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A MIGS Compliance Compendium

The terms "Minimally Invasive Glaucoma Surgery" and "Micro Invasive Glaucoma Surgery (MIGS)" were coined by Iqbal K. Ahmed, MD, FRCSC, and, as described by him, are generally defined by these characteristics:

"MIGS procedures share five distinct qualities: (1) an ab interno, microincisional, conjunctiva-sparing approach; (2) minimal trauma to and disruption of normal anatomy and physiology, with devices that exhibit a high level of biocompatibility; (3) moderate to high IOP-lowering efficacy; (4) an extremely positive safety profile; and (5) rapid recovery by the patient. Although other procedures may share some of these traits, they do not necessarily fit the true definition of MIGS."[1]

When a new technology is presented, there are many administrative, reimbursement, and compliance obstacles that confront both physicians and ASCs. This review outlines the principal issues and describes how they should be handled in terms of Medicare reimbursement. Each commercial payor has the right to make individual rules that may deviate from those of Medicare.

Reimbursement

FDA Approval. The type of FDA approval influences whether or not a given Medicare Administrative Contractor (MAC) will cover a given procedure. Premarket Approval (PMA) is issued based on full clinical trials, whereas what is known as a 510K approval is based on the safety of the device being similar to other approved ones, but without extensive clinical trials having been performed.

> Example: *The MAC, NGS Medicare, after physicians' appeals for coverage, reconsidered and issued coverage for the use of Xen45 Gel Stent (Allergan) — but only for the indication of refractory glaucoma; however, it was* ***not*** *approved for use in mild to moderate glaucoma. This is explained in their Local Coverage Determination (LCD) and is based on Xen45 Gel Stent having only 510K approval from the FDA.*[2]

ASC Reimbursement. Medicare ASC reimbursement is based on a fee schedule derived from the Outpatient Prospective Payment System (OPPS) and hospital reimbursement. The facility payment usually, but not always, includes the drug or device. Currently, any MIGS surgery fee includes payment for a ***single*** device. Although the Current Procedural Terminology (CPT) book includes codes for the insertion of additional devices, if the FDA approval mandates the surgery be performed in conjunction with cataract extraction, and for the ***initial*** insertion, then neither the ASC nor the physician will be reimbursed for insertion of an additional device.

> Example: *For iStent (Glaukos), only a single device may be implanted concurrently with the cataract surgery, and use of an additional device would be considered an off-label use. However, for iStent Inject (Glaukos), it is normal usage because both Inject devices are contained within the single inserter.*

Physician Reimbursement. When classified as a CPT Category III Code (Emerging Technology), Medicare payment for the surgeon's reimbursement is solely under the jurisdiction of each individual MAC and the amount is what each MAC determines is suitable … but only for as long as the given MAC wants to pay that amount. Each MAC can change the amount of the physician reimbursement at any given time, as we all have witnessed. There remain constant flurries of change, often based on less than accurate information and questionable comparability for procedure code crosswalks. Because the devices are currently listed as Category III codes, there are

challenges, such as the fees not being posted on the MAC's fee schedule or Fee Lookup schedule, even though it is being paid.

Examples: *Currently, Novitas-Solutions, Inc. covers CyPass (Alcon) but the pricing is not published on either of the above noted fee schedules. Noridian currently pays $0.01 and might pay more on appeal.**

Off-label Use

All MIGS implants are considered devices by the FDA and, when used off-label, involve numerous compliance regulations that must be followed.

The FDA approves drugs and devices for specific usages. The package insert or "labeling" describes those that are approved. The FDA regulates the written materials a manufacturer can use to describe a product's uses. An "off-label" use is one the FDA has not expressly approved. Sometimes a procedure becomes so common that no one bothers identifying it as off-label; however, with devices there are stricter regulations. Using any MIGS device for something other than the FDA-approved use is considered an off-label use.

A medical device or drug may neither be marketed nor promoted for "off-label" uses, i.e., those that have not been approved by the FDA. Furthermore, there may be a National Coverage Determination that can be supplemented by the MAC in an LCD. When looking through a MAC listing of LCDs, the off-label information, as well as approval of the use of a Category III code, is often found under an LCD titled "Services that are not Reasonable and Necessary," or a similar one.

