Neurol Ther (2025) 14:1115–1127
https://doi.org/10.1007/s40120-025-00756-4

BRIEF REPORT

Characterizing the Journey of Early Alzheimer's Disease in Patients Initiating Lecanemab Treatment in the United States: A Real-World Evidence Study

Marwan N. Sabbagh · Chenyue Zhao · Malena Mahendran · Se Ryeong Jang · François Laliberté · Hideki Toyosaki · Kaixin Zhang · Feride Frech · Kavita V. Nair

Received: February 23, 2025 / Accepted: April 15, 2025 / Published online: May 4, 2025

ABSTRACT

Introduction: With the advent of disease-modifying therapies for early Alzheimer's disease (AD), a comprehensive characterization of patients initiating lecanemab in the USA is needed to understand its use in real-world settings.

Methods: This retrospective observational study used administrative claims from the Komodo Research Database (1/1/2023–6/30/2024). Eligible patients had ≥ 1 lecanemab administration (first claim defined the index date) and ≥ 12 months of clinical activity/insurance eligibility before the index date. Patient characteristics, diagnostic process, and AD-related medications were evaluated within 12 months before the index date (baseline), whereas lecanemab treatment patterns and concomitant medications were evaluated on or after the index date (follow-up). Outcomes were reported using descriptive statistics and persistence to lecanemab was evaluated using Kaplan–Meier analysis.

Results: Of 3155 patients included in the study, mean age was 75.0 years, 55.8% were female, 44.2% were male, and most (93.3%) received their index lecanemab administration in an urban setting. Diagnoses of AD (83.8%) and mild cognitive impairment (60.8%) were common at baseline, and 67.6% of patients used AD symptomatic medications. Average time from earliest diagnosis to first lecanemab administration was 4.9 months among patients with a diagnosis in January 2023 (accelerated approval date) or onwards. Over a mean follow-up of 138.8 days, the monthly mean number of administrations of lecanemab was 1.9, with an average of 16.5 days between consecutive administrations and 47.4 days to the first follow-up head magnetic resonance imaging. Persistence to lecanemab was 87.6% at 4 months after treatment initiation.

Prior Presentations: Part of the material in this manuscript was presented at the 59th American Society of Health System Pharmacists (ASHP) Midyear Clinical Meeting & Exhibition held December 8–12th, 2024 in New Orleans, LA, as a poster presentation.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40120-025-00756-4.

M. N. Sabbagh
Department of Neurology, Barrow Neurological Institute, Phoenix, AZ, USA

C. Zhao (✉) · S. R. Jang · H. Toyosaki · F. Frech
Eisai Inc., 200 Metro Blvd, Nutley, NJ 07110, USA
e-mail: Chenyue_Zhao@eisai.com

M. Mahendran · F. Laliberté · K. Zhang
Group d'analyse SRI, Montréal, QC, Canada

K. V. Nair
Department of Neurology, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

***Conclusion*:** Lecanemab was utilized in appropriate patient populations according to the prescribing information approved by the US Food and Drug Administration. Findings from our study provide first insights into the real-world use of lecanemab in the USA and shed light on the need for increased and timely lecanemab initiation for the long-term management of early AD.

Keywords: Alzheimer's disease; Disease-modifying therapy; Lecanemab; Treatment patterns; Diagnostic patterns; Administrative claims; Retrospective study

Key Summary Points

Why carry out this study?

With the advent of lecanemab as a novel disease-modifying therapy for early Alzheimer's disease (AD), a comprehensive characterization of patients initiating lecanemab is needed to understand its use in real-world settings.

This retrospective observational study used open and closed administrative claims data to evaluate patient characteristics, diagnostic process, and treatment patterns among patients with early AD initiating lecanemab in the USA.

What was learned from this study?

Lecanemab was used according to the approved prescribing information with relatively high patient adherence and persistence.

Lecanemab initiation was limited among minority groups and in rural service areas, suggesting that outreach programs may help improve lecanemab access for underserved communities.

INTRODUCTION

Alzheimer's disease (AD) is an irreversible, progressive neurodegenerative disorder that impairs thinking, memory, and independence [1]. It is the most prevalent form of dementia globally [2]. By 2025, 7.2 million individuals are projected to have clinical AD in the USA, where it is one of the leading causes of death in older adults [1, 3]. As the population continues to age, the prevalence of AD is expected to increase to nearly 14 million by 2060 [3].

AD is a continuum, consisting of preclinical AD, which can begin decades before initial manifestation of clinical symptoms (e.g., mild cognitive impairment, MCI) [4], and ultimately progressing to AD dementia [5]. Together, MCI due to AD and mild dementia are characterized as early AD [1, 5]. Between 12% and 18% of adults over 60 years of age in the USA are living with MCI [6], and approximately one-third of them will develop dementia within 5 years [7]. Early AD represents a critical stage for timely intervention [5]. However, many patients are not diagnosed with AD until later stages when the burden of disease on patients, caregivers, and the healthcare system are considerable [5, 8].

