Point/Counterpoint: Should Patients Share the Cost of MIGS Procedures?

Yes, they deserve an opportunity to consider all of their options.

By John Berdahl, MD

Patients already share the cost of their care, and they should—to a degree. The question is, how much should be borne by the patient? Currently in the United States, the financial incentives are incredibly misaligned. Payers are motivated to pay as little and as infrequently as possible for medical care. Doctors are financially incentivized to order more tests and perform more services (both to decrease the risk of litigation and potentially to increase revenue), and patients have little skin in the game, so to speak, when it comes to the cost of their care (especially when deductibles are met). Of course, doctors have taken an oath to put patients' needs before their own, and the vast majority of doctors take this oath very seriously. I suspect few doctors actually perform unnecessary tests or procedures in order to line their pockets. Assuming that doctors are always trying to put the needs of their patients first allows a conversation about whether or not microinvasive glaucoma surgery should have a self-pay component for patients.

DISTINCTIONS IN REIMBURSEMENT

The first matter is to distinguish between on-label, off-label, and third-party reimbursement. *On label* simply means that the FDA and the manufacturer have used the available data to negotiate a label that describes indications, effectiveness, and safety parameters. *Off label* is when a drug or device is not used in strict adherence to the negotiated label. Many procedures and even approaches that are the standard of care are off label such as the use of antibiotics after cataract surgery. Third-party reimbursement does

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No, patients should not have to pay.

By Quang H. Nguyen, MD

The evolving technology of microinvasive glaucoma surgery (MIGS) has stirred excitement. The development of microstents and delivery systems for their implantation is broadening the options for the surgical treatment of glaucoma. Although factors other than elevated IOP may cause glaucomatous optic neuropathy, lowering pressure remains the mainstay of therapy. The traditional stepwise approach to reducing IOP begins with topical medication and/or laser trabeculoplasty, progresses to adjunctive medical therapy, and escalates to more aggressive intervention such as filtration surgery with an antimetabolite or implantation of a glaucoma drainage device. We ophthalmologists can now stage our approach to surgical glaucoma treatment with MIGS devices and delay aggressive surgical intervention, which may be fraught with vision-threatening complications.

Although many MIGS devices are still in clinical trials, data from outside the United States on the combination of these implants with cataract surgery are encouraging,

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Do you believe that patients should share the cost of MIGS procedures?

☐ Yes
☐ No

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not depend on the FDA label. Third-party reimbursement is much more of a "black art" that occurs as companies and physicians reach out to the Centers for Medicare & Medicaid Services or third-party payers in an effort to convince them with the available data, experience, or standard of care that a particular product or service should be reimbursed. This process often takes years after the accumulation of well-established data or experience.

THE PHYSICIAN'S RESPONSIBILITY

Physicians' primary job is to do the right thing for the patient in front of them. The most important question I ask myself in every encounter with patients is, "What would I do if this were my eye?" Considering this question helps me cut through the noise to focus on my responsibility to my patient and the oath that I took. I should note that what is best for a patient's eye is not always what is best for his or her life. Many times, a patient simply cannot afford the ideal approach to care, which is unfortunate. My starting point is always the best thing for the eye, however, and then I see if that can fit in with the patient's financial situation and other issues going on in his or her life.

A good example of this approach is the placement of a second iStent Trabecular Micro-Bypass Stent (Glaukos) in the setting of moderate to severe glaucoma. A reasonable amount of data suggests that a second iStent can incrementally lower IOP.[1] If a person has a cataract and moderate to severe glaucoma and is using two IOP-lowering medications, my preferred approach is cataract surgery plus the placement of two iStents. In fact, I almost always try to perform a microinvasive glaucoma surgical procedure prior to advancing to a tube or a trabeculectomy. Given the abysmal long-term outcomes reported in the Tube Versus Trabeculectomy (TVT) study,[2] if it were my eye, I would certainly want two stents plus or minus endocyclophotocoagulation prior to moving on to a much more invasive and risky surgical intervention.

PAYMENT

Because many (but not all) payers will not pay for a second iStent, should the patient have the option to cover the cost? Of course! Should doctors, ambulatory surgery centers, or hospitals bear the cost of a second iStent? I would argue no. We are providing a service to the patient. After receiving clear and transparent education on the risks, benefits, and alternatives, and after completing a strong financial informed consent with an Advanced Beneficiary Notice of Noncoverage, patients should be able to choose and pay for the treatment that they and their doctor agree is best for the patient's eye. I feel that physicians are obligated to offer patients all of the options that are best for their eyes, with financial considerations being an important element of that discussion.

