or the next few years, it appears that minimally invasive glaucoma surgery (MIGS) procedures will continue as Category III Current Procedural Terminology (CPT) codes. However, coding for complications may often utilize Category I CPT codes. The various aspects of coding and compliance that affect reimbursement, as well as a snapshot review of the current status, will be reviewed here. Reimbursement information is based on Medicare guidelines.

BACKGROUND: Updated Medicare Payment Guidelines for Device-intensive Procedures Affect MIGS Procedures ASC Reimbursement

For 2017, there was a restructuring of the Outpatient Prospective Payment System (OPPS) for procedures performed in a Hospital Outpatient Patient Department (HOPD). The prior reimbursement system had adversely affected keratoprosthesis surgery (CPT code 65770). In 2016, ASC reimbursement had dropped to $2,261.69. Because the ASC reimbursement includes the cost of the device ($5,000 to $6,000 depending on the model), it was impossible for ASCs to host these procedures due to a significant amount of money lost on each case.

The Centers for Medicare and Medicaid Services (CMS) in the 2017 Fee Schedules (OPPS/ASC), effective Jan. 1, 2017, presented a new methodology for calculating reimbursement of device-intensive procedures, such as the keratoprosthesis surgery (CPT code 65770), and other MIGS codes, such as iStent (CPT code 0191T). A device-intensive procedure is defined as one in which the cost of the device accounts for 40% or more of the reimbursement. The totally new reimbursement calculations for device-intensive procedures are based on CPT code rather than an APC (Ambulatory Payment Classification). This resulted in a significant increase in reimbursement for these procedures with the 2017 national reimbursement for 65770 increasing to $6,490.10. Thus, it is once again viable for keratoprosthesis procedures to be performed in an ASC. Because the ruling was applied to all device-intensive procedures, it now includes other MIGS codes, such as 0191T (iStent), for which the national average reimbursement in 2016 was $1,793.90. The 2017 reimbursement increased to $2,553.77.

UPDATE ON MIGS DEVICES

Table 1 presents a “snapshot” of the current status of various MIGS devices being used in the United States. Some of the devices have received FDA approval in the past year and have been assigned a CPT Category III code. This is a rapidly changing field and, like last year’s grid, will probably change sooner rather than later. Several companies were bought out, so current ownership information is also listed in Table 1.

Implementation of Category III Codes. The CPT Editorial Panel system for implementation of a Category III code involves the following: once the code is initially issued, its actual implementation occurs 6 months afterward. During the interval, there is no way to bill for the procedure until the implementation date. Neither unlisted code 66999 - Unlisted procedure, anterior segment of eye, nor 92499 - Unlisted ophthalmological service or procedure is an appropriate code. There is no mechanism for processing Medicare reimbursement when using any of the unlisted codes for ASC coding.

An example: CyPass (Alcon) received approval for a Category III code at the Fall 2016 meeting of the CPT Editorial Panel and was added to the Category III list on Jan. 1, 2017 for implementation on July 1, 2017. For the first 6 months, the procedure cannot be billed to Medicare and, most likely, other insurers as well. Furthermore, attempts at using the unlisted CPT codes

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### TABLE 1:
**A SNAPSHOT OF THE CURRENT STATUS OF MIGS IMPLANTED DEVICES**
*DATA AS OF APRIL 2017*

