

BLOOD-BASED BIOMARKERS IN EARLY ALZHEIMER’S DISEASE: REAL-WORLD ADOPTION TRENDS AND THE TRANSFORMATION OF DIAGNOSTIC PATHWAYS



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Introduction

- Anti-amyloid therapies for early Alzheimer’s disease (AD) require confirmation of amyloid pathology prior to treatment initiation¹⁻³
- Blood-based biomarkers (BBMs) are emerging as a testing modality, potentially redefining and streamlining the diagnostic pathways⁴⁻⁷
- This study evaluated real-world utilization of amyloid testing modalities among patients initiating anti-amyloid therapy, focusing on BBM adoption trends, and the timing of diagnosis and testing relative to treatment initiation
- The objectives of the analysis include:
 - Determine the utilization of BBM testing as the only confirmatory test prior to the initiation of lecanemab and donanemab
 - Determine the timing and order of AD diagnosis, confirmatory tests, and initiation of lecanemab and donanemab trends over time
 - Examine demographic differences (age, gender, urban/rural locations) in the diagnostic tests used to confirm AD diagnosis

Methods

- This retrospective database study used 100% Medicare Part B Fee-For-Service claims
- Patients who had an AD or mild cognitive impairment (MCI) diagnosis between June 2021 and December 2025, and initiated lecanemab or donanemab treatment were included
- To describe trends in PET, CSF and BBM test use for amyloid, claims in the 24 months prior to treatment initiation were analyzed
- Besides biomarker test utilization, timing and sequence leading to an AD diagnosis and anti-amyloid therapy initiation were evaluated
- Confirmatory test was defined as the most recent amyloid test prior to initiation of anti-amyloid treatment
- Descriptive analyses were performed to evaluate testing patterns and sequence

Results

- The study cohort consisted of 25,485 patients who received anti-amyloid treatment, with mean age 75.9 (SD 5.7), 56% female, and 85% living in urban areas
 - Of all identified tests, 97% were conducted in urban settings
- Among patients with any amyloid testing claims during the study period, the most common confirmatory modalities were amyloid PET (51%), followed by BBM combined with PET or CSF (34%), and BBM only (8%) (**Table 1**)

