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Catalyzing Innovation for Healthy Aging

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Chairman Pat Toomey
Senate Finance Committee
Subcommittee on Health Care
219 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Debbie Stabenow
Senate Finance Committee
Subcommittee on Health Care
248 Russell Senate Office Building
Washington, DC 20510

***Testimony on Alzheimer's Awareness: Barriers to Diagnosis, Treatment and Care Coordination***

Dear Chairman Toomey and Ranking Member Stabenow,

The Alliance for Aging Research, www.agingresearch.org, is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal experience of aging and health. We would like to express our sincere appreciation to the Senate Finance Subcommittee on Health Care for holding a hearing last November on barriers to the diagnosis, treatment, and care coordination for Alzheimer's disease and for soliciting feedback on policy solutions from stakeholders on these important issues.

In response to the Subcommittee's solicitation, we recommend the below policy solutions to inform the development of future legislation on Alzheimer's disease and related dementias.

**Care Coordination in Federal Health Care Programs**

In 2019, the Alliance for Aging Research commissioned a study with the actuarial firm Milliman to examine the real-world costs of Alzheimer's disease on the Medicare program.[1] We undertook this work because actual Medicare spending on the disease is rarely discussed. Instead, "associated costs of care"—that combines Medicare and Medicaid spending, often with out-of-pocket spending by families, is generally used to effectively advocate for increased federal investment in research. The preference for using associated costs is understandable, however, policymakers should know what the Medicare program is doing, and not doing, for people with Alzheimer's disease.

Published in the July 2019 issue of the *Journal of Managed Care and Specialty Pharmacy* the study found that Medicare spending on Alzheimer's disease is low. The study examined almost 340,000 Medicare beneficiaries for up to 10 years and found that risk-adjusted annual costs were $2,101 (2015 U.S. dollars) higher for Alzheimer's disease and $1,870 higher for general dementia than beneficiaries without a diagnosis. In the last year of life, Medicare spent $1,300 *less* on patients with Alzheimer's disease than other beneficiaries. The lower costs were often due to avoiding complex care, such as chemotherapy for cancer, for loved ones with advanced dementia.

[1] The Real-World Medicare Costs of Alzheimer Disease: Considerations for Policy and Care, Bruce Pyenson, Tia Goss Sawhney, *Journal of Managed Care & Specialty Pharmacy* 2019 25:7, 800-809. Open-access available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2019.25.7.800.

The relatively low Medicare spending on Alzheimer's disease makes sense. Medicare pays for medical care and only some short-term supportive care.

But lower Medicare costs do not mean low overall care costs. Alzheimer's patients and their families pay a substantial amount in out-of-pocket costs for care. A 2015 study in the *Annals of Internal Medicine* found that average out-of-pocket spending for patients with dementia was 81 percent higher than spending for patients without dementia.[2]

Most people with Alzheimer's disease have Medicare, but patients often need Medicaid to fill in the coverage gaps. Medicaid covers services that Medicare does not, such as long-term care in nursing homes, assisted living and at-home care. According to the Kaiser Family Foundation, a quarter of adults with dementia living in the community are covered by Medicaid for a year.[3]

As the pipeline for Alzheimer's disease and other dementias matures there will be more therapies and hopefully a cure on the market. From a cost-savings standpoint, the Medicaid program would benefit most by a disease-modifying therapy entering the market. The recent positive reanalysis of aducanumab by Biogen is indicative that disease-modifying therapies could be here sooner rather than later. As disease-modifying therapies get closer to entering the market, conversations between payers will intensify as to who should be covered and how these therapies will be financed. The most important of these conversations will happen at the Centers for Medicaid and Medicare Services (CMS).

There are adverse consequences of poor integration of Medicare and Medicaid after disease-modifying therapy enters the market. As noted, with future treatments entering the market, it will be the Medicare program that pays for the treatments but the Medicaid program that reaps most of the savings from delayed symptoms and progression of the disease. Adequate integration between Medicare and Medicaid for dealing with the financing of Alzheimer's disease medications will be paramount.

Additionally, the needs of patients with Alzheimer's disease and related dementias are complex, demanding coordination across various health settings. The Center for Medicare and Medicaid Innovation (CMMI) has funded multiple different models to test plans to improve care coordination for dementia patients and their caregivers. We would encourage CMMI to test a model coordinating the Medicare and Medicaid programs for the treatment of Alzheimer's disease.