Over the past few decades, treatment options for AD primarily focused on symptom management [5, 9]. Pharmacologic therapies used to treat cognitive symptoms in AD dementia include acetylcholinesterase inhibitors (e.g., donepezil, rivastigmine, galantamine) and *N*-methyl-D-aspartate receptor antagonists (e.g., memantine) to support cognitive function, behavior, and activities of daily living [9, 10]. However, these treatment options do not alter the underlying disease course and only provide temporary relief from symptoms [8, 11]. Recent advancements have transformed the AD treatment landscape, with the approval of anti-amyloid monoclonal antibodies by the US Food & Drug Administration (FDA) [12]. These novel treatments target the underlying pathogenesis of AD and have shown the ability to slow clinical decline in affected patients [13, 14]. Timely and accurate diagnosis of AD is critical to optimally manage the condition and enhance patient outcomes.

The development and progression of AD is marked by two key pathologic drivers, the accumulation of amyloid beta plaques and neurofibrillary tangles [2, 15]. Lecanemab is the first humanized IgG1 monoclonal antibody that selectively targets and reduces neurotoxic amyloid beta protofibrils, which are thought to form and drive AD pathophysiology in the brain, while clearing amyloid beta plaques [16, 17]. Lecanemab was approved by the FDA on January 6, 2023 via the accelerated approval pathway for the treatment of AD based on a double-blind, placebo-controlled, dose-finding phase 2 trial demonstrating significant dose- and time-dependent reduction of amyloid beta plaques [18, 19]. In a randomized, double-blind, phase 3 clinical trial, lecanemab slowed cognitive and functional impairment and led to greater reductions in amyloid burden as confirmed by amyloid positivity compared with placebo at 18 months among patients with early AD [13]. On the basis of verification of clinical benefit observed in patients treated with lecanemab, the FDA granted full approval to lecanemab on July 6, 2023 [20]. Soon thereafter, the Centers for Medicare and Medicaid Services (CMS) expanded access to beta amyloid positron emission tomography for Medicare beneficiaries on October 13, 2023 [21].

Administering lecanemab according to FDA-approved prescribing information is essential to optimize treatment safety and efficacy. The prescribing information indicates lecanemab for the treatment of MCI or mild dementia due to AD [22]. Baseline brain magnetic resonance imaging (MRI) should be obtained within the 12 months prior to treatment initiation, after which lecanemab should be administered as an intravenous infusion once every 2 weeks and follow-up MRIs should be obtained prior to the 5th, 7th, and 14th infusion to monitor for amyloid-related imaging abnormalities (ARIAs) [22]. However, given the recent introduction of lecanemab as a novel treatment for AD, evidence is needed to shed light on the profile of lecanemab users and their disease management patterns in a post-approval real-world setting. Considering these gaps, this study aimed to provide an overview of the demographics, clinical characteristics, diagnostic patterns, and treatment patterns of patients initiating lecanemab in the USA.

METHODS

Study Design and Data Source

This retrospective observational study used open and closed claims from the Komodo Research Database (January 1, 2023 to June 30, 2024), a comprehensive US database with over 330 million distinct patients [23]. Open claims data are primarily derived from clearing houses, pharmacies, and physician billing systems, whereas closed claims data are derived from payers across all medical or pharmacy encounters and incorporate complete claims records, resulting in longer data lag than open claims [24]. Clinical activity identified in open claims data served as a proxy for insurance eligibility. Clinical activity was considered continuous if at least one medical or pharmacy claim was available for consecutive calendar quarters (e.g., January to March, April to June). The index date was defined as the date of the first lecanemab administration (based on medical claims and dispensing of lecanemab on pharmacy claims) on or after January 6, 2023. A 12-month baseline period prior to the index date was used to describe patient demographics, clinical characteristics, diagnostic patterns, and AD symptomatic medications. The observation period spanned from the index date until the earliest date of end of data availability (i.e., June 30, 2024), clinical activity (open claims data only), or insurance eligibility (closed claims data only), during which lecanemab treatment patterns and concomitant medication use were described. The study was considered exempt research under 45 CFR § 46.104(d)(4) as it involved only the secondary use of data that were de-identified in compliance with the Health Insurance Portability and Accountability Act (HIPAA), specifically, 45 CFR § 164.514. The data used for this analysis were provided with permission and under license from Komodo Health.

Eligibility Criteria

The overall study sample included unique patients selected from open and closed claims who had (1) at least one medical or pharmacy claim for lecanemab, and (2) a minimum of 12 months of continuous insurance eligibility or clinical activity before the index date. The closed claims cohort included the subset of patients with at least 12 months of continuous insurance eligibility in closed claims data only. The overall study sample was assessed to maximize the population of patients initiating lecanemab, enhancing the generalizability of the study findings. The closed claims cohort was assessed to confirm trends observed in the overall study sample, providing additional validation and ensuring consistency in study findings.

Statistical Analysis

Patient demographics on the index date and clinical characteristics, diagnostic patterns, and AD symptomatic medications during the 12-month baseline period were reported using descriptive statistics. Descriptive statistics included means with standard deviations (SDs) and medians for continuous characteristics, and frequencies with proportions for categorical characteristics. Lecanemab treatment patterns, monitoring with MRI, and concomitant medications during the observation period were evaluated among patients with at least two administrations of lecanemab and reported using descriptive statistics. Monthly persistence to lecanemab was assessed using the Kaplan–Meier method, with discontinuation defined as a gap of at least 90 days between two consecutive claims for lecanemab, or between the last claim for lecanemab and the end of the observation period. Treatment reinitiation after at least 90 days was not captured among patients who discontinued lecanemab. Patients who did not discontinue lecanemab were censored at the end of observation.

