BRIEF REPORT

Lecanemab Therapy Use Patterns for Alzheimer's Disease Among Early Initiators in a Large National Health Plan

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ABSTRACT

Background: Lecanemab, an anti-amyloid monoclonal antibody, has been approved for treatment of early Alzheimer's disease. However, real-world data remain limited regarding use.

Methods: Using data from a large national health plan with primarily Medicare Advantage enrollees, we characterized demographic and clinical characteristics in the 6 months preceding the initial infusion among individuals who initiated lecanemab between 1/1/2023 and 06/30/2024. We also characterized the patterns of infusions and the timing of MRIs for safety monitoring following the initial infusion among initiators who had ≥ 3 months of follow-up. We further assessed trends in lecanemab use between 1/1/2023 and 12/31/2024.

Results: Of the 195 lecanemab initiators, the average age was 74.6 (SD = 5.5) years, 62.1% were female, 87.7% were White, 4.1% were Black, 1.5% were Hispanic, and 98.5% were on a Medicare Advantage plan. Almost all initiators resided in nonrural areas (96.4%); 2.6% used anticoagulants, and 1.5% used antiplatelets. Among the 119 initiators who had ≥ 3 months of follow-up, 40 (33.6%) received 7 total infusions, the expected number of infusions based on the recommended schedule of every 2 weeks. From the initial infusion, the average number of days to the first MRI was 47.1 (SD = 15.8), and to the second MRI scan was 73.4 (SD = 12.0) days, consistent with the recommended schedule. During 2023–2024, there were 526 patients who had ever received lecanemab. The increase in new initiators was modest over 2024, with only 43 more initiators during the final (*n* = 137) versus the first quarter (*n* = 94) of 2024.

Conclusions: This study demonstrated slow uptake of lecanemab among Medicare Advantage beneficiaries. Adherence to the ideal treatment schedule was less than recommended. Early lecanemab users were not representative of the population likely eligible for treatment nationally. Further research is warranted to track longer-term trends in utilization, as well as reasons for treatment interruption or discontinuation in real-world populations.

1 | Introduction

Anti-amyloid monoclonal antibodies—lecanemab (2023) and donanemab (2024)—have been approved for the treatment of early Alzheimer's disease (AD) [1, 2]. However, questions exist around their use in real-world settings, including the rate of uptake and utilization patterns. Early utilization patterns of these novel therapies have been described for single memory clinics [3]. Other studies have employed aggregated data from multiple health systems [4], multiple insurance plans [5], or

Summary

- Key points
  - Uptake of lecanemab in Medicare Advantage beneficiaries has been slow.
  - Early initiators of lecanemab are not representative of patients with early Alzheimer's disease nationally.
  - Among patients initiating lecanemab therapy, two thirds received fewer than the expected number of infusions over the first 3 months following the initial infusion.
- Why does this paper matter?
  - This study describes early initiators of lecanemab therapy, including patterns of treatment and safety monitoring, in a large U.S. health plan comprised largely of Medicare Advantage beneficiaries.

the population of Medicare fee-for-service beneficiaries [6]. However, little information is available regarding the use of these therapies in Medicare Advantage enrollees with AD. Enrollment in the Medicare Advantage program is rapidly growing [7], as are the number of enrollees with AD, underscoring the importance of better understanding the care these patients are receiving [8]. In the present study, we report on early initiators of lecanemab, including patterns of treatment and safety monitoring, and trends in use in a large national health plan comprised largely of Medicare Advantage beneficiaries.

2 | Methods

2.1 | Setting

This study was conducted in a national health plan with a large Medicare Advantage enrollment. In 2022 alone, 198,561 members had at least one diagnosis code for mild cognitive impairment or AD, suggesting that a large number of members were living with mild cognitive impairment or AD (International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification [ICD-10-CM] codes: mild cognitive impairment G31.84; AD G30.0, G30.1, G30.8, G30.9) [9]. For the purpose of this study, we identified users of lecanemab based on a claim with Healthcare Common Procedure Coding System (HCPCS) code J0174 or National Drug Code (NDC) codes (62856021201, 62856021501).