<table>
<thead>
<tr>
<th>BRAND NAME</th>
<th>MANUFACTURER</th>
<th>MECHANISM OF ACTION</th>
<th>CPT CODE</th>
<th>FDA APPROVALS</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| CyPass Micro-Stent | Alcon        | Shunts aqueous from the anterior chamber to the supraciliary/suprachoroidal space.  | 0474T (effective July 1, 2017) | Yes            | ➤ Requires performance in conjunction with cataract extraction.  
➤ For use with mild to moderate glaucoma.                                                   |
| Hydrus Microstent | Ivantis       | Implanted within Schlemm’s canal to facilitate aqueous outflow by stretching the wall and scaffolding the canal, potentially allowing for a larger area of flow within the aqueous outflow distal system. | No code at this time | No             | ➤ Requires performance in conjunction with cataract extraction.  
➤ For use with mild to moderate glaucoma.  
➤ Current treatment with ocular hypotensive medication.                                     |
| InnFocus Microshunt | Santen       | Shunts fluid from anterior chamber to subconjunctival space under a subconjunctival-subTenon’s flap. | 66183    | No             | ➤ Can be performed in conjunction with or without cataract surgery.  
➤ A minimally invasive stand-alone procedure for mild, moderate, and severe stages of open-angle glaucoma. |
| iStent            | Glaukos       | Shunts aqueous from the anterior chamber through the trabecular meshwork into the Canal of Schlemm. | 0191T+0376T (for each additional device)**|| Yes | ➤ Requires performance in conjunction with cataract extraction.  
➤ For use with mild to moderate glaucoma.  
➤ Current treatment with ocular hypotensive medication.                                     |
| iStent Supra Micro-Bypass Stent | Glaukos | Shunts aqueous into the suprachoroidal space to facilitate aqueous outflow. | 0253T* | No             | ➤ Can be performed in conjunction with or without cataract surgery.  
➤ For use with mild to moderate glaucoma.                                                   |
| iStent Inject     | Glaukos       | Stents shunt aqueous from the anterior chamber through the trabecular meshwork into the Canal of Schlemm. Two stents are implanted sequentially using an injector inserted once into the trabecular meshwork. | 0191T | No             | ➤ Can be performed in conjunction with or without cataract surgery.  
➤ For use with mild to moderate glaucoma.                                                   |
| iTrack            | Ellex         | Microcatheter insertion and removal followed by viscodilation of Schlemm’s canal, thus, opening of collapsed collector channels and trabecular meshwork. | 66174    | Yes            | ➤ Can be performed in conjunction with or without cataract surgery.  
➤ For use with mild to severe glaucoma.                                                     |
| XEN Gel Stent     | Allergan      | Shunts aqueous from the anterior chamber to subconjunctival space creating an ab interno bleb that becomes, over time, a low-lying drainage area. | 0449T+0450T (for each additional device)**| Yes | ➤ Can be performed in conjunction with or without cataract surgery.  
➤ For use with mild to moderate and severe glaucoma.  
➤ For use when medical and surgical therapy has failed and for cases of primary open-angle glaucoma and pseudo-exfoliation or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy. |

* Procedures cannot be billed until clinical trials are complete and device receives FDA approval.  
** Off-label use/multiple stents are packaged together and not payable by Medicare.  
= Medicare packages additional codes so that only one device is reimbursed. At this time use of a second device is an off-label use.  
+ Add-on codes (indicated by a +) must be used with a primary code and cannot be used independently.
66999 or 92499 will result in nonprocessing of the Medicare claim for the ASC.

**OFF-LABEL USE WITH MIGS DEVICES (TABLE 2)**

When a drug or device (all MIGS implants are considered devices by the FDA) is used off-label, there are numerous compliance regulations that must be followed. Some of them are presented here.

As noted in the May 2016 *Ophthalmic ASC* article, “Coding for Current Concepts in Glaucoma Surgery,” the chart documentation for each procedure performed in an ASC should be comprehensive in its own right, and the ASC chart should be able to withstand a Medicare audit in terms of medical necessity on its own documents.¹

First and foremost, drugs and devices (only devices are discussed in this paper) can be utilized only for the usage approved by the FDA when billing Medicare. Any other usage is considered off-label.

As an example, The FDA has approved the use of iStent in conjunction with cataract surgery in patients with mild to moderate glaucoma currently on hypotensive medication — and only for the initial insertion. The following procedures would be considered an off-label use: using Category III code 0376T (each additional device insertion), using the device as a stand-alone procedure without cataract surgery, and use of the device in multiples.

