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

Alliance to Improve Dementia Care

Presented to AGREEDementia | 9/1/26

September 2026

Alliance to Improve Dementia Care

A multisector coalition advancing risk reduction, improving early detection and access to treatment, and scaling comprehensive dementia care for people at risk or living with dementia and their care partners.



Milken Institute

Milken Institute Health

Future of Aging

Founded in 2020

Areas of Focus

1. Prevention and Risk-Reduction
2. Workforce and Systems Capacity Building
3. Comprehensive Dementia Care Models

Alliance to Improve Dementia Care

Steering Committee

AARP · alzheimer's association · Alzheimer's Drug Discovery Foundation · Bank of America · Biogen · BrightFocus Foundation · caringkind · Edward Jones · Eisai · Gates Ventures · Genentech · Institute for Healthcare Improvement · The John A. Hartford Foundation · Lilly · Lundbeck · novo nordisk · Otsuka · Roche · The SCAN Foundation · Washington University in St. Louis School of Medicine · west foundation

+170 leading organizations across eight key stakeholder groups

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2026 All-Member Meetings

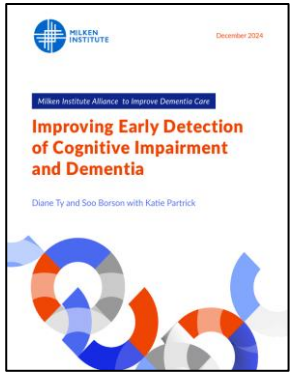
January	Senior Housing and Cognitive Impairment	NIC, Asbury Kinnections Brain Health	July	Music Therapy	international arts+mind LAB, SingFit
February	Lewy Body Dementia	LBDA, UHealth	August	Blood-Based Biomarkers	
March	Speech Detection & US POINTER	Alzheimer's Drug Discovery Foundation, Diagnostics Accelerator, U.S. POINTER	September	Subcutaneous Anti-Amyloid	Eisai, Pentara
April	Person-Centered Trust Building	DEER, HFC	October	Symptoms Beyond Memory	
May	Flourishing with Dementia	The Hastings Center for Bioethics	November	AI in ADRD	
June	Hearing & Brain Health	GN Listen to This, Johns Hopkins Medicine	December	2026 Year Review	

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[Previous Meeting Recordings]

Recent Alliance Activities

Early Detection and Diagnosis



Improving Early Detection of Cognitive Impairment and Dementia

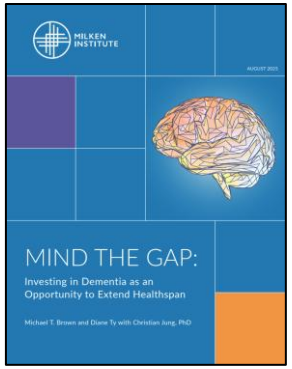
December 2024



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

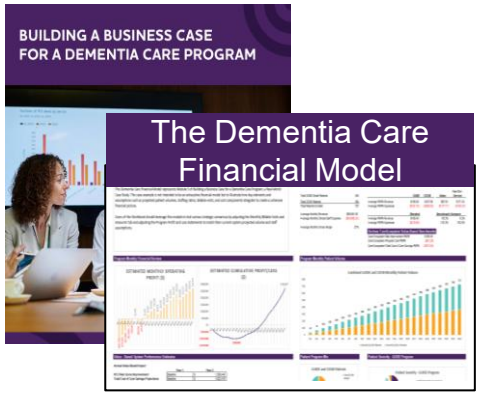
July 2026

Generating Investment and Building the Business Case



Investing in Dementia as an Opportunity to Extend Healthspan

August 2025

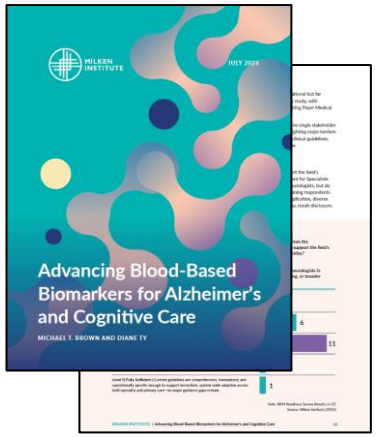


Building the Business Case for Dementia Care

February 2026

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Advancing Blood-Based Biomarkers (BBMs)

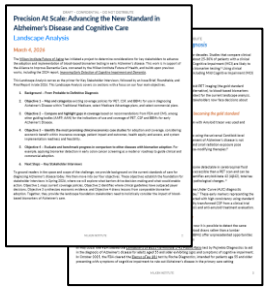


Our Core Question:

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

The Process:

Landscape Analysis



Background research and problem development

February – March 2026

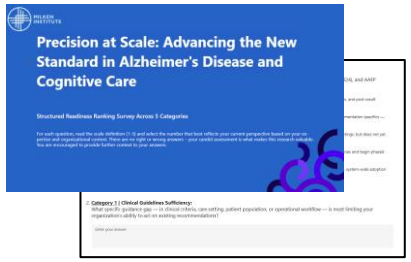
Stakeholder Interviews & Focus Group



32 Stakeholder Interviews and a Patient Focus Group

April – May 2026

Readiness Survey



22 Survey Participants

April – May 2026

Initial Report Published



Shared at AAIC'26

July 21, 2026

Roundtable to Design Recommendations



Milken DC Office

October 1, 2026

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Participating Stakeholders Segments

