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MIGS 2020

Medicare's new compliance and reimbursement regulations

The year 2020 heralds significant news from Medicare regarding billing/coding regulations and adherence to strict compliance rules when surgically implanting minimally or micro-invasive glaucoma surgery (MIGS) devices. Physicians, as well as ASC personnel, would do well to pay close attention to all the issues addressed.

This year's grid (Table 1) differs from my others in that it includes only FDA-approved MIGS devices that are intended for permanent implantation barring unforeseen complications.

Instruments Versus Surgical Techniques

The MIGS acronym has been described as either "Micro-Invasive Glaucoma Surgery" or "Minimally Invasive Glaucoma Surgery." However, in either case, the operation is coded using the surgical technique in the Current Procedural Terminology (CPT) descriptor—not the instrument used nor the branded device itself. Thus, "insertion of aqueous shunt" or "insertion of aqueous drainage device" describes a surgical procedure or technique, whereas the Kahook Dual Blade, Trabectome, and Omni Surgical System are essentially instruments used to perform a procedure. Instruments are not issued CPT codes; surgical procedures are. In contrast, Food and Drug Administration (FDA) pre-market approval may be obtained for instruments or devices used in performing a surgical procedure. Qualifications and quantifications regarding usage may also be issued.

Off-Label Use of MIGS Devices

In the medical field the term "Off-Label" is well-known, but few physicians pay great attention to the attendant regulations that should be followed if a product is used off-label. It is imperative that ASC personnel and surgeons understand the responsibilities inherent in an off-label use.

FDA Approved Usage. An **approved** usage of a device occurs when the product is used in accordance with the diagnostic parameters specified on the product label and using surgical techniques that are in compliance with the corresponding restrictions as specified by the FDA.

Example: Xen 45 Gel Stent (Allergan) is only approved for using ab interno *surgical approach and for treatment of refractory glaucoma, etc. (See Table 1).*

FDA-Approved Device/Not-Approved Usage. This occurs when a given device is used for treatment of a condition or usage **not specifically approved by the FDA on the label,** although the device is FDA approved for another indication. An off-label use of an FDA-approved device may be awarded a Category III CPT code; however, this is not synonymous with obtaining payment. Category III codes do not require FDA approval, whereas Category I codes do.

Example: iStent (Glaukos) is approved for the treatment of mild to moderate glaucoma. It is not approved for treatment of refractory glaucoma. Currently, the latter use would be considered an off-label usage, as would stand-alone usage without concurrent cataract surgery.

Example: Xen 45 Gel Stent inserted via an ab externo approach.

FDA Not-Approved Device/Not-Approved Usage. If a given device has not received FDA approval to be marketed in the U.S., it cannot be used in the U.S. Use of the device cannot be billed to Medicare or other insurers. Further clarification regarding these issues is best provided by a healthcare attorney.

A non-approved medical device is one that has not been approved, cleared, nor licensed by the FDA to be marketed. A non-approved medical product(s) will not be paid for by Medicare, or by any other payer in the U.S., and, if wittingly submitted for payment, could be considered insurance fraud.

Example: A device is approved by a local hospital's Institutional Review Board (IRB) and is also approved and used for treatment outside the U.S. It does not

