

September 14, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comment on CMS-2026-2377, CY 2027 Medicare Physician Fee Schedule Proposed Rule — Comment Solicitation (63): Payment for Physician-Patient Clinical Trial Discussions

Dear Administrator Oz:

Thank you for the opportunity to comment on CMS's solicitation regarding payment for physician-patient clinical trial discussions in the CY 2027 Physician Fee Schedule proposed rule. Our work at the USC Clinical Trial Recruitment Lab focuses on the structural, clinical, and reimbursement barriers that keep eligible patients from ever reaching a clinical trial, with a particular focus on Alzheimer's disease and related disorders (ADRD). As researchers and policy experts devoted to discovering the barriers to clinical trial recruitment, we support the creation of a dedicated HCPCS G-code for clinical trial counseling and urge CMS to design and value that code in a way that reflects the added complexity of trials designed to study the efficacy of cognitive-impairment treatments.*

In summary, we recommend that CMS (1) finalize a dedicated, adequately valued HCPCS G-code for physician-patient clinical trial counseling; (2) keep documentation requirements minimal, consistent with the lean approach CMS has proposed; (3) value the code in a way that reflects the added time needed to address caregiver/study-partner burden, which is commonly high in ADRD trials; and (4) make the service available via Medicare telehealth to protect access for rural and underserved patients. Each recommendation is discussed in turn below.

Why CMS Should Act

1. The referral gap CMS identifies in oncology is at least as severe in Alzheimer's disease

CMS notes that fewer than 7% of adult cancer patients enroll in clinical trials, and that 70% of oncologists discuss trials with fewer than a quarter of their patients. The comparable figures for Alzheimer's disease are, if anything, starker. A [Schaeffer Center white paper](#) synthesizing interviews and surveys of nearly 900 Alzheimer's disease stakeholders estimated that

*The opinions expressed herein represent those of the authors and do not represent the positions of any of their affiliated organizations, including the University of Southern California or USC Schaeffer.

approximately 99% of potential participants are never referred to or even consider participating in an AD clinical trial, and that even when a patient's cognitive decline is recognized, referral is generally ad hoc and is not integrated into a systematic clinical process.^{1,2} A 2025 review of AD clinical trial recruitment reached a parallel conclusion: most physicians remain unaware of ongoing AD trials or lack the detailed knowledge to refer patients effectively, and time-constrained providers are often unable to review records thoroughly enough to determine a patient's eligibility.³ The downstream effect is significant: the Global Alzheimer's Platform Foundation reports that 90% of Alzheimer's disease studies, and 80% of Parkinson's disease studies, are delayed due to insufficient recruitment.⁴

2. Time and reimbursement constraints are independently documented as barriers to dementia care and disclosure, compounding the trial-referral gap

The barriers CMS identifies for oncology (documented in the Kumar et al. study CMS cites) have close, independently documented analogues in Alzheimer's disease and related disorders (ADRD). A systematic review of missed and delayed dementia diagnosis in primary care found that physicians in seven separate studies cited the brief time available in a typical visit as a limitation on their ability to assess symptoms, and separately identified low financial reimbursement for dementia care as a system-level barrier to diagnosis and management in its own right.⁵ A continuing-medical-education review of dementia disclosure practice similarly lists significant time constraints and low reimbursement alongside gaps in clinician communication training as the central barriers preventing timely, structured disclosure conversations, the same conversations into which a trial discussion would need to be embedded.⁶ The American Academy of Family Physicians has noted that primary care physicians often cite time constraints as a reason cognitive assessment is skipped altogether, let alone extended into a discussion of research options.⁷ These constraints are not limited to primary care: overburdened neurologists and memory-clinic specialists report that time limitations impede the manual chart review needed to determine trial eligibility in the first place, well before any conversation with the patient occurs.³

Taken together, this literature indicates that the barrier CMS is targeting with this G-code, the absence of compensated time for structured trial counseling, operates upstream in the U.S. healthcare system. In the case of cognitive care, a payment mechanism for trial counseling could be understood as one piece of a broader reimbursement gap that CMS has already begun to address through the cognitive assessment and care planning code (CPT 99483) and that should now extend explicitly to discussions related to research participation. This would ensure that people not only get access to existing therapies, but also have the choice to contribute to the development of new ones, at a time where the research pipeline is extremely rich.⁸ A dedicated counseling code could also help broaden access to trial participation, improving the representativeness of enrolled populations and, in turn, the quality and generalizability of the evidence generated.⁹