John Berdahl, MD, is a clinician and researcher with Vance Thompson Vision in Sioux Falls, South Dakota. He is a consultant to and has received lecture fees from Glaukos. Dr. Berdahl may be reached at johnberdahl@gmail.com.

1. Belovay GW, Naqi A, Chan BJ, et al. Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. *J Cataract Refract Surg*. 2012;38:1911-1917.
2. Gedde SJ, Schiffman JC, Feuer WJ, et al. Treatment outcomes in the Tube Versus Trabeculectomy (TVT) study after five years of follow-up. *Am J Ophthalmol*. 2012;153:789-803.e2.

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so companies are racing to produce meaningful US data. All MIGS clinical trials here are in conjunction with phacoemulsification cataract surgery, and they have a rigorous protocol and ambitious primary outcome measure. Current trials are planned to last 2 years; they will evaluate unmedicated IOP before randomization and again at the end of 2 years to identify the effect of the device. In other words, use of a washout IOP will separate the efficacy of the device at lowering IOP versus that of cataract surgery alone. The primary outcome measure is to achieve a 20% reduction in IOP with no medications at the end of 2 years in addition to proving safety. A secondary outcome is to examine the burden of glaucoma medication.

As the data of these long clinical trials slowly accrue, we surgeons need to think ahead about how to employ this technology to provide the best possible care to our patients who will ultimately benefit from MIGS devices. Let us imagine being able to offer a glaucoma patient a MIGS device in conjunction with cataract surgery and achieving a 20% reduction in IOP without medication for at least 2 years, all with the advantage of an excellent safety profile. This would be a game changer! Reality, however, dictates that we also consider how these new MIGS devices will be paid for as they become available.

US health care delivery is changing dramatically. As we transition from volume- to value-based performance in medicine, cost-effectiveness and patients' outcomes are intertwined. The fee-for-service model is unsustainable. Rather, the fee-for-value model will become dominant. *Value* is simply defined as quality (outcomes, safety, and services) per cost of care. The purpose of this article is *not* to discuss the efficacy data of MIGS devices but to argue that patients should not have to pay for these technologies.

THE COST OF CARE

Glaucoma is a chronic disease with no cure. The cost of treating this disease increases substantially as it progresses. In a retrospective study involving the review

of 151 patients' charts at 12 different sites in the United States, the annual direct cost of treatment per Medicare patient was $1,581. The average cost was $618 per patient in the earliest stage of the disease and rose to $2,203 per patient in the advanced stage of the disease.[1]

At present, the only FDA-approved MIGS implant is the iStent Trabecular Micro-Bypass Stent (Glaukos). It costs approximately $1,195 in conjunction with cataract surgery and is indicated for mild to moderate disease. It is important to note that the clinical trials of this device were not powered to show a superior IOP-lowering effect with the stent in conjunction with cataract surgery versus the cataract surgery alone and that there was no washout IOP.

It seems fair to speculate that the cost of future MIGS devices will be similar to that of the iStent. Owing to the more rigid protocol now required by the FDA (ie, to demonstrate superior IOP lowering with the combination of a MIGS device and cataract surgery vs cataract surgery alone and a significant reduction in the need for topical glaucoma medication), we can appreciate the value of future approved MIGS devices in terms of patients' outcomes, satisfaction, and quality of life (ie, not having to instill eye drops daily). The cost-effectiveness of MIGS devices is also clear when compared with the annual cost of medication per patient. If my arithmetic is correct, compared with the cost of medication, the US government would save a huge amount of money over 2 years if Medicare patients—considering the growing and aging US population—were offered one-time coverage of a MIGS device.

CONCLUSION

If we can safely and effectively reduce glaucoma patients' IOP by 20% for at least 2 years after the placement of a MIGS device in conjunction with cataract surgery and without the need for medication, the decision to offer this option will be a no-brainer. The US government will be incentivized to pay for MIGS over medication if FDA trial data unequivocally demonstrate superior IOP lowering from MIGS in conjunction with cataract surgery versus cataract surgery alone. Medicare coverage of MIGS would fit beautifully into the value-based performance and fee-for-value health care model. ■

Quang H. Nguyen, MD, is the associate head of the Division of Ophthalmology and director of the Glaucoma Service at Scripps Clinic in La Jolla, California. He is or has been an investigator for AqueSys, Glaukos, Ivantis, and Transcend Medical. Dr. Nguyen may be reached at (858) 554-9101; nguyen.quang@scrippshealth.org.

1. Lee PP, Walt JG, Doyle JJ, et al. A multicenter, retrospective pilot study of resource use and costs associated with severity of disease in glaucoma. *Arch Ophthalmol*. 2006;124(1):12-19