TABLE 1

A SNAPSHOT OF THE CURRENT STATUS OF FDA-APPROVED MIGS IMPLANTED DEVICES

Data as of January 2020 • ©2020 Riva Lee Asbell

Brand Name	Manufacturer	Mechanism of Action	CPT Code	FDA Approvals	Comments
CyPass Micro-Stent	Alcon, Inc	Shunts aqueous from the anterior chamber to the supraciliary space.	0474T	**NO** **Approval withdrawn by Alcon and FDA in 2018**	→Requires performance in conjunction with cataract extraction. →For use with mild to moderate glaucoma. See article for removal and revision information.
Hydrus Microstent	Ivantis, Inc.	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.	0191T* (Manufacturer's Recommendation)	**YES**	→Requires performance in conjunction with cataract extraction. →For use with mild to moderate glaucoma.
iStent	Glaukos, Inc.	Shunts aqueous from the anterior chamber through the trabecular meshwork into Schlemm's canal.	0191T* [+0376T* 🖬#]	**YES** **FDA approval only for Initial Stent Insertion**	→Requires performance in conjunction with cataract extraction. →For use with mild to moderate glaucoma. →Current treatment with ocular hypotensive medication.
iStent *Inject*	Glaukos, Inc.	Two 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 one time into the canal of Schlemm.	0191T*🖬	**YES** MEDICARE LCDs **PROHIBIT BILLING FOR TWO DEVICES WHEN USING ONE INJECTOR LOADED WITH TWO DEVICES.** APPLIES TO ASC AND PHYSICIAN SERVICES	→Requires performance in conjunction with cataract extraction. →For use with mild to moderate glaucoma.
XEN 45 Gel Stent	Allergan, Inc.	XEN 45 Gel Stent 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** **MOST MACs APPROVE ONLY FOR REFRACTORY GLAUCOMA** and **REQUIRE SPECIFIC GLAUCOMA TRAINING and EXPERIENCE OF THE SURGEON**	FDA approved use of the XEN 45 Gel Stent and the XEN Injector for patients with refractory glaucoma who failed previous surgical treatment or in patients with primary open angle glaucoma, pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

**Medicare does not consider additional stent placement as medically necessary.*

🖬 *Medicare packages additional codes so that only one device is reimbursed. At this time use of a second device is an off-label use and considered a non-covered code. Two devices packaged in one injector will be reimbursed as one procedure only.*

+ Add-on codes (indicated by a +) must be used with a primary code and cannot be used independently.

 # Category III Codes +0376T and +0450T are **not** *eligible for Medicare reimbursement. (See Footnote 2.)*

have FDA approval. This is a totally non-covered service for both the ASC and the surgeon. It is illegal to bill Medicare for the surgery or the device.

Example: Insertion of a MINInject device from Europe. (See Footnote 1.)

Informed Consent. When a device is used off-label, it is mandatory that a separate informed consent be issued to the patient that specifies it is being used as such. This may be one of the most overlooked compliance issues in ophthalmology and is extremely important. OMIC has a sample informed consent form for off-label use on its website (https://bit.ly/37Imw83).

Furthermore, if a risk management event does occur, the physician may not be able to present a sufficient defense. The ASC may be co-joined. It is best to consult with a healthcare attorney on this issue.

Medicare's New/Revised Local Coverage Determinations (LCDs) for MIGS Surgery

New LCDs have been issued or revised resulting in only one Medicare Administrative Contractor (MAC)—Wisconsin Physician Services—that defaulted on issuing a MIGS surgery LCD by the end of 2019.

In summary, currently only 15 out of the 50 states + U.S. territories do not have a policy specific to iStent Inject, although there are policies regarding other MIGS devices. So, with the exception of states covered by Wisconsin Physician Services, physicians billing for MIGS surgery in all the other states and territories are obliged to follow their MAC's LCD. Let's take a look at some of the main provisions and reimbursement regulations generally found.

Billing/Coding for More Than One Surgery and/or Device. For ASCs this is quite straightforward: the use of any additional devices used in MIGS surgery is regulated by the N1 modifier signifying that additional devices are packaged and ***may only be billed once*** by the ASC. This applies to iStent as well as iStent Inject and other products such as Hydrus and Xen 45 Gel Stent.

Billing/Coding for Supraciliary or Suprachoroidal Devices. It is unlikely that the FDA will approve future supraciliary or suprachoroidal devices without long-term studies of corneal endothelial loss.

Sample Regulation Found in Medicare (MACs) LCDs. Excerpts from the Novitas-Solutions, Inc. LCD (L38223) Micro-Invasive Glaucoma Surgery (MIGS) and Article (A56633) Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) are presented (boldface added by author): https://bit.ly/2QV5pZF.

