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September 17, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals (CMS-1753-P)**

Dear Administrator Brooks-LaSure,

On behalf of the Alliance for Aging Research (the “Alliance”), we appreciate the opportunity to offer comments for the CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1753-P). 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.

Our comments on the proposed rule pertain to coverage for diagnostics for Alzheimer’s disease and other dementias, and continued access to procedures used to treat glaucoma. The Alliance has served as a leader in both fields, convening the Accelerate Cures and Treatments for All Dementias (ACT-AD) coalition and providing patient education around vision loss, including age-related macular degeneration, diabetic retinopathy, and glaucoma. Proactive treatment of these diseases can improve long-term outcomes. The Alliance submits the following remarks in support of ensuring access to care that can promote health and reduce long-term program expenditures.

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## **Positron Emission Tomography (PET) Scans**

Patients are currently assessed for Alzheimer’s disease in the clinical setting based on their symptoms. It is typically a diagnosis of exclusion, where other potential causes for memory problems are ruled out first. Before positron emission tomography (PET) imaging, a definitive diagnosis of the disease could only be made by examining brain tissue post-mortem for the presence and distribution of both amyloid-beta plaques and tau neurofibrillary tangles. With the availability of FDA-approved radiopharmaceuticals targeting amyloid plaques and tau tangles, evaluation through PET imaging has become central in patient diagnosis and is commonly used in clinical trials for staging and to identify patients that may benefit from treatment.

In May 2020, the FDA approved the first radiopharmaceutical for PET imaging of tau tangles for use in adults with cognitive impairment who are being evaluated for Alzheimer’s disease. However, tau PET was not covered by Medicare after its FDA approval due to preamble language included under section 220.6 of CMS’ NCD Manual that states, “a particular use of PET scans is not covered unless this manual specifically provides that such use is covered.”

**Fortunately, in the CY 2022 Physician Fee Service Proposed Rule, CMS proposes retiring section 220.6’s language, which the Alliance supports.**

Additionally, in 2013, Medicare decided to nationally cover amyloid PET imaging, but only under the coverage with evidence development (CED) protocol, citing insufficient evidence that the imaging would make a difference for patients with a disease due to the lack of a disease-modifying treatment for the disease and limited symptomatic treatment.<sup>1</sup> Published appropriate use criteria, which CMS adopted in its two designated CED studies, required that 1) knowledge of amyloid PET results was expected to change diagnosis and management and 2) whether amyloid PET is associated with improved clinical outcomes.

To address whether amyloid PET results were expected to change diagnosis and management, the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study ran from February 2016 to December 2017. The study involved more than 18,000 Medicare beneficiaries with mild cognitive impairment or dementia who underwent amyloid PET to determine if their brains contain the amyloid plaques associated with Alzheimer’s disease.<sup>2</sup>

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<sup>1</sup> [Centers for Medicare & Medicaid Services. Decision memo for beta amyloid positron emission tomography in dementia and neurodegenerative disease \(CAG-00431N\).](#)

<sup>2</sup> Rabinovici GD, Gatsonis C, Apgar C, et al., “[Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia,](#)” JAMA 2019;321(13): 1286-1294.

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A positive test for amyloid plaques does not definitively mean someone has Alzheimer's disease; however, a negative result rules the disease out. The IDEAS data analysis, published in the Journal of the American Medical Association (JAMA) in April 2019, found approximately 36 percent of patients clinically diagnosed with Alzheimer's disease and 61 percent of patients with mild cognitive impairment (MCI) were negative for the amyloid plaque by amyloid PET scan.<sup>3</sup> These PET results profoundly impacted the primary study endpoint, which was the post-PET care management plan. More than 60 percent of study participants in both the MCI and dementia patient groups had changes in care plans post-PET. Care changes occurred most notably in the starting, stopping, or modification of Alzheimer's disease drug therapy, but also in the use of other drug therapies and/or counseling about safety and future planning. Additionally, physicians reported that PET results contributed substantially to the post-PET management plan in 85.2 percent of instances in which a change was made, further validating the usefulness of the diagnostic.<sup>4</sup> Therefore, PET scans had a direct impact on changing patient diagnosis and management.

