IS GLAUCOMA POLICY SHORT-SIGHTED?

Redefining innovation to keep an eye on patient access.

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Glaucoma is an incurable disease and a leading cause of blindness that is expected to affect up to 120 million people by 2040.[1] In the United States, glaucoma specialists complete at least 13 years of rigorous training to manage this prevalent disease, yet reimbursement for glaucoma care is largely dictated by US health insurance payers. Last year, multiple Medicare Administrative Contractors (MACs) announced that they would no longer cover several MIGS procedures. Ultimately, lobbying by patient advocacy groups, glaucoma specialists, and ophthalmology societies, among others, led to the reversal of this controversial coverage policy.[2] Nevertheless, other modern and effective glaucoma treatments such as certain standalone and combined MIGS procedures, drug delivery systems, new antiglaucoma medications, and preservative-free antiglaucoma drugs remain at risk of coverage restrictions. When insurers do not cover costs, patients must either pay out of pocket or lose access, potentially worsening inequities in eye care.[3]

Health care policy plays a crucial role in controlling the costs of care at a population level. However, policies guiding glaucoma care should also account for the lack of curative therapies, the limitations of feasible research, patient-specific factors directing treatment, and the burden of patient nonadherence. In this sense, we would argue that, for glaucoma policy, reimbursement rules should not be designed to discourage research and innovation and that, for ophthalmologists, innovation should not stop at the development of new drugs and devices. To balance care and costs, innovation should continue through the long-term study of cost-effectiveness and quality-of-life improvements that existing glaucoma drugs and devices can offer. With the help of industry and government, ophthalmologists should be ready to lead data-driven policy reform, ensuring that patients can access the care they need and deserve.

COST-EFFECTIVE MIGS

Before multiple MACs decided to deny coverage for MIGS, a Contractor Advisory Committee of glaucoma specialists, including one of the authors of this article (D.S.D.V.), was called on to review evidence.[4] Since the 2000s, MIGS procedures have been reported to have a promising safety and recovery profile and to be modestly efficacious in comparison to traditional and more invasive glaucoma filtration surgeries.[5-12] Evidence presented by the Contractor Advisory Committee for MIGS was outweighed by years of randomized controlled trial (RCT) evidence on filtration surgery. Rather than replace trabeculectomy and tube shunt surgery, it is our position that MIGS can bridge and extend the gap between noninvasive treatment paradigms and filtration surgery.[13,14] Implementing MIGS at earlier stages of glaucoma may enhance outcomes, delay the need for invasive surgery, reduce long-term costs, and improve patients' quality of life.[5-17]

AT A GLANCE

- Glaucoma policy determinations may be failing to meet the goals of patients and practitioners as well as the overall policy goal of controlling costs.
- The ophthalmology community and policymakers must take innovation a step further by studying the long-term cost-effectiveness of existing treatments and the impact that restrictive coverage policies can have on patients' quality of life.
- In addition to IOP lowering and visual field preservation, policies determining patient care must be shaped by patient experience. To do this, ophthalmologists together with industry and government must take a policy-oriented approach to research, ensuring essential care is covered and accessible to patients.

Many published RCTs have provided high-caliber evidence in favor of MIGS, but much of the existing MIGS literature is composed of high-quality retrospective and observational studies. The findings are extensive and should be valued by policymakers, albeit with understandable limitations. The MIGS field is evolving rapidly and will continue to present new treatment options.

Critics and payers still question the cost-effectiveness of MIGS. With more randomized trials of filtration surgery compared to MIGS, the future of MIGS coverage remains uncertain. A growing body of evidence, however, supports that MIGS can be cost-effective when (1) paired with cataract surgery in patients who have mild to moderate glaucoma and (2) evaluated in the long-term context of cost savings from relative decreases in glaucoma morbidity. Furthermore, improvements in the patient's quality of life support the routine use of MIGS. We believe that health care policy should, too.

