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Centers for Medicare & Medicaid Services
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Dr. Seshamani:

RE: CY 2025 Clinical Laboratory Fee Schedule Preliminary Determinations: Category 1 CPT®[1] Codes and Assays for Fluid-Based Amyloid Beta and Tau Protein Biomarkers

Alzheimer's disease and related dementias are only diagnosed about half of the time. The pathology is detected and diagnosed late in the disease progression, if at all, in Black and Hispanic Americans. No diagnosis or late diagnosis robs these people of information they need to consider new disease-modifying therapies, make lifestyle changes that might slow progression, plan their lives or seek other appropriate therapy or clinical trials.

Blood tests could provide a less expensive, easier-to-access means to obtain diagnosis for people with Alzheimer's disease. Increased access to a reliable test could be particularly important for the health of rural Americans who often live far from an urban setting where a PET scan is available.

This revolution for people living with early Alzheimer's and those who love them is threatened by the proposed Clinical Laboratory Fee Schedule for next year. As we understand it, the advisory panel recommended a reimbursement rate of $130 per test for beta-amyloid 1-40, beta-amyloid 1-42, neurofilament light chain, total tau, and phosphorylated tau. However, your proposed Fee Schedule would reimburse the labs who might perform these tests at $17, just over 10% of that amount, which may be less than what such a test would cost a laboratory to process the test. As a result, as a practical matter, blood tests could simply not be used by physicians. As patient advocates, we are not experts in the costs of performing blood tests, but we expect that your advisory panel is. If Medicare sets rates so much lower than they recommend, we expect that many labs would simply not offer these crucial tests. This would be awful for people living with dementia—particularly historically underserved populations.

We cannot imagine that this is Medicare's intention.

The opportunity for someone with Alzheimer's disease to access the medicines or make the lifestyle changes that may improve their prognosis may be lost if patients are unable to get the appropriate lab test because reimbursement rates are too low.

The last few years have also made exciting new disease-modifying treatments available to physicians and their Alzheimer's patients – if a diagnosis can be made while the patient is still in the early stages of the disease. The FDA has granted traditional approval to – and Medicare is now covering, with restrictions under a CED – two drugs that slow both the cognitive and

functional rate of decline that are the hallmarks of Alzheimer's disease. Again, these drugs are indicated only for people with mild cognitive impairment or early-stage Alzheimer's dementia, and anything that delays a diagnosis will mean that some patients will have advanced too far to use these medications.

Lack of access to these lab tests would exacerbate health inequities for Alzheimer's disease that hit traditionally underserved communities hard. Black Americans are twice as likely, and Latino Americans are one and one-half times more likely, to develop dementia than White Americans. More available and more affordable means of diagnosing Alzheimer's disease could help these groups of people.

People living with Alzheimer's disease waited more than two decades for new medications to be approved by the FDA, and we now have the first two disease-modifying drugs ever. Evidence about the effectiveness of lifestyle intervention is continually growing and becoming more prescriptive. These are exciting developments – but their impact will be limited if people cannot get affordable tests and early diagnosis. Please do not let blood test reimbursement rates create yet another roadblock to effective treatment.

As Medicare works to finalize its proposed reimbursement rate for blood tests, we urge you to follow the advisory panel recommendations for tests for Alzheimer's pathology and set an appropriate rate. Setting rates that do not cover the laboratories' cost of conducting the tests will harm patients and their families.

Please let us know if we can be helpful.

Sincerely,

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Alliance for Patient Access
Alliance for Women's Health and Prevention
American Senior Alliance
Caregiver Action Network
Davos Alzheimer's Collaborative
The Global CEO Initiative on Alzheimer's Disease
Global Alzheimer's Platform Foundation
HealthyWomen
National Consumers League
National Grange
Partnership to Fight Chronic Disease
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