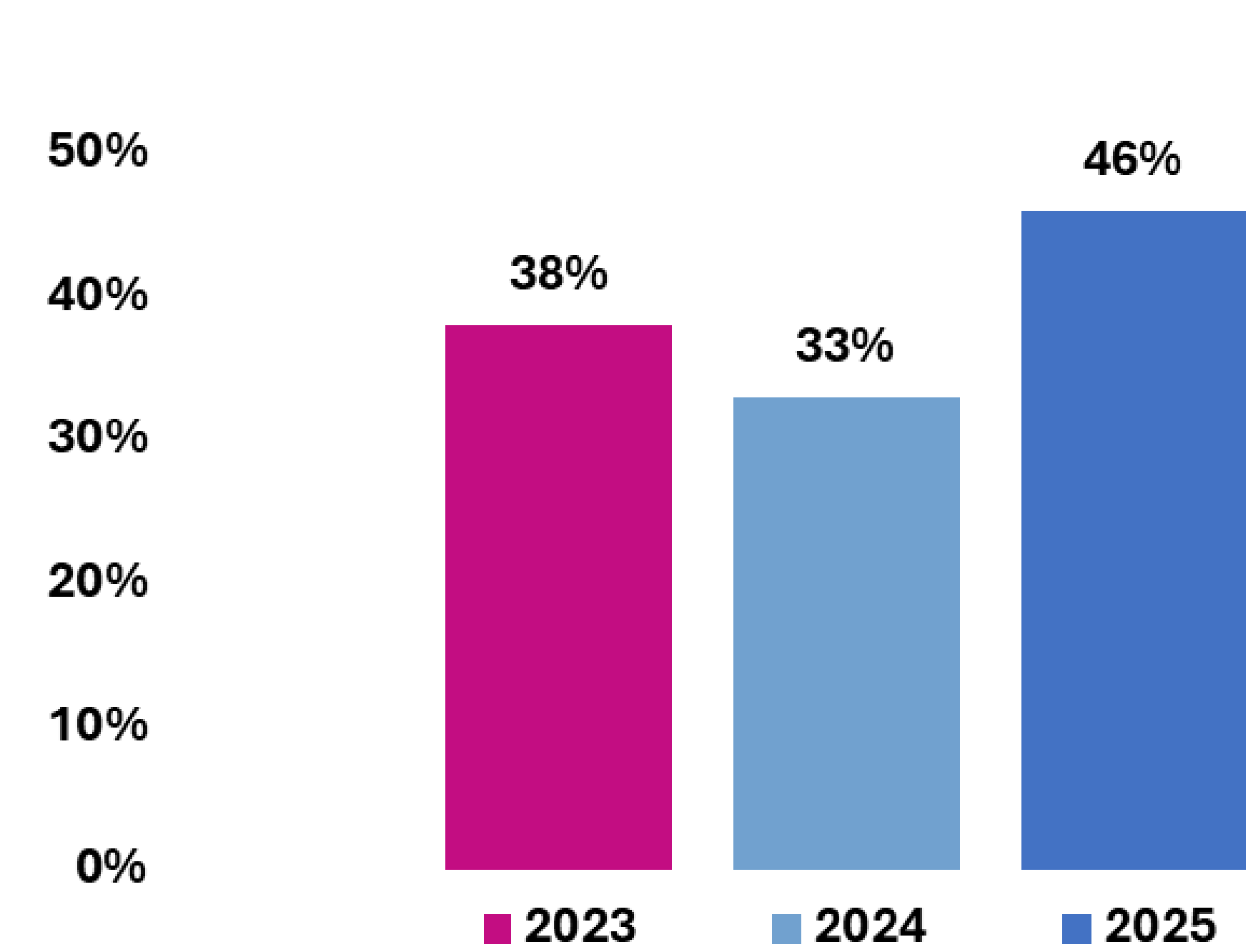
Table 1. Testing Utilization Rates

Test Groups	% of patients who received an amyloid confirmation test
PET Only	51%
BBM + PET/CSF	34%
BBM Only	8%
CSF Only	6%
PET + CSF + No BBM	1%

- Between 2023 and 2025, the proportion of patients receiving any BBM testing increased from 17% to 37% (**Figure 1**)