2.2 | Characteristics of Early Initiators

To characterize initiators of lecanemab therapy, we identified individuals who initiated therapy between January 1, 2023 and June 30, 2024 and who had ≥ 6 months of continuous enrollment with medical and drug coverage prior to the initial lecanemab infusion. We characterized the following demographic and clinical characteristics in the 6 months preceding the initial infusion: age; sex; race/ethnicity; geographic region; insurance type; rural–urban area; combined Charlson/Elixhauser comorbidity score [10]; frailty index [11]; presence of ICD-10-CM diagnosis codes for mild cognitive impairment or AD; use of symptomatic

drugs for AD, anticoagulants, and antiplatelets; and the performance of Apolipoprotein E (APOE) genetic testing.

In addition, we also compared the age, sex, race, and ethnicity distribution of this cohort with the distribution of participants in the pivotal Clarity-AD trial [12].

2.3 | Patterns of Infusions and Safety Monitoring

To assess the pattern of infusions and performance of brain MRIs following initiation, we identified individuals who initiated lecanemab therapy between January 1, 2023 and June 30, 2024, with ≥ 6 months of continuous enrollment with medical and drug coverage prior to the initial infusion and ≥ 3 months of follow-up after the initial infusion. We characterized patients according to the number of infusions received and assessed the timing of the first and second MRI scans following the initial infusion. According to the recommended infusion schedule (once every 2 weeks in the first 18 months), patients would ideally receive 7 infusions over 3 months and have 2 MRI scans performed, one prior to the 5th infusion and another prior to the 7th infusion [13, 14].

2.4 | Overall Trends in Use of Lecanemab

To assess overall trends in lecanemab use, we also identified all individuals who initiated lecanemab between January 1, 2023 and December 31, 2024. We determined the number of initiators in each quarter and cumulative counts over this time period.

Analyses were conducted using RStudio v2024.12.1. The study was approved by Harvard Pilgrim Health Care institutional review board and followed the STROBE reporting guideline.

3 | Results

3.1 | Characteristics of Early Initiators

Of the 195 lecanemab initiators who met the inclusion criteria, the average age was 74.6 years (SD = 5.5), 62.1% were female, 87.7% were White, 4.1% were Black, 1.5% were Hispanic, and 98.5% were on a Medicare Advantage plan. Almost all patients resided in nonrural areas (96.4%). During the 6-month period preceding the initial infusion, 72.8% used symptomatic drugs for AD, 2.6% used anticoagulants, and 1.5% used antiplatelets. We identified a healthcare claim for APOE testing in 41.5% of initiators. Compared to Clarity-AD trial participants [12], health plan members receiving lecanemab were older and more likely to be female, White, and using symptomatic drugs for AD (Table 1).

3.2 | Patterns of Infusions and Safety Monitoring

Among the 119 initiators who had ≥ 3 months of follow-up, only 40 (33.6%) received 7 infusions, the expected number according to the recommended schedule of every 2 weeks (Figure 1) [13, 14]. From the initial infusion, the average time to the first

TABLE 1 | Select characteristics of initiators of lecanemab for AD between January 2023 and June 2024.

Characteristic	Current study (N=195)		Clarity-AD[a] (N=1734)	
	N	%	N	%
Age, year, mean (SD)	74.6	5.5	71.2	7.8
Sex				
Female	121	62.1	907	52.3
Male	74	37.9	827	47.7
Race				
White	171	87.7	1332	76.8
Black	8	4.1	44	2.5
Other or unknown	16	8.2	358	20.6
Hispanic				
Yes	3	1.5	215	12.4
No	181	92.8		
Unknown	11	5.6		
Insurance type				
Medicare Advantage	192	98.5		
Commercial	2	1.0		
Medicaid	1	0.5		
Geographical region				
South-Atlantic	141	72.3		
Midwest	35	17.9		
Mountain	12	6.2		
Other	7	3.6		
Rural–urban commuting area[b]				
Urban	136	69.7		
Suburban	52	26.7		
Rural	7	3.6		
Combined comorbidity score[c], mean (SD)	2.75	1.90		
Kim's claims-based frailty index[d], mean (SD)	0.20	0.04		
Clinical subgroup[e]				
Presence of MCI diagnosis codes	192	98.5	528	61.5
Presence of ADRD diagnosis codes	193	99.0	331	38.5
Use of anticoagulants	5	2.6		
Use of antiplatelets	3	1.5		

(Continues)

TABLE 1 | (Continued)

Characteristic	Current study (N=195)		Clarity-AD[a] (N=1734)	
	N	%	N	%
Use of medications for symptoms of AD	142	72.8	447	52.0
Apolipoprotein E (APOE) testing				
Presence of APOE testing	81	41.5		
Days of most recent testing before initial infusion, mean (SD)	86.3	42.0		

