Coverage Gaps: Do US Commercial Health Plans Have Concordant Alzheimer's Disease Therapy and Testing Policies?

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Background

- In 2024, an estimated 6.9 million Americans aged ≥ 65 years (about 1 in 9) were living with Alzheimer's dementia (AD), a neurodegenerative disease marked by amyloid beta (Aβ) plaques and tau neurofibrillary tangles.[1,2] AD prevalence in the United States (US) is projected to double by 2060.[3]
- Two Food and Drug Administration (FDA)-approved amyloid-targeting therapies (lecanemab and donanemab) have been shown to slow disease progression in early symptomatic AD and require confirmation of Aβ pathology prior to initiation.[4,5]
- Aβ pathology confirmation is currently available using 2 FDA-approved testing methods: amyloid positron emission tomography (PET) imaging and cerebrospinal fluid (CSF) biomarker testing (e.g., pTau181/Aβ42, tTau/Aβ42, or Aβ40/Aβ42). Plasma-based biomarkers are currently in development and expected to be available for clinical use in the near future.[6]
- The largest public payer in the US (CMS) has issued national coverage determinations (NCD) for the 2 approved amyloid-targeting therapies and a separate NCD (retired) for amyloid PET; however, there has not been an NCD issued for CSF biomarker testing.
- In the US, commercial health plans retain autonomy in determining their own coverage policies for commercial beneficiaries. They often have separate committees reviewing diagnostic tests and therapies, which may result in potential disparities in access to essential testing and amyloid-targeting treatments for patients with early AD.

Objective

- Detecting AD in its early stages is critical for patient management and therapy considerations. Our goal was to assess the alignment between coverage policies for amyloid-targeting therapies and prerequisite diagnostic testing to identify any access inequity across major commercial insurers.

Methods

- We analyzed publicly available medical policies from 30 commercial health plans, representing 90% of the commercially insured US population.[7]
- These policies, effective from 1 January to 31 December 2024, included FDA-approved AD diagnostic tests (amyloid PET and CSF biomarkers) and amyloid-targeting therapies (lecanemab and donanemab).
- We categorized the retrieved medical policies, classifying them according to the **coverage determination** made by the health plan:
  - **Covered:** Considered medically necessary.*
  - **Noncovered:** Not a covered benefit, considered experimental or investigational.
  - **Silent:** No publicly available policy to assess the coverage determination.

* "Medical necessity" refers to a determination that a procedure is warranted based on the patient's medical condition. In general, a service/technology/procedure must be deemed medically necessary to be a covered benefit.

- We compared the clinical criteria for testing within drug policies against corresponding biomarker testing policies in the same health plan (if available), examining whether any payers covered the therapy but not the testing or restricted any or all therapy or testing options.
- The **concordance** was classified as follows:
  - **Concordant covered**: At least 1 therapy and 1 test were both covered.
  - **Concordant noncovered**: Neither therapy nor testing were covered.
  - **Discordant**: Either the test was covered but not the therapy, or the therapy was covered but not the test.
  - **Silent**: No publicly available policy for comparison.

Limitations

- Medical policies included in the analyses were required to be available to consumers on the public website and may not be representative of those available to healthcare providers on a plan portal.
- Policies may have changed since the date of data collection and analyses, therefore, may not reflect today's coverage determination status.
- Not all US commercial health plans were included in the analyses.

Results

- Each payer could potentially have up to 4 published AD medical policies (2 for testing and 2 for therapies) for their commercial beneficiaries **(Figure 1).**
- We searched for a total of 120 individual policies for amyloid-targeting therapies and/or related diagnostic testing.
- We retrieved 77 of the 120 potential AD coverage determinations; the breakdown of medical policies was:
  - 42 for therapy, and
  - 35 for testing.
- Forty-three of the 120 potential AD coverage determinations were silent (not publicly available); the breakdown of unknown medical policies was:
  - 18 for therapy, and
  - 25 for testing.

