MILKEN INSTITUTE

JULY 2026

EXECUTIVE SUMMARY

Advancing Blood-Based Biomarkers for Alzheimer's and Cognitive Care

The Food and Drug Administration's (FDA) recent clearance of blood-based biomarkers (BBMs) to aid in the diagnosis of symptomatic Alzheimer's disease (AD) marks a paradigm shift in early detection and diagnostic care. For health-care systems and payers, now is the time to assess and close gaps in system readiness to advance wide-scale implementation in the US.

To help make this assessment, the Milken Institute Future of Aging and its Alliance to Improve Dementia Care interviewed 32 experts in April and May of 2026 across six stakeholder segments: health systems and medical groups, payers, clinical guideline developers and policymakers, patient voice and advocacy groups, diagnostic and treatment manufacturers, and innovative care platforms. We paired these interviews with a landscape analysis, a patient focus group moderated by the National Council of Dementia Minds, and a five-category BBM Readiness Ranking Survey.

The BBM landscape is moving quickly, with two FDA-cleared tests: one measuring the ratio of pTau217 to β-amyloid 1-42 in plasma, and another measuring the presence of pTau181. Tests identifying pTau217 are approved for use in Europe and are currently undergoing FDA review for approval in the US. The next wave of biomarkers will measure tau tangle pathology for a more complete picture of AD.

When used early, these tests open new care pathways for individuals experiencing cognitive impairment, including evaluation for anti-amyloid targeting treatments, qualifications for early-stage clinical trials, referrals to education and support programs, and informed decision-making on advanced life planning across financial, legal, and medical matters.

Regulatory clearance alone does not automatically lead to access and coverage. To examine the remaining barriers to implementation, 22 experts were asked to rate the field's current readiness from Level 1 (insufficient) to Level 5 (fully sufficient) across five categories: Clinical Guidelines, Diagnostic Positioning, Evidence Generation for Coverage, Payer Medical Policy Acceptance, and Health Equity and Access. (View a Readiness Ranking Framework in the full report.)

In four out of five categories, the results clustered around Levels 2 or 3 out of 5, past insufficient but far from fully sufficient. In aggregate, the responses indicate that the field is more clinically ready (with Diagnostic Positioning rated at Level 4) and less payer-ready (with Payer Medical Policy Acceptance rated at Level 2). This gap between clinical acceptance and payer acceptance translates to stalled adoption of these diagnostic innovations.

The experts and stakeholders note additional remaining barriers and accelerators to the adoption of BBMs, including the need for up-to-date guidelines and education on interpreting and acting on test results. Other factors to incentivize adoption in primary care include coverage of cognitive assessments

and ways to expand capacity between primary and specialty care to facilitate cognitive impairment workups, BBM ordering, and treatment evaluation.

The report provides four examples of health systems successfully embedding BBMs into cognitive care models, demonstrating that, with specific training and support, primary care providers can be equipped to order and interpret initial triage tests, streamlining patients into efficient specialized care pathways.

Other adoption accelerators include economic studies demonstrating that accurate diagnosis has a stand-alone value and cautioning that insurance coverage should not be strictly tied to patients eligible for anti-amyloid treatment. Evidence generation for coverage was rated as "building momentum," with experts anticipating that early innovative payers will adopt coverage policies over the next two years based on real-world performance data in diverse populations, evidence of management change, avoided downstream costs, and visible payer-by-payer adoption that builds market confidence.

Early payer movement indicates Medicare administrative contractors (MACs) are actively reviewing the impact of BBMs and are willing to make changes to match the recommendations of prescription drug labels, detailed in a case study reviewing the removal of barriers to APOE genetic testing. However, stakeholders note a consistent lack of clarity on BBM coverage in current medical policies. In certain cases, clinicians reported having to acknowledge that patients may incur high out-of-pocket costs for a BBM, leading patients to decline the test. Payers should recognize that there is no single "perfect diagnostic workflow" and that overly restrictive utilization management can lead to overutilization of imaging in straightforward cases and delayed time to treatment in others.

What the field requires now is not more diagnosis of the problem but coordinated action toward effective solutions that drive the adoption of BBMs as the new standard of care. Whether you lead a health system, set payer policy, contribute to guidelines, advocate for patients, develop diagnostics and treatments, or operate a care platform, know that your role matters.

TO VIEW THE FULL REPORT, SCAN THE QR CODE BELOW.