

# **Mind the Coverage Gap: A review of U.S. payer policies in the new era of Alzheimer's disease tests and treatments**

Presentation to LEAD COALITION

June 10, 2026

Yamina Rajput, National Payer Account Executive West  
Matt DeNave, Access Strategy Leader Neurology

# Key takeaways



## CMS Policy Impact

The existence of an NCD/LCD is the primary lever for Medicare patient access. Without it, coverage variability dominates.



## Medicare Advantage

Despite MA DMT coverage and need for amyloid confirmation, MA diagnostic policies are currently as restrictive as Commercial plans.



## Biomarker Barriers

Few payers currently include BBBMs in DMT initiation criteria or within standalone diagnostic policies, creating a clinical bottleneck.

# The alphabet soup defined



## NCD

### National Coverage Determination

Policy from CMS dictating coverage across all states.



## LCD

### Local Coverage Determination

Jurisdictional decision made by a MAC for a specific region.



## Coverage

Clinical criteria to determine eligibility for insurance payment.



## Access

Real-world ability for patients to obtain care and required diagnostic procedures.



## DMT

### Disease-Modifying Therapy

Advanced therapies targeting the pathophysiology of AD.



## Amyloid PET

Imaging scan used to quantify amyloid plaques in the brain to confirm diagnosis.



## CSF / BBBM

### Cerebral Spinal Fluid or blood-based

Biomarker testing (A $\beta$ 42, tau, etc.) via fluid or blood samples.



## Medicare

Contrast between Original (FFS) vs Advantage (MA) insurance frameworks.

# Medicare framework: contrast between drug coverage & access to diagnostic tests

## When Medicare Guidance Exists (Drugs)

**Medicare Advantage (MA):** Statutorily required to follow established CMS coverage determinations.

**Commercial:** Maintain autonomy to set their own medical policies regardless of NCD/LCD presence.

 **FDA Approval**

 **DMT NCD Established**

 **Medicare FFS Plans Cover**

 **MA Plans Cover**

- FDA authorization for a drug often results in positive insurer coverage and payment, both FFS and MA plans required to cover them.
- The NCD mandates an amyloid pathology confirmation test before treatment, but doesn't specify modality.

## When Guidance Does Not Exist (Tests)

**Medicare Advantage (MA):** In the absence of NCD/LCD, MA organizations have discretion to create their own evidence-based determinations.

**Commercial Plans:** Maintain autonomy.

 **FDA Clearance**

 **Lack of Testing NCD/LCD**

 **Medicare FFS Plans Claim-By-Claim**

 **MA Plans Cover**

- FDA clearance for a test does not equal "medically necessary" for insurer coverage and payment.
- DMTs requirement for amyloid pathology confirmation does not equal coverage for the diagnostic test.

# Research roadmap: quantifying the diagnostic coverage landscape

## Analysis 1: Market Comparison

### Focus:

Evaluating coverage across **Medicare Advantage** vs. **Commercial** plans and their DMT and diagnostic policies.

### Key Question:

*Does the lack of a NCD/LCD for AD biomarker testing impact coverage differently across these plan types?*

## Analysis 2: Biomarker Adoption

### Focus:

Evaluating inclusion of FDA-cleared **Blood Based Biomarkers (BBBM)** within the clinical criteria for DMT coverage policies.

### Key Question:

*How are DMT payer policies incorporating the rapid innovation of Alzheimer's disease biomarker testing?*

These analyses aim to quantify current coverage for both CSF and blood-based biomarkers to identify potential access bottlenecks for AD patients

# Analysis 1: Market comparison of Medicare advantage & commercial coverage

**FINDING:** We observed a “Mirroring effect” - i.e. in the absence of Medicare coverage determinations, MA plans typically adopt (*mirror*) the more restrictive policies of commercial plans.