Chart Documentation. The chart documentation for each procedure performed in an ASC or by the physician 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. This is of utmost importance and is discussed in more detail later in this article.[3]

Informed Consent. When a device is used off-label, it is mandatory that an informed consent be used that specifies that it is an off-label use. OMIC has a sample form on its website (omic.com/informed-consent-for-off-label-use-of-a-drug-or-device).[4] An additional informed consent is generally recommended for the procedure itself and should be device specific. In the event of risk management events, such as malpractice suits, the physician is not protected without it.

ASC Payment Consequences. When a second stent is implanted at the same session, the ASC should ascertain that risk management protocols are followed and be aware of the payment consequences. CPT code +0376T is an add-on code, which means it is used for multiple stents that are separately inserted at the same session. An add-on code is always attached to a primary code and cannot be billed alone. From the ASC perspective, the patient cannot be billed for additional stents because they are packaged together in the single payment to the ASC.

Example: *The current FDA approval of iStent is for initial insertion of a single device at a given session. The use of an additional iStent at the same session (CPT code +0376T) is not FDA approved. The ASC payment is packaged with*

TABLE 1. MIGS OFF-LABEL SURGICAL CODING PARAMETERS
ASC & PHYSICIAN REIMBURSEMENT

Type of Procedure	Considered Off-label Use?	CPT Code	Comments
Removal of device	No	65920	ASCs cannot be paid for Medicare claims using CPT codes 66999 or 92499 due to a lack of any administrative mechanism to determine payment.
Exchange of device	Yes/No	65920 for removal only — the secondary insertion may be an off-label use	Insertion of new second device can be performed if it has FDA approval for insertion as a stand-alone device.
Stand-alone procedure	Yes/No	*Applicable CPT Code*	Not off-label when FDA-approved for stand-alone device.
Discontinued procedure	No	CPT code followed by appropriate modifier	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.

*At press time, CyPass devices have been recalled until further notice.

that of 0191T. It has an N1 Payment Indicator (PI) and no extra payment is made to an ASC for additional packaged items. The January 2018 national ASC payment amount for procedure code 0191T is $2,573.27. No payment is made for more than one stent.

Physician Financial and Compliance Responsibilities. It is incumbent upon the physician to follow proper protocols regarding off-label use when inserting multiple iStents or other devices. This includes the following:

- An addendum to the iStent informed consent form if you use the one OMIC (Ophthalmic Mutual Insurance Company) provides, or any other one, regarding the use of multiple stents at the same session;
- A separate informed consent for using the second device as off-label;
- A written confirmation that informs the patient of financial responsibilities for the procedure/device and having a signed ABN (Advanced Beneficiary Notice) when applicable.

The ASC should ensure all of the above are in order before scheduling multiple stent procedures.

Stand-alone Procedures. When any of the MIGS procedures that the physician elects to use as a stand-alone procedure is contemplated — and if that device is FDA approved only under certain circumstances, such as in conjunction with cataract surgery — then that is an off-label use of the device and all regulations of off-label devices must be adhered to.