3. Evidence supports a dose-response relationship between physician-initiated discussion and willingness to enroll

CMS cites Unger et al.'s finding that more than 50% of eligible oncology patients enroll when actively offered a trial. A nationally representative survey conducted through the University of Michigan National Poll on Healthy Aging found a comparable pattern for dementia prevention research: respondents who had discussed dementia prevention with a doctor were more than twice as likely to report willingness to participate in a trial as those who had never had that conversation (odds ratio 2.20), and this association held regardless of race, ethnicity, or other sociodemographic factors.¹⁰ Notably, only about 5% of the surveyed population had ever had such a conversation with a physician - underscoring how large the untapped opportunity is if compensated time made these conversations routine rather than incidental.¹⁰ Programs like the Global Alzheimer's Platform Citizen Science Award show the positive impact of clinical trial participation for patients themselves.⁴

How CMS Should Design the Code

4. Precedent: a dedicated, time-based counseling code changes physician behavior, but documentation burden can blunt its impact, and CMS should design accordingly

CMS has direct precedent for the proposition that creating a compensated, time-based counseling code changes physician behavior. In 2015, CMS created CPT codes 99497/99498 for advance care planning specifically because lack of a payment mechanism, alongside time constraints and insufficient training, had been documented as a barrier to physicians having these conversations at all.¹¹ We believe the same logic supports creating a dedicated G-code for clinical trial counseling.

At the same time, CMS's experience with CPT 99483 (Cognitive Assessment & Care Plan Services) is an important cautionary data point for how this new code is designed. Despite a 2021 payment increase to approximately \$282 and CMS's inclusion of the service in Medicare Shared Savings Program primary-care definitions, GAO found that utilization remained low despite tripling between 2018 and 2022 and identified several barriers, including the time required, billing limitations, limited provider training, stigma, and lack of beneficiary awareness.^{12,13} Although GAO did not isolate documentation burden as the primary cause, the experience with CPT 99483 illustrates the importance of designing a code that is straightforward to use and compatible with clinical workflow. We urge CMS to keep the documentation requirements for the new clinical trial counseling G-code deliberately lean, consistent with what CMS has already proposed (the trial(s) discussed and the patient's decision), rather than layering on care-plan-style documentation elements that have measurably suppressed uptake of comparable codes.

5. Valuation should reflect the added complexity of trial counseling in dementia care

We support a work RVU at the upper end of the proposed 1.00–1.50 range for services involving cognitive-impairment diagnoses. Dementia clinical trials carry structural counseling burdens that most other therapeutic areas do not. Many dementia trials require an accompanying study partner who must understand and agree to substantial ongoing responsibilities and, in some cases, separately consent to study procedures involving the partner. Even among patients who reach the point of a trial discussion, earlier studies estimated that only 10-27% ultimately meet inclusion criteria once comorbidities and logistical constraints are considered.¹⁴ Considerable time is required for caregiver/study-partner logistics alone, before eligibility, risks, and benefits have been addressed. We ask CMS to acknowledge this added complexity explicitly in the final valuation methodology, and to confirm that time spent counseling an accompanying caregiver or study partner, which is clinically necessary and often required by the trial protocol itself, counts toward the code's time threshold.

CMS will need to clarify how the new G-code is intended to interact with existing billing. Specifically, clarification is needed on whether the code may be billed as a stand-alone service or only as an add-on to an evaluation and management visit, and whether it may be billed on the same day as CPT 99483 (Cognitive Assessment & Care Plan Services) when both services are separately identifiable and medically necessary.

We recognize that establishing a new work RVU-bearing code has implications for the Physician Fee Schedule's budget-neutrality adjustment. We nevertheless believe that the absence of payment for this distinct physician service should not prevent CMS from appropriately recognizing and valuing the work involved. We also encourage CMS to consider these costs relative to the challenges they are meant to address: patients who are never referred to a trial, and trials that are delayed because of insufficient participants. Although these broader benefits would not necessarily appear as direct offsets in the Physician Fee Schedule, improving recruitment could help reduce costly trial delays and accelerate the development of innovative and effective medical treatments.

6. Telehealth availability is particularly important for dementia patients

We support making this service available via Medicare telehealth. Access to dementia specialists and clinical-trial sites varies substantially by geography, creating substantial burdens for rural patients and others who must travel long distances for specialty care. Allowing trial counseling through telehealth could reduce one important barrier to learning about potentially appropriate studies.