RESULTS

Patient Demographics and Clinical Characteristics

A total of 3155 patients initiating lecanemab were included in the overall study sample, of whom 515 (16.3%) were included in the closed claims cohort. Overall, most patients initiating lecanemab (mean age 75.0 [SD 6.8] years) were white (84.3%), female (55.8%; 44.2% male) Medicare beneficiaries (89.4%), resided in the South (53.7%), and received their first administration of lecanemab in an urban setting (93.3%) (Table 1).

Common comorbidities observed among lecanemab users included dyslipidemia (54.4%), hypertension (45.7%), and sleep disorders (25.2%) (Table 1). The prevalence of type 2 diabetes, as defined by International Classification of Diseases codes, was 15.2% ($n = 481$, data not shown). More than half (57.6%) of lecanemab users were using other medications before treatment initiation, mostly antidepressants (45.5%) or benzodiazepines (17.0%). Use of prescription antiplatelets and anticoagulants during the baseline period was observed in 4.1% and 3.7% of patients, respectively (Fig. 1). Demographics and clinical characteristics were generally similar in the closed claims cohort (Table 1 and Fig. 1).

Diagnostic Patterns

In the 30 days before and including the index date, diagnoses of AD (76.5%) were more common than diagnoses of MCI (6.0%; data not shown), whereas during the 12-month baseline period, diagnoses of both AD (83.8%; 19.4% early onset AD) and MCI (60.8%) were common (Fig. 1). Mean time from the earliest observed diagnosis of AD or MCI to the first lecanemab administration was 4.9 (SD 4.4) months among

Table 1 Characteristics of patients initiating treatment with lecanemab

	Overall study sample *N* = **3155**	**Closed claims cohort** *N* = **515**
Age, years, mean ± SD [median]	75.0 ± 6.8 [76]	73.6 ± 7.6 [75]
< 50 years	26 (0.8)	4 (0.8)
50–59 years	103 (3.3)	34 (6.6)
60–64 years	142 (4.5)	40 (7.8)
≥ 65 years	2884 (91.4)	437 (84.9)
Sex, *n* (%)		
Female	1762 (55.8)	321 (62.3)
Male	1393 (44.2)	194 (37.7)
Region, *n* (%)		
South	1693 (53.7)	231 (44.9)
West	588 (18.6)	59 (11.5)
Northeast	447 (14.2)	142 (27.6)
Midwest	425 (13.5)	82 (16.0)
Unknown	2 (0.1)	1 (0.2)
Race/ethnicity,[a] *n* (%)		
White	2661 (84.3)	419 (81.4)
Hispanic or Latino	150 (4.8)	18 (3.5)
Black or African American	67 (2.1)	14 (2.7)
Asian or Pacific Islander	46 (1.5)	4 (0.8)
Other	47 (1.5)	8 (1.6)
Unknown	184 (5.8)	52 (10.1)
Insurance plan type, *n* (%)		
Medicare	2822 (89.4)	415 (80.6)
Fee-for-service	1792 (56.8)	35 (6.8)
Advantage	981 (31.1)	380 (73.8)
Unknown	49 (1.6)	0 (0.0)
Commercial	303 (9.6)	99 (19.2)
Medicaid	12 (0.4)	1 (0.2)
Unknown	18 (0.6)	0 (0.0)
Service area type,[b] *n* (%)		
Urban	2944 (93.3)	456 (88.5)

Table 1 continued

	Overall study sample $N = 3155$	Closed claims cohort $N = 515$
Rural	163 (5.2)	32 (6.2)
Unknown	48 (1.5)	27 (5.2)
Most common comorbidities,[c] *n* (%)		
Dyslipidemia	1715 (54.4)	356 (69.1)
Primary hypertension	1442 (45.7)	264 (51.3)
Sleep disorders	794 (25.2)	162 (31.5)
Joint disorders	766 (24.3)	154 (29.9)
Dorsalgia	704 (22.3)	138 (26.8)

Characteristics were assessed on the index date (i.e., first medical or pharmacy claim for lecanemab), unless otherwise specified

ICD-10-CM International Classification of Diseases, tenth revision, clinical modification; *N* number; *SD* standard deviation

[a]Race and ethnicity were captured as mutually exclusive categories in the Komodo Research Database

[b]Service area type was defined by the Komodo Research Database as an indicator of the location of service, based on zip code and state. Komodo Health follows Centers for Medicare & Medicaid Services' definition and billing guidance to determine rural or urban designation

[c]Comorbidities are evaluated as the most frequent primary or secondary diagnosis based on 3-character ICD-10-CM diagnosis codes on medical claims observed on the index date or during the 12-month baseline period

patients with a diagnosis in January 2023 (accelerated approval date) or onwards and 2.1 (SD 2.8) months among patients with a diagnosis in July 2023 (traditional approval date) or onwards (Table 2).

