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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure,

The [Alliance for Aging Research](http://www.agingresearch.org) (Alliance) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services' (CMS) 2022 Medicare Physician Fee Schedule (PFS) Proposed Rule. The Alliance is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health.

The Alliance has served as a leader in providing patient education around vision loss, including age-related macular degeneration, diabetic retinopathy, and glaucoma. These diseases exact a toll not only on a beneficiaries' vision, but impact their quality of life, increase the need for additional services and supports, and expand caregiver burden to assist with activities of daily living. Proactive treatment of these diseases can improve long-term outcomes and curtail the need for ongoing supports. The Alliance submits the following remarks in support of ensuring access to care that can promote health and reduce long-term program expenditures.

Background on Glaucoma and Medication Non-adherence

Glaucoma is one of the nation's leading causes of blindness. approximately three million Americans are afflicted with glaucoma.¹ Risk factors for glaucoma include advancing age, female gender, and family

¹ "Don't Let Glaucoma Steal Your Sight!" *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 24 Nov. 2020, www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html.

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history. Black Americans age 40 and older are at the highest risk of developing the disease compared with people of other races. By age 69, nearly six percent of Black Americans have glaucoma, and this percent rises to nearly 12 percent after age 80. Due to the aging of the U.S. population, the number of Americans with glaucoma is expected to more than double from 2.7 million to 6.3 million between 2010 to 2050. Because of their longer life expectancy, women account for 61 percent of glaucoma cases in the U.S.²

While tens of thousands of Americans are blind today as a result of this progressive and irreversible disease, sight degeneration can be significantly slowed by reducing pressure within the eye which can prevent damage to the optic nerve. Most commonly, prescription eye drops are often the first choice for treating patients.³ However, cross-sectional analyses of glaucoma medication-taking behavior, including medication refill data,^{4,5} estimate that rates of medication adherence in the United States are approximately 50 percent. Rates of persistence with glaucoma medications, or the continued use of prescribed medication over the long term, are even lower. A retrospective cohort study of 1,234 patients newly diagnosed with open-angle glaucoma found that only 15 percent showed persistently strong adherence over four years of follow-up.⁶

The impact of non-adherence to glaucoma medication on disease progression is significant. The Collaborative Initial Glaucoma Treatment Study (CIGTS) followed patients on medication therapy for an average of seven years and found a statistically and clinically significant association between medication nonadherence and visual field loss—as much as 72 percent worse in those who reported missing their medication at more than two-thirds of visits, compared to those who never missed a dose.⁷ Social determinants of health play a role in likelihood of poor glaucoma medication adherence. A study of participants in the Support, Educate, Empower (SEE) personalized glaucoma coaching program pilot program found that lower income, lower educational attainment and a higher level of glaucoma-related distress all predicted lower adherence to glaucoma medications.⁸ These are important health equity issues for CMS to consider as the agency sets its PFS for 2022.

² “Glaucoma.” *National Eye Institute*, U.S. Department of Health and Human Services, 28 July 2020, www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/glaucoma#section-id-31.

³ “Medication Guide.” *Glaucoma Research Foundation*, Glaucoma Research Foundation, 19 June 2020, www.glaucoma.org/treatment/medication-guide.php.

⁴ Feehan, Michael, et al. “Adherence to Glaucoma Medications over 12 Months in Two US Community Pharmacy Chains.” *Journal of Clinical Medicine*, vol. 5, no. 9, 2016, p. 79., doi:10.3390/jcm5090079.

⁵ Sheer, Richard, et al. “Predictors of Nonadherence to Topical Intraocular Pressure Reduction MEDICATIONS Among Medicare Members: A CLAIMS-BASED Retrospective Cohort Study.” *Journal of Managed Care and Specialty Pharmacy*, vol. 22, no. 7, 2016, pp. 808–817., doi:10.18553/jmcp.2016.22.7.808.

⁶ Newman-Casey, Paula Anne, et al. “Patterns of GLAUCOMA Medication Adherence over Four Years of Follow-Up.” *Ophthalmology*, vol. 122, no. 10, 2015, pp. 2010–2021., doi:10.1016/j.ophtha.2015.06.039.

⁷ Newman-Casey, Paula Anne, et al. “The Association between Medication Adherence and Visual Field Progression in the Collaborative Initial Glaucoma Treatment Study.” *Ophthalmology*, vol. 127, no. 4, 2020, pp. 477–483., doi:10.1016/j.ophtha.2019.10.022.

⁸ Salman, Mariam, et al. “Psychosocial Predictors of Glaucoma Medication Adherence among the Support, Educate, Empower (See) Personalized Glaucoma Coaching Pilot Study Participants.” *American Journal of Ophthalmology*, vol. 216, 2020, pp. 207–218., doi:10.1016/j.ajo.2020.02.009.