ASC payment is also impacted in that the payment for two iStent devices codes implanted in the same session is packaged together, thereby preventing billing and reimbursement for the second device. Also note that the patient cannot be billed.

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**Informed Consent.** When a drug or device is used off-label, it is mandatory that an informed consent be used that specifies that. OMIC has a sample form on its website (http://www.omic.com/informed-consent-for-off-label-use-of-a-drug-or-device/). In the event of risk management events, such as malpractice lawsuits, the physician is not protected without it. When a second stent is implanted in the same session, the ASC should ascertain that risk management protocols are followed and be aware of the payment consequences.

**Use of CPT code 66999 (Unlisted procedure, anterior segment of eye) or 92499 (Unlisted ophthalmological service or procedure).** The usual employment of an unlisted code is when a procedure is performed that is not exactly described by another CPT Category I code. For physicians, Medicare has a mechanism in place for determining payment of an unlisted code, whereby a reviewer analyzes the procedure performed and assigns a payment value; however, no such mechanism is in place for ASC procedures — thus rendering the use of an unlisted code in any specialty not payable.

**CASE STUDIES**

**Case 1.** The patient had a nuclear cataract and moderate stage open-angle glaucoma in the right eye. The cataract surgery using phacoemulsification with insertion of an intraocular lens was successfully completed. Placement of the iStent was started; however, the surgeon was unable to successfully position the iStent, and the surgery was aborted.

Diagnosis: 1) T85.698A Mechanical complication of implanted material; 2) H40.1112 Primary open-angle glaucoma, right eye moderate stage; 3) H25.11 Age-related nuclear cataract, right eye.

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**TABLE 2: MIGS OFF-LABEL SURGICAL CODING PARAMETERS IN ASCs**

<table>
<thead>
<tr>
<th>TYPE OF PROCEDURE</th>
<th>CONSIDERED OFF-LABEL USE</th>
<th>CPT CODE</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removal of device</td>
<td>No</td>
<td>65920</td>
<td>ASCs will not be paid for claims using CPT codes 66999 or 92499.</td>
</tr>
<tr>
<td>Exchange of device</td>
<td>Yes/No</td>
<td>65920 for removal only — the secondary insertion may be an off-label use</td>
<td>Insertion of new second device can be performed when it has FDA approval for insertion as a stand-alone device. <em>(See Table 1)</em></td>
</tr>
<tr>
<td>Stand-alone procedure</td>
<td>Yes/No</td>
<td>See Table 1</td>
<td>Not off-label when FDA approved for stand-alone device. <em>(See Table 1)</em></td>
</tr>
<tr>
<td>Discontinued procedure</td>
<td>No</td>
<td>CPT code followed by appropriate modifier</td>
<td>Use the MIGS CPT code and Modifier 73 (before anesthesia) or 74 (after induction of anesthesia) for ASC coding. For physician coding modifier 53 may only be used after the surgery has commenced.</td>
</tr>
</tbody>
</table>
**Case 2.** The patient presented with malpositioning of an iStent in the left eye. Original surgery consisting of phacoemulsification with insertion of an IOL for the cataract surgery and insertion of an iStent had been performed 6 weeks earlier, so the patient was in the global period. Surgery consisted of removal of the originally inserted iStent.

Diagnosis: 1) T85.698A Mechanical complication of implanted material; 2) Z98.89 Personal history of surgery.

### Case 2: Surgery Coding

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Modifiers</th>
<th>Diagnoses</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASC Coding</td>
<td>65920-LT</td>
<td>1, 2</td>
<td>It is not necessary to use the modifiers 58, 78, or 79 for ASC Medicare coding in cases being performed in the global period.</td>
</tr>
<tr>
<td>Physician Coding</td>
<td>65920-78-LT</td>
<td>1, 2</td>
<td>For physician coding, one of the modifiers must be used when a procedure is performed in the global period. Because this surgery is related to the prior surgery, it is modifier 78.</td>
</tr>
</tbody>
</table>