Use of AD Symptomatic Medications

During the baseline period, most patients (67.6%) used symptomatic AD medications (i.e., acetylcholinesterase inhibitors and/or memantine) during the baseline period, with donepezil (54.2%) and memantine HCl (31.6%) as the most common agents observed. Use of rivastigmine, galantamine, and memantine/donepezil was infrequent (< 7%) (Fig. 1). Similar AD symptomatic medication use was observed before lecanemab initiation among the closed claims cohort (Fig. 1).

Use of symptomatic AD agents following lecanemab initiation was observed in 52.4% of patients. Donepezil was the most frequently observed agent (36.9%), followed by memantine HCl (24.1%). Fewer than half (43.8%) of patients used concomitant medications, including antidepressants (34.9%) and benzodiazepines (8.8%). The proportion of patients treated with prescription antiplatelets and anticoagulants was low (2.5% and 2.1%, respectively) (Table 2).

MRI Examinations

It is possible that some diagnostic and monitoring procedures were not captured, such as MRI examinations. For example, in the overall study sample, 61.6% of patients had at least one all-cause brain MRI recorded during the baseline period in the database, and 50.8% of patients had at least one MRI examination recorded after the index date (data not shown). Among patients with at least one MRI examination after the index date, mean time from lecanemab

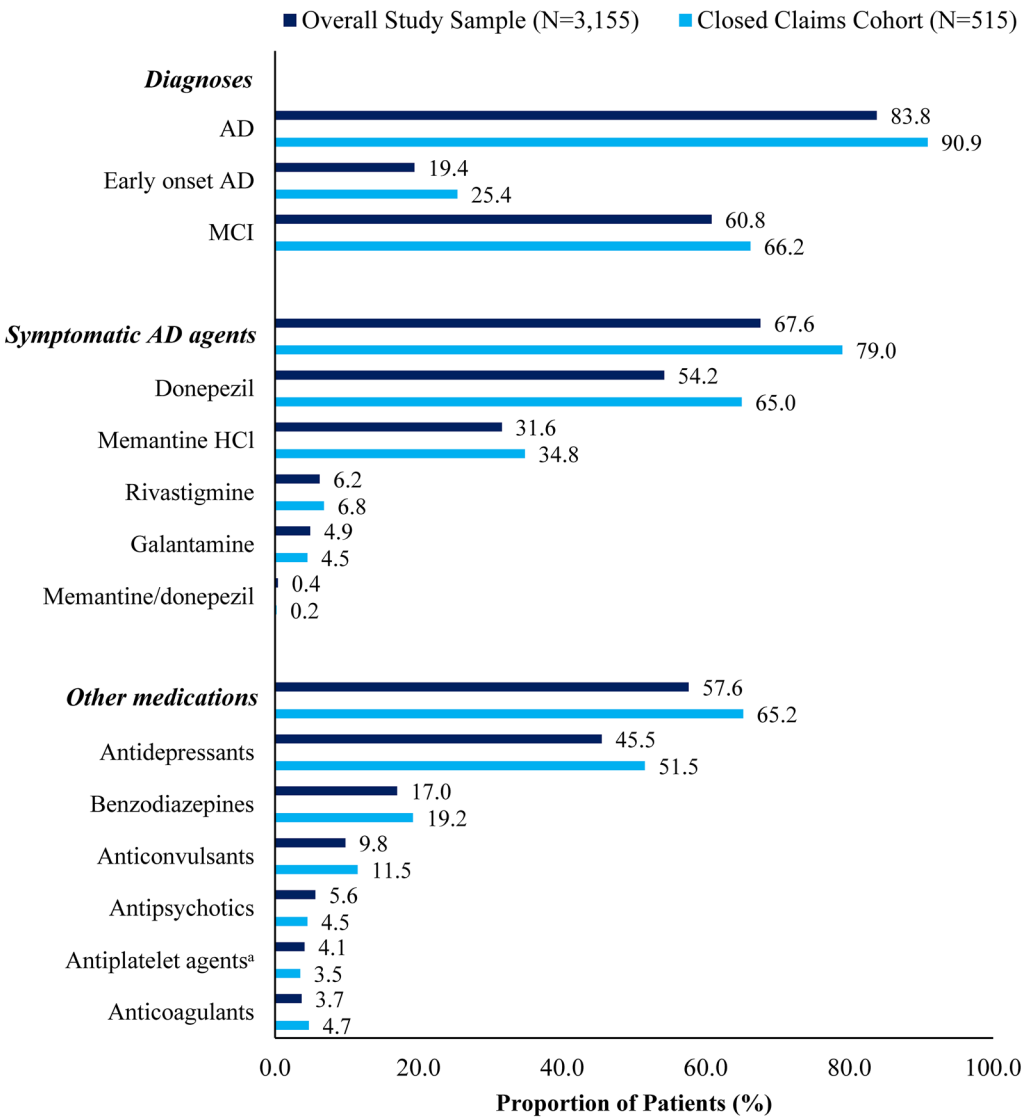


Fig. 1 Diagnoses, procedures, and medications used during the baseline period. *AD* Alzheimer's disease, *MCI* mild cognitive impairment. [a]Only prescription antiplatelets were evaluated

initiation to the first MRI monitoring date was 47.4 (SD 23.1) days.