Conclusion

Like oncology, the evidence on ADRD points to substantial barriers to enrollment in clinical trials and suggests physician conversations to support participation. We urge CMS to finalize a dedicated, adequately valued HCPCS G-code for physician-patient clinical trial counseling; to keep documentation requirements minimal, informed by the experience with underutilization of CPT 99483; value the code in a way that reflects the added caregiver/study-partner counseling burden common to dementia trials; and make the service available via telehealth to protect access for rural and underserved patients. We would welcome the opportunity to discuss this comment further and to share additional data from our recruitment research.

Respectfully submitted,

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References

1. Aisen P, Peneva D, Manetas MA, Jacobson M, Goldman D, Bose N, Ferrell PB, Vu VK, Raman R. Advancing the science of recruitment for Alzheimer's clinical trials: challenges and opportunities. *J Prev Alzheimers Dis*. 2025; 12(4): 100230. doi:10.1016/j.tpad.2025.100230.
2. Leonard D. Schaeffer Center for Health Policy & Economics, University of Southern California, and Gates Ventures. Key Barriers to Clinical Trials for Alzheimer's Disease (white paper, based on interviews and surveys of nearly 900 AD stakeholders). Published August 17, 2020. Available at: <https://schaeffer.usc.edu/research/key-barriers-for-clinical-trials-for-alzheimers-disease/>
3. Yigamawano FK, Odom AR, Xue C, Pandey HK, Kolachalama VB. AI-augmented frameworks for enhancing Alzheimer's disease clinical trials: A memory clinic perspective. *J Prev Alzheimers Dis*. 2025 Dec 1;13(1):100396. doi: 10.1016/j.tpad.2025.100396.
4. Global Alzheimer's Platform Foundation. Citizen Scientist Awards. Available at: <https://globalalzplatform.org/citizen-scientist-awards/> (noting that 90% of Alzheimer's disease studies and 80% of Parkinson's disease studies are delayed due to insufficient recruitment, and profiling participants and study partners whose involvement advanced trial completion).
5. Bradford A, Kunik ME, Schulz P, Williams SP, Singh H. Missed and delayed diagnosis of dementia in primary care: prevalence and contributing factors. *Alzheimer Dis Assoc Disord*. 2009;23(4):306-314. doi:10.1097/WAD.0b013e3181a6bebc.
6. Goldfarb D, Sheard S, Shaughnessy L, et al. Disclosure of Alzheimer's disease and dementia: patient- and care partner-centric decision-making and communication. *J Clin Psychiatry*. 2019 Mar 19; 80(2):MS18002BR1C.
7. O'Brien, K.S., Harkins, K., Peifer, M. *et al*. Designing an intervention to improve cognitive evaluations in primary care. *Implement Sci Commun* 2025; 6(9). <https://doi.org/10.1186/s43058-025-00693-1>.
8. Cummings JL, Zhou Y, Yang Y, Zhong K, Fonseca J, Leisgang Osse A, Cheng F. Alzheimer's disease drug development pipeline: 2026. *Alzheimer's Dement (N Y)*. 2026;12(2):e70251. doi:10.1002/trc2.70251.
9. National Academies of Sciences, Engineering, and Medicine. 2022. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26479>
10. Cox CG, Davis MA, Grill JD, Roberts JS. US adults' likelihood to participate in dementia prevention drug trials: results from the National Poll on Healthy Aging. *J Prev Alzheimers Dis*. 2023;10(1):34-40. doi:10.14283/jpad.2022.86.
11. Centers for Medicare & Medicaid Services. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 (Final

Rule establishing CPT codes 99497/99498 for advance care planning), 80 Fed. Reg. 70886 (Nov. 16, 2015).

12. U.S. Government Accountability Office. Medicare: Cognitive Assessments: Utilization Tripled Between 2018 and 2022, but Challenges Remain. GAO-24-106328, 2023.

<https://www.gao.gov/products/gao-24-106328>

13. Centers for Medicare & Medicaid Services. Cognitive Assessment and Care Plan Service. 8/28/2022 <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59036>

14. Grill, J., Galvin, J. Facilitating Alzheimer Disease Research Recruitment. *Alzheimer Disease & Associated Disorders*, 2014; 28(1), 1–8. <https://doi.org/10.1097/WAD.0000000000000016>