One way to more efficiently integrate Medicare and Medicaid services is by offering home and community-based services, which cost less than nursing home care—much like what has been done in Medicare Advantage programs but as funded benefits. Programs that offer support services for caregivers of Alzheimer's disease and dementia patients have been shown to achieve cost savings and positive outcomes for patients and their caregivers.[4]

Care coordination solutions should also examine the role of respite care. Alzheimer's-related family caregiving takes a toll—both physically and mentally—with older spousal family caregivers experiencing higher mortality rates, rates of acute and chronic conditions, and depression than non-caregivers. Respite is short-term care that offers individuals or family members temporary relief from the daily routine and stress of providing care and serves as a critical component to bolstering family stability and maintaining family caregiver health and well-being. Respite is a frequently requested support service among family caregivers,

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[2] Open-access available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4809412/.

[3] https://www.kff.org/medicaid/issue-brief/medicaids-role-for-people-with-dementia/.

[4] Long KH, Moriarty JP, Mittelman MS, Foldes SS. Estimating the potential cost savings from the New York University Caregiver Intervention in Minnesota. Health Affairs (Millwood). 2014;33(4):596-604.

but 85% of family caregivers of adults receive no respite.[5] Not surprisingly, high burden family caregivers (defined as those who assist their loved one with personal care such as getting dressed or bathing) cite lack of respite as one of their top three concerns.

The Lifespan Respite Care Program was enacted in 2006 with strong bipartisan support and provides competitive grants to states to establish or enhance statewide Lifespan Respite systems that maximize existing resources and help ensure that quality respite is available and accessible to all family caregivers. Though the program has been drastically underfunded since its inception, thirty-seven states and the District of Columbia have received grants and are engaged in impressive work such as identifying and coordinating respite services available through various state agencies, including veterans caregiver services; helping unserved families pay for respite through participant-directed voucher programs or mini-grants to community and faith-based agencies; building respite capacity by recruiting and training respite workers and volunteers, and raising awareness about respite through public education campaigns.

On February 24, the Senate passed the Lifespan Respite Reauthorization Act by voice vote. Now this bill will have to be reconciled with the House-passed bill or go directly to the House floor for final passage. The Senate Finance Committee can help to promote the final passage of this important legislation.

Recommendations:

- The Senate Finance Committee should advocate for CMS to, once and for all, create integration between the Medicare and Medicaid programs to include home and community-based services.
- The Senate Finance Committee should help promote the final passage of the Lifespan Care Respite Care Act Reauthorization and funding.

**Improving Detection**

A major shortcoming in Alzheimer's disease clinical care is that as many as half of dementia cases are missed in the primary care setting. Many people are first diagnosed with Alzheimer's disease during a hospital stay for an unrelated issue, as opposed to by their primary care provider.

In 2017, the Centers for Medicare & Medicaid Services created a new primary care code (99483) to help doctors better recognize dementia, which allows for earlier care and planning. But, according to an Alzheimer's Association analysis, out of a projected 910,000 new cases of Alzheimer's disease in 2017, the code was utilized for only 20,000 Medicare beneficiaries. CMS has not offered education about this new code through its MLN Matters program or promoted it on its beneficiary website. The Senate Finance Committee should encourage CMS to do so.

Going back even further to 2010, the Senate Finance Committee led the way in creating the Medicare Annual Wellness Visit (AWV), which includes "detection of any cognitive impairment" provision, and is available for Medicare beneficiaries who have had Medicare Part B for longer than 12 months.[6] This provision was added separately because the U.S. Preventive Services Task Force (USPSTF) has given an "I" grade to its screening for cognitive impairment in older adults—a recommendation that has not changed in nearly 20 years.[7]

There are multiple issues with the AWV and USPSTF that the Senate Finance Committee should explore. First, in its final rule on the AWV, CMS interpreted the "detection of any cognitive impairment" provision to

[5] https://archrespite.org/

[6] https://www.medicare.gov/coverage/yearly-wellness-visits.

[7] https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/cognitive-impairment-in-older-adults-screening1.

include "direct observation" of the beneficiary by the provider. However, no authoritative source or evidence-based rationale is supporting the use of direct observation as a means of adequately detecting cognitive impairment. Direct observation cannot detect cognitive impairment any more than it can detect cancer or heart disease.

Alternatively, CMS directs providers to "use a brief validated structured cognitive assessment tool" and provides a link to the National Institute on Aging's Alzheimer's and Dementia Resources for Professionals website. However, they qualify this direction with the phrase "if appropriate," providing no further guidance on what "if appropriate" means.

Patient advocacy organizations are currently in dialogue with CMS regarding this confusing interpretive guidance from CMS. However, the Senate Finance Committee could help move this process along faster than its current glacial pace.