Covered Indications

Glaucoma surgical aqueous drainage devices will be considered medically reasonable and necessary when approved by the FDA and used within accordance of the FDA-approved/cleared indications.

1. ***A single insertion per eye of an anterior segment aqueous drainage device(s),*** *without extraocular reservoir, via internal approach into the* ***trabecular meshwork*** *or with creation of intraocular reservoir into the supraciliary space is considered medically reasonable and necessary in conjunction with cataract surgery for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication.*
2. ***A single insertion per eye of an aqueous drainage device(s) without extraocular reservoir,*** *via* ***internal approach*** *into the* ***subconjunctival space*** *is considered medically reasonable and necessary as a* ***standalone treatment*** *for refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and/or mean diurnal medicated IOP greater than or equal to 20 mmHg) on maximally tolerated medical therapy (i.e., greater than or equal to 4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues).*

Limitations

The following are considered **not medically reasonable and necessary:**

1. *Glaucoma drainage devices that* ***do not have FDA approval/clearance*** *and/or devices that have been* ***recalled.***
2. *Glaucoma drainage devices used* ***outside of the FDA approval/clearance.***
3. *Insertion of an anterior segment aqueous drainage device without extraocular reservoir, via internal approach into the* ***suprachoroidal space.***
4. ***Additional*** *insertions of anterior segment aqueous drainage device(s) without extraocular reservoir, via internal approach into the* ***trabecular meshwork.***
5. ***Additional*** *insertions of aqueous drainage device(s) without extraocular reservoir, via internal approach into the* ***subconjunctival space.***

6. *A single insertion of an FDA-approved/cleared anterior segment aqueous drainage device(s) without extraocular reservoir, via internal approach into the trabecular meshwork or with creation of intraocular reservoir via internal approach into the supraciliary space* ***not performed in conjunction with cataract surgery.***
7. ***Goniotomy*** *procedure performed in conjunction with the insertion of a glaucoma drainage device.* ***Routine performance*** *of goniotomy with insertion of a glaucoma drainage device may be subject to* ***focused medical review.***
8. ***Trabeculectomy*** *procedure performed in conjunction with the insertion of a glaucoma drainage device.* ***Routine performance*** *may be subject to* ***focused medical review.***
9. *Insertion of glaucoma drainage device(s) (e.g., one or two microstents) into the trabecular meshwork or into the supraciliary space are* ***limited to one insertor per eye*** *when performed in conjunction with cataract surgery and when the medically reasonable and necessary criteria as stated above are met.*
    - ***Additional insertor use for device insertions on one eye is considered not medically reasonable and necessary.***
10. *Insertion of glaucoma drainage device(s) into the subconjunctival space are limited to one insertion per eye per day when the medically reasonable and necessary criteria as stated above are met.*
    - ***Additional device insertions are considered not medically reasonable and necessary.***

At this point in time, MACs ***neither cover nor pay for the add-on code +0376T*** (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork; each additional device insertion [list separately in addition to code for primary procedure]) and this second device is not considered medically necessary. ***The insertion of a second stent never did receive FDA premarket approval*** even when CPT Category III code +0376T was issued. The idea was to use an additional device concurrently in conjunction with placement of an iStent. It is sometimes erroneously recommended to bill for a second device on the physician side after placing an iStent or iStent *Inject.* The new LCDs are quite clear on this. How could an ASC bill for two iStent *Injects* when only one device containing one injector and two stents is purchased as one unit?

In summary, these are new regulations that have not been previously delineated by Medicare in-depth nor as detailed as they now are, so it behooves each physician performing the surgery, reimbursement personnel, and individuals responsible for compliance to ascertain that all procedures are coded and billed properly. ASCs may want to monitor the surgeon's coding to make sure it is correct and corresponds to their own.

Provider Education and Qualifications

The Novitas-Solutions, Inc. policy addresses—as do others—physician training and qualifications pertaining to the performance of MIGS procedures:

Provider Qualifications

Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. This training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty or must reflect extensive continued medical education activities. If these skills have been acquired by way of continued medical education, the courses must be comprehensive, offered or sponsored or endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States, and designated by the American Medical Association (AMA) as Category I Credit.