Results (continued)

Figure 1. Any BBM Test Utilization Rates Over Time



- Use of BBM was associated with a shorter time from clinical diagnosis to initial amyloid testing compared with PET (23.4 vs. 30.0 weeks) (**Table 2**)

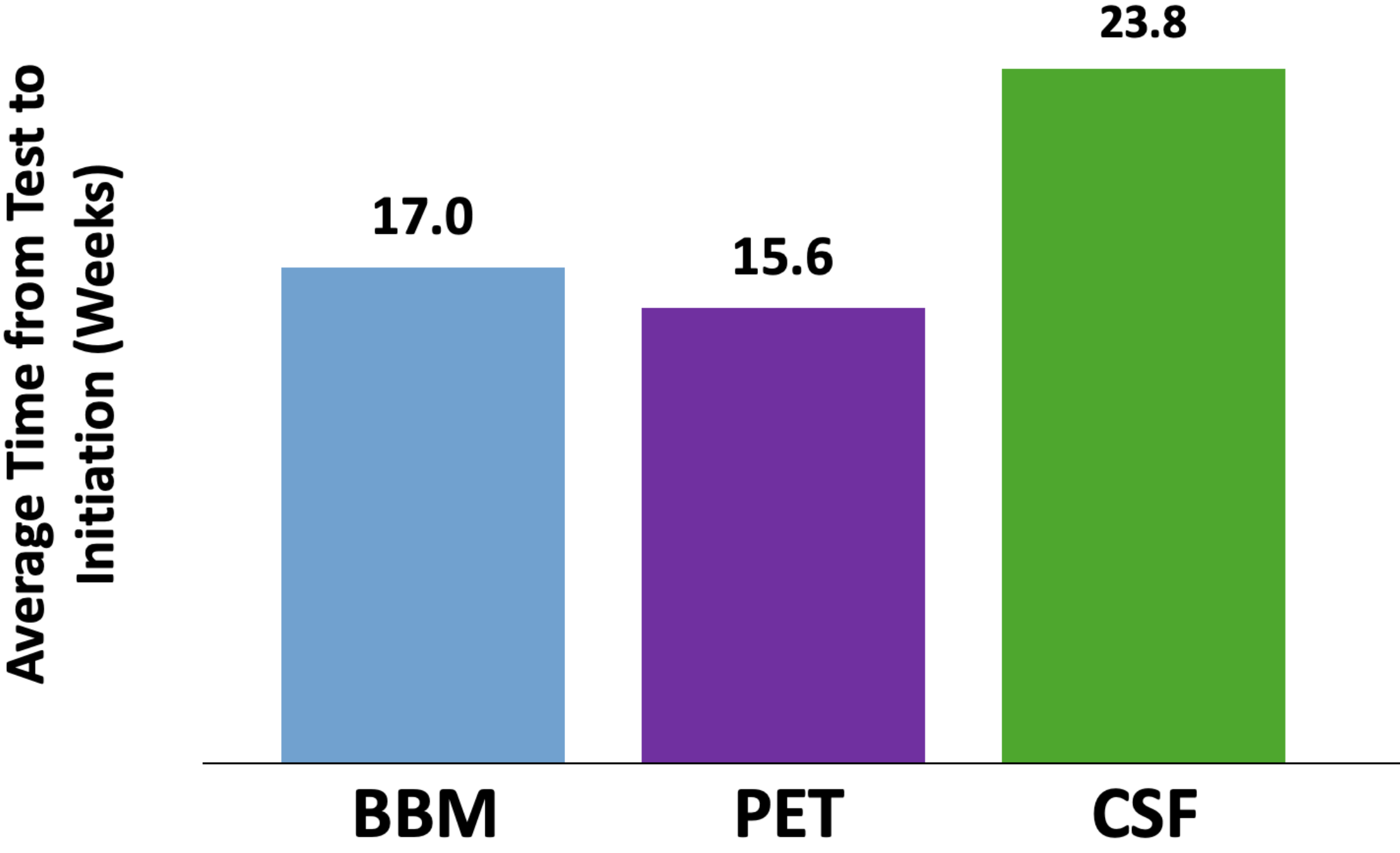
Table 2. Time from AD/MCI Diagnosis to Initial Amyloid Testing*