Additionally, the Senate Finance Committee should invite the USPSTF to the Hill for a briefing on its "I" screening recommendation for cognitive impairment in older adults. Let's define the specific evidence gaps that still exist and fill them.

Recommendations:

- The Senate Finance Committee should encourage CMS to offer education about its new primary care code through both its MLN Matters program and its beneficiary website.
- The Senate Finance Committee should ask CMS to clarify and correct its interpretive guidance on the "detection of any cognitive impairment" provision in the AWV.
- The Senate Finance Committee should invite the USPSTF to the Hill for a briefing on its nearly 20-year "I" screening recommendation for cognitive impairment in older adults.

**Protecting Vulnerable Patients**

The Alliance for Aging Research is a co-convening organization for the Psychoactive Appropriate Use for Safety and Effectiveness (PAUSE) Project, a coalition of patient advocacy and provider organizations concerned with the safety and effectiveness of antipsychotic medication utilization in American's nursing homes. The coalition was formed to curb the inappropriate use of antipsychotics and ensure access and appropriate use of these medications by patients who may clinically benefit.

There is a large unmet medical need in long-term care (LTC) settings for the diagnosis and management of neuropsychiatric symptoms (NPS) in dementia. One or more NPS, such as wandering, sleep issues, agitation, depression, apathy, aggression, and psychosis affect nearly every person with dementia over the disease trajectory. There is evidence to support that these symptoms often result in greater impairment in activities of daily living, poorer quality of life, more rapid disease progression, greater morbidity, and increase the direct cost of care, and earlier institutionalization.[8,9,10,11,12,13] The manifestation of these symptoms often results in

[8] Karttunen K, Karppi P, Hiltunen A, et al. Neuropsychiatric symptoms and quality of life in patients with very mild and mild Alzheimer's disease. Int J Geriatr Psychiatry. 2011;26(5):473–482.

[9] Lyketsos CG, Carrillo MC, Ryan JM, et al. Neuropsychiatric symptoms in Alzheimer's disease. Alzheimers Dement. 2011;7(5):532–539.

[10] Banerjee S, Smith SC, Lamping DL, et al. Quality of life in dementia: more than just cognition. An analysis of associations with quality of life in dementia. J Neurol Neurosurg Psychiatry. 2006;77(2):146–148.

[11] Steele C, Rovner B, Chase GA, et al. Psychiatric symptoms and nursing home placement of patients with Alzheimer's disease. Am J Psychiatry. 1990;147(8):1049–1051.

[12] Brodaty H, Donkin M. Family caregivers of people with dementia. Dialogues Clin Neurosci. 2009;11(2):217–228

[13] Murman DL, Chen Q, Powell MC, et al. The incremental direct costs associated with behavioral symptoms in AD. Neurology. 2002;59(11):1721–1729.

increased burden on caregivers due to the multifactorial difficulties, such as emotional, financial, and physical stress associated with having to care for persons exhibiting these symptoms.

Effectively managing or preventing NPS that causes distress and potential harm to self and others is a key part of person-centered care and crucial to the wellbeing of residents and family caregivers. However, residents in long-term care facilities who have dementia-related psychosis or other conditions that could benefit from antipsychotic medication (e.g., bipolar depression) may face barriers to accessing appropriate pharmacotherapy. Discontinuing antipsychotic medication upon admission to a long-term care facility can precipitate a further decline in function and behavior and set the resident on a trajectory of decline.

To address this challenge, CMS documents and reports antipsychotic utilization rates in long-term care settings throughout the country. In March 2012, CMS launched a quality initiative to decrease the use of antipsychotics in nursing homes by 15% by the end of 2012. This initiative established the current antipsychotic utilization rate quality measure and created The National Partnership to Improve Dementia Care (the Partnership). The Partnership's official measure to determine antipsychotic utilization rates is the percentage of long-stay nursing home residents who are receiving an antipsychotic medication, excluding those residents diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome and the percentage of short-stay nursing home residents who are initiated on an antipsychotic after admission to the skilled nursing facility. The Partnership adopted these three excluded conditions as they have been recognized under CMS regulations since 2006, but it is important to note that these conditions are not the only U.S. Food and Drug Administration (FDA) approved indications for antipsychotic medication use. Project PAUSE has compiled a full list of FDA-approved adult indications for first-generation antipsychotics and second-generation antipsychotics.

