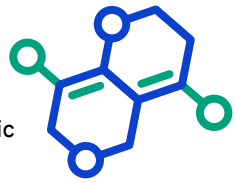
Benefits of Biomarker Testing for Early Disease-Stage Alzheimer's Diagnosis

~90% **of the expected 8 million Americans with mild cognitive impairment remain undiagnosed.**[1]

Early disease-stage Alzheimer's diagnosis of patients with cognitive decline is key for:



Access to disease-specific therapies: Newly FDA-approved amyloid targeting therapies (lecanemab and donanemab) are indicated for individuals in early symptomatic stages (MCI and mild dementia) where they are most effective.[2,3]

Clinical trial enrollment: Patients may access programs to connect patients with innovative research and enable continued research into new, more effective therapies.

Emotional and societal benefits: Families may plan for the future (advanced care planning) and prompt safety measures for driving and medication adherence.

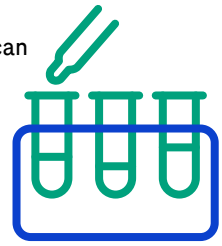
Cognitive preservation via lifestyle changes: Ongoing research (US POINTER) supports the initiation of structured lifestyle interventions including diet, exercise, cognitive training and vascular risk management to preserve cognitive function.[4]

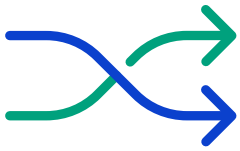
Biomarker testing in patients with cognitive impairment in primary care

Facilitate early detection and early diagnosis: Using rule-out tests, like the Elecsys® pTau181 test, in addition to other clinical investigations allows primary care providers to triage patients with early disease symptoms and streamline their referral to specialists for more comprehensive assessments and final diagnosis. The pTau181 plasma test is the only rule-out test indicated for use in primary care settings.

Improve diagnosis accuracy: Using a triage test with high negative predictive value (the Elecsys pTau181 plasma test has a 97.9% NPV) can help PCPs confidently stop the Alzheimer's disease workup and focus on non-AD causes for cognitive decline.[5]

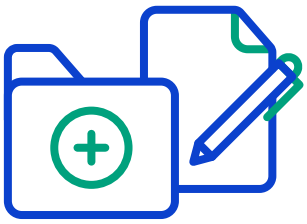
Preserves specialty resources: Blood tests can prevent unnecessary specialist referrals and reduce costly or invasive confirmatory testing in 45% of patients tested.[5]





Considerations: Clinicians should engage in thorough pre-test discussion to ensure the patient understands the risks and benefits, the follow-up and impact of positive or negative results.

Medical record: Test results may impact insurance, driver's license or employment.



Insurance coverage: Medicare FFS does not currently have established coverage determinations, which means they are reviewing this testing on a claim-by-claim basis. For Medicare Advantage and commercial payers, there is currently limited coverage for this testing, but a few payers have recently established coverage. As with any new diagnostic category, reimbursement will evolve over time as adoption and evidence grow.

Comorbidities: Can interfere with test accuracy or the patient's eligibility for subsequent follow-up care and disease-modifying therapies.

1. Mattke, S., Jun, H., Chen, E. et al. Expected and diagnosed rates of mild cognitive impairment and dementia in the U.S. Medicare population: observational analysis. Alz Res Therapy 15, 128 (2023) https://doi.org/10.1186/s13195-023-01272-z
2. Leqembi label. Accessed March 20, 2026
3. Donanemab label. Accessed March 20, 2026
4. 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. https://doi.org/10.1001/jama.2025.12923
5. Elecsys Phospho-Tau (181p) Plasma decision summary Accessed February 2026. https://www.accessdata.fda.gov/cdrh_docs/reviews/K252163.pdf