MILKEN INSTITUTE

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

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Project Overview and Methodology

Recent Food and Drug Administration (FDA) clearances of new blood tests to aid in the diagnosis of symptomatic Alzheimer's disease (AD), commonly referred to as blood-based biomarkers (BBMs), promise to transform early detection and diagnostic care pathways. For health-care systems and payers, now is the time to assess and close gaps in system readiness for wide-scale implementation.

To help make this assessment, the Milken Institute Future of Aging and the Institute's Alliance to Improve Dementia Care leadership interviewed 32 experts in April and May of 2026 across six key stakeholder segments: health systems and medical groups, payers, clinical guideline and policymakers, patient voice and advocacy groups, diagnostic and treatment manufacturers, and innovative care platforms. In addition, the team conducted a landscape analysis using academic and grey literature, held a patient focus group moderated by the National Council of Dementia Minds, and fielded a five-category BBM Readiness Ranking Survey.

This report represents a synthesis of these inputs as part one of a two-part project. Part two of this project will include an in-person roundtable convening and further analysis of effective implementation tools to advance BBMs as the new standard in AD care.

This work builds on previous Alliance work, including *Building Workforce Capacity to Improve Detection and Diagnosis of Dementia* (2021), *Improving Early Detection of Cognitive Impairment and Dementia* (2024), and *Mind the Gap: Investing in Dementia as an Opportunity to Extend Healthspan* (2025).

While reading this report, we charge readers to consider the core question:

What will it take to advance blood-based biomarkers as the new standard of care in Alzheimer's disease?

To answer this question, we first ground the reader in today's diagnostic journey and the science that has finally begun to catch up with the disease. We surface the top barriers identified by key stakeholders, highlight the accelerators already in play, and outline considerations for each stakeholder group to support the implementation of these advanced detection methods.

Diagnostic Background

Today's Diagnostic Journey

Today, the diagnostic journey for identifying cognitive impairment and its underlying causes is often sequential, slow, and structurally biased toward those with resources and access. During a focus group, members of the National Council of Dementia Minds described the period prior to diagnosis as one of the worst parts of the illness. Many recalled being repeatedly dismissed or told their symptoms were simply a normal part of aging, stress-related, or attributable to other factors.

During our interviews, stakeholders noted that delayed and missed diagnoses are driven by a combination of stigma, limited use of structured cognitive assessments, primary care capacity constraints, fragmented referral pathways, unequal access to specialists and biomarker testing, and the persistent misconception that little can be done, even when impairment is identified early.

In 2026, the Alzheimer's Association reports that 7.4 million people in the United States are living with Alzheimer's dementia.[1] Yet, only a fraction of these individuals are diagnosed, and even fewer early enough to take meaningful disease-modifying action; these are deemed the "fortunate few."

Game-Changing Innovations

For the first time, we now have two reasons to take action against AD: (1) simple, accurate diagnostics and (2) approved treatments that slow progression. Dementia science has advanced at a remarkable pace, transforming Alzheimer's from a condition defined largely by late-stage symptom recognition into one that can increasingly be detected and addressed earlier in the disease continuum.

> **"In my experience in 30 years of working in health systems, two things catalyze change. One is the diagnostic, and one is the treatment. And forever, there's been neither of those things for Alzheimer's. In the last few years, we've had both."**
>
> ***—Fiona Carragher, Alzheimer's Society***

However, with progressive conditions, we must move quickly. An estimated 3,000 people a day progress from mild stages to severe stages of AD and out of the current drug treatment window.[2] Even with regulatory approval, coverage is not guaranteed.

Studies show the average time from FDA approval to Medicare coverage for a diagnostic test is nearly 5.7 years.[3] Therefore, the field must move urgently to increase adoption of new diagnostic technologies poised to enable early detection and accurate diagnosis, which, in turn, will improve outcomes for people battling these diseases.

From Probable to Confirmatory Diagnosis

Historically, a confirmed diagnosis of AD could only be made post-mortem through autopsy. Today, the advent of in vivo diagnostic technology such as positron emission tomography (PET) imaging, testing cerebrospinal fluid (CSF), and emerging BBMs is transforming the field. Yet, these advancements raise a fundamental question in the medical community: *What is required to diagnose AD?*

CURRENT GUIDANCE

- The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) accepts clinical evaluation (use of cognitive assessments) for "probable" or "possible" AD.[4]
- The International Working Group recommends a "clinical-biological construct" that combines clinical phenotype (cognitive symptoms) and pathophysiological biomarkers.[5]
- The Alzheimer's Association 2024 Working group recommends that a "Core 1 biomarker" (amyloid and/or tau) alone is sufficient, with symptoms understood as a downstream result of the disease process, not necessary for the diagnosis of AD.[6]

Enter Blood-Based Biomarkers

Recent advances in ultra-sensitive laboratory equipment enable the detection of the same biomarkers found in CSF—amyloid-beta 42 (Aβ42) and phosphorylated tau (p-tau)—by analyzing plasma from whole blood collected via a standard venous blood draw. These blood-based biomarkers offer unprecedented opportunities for scalable, minimally invasive, cost-effective approaches to aid clinicians in early detection and accurate diagnosis of symptomatic AD.

RECENT BBM ADVANCEMENTS

- In May 2025, the FDA cleared the Lumipulse® G pTau217/β-Amyloid 1-42 Plasma Ratio test by Fujirebio Diagnostics to aid in the diagnosis of Alzheimer's disease for adults aged 55 and older exhibiting signs and symptoms of cognitive impairment.
- In October 2025, the FDA cleared the Elecsys® pTau 181 test by Roche Diagnostics, intended for patients aged 55 and older presenting with symptoms of cognitive impairment to rule out Alzheimer's disease in the primary care setting.
- In May 2026, Roche Diagnostics received Conformité Européenne mark approval for Elecsys® pTau217 as the first blood test for AD pathology with a single-assay design, intended to rule in and rule out amyloid pathology across primary and secondary care.
- Several more manufacturers have submitted biomarker tests under FDA review for amyloid beta

ratios and pTau217. Other emerging biomarkers target tau tangle pathology, together providing a more complete picture of AD, extending beyond amyloid pathology.[7]

These current cleared tests are indicated for use in individuals with confirmed cognitive impairment to determine the presence of amyloid pathology. When detected early, people living with cognitive impairment may benefit from access to new treatments, early-stage clinical trials, referrals to education and social support programs, and advanced life planning that enables joint financial, legal, and medical decision-making.[8]

With these new tests clinically available, how can we ensure our health systems are ready to support BBMs as the new standard of care?

Implementation Readiness

To assess the health-care industry's readiness to adopt BBMs, we asked 22 of our experts to rate the field's current readiness standing across five categories that must align for BBMs to become a standard of care. If all fully sufficient, the categories—Clinical Guidelines, Diagnostic Positioning, Evidence Generation for Coverage, Payer Medical Policy Acceptance, and Health Equity and Access—would pave the way for successful implementation. Respondents were asked to place the field on a five-point readiness level, with tailored definitions for what constitutes a "Level 1" (lowest readiness, e.g., insufficient or investigational) to a "Level 5" (highest readiness, e.g., system alignment or equitable standard).

