

Submitted via regulations.gov

September 14, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1848-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Request for Information on Intensive Lifestyle Interventions to slow progression of Alzheimer's disease

Dear Dr. Oz:

The American Geriatrics Society (AGS) greatly appreciates the opportunity to respond to the request for information (RFI) from the Centers for Medicare & Medicaid Services (CMS) on intensive lifestyle interventions to slow progression of Alzheimer's disease. AGS has submitted comments separately about specific policy issues in the 2027 Medicare Physician Fee Schedule (MPFS) proposed rule.

The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners (NPPs) who are devoted to improving the health, independence and quality of life of all older adults. Our 6,000+ members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician associates, pharmacists, and internists who are pioneers in serious illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. AGS believes in a just society, one where we all are supported by and able to contribute to communities where ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. AGS advocates for public policy that promotes the health and independence of older

Americans, with the goal of improving health, quality of life, and healthcare systems serving us all as we age.

We appreciate CMS' interest in learning more about the role that intensive lifestyle interventions can play in preventing or delaying the progression of Alzheimer's Disease and Related Dementias (ADRD). We welcome the opportunity to work with you moving forward on ways to improve care of older adults with and at risk of ADRD.

Below we address CMS' specific questions.

1. Given the discussion of the evidence to date on the effectiveness of intensive lifestyle interventions for CMS to pursue, we are particularly interested in demonstrations of cost-savings associated with these and other interventions. Please cite any evidence available in your discussion.

We appreciate CMS' interest in the cost effectiveness of prevention programs. AGS believes that lifestyle interventions are an important tool in prevention of Alzheimer's Disease and Related Dementias (ADRD) particularly given the toll that dementia has on patients and families. It is critical that CMS consider the scientific evidence for such interventions and accessibility before implementation of any program. Several studies support implementation of a multimodal prevention program.

In a 2024 published scoping review and qualitative synthesis, Braun et al.¹ concluded that multimodal prevention programs targeted for at-risk populations can be cost effective and cost efficient and that early intervention maximizes cost-effectiveness. Another study published in 2023 estimated the long-term cost-effectiveness of the FINGER (Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability) multidomain prevention program,² which combines dietary counseling, physical exercise, cognitive training, and monitoring/management of vascular and metabolic risk factors. The model found that FINGER could potentially be cost-saving and improve health when compared to usual care.

The Alzheimer's Association conducted the U.S. POINTER Study (*Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk*), a two-year randomized controlled trial that tested whether multidomain lifestyle interventions can protect cognitive function

¹ Braun A, Höfler M, Auer S. Cost-Effectiveness of Prevention for People at Risk for Dementia: A Scoping Review and Qualitative Synthesis. *J Prev Alzheimers Dis.* 2024;11(2):402-413. doi: 10.14283/jpad.2024.12. PMID: 38374746.

² Wimo A, Handels R, Antikainen R, Eriksdotter M, Jönsson L, Knapp M, Kulmala J, Laatikainen T, Lehtisalo J, Peltonen M, Sköldunger A, Soininen H, Solomon A, Strandberg T, Tuomilehto J, Ngandu T, Kivipelto M. Dementia prevention: The potential long-term cost-effectiveness of the FINGER prevention program. *Alzheimers Dement.* 2023 Mar;19(3):999-1008. doi: 10.1002/alz.12698. Epub 2022 Jul 16. PMID: 35841619.

in older adults at increased risk for dementia. It is the first large-scale trial in the U.S. to confirm and expand findings from the Finnish FINGER study, which showed that combining physical exercise, a healthy diet, cognitive/social stimulation, and heart health monitoring can slow cognitive decline.³

2. Given CMS' concern for addressing fraud, waste, and abuse throughout the Medicare program, please comment on any potential or observed FWA in diagnosis, treatment, or management of AD/ADRD.