TABLE 2. CATARACT & COMPLEX CATARACT SURGERY MEDICAL NECESSITY & CHART DOCUMENTATION
ASC & PHYSICIAN CHECKLIST

CATARACT SURGERY WITH IOL (CPT 66984)	
MEDICAL NECESSITY	❑ Chart and ADL Questionnaire VF-R8 substantiates ADL problems and/or symptoms specific to presence of cataract in eye designated for surgery ❑ Comprehensive eye examination including vision with and without correction/PH ❑ Copy of office visit when decision for surgery was made ❑ Copy of witnessed ADL form signed by patient ❑ Narrative rationale for medical decision for surgery ❑ Other_____
COMPLEX CATARACT SURGERY WITH IOL (CPT CODE 66982)	
MEDICAL NECESSITY	❑ Mandatory documentation in addition to that listed above that is required to code complex cataract ❑ Narrative in chart documentation detailing why case is complex ❑ Devices and/or surgical techniques not ordinarily used in regular cataract surgery (planned use) ❑ Iris expansion devices ❑ Suturing of IOL ❑ Primary posterior capsulorhexis ❑ Patient is in amblyogenic age group ❑ Synechiolysis ❑ Capsular tension ring ❑ Other
EXAMINATION & SURGERY PLANNING	❑ Examination ❑ Pupillary size Before dilation_____ After dilation_____ ❑ Synechiae Type_____ ❑ Type of cataract and density _____ ❑ Patient on Flomax/possible intraoperative floppy iris syndrome ❑ Other_____
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Chart Documentation

This is the area in which nearly all of ASCs and physicians readily are found at fault due to the lack of proper training combined with the proliferation of Medicare auditing. Once a practice or ASC is aware of the rather straightforward rules, it is fairly easy to achieve compliance.

Tables 2 and 3 are excellent tools to be used per patient/per surgery, and both forms provide the needed chart documentation for audits.[5]

ASC Chart Documentation. In a previous article from the February 2018 issue of *The Ophthalmic ASC*[3] — one I strongly urge you to read — a case study is included wherein ***both*** the physician's chart notes and the ASC chart notes failed to document Medical Necessity for the procedures, resulting in the recoupment of monies from ***both*** entities. When auditing ASCs, I find that most practices succeed in passing accreditation for Conditions of Coverage, and many succeed in successfully coding the surgeries; however, very few actually document medical necessity for the cataract surgery. If Medical Necessity is not documented in the physician's chart and the ASC has also failed to document it separately, then the auditor will fault the ASC and demand repayment of funds.

It is recommended that the ASC ascertain, either by having the practice complete paperwork (such as found in Tables 2 and 3) specifically for the ASC, or send the ASC copies of those completed documents for the ASC chart. Whenever cataract surgery is being performed, the ASC must also have chart documentation from the surgeon that includes a copy of the office visit where the determination for surgery is made and a copy of the Activities of Daily Living form for the cataract surgery. *The ASC chart must stand and be in compliance on its own regarding medical necessity for each procedure performed.*

Physician Chart Documentation. In addition to the mandatory medical necessity and chart documentation requirements for cataract surgery, medical necessity for the glaucoma surgery must be documented separately and includes the items in Table 3.

With the advent of electronic health records, the chart documentation has become poorer and quite robotic. It is important to individualize the chart notes — make them less cookie cutter — particularly on the notes for the date of service when the glaucoma surgery is recommended. ■

TABLE 3. MIGS DEVICES
MEDICAL NECESSITY & CHART DOCUMENTATION
ASC & PHYSICIAN CHECKLIST

CHART DOCUMENTATION SUPPORT OF MEDICAL NECESSITY	
MEDICAL NECESSITY	**MAC/INSURER GUIDELINES** ❑ Device is Medically Necessary as described in MAC LCD ❑ Device is Medically Necessary as described in MAC Article ❑ Device is approved for physician payment by the MAC ❑ Device is approved for payment on CMS ASC National Fee Schedule
EXAMINATION CHART DOCUMENTATION	**CLINICAL CONDITIONS** The following are documented in the chart preoperatively supporting medical necessity: ❑ Elevated IOP ❑ Currently on glaucoma medication ❑ Possibility of IOP control without medications or reduction of medication(s) exists as result of MIGS surgery ❑ Narrative description of rationale for MIGS surgery that includes exam findings, difficulty controlling pressure and possible social/ADL factors, such as difficulty in installing medications, confusion, etc. ❑ Other_____ **EXAMINATION** ❑ Comprehensive eye exam ❑ Narrative description of current conditions and why MIGS surgery is Medically Necessary ❑ IOP and narrative description of any issues regarding IOP control, compliance issues with medications, etc.
DIAGNOSTIC TESTS FOR GLAUCOMA	❑ Visual Fields: Comments_____ ❑ OCT: Comments_____ ❑ Other: _____

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