Health Systems and Medical Groups

Washington University in St. Louis
Norton Healthcare
UCSF Geriatrics Department of Medicine
UT Health San Antonio
Penn Memory Center — University of Pennsylvania Health System
UCLA Health
UHealth — University of Miami Health System
Indiana University School of Medicine
Permanente Medicine — The Permanente Medical Group
Memorial Health System
AdvocateHealth
Cognition in Primary Care
Emory Healthcare
USC Dornsife

Payers

CMS — Centers for Medicare & Medicaid Services
Rubrum Advising
Bruce Quinn Associates LLC — Health Innovation Made Real.

Clinical Guideline and Policy Makers

American Academy of Family Physicians — Strong Medicine for America
Global CEO Initiative on Alzheimer's Disease
alzheimer's association

Patient Voice and Advocacy Groups

National Council of Dementia Minds — Insights of Persons Living Well with Neurocognitive Disorders
AfPA Alliance for Patient Access
Davos Alzheimer's Collaborative
Alzheimer's Society
BrightFocus Foundation — Cure in Mind. Cure in Sight.

Diagnostic and Treatment Manufacturers

Lilly
Roche
Genentech — A Member of the Roche Group
Eisai
Lucent Diagnostics — A Quanterix Brand
ALZpath
Biogen

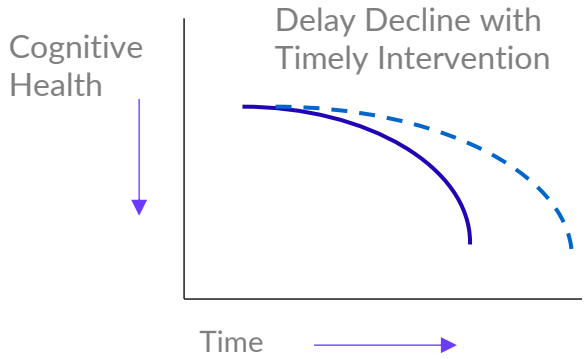
Innovative Care Platforms

BetterBrain
Isaac Health

How are Blood-Based Biomarkers Transforming Cognitive Care?

Enabling Early Detection For Timely Intervention

Time is Brain [1]



- 95% of diagnosed cases of Alzheimer's and related disorders are age 65+[3]
- The disease process starts decades before and these tests are indicated for **40+**

An estimated **3,000 people a day** progress from early stages to moderate and severe stages of AD, out of the current drug treatment window.

Growing Diagnostics, Treatments, and Interventions

Patients Have Options [2]

April 2022
CMS finalizes NCD 200.3 on Anti-Amyloids

July 2023
LEQEMBI® receives FDA approval
CMMI GUIDE Model Announced

July 2024
Kisunla™ receives FDA approval

May 2025
Lumipulse pTau217/ β-Amyloid 42 FDA Clerance

October 2025
Elecsys® Phospho-Tau (181p) Plasma FDA Cleared

July 2026
LEQEMBI IQLIK® Subcutaneous injection approved for initiation

August 2026
PrecivityAD2® FDA Cleared
Elecsys® Phospho-Tau (217) Plasma FDA Cleared

Source: [1] Milliman (2023), [2] Milken Report (2026), [3] CMS (2022)

Testing Health System Readiness to Adopt BBMs

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**

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Clinical Guidelines

Clinical Guidelines

Barriers	Need for up-to-date guidelines and clear interpretation of results
Accelerators	Referencing lessons from other disease models
Readiness Ranking	**Level 3 Sufficient for Specialists**