Two potential areas for waste that CMS should consider strategies for mitigating the risk of unnecessary testing and treatment are:

- Individuals without objective cognitive impairment are undergoing expensive and unnecessary diagnostics for AD/ADRD. Current guidelines are not to do those diagnostics in individuals without memory disorder and HHS/CMS could take steps to educate the American public as to the appropriate use of these diagnostic tests.
- Similarly, for individuals with memory disorder due to co-pathologies, there is a chance that they will be treated for Alzheimer's disease when non-alzheimer pathology is the pre-dominant etiology of the memory disorder and subsequently be treated with anti-amyloid infusion treatment without confirmation that AD is the primary etiology. CMS should consider strategies for mitigating the risk that patients with mixed neurocognitive disorder due to co-pathologies are fully evaluated to determine the primary cause for any memory disorder they are experiencing.

3. Given the emerging role of biomarker diagnostic testing (for example, p-tau217, et. al) for AD/ADRD leading to early diagnosis, please provide any evidence supporting earlier detection and its role in supporting improving AD/ADRD care and any potential role in identifying eligibility for an intensive lifestyle intervention focused on AD/ADRD.

While blood based biomarkers for AD (such as p-tau217) have prognostic significance⁴, we do not believe there is sufficient evidence to support biomarker or other specialized diagnostic testing as a prerequisite for entry into an intensive lifestyle intervention for AD/ADRD. Furthermore, by the time biomarkers turn positive, it may be too late for these lifestyle interventions to have their full impact. Rather these interventions should be started

³ Baker LD, Espeland MA, Whitmer RA, et al. Structured vs Self-Guided Multidomain Lifestyle Interventions for Global Cognitive Function: The US POINTER Randomized Clinical Trial. *JAMA*. 2025;334(8):681–691. doi:10.1001/jama.2025.12923

⁴ Buckley RF, Townsend DL, Birkenbihl CJ, et al. Prognostic Value of Blood-Based P-Tau217 Levels for Progression to Cognitive Impairment. *JAMA*. Published online July 14, 2026. doi:10.1001/jama.2026.12556)

in mid-life, at the latest, with the aim of preventing biomarkers from turning positive (though unproven) and to benefit many other diseases (e.g., cardiovascular, obesity-related disorders).

Additionally, requiring such testing could further marginalize populations that do not have ready access to these measures, specialty care, or providers who routinely use biomarker testing as part of diagnosis. This could create an unnecessary barrier to participation, particularly in areas where these resources are not readily available.

4. What are the essential domains to address in a multi-domain intensive lifestyle intervention to reduce the risk of cognitive decline for older adults at risk for developing AD/ABRD that would be appropriate to include under Medicare?

The U.S. POINTER (U.S. Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk) demonstrated that a structured multidomain lifestyle programs can significantly improve and protect cognition in older adults at risk for dementia. Interventions encouraged increased physical and cognitive activity, healthy diet, social engagement, and cardiovascular health monitoring.¹

Interventions should be flexible and tailored to the individual beneficiary. Essential domains that should be considered include:

- Diet and Nutrition⁵
- Exercise⁶
- Cardiovascular Risk Management^{7 8 9}
- Avoiding High Risk Behaviors (e.g. smoking)¹⁰

⁵ Chen H, Hailili G, Tong L, et al. Adherence to the MIND diet and longitudinal brain structural changes over a decade: evidence from the Framingham heart study offspring cohort J Neurol Neurosurg Psychiatry doi:10.1136/jnnp-2025-336957

⁶ Marino FR, Lyu C, Li Y, Liu T, Au R, Hwang PH. Physical Activity Over the Adult Life Course and Risk of Dementia in the Framingham Heart Study. JAMA Netw Open. 2025;8(11):e2544439. doi:10.1001/jamanetworkopen.2025.44439

⁷ Cortes-Canteli M, Iadecola C. Alzheimer's Disease and Vascular Aging: JACC Focus Seminar. J Am Coll Cardiol. 2020 Mar 3;75(8):942-951. doi: 10.1016/j.jacc.2019.10.062. PMID: 32130930; PMCID: PMC8046164.