Table 1. Readiness Ranking Framework

	Clinical Guidelines	Diagnostic Positioning	Evidence Generation for Coverage	Payer Medical Policy Acceptance	Health Equity and Access
Barriers	Need for up-to-date guidelines and clear interpretation of results	Need for primary and specialty care incentives and capacity	Diagnostic value tied too narrowly to treatment	Lack of coverage and clarity from payers	Concerns for patient equity, access, and protections
Accelerators	Referencing lessons from other disease models	Embedding BBMs in successful cognitive care models	Engaging with payers early for evidence generation	Highlighting early payer movement	Connecting to promising programs
Readiness Ranking	**Level 3 Sufficient for Specialists**	**Levels 2 and 4 Rule-Out Standard and Conditional Replacement**	**Level 3 Building Momentum**	**Level 2 Skeptical and Outcome Linked**	**Level 3 Uneven Progress**

Source: Milken Institute (2026)

In four out of five categories, the results clustered around Levels 2 and 3, past investigational 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 most respondents rating Payer Medical Policy Acceptance at Level 2.

The survey provides a baseline for measuring field readiness, and the findings signal that no single stakeholder can advance adoption alone. The following category sections examine each in turn, highlighting major barriers and accelerators that influence the advancement and adoption of BBMs. We begin with clinical guidelines, often considered the basis that sets practice standards for the rest of the system to follow.

Clinical Guidelines

When asked "How sufficient are the current guidelines and recommendations to support the field's adoption and implementation of BBMs?", respondents clustered around Level 3 Sufficient for Specialists (see Figure 1). The guidelines provide adequate guidance for memory specialists and neurologists, but do not yet address primary care, screening, or broader health system workflows. The remaining respondents rated guidelines and recommendations at Levels 1 and 2, citing gaps in primary care application, diverse populations, post-result management, and operational specifics such as ordering criteria, result disclosure, care pathways, and electronic health record (EHR) integration.

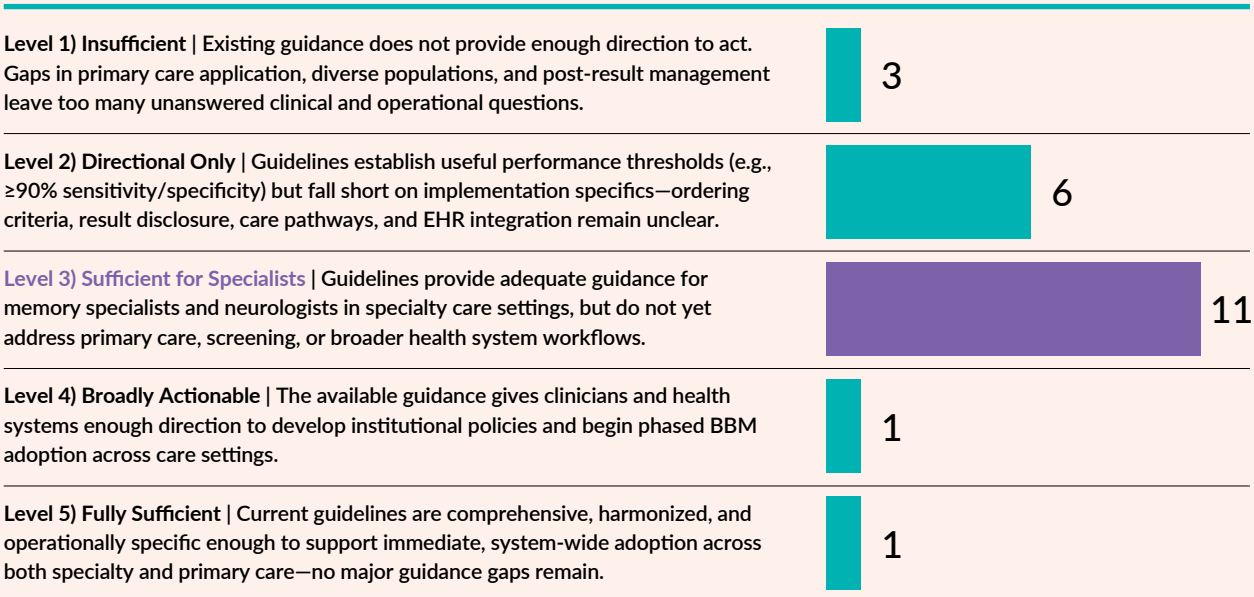
Figure 1. Category 1: Clinical Guidelines Sufficiency

Question

How sufficient are the current guidelines and recommendations—from the Alzheimer's Association (2025), CEOi (2024), and AAFP (2022)—to support the field's adoption and implementation of blood-based biomarkers (BBMs) today?

Top Answer

Level 3 | Sufficient for Specialists
Guidelines provide adequate guidance for memory specialists and neurologists in specialty care settings, but do not yet address primary care, screening, or broader health system workflows.



Note: BBM Readiness Survey Results, n=22
Source: Milken Institute (2026)

BARRIER: NEED FOR UP-TO-DATE GUIDELINES AND CLEAR INTERPRETATIONS OF RESULTS

Notably, the American Academy of Neurology has not updated its Alzheimer's diagnostic practice guidelines since 2018. The current prominent guidelines and recommendations include American Academy of Family Physician's 2022 recommendations for shared decision-making, the Alzheimer's Association's 2024 guidelines,[9] and the CEOi BBM Workgroup's 2024 recommended performance benchmarks.[10]

Stakeholders acknowledged that producing official clinical practice guidelines is a high bar and a lengthy process, leading to medical innovations outpacing practice guidelines.

> **"Published guidelines aren't the only vehicle for shaping clinical practice. Appropriate use recommendations, best practice publications, and training competencies often do more practical work and can move faster when evidence is still emerging."**
>
> ***—Joel Salinas, MD, Isaac Health***

The Advisory Group on Risk Evidence Education for Dementia (AGREED) provides several materials from multiple sources (see Table 2) to facilitate shared decision-making among a clinician, a patient, and, if available, a care partner. It must be clear that a positive result does not automatically equal a diagnosis, and clinicians will base the diagnosis not only on the results of the AD blood test but also on the person's other health conditions, symptoms, function, and results of other diagnostic tests, including cognitive testing and brain imaging.

Stakeholders noted limitations of the current BBMs and key considerations, such as understanding the pre-test probability of a positive or negative result. The positive predictive value is expected to be higher in older patients, specialty settings, areas of higher disease prevalence, and in cases with standard presentations of amnestic cognitive impairment.[11] In complicated cases, such as younger patients or those with chronic kidney disease that influences BBM levels through reduced renal clearance[12] or obesity, which has been shown to correlate with lower levels of pTau217 at baseline, results may be less certain, and more studies are needed. It is critical to incorporate BBM results in conjunction with other clinical testing. For specific BBMs to become standard, test manufacturers should participate in cross-test biomarker harmonization so that scores can be compared across tests, similar to the use of common lipid and cholesterol blood panels.

> **"Pretest probability has to be part of the conversation. Factors like age and family history should guide practitioners in determining when a blood-based biomarker test is appropriate. A 75-year-old with a family history of Alzheimer's and cognitive complaints who tests positive presents a very different clinical picture than a 55-year-old with no family history and a similar result. The science is advancing faster than the guidelines, and we need frameworks that help practitioners navigate that complexity today, while remaining flexible enough to evolve as our understanding matures."**
>
> ***—Jim Hendrix, PhD, Eli Lilly***

ACCELERATOR: REFERENCING LESSONS FROM OTHER SUCCESSFUL DISEASE MODELS

Stakeholders repeatedly drew parallels to early detection methods in oncology, such as mammograms, colonoscopies, prostate-specific antigen (PSA) tests, and new multi-cancer detection panels. The field can reference lessons from other successful disease models, such as preventive strategies for cardiovascular disease (CVD). CVD mortality has declined substantially over the past two decades due to widespread mid-life cholesterol screening, statin therapy, and public health messaging.[13]

This highly successful preventive approach was built on biomarker-driven risk stratification and early triage, rather than waiting for advanced symptoms to appear. Similar disease trajectories, such as using hemoglobin A1c for diabetes management in the "pre-diabetes" stage and a Dual-Energy X-ray Absorptiometry (DEXA) scan for osteoporosis risk, follow the same strategy to achieve wide-scale adoption in primary care, although not without their own implementation barriers.