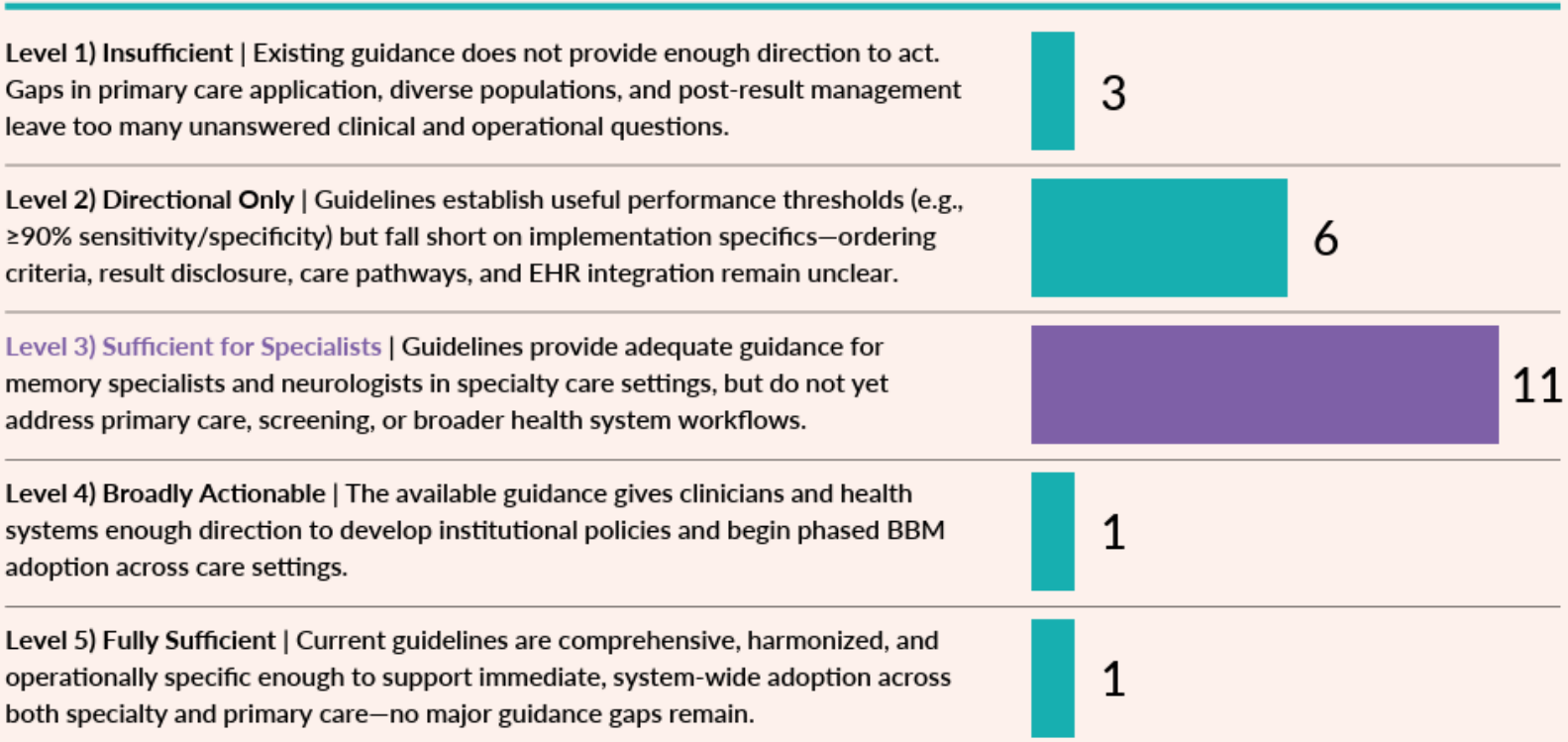
Question

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.



Clinical Guidelines

Barrier

Need for Up-To-Date Guidelines and Clear Interpretation of Results

"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

"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

- It must be clear that a positive result does not automatically equal a diagnosis
- Upfront Understanding of Pre-Test Probability for Positive/Negative Results

Diagnostic Positioning

Diagnostic Positioning

Barriers	Need for primary and specialty care incentives and capacity
Accelerators	Embedding BBMs in successful cognitive care models
Readiness Ranking	**Levels 2 and 4 Rule-Out Standard and Conditional Replacement**