⁸ The SPRINT MIND Investigators for the SPRINT Research Group. Effect of Intensive vs Standard Blood Pressure Control on Probable Dementia: A Randomized Clinical Trial. JAMA. 2019;321(6):553–561. doi:10.1001/jama.2018.21442

⁹ Elena Olmastroni, Giulia Molari, Noemi De Beni, Ornella Colpani, Federica Galimberti, Marta Gazzotti, Alberto Zambon, Alberico L Catapano, Manuela Casula, Statin use and risk of dementia or Alzheimer's disease: a systematic review and meta-analysis of observational studies, *European Journal of Preventive Cardiology*, Volume 29, Issue 5, March 2022, Pages 804–814, <https://doi.org/10.1093/eurjpc/zwab208>

¹⁰ Durazzo TC, Mattsson N, Weiner MW; Alzheimer's Disease Neuroimaging Initiative. Smoking and increased Alzheimer's disease risk: a review of potential mechanisms. *Alzheimers Dement*. 2014 Jun;10(3 Suppl):S122-45. doi: 10.1016/j.jalz.2014.04.009. PMID: 24924665; PMCID: PMC4098701.

- Prevention and treatment of clinical conditions including diabetes, herpes^{11 12}
- Addressing depression, anxiety, sleep, and hearing-related issues¹³
- Addressing socio-economic factors¹⁴

In addition to the above domains, a broader educational effort for Medicare beneficiaries should be a part of any dementia prevention program. Both the public and providers should be educated about the strong relationship between cardiovascular health and brain health and that many of the life-style choices that promote good heart health also promote good brain health.

5. Should these interventions be made available as a one-time service (that is, to teach older adults how to make changes in their lifestyle to help reduce AD/ABRD risk) or on a recurring (for example, annual) basis?

These interventions should not be offered only as a one-time service. Lifestyle interventions are longitudinal in nature, and adherence, which requires behavioral change, can be difficult to sustain. Individuals require regular check-ins and follow-up to ensure that they are adhering to recommendations and, equally importantly, that they remain actively engaged in treatment. These interventions need to be supervised and continuous. A one-time educational intervention or service would therefore be insufficient. There should be an ongoing mechanism for reinforcement, reassessment, and continued engagement.

The comparison arm in the US POINTER study¹, which had less benefit, included self-guided direction for these components. Moreover, some activities, particularly exercise, have higher adherence when provided with structured programs, often in group visits. One-time and even annual intervention advice are likely to fail.

¹¹ Cao F, Yang F, Li J, Guo W, Zhang C, Gao F, Sun X, Zhou Y, Zhang W. The relationship between diabetes and the dementia risk: a meta-analysis. *Diabetol Metab Syndr*. 2024 May 14;16(1):101. doi: 10.1186/s13098-024-01346-4. PMID: 38745237; PMCID: PMC11092065.

¹² Eyting, M., Xie, M., Michalik, F. *et al*. A natural experiment on the effect of herpes zoster vaccination on dementia. *Nature* 641, 438–446 (2025). <https://doi.org/10.1038/s41586-025-08800-x>

¹³ Lin FR, Pike JR, Albert MS, Arnold M, Burgard S, Chisolm T, Couper D, Deal JA, Goman AM, Glynn NW, Gmelin T, Gravens-Mueller L, Hayden KM, Huang AR, Knopman D, Mitchell CM, Mosley T, Pankow JS, Reed NS, Sanchez V, Schrack JA, Windham BG, Coresh J; ACHIEVE Collaborative Research Group. Hearing intervention versus health education control to reduce cognitive decline in older adults with hearing loss in the USA (ACHIEVE): a multicentre, randomised controlled trial. *Lancet*. 2023 Sep 2;402(10404):786-797. doi: 10.1016/S0140-6736(23)01406-X. Epub 2023 Jul 18. PMID: 37478886; PMCID: PMC10529382.

¹⁴ Walsh S, Klee M, Hui EK, Saeed U, Waters S, Kuhn I, Siette J, Orgeta V, Stafford J, Smith LJ, Tamburin S, Jensen DEA, Mantovani E, Chandra A, James SN, Tang EYH, Llewellyn DJ, Foote IF, Chiesa ST, Geraets AFJ; DEMON SDOH International Research Group. Social determinants of dementia: A scoping review. *Alzheimers Dement*. 2025 Jul;21(7):e70524. doi: 10.1002/alz.70524. PMID: 40717690; PMCID: PMC12301702.