> **"Diabetes used to be described as an end-organ disease. When it was affecting the kidneys, it was diabetes. And as time goes on, we've moved that back farther and farther so we can catch it early, so we prevent that end-organ damage."**
>
> ***—Cara Leahy, DO, Memorial Healthcare***

Primary care providers (PCPs) do not need to manage advanced therapeutic delivery independently, but they should feel equipped to order and interpret initial triaging tests to streamline patients into efficient specialized care pathways. Guidelines and recommendations help define clinical practice, but there needs to be agreement on where tests should be performed and who actually owns the workup. The next category reviews whether BBMs are best for triaging in primary care, diagnosing in specialty care, or both.

Diagnostic Positioning

Category 2, Diagnostic Positioning (see Figure 2), received split respondents between Level 2, fit for ruling out AD, and Level 4, conditionally fit as a standalone diagnostic when performance is greater than 90 percent sensitivity and specificity in specialty care. When asked "How would you characterize the clinical community's current readiness to incorporate blood-based biomarkers into the diagnostic pathway?", respondents would consider BBMs with greater than 90 percent sensitivity and specificity as a standalone diagnostic in specialty care settings for both ruling in and ruling out AD. CSF and/or PET should be reserved for ambiguous or complex cases. Equally, as many respondents felt BBMs were reliable as a rule-out tool in primary care for symptomatic patients—confidently excluding AD and reducing unnecessary specialty referrals and confirmatory testing.

To further advance diagnostic positioning, respondents mentioned the field would need standardized cut-offs, drug labeling to recognize BBMs as qualifying methods for anti-amyloid therapy with caveats based on specific considerations mentioned above, and a broader definition of actionability, uncoupled to anti-amyloid therapy.

Figure 2. Category 2: Diagnostic Positioning

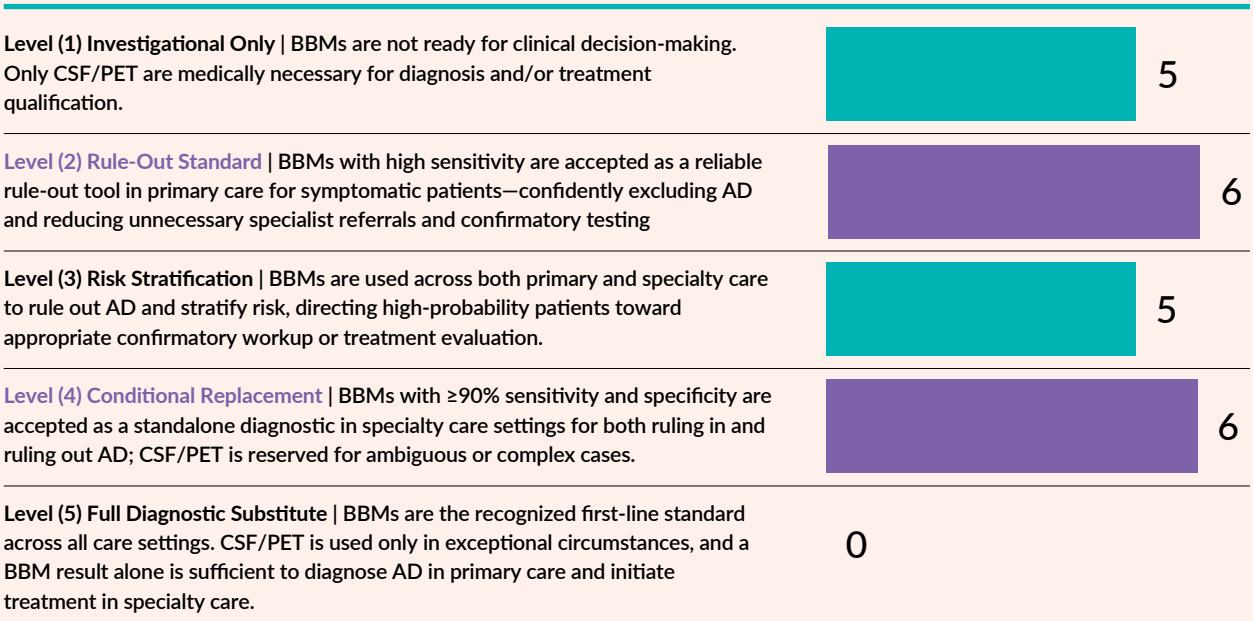
Question

How would you characterize the clinical community's current readiness to incorporate blood-based biomarkers into the diagnostic pathway—from ruling out Alzheimer's disease in primary care to serving as a standalone diagnostic tool in secondary care?

Top Answer

Level 4 Conditional Replacement | BBMs with ≥ 90% sensitivity and specificity are accepted as a standalone diagnostic in specialty care settings for both ruling in and ruling out AD; CSF/PET is reserved for ambiguous or complex cases.

Level 2 Rule-Out Standard | BBMs with high sensitivity are accepted as a reliable rule-out tool in primary care for symptomatic patients—confidently excluding AD and reducing unnecessary specialist referrals and confirmatory testing.



Note: BBM Readiness Survey Results, n=22
Source: Milken Institute (2026)

BARRIER: THE NEED FOR PRIMARY CARE AND SPECIALTY INCENTIVES AND CAPACITY

The field expects BBMs to be comparable to PET and CSF in specialty care, but not yet in primary care, where the bulk of Alzheimer's and dementia care occurs. PCPs are the overseeing clinicians for 87 percent of people living with dementia, yet 39 percent of PCPs report "never" or "sometimes" feeling comfortable making a diagnosis of Alzheimer's or other dementias, in part due to time constraints. Many PCPs lack specialized training in dementia assessment and feel unprepared to interpret the results of newly approved BBM tests, especially for older adults often presenting with multiple chronic conditions, multiple medications, and cognitive impairment.[14]

Meanwhile, 55 percent of PCPs report a shortage of dementia specialists in their area, even as 32 percent report making a

> **"There are 15,000 neurologists in the United States. That's one neurologist for every 23,600 people. Of the 15,000 neurologists, only about 600 of them are cognitive neurologists. So, we can't do this alone."**
>
> ***—James Galvin, MD, University of Miami***

dementia specialist referral at least once a month.[15] Cognitive neurologist capacity is a systemic constraint and poses a barrier to BBM adoption if they are recommended only for use in specialty care settings. There are simply not enough cognitive neurologists to handle the increased capacity for detection, diagnosis, and treatment, which would exacerbate wait times to see a neurologist.

> **"It took me a few months—four months—to get into a neurologist. I was fortunate that my PCP took me seriously enough to send me to a neurologist, but it would be so much easier if your PCP could start the process, start the ball rolling."**
>
> ***—A person living with mild cognitive impairment due to Alzheimer's, National Council of Dementia Minds***

Among patients whose PCP recommended BBM testing, 85 percent were willing to undergo it.[16] Therefore, education and training in primary care will have real benefits, reducing reliance on already-constrained specialty capacity. However, empowering PCPs does not just mean access to and education on using BBMs; it means providing support and reimbursement for cognitive assessments, facilitating the scheduling of cognitive health-focused appointments, and building referrals to neurology and geriatrics. Several stakeholders cited the need for a direct billing code for a brief cognitive assessment, which would cover the cognitive assessments PCPs must complete before ordering BBMs. Without these systematic support infrastructures, BBMs will not reach their full potential either in PCP or specialist offices.