Lecanemab Treatment Patterns

In the overall study sample, the mean observation period following lecanemab initiation was 138.8 (SD 88.8) days. The mean number of administrations of lecanemab per patient per month (PPPM) was 1.9 (SD 0.7), with 16.5 (SD 9.2) days between consecutive administrations on average. Times between the 4th and 5th administration, 6th and 7th administration, and 13th and 14th administration were similar, with a median of 14 days (Table 2). Persistence to lecanemab was 87.6% at the fourth month following initiation among patients with at least two lecanemab administrations (Fig. 2). The proportion of patients initiating lecanemab increased over time, with a notable rise observed starting from July 2023 (traditional approval date) (Supplementary Fig. S1). Lecanemab

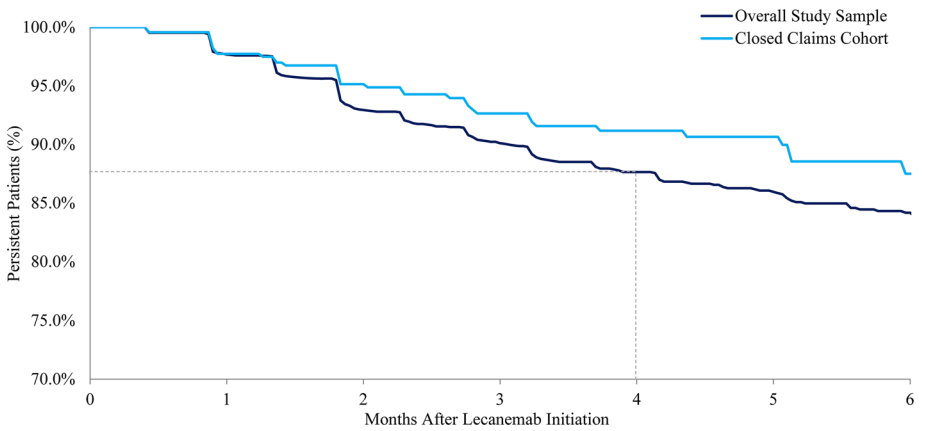
Table 2 Treatment patterns following lecanemab initiation among patients with ≥ 2 lecanemab administrations

Treatment patterns	Overall study sample *N* = 2754	Closed claims cohort *N* = 463
Time from earliest observed AD or MCI diagnosis to index date, months, mean ± SD [median]		
Diagnosis in January 2023 or onwards	4.9 ± 4.4 [4]	6.5 ± 4.4 [6]
Diagnosis in July 2023 or onwards	2.1 ± 2.8 [0]	1.8 ± 2.6 [0]
Observation period, days, mean ± SD [median]	138.8 ± 88.8 [122]	130.3 ± 78.8 [118]
Number of lecanemab administrations, mean ± SD [median]		
Per patient	7.7 ± 5.2 [6]	7.3 ± 4.9 [6]
PPPM	1.9 ± 0.7 [2]	1.9 ± 0.7 [2]
Time between lecanemab administrations,[a] days, mean ± SD [median]		
Consecutive administrations	16.5 ± 9.2 [14]	16.5 ± 9.7 [14]
Between 4th and 5th administration	16.9 ± 11.6 [14]	15.9 ± 6.6 [14]
Between 6th and 7th administration	16.4 ± 9.4 [14]	17.0 ± 10.6 [14]
Between 13th and 14th administration	16.1 ± 7.9 [14]	14.4 ± 2.6 [14]
Time to first brain MRI after lecanemab initiation, days, mean ± SD [median]	47.4 ± 23.1 [48]	44.7 ± 18.8 [47]
Any use of symptomatic AD agents, *n* (%)	1443 (52.4)	298 (64.4)
Donepezil	1017 (36.9)	222 (47.9)
Memantine HCl	664 (24.1)	128 (27.6)
Rivastigmine	134 (4.9)	27 (5.8)
Galantamine	96 (3.5)	15 (3.2)
Memantine/donepezil	8 (0.3)	1 (0.2)
Concomitant medications, *n* (%)	1206 (43.8)	233 (50.3)
Antidepressants	961 (34.9)	192 (41.5)
Benzodiazepines	242 (8.8)	43 (9.3)
Anticonvulsants	174 (6.3)	35 (7.6)
Antiplatelets[b]	68 (2.5)	12 (2.6)
Anticoagulants	58 (2.1)	9 (1.9)

AD Alzheimer's disease, *MCI* mild cognitive impairment, *MRI* magnetic resonance imaging, *N* number, *PPPM* per patient per month, *SD* standard deviation

[a]Evaluated among patients with sufficient follow-up duration (i.e., those who had ≥ 1 lecanemab administration, ≥ 5 administrations, ≥ 7 administrations, and ≥ 14 administrations, respectively)

[b]Only prescription antiplatelets were evaluated



Overall Study Sample							
Patients at risk	2,754	2,515	2,023	1,489	1,132	813	564
Patients discontinued[b]	0	61	171	224	261	280	295
Closed Claims Cohort							
Patients at risk	463	421	348	270	196	136	79
Patients discontinued[b]	0	10	20	28	32	33	37

Fig. 2 Persistence to lecanemab among patients with ≥ 2 administrations[a]. [a]Persistence to lecanemab at 4 months following treatment initiation is indicated in the figure for the overall study sample. [b]Cumulative number of patients who had discontinued since treatment initiation

treatment patterns were generally consistent between the overall cohort and the closed claims cohort.