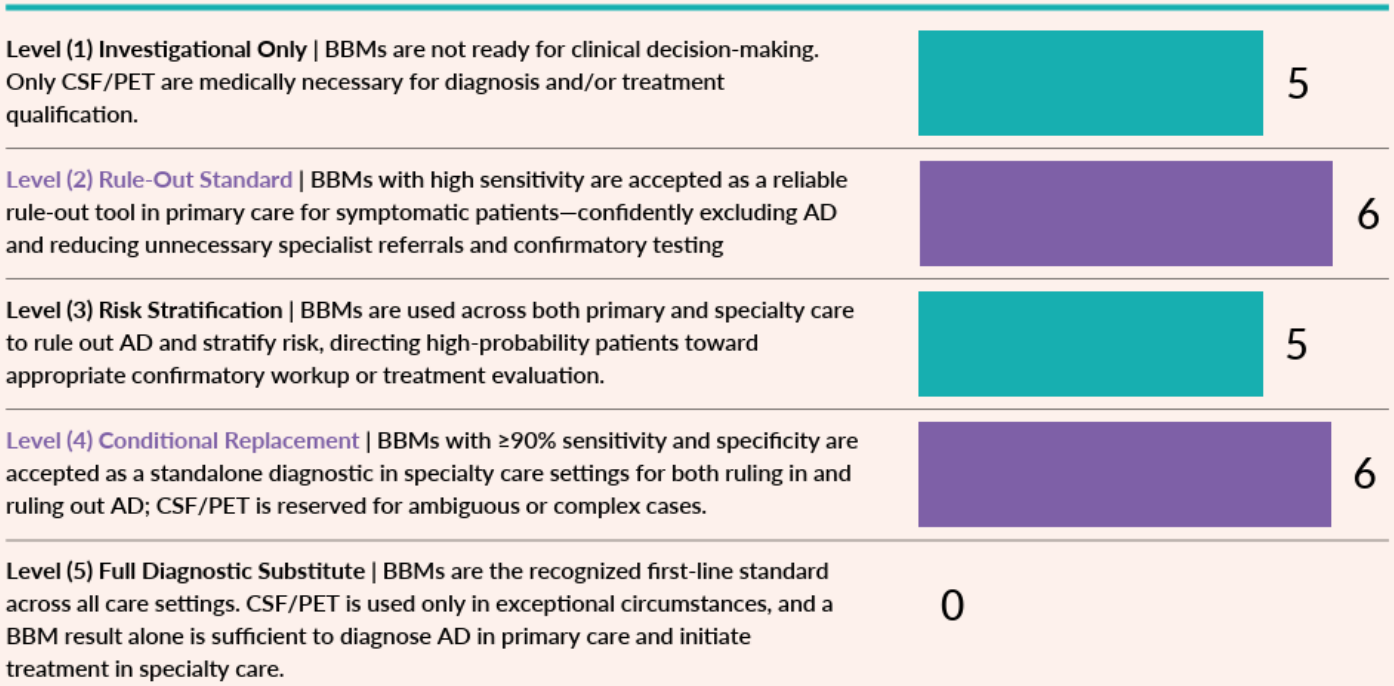
Question

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.



Successful Cognitive Care Models Embedding BBMs

MindCare 365

ADVOCATE HEALTH
Wake Forest University School of Medicine

Lead: Advanced Practice Providers (APPs)
What they do: Telephonic cognitive testing + MRI + BBM
Outcomes: 35% are cognitively normal / 65% impaired,

- 10% are eligible for anti-amyloids,
- 90% receive care plans, brain health coaching, and clinical trial referrals

Brain Health Navigator

Indiana University Health

Lead: Brain Health Navigator (Registered Nurse)
What they do: Propose order to PCP for Labs, Imaging, and BBM – coordinating handoff between PCP and Specialists
Outcomes: Patients referred to a BHN received a Mild Cognitive Impairment (MCI) diagnosis at nearly four times the rate as those that were not.

Brain Health Care Accelerator

KU MEDICAL CENTER
The University of Kansas

Lead: Primary Care with EHR decision support and E-Consults to Neurology
What they do: If cognitive impairment detected, order MRI + BBM, review e-consult with specialist, and move to confirmatory PET prior to anti-amyloid therapy
Outcomes: Increased diagnostic capacity by 60% over 12 months by embedding BBMs

Primary Care-Cognitive Initiative

EMORY HEALTHCARE

Lead: Primary Care with a digital cognitive assessment and EHR decision support, APP support and e-consults
What they do: Administer DCA, order imaging and BBM, use e-consult to support diagnosis and care pathway triage
Outcomes: Expanding model into a prevention study and tracking e-consults completed and reduced specialty wait times.

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Davos Alzheimer's Collaborative (DAC) has supplied initial seed funding through philanthropy. These models are still searching for a sustainable business case.