ACCELERATOR: EMBEDDING BBMS IN SUCCESSFUL COGNITIVE CARE MODELS

To demonstrate how BBMs can be embedded into care today, four care programs are highlighted below in Table 2. These programs share a common architecture. BBMs sit in primary care with support through tele-health "e-consults" from specialists, dedicated advanced practice providers (APPs), or specially trained brain health navigators. Shared decision frameworks anchor the patient's conversations at every step, and EHR integration drives consistent ordering. These models preserve scarce cognitive neurologists for the most complex cases and treatment-eligible patients, ultimately reducing neurology wait times, improving rates of under- or misdiagnosis, and getting qualified patients on treatment faster.

Table 2. Example Cognitive Care Models

Wake Forest Mindcare 365	Indiana University Health Brain Health Navigator
Where it sits: EHR-embedded care pathway operating alongside PCP and neurology across 40–50 primary care practices **Who leads it:** APPs **What they do:** Telephonic cognitive testing; cognitively impaired individuals receive a magnetic resonance imaging (MRI) and BBM test and APPs review results in a group case review **Early outcomes:** Approximately 35 percent of those referred are cognitively normal with annual follow-up. Of those cognitively impaired, about 10 percent are eligible for anti-amyloid therapy, and the other 90 percent receive care plans, brain-health coaching, and clinical trial referrals. The program received initial support from the Alzheimer's Association, with funding from the Davos Alzheimer's Collaborative (DAC), to expand blood biomarker testing.	**Where it sits**: Embedded within primary care with order proposal by the brain health navigator (BHN) to the PCP **Who leads it:** BHN (registered nurse) **What they do**: Order proposal to PCP for imaging, labs, BBM using shared decision-making framework (AGREED), and coordinated handoff between PCP and specialists **Early outcomes:** Patients referred to a BHN received a mild cognitive impairment (MCI) diagnosis at nearly four times the rate of those who were not.[17] The program is working with DAC to expand the model to other organizations.

University of Kansas Brain Health Care Accelerator	Emory Healthcare Primary Care-Cognitive Initiative
Where it sits: Primary care with structured cognitive assessment visits and embedded EHR decision-support **Who leads it:** Trained primary care providers with multidisciplinary specialists co-managing e-consults **What they do:** PCPs trained upfront. If cognitive impairment is detected, order MRI and BBM (pTau217), review e-consult with specialist, and move to confirmatory PET prior to initiating anti-amyloid therapy **Early outcomes:** The accelerator increased diagnostic capacity by 60 percent over 12 months through use of BBMs and workflow design;[18] the model recently received $5 million from the state of Kansas to expand the program, with initial support from DAC.[19]	**Where it sits:** Primary care with embedded digital cognitive assessment and EHR decision support **Who leads it:** Trained PCPs supported by APPs and cognitive neurologists via e-consults **What they do:** Administer digital cognitive assessments, order imaging and BBM, and use e-consults to support diagnosis and care pathway triage **Early outcomes:** The model is supported by DAC and is expanding into prevention, with e-consults completed and reduced specialty wait times.

Source: Milken Institute (2026)

These care models demonstrate that embedding BBMs in primary care is possible today with tailored education and advanced practitioner support, but scaling them into the standard of care requires payers to recognize the value they generate. That recognition requires the collective generation of evidence in forms that payers will accept.

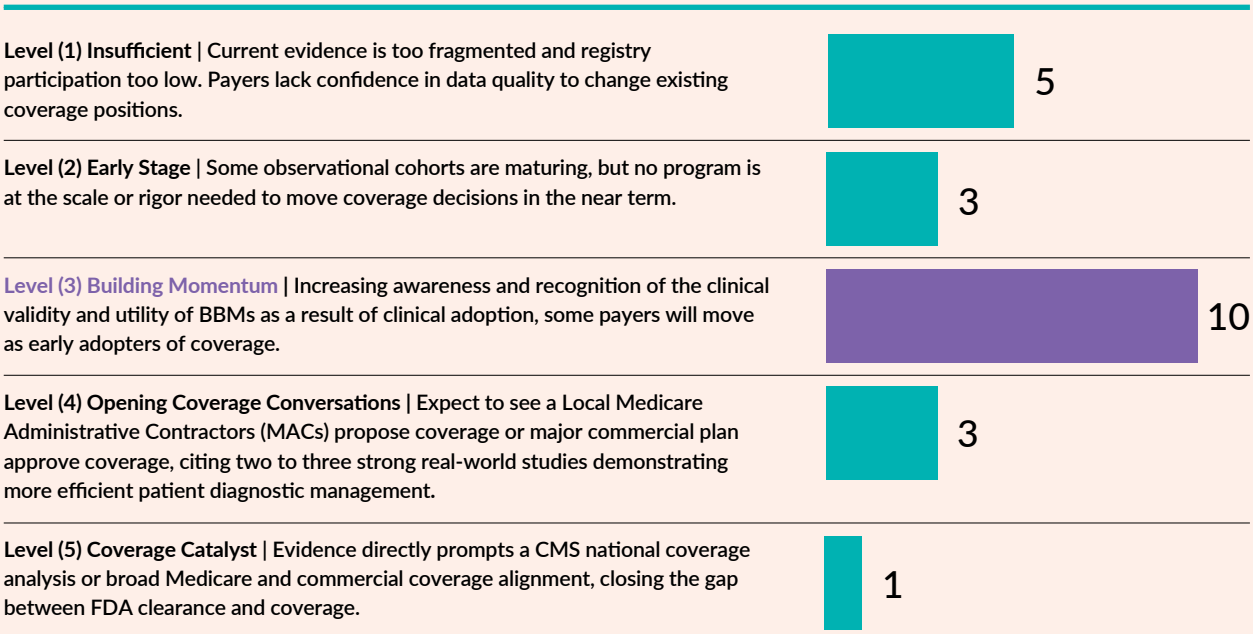
Evidence Generation for Coverage

For Category 3 (see Figure 3), Evidence Generation for Coverage, respondents were asked "How would you rate the current level of available evidence to sufficiently shift payer coverage decisions in the next two years?" There was significant consensus around Level 3, Building Momentum, or increasing awareness and recognition of the clinical validity of BBMs as a result of clinical adoption; some payers will move to adopt coverage as early adopters. Respondents provided examples of what would convert momentum into coverage: real-world performance data in diverse populations, evidence of management change, avoided downstream costs, and visible payer-by-payer adoption that builds market confidence.

Figure 3. Category 3: Evidence for Coverage

Question How would you rate the current level of available evidence to sufficiently shift payer coverage decisions within the next two years?

Top Answer Level 3 Building Momentum | Increasing awareness and recognition of the clinical validity and utility of BBMs as a result of clinical adoption, some payers will move as early adopters of coverage.



Note: BBM Readiness Survey Results, n=22
Source: Milken Institute (2026)

BARRIER: THE DIAGNOSTIC VALUE IS TIED TOO NARROWLY TO TREATMENT

There is a major adoption risk if the utility of BBMs is tied too narrowly to treatment, given the apparent lack of early and accurate diagnosis in Alzheimer's disease and related disorders (ADRD). Only about half of Medicare beneficiaries who have an ADRD diagnosis in their Medicare billing records report being told of the diagnosis.[20] Using clinical judgment alone, primary care physicians correctly diagnose MCI due to AD only 34 percent of the time and mild dementia due to AD 58 percent of the time.[21] BBMs offer a clear path to closing that gap, regardless of whether a patient is treatment-eligible.

A review of five major health plans covering more than 68 million members shows that PET and CSF biomarkers are widely covered, but only when tied to anti-amyloid therapy eligibility, not for diagnostic value alone (see Appendix). Across the same five plans, BBMs are either labeled as investigational or not mentioned, leaving clinicians and patients without clear coverage signals despite FDA clearance.