DISCUSSION

This real-world study is the first to comprehensively characterize patients initiating lecanemab and examine lecanemab utilization patterns in the USA. Lecanemab treatment appeared to be initiated in appropriate patient populations and used according to the FDA-approved prescribing information in both the overall study sample and closed claims cohort [19], which are important for patient safety. Compliance to baseline MRI monitoring recommendations was descriptively higher in the closed claims cohort before and after lecanemab initiation, highlighting the complete capture of patient information in closed claims. Notably, lecanemab initiation was rare among racial and ethnic minority groups, as well as in rural service areas. Treatment pathways and outreach programs may help improve lecanemab access for underserved communities.

In the present study, there was a high prevalence of both AD and MCI diagnoses during the 12-month period prior to lecanemab initiation. Following the traditional FDA approval of lecanemab, average time from diagnosis of AD or MCI to treatment initiation reduced by approximately 3 months, suggesting that full approval may have enhanced the process for patients to access timely treatment. Additionally, most patients in the closed claims cohort received a baseline head MRI, aligned with prescribing recommendations prior to initiating lecanemab. Following initiation, the average time to the first follow-up MRI examination (47.4 days) was in line with the required MRI monitoring schedule prior to the 5th administration. Consistent with FDA-approved prescribing information, patients received an average of two lecanemab administrations PPPM, with a median of 14 days between administrations, including between administrations when follow-up MRI examinations are recommended by the FDA (prior to the 5th, 7th, and 14th infusions). Despite the lack of safety outcomes in claims data, these results suggest that neither MRI monitoring nor possible adverse events interfered with lecanemab

dosing. Lecanemab initiation in this study increased nine-fold from July 2023 (i.e., traditional approval date) and tripled from October 2023, (i.e., CMS policy change) underscoring the rapid uptake of this novel medication following promising regulatory changes for the diagnosis and treatment of patients with AD.

Additionally, this study is the first to quantify real-world persistence to lecanemab, which was approximately 90% in both the overall study sample and closed claims cohort 4 months following treatment initiation. However, reasons for lecanemab treatment discontinuation could not be evaluated in this study because of limitations of claims data. Previous research suggests that persistence rates of symptomatic AD medications, such as cholinesterase inhibitors, range between 57% and 69% at 6 months [25]. While our results found that symptomatic AD medications were common in the study population prior to lecanemab initiation, limited proportions of patients received other medications, such as antithrombotics. Further research is needed to examine the real-world impact of lecanemab initiation among patients requiring these medications.

Despite Hispanic or Latino and Black or African American populations having higher rates of AD compared to white populations [3, 26], these two minority groups represented very small proportions (4.8% and 2.1%, respectively) of the study population treated with lecanemab. Most patients in the current analysis were white and treated in urban settings, suggesting that treatment pathways and outreach programs are needed to improve health equity and extend lecanemab access to minority populations and underserved communities. Furthermore, while the reported prevalence of AD is slightly lower in rural versus urban settings, this difference is likely due to an underdiagnosis of AD and a lack of access to care in rural counties [27]. CMS recently launched the national Guiding and Improved Dementia Experience (GUIDE) model to help coordinate access to care for patients with AD [28]. As fragmented care disproportionately affects marginalized racial and ethnic populations, the GUIDE model aims to reduce disparities in access to AD care services. Incorporating lecanemab as a treatment option within such a model could likewise reduce disparities in lecanemab access. Similarly, connecting patients in rural communities that lack medical specialists with an expanded workforce that includes infusion nurses and radiologists will be required to offer lecanemab outside of urban centers [1]. Although addressing the overarching challenges with healthcare system readiness for intravenous AD treatments is needed to improve the real-world uptake of lecanemab [29, 30], the availability of a subcutaneous formulation may introduce a convenient treatment paradigm, reducing the need for outpatient treatment administrations and enhancing treatment persistence [31]. Despite increasing access since full FDA approval, barriers such as limited health system readiness may cause delay between symptom onset and lecanemab initiation. With the advent of disease-modifying therapies for the treatment of AD, timely diagnosis and treatment initiation in clinical practice settings is crucial for optimizing patient care in early stages of this disease, facilitating prolonged quality of life and slowing the decline in cognitive and behavioral functions [32, 33].

This study has certain limitations. Continuous enrollment of patients in the open claims data was not guaranteed, and the use of claims data derived from various sources may result in data fragmentation. Inherent to all retrospective studies using real-world administrative claims, the data may be subject to coding inaccuracies or omissions of certain clinical interactions, such as non-billable services or off-label treatment. As a result, it is possible that some diagnoses, procedures, and medications may not have been captured, such as MRI examinations, amyloid testing, and APOE genetic testing. Additionally, certain MRI scans and AD or MCI diagnoses may not have been captured, if they occurred prior to the 12-month baseline period. Diagnostic codes do not allow the determination of AD severity, since clinical data that may have provided additional AD-related context, such as amyloid positivity and cognitive test results, were not available. Longitudinal data and specific geographic service locations were also unavailable in the database. Despite these limitations, findings

from this study provide novel insights on contemporary lecanemab utilization patterns in the real-world shortly following its approval. Future research may shed light on how these findings compare to utilization patterns in other real-world settings and how they may evolve over longer periods of time. Investigating patient-reported outcomes and the occurrence of clinical events such as ARIA would also be of interest in future research.

