The Diagnostic Bottleneck: *Are Payer Policies Keeping Pace With Rapid Innovation In Alzheimer's Disease Diagnostic Testing?*

MT11

Yamina Rajput, MSc[1]; Matthew DeNave, MBA[1]; Sophie Roth, MSc[2] | 1 Roche Diagnostics Corp., Indianapolis, IN; 2 Roche Diagnostics International Ltd., Rotkreuz, Switzerland

Background: The recent FDA approval of Blood-Based Biomarkers (BBBMs) marks a breakthrough in Alzheimer's disease (AD) diagnosis. Anti-amyloid disease-modifying therapies (DMTs) require clinical confirmation of amyloid pathology prior to treatment initiation. While Positron Emission Tomography (PET) imaging & Cerebrospinal Fluid (CSF) biomarker are established, scalable AD testing like BBBMs is critical to prevent diagnostic bottlenecks and ensure equitable patient access.

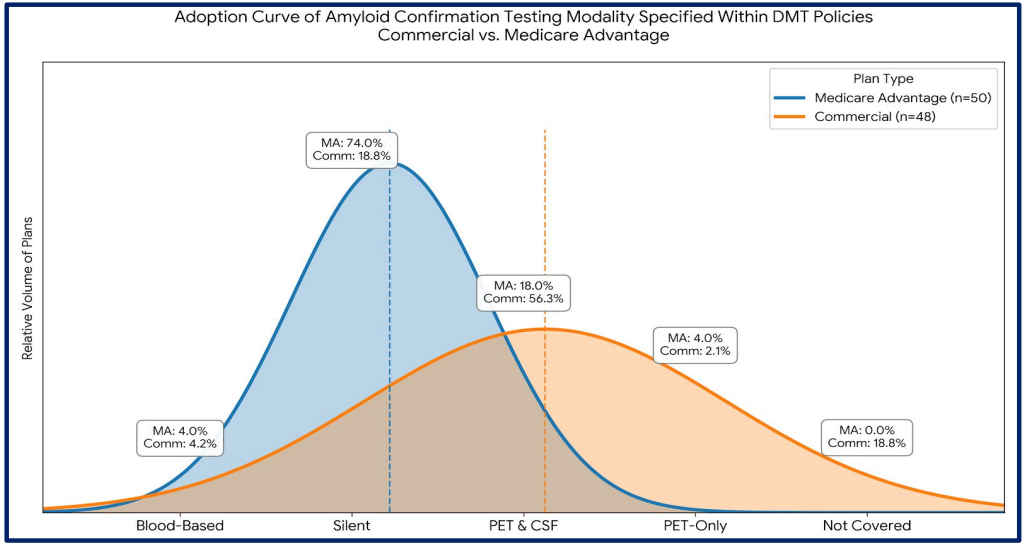
Objective: Assess the alignment of payer policies with AD diagnostic innovations by evaluating the inclusion of BBBMs in DMT coverage criteria allowing timely, informed treatment decisions by patients and providers.

Methods: Evaluate payer coverage policies for FDA-approved DMTs (lecanemab, donanemab)

- Data Sample: Published policies from Medicare Advantage (MA) & Commercial lines of business across 25 major U.S. payers.
- Timeframe: January 1, 2024 to December 31, 2025.
- Comparison: Inclusion of BBBMs within the clinical criteria for treatment initiation vs. traditional testing (PET, CSF).
- Classification: Categorized diagnostic testing requirements as
  - Covered: Explicitly allows BBBMs.
  - Not Covered: Explicitly excludes BBBMs.
  - Silent / Implicit: No specific diagnostic modality is mandated.

Results: Our analysis yielded data across 98 distinct policies.* Percentages based on plans providing DMT coverage (n=39).

Line of Business	DMT Coverage	PET Included	CSF Included	BBBM Included
Medicare Advantage (n=50)	Implicitly Covered	26%	22%	4%
Commercial (n=48)	81% Covered	77%*	74%*	5%*



Disclaimer: The percentage differences between the Results Table and the Innovation Curve stem from differing denominators and categorizations. The Table evaluates each testing modality independently based only on Commercial plans offering DMT coverage (n=39). The Curve categorizes the entire Commercial sample (n=48) into mutually exclusive policy archetypes (e.g., separating "PET-only" from overlapping "PET & CSF" requirements).

Discussion: The adoption curve illustrates a disconnect between the rate of innovation in AD biomarker testing and evolution of payer policies. Commercial plans often require both PET and CSF or specify one to the exclusion of others creating a barrier for patients who cannot access specialized imaging centers or for whom lumbar punctures are contraindicated. BBBMs offer a scalable, more accessible diagnostic entry point that is currently underutilized. MA plans are predominantly silent on specific testing modalities, likely due to lack of medicare coverage determination for AD biomarker testing. Collectively, these policy restrictions create uncertainty for providers and patients regarding BBBM reimbursement, preventing fully informed treatment decisions.

CONCLUSIONS

Recommendations to improve access and adoption of BBBMs:

Clinical Utility Evidence
Further data demonstrating the clinical utility of BBBMs may be required to shift payer perspectives.

Guidelines
Integrating BBBMs into DMT appropriate use recommendations is needed for policy updates.

CMS Integration
Including BBBMs in the CMS DMT Registry and Local Coverage Determinations would provide the framework for MA and Commercial plans to broaden their coverage.

Standardization
Bridging the gap between diagnostic policy and DMT coverage policy is critical to ensure that patients who qualify for treatment can actually access the required diagnostic confirmation.

References
Alzheimer's Association. 2024 Alzheimer's disease facts and figures. Alzheimers Dement. 2024;20(5):1706-1821.
Cummings J, Apostolova L, Rabinovici GD, et al. Lecanemab: Appropriate Use Recommendations. J Prev Alzheimers Dis. 2023;10(3):362-377.
Cubanski J, Neuman T. Medicare's Role for People with Alzheimer's Disease. KFF (Kaiser Family Foundation). Published July 2023. Accessed April 2026.
Code of Federal Regulations. 42 CFR § 422.101 - Requirements relating to basic benefits. Centers for Medicare & Medicaid Services.
Centers for Medicare & Medicaid Services (CMS). Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections. Section 90.4 & 90.5. Baltimore, MD: CMS; updated 2024.

Limitations: Analysis based on publicly available policies; proprietary provider portals not included.
Some policies allowed for use of both PET and CSF.
MA policies assumed consistent with DMT NCD.
Analysis used a sample of 25 major US health plans, which may not represent all regional or smaller payers.
Commercial plan analysis was based on a smaller subset as some payers only offers MA plans.
Payer medical policies are dynamic; coverage statuses reflect a specific point in time and may have since been updated.

ISPOR 2026
May 17-20 | Philadelphia, PA