

Reimbursement Challenges and Solutions With “New” Glaucoma Procedures

The long, bumpy road to payment.

BY ADAM C. REYNOLDS, MD

At a meeting a few years ago where physicians and industry innovators discussed novel glaucoma surgeries, a venture capital expert commented that, no matter how good a new surgical technique for glaucoma was, if health insurance companies would not pay for it, it had no viability in the US market. Although a small number of patients are willing to pay cash for noncovered glaucoma procedures, overall, market expectations are different in this field than for oculoplastics, refractive surgery, or premium IOL services. Unless the system changes, any new glaucoma procedure must be primed for eventual adoption and coverage by a majority of third-party payers. A book could probably be written about strategies for gaining reimbursement from third-party payers for new glaucoma procedures, but this article identifies some important points.

WHAT FDA APPROVAL DOES NOT MEAN

A common misconception among clinicians is that FDA approval or clearance guarantees reimbursement. Rather, the Centers for Medicare & Medicaid Service (CMS) determines a Technical (T) code and an Ambulatory Payment Classifications code that sets reimbursement for the procedure for the hospitals and ambulatory surgery centers. Individual Medicare carriers decide whether or not to reimburse physicians for new procedures and devices and, if so, the amount of payment for the surgical fee to physicians. To make this determination, some carriers rely on peer-reviewed data. Others seek guidance from subspecialty organizations; for new glaucoma procedures, usual sources are the American Academy of Ophthalmology, American Glaucoma Society, and American Society of Cataract and Refractive Surgery. Early in the reimbursement process, however, these organizations are reluctant to issue official statements on new technology owing to a lack of research outside of pivotal FDA phase 1 to 3 trials that is not sponsored

by industry. In my experience and based on my conversations with others involved in these matters, at the level of medical director, carriers rely heavily on the advice of certain “experts” in the field with whom they consult or who have contacted them about ophthalmic issues in the past. The weight of these opinions should not be underestimated.

Another step is assignment of a Current Procedural Terminology (CPT) code by the CMS. There are three categories of CPT codes: primary codes (I), supplemental tracking codes (II), and temporary codes for new and emerging technologies (III). When a procedure or code has a Category I CPT code, commercial carriers generally follow the CMS’ lead on reimbursement. When a procedure has a Category III CPT code, the process can be somewhat arbitrary but is usually linked somehow to reimbursement for a “similar” procedure and its CPT code. Carrier advisory committees (CACs) are bodies of clinicians from different medical specialties who advise Medicare carriers for their regions on a wide range of issues. A significant part of this advice pertains to local coverage decisions on new technologies and codes. CACs have great influence on Medicare carriers’ decisions whether or not to cover new glaucoma procedures and devices with a Category III CPT code as well as on physicians’ reimbursement. Physicians’ communication—both in person and via letter and e-mail—with their ophthalmology CAC representative is crucial to the process (Table).

FIRST MEDICARE, THEN PRIVATE PLANS

Private insurers typically deem any procedure using a T code to be experimental and therefore not covered, at least as long as it has a Category III CPT code. Some private insurance coverage changes as soon as a procedure receives a Category I CPT code but not always. It appears that certain large, national private plans are beginning to cover 0191-T, the code used for the iStent Trabecular Micro-Bypass Stent (Glaukos Corporation). Until the CMS grants

TABLE. NEW GLAUCOMA SURGICAL CODES AND STATUS

CPT Codes	Description	FDA-Cleared Devices	Technologies in Development	Status
66174 66175	Circumferential dilation of Schlemm canal with or without stent	iTrack 250 (Ellex iScience, Inc.)	Glaucolight (DORC International BV)	100% Medicare covered, approximately 50% covered by private insurance
66183 (formerly 0192-T)	Aqueous shunt without reservoir, external approach	• AquaFlow Collagen Glaucoma Drainage Device (STAAR Surgical Company) • Ex-Press Glaucoma Filtration Device (Alcon Laboratories, Inc.)	• InnFocus MicroShunt (InnFocus, Inc.) • Solx Gold Shunt (Solx, Inc.)	Covered by most Medicare carriers, few local carrier decisions, some private payers. Just started Category I status on January 1, 2014.
0191-T	Aqueous shunt without reservoir, internal approach	iStent Trabecular Micro-Bypass Stent (Glaukos Corporation)	• Hydrus (Ivantis Inc.) • iStent Inject (Glaukos Corporation) • Xen Gel Stent (AqueSys, Inc.)	Coverage by some private insurers. Category I CPT code in 2018?
0253-T	Aqueous shunt without reservoir, internal approach, suprachoroidal space	None yet	• CyPass Micro-Stent (Transcend Medical) • iStent Supra (Glaukos Corporation)	Awaiting FDA clearance

Abbreviation: CPT, Current Procedural Terminology.

the device a Category I CPT code, however, many private payers probably will not cover it.

Again, commercial insurance payers' decisions to cover new procedures, whether they have Category I or III CPT codes, depend on the strength of peer-reviewed research data and input from expert consultants. Another factor is how many claims are being made. Industry representation in this process is important. Privately financed research and ophthalmic representation not connected with industry, however, often carry more weight in the determination of coverage reimbursement. In my experience, research not supported by industry and appropriate subspecialty societies' support of a new procedure have a lot of weight with medical directors and CACs considering these questions.

HOW TO ADVISE PATIENTS

Physicians, of course, are free to use technology in accordance with its FDA-approved indications. When discussing with Medicare patients any procedure that has a Category III CPT code or that may not be covered by private insurance, clinicians must implement an Advance Beneficiary Notice of Noncoverage. Despite a local coverage decision in favor of a procedure or device, it is never safe to assume complete coverage of a Category III CPT code. Confusion over policies—especially early in the process of coding and reimbursement—creates instances

when a surgeon's fees are not covered but facility fees are and vice versa. Patients need to understand that all or part of a procedure may not be covered in this situation and that they may be required to pay the difference.

Physicians can always appeal any denial of coverage by a Medicare carrier or private insurance plan. Direct communication with medical directors via thoughtful letters about specific cases as well as a reiteration of all of the appropriate peer-reviewed research is important. Some industry representatives have attempted to directly aid clinicians in the process, which can be helpful.

PATIENCE AND UNDERSTANDING

Obtaining FDA approval of and reimbursement for a new glaucoma procedure is a messy process. It requires physicians' communication with insurance carriers' medical directors and committees, CAC representatives, and patients. Doctors' understanding of the process, their patience, and their commitment to working within the system, as imperfect as it is, are key. ■

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