CONCLUSION

Findings from this retrospective study suggest that real-world lecanemab initiation and treatment patterns are consistent with FDA-approved prescribing information. Limited lecanemab use in rural settings and minority populations may require pathways and outreach programs to address the unmet need for treatment. As lecanemab access in the USA continues to expand, future studies are warranted to evaluate the impact of lecanemab treatment on patient outcomes.

Medical Writing/Editorial Assistance. Medical writing assistance was provided by professional medical writers, Molly Gingrich, MSc, and Loraine Georgy, PhD, MWC, employees of Group d'analyse, SRI, a consulting company that has provided paid consulting services to Eisai, Inc. as well as by Cody Patton, BSc, an independent consultant.

Author Contributions. All the named authors (Marwan N. Sabbagh, Chenyue Zhao, Malena Mahendran, Se Ryeong Jang, François Laliberté, Hideki Toyosaki, Kaixin Zhang, Feride Frech, and Kavita V. Nair) have made substantial contributions to the conception or design of the study, or the acquisition, analysis, or interpretation of data, drafting the manuscript and revising it critically for important intellectual content, and have provided final approval of this version to be published and agree to be accountable for all aspects of the work.

Funding. This study was sponsored by Eisai Inc. (Nutley, NJ, USA) and Biogen (Cambridge, MA, USA), including funding for the journal's Rapid Service Fees.

Data Availability. The data that support the findings of this study are available from Komodo Health. Restrictions apply to the availability of these data, which were used by the authors with permission and under license for this study.

Declarations

Conflict of Interest. Marwan N. Sabbagh has stock or stock options in NeuroTau, uMethod Health, Versanum, Athira, TransDermix, Seq BioMarque, NeuroReserve, Cortexyme/Quince Therapeutics, Lighthouse Therapeutics. Marwan N. Sabbagh is a consultant for Alzheon, Biogen, Roche-Genentech, Eisai Inc., KeifeRx, Lilly, Synaptogenix, NeuroTherapia, T3D, Signant Health, Novo Nordisk. Marwan N. Sabbagh receives royalties from Humanix. Marwan N. Sabbagh is a Board of Director for EIP Pharma. Marwan N. Sabbagh is Editor in Chief of *Neurology and Therapy*. Marwan N. Sabbagh was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Kavita V. Nair is a consultant/and has received an honorarium from Eisai, Inc., Sanofi, Genentech, TG Therapeutics, AstraZeneca, Alnylam, Amgen, Alzheon, MJH Lifesciences, American Academy of Neurology, ICER and Applied Patient Experience. Chenyue Zhao, Feride Frech, Se Ryeong Jang, and Hideki Toyosaki are employees of Eisai Inc. Malena Mahendran, Kaixin Zhang, and François Laliberté are employees of Group d'analyse, SRI, a consulting company that has provided paid consulting services to Eisai Inc. and Biogen Inc., which funded the development and conduct of this study and short communication.

Ethical Approval. The study was considered exempt research under 45 CFR § 46.104(d)(4) as it involved only the secondary use of data that were de-identified in compliance with the Health Insurance Portability and Accountability

Act (HIPAA), specifically, 45 CFR § 164.514. The data used for this analysis were provided with permission and under license from Komodo Health.

REFERENCES

1. Alzheimer's Association. 2024 Alzheimer's disease facts and figures. Alzheimers Dement. 2024;20(5):3708-821

2. DeTure MA, Dickson DW. The neuropathological diagnosis of Alzheimer's disease. Mol Neurodegener. 2019;14(1):32.

3. Rajan KB, Weuve J, Barnes LL, McAninch EA, Wilson RS, Evans DA. Population estimate of people with clinical Alzheimer's disease and mild cognitive impairment in the United States (2020–2060). Alzheimers Dement. 2021;17(12):1966–75.

4. Villemagne VL, Burnham S, Bourgeat P, et al. Amyloid β deposition, neurodegeneration, and cognitive decline in sporadic Alzheimer's disease: a prospective cohort study. Lancet Neurol. 2013;12(4):357–67.

5. Porsteinsson AP, Isaacson RS, Knox S, Sabbagh MN, Rubino I. Diagnosis of early Alzheimer's disease: clinical practice in 2021. J Prev Alzheimers Dis. 2021;8(3):371–86.

6. Alzheimer's Association. Special report—more than normal aging: Understanding mild cognitive impairment 2022. https://www.alz.org/media/Documents/alzheimers-facts-and-figures-special-report-2022.pdf. Accessed 5 Nov 2024.

7. Ward A, Tardiff S, Dye C, Arrighi HM. Rate of conversion from prodromal Alzheimer's disease to Alzheimer's dementia: a systematic review of the literature. Dement Geriatr Cogn Dis Extra. 2013;3(1):320–32.