> **"My first job as a physician is to diagnose even if treatment is not an option."**
>
> ***—Cara Leahy, DO, Memorial Healthcare***

> **"We're so focused on detection and diagnosis that we sometimes overlook the value of a clear negative result. For patients, clinicians, and the health system, knowing that Alzheimer's pathology is less likely can be just as important as identifying when it is present, especially when a large share of tests come back negative."**
>
> ***—Lindsey Mette, Lucent Diagnostics***

If the dominant payer policy frame is for BBMs to be only approved in relation to anti-amyloid therapy, a substantial population would be left out. Patients who will not qualify for anti-amyloid therapy still benefit from diagnosis, prognosis, care planning, family clarity, and clinical trial eligibility, and a negative result redirects clinicians to other causes of cognitive impairment.

ACCELERATOR: ENGAGING WITH PAYERS EARLY FOR EVIDENCE GENERATION

The Centers for Medicare & Medicaid Services (CMS) has a statutory requirement to cover "reasonable and necessary care." The agency determines coverage through national coverage determinations (NCDs) at the national level, regional local coverage determinations (LCDs) made by privately contracted Medicare administrative contractors (MACs), and individual coverage determinations on a claim-by-claim basis.[22]

> **"We want to make sure there is the right evidence before anything formal and ensure whatever [the MACs] are writing is representative of the current evidence base."**
>
> ***—Matthew DeNave, Roche Diagnostics***

Manufacturers, lab providers, and advocacy groups need to engage with all four major payer types—traditional Medicare, Medicaid, Medicare Advantage, and commercial insurance—and understand that diagnostic and prescription policies are often siloed within health plans, leading to discordance between covered diagnostics and the prescriptions they qualify for. Stakeholder interviews indicated that an LCD from an innovative MAC would likely accelerate coverage adoption, provide other LCDs with a reference for drafting policy, and prompt Medicare Advantage to follow suit. However, stakeholders cautioned that an LCD may result in coverage that is stricter than the current claim-by-claim strategy. Since BBMs are in the early stages of gathering real-world evidence, diagnostic manufacturers can work with plans early to test the assumptions made in economic models, with initial integration models projected to be highly cost-effective.

Payers seek cost-effectiveness models to evaluate the economic advantage of new coverage decisions. The average cost per confirmed early AD case using the current diagnostic pathway is estimated at $45,531. Using a BBM, with a sensitivity of 88 percent and specificity of 90 percent, as a rule-out triage test is estimated to reduce the average cost per confirmed early AD case by 47 percent.

Inserting a rule-in confirmatory test would reduce costs by 86 percent. The price per test for a cost-neutral (value-based maximum price) diagnostic pathway would be $290 for a triage test and $1,150 for a confirmatory test to be used in primary care.[23]

Payers can reference the work of consortia such as the Tufts Medical Center's *Roadmap 2030: Transforming Early Alzheimer's Disease Care* and the CEOi BBM Workgroup's *Hub for Alzheimer's Diagnostic Resources and Best Practices* to review available biomarker tests and performance data at a glance.

Generating evidence is necessary, but evidence alone does not change patient access. Medical policy committees must translate evidence into formal coverage, yet the readiness survey results signal that coverage is a risk to accelerating adoption.

Payer Medical Policy Acceptance

Payer Medical Policy Acceptance was rated the least ready category at Level 2 (see Figure 4). When asked "To what extent do you believe payer Medical Policy and Health Technology Assessment (HTA) committees will use endpoints showing a change in patient management, for example, 'time-to-diagnosis' or 'avoided additional testing'?", respondents clustered around Level 2, assuming committees might accept faster time-to-diagnosis only if companies demonstrate delays are causing patient harm by progressing past the treatment window.

Respondents at Level 2 stressed that until payers believe anti-amyloid therapies meaningfully improve patient outcomes, endpoints such as reduced time-to-diagnosis and avoidance of unnecessary testing will carry limited weight.

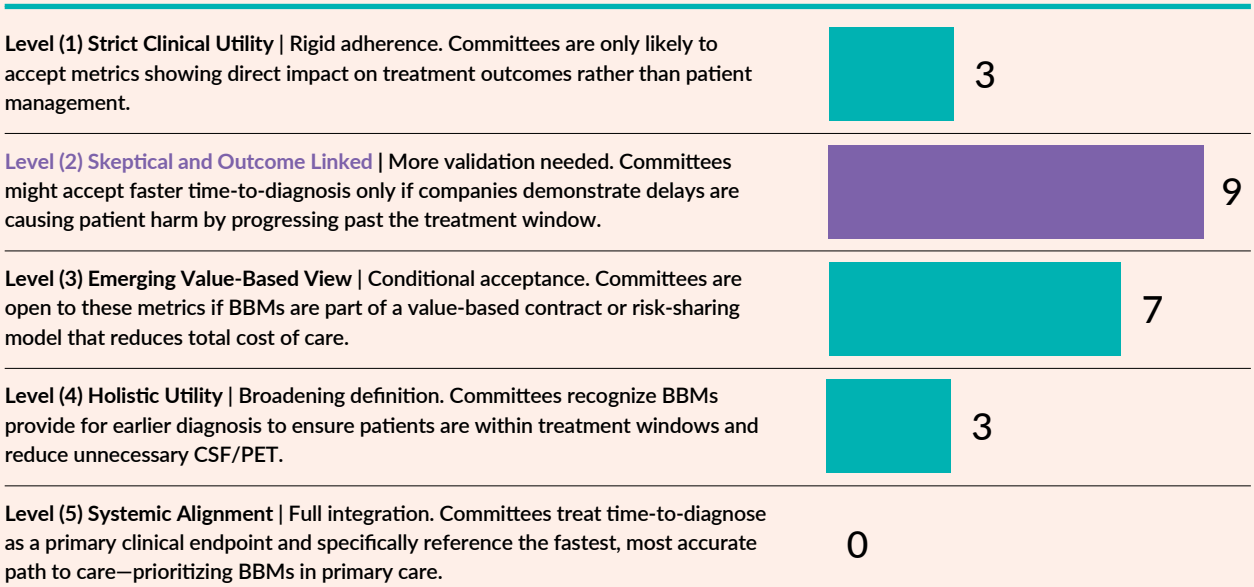
Figure 4. Category 4: Payer Medical Policy Acceptance

Question

To what extent do you believe payer Medical Policy and Health Technology Assessment (HTA) committees will use endpoints showing a change in patient management, for example, "time to diagnosis" or "avoided additional testing," as valid metrics for Medical Necessity?

Top Answer

Level 2 Skeptical and Outcome Linked | More validation needed. Committees might accept faster time-to-diagnosis only if companies demonstrate delays are causing patient harm by progressing past the treatment window.