EARLIER INTERVENTION REDUCES PATIENT BURDEN

The pivotal prospective randomized HORIZON trial compared MIGS using the Hydrus Microstent (Alcon) to phacoemulsification alone.[10] The outcomes supported early MIGS intervention following uncomplicated cataract surgery. The trial demonstrated continued reductions in the number of medications, higher rates of medication-free IOP control, and up to a 50% reduction in the need for subsequent surgeries in the MIGS-phaco patients compared to phaco-only patients.[10,15,16] A retrospective study showed that cataract surgery combined with Hydrus Microstent implantation or goniotomy produced similar results in terms of IOP lowering and medication reduction.[17]

IOP remains the main modifiable risk factor in glaucoma. A reduction signals relief from the burden of patient nonadherence and drug side effects. Eliminating one or two antiglaucoma medications may amount to one to six fewer drops per day.[18-21] If topical drops are administered in intervals of 5 minutes or more as prescribed, the reduction in the number of drugs can decrease the amount of time patients spend on treatment by as much as 30 minutes per day.

ADDRESSING COMORBIDITIES

Cost-effectiveness estimates of MIGS should account for the surgical costs of planned cataract surgery incurred by patients with visually significant cataracts and mild to moderate glaucoma. Combining one or multiple MIGS procedures with cataract surgery has been shown to be more cost-effective than performing cataract surgery alone.[22-24] Further benefits of this combined approach were demonstrated in the HORIZON trial and in an Intelligent Research in Sight (IRIS) Registry study.[10,25] The IRIS Registry study showed that, when MIGS was performed with phacoemulsification, patients had lower reoperation rates. Reoperation was defined as "any subsequent occurrence of MIGS procedures or traditional glaucoma surgeries occurring 1 month to 3 years after" the initial surgery.[25] Both reductions in IOP and the need for subsequent surgeries can reduce long-term costs for the health care system.

COMBINED MIGS: LIMITATIONS OF STUDYING SURGICAL INNOVATION

In assessing Medicare coverage for MIGS, the MACs overemphasized RCT evidence, creating a burden of proof. The burden for conducting RCTs for the numerous MIGS products and their different mechanisms of action, in addition to comparative and combination studies, is high and requires considerable time and funding. Medicare and other policymakers can therefore be expected to determine coverage for MIGS based not only on the existing yearslong body of RCTs but also on high-quality retrospective and observational research.

There is growing interest in combining MIGS procedures for synergistic or additive effects.[20,21] A recent review found that combined MIGS reduced patients' medication burden for up to 1 year compared to single MIGS.[26] Combined MIGS procedures can potentially benefit patients, but studying the procedures can be difficult. Industry funding for RCT or other research would likely be harder to obtain given that products are usually manufactured by multiple corporations. The fast pace of surgical device innovation is another well-known obstacle.[27-29] By the time an RCT is conducted on one generation of a device, the next generation may be available. This challenge is exacerbated in combined MIGS research. Real-world studies using retrospective or observational data (such as the IRIS Registry or other sources) are a more practical and timely way to understand surgical innovations such as combined MIGS.

WHAT'S IN AN EYE DROP?

Medicare Part D and Medicare Advantage commercial plans, among others, restrict coverage of preservative-free topical anti-glaucoma medications and newer preservative-containing antiglaucoma medications that may be safer, be more effective, or have relatively easier dosing schedules. Insurance plans cover costs for their preferred agents, which are typically lower-cost drugs that contain preservatives or have more demanding dosing schedules. Coverage restriction policies can require a less expensive drug on their formulary to be tried before a more expensive one (step therapy), prior approval of the insurance plan (prior authorization), patient cost sharing (up-front copays/coinsurance), and/or a tier exception form to be filled out to reduce a patient's out-of-pocket costs.[30] These restrictions can act as barriers to care, especially in high-risk populations.

Racial and ethnic minorities are six to 15 times more susceptible to blindness from glaucoma and are at greater risk of developing the disease.[31] With increased enrollment of racial and ethnic minorities in the Medicare Advantage plans that enforce utilization management policies,[32] limitations in coverage can limit care for these populations. With some specialists seeing 60 or more patients per day, the administrative burden can become onerous when there is a need to bypass restrictions on nonpreferred/nonformulary agents, fill out tier exceptions or prior authorization forms, and call pharmacies to sort out insurance coverage or availability issues.

Policies have an impact on patients' quality of life and adherence to medication regimens. Pushing patients toward generic preservative-containing antiglaucoma medications can likely result in ocular irritation, dry eye disease, and conjunctivitis medicamentosa.[33] Restricting coverage of quality antiglaucoma medications can be costly.