8. Zhang J, Zhang Y, Wang J, Xia Y, Zhang J, Chen L. Recent advances in Alzheimer's disease: mechanisms, clinical trials and new drug development strategies. Signal Transduct Target Ther. 2024;9(1):211.

9. Tahami Monfared AA, Phan NTN, Pearson I, et al. A systematic review of clinical practice guidelines for Alzheimer's disease and strategies for future advancements. Neurol Ther. 2023;12(4):1257–84.

10. Winslow BT, Onysko MK, Stob CM, Hazlewood KA. Treatment of Alzheimer disease. Am Fam Phys. 2011;83(12):1403–12.

11. Cummings J, Fox N. Defining disease modifying therapy for Alzheimer's disease. J Prev Alzheimers Dis. 2017;4(2):109–15.

12. Cummings J. Anti-amyloid monoclonal antibodies are transformative treatments that redefine Alzheimer's disease therapeutics. Drugs. 2023;83(7):569–76.

13. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. N Engl J Med. 2023;388(1):9–21.

14. Mintun MA, Lo AC, Evans CD, et al. Donanemab in early Alzheimer's disease. N Engl J Med. 2021;384(18):1691–704.

15. Alzheimer's Association. 2024 Alzheimer's disease facts and figures 2024. https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf. Accessed 5 Nov 2024.

16. McDade E, Cummings JL, Dhadda S, et al. Lecanemab in patients with early Alzheimer's disease: detailed results on biomarker, cognitive, and clinical effects from the randomized and open-label extension of the phase 2 proof-of-concept study. Alzheimers Res Ther. 2022;14(1):191.

17. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. Alzheimers Res Ther. 2021;13(1):80.

18. US Food & Drug Administration. FDA grants accelerated approval for Alzheimer's disease treatment 2023. https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-disease-treatment. Accessed 5 Nov 2024.

19. Eisai Inc. LEQEMBI™ (lecanemab-irmb) injection prescribing information 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s001lbl.pdf. Accessed 5 Nov 2024.

20. US Food & Drug Administration. FDA converts novel Alzheimer's disease treatment to traditional approval 2023. https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval. Accessed 6 Nov 2024.

21. Centers for Medicare & Medicaid Services. NCD 220.6.20 - beta amyloid positron emission tomography in dementia and neurodegenerative disease 2023. https://www.cms.gov/files/document/r12364cp.pdf. Accessed 6 Nov 2024.

22. Leqembi (lecanemab-irmb) highlights of prescribing information July 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s001lbl.pdf. Accessed 30 Oct 2024.

23. Komodo Health. Tracking the entire patient journey. https://www.komodohealth.com/hubfs/2022%20PDF%20Documents/220831_Komodo%20Healthcare%20Map_FINAL.pdf. Accessed 19 Nov 2024.

24. Komodo Health Editorial Team. The difference between "open" and "closed" claims data (and why you need both) 2024. https://www.komodohealth.com/hubfs/_2024/Understanding_the_Differences_in_Open_and_Closed_Claims_Data.pdf. Accessed 19 Nov 2024.

25. Massoud F. Persistence with cholinesterase inhibitor treatment in Alzheimer's disease. Can J Neurol Sci. 2013;40(5):623–4.

26. Power MC, Bennett EE, Turner RW, et al. Trends in relative incidence and prevalence of dementia across non-Hispanic Black and White individuals in the United States, 2000–2016. JAMA Neurol. 2021;78(3):275–84.

27. Rahman M, White EM, Mills C, Thomas KS, Jutkowitz E. Rural-urban differences in diagnostic incidence and prevalence of Alzheimer's disease and related dementias. Alzheimers Dement. 2021;17(7):1213–30.

28. Guiding an improved dementia experience (GUIDE) model July 2024. https://www.cms.gov/priorities/innovation/innovation-models/guide. Accessed 30 Oct 2024.

29. Mattke S, Chen J, Hanson M. Is the US infusion capacity sufficient for the expected demand with the emergence of disease-modifying Alzheimer's treatments? Alzheimer's Association International Conference; Philadelphia, PA, 2024.

30. Silber A, Athavale A, Kulkarni A, O'Hara M, Mattke S, Bajaj PS. HSD48 US infusion center capacity to accommodate anti-amyloid treatments for Alzheimer's disease: A quantitative survey. Value in Health; 2024/06/01/2024. p. S229.

31. Willis BA, Penner N, Rawal S, Aluri J, Reyderman L. Subcutaneous (SC) lecanemab is predicted to achieve comparable efficacy and improved safety compared to lecanemab IV in early Alzheimer's disease (AD). Alzheimers Dement. 2023;19(S24):e082852.

32. Liss JL, Seleri Assuncao S, Cummings J, et al. Practical recommendations for timely, accurate diagnosis of symptomatic Alzheimer's disease (MCI and dementia) in primary care: a review and synthesis. J Intern Med. 2021;290(2):310–34.

33. Rasmussen J, Langerman H. Alzheimer's disease - why we need early diagnosis. Degener Neurol Neuromuscul Dis. 2019;9:123–30.