Note: Clinical characteristics (combined comorbidity score, frailty index, MCI or ADRD diagnosis codes), use of drugs (anticoagulants, antiplatelets, medications for symptoms of AD [donepezil, rivastigmine, galantamine, memantine, or their combinations]), APOE testing was assessed in the 6 months prior to initial infusion.
Abbreviations: AD, Alzheimer's disease; ADRD, Alzheimer's disease and related dementias; MCI, mild cognitive impairment; SD, standard deviation.
[a]The characteristics of the overall participants in the Clarity-AD trial are derived using the statistics presented in Table 1 of the trial publication [11].
[b]Derived using zip codes, https://www.census.gov/newsroom/blogs/random-samplings/2022/12/redefining-urban-areas-following-2020-census.html.
[c]The Charlson-Elixhauser combined comorbidity score was originally developed to predict mortality risk in older patients [9]; we used the score as a proxy for general health status.
[d]The claims-based frailty index measures frailty using information regarding health deficits documented in healthcare claims (e.g., diagnoses, procedures, medications). It has been validated against clinical measures of frailty and adverse health outcomes [10].
[e]In the current study, the proportions show those with diagnosis codes required by CMS billing for lecanemab: MCI (G31.94), AD (G30.0, G30.1, G30.8, G30.9); while in Clarity-AD, the proportions show individuals had these conditions based on clinical assessment.
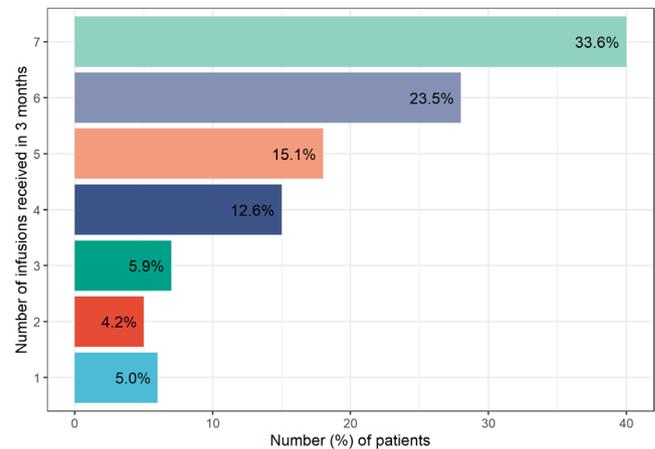
FIGURE 1 | Patterns of lecanemab infusions within 3 months after initiation. Figure shows the number of infusions within 3 months after initiation of lecanemab therapy among 119 patients who initiated treatment between January 1, 2023 and June 30, 2024 and who had at least 3 months of follow-up time after initial initiation.

MRI scan was 47.1 (SD = 15.8) days, and to the second MRI scan was 73.4 (SD = 12.0) days, consistent with the recommended schedule of receiving one scan prior to the 5th infusion (i.e., before 56 days following the first infusion), and another prior to the 7th infusion (i.e., before 84 days following the first infusion) [13, 14].
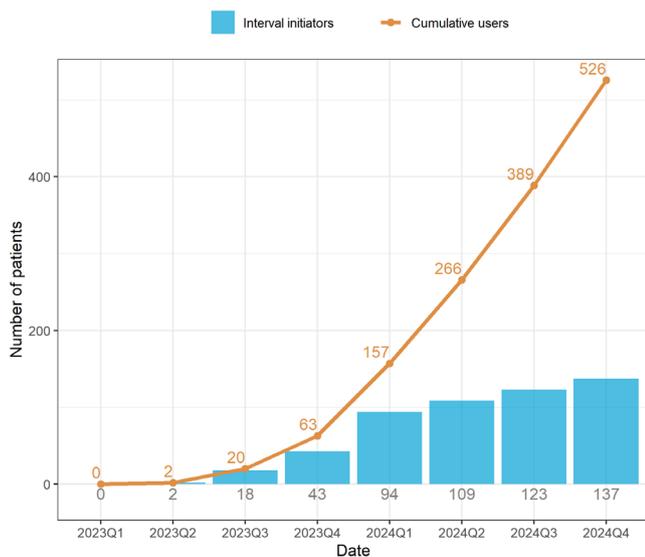
FIGURE 2 | Trends in lecanemab initiations in a large national health plan comprised largely of Medicare Advantage beneficiaries. Figure shows the number of health plan members who initiated lecanemab therapy in each quarter of 2023–2024 separately (interval initiators; blue bars) and cumulatively (cumulative users; orange dots).

