November 17, 2023

Meredith Loveless, M.D.
Contractor Medical Director, Cigna Government Services
Attn: Medical Review
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685
CMD.Inquiry@CGSAdmin.com

Sent electronically

Re: Notice Period for L37578 Micro-Invasive Glaucoma Surgery (MIGS) & A56491 Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS)

Dear Dr. Loveless,

On behalf of the American Glaucoma Society[i], American Academy of Ophthalmology[ii] , American Society of Cataract and Refractive Surgery[iii], and Outpatient Ophthalmic Surgery Society[iv], we appreciate the designation of trabecular aqueous stent devices, subconjunctival space stents or trabecular stents, and goniotomy or ab interno trabecular bypass surgery as procedures considered reasonable and medically necessary in the final versions of local coverage determination (LCD) L37578 Micro-Invasive Glaucoma Surgery (MIGS) and local coverage article (LCA) A56491 Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS).

However, we have continued serious concerns that these policies will restrict CGS beneficiaries' access to proven, medically necessary care by stifling innovation, severely limiting coverage of cyclophotocoagulation, and creating confusion about which procedures are covered. Furthermore, we are concerned that the procedure for public comment process has not fully occurred. The final policies include several new coverage criteria that were not in the proposed versions; thus, the public has not had an opportunity to provide feedback. Until the public has the opportunity to weigh in on these new criteria, we feel it is in the best interest of glaucoma patients for CGS to withdraw L37578 and A56491. We encourage CGS to

reopen these policies to public comment so that all stakeholders may have the opportunity to participate in the coverage determination process.

The complex and challenging nature of glaucoma management cannot be overstated. It requires a high level of clinical expertise and close collaboration between physicians, our patients, and the healthcare system. Patients require lifelong, and often escalating therapy from diagnosis through the end of their lives. Patients with glaucoma, which disproportionately affects Black and Hispanic persons[1], need access to a range of surgical procedures reflecting their individual anatomical and disease features with varied levels of intraocular pressure (IOP) targets for disease stability. Of note, the level of IOP control needed may often change over time as the disease evolves.

MIGS procedures are critically important surgical options offering a range of IOP control. These surgeries have been embraced because of their less-invasive nature and lower risk profile than traditional glaucoma procedures such as trabeculectomy and tube shunts. These advantages make them the procedure of choice for patients needing a modest reduction in IOP or a reduction in the number of eye drops being prescribed.

An ophthalmologist's success in preventing vision loss and improving quality of life is dependent on access to a range of safe and effective medical and surgical treatments. Our organizations agree with FDA approval as a requirement for a current or future MIGS device to be considered reasonable and necessary. However, we feel strongly that demonstrated effectiveness of ≥20% or more reduction of IOP on the same or reduced medication for duration of 24 months or longer demonstrated by moderate-high quality literature is an unreasonably high and scientifically unsound requirement. The criteria ignore two specific clinical scenarios:

1. Patients with borderline pressure control where a small reduction in IOP will stabilize glaucoma progression. From multicenter prospective clinical trials, we know that every mm Hg of IOP lowering counts.
2. Patients with difficulty adhering to their current topical therapy due to ocular side effects, cost, or simply due to an inability to keep up with the number of drops required. These patients will benefit from a surgical intervention which reduces their drop burden without additional IOP lowering.

---

[1] Centers for Disease Control and Prevention. (2022, November 7). *Current Glaucoma Programs*. Vision Health Initiative. https://www.cdc.gov/visionhealth/research/projects/ongoing/glaucoma.htm

In both of these scenarios, the current restrictive criteria would prevent access to medically necessary care that can represent the difference between preservation of vision vs. progression to blindness.

We urge CGS to remove the overly strict requirement for demonstrated effectiveness from L37578 or any subsequent coverage policies should L37578 be withdrawn.

Our organizations are encouraged to see cyclophotocoagulation included as a medically reasonable and necessary procedure for patients with refractory glaucoma; however, we are concerned that the indications limit coverage to a point where patients who need the surgery will not be able to obtain it.