Eight years ago, when CMS finalized its amyloid PET NCD for dementia, there were no FDA-approved disease modifying therapies (DMTs) for Alzheimer's disease. In the absence of effective dementia therapies, it was postulated that amyloid PET would need to show significant changes in dementia diagnosis and management and demonstrate improved clinical outcomes compared to those beneficiaries with dementia who had not undergone amyloid PET. These latter, claims-based analysis results are not yet published, so CMS has thus far delayed closing this CED and has not responded to requests to open a reconsideration. However, the capability to more accurately diagnose beneficiaries for Alzheimer's disease, and importantly to exclude individuals without the presence of amyloid beta or tau from treatment, will become especially important as clinicians assess the appropriateness of monoclonal antibody (mAB) treatments for their patients. **Now that a presumed disease-modifying mAB therapy has recently received FDA accelerated approval – and other mAB therapies in development have received breakthrough designations from the FDA – CMS should end its NCD for amyloid PET under CED and encourage local coverage to the FDA-approved label.**

Last, reimbursement for PET is currently bundled with the related imaging procedure in the hospital setting, which may disincentivize provision of these diagnostics. **Therefore, we also strongly encourage the agency to pay separately, and not bundle payment, for these amyloid and tau PET tracers.**

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<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

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## Physician Reimbursement for Micro-invasive Glaucoma Surgery

### *Glaucoma and Medication Non-adherence*

Glaucoma is one of the nation's leading causes of blindness. approximately three million Americans are afflicted with glaucoma.<sup>5</sup> Risk factors for glaucoma include advancing age, female gender, and family 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.<sup>6</sup>

While tens of thousands of Americans are blind today because 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.<sup>7</sup> However, cross-sectional analyses of glaucoma medication-taking behavior, including medication refill data,<sup>8,9</sup> 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.<sup>10</sup>

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

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<sup>5</sup> "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](http://www.cdc.gov/visionhealth/resources/features/glaucoma-awareness.html).

<sup>6</sup> "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](http://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/glaucoma#section-id-31).

<sup>7</sup> "Medication Guide." *Glaucoma Research Foundation*, Glaucoma Research Foundation, 19 June 2020, [www.glaucoma.org/treatment/medication-guide.php](http://www.glaucoma.org/treatment/medication-guide.php).

<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> 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.

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between medication nonadherence and visual field loss— outcomes were as much as 72 percent worse in patients who reported missing their medication at more than two-thirds of visits, compared to those who never missed a dose.<sup>11</sup> Social determinants of health also 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.<sup>12</sup> These are important health equity issues for CMS to consider as the agency sets its PFS for 2022.

In addition to the enormous human toll of vision loss resulting from these challenges, it is estimated that U.S. taxpayers may lose \$1.5 billion annually as a result of increased Social Security benefits due to blindness, lost tax revenues, and increased healthcare costs for patients who have progressive glaucoma due to medication non-compliance.<sup>13</sup>

### *Proposed Reimbursement Changes 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.<sup>14</sup>

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

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<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> Friedman, David S., et al. "Prevalence of Open-angle Glaucoma Among Adults in the United States." *Arch Ophthalmol*. 2004 Apr;122(4):532-8. doi: 10.1001/archoph.122.4.532.

<sup>14</sup> 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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(ASCs) on an outpatient basis. Functionally, the MIGS procedures serve as a way to ensure that patients unable to comply with the traditional standard of care are not relegated to vision loss.

The MIGS procedure often occurs in conjunction with a cataract surgery due to the high cooccurrence of cataracts and high intraocular pressure. In the corresponding PFS proposed rule, CMS recommended 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. This change would occur in conjunction with the proposed 25 percent reduction in the ASC payment rate, from \$3,353 to \$2,562.

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 procedure has a faster recovery period than traditional surgery and can 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

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models should encourage treatment choices that coincide with clinical outcomes, patient-centered humanistic outcomes, and total cost to the health care system.”<sup>15</sup>

**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 Ryne Carney, the Alliance’s Manager of Public Policy, at [rcarney@agingresearch.org](mailto:rcarney@agingresearch.org) or (202) 688-1242 with questions or follow up regarding these recommendations.

Sincerely,



Michael Ward  
Vice President of Public Policy



Ryne Carney  
Manager of Public Policy

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<sup>15</sup> 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.