Note: BBM Readiness Survey Results, n=22
Source: Milken Institute (2026)

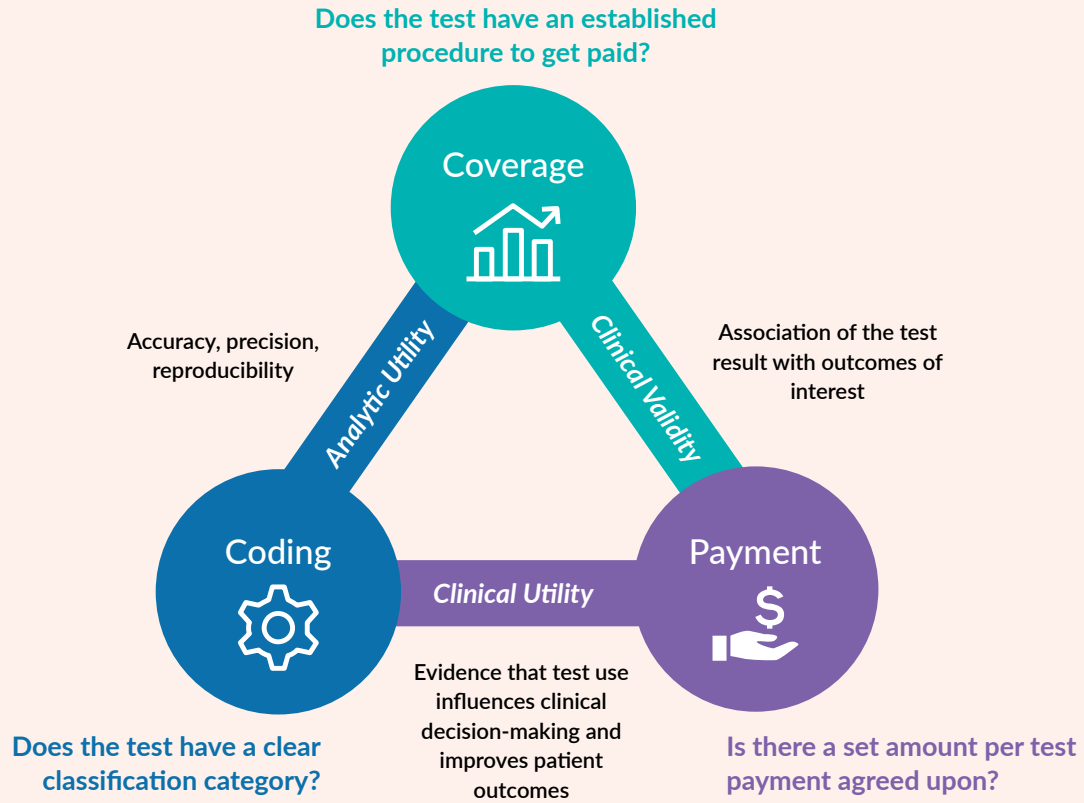
BARRIER: A LACK OF COVERAGE AND CLARITY FROM PAYERS

An NCD exists for anti-amyloid treatments for early symptomatic AD, but it does not extend to the diagnostic tools used to qualify patients for those treatments. Traditional Medicare reimburses BBMs on a claim-by-claim basis, but Medicare Advantage plans may require prior authorization or deny reimbursement. As of May 2026, commercial coverage is nearly nonexistent, representing a significant access gap, since BBMs are cleared for people aged 55 and older.

Commonly, expert clinicians acknowledge that blood tests are reimbursed; however, "reimbursement" is not synonymous with "coverage." Coverage establishes a policy to systematically pay claims, whereas reimbursement determines the amount a plan will pay. For a complete reimbursement strategy, manufacturers require clarity across coding (Current Procedural Terminology [CPT] codes), payment (the negotiated rates), and coverage, depicted in Figure 5.

The lack of consistent coverage and clarity from payers leaves clinicians and billing teams unable to answer patients' simple cost-sharing questions. 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 also recognize that there is no single "perfect diagnostic workflow" and that overly prescriptive utilization management steps risk overutilization of imaging in straightforward cases and delayed time to treatment in others.

Figure 5. A Complete Reimbursement Strategy



Source: Milken Institute (2026)

ACCELERATOR: HIGHLIGHTING EARLY PAYER MOVEMENT

The health-care landscape has experienced unprecedented breakthroughs in Alzheimer's diagnostics and treatment since 2022, when the first anti-amyloid treatments were approved. Since the FDA clearance of the first two BBMs in May 2025, there have been several movements to highlight.

CMS

Under the NCD, CMS issued Coverage with Evidence Development, meaning patients must first be enrolled in a CMS-approved study and participate in a data collection registry. Providers enter the diagnostic method used to confirm amyloid before initiating treatment into the registry. CMS has updated the registry fields to allow providers to list BBMs as a method of confirming amyloid, along with PET, CSF, or "other information." While this move does not indicate a change in payer coverage status, it does show acknowledgment of BBMs as a potential method for qualifying patients for treatment.

Commercial Plans

Under commercial coverage, Avalon Healthcare Solutions, a laboratory benefits manager contracted with the Blue Cross and Blue Shield (BCBS) plans in the states of Michigan, North Carolina, and Vermont to update its "Biochemical Markers for Alzheimer Disease and Dementia" policy in September 2025. The plans now include the FDA-cleared Fujirebio Lumipulse G pTau217/ß-Amyloid 1-42 Plasma Ratio, as the insurer determined it meets coverage criteria for individuals with suspected AD or MCI.[24]

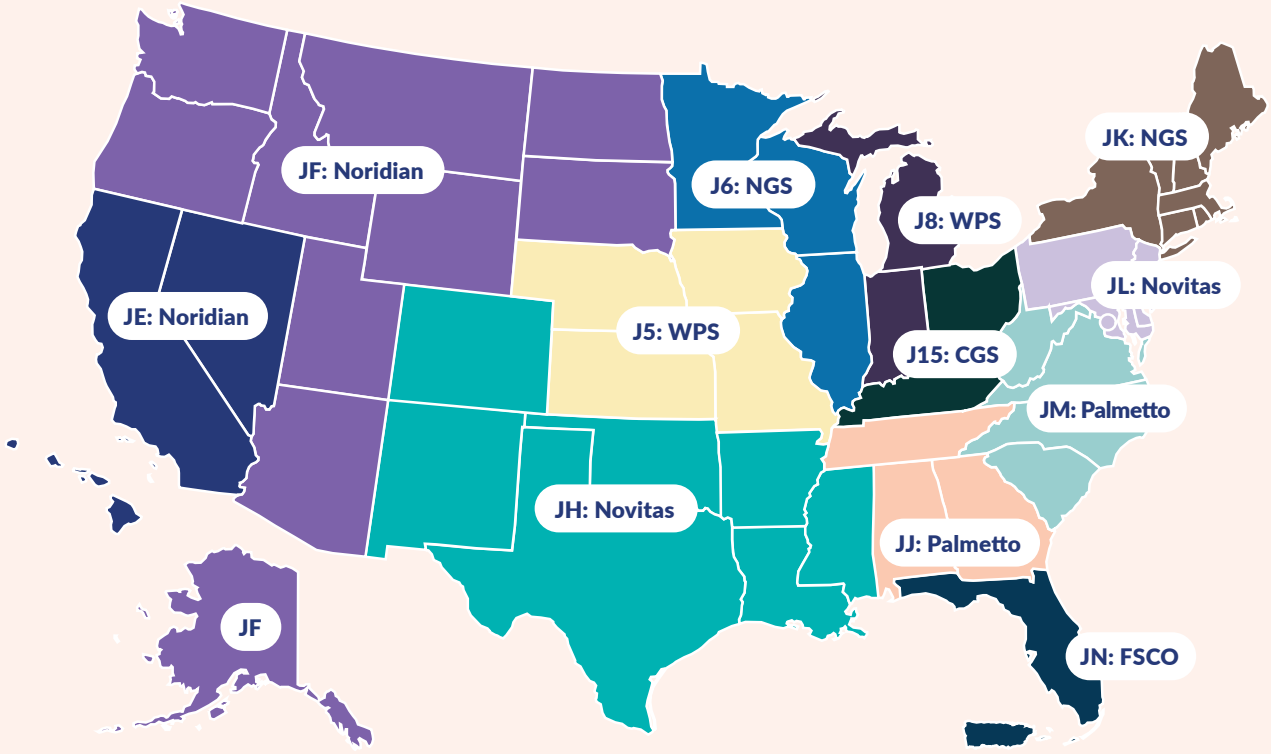
While this coverage change applies to three plans, these plans are not independently deciding on coverage, but rather following the recommendations of a supporting lab contractor electing to be an early mover. Avalon also covers BCBS of Louisiana, but this insurer has not yet approved the new policy. Further, the policy does not include the latest FDA-cleared test, the Roche Elecsys® pTau 181 test, nor does it specify coverage of Apolipoprotein E (APOE) gene testing for genetic risk.