3.3 | Overall Trends in Use of Lecanemab

During January 1, 2023–December 31, 2024, we identified 526 patients who had received lecanemab therapy. Trends in lecanemab utilization over the study period are depicted in Figure 2. The number of initiators more than doubled from the fourth quarter of 2023 ($n = 43$) to the first quarter of 2024 ($n = 94$). The increase in new initiators was modest over 2024, with 137 new initiators during the final quarter of 2024, an absolute increase of only 43 compared with the first quarter of that year.

4 | Discussion

In a large national health plan comprised primarily of Medicare Advantage beneficiaries, uptake of lecanemab was slow. This finding is consistent with other reports relating to utilization patterns in different study populations [3–6]. The reasons for slow uptake could include concerns about the modest benefits of therapy, risks of amyloid-related imaging abnormalities (ARIA) and associated symptoms, and the high costs of lecanemab [15]. The time, resources, and infrastructure necessary to scale up specialized, multidisciplinary clinics in health systems to deliver anti-amyloid therapy efficiently and safely may also be an explanation for slow uptake [16]. In addition, patient and caregiver treatment burden may be another explanation in view of the infusion schedule and the need for serial MRIs to monitor for ARIA.

In our study, only a third of patients received the recommended number of infusions over the first 3 months of therapy, suggesting that two thirds of patients may have interrupted, delayed, or discontinued treatment. Treatment interruption and discontinuation were also reported by other studies [5, 6]; however, the reported rates are not directly comparable due to the different definitions. Potential explanations for this finding of less-than-ideal adherence could be discontinued or delayed treatment due to adverse effects, or a "perceived" lack of demonstrable clinical benefit by patients and caregivers.

There is obvious concern about the risk of ARIA with use of anti-amyloid agents, but we were unable to identify the occurrence of ARIA using claims data due to the lack of validated claims-based algorithms (i.e., a set of specific rules or logic consisting of diagnoses, procedures, medications and/or other services to classify certain events or conditions based on the claims data). The timing of MRIs for monitoring suggests that real-world practice largely comports with recommendations. It is also interesting that very few patients were on anticoagulants, as these patients are felt to be at substantially higher risk of ARIA-H and intracerebral hemorrhage [14].

One important consideration regarding lecanemab therapy is the need for APOE genetic testing to inform benefit–risk considerations because ApoE ε4 gene carriers, especially homozygous individuals (which is approximately 15% of the AD population), are at the highest risk of ARIA, symptomatic ARIA, and recurrent ARIA [13]. However, APOE testing is recommended, but not a prerequisite for initiation of therapy in the US. An FDA-authorized test for the detection of ApoE ε4 alleles to identify patients at risk of ARIA if treated with lecanemab is not currently available. This may explain why fewer than 50% of initiators received APOE testing in our study, although we could not rule out incomplete capture of information on the performance of APOE testing among lecanemab initiators.

Early initiators differed from the participants in the Clarity-AD trial in age, gender, race-ethnicity, and the use of symptomatic drugs. These health plan members were not representative of patients nationally either; for example, in our study, early initiators among Medicare Advantage enrollees had a high prevalence of White individuals (87.7%), while Black and Hispanic individuals represented only 4.1% and 1.5%, respectively. However, AD impacts Black and Hispanic patients at rates that are twice and 1.5 times higher than in White patients [17–19]. Such findings are similar to those reported by other investigators [6]. Determining the reasons for these disparities requires further investigation but may relate to access to specialty care and treatment, preferences and uncertainties about the use of novel therapies, and costs. In addition, for patients living in rural areas, there may be special challenges in accessing healthcare facilities with diagnostic and treatment capabilities.

In summary, our study characterized lecanemab use in a national health plan among primarily Medicare Advantage beneficiaries, characteristics of early initiators, as well as patterns of treatment and safety monitoring. Further research is warranted to determine the reasons for treatment interruption or discontinuation, longer-term trends in and patterns of use, and comparative effectiveness and safety of different anti-amyloid therapies in real-world patient populations [20, 21].

Conflicts of Interest

Data Availability Statement

The data that support the findings of this study are available from the health plan. Restrictions apply to the availability of these data, which were used under license for the current study. Thus, the data are not publicly available.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.