## Methodology

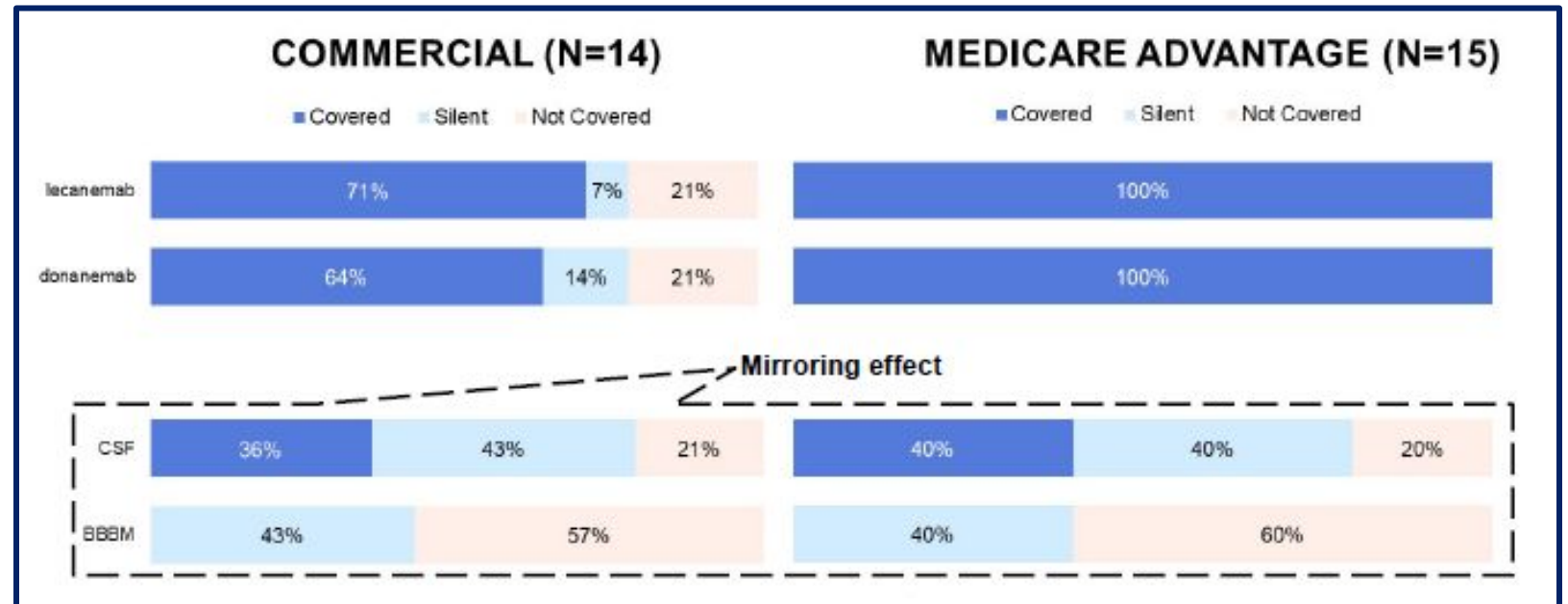
**15 major U.S. payers** (Medicare Advantage & Commercial)

**Jan 1, 2024 – Dec 31, 2025**  
Policy review timeframe.

**Coverage policies** for FDA-approved DMTs & FDA-cleared CSF/BBBM testing

### Coverage Tiers

- **Covered:** "medically necessary"
- **Not Covered:** "investigational"
- **Silent:** No policy available




Note: Analysis 1 did not include amyloid PET; commercial N=14 insurer didn't offer plan type


**As DMTs are indicated strictly for early-stage Alzheimer's disease, delays caused by restrictive diagnostic coverage risk pushing beneficiaries past the window of clinical eligibility.**

# Analysis 2: BBBM inclusion within clinical criteria of DMT policies

**FINDING:** Commercial plans often require both PET and CSF testing or specify one modality over the other; while MA plans are silent regarding specific testing methods likely due the “confirmed presence of amyloid beta pathology” language in the DMT NCD