In an effort to ensure that elderly patients have access to critical medications and that we continue to encourage groundbreaking new therapies to address symptoms associated with Alzheimer's disease, Project PAUSE is urging the following improvements to CMS' quality measure:

- Expand CMS recognition of FDA approved uses for psychotropic and antipsychotic medications for the treatment of neuropsychiatric disorders in late life;
- Update the current measure to meet the Program-Specific Measure Needs and Priorities set forth by CMS' Center for Clinical Standards and Quality (CCSQ)
- Improve CMS integration of diagnostic criteria and clinical guidelines into nursing home operator, medical director, nursing, and surveyor trainings;
- Take advantage of the interdisciplinary use of the Long-Term Care Facility Resident Assessment Instrument (RAI) User's Manual;
- Further, promote quality excellence through incorporating advanced practice practitioners (APPs) and consultant pharmacist's review of antipsychotic medications in the documentation of antipsychotic use in the RAI User's Manual.

We have attached Project PAUSE's formal recommendations for encouraging new therapies and protecting patient access to needed Alzheimer's disease medication therapies.

Recommendations are attached.

**Encouraging Innovation**

A key component of ensuring access to future disease-modifying Alzheimer's disease treatments will be improving our nation's capacity for routine screening and testing and our healthcare systems diagnostic

capacity. The primary pathological hallmark of Alzheimer's disease is the accumulation of plaques known as beta-amyloid. The biomarker testing for amyloid is performed by a positron emission tomography imaging or PET, which is the only Food and Drug Administration approved modality for clinical use. However, Medicare and most private insurance plans do not cover the use of testing for PET for the diagnosis of Alzheimer's disease.

In 2013, Medicare declined to cover amyloid positron emission tomography (PET) imaging outside of a clinical trial, citing insufficient evidence that the imaging would make a difference for patients with a disease for which there is no cure and limited symptomatic treatment.[14] As a result, PET imaging is only covered under Medicare coverage with evidence development through the Amyloid imaging in the Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) Study. The first arm examined how the use of amyloid PET scans altered physician diagnosis and treatment plans for the more than 11,000 participants. The study found that the clinical management of 60 percent of patients changed. The most common change in clinical management was prescribing drugs for the treatment of Alzheimer's disease, followed by counseling.[15] The second arm of the IDEAS Study will examine whether the use of amyloid PET scans improved the clinical outcomes of study participants. The data from these studies will influence whether Medicare will cover these scans in the future. The Finance Committee should follow these studies but should ask CMS to transition the NCD for beta-amyloid positron emission tomography (PET) imaging from a CED to coverage to FDA-approved label.

A key barrier to access to an eventual cure for Alzheimer's disease will be the diagnostics that determine if a patient has Alzheimer's disease. A key component will be ensuring that these tests are adequately reimbursed to incentive their adoption by physicians. Under the current Medicare Hospital Outpatient Prospective Payment System (OOPS), radiopharmaceuticals drugs are not appropriately reimbursed, limiting both patient access and disincentivizing innovation in the space. H.R. 3772, the *Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019*, would direct the Department of Health and Human Services to appropriately reimburse radiopharmaceuticals in a budget neutral manner.

Finally, the NIH released its Professional Judgement Budget for FY2021 estimating the amount of additional funding for research it will require to meet the federal government's goal of having a treatment or cure for Alzheimer's disease and related dementias by 2025. The NIH estimated that it will require $2.822 billion in total funding for research or a $354 million increase from FY 2020. These additional fund research that will deepen our understanding of the genetic risk factors of Alzheimer's disease, disease mechanisms, assist in biomarker development, potential novel targets, and clinical trial design.

<u>Recommendations</u>

- The Finance Committee should ask CMS to transition the NCD for beta-amyloid positron emission tomography (PET) imaging from a CED to coverage to FDA-approved label.
- The Senate Finance Committee should support the passage of the Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019.
- Members of the Senate Finance Committee should support an increase in funding for NIH Alzheimer's disease and related dementia research by $354 million for FY 2021.

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[14] Centers for Medicare & Medicaid Services. Decision memo for beta amyloid positron emission tomography in dementia and neurodegenerative disease (CAG-00431N). September 27, 2013. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=356&ncdver=1&bc=AAAAQAAAAAAA&.

[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. doi:10.1001/jama.2019.2000

The Alliance applauds your leadership in convening a meeting to improve the treatment and care of people living with Alzheimer's disease and related dementias. If you have questions for our organization, please do not hesitate to contact the Alliance's Public Policy Manager, Ryne Carney at (202) 688-1242 or rcarney@agingresearch.org.

Thank you for your consideration and please consider our organization a resource to your respective staffs.

Sincerely,

Susan Peschin, MHS
President and CEO

Ryne Carney
Public Policy Manager