in the ASC and HOPD. **It is still important that facilities include the iStent device on their claim forms to payers as this permits appropriate tracking of the full costs of the procedure(s).**

**Private Payer Payment**

**Physician Payment**

Private payers typically establish their own payment rates for services and procedures and may provide this information on a publicly accessible fee schedule.

As with Medicare, payment for Category III CPT codes will be determined by private payers on a case-by-case basis. Physicians need to establish a charge amount to be submitted with these types of codes. Claims for professional services submitted under Category III CPT codes are often manually reviewed by payers.

The payment methodology for a procedure submitted under a Category III CPT code varies. In some instances, private payers will calculate payment based on the amount charged on the claim. In other cases, payment will be determined by comparing work involved with the iStent to other similar procedures.

Payment rates for specific CPT codes may be obtained from the payer’s published physician fee schedule or by contacting the payer directly.

**Facility Payment**

Private payers each employ their own methodology to determine payment amounts for facility services based on the CPT, ICD-9 and HCPCS codes billed on the claim. Facility billing departments should check the service contracts with individual private payers or contact each payer directly to verify the applicable reimbursement methodologies and/or amounts for the iStent implantation, the associated cataract procedure and for the iStent device itself. As with Medicare, **it is important that facilities include the iStent device on their claim forms to payers in order to capture the full cost of providing the service.**
**Setting Charges**

Providers must determine a charge for Category III CPT codes. There are many variables that may account for the determination of a charge for a particular service. For example, the American Academy of Orthopedic Surgeons suggests that providers consider the following when establishing a charge to submit for a Category III CPT code:

- Time, effort, equipment, RVUs, and cost related to geographic variability of the procedure
- Referencing another CPT code of similar complexity to that of the procedure
- Comparing the preoperative, intraoperative, and postoperative services of the similar procedure to that of the new procedure
- Contrasting the factors that differentiate the services (more difficult or less difficult) and setting the charges accordingly

Additionally, the Practice Management Information Corporation suggests that the following additional resources may also be helpful when determining appropriate charges.

- Payer policies
- Current coding books
- Relative value data for existing Category I CPT codes
- Medicare Fee Schedules for existing Category I CPT codes

Whichever process the provider uses, it should be described in the supporting documentation that accompanies the claim.

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Frequently Asked Questions

Q1. How can I tell whether a private payer will cover the iStent implantation procedure? I can't tell from their coverage policies.

A1. When it is unclear whether a private payer will cover the iStent, the provider may choose to obtain prior authorization for the patient's iStent implantation procedure.

Q2. How can I tell whether Medicare will cover the iStent implantation procedure? I can't tell from their local coverage determinations.

A2. Because Medicare does not have a process to review prior authorization requests, a provider may be required to complete an ABN. Note that an ABN is required for both assigned and non-assigned claims and modifier GA should be appended to the appropriate CPT or HCPCS code. By signing an ABN, the Medicare beneficiary is acknowledging that he or she has been informed that Medicare might not pay for the services being rendered and agrees to be responsible for payment in the event that Medicare does not pay. For a copy of the ABN, please see the Appendix.

In addition, please check with your Glaukos Regional Business Manager for the most current information regarding coverage of implantation of the iStent by your local Medicare contractor.

Q3. Can I bill for the implant of the iStent (0191T) and cataract surgery (66983 or 66984) on the same day for the same patient?

A3. The National Medicare Correct Coding Initiative (CCI) edits do not prohibit billing 0191T and 66983 or 66984 on the same day for the same patient.

Q4: My patient is covered through our local Medicare Administrative Contractor (MAC), and I don't think they will cover the iStent implantation procedure. What should I do?

A4. If your local Medicare Administrative Contractor (MAC) is not yet routinely covering the implantation of the iStent, you may consider having the patient sign an ABN. For a copy of the ABN, please see the Appendix.

Q5. My claim for the iStent procedure was denied. What should I do?

A5. Since Category III CPT codes represent newer – and lesser-known – technologies, payers may request additional documentation showing medical necessity before paying a claim with a Category III CPT code.

Providers are advised to pursue an appeal via the appeals process, which usually involves providing product information, clinical literature, and an explanation describing why the procedure was medically necessary for the patient. Contact the payer in question to get information on the appeals process and the materials they require to show medical necessity.

To see whether you qualify for Glaukos assistance with your iStent medical necessity appeal, contact your Glaukos Regional Business Manager.
Q6. How do I bill Medicare for the iStent when used in the hospital outpatient setting of care?

A6. Hospital outpatient facilities should use revenue code 278 on the UB-04 claim form to bill for the iStent in this setting. Medicare reimbursement for hospital outpatient departments is based on the APC payment system. CPT code 0191T maps to APC 0673.

Q7. What diagnosis codes are covered for use with the iStent? I have a patient who I think would be a good candidate but I don’t know whether his condition would result in on- or off-label use of the iStent.

A7. Providers should check with a patient’s insurer to determine which indications are currently covered, and the appropriate course of action when submitting claims for non-covered indications.

Q8. What procedure code should I use to report the implantation of the iStent?

A8. Providers should bill for the iStent implantation procedure using the Category III CPT code 0191T. As payers typically flag claims with Category III CPT codes for manual review, you should be prepared to provide product information, clinical literature, and an explanation describing why the procedure was medically necessary for the patient.
Appendix

Sample Physician Claim Form (CMS-1500)
Sample ASC Claim Form (CMS-1500)
Sample Hospital Claim Form (UB-04)
CMS Advance Beneficiary Notice (ABN) Form