## Methodology

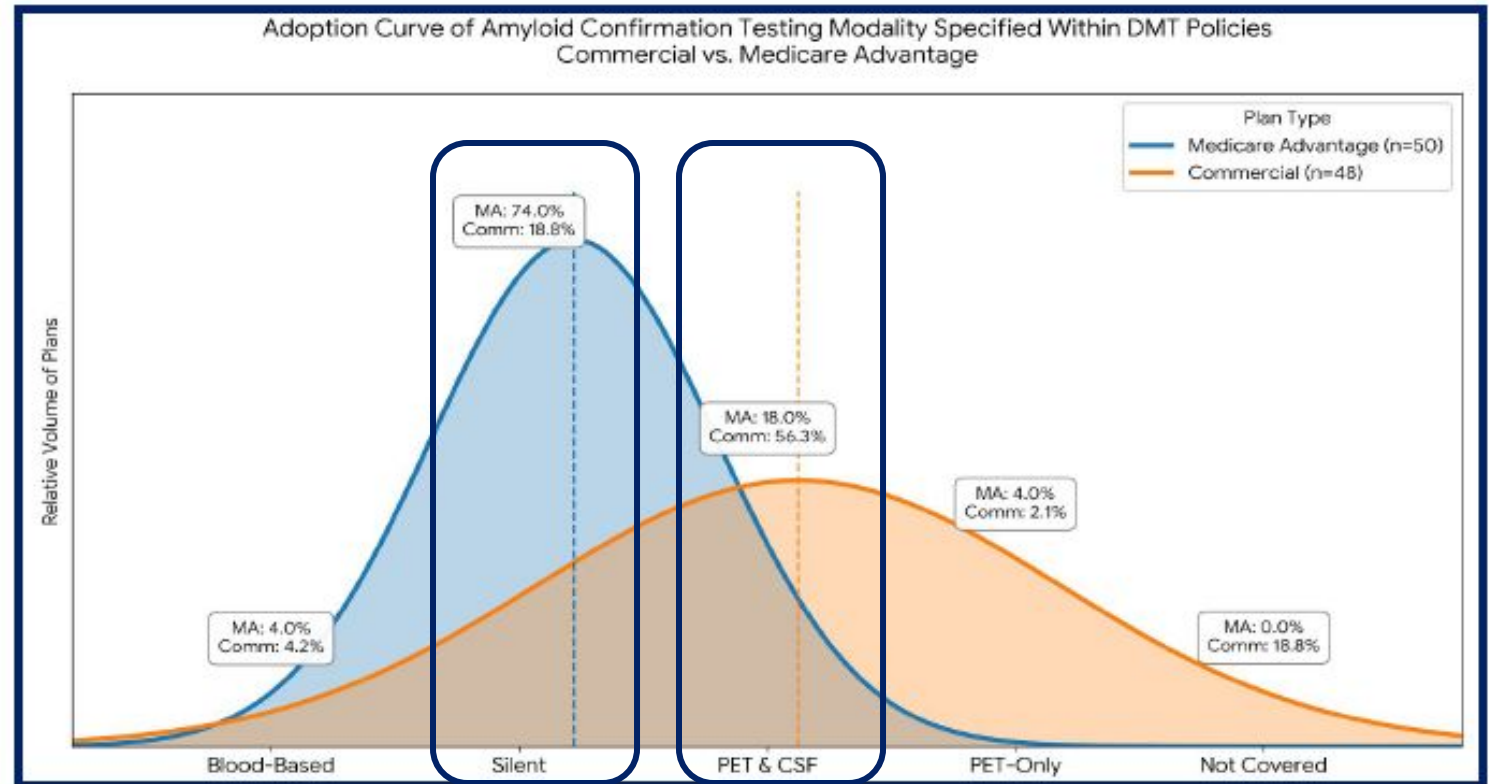
 **25 major U.S. payers** (Medicare Advantage & Commercial)

 **Jan 1, 2024 – Dec 31, 2025**  
Policy review timeframe.

 **Payer coverage policies** Clinical criteria to confirm amyloid pathology within FDA-approved DMTs

### Diagnostic Classification:

- **Covered:** Explicitly allows BBBMs
- **Not Covered:** Explicitly excludes BBBMs
- **Silent:** No policy available/ No specific modality mandated



Collectively, these restrictions create uncertainty for providers and patients regarding BBBM reimbursement

# Key takeaways



## CMS Policy Impact

The existence of an NCD/LCD is the primary lever for Medicare patient access. Without it, coverage variability dominates.



## Medicare Advantage

Despite MA DMT coverage and need for amyloid confirmation, MA diagnostic policies are currently as restrictive as Commercial plans.



## Biomarker Barriers

Few payers currently include BBBMs in DMT initiation criteria or within standalone diagnostic policies, creating a clinical bottleneck.

**Doing now what patients need next**