Evidence Generation for Coverage

Evidence Generation for Coverage

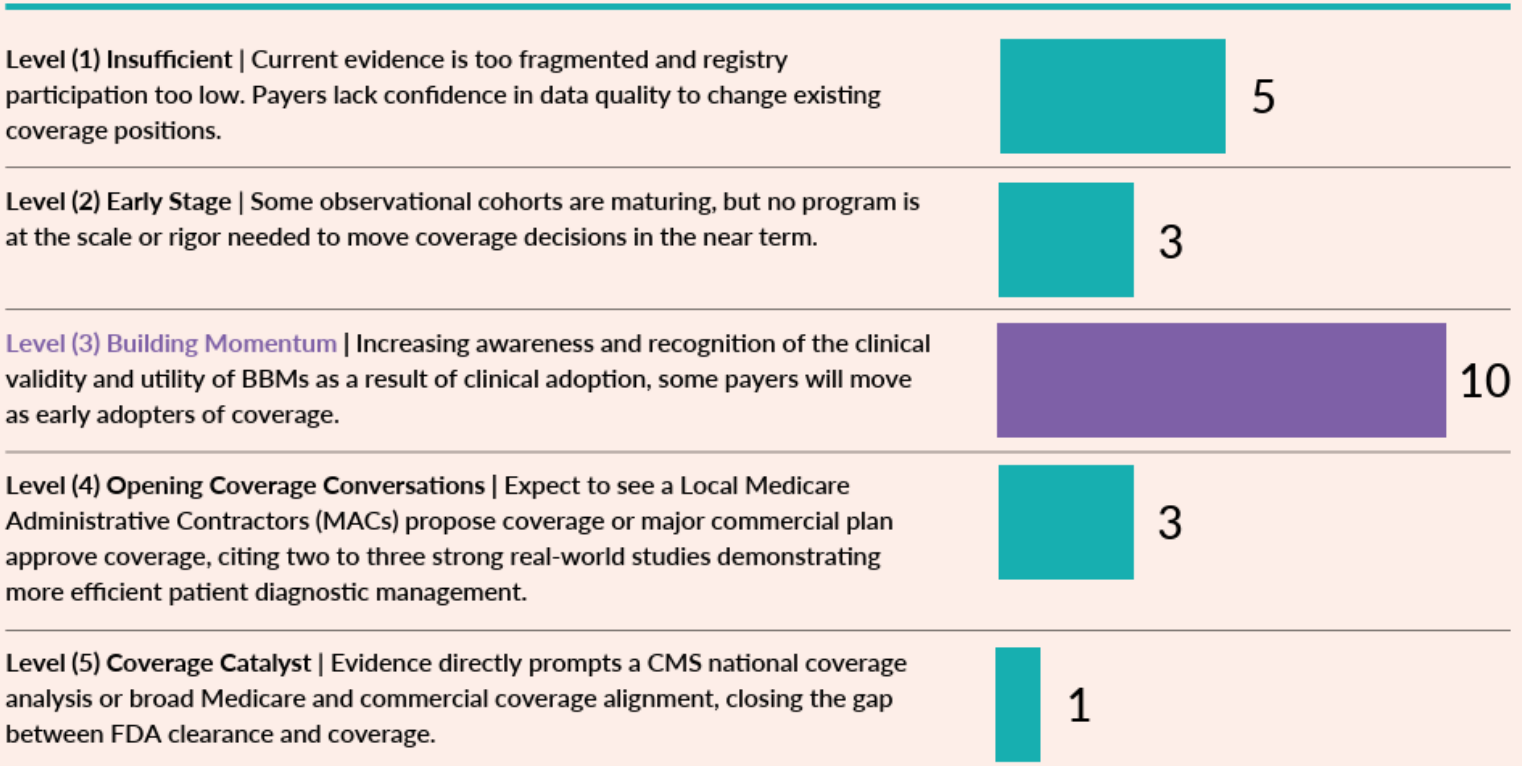
Barriers	Diagnostic value tied too narrowly to treatment
Accelerators	Engaging with payers early for evidence generation
Readiness Ranking	**Level 3 Building Momentum**

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.



Source: n=22, Milken Institute (2026)

Evidence Generation for Coverage

Barrier

Diagnostic value is too narrowly tied to treatment

- How can we value the quick and accurate diagnosis of Alzheimer's or other causes of dementia, even if a treatment is not available?
- Today PET scans and CSF Biomarkers are covered by major plans almost exclusively for anti-amyloid therapy evaluation.
- Do not underestimate the value of a negative result.

Accelerator

Manufacturers are eager to engage with Payers early but also recognize risks to proactive utilization management.

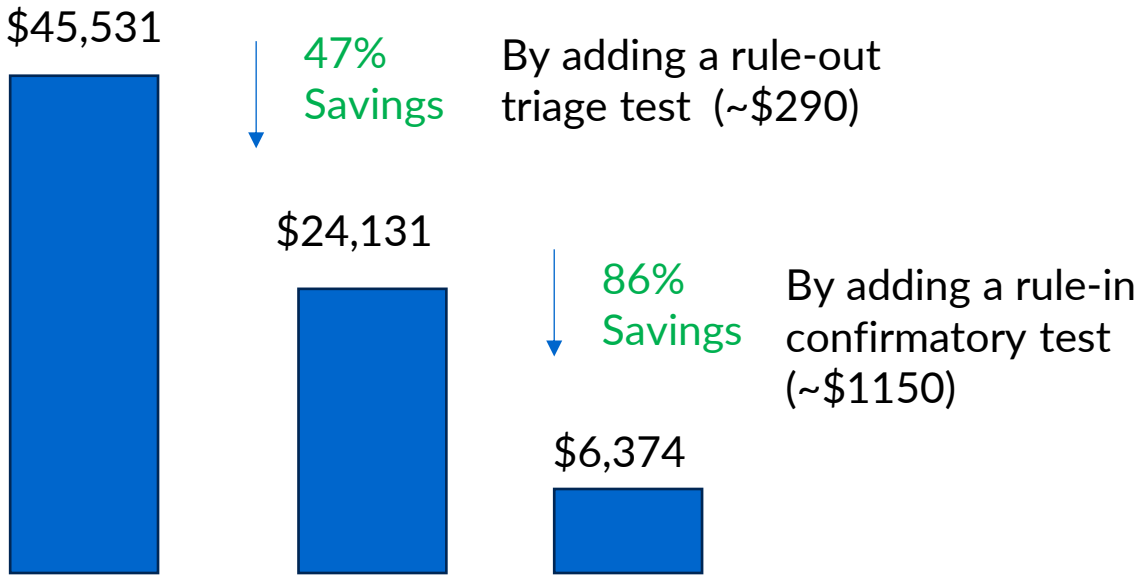
- Stakeholders indicate that a Local Coverage Decision (LCD) would likely accelerate coverage, assist other LCDs with drafting policies, and prompt Medicare Advantage to follow.
- Caution that an LCD may result in coverage that is stricter than the current claim-by-claim strategy.