Figure 1. Flowchart of AD Medical Policies for Commercial Beneficiaries

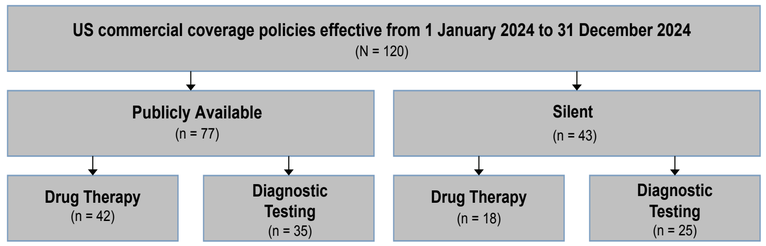
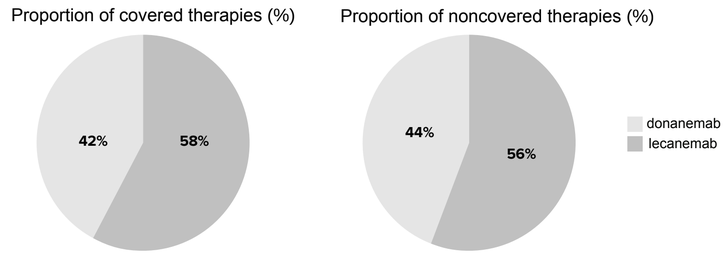


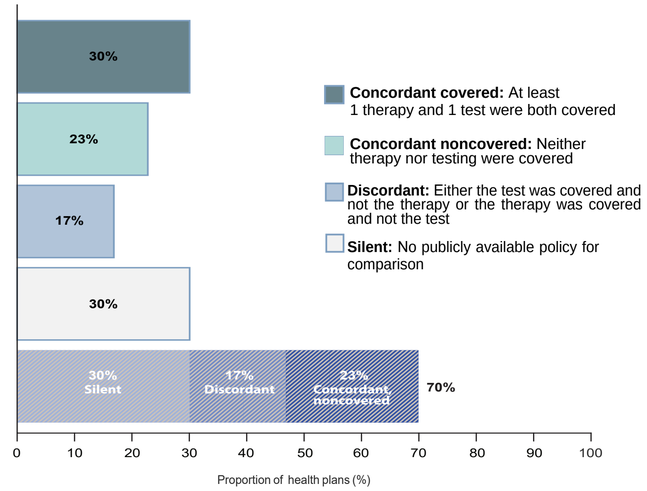
Figure 2a. Coverage Determinations of FDA-Approved AD Diagnostic Testing

Figure 2b. Coverage Determinations of FDA-Approved AD Drug Therapies



- Of the publicly available policies (N = 77) **(Figure 2a and Figure 2b)**:
  - 55% (n = 42) were categorized as covered.
    - 26 therapy policies (15 lecanemab, 11 donanemab).
    - 16 testing policies (8 CSF, 8 PET).
  - 45% (n = 35) of policies were categorized as not covered.
    - 16 therapy policies (9 lecanemab, 7 donanemab).
    - 19 testing policies (13 CSF, 6 PET).

Figure 3. Concordance of AD Therapy and Testing Across All Commercial Health Plans (N = 30)



- Our analysis to determine concordance between AD testing and therapy policies among the 30 commercial payers found **(Figure 3)**:
  - 30% (n = 9) were concordant covered.
  - 23% (n = 7) were concordant noncovered.
  - 17% (n = 5) were discordant.
  - 30% (n = 9) were silent/unknown (did not have publicly available policies for therapies and testing to compare).
- Only 30% of US commercial health plans covering amyloid-targeting therapies and the diagnostic testing required to use them (concordant covered). Seventy percent of payers have restrictive (discordant), none (concordant noncovered), and unknown (silent) coverage policies.
- There were more negative coverage determinations for diagnostic testing than for the therapies (concordant noncovered; 19 vs. 16), and a bigger proportion of the negative testing policies were for CSF biomarkers (13/19) compared with amyloid PET (6/19).

Conclusions

- Our research revealed that patient access to AD care was limited, with fragmentation across the AD diagnosis-to-therapy pathway. A total of 21 of the 30 commercial payers had restrictive (discordant), none (concordant noncovered), and unknown (silent) coverage policies.
- The disparity in AD biomarker coverage is concerning given:
  - It is contrary to the scientific evidence demonstrating high concordance of CSF biomarkers to PET and contrary to the testing Appropriate Use Recommendations for amyloid-targeting therapies.
  - The development of new and innovative diagnostic technologies for amyloid-pathology testing, such as plasma-based biomarkers that offer an operational and economic alternative to PET scans.
- It is important for health plans to expand coverage for diagnostic testing and align it with therapy coverage to improve patient outcomes, reduce healthcare costs, and, ultimately, enhance the quality of life for those living with AD.

Scan the QR code to access the full reference list.

Presented at ISPOR; Montréal, Quebec, Canada; 13-16 May 2025

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