Testing Scenario Pathway	Unique Beneficiary Count (N = 15,649)	% of Patients	Time from Clinical Diagnosis to Biomarker Testing	
			Mean (Weeks)	Median (Weeks)
Diagnosis to PET	9,548	61%	30.03	21.14
Diagnosis to BBM	5,246	34%	23.4	11.71
Diagnosis to CSF	855	5%	22.5	16.14

* Among patients who received an AD/MCI diagnosis and an amyloid confirmation test

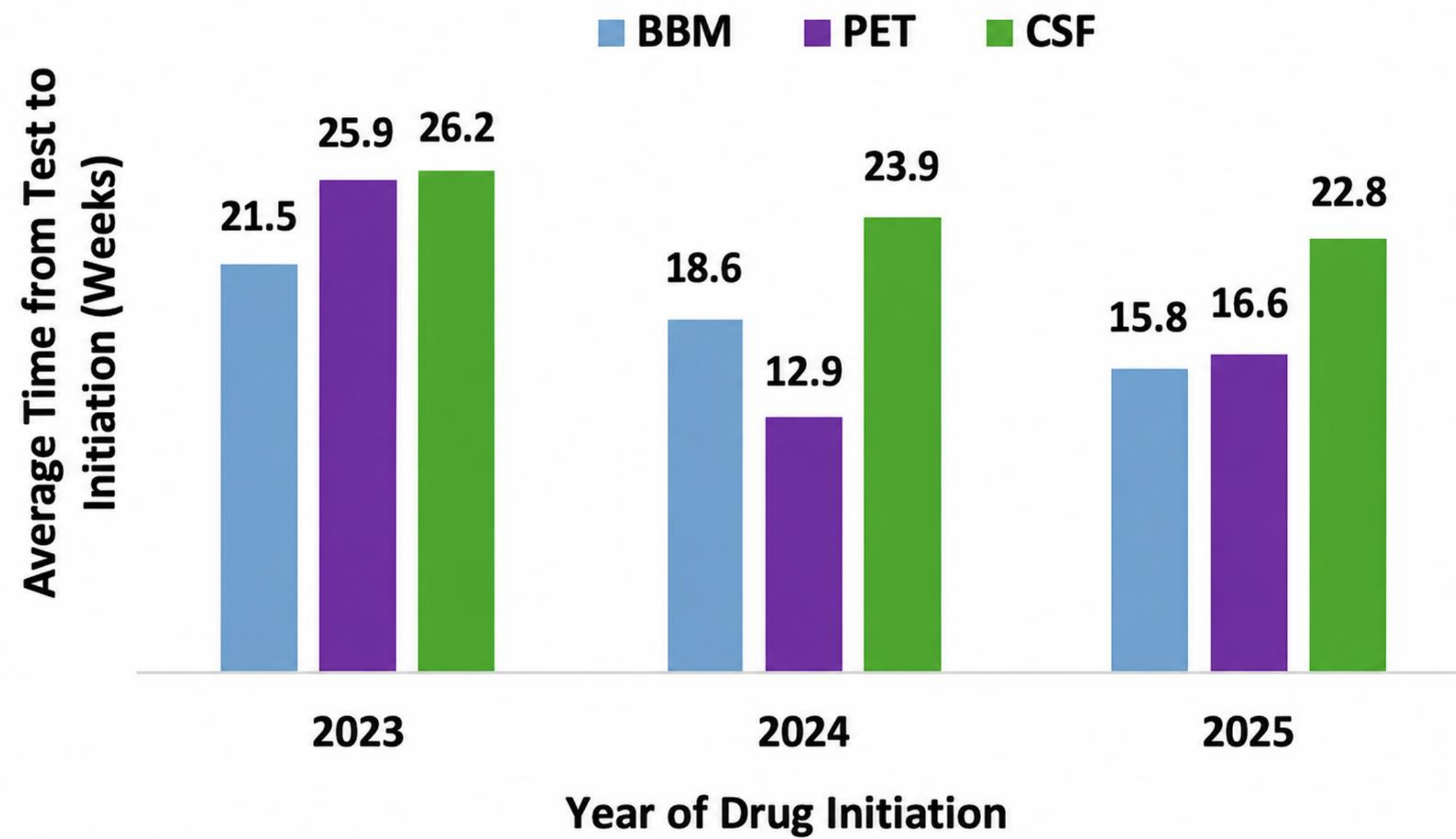
- Overall, time from confirmatory testing to treatment was similar for BBM and PET (mean 17.0 vs. 15.6 weeks; median: both 12.0 weeks), and shorter compared to CSF (mean 23.8 weeks; median 16.3 weeks; **Figure 2**)

Figure 2. Time from Test to Anti-Amyloid Treatment Initiation



- Between 2023 and 2025, time from BBM testing to treatment initiation declined by 5.7 weeks (from 21.5 weeks to 15.8 weeks; **Figure 3**)

Figure 3. Time from Test to Drug Initiation by Year



- Majority of the treated beneficiaries are aged 70–79 years (~55-66%) followed by those aged 80–89 years (17-29%)
 - BBM only test group mirrors the overall results with volume concentrated in ages 70–79 (61%) and 80-89 years (26%)
- Similar sex distribution with a slight, but consistent, female dominance in the rates across all testing categories
- The majority of all diagnostic tests taking place in an Urban or Suburban facility location
- Across all confirmatory testing modalities, testing was predominantly conducted in urban locations, with PET testing showing the highest urban concentration (97.3%), followed by BBM (95.9%) and CSF (87.0%)
 - Testing in rural locations was limited across modalities (~1%) (**Table 3**)

Table 3. Distribution of Confirmatory Tests* by Urban/Rural Location

Urban/Rural Location	BBM Test Claim Count (N, %)	PET Test Claim Count (N, %)	CSF Test Claim Count (N, %)
Urban	9,236 (95.9%)	25,037 (97.3%)	2,377 (87.0%)
Suburban	338 (3.5%)	584 (2.3%)	319 (11.7%)
Rural	59 (0.6%)	111 (0.4%)	36 (1.3%)

Limitations

- The study depended on available billing codes for amyloid confirmation, which face challenges due to rapidly evolving medical technology, fragmented coverage policies, and strict coding requirements
- This study used fee-for-service Medicare data and may not reflect the experience of patients with Medicare Advantage or commercial insurance coverage

Conclusions

- Real-world diagnostic pathways for anti-amyloid therapy are shifting toward greater use of BBM, suggesting a more efficient and accessible testing approach
- Despite these trends, variability in testing practices highlight unmet needs in standardizing diagnostic pathways and ensuring timely access to treatment

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