According to the American Academy of Ophthalmology Glaucoma Preferred Practice Pattern and strongly supported by the provided literature, cyclophotocoagulation is a "good surgical option for eyes with limited visual potential or that are otherwise poor candidates for incisional ocular surgery." [2] Appropriate covered indications should include patients with refractory glaucoma and:

1. Failed extraocular aqueous drainage surgery (e.g., trabeculectomy or tube shunt) OR
2. Limited visual potential OR
3. Who are poor candidates for incisional surgery.

Our organizations recommend that CGS revise the indications for cyclophotocoagulation to support coverage when a patient has refractory glaucoma and any of the three additional indications enumerated above prior to implementation of a final LCD.

We appreciate the inclusion of definitions of key terms in the policies and feel additional clarification could benefit physicians, patients, coders, and payors. Our organizations feel strongly that the coding of a procedure should be based upon the work that is done irrespective of the tool used to do the work. The LCD seems to give conflicting coverage guidance for several MIGS procedures.

---

[2] Gedde SJ, Vinod K, Wright MM, et al. (2020, November 12). Primary open-angle glaucoma preferred practice pattern®. *Ophthalmology*. 2021;128(1):P71-P150. DOI: https://doi.org/10.1016/j.ophtha.2020.10.022

Gonioscopy-assisted transluminal trabeculotomy (GATT) and canaloplasty when combined with trabeculotomy ab interno meet the LCD's definition of goniotomy and should be covered. In these procedures, a surgical instrument (i.e., a microcatheter or suture) is used "to create an opening from Schlemm's canal into the anterior chamber, via the internal approach…", thereby meeting the definition and providing suitable improvement in aqueous outflow allowing IOP control. To avoid confusion, we urge CGS to reclassify GATT and canaloplasty when combined with trabeculotomy ab interno as reasonable and medically necessary.

Thank you for your consideration of these recommendations. We urge CGS to withdraw L37578 and A56491 because the procedure for public feedback is not yet complete. We encourage CGS to reopen these policies to public comment so that interested stakeholders may participate in the coverage determination process. Our societies represent the vast majority of US ophthalmologists, and we welcome the opportunity to share our expertise and the experiences of our patients to better inform policymaking.

Please contact Brandy Keys, Director of Health Policy, AAO, bkeys@aao.org, 202.737.6662; Mark Cribben, Director of Government Affairs, ASCRS, mcribben@ascrs.org, 703.591.2220; Deborah Nysather, Executive Director, AGS, dnysather@aao.org, 415.447.0275; and, Michael Romansky, JD, Washington Counsel, OOSS, mromansky@OOSS.org, 301.332.6474 with any further questions or to set up a meeting.

Sincerely,

Michael X. Repka, MD, MBA
Medical Director, Governmental Affairs
American Academy of Ophthalmology

Leon W. Herndon Jr., MD
President, American Glaucoma Society

Parag Parekh, MD, MPA
Chairman, Government Relations Committee
American Society for Cataract and Refractive Surgery

David George, MD
President, Outpatient Ophthalmic Surgery Society

The following societies support the recommendations of this letter:

Kentucky Academy of Eye Physicians and Surgeons

Ohio Ophthalmological Society

[i] The American Glaucoma Society (AGS) has 1,700 members and provides the voice of the glaucoma community in the US. AGS is the leading professional society for glaucoma subspecialists, surgeons, and researchers who are dedicated to improving the lives of people with glaucoma through education, research, advocacy, and leadership. As part of our educational mission, we are pleased to work with you and your colleagues to promote Medicare policies that help prevent, diagnose, and most effectively treat glaucoma and other causes of vision impairment and blindness.

[ii] The American Academy of Ophthalmology (the Academy) is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education, supporting research, and advocating for our patients and the public.

[iii] The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing 6,500 ophthalmologists in the United States and abroad who share a particular interest in and commitment to advancing the art and science of ophthalmic surgery.

[iv] The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical society that represents over 4,000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in the cost-effective ambulatory surgical center environment.