Medicare Administrative Contractors

Without an NCD on diagnostics, Medicare coverage is delegated locally to the MACs (see Figure 6).[25] A case study shows that the NGS MAC issued an LCD Reference Article regarding genetic testing for APOE 19 months after the FDA approved Kisunla™, which included APOE testing as recommended by the drug label. In this instance, a blocking policy was already in place, and the MAC had to make a change to increase access (see Figure 7).[26] However, in the case of BBMs, there is no active blocking of coverage.

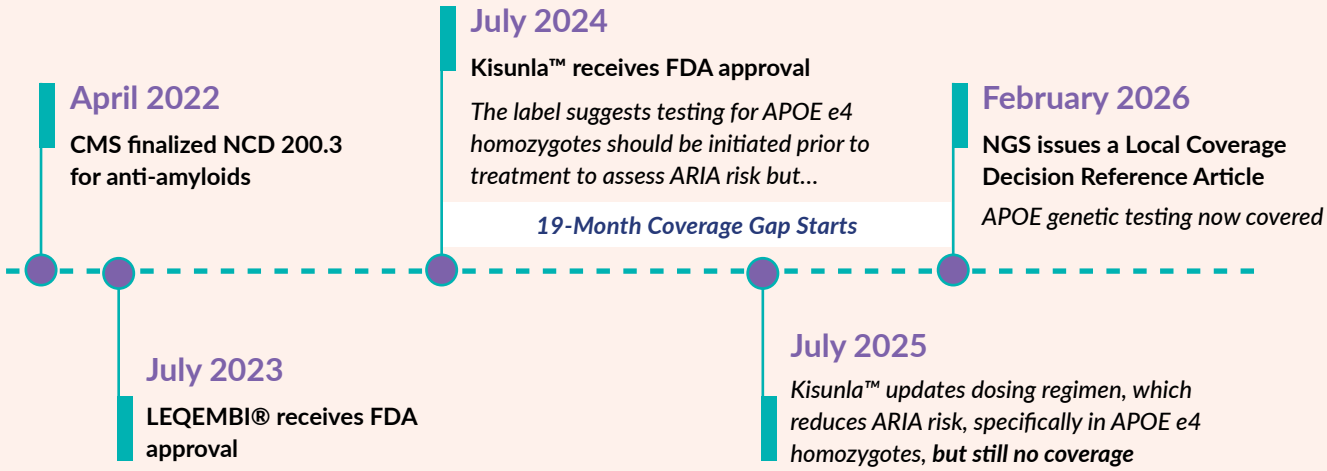
During the interviews, stakeholders suggested it may be plausible to see movement from an MAC on BBM policies by the end of 2026 or early 2027.

Figure 6. Medicare Administrative Contractors



Source: Milken Institute (2026) adapted from CMS (2023)

Figure 7. Coverage Case Study: Closing a 19-Month MAC Coverage Gap for APOE Genetic Testing



Source: Milken Institute (2026)

Coverage establishes payment, but payment alone does not guarantee access; it requires whole-system adoption. For BBMs to become standard of care, the patients who reach testing must reflect the full population at risk, not just those the current system already serves well.

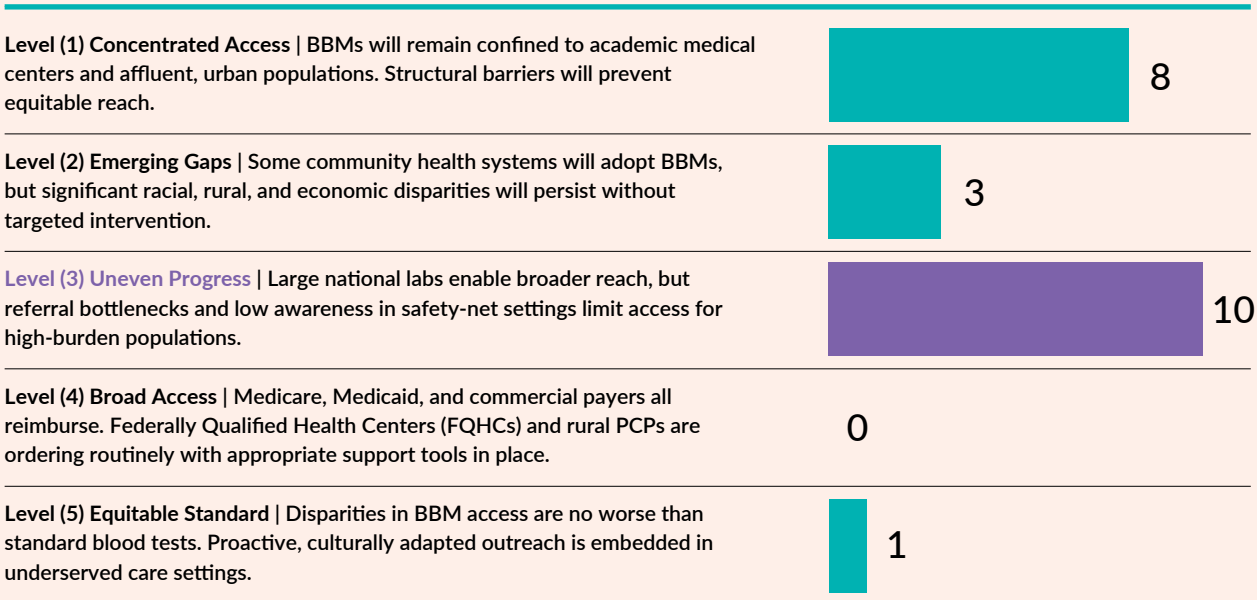
Health Equity and Access to Programs

For Category 5, Health Equity and Access (see Figure 8), respondents were asked "How confident are you that blood-based biomarkers will reach patients equitably—across race, geography, and income level—within the next three years?" Most responses were at Level 3, Uneven Progress. Here, large national labs enable broader reach, but referral bottlenecks and low awareness in safety-net settings limit access for high-burden populations. Respondents noted that use of BBMs is likely outpacing the availability of confirmatory PET scans, which would create a bottleneck for access and a gap in a complete diagnosis.

Figure 8. Category 5: Health Equity and Access

Question How confident are you that blood-based biomarkers (BBMs) will reach patients equitably—across race, geography, and income level—within the next three years?

Top Answer Level 3 Uneven Progress | Large national labs enable broader reach, but referral bottlenecks and low awareness in safety-net settings limit access for high-burden populations.



Note: BBM Readiness Survey Results, n=22
Source: Milken Institute (2026)

BARRIER: CONCERNS FOR PATIENT EQUITY, ACCESS, AND PROTECTIONS

Stakeholders recognized that BBMs offer a tremendous opportunity to improve equity and access to early, accurate diagnosis, particularly for those without access to amyloid PET or specialists. But stakeholders noted that coverage alone will not close equity and access gaps, and without sufficient resources devoted to care navigation, families will still face long diagnosis-to-treatment and care timelines.

