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35 Years of Patient Advocacy

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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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1772-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 2023 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1772-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 reimbursement amounts that ensure clinically supported access to procedures used to treat glaucoma and diagnostics for Alzheimer's disease and other dementias. 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.

Reimbursement for Micro-invasive Glaucoma Surgery

Glaucoma and Medication Non-adherence

Glaucoma is one of the nation's leading causes of blindness and approximately three million Americans are afflicted with glaucoma.[1] Risk factors for glaucoma include advancing age, female gender, and family history. Black Americans ages 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 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.[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 persistent adherence 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— outcomes were as much as 72 percent worse in patients who reported missing their medication at more than two-thirds of visits,

[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.
[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.

compared to those who never missed a dose.[7] 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.[8] These are important health equity issues for CMS to consider as the agency sets its payment rates for 2023.

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.[9]

Proposed Reimbursement Changes for Micro-invasive Glaucoma Surgery

The goal of 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 are more invasive have a long list of potential complications.[10]

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. Some types of MIGS procedures are FDA approved to be performed only in conjunction with cataract surgery. More recently, MIGS technologies have advanced to permit patients who are either not yet candidates for cataract surgery or who have previously had the procedure to receive an implant through a standalone operation. Functionally, the MIGS procedures serve to ensure that patients unable to comply with the traditional standard of care are not relegated to vision loss.

In the proposed OPPS rule, CMS recommends assigning CPT code 0671T, Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more, to APC 5491, which corresponds to Level I

[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.
[9] 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/archopht.122.4.532.
[10] 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.

Intraocular Procedures. However, the proposed assignment to APC 5491 was identified as being inappropriately low based on 2021 claims data presented to the Medicare Advisory Panel on Hospital Outpatient Payment (HOP Panel) on August 22, 2022. Following the presentation, the HOPS Panel recommended moving 0671T stand alone to APC 5492 to better reflect the geometric mean cost.

If the proposed payment rates take effect, facilities could experience a financial loss on each procedure, which may disincentivize them from offering it to patients for whom it is medically appropriate. 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 established, effective, minimally invasive treatment that could stem the progression of glaucoma. Further, the MIGS procedure has a faster recovery period than traditional surgery and in most cases is performed in the ASC setting.

In short, Medicare should not attempt to classify a procedure to a payment code that fails to reflect the cost of care. Medical advances, though they may have a higher initial cost, can make certain procedures more efficient and result in reduced overall costs to our healthcare system due to improved patient outcomes. Fundamentally, reimbursement should support the provision of care that aligns with Medicare beneficiaries' preferred outcomes, which often include shorter recovery times and the mitigation of potential disease progression. However, additional work is needed to ensure payment supports patient-centered preferences and 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."[11]

The Alliance respectfully asks CMS to adopt the recommendation from CMS's HOP Panel, which recommended the assignment of HCPCS code 0671T to APC 5492, Level 2 Intraocular Procedures.[12] Assigning the HCPCS code to the appropriate APC will ensure that reimbursement covers the associated costs of the procedure and does not create an artificial payment barrier to patient access.

[11] 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.
[12] Centers for Medicare and Medicaid Services. August 22, 2022, HOP Panel Meeting Materials, Recommendations, and Rebroadcast. https://www.cms.gov/files/zip/august-22-2022-hop-panel-meeting-materials-recommendations-and-rebroadcast.zip

Positron Emission Tomography (PET) Scans

Patients are most assessed for Alzheimer's disease in the clinical setting based on their presenting 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 accurate patient diagnosis and is commonly used in clinical trials for staging and to identify patients that may benefit from treatment.

In 2013, Medicare decided to nationally cover amyloid PET imaging 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.[13] 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. In June 2020, CMS announced a re-opening of the national coverage determination (NCD) to consider changes to the current one amyloid PET scan per beneficiary per lifetime limit. The Alliance's comments on the NCD reconsideration can be accessed here.[14]

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.[15]

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

[13] Centers for Medicare & Medicaid Services. Decision memo for beta amyloid positron emission tomography in dementia and neurodegenerative disease (CAG-00431N).
[14] Alliance for Aging Research. RE: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG-00431R). https://www.agingresearch.org/wp-content/uploads/2022/09/CMS-NCA-Comment-Letter-on-Beta-Amyloid-PET-7-15-2022.pdf
[15] 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.

with mild cognitive impairment (MCI) were negative for the amyloid plaque by amyloid PET scan.[16] 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.[17] Therefore, PET scans had a direct impact on changing patient diagnosis and management.

Reimbursement for PET is currently bundled with the related imaging procedure in the hospital setting, which may disincentivize provision of these diagnostics. To better understand the impact of amyloid PET on communities of color, the IDEAS 2.0 study was launched in 2000.[18] However, the bundling of amyloid and tau PET tracers – which are separately approved for use by the FDA as drugs or biologics – with the cost of the procedure leads to a shortfall, where the cost of providing the procedure is greater than Medicare's reimbursement rate. As a result, the New IDEAS study has experienced difficulties in recruiting study sites. A Government Accountability Office investigation found that "hospitals, which had all participated in the original IDEAS Study, declined to participate because the packaged payment would cause them to incur a financial loss for each procedure performed."[19] **In effect, CMS's earlier decision to bundle payment for amyloid PET is presently undermining efforts to collect relevant data on the impacts of the procedure on communities of color that can help fulfill CED requirements**.

We strongly encourage the agency to pay separately, and not bundle payment, for these amyloid and tau PET tracers for PET scans to provide appropriate reimbursement that supports appropriate care and CMS's strategic pillar of advancing equity.

Conclusion

Thank you for your consideration of our comments and your commitment to quality health care for our nation's older adults. Please contact me at mward@agingresearch.org or (202) 688-1230 with questions or follow up regarding these recommendations.

[16] Ibid.
[17] Ibid.
[18] Clinicaltrials.gov. New IDEAS: Imaging Dementia-Evidence for Amyloid Scanning Study. https://clinicaltrials.gov/ct2/show/NCT04426539
[19] Government Accountability Office. Medicare Part B: Payments and Use for Selected New, High Cost Drugs. March 2021. https://www.gao.gov/assets/720/712727.pdf

Sincerely,

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