6. Should the eligibility for these services be restricted to beneficiaries with a diagnosis of mild cognitive impairment (MCI), or early-stage dementia? If so, how should this diagnosis be made or confirmed?

These services should be available to all, for their benefits on brain health and cardiovascular diseases. Starting them after a diagnosis of MCI or early-stage dementia represents a missed opportunity for prevention. The benefits of these services extend beyond dementia risk reduction, benefiting the broader population and not only those already at elevated risk. It should be delivered across all age groups and through robust primary care. Further, lifestyle interventions have a positive impact on other diseases (e.g., diabetes, cardiovascular disease) and we encourage CMS to consider how best to enhance support for such interventions in Medicare and Medicaid payment.

For those with MCI or early dementia and individuals identified at higher risk for dementia, whether by blood biomarkers, vascular disease, or family history, special focus similar to the [National Diabetes Prevention Program \(National DPP\)](#) could be implemented. This could be done virtually or in person through vetted entities paired with primary care offices.

7. Given ILI's are multi-domain, and likely include physical activity, nutrition, potentially additional domains such as sleep and stress management, who are the essential interdisciplinary team members that CMS should account for in developing appropriate resource costs for future services?

In addition to primary care clinicians who can initiate the discussions of ILIs and provide continuous encouragement, members of the multidisciplinary team should include access to the following expertise:

- a registered dietitian or nutritionist;
- an exercise specialist, which could include a physical therapist, exercise physiologist, or appropriately trained exercise professional;
- behavioral health therapist or coaches;
- sleep therapists; and
- a care manager or social worker.

The team structure should support the major domains of the intervention without being so prescriptive that it limits implementation in less-resourced settings.

8. How should supervision be determined for AD/ADRD ILI's? Is general supervision sufficient for ensuring clinical safety and oversight? Is direct supervision required?

Intensive lifestyle interventions that include physical activity can generally be delivered safely with appropriate clinical oversight. Direct supervision should not be universally required.

The supervision standard should balance safety with scalability. Requiring direct supervision for all participants would make implementation substantially more difficult without necessarily being needed for every beneficiary. General supervision should be sufficient for most participants and would allow for the interventions to reach a larger population.

9. What is the minimum frequency of sessions for an AD/ADRD ILI per week? What is the minimum number of weeks that will be necessary?

For the minimum frequency of sessions per week, 3 times per week seems to be a commonly employed strategy. However, we suggest that CMS avoid establishing a rigid minimum number of sessions per week. Highly prescriptive visit schedules can be problematic for both patients and providers and may create unnecessary utilization and access barriers. We would favor flexibility in visit frequency based on individual need and capacity rather than a fixed weekly requirement.

For the minimum number of weeks, an intensive intervention should last at least 10 to 12 weeks as a bare minimum, but the broader model should recognize that lifestyle intervention is longitudinal and requires continued follow-up beyond the initial intensive period. The visits should be continuous as long as the person can physically participate.

10. Should CMS require a future AD/ADRD ILI to be delivered in person? Can it be delivered virtually?

It will likely be more effective if delivered in person and, if community-based organizations are partners, there should be sufficient capacity to do so. However, making both options available may help ILIs reach larger populations.

11. How should CMS support the development of our Health Technology Ecosystem to support older adults reducing their risk for developing AD/ADRD using intensive lifestyle changes?

Technology should be used to support access, engagement, encouragement, and longitudinal follow-up. Virtual platforms may be particularly useful for allowing beneficiaries to remain engaged with multidisciplinary care, especially when local

resources are limited. Technology should facilitate participation rather than become an additional requirement or barrier for beneficiaries who have limited access to devices, broadband, or specialty health systems. Additionally, incorporating lifestyle assessment tools in EHRs can prompt appropriate referral programs or best practice recommendations.

The AGS appreciates the opportunity to provide the above comments and recommendations. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Alison A. Moore".

Alison A. Moore, MD, MPH, FACP, AGSF
President

A handwritten signature in black ink, appearing to read "Nancy E. Lundebjerg".

Nancy E. Lundebjerg, MPA
Chief Executive Officer