> "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*

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Evidence Generation for Coverage

The Economic Case

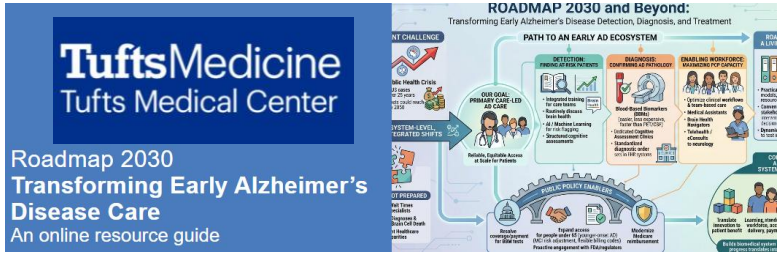


Cost per confirmed early AD Case

*Assumed 88% Sensitivity and 89% Specificity used in Primary Care Setting

Resources to Stay Up To Date

System Planning



Tests on Market



Shared Decision Making



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Source: Mattke et. al. USC Brain Health Observatory (2025)

Payer Medical Policy Acceptance

Payer Medical Policy Acceptance

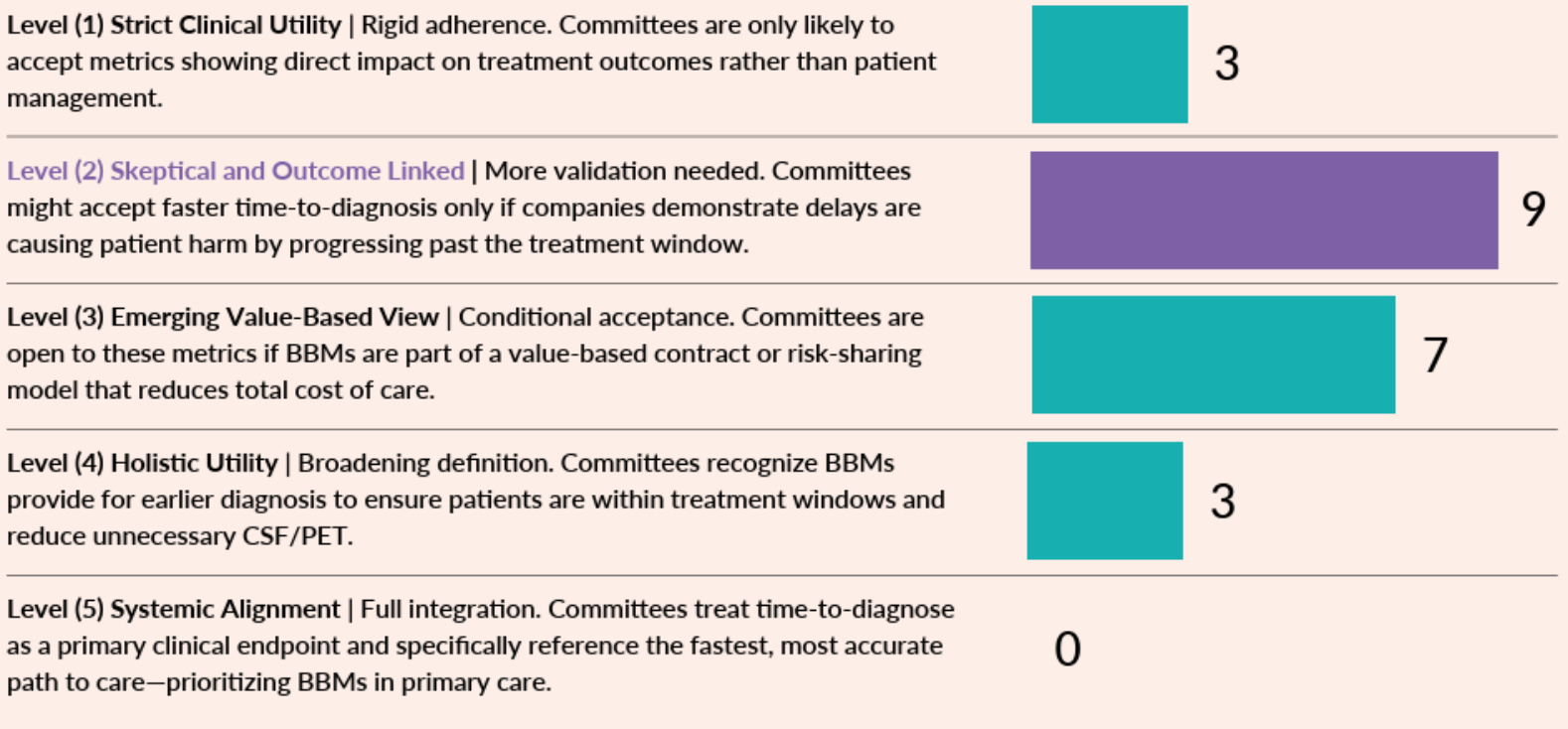
Barriers	Lack of coverage and clarity from payers
Accelerators	Highlighting early payer movement
Readiness Ranking	**Level 2 Skeptical and Outcome Linked**

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.