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Physician Reimbursement for Micro-invasive Glaucoma Surgery

The goal of all glaucoma surgery is to lower eye pressure to prevent or reduce damage to the optic nerve. Standard glaucoma surgeries—trabeculectomy and ExPRESS shunts, external tube-shunts like the Ahmed and Baerveldt styles—are major surgeries. While they are very often effective at lowering eye pressure and preventing progression of glaucoma, they have a long list of potential complications.⁹

The micro-invasive glaucoma surgeries (MIGS) group of operations have been developed in recent years to reduce some of the complications of most standard glaucoma surgeries. The MIGS procedures work by using microscopic-sized equipment and tiny incisions. MIGS can be thought of in a few broad categories, either enhancing fluid outflow using the eye's inherent drainage system, shunting fluid to the outside of the eye, or decreasing production of fluid within the eye. Some types of MIGS procedures are FDA approved to be performed only in conjunction with cataract surgery whereas other MIGS procedures are approved to be performed independent of cataract surgery. The MIGS procedures are typically performed in ambulatory surgical centers (ASCs) on an outpatient basis. Functionally, the MIGS procedures serve as a way to ensure that patients are unable to comply with the traditional standard of care are not relegated to vision loss.

The MIGS procedures often occurs in conjunction with a cataract surgery due to the high cooccurrence of cataracts and high intraocular pressure. In the PFS proposed rule, CMS recommends combining MIGS procedures and cataract surgeries under one code and one payment amount. The newly combined payment level would equal \$565, broken out as \$531 for the cataract surgery and \$34 for the MIGS procedure. This represents a sharp reduction from the median physician payment amounts for MIGS procedures over the past decade of between \$300-\$350. Reducing it to \$34 is extreme and does not provide payment for the work associated with insertion of the device as well as the follow-up care for patients. The planned PFS reduction comes in conjunction with a reduction in the procedures' payment rate in the OPFS proposed rule.

If these payment rates take effect, many MIGS providers and facilities could experience a financial loss on each procedure, which may disincentivize them from continuing to offer it. In addition to the 90 percent reduction in the proposed PFS, the ASCs where most MIGS procedures occur will experience reimbursement reductions of more than 25 percent compared to CY 2021.

The impact of these financial decisions would result in hardships for patients. Beneficiaries for whom traditional treatment care plans are ineffective would experience reduced access to an effective, minimally-invasive treatment that could stem the progression of glaucoma. Further, the MIGS

⁹ Sahoo, Niroj Kumar, et al. "Retina and Glaucoma: Surgical Complications." *International Journal of Retina and Vitreous*, vol. 4, no. 1, 2018, doi:10.1186/s40942-018-0135-x.

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procedure has a faster recovery period than traditional surgery and is able to be performed in the ASC setting – which typically is less expensive than the hospital outpatient setting.

Excessively lowering reimbursement in the PFS and ASC rules for the procedure could result in higher overall costs to Medicare if care for these patients shifts to an OPPS setting or if disease progression requires additional, ongoing medical supports. It should be noted that historically this rule, as with other annual payment rules for outpatient and physician payments, tend to conform to longstanding payment policies and may lag advances in medicine that make the practice of medical care more efficient. Advances that may make certain procedures more efficient may result in a reduced overall payment for the procedure due to reduced length of stay and improved patient outcomes. For example, the CY 2019 IPPS rule reduced the weighted national payment average for transcatheter aortic valve replacement (TAVR) by 4.4 percent from the previous year due to associated efficiencies while increasing payment for open-heart surgical repair alternatives. In a 2018 Health Affairs blog on the TAVR issue, authors noted, “Payment models should encourage treatment choices that coincide with clinical outcomes, patient-centered humanistic outcomes, and total cost to the health care system.”¹⁰

Instead, we request that CMS reconsider and implement a reimbursement amount for the procedure that aligns with the recommendation submitted by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC). The RUC’s data and recommendations often serve as a guide for payment, and we believe the RUC’s proposed amount would preserve patient access to the MIGS procedure.

Conclusion

Thank you for your consideration of our comments, as the Alliance believes preserving access to this procedure is likely to improve long-term health outcomes for many beneficiaries with glaucoma. Please contact Michael Ward, the Alliance’s Vice President of Public Policy, at mward@agingresearch.org or (202) 688-1230 with questions or follow up regarding this recommendation.

Warmly,



Susan Peschin, MHS
President and CEO

¹⁰ Mattke, Soeren, et al. “The Long Road to Value-Based Payment: The Case of Transcatheter Aortic Valve Replacement.” *Health Affairs*, 26 July 2018, doi:10.1377/hblog20180725.321773.