Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

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

RE: CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1786-P)

Dear Administrator Brooks-LaSure,

The Alliance for Aging Research (Alliance) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) annual Hospital Outpatient Prospective Payment System (OPPS) proposed rule for 2024.

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. We believe that advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term.

Below, we offer feedback on several aspects of the CY 2024 OPPS/ASC proposed rule.

Packaging Policy for Diagnostic Radiopharmaceuticals

The Alliance supports CMS efforts to decouple payment for radiopharmaceuticals used in diagnostics. The cost of radiopharmaceuticals often causes the cumulative cost of diagnostics to exceed the bundled rate, limiting uptake and utilization of clinically valuable tests.

We understand that the agency is soliciting comments as part of a broader consideration of payment packaging for radiopharmaceuticals, which the agency will consider for future rulemaking. However, this process is likely to last beyond the current year. **Given recent changes in the availability and CMS coverage for disease-modifying therapeutics for Alzheimer's disease, we ask CMS to take immediate action to finalize separate reimbursement for**

radiopharmaceuticals used in amyloid beta (Aβ) positron emission tomography (PET) in the CY 2024 OPPS/PFS Final Rule.

Patients are most often 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 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. For FDA-approved disease-modifying monoclonal antibody therapeutics, PET imaging or a lumbar puncture is required in order to confirm the presence of amyloid beta pathology.[1]

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.[2] 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.[3] 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 Aβ PET on communities of color, the IDEAS 2.0 study was launched in 2020.[4] 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

[1] Leqembi Prescribing Informationhttps://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf
[2] 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.
[3] Ibid.
[4] Clinicaltrials.gov. New IDEAS: Imaging Dementia-Evidence for Amyloid Scanning Study. https://clinicaltrials.gov/ct2/show/NCT04426539

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."[5] In effect, bundled payment for Aβ 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.

Under current policy established by CMS, the rate that the Medicare program pays is uniform for all PET scans, irrespective of factors like the specific body area being scanned, the clinical utility, or the cost of the diagnostic radiopharmaceutical employed. This rate is designed to cover both the cost of the radiopharmaceutical and the expenses related to labor, equipment, and supplies required for the procedure. However, it is essential to note that PET scans used for the diagnosis of AD incur significantly higher costs than that average rate. It is a significant financial burden for hospitals to provide these specialized scans to patients, as they incur substantial losses for each scan.

With the increasing prevalence of AD and the potential for new treatments, the need for PET scans is expected to rise significantly. Other sectors of the Medicare system are working to make PET scans more widely available by removing them from the Coverage with Evidence Development paradigm.[6] The current reimbursement shortfall issue threatens to exacerbate access challenges precisely when the demand for these scans is set to increase as therapeutics are approved.

We applaud CMS for revisiting packaging of radiopharmaceuticals with diagnostics. However, decoupling for Aβ PET cannot wait for the next annual OPPS cycle. Millions of Americans currently have Alzheimer's and undergoing disease progression and thousands of beneficiaries will progress to the moderate stage of the disease and unlikely to benefit from currently available therapies within the next year. We strongly urge CMS to unbundle payments for PET scans for AD from other radiopharmaceuticals in this year's final rule, as the agency simultaneously considers a broader update of the packaging policy.

Updating the Conversion Factor for Rural Hospitals to Ensure Equitable Healthcare Access for Older Adults

The Alliance acknowledges and appreciates CMS' proposed 2.8% payment update for current year (CY) 2023, which will create an estimated 4.4% increase in funding for rural hospitals. However, there is a persistent disparity between Medicare payment rates and the genuine impact of inflation

[5] 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
[6] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=308#:~:text=Conclusion,)(A)%20of%20the%20Act.

on healthcare costs, particularly for older adults who rely on these facilities. In recent years, the population of older adults in rural areas has expanded significantly, with people over the age of 65 comprising 17.5% of the rural population in the US,[7] and the older population in rural areas faces significantly worse health outcomes. Specifically, older adults in rural areas face a 20% higher all-cause mortality rate and an expected lifespan that is three years shorter than their urban counterparts.[8,9]

Right now, there are significant financial challenges facing rural hospitals, including labor and supply cost pressures, workforce shortages, and the aftermath of the COVID-19 pandemic, which all demand urgent attention. Approximately 153 rural hospitals have closed since 2010, with 12 closures in 2023 alone, and 450 more that are vulnerable.[10] These closures are seriously detrimental to the provision of critical services in rural areas. We urge CMS to prioritize equitable healthcare access for older adults living in rural areas by addressing the inflation-related payment gap and implementing higher payment rates for CY 2024.

Conclusion

The Alliance for Aging Research firmly believes that ensuring continued access to essential healthcare services is paramount to ensuring a more effective and more equitable healthcare system. We are committed to working collaboratively with CMS and other stakeholders to shape policies that benefit older adults and promote their well-being. With any questions, please contact Adina Lasser, Public Policy Manager at the Alliance for Aging Research, at alasser@agingresearch.org.

Sincerely,

Adina Lasser

Adina Lasser, Public Policy Manager
Alliance for Aging Research

[7] Smith, A. S., & Trevelyan, E. (2019). The older adult population in rural America: 2012-2016. United States Census Bureau. https://www.census.gov/content/dam/Census/library/publications/2019/acs/acs-41.pdf
[8] Croft, J. B., Wheaton, A. G., Liu, Y, et all. " Urban-rural county and state differences in chronic obstructive pulmonary disease: United States." 2015. Morbidity and Mortality Weekly Report, 67(7), 205-211.
[9] Harrington, R. A., Califf, R. M., et al. "Call to action: Rural health: A presidential advisory from the American Heart Association and American Stroke Association." Circulation, 141(10), e615-e644
[10] Rural Hospital Closures, N.C. Rural Health Research Center, Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill https://www.shepscenter.unc.edu/programsprojects/rural-health/rural-hospital-closures/