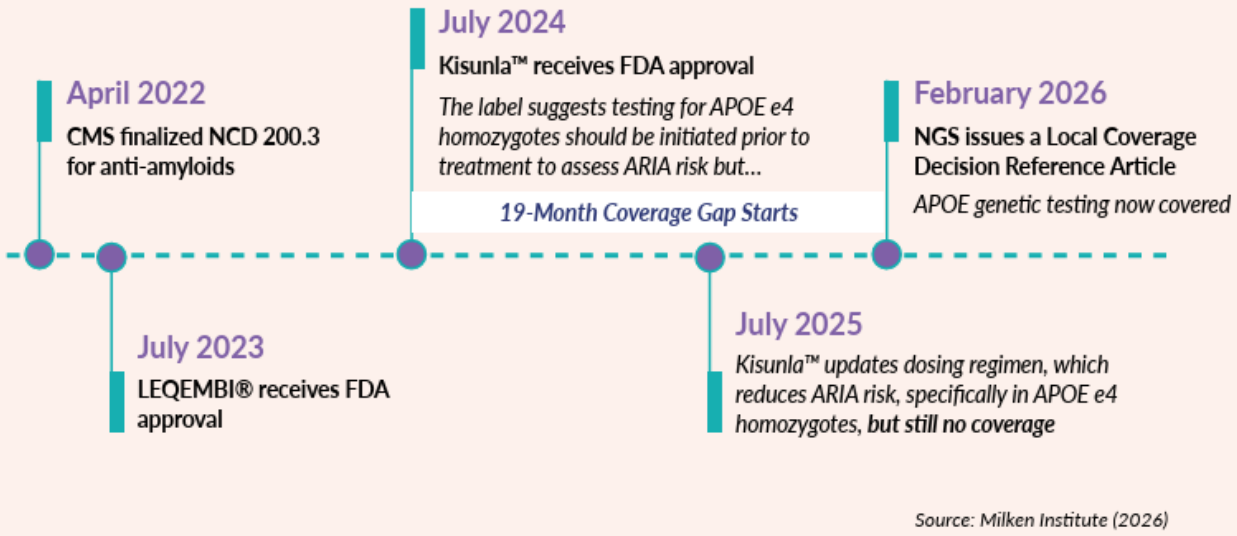
Source: n=22, Milken Institute (2026)

Payer Medical Policy Acceptance

Accelerator Highlighting Early Payer Movement

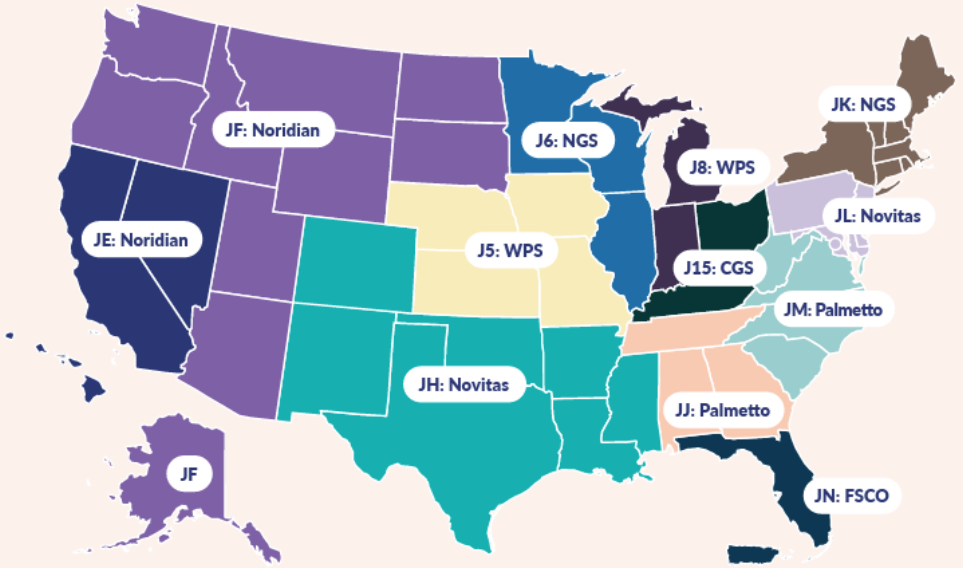
Case Study on removing barriers to APOE genetic testing

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



Source: Milken Institute (2026)

Figure 6. Medicare Administrative Contractors



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

Payer Medical Policy Acceptance

Concerns

- **Lack of clarity on coverage and cost**
- The National Coverage Decision (NCD) on anti-amyloids does not include diagnostic method
- Most Medicare Advantage plans are “silent” on coverage
- Diagnostic and Pharma policies are developed in silos
- **Policies and payments around cognitive assessment and genetic testing also factor into the utilization of BBMs.**

Early Coverage

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

Source: Milken Institute (2026)