Stakeholders acknowledged that the field is moving faster in diagnostic certainty than in treatment certainty. BBMs are advancing rapidly as diagnostic tools, while confidence in disease-modifying therapies is still developing among clinicians, payers, and health systems. Stakeholders emphasized affordability and equity for access, not only to the new blood tests but also to the services and programs that help support patients through detection, diagnosis, treatment, and care.

> **"In the clinics where I see patients, we primarily serve low-income patients, many of whom are socially isolated, many of whom are caregivers themselves, many of whom have no care partners or family and many barriers to care… So requiring anything of them often does nothing other than causes them to completely lose access to whatever service might otherwise be available."**
>
> *—Deanna Willis, MD, Indiana University*

If these biomarker tests are used in patients with very subtle symptoms or no symptoms, stakeholders raised concerns about protections for sensitive proteomic data and the need for an act similar to the Genetic Information Nondiscrimination Act (GINA), signed into law in 2008, which protects Americans from discrimination based on their personal genetic information in health insurance and employment.[27] Without appropriate protection, individuals could face unintended consequences related to employment, health insurance, life insurance, long-term care insurance, or other types of coverage.

ACCELERATOR: CONNECTING TO PROMISING PROGRAMS

Diagnosis is a start, but it is not the goal. The goal is to direct patients to effective treatments, interventions, and care programs. Several innovative care platforms are exploring how BBMs integrate into prevention and risk-stratification models, not only for diagnostic confirmation. Emerging programs are pairing lifestyle interventions, cognitive specialty care, biospecimen collection, and even testing new retinal imaging to create a longitudinal, prevention-oriented model of care. The Alzheimer's Association is planning the next phase of US POINTER, a lifestyle intervention clinical trial, which incorporates diet, exercise, cognitive training, social engagement, and vascular risk management to slow brain aging.[28]

> **"If our younger generation really understood that everything from the metabolic stuff to inflammation to all of the chronic diseases, there's so much more than that one little organ that's affected today. And … if I knew then what I know now, I would have cared a whole lot more about my health in all of those areas."**
>
> *—Person living with Alzheimer's, National Council of Dementia Minds*

> **"There's a compelling prevention case to make to payers: Brain health and general health are deeply intertwined, so interventions like exercise, sleep, and nutrition may also lower total cost of care over time, and protecting your brain is a far more powerful motivator than avoiding chronic disease. We're in the early innings, but that's the evidence we intend to generate."**
>
> ***—Cedric Gousseau, Better Brain***

The next promising phase of early Alzheimer's care is accurate *prognosis*, along with early *diagnosis*. A person with MCI can remain stable for years without progressing to dementia. As the prevention trials currently underway read out over the next 12 to 24 months, BBM use cases will continue to evolve, particularly for asymptomatic high-risk populations.

Combined, these five categories—Clinical Guidelines, Diagnostic Positioning, Evidence for Coverage, Payer Medical Policy Acceptance, and Health Equity and Access—represent a field that is starting to move forward, but unevenly. The next step is to take what is working and make it the standard, not just for the "fortunate few," but for every person at risk of AD.

Next Steps

Considerations for Stakeholders

This work has surfaced the barriers currently slowing the field and the promising accelerators poised to shorten implementation timelines across five key categories. Now, each stakeholder has an important role to play to advance to a new standard.

Health Systems and Medical Groups

- Embed BBMs in primary care with a structured specialist e-consult support via telehealth and a clear results-delivery pathway.
- Integrate EHR ordering decision support and shared decision-making frameworks (e.g., the AGREED model or similar).
- Use brain health navigators, APPs, and registered nurses to extend physician capacity for results delivery, care planning, and referral pathways from PCP to neurology and geriatrics for complex cases.
- Become familiar with the four care models mentioned in Table 2, leading the way toward operational feasibility at scale.

Payers

- Coordinate diagnostic and pharmaceutical policy teams so that coverage decisions are in concordance, not developed in isolation where they may be in conflict (e.g., covering treatments but not the diagnostics needed to qualify patients).
- Ensure Medicare Advantage and commercial diagnostic coverage is no more restrictive than the existing CMS anti-amyloid treatment NCD.
- For commercial insurers, recognize the age 55 indication and specific vulnerable under-65 populations, including young-onset AD, MCI populations, and non-AD dementias such as frontotemporal degeneration.
- Use available claims and registry data to build the evidence base for future coverage clarity.

Clinical Guideline and Policymakers

- Prioritize clinician society guidelines and best-practice recommendations written for a non-specialist primary care audience.
- Develop dedicated cognitive assessment CPT codes for primary care.
- Recognize MCI in Medicare Advantage risk-adjustment to align incentives with early detection.
- Pursue legislation for sensitive proteomic data, modeled on GINA, to prevent discrimination from taking place.

Patient Voice and Advocacy Groups

- Consolidate a unified patient-facing framework on what BBM results mean and next steps for treatment and care.
- Develop scripting and printed resources for patients and care partners to take to clinical visits.
- Provide success stories from first-person patient testimonials about the advantages of BBM-driven detection and early action, and disseminate at the point-of-care or within the community.
- Advocate for screening in communities and awareness to raise cognitive concerns early with providers.

Diagnostic and Treatment Manufacturers

- Bring payers to the table early with an evidence-generating framework to fit their needs, such as data on time-to-diagnose, evidence of management change, avoided unnecessary imaging, and downstream cost reduction.
- Consider precompetitive harmonization across BBM test platforms so that cross-test interpretation is consistent.
- Consider updating drug labels to add clarity on acceptable diagnostic methods.
- Recognize commercial coverage may lag furthest behind and require specific legislation to close the gap for individuals under age 65 with ADRD.

Innovative Care Platforms

- Maintain appropriate use criteria and shared decision-making before using emerging BBMs on asymptomatic individuals.
- Continue to bridge clinical research, primary care, and lifestyle medicine, modeling the longitudinal, prevention-oriented care that BBMs make possible.
- Use rigorous analytics to track the effectiveness of interventions and begin working with payers early to generate evidence for coverage.
- Collaborate with providers and established health systems as operational partners, allowing the system to scale and allocate clinical resources and health-care dollars optimally.

A Call for Collective Action

The barriers identified in this report are real but surmountable. There are promising accelerators working, but only for the "fortunate few." What the field requires now is not more diagnosis of the problem but coordinated action toward effective solutions that drive the adoption of blood-based biomarkers 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. We invite you to join us in advancing the new standard of care at the Alliance to Improve Dementia Care.

Appendix

Table 3. Select Health Plan Coverage Policies

Plan	PET	CSF	BBM
Humana Medicare Advantage (5.8M covered lives)[29]	covered to confirm AD in MCI/mild dementia	covered when considering anti-amyloid therapy	not mentioned
BCBS Federal Employee Program (5.5M covered lives)[30]	covered for MCI/mild dementia due to AD for anti-amyloid therapy	covered when considering anti-amyloid therapy	investigational
Aetna Commercial (22M covered lives)[31]	covered for MCI due to AD considered for anti-amyloid treatment	covered for diagnosis or management of AD	experimental, investigational, or unproven
Elevance Commercial (27.1M covered lives)[32]	updated brain imaging policy for AD anti-amyloid therapy	covered when considering anti-amyloid therapy	covered for FDA-cleared tests or measures of p-tau217 to triage the need for CSF testing or PET imaging
UHC Community Plan Medicaid (8.1M covered lives)[33]	required before prescribing anti-amyloid treatment	not mentioned	not mentioned
BCBS Michigan Commercial (4.5M covered)[34]	one-time evaluation to differentiate between frontotemporal dementia and AD	covered for diagnosis and when considering anti-amyloid therapy	ratio of pTau217 to Aβ42 in plasma when using an FDA-approved test for individuals with suspected AD or MCI

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