- ***Provider Specialties***
    - *Insertion of glaucoma drainage devices addressed in this LCD must be performed by a qualified physician (MD or DO) who is a board certified ophthalmologist having completed a residency and/or fellowship program and maintains ongoing certification in ophthalmology.*
    - *In addition, insertion of a substitute standalone drainage device into the subconjunctival space without associated cataract extraction must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.*

Coding for Complications of MIGS Procedures

Complications occurring with MIGS-implanted devices need to be coded properly in order to obtain reimbursement. A complication that occurs after the surgery is often coded differently from complications that occur intraoperatively that only require use of a modifier. Guidance for coding subsequent procedures related to handling of complications related to the initial insertion, regardless of time frame, is offered here.

Removal of the Device. Subsequent removal of the implant is correctly coded using CPT code 65920 and is paired with ICD-10-CM diagnosis codes as indicated. Category III codes for removal are generally not paid.

DIAGNOSIS: 1) T85.698A Other mechanical complications of other specified internal prosthetic devices, implants and grafts

2) Z98.890 Personal history of surgery not elsewhere classified

Surgery: Diagnosis	Procedure Code(s)	Modifier(s)
1) 1, 2	**65920** Removal of implanted material, anterior segment of eye	*Use location modifier RT or LT.* If in the global period of the original insertion modifier 78 should be appended

NOTE: *This is* **not** *to be used when insertion and removal are performed or the insertion is not completed in the* **same session.**

Inability to Complete the Insertion of the Device. In the event that the surgeon encounters complications during the procedure precluding insertion of the device, the appropriate CPT code should be used with modifier 74 on the ASC claim and modifier 53 on the physician claim.

Repositioning/Trimming of the Device. There is **no specific CPT code for repositioning or trimming of any MIGS device.** CPT mandates that the code selected must be specific and not merely an approximation—an unlisted code (one that ends in "99") must be used when a precise CPT code does not exist. Technically, both the surgeon and the ASC must use CPT code 66999. **However, an ASC has no mechanism for obtaining reimbursement for unlisted codes and thus cannot accept these cases. The cases would have to be performed in a hospital setting rather than an ASC.**

For Medicare physician reimbursement, the claim is sent for medical review and the payment amount is thus determined. When submitting claims using any unlisted code, the physician should send in a clinical summary and operative notes.

Sources For Advice

Chart Documentation and Medical Necessity. In the February 2018 issue of *Ophthalmic ASC*, I wrote an article titled "ASC & Physician Medicare Audits: Cataracts & MIGS Surgery" that is replete with checklists and forms that both ASCs and practices can use to properly and completely document their procedures. I suggest you look it up and consider using these forms *(ophthalmologymanagement.com/supplements/2018).*

Ah! The Conundrum. I seriously recommend that when a third-party payer—be it Medicare or any other insurer—is involved in payment for your services (ASC or physician) that the insurer be the final decision-maker and its policies be followed…surely this is true for Medicare. Thus, advice offered by none of following should be used as justification for deviating from Medicare or other insurer's published policies: employees in any capacity, physician opinions, society newsletters/courses, consultants, and corporations that manufacture and/or sell the product(s). Rationalization does not produce a safe policy for practices to follow. It is not only audits that providers and facilities should be aware of—the greater risk might very well be not being able to provide a good defense in case of a malpractice lawsuit. That being said, it behooves ASCs and surgeons to look up and closely study their MAC's LCD(s). ■

Footnotes

1. FDA approvals for supraciliary/suprachoroidal MIGS devices are pretty much on hold due to the absence of clinical trials demonstrating no long-term damaging of the endothelial cells.
2. Category III CPT codes do not require FDA approval whereas Category I codes do.

References & Resources

1. Asbell, RL. 2015 ASC Coding Update for Glaucoma Surgery. *Ophthalmic ASC*. February 2015.
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