Harmful Preservatives

During an interview at the 2024 AGS Annual Meeting, Danish clinician-scientist and professor at the University of Copenhagen, Miriam Kolko, MD, PhD, said, "Why add preservatives to a drug for chronic use when you don't need to?" Benzalkonium chloride (BAK) is commonly found in IOP-lowering drops. Even in low concentrations, BAK and similar detergents penetrate the ocular surface, leading to conjunctival goblet cell loss, neurotrophic loss of corneal sensitivity, and dry eye/ocular surface disease.[33,34] This iatrogenic injury is additive over a lifetime.

Preservative-free antiglaucoma drug options are limited, but newer alternatives such as netarsudil (Rhopressa, Alcon), a fixed combination of netarsudil and latanoprost (Rocklatan, Alcon), and latanoprostene bunod (Vyzulta, Bausch + Lomb) could serve as quality first-line therapy for patients.[35] Unfortunately, many coverage policies label brand-name drugs like these and preservative-free antiglaucoma medications as *nonformulary* or *nonpreferred*, meaning they come at an additional cost to patients. Not only are the BAK-containing antiglaucoma medications preferred by most insurance plans more likely to cause side effects, but many must also be dosed multiple times per day. In contrast, some of the newer alternatives are instilled only once at night.[35]

Covering the costs of preservative-free and newer antiglaucoma drugs could increase patient adherence, improve quality of life, reduce side effects and unnecessary office visits, and possibly even improve surgical outcomes.[36-44]

Increased Utilization Burden

Preservatives such as BAK, which are included in most formulary glaucoma medication options, may influence the outcome of filtration procedures.[39-41] If the MIGS coverage denial had not been reversed, filtration surgery would have been the reimbursable surgical option for many patients requiring a reduction in IOP and medication burden. By harming ocular tissues, preservatives can limit the success of filtration surgery.[39,41] Preservatives have also been linked to cataract development, contributing to comorbidity.[42]

Studies in which patients were switched from preserved to nonpreserved antiglaucoma medications found an increase in treatment tolerance and a possible reduction in the number of patient encounters.[45,46] The Patient Satisfaction and Tolerability After Switching to Preservative-Free Latanoprost Study (PASSY) showed that drug tolerance improved for patients after they switched to preservative-free latanoprost ophthalmic solution 0.005% (Iyuzeh [Monoprost in Europe], Théa Pharma). Some patients switched antiglaucoma drugs up to 20 times, typically requiring visits to their doctor, before starting therapy with a preservative-free antiglaucoma drug.[45] The Follow-up of Glaucoma Patients Treated with Prostaglandins Eyedrops (FREE) study also showed a significant improvement in comorbid ocular conditions after patients switched to preservative-free treatment.[46]

Unfortunately, the up-front costs in a patient's insurance plan can prevent the selection of a preservative-free or newer antiglaucoma drug as first-line therapy. Instead, step therapy may be initiated, leading to additional visits for the treatment of ocular iatrogenic injury from preservatives such as BAK. Ocular surface disease is already a leading reason why patients seek eye care.[47]

WHERE POLICY MEETS CARE

The goals of glaucoma care are clear: Reduce the treatment burden, increase patient adherence, and improve quality of life while preventing irreversible blindness and associated morbidity. We believe that existing glaucoma policies could be failing to produce the cost-saving benefits that they are intended to achieve. One of us (D.S.D.V.) is the only glaucoma surgeon within about a 100-mile radius of their practice. This shortage of ophthalmologists is predicted to increase by 2035.[48] Making it easier for physicians to provide, and for patients to receive, quality ophthalmology care in the United States could decrease the economic burden of vision loss, which currently reaches more than $134 billion.[49]

Is glaucoma policy short-sighted? The emphasis on up-front cost savings can ignore the long-term cost-effectiveness of existing drugs and devices. Insurers create rules that can increase utilization (eg, unnecessary visits and the need for reoperations) and spending once vision is lost (eg, low vision equipment and disability coverage). More research and data are needed to understand the cost-saving potential and impact of these coverage policies.

We urge ophthalmologists and policymakers to work together to determine how cost-controlling policies might be leading to unnecessary spending downstream. Dr. Kolko's story is an example of how policy advocacy can lead to changes in law: "Eye drops in Denmark now require generic medications to be of the same quality as brand-name medications."

This article covers only some of the evidence available. We acknowledge that there is much nuance to the topics addressed. Going forward, we hope our engagements with policymakers are more proactive than reactive. ■

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