Health Equity and Access to Programs

Health Equity and Access

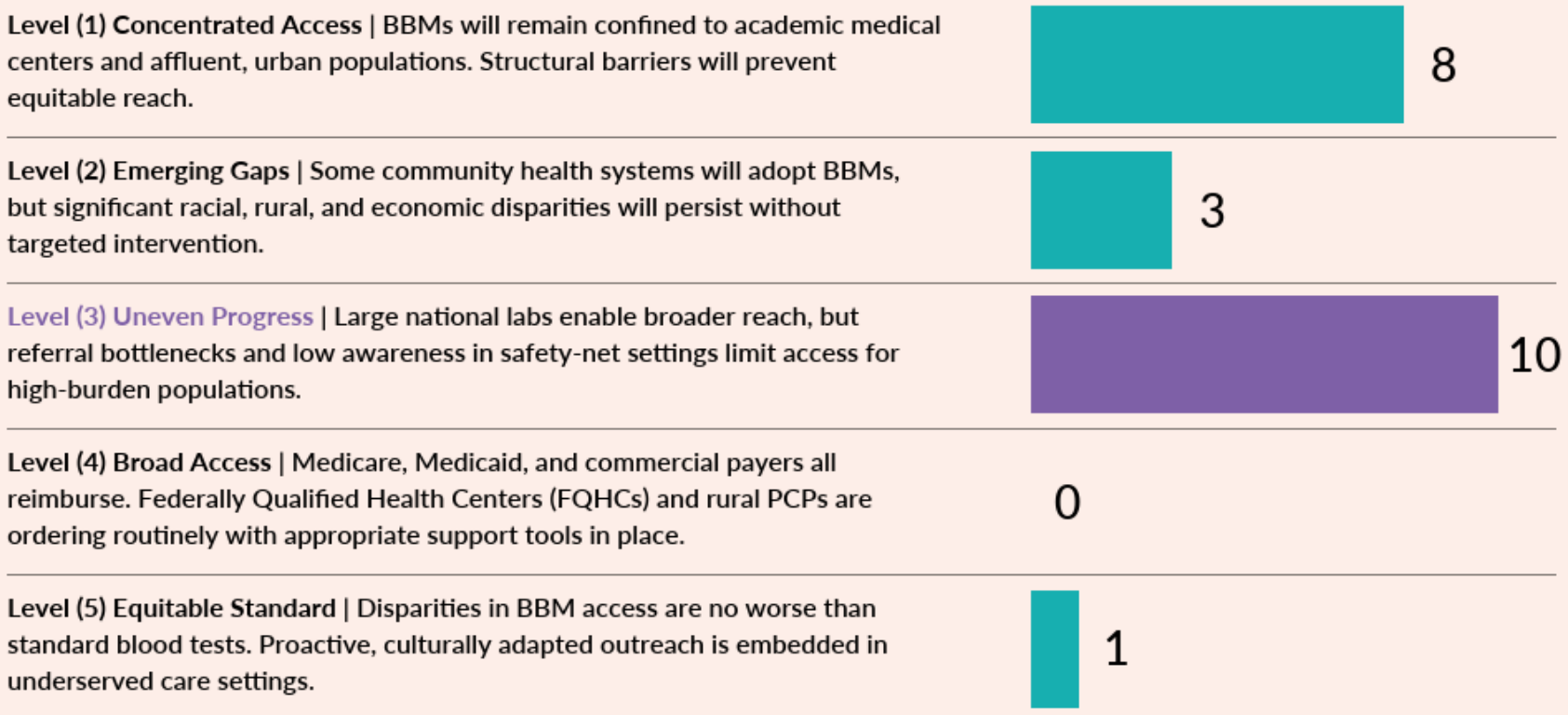
Barriers	Concerns for patient equity, access, and protections
Accelerators	Connecting to promising programs
Readiness Ranking	**Level 3 Uneven Progress**

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.



Key Considerations

Payers

Coordinate diagnostic and pharmaceutical policies so that decisions are aligned (Dx and Tx covered)

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 populations, including young-onset AD, early MCI patients, and non-AD dementias

Use available claims and registry data to build the evidence base for future coverage clarity

Policy Makers

Prioritize clinical society guidelines and best-practice recommendations for non-specialty primary care

Develop dedicated brief cognitive assessment CPT codes for primary care

Recognize Mild Cognitive Impairment (MCI) in Medicare Advantage risk-adjustment to align incentives with early detection

Pursue legislation for sensitive proteomic data, modeled on GINA, to prevent discrimination on biomarker results

Help Design Our Round Table Exercises

Who do we need at the table?



What do we need to solve for?

Impactful Endpoints

Aligning key stakeholders on best practices for generating **real-world evidence.**

- How to design effective clinical utility studies?
- How to demonstrate biomarker results have value unconnected to anti-amyloid treatment?

Results Implications

Develop best practices on sharing results

Advocate for the protection of patients who receive positive results

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Thank you!



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Diane Ty

Managing Director, Future of Aging | Milken Institute Health

Michael Brown

Director, Alliance to Improve Dementia Care | Milken Institute Health