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SHORT REPORT

# Demographic and clinical characteristics of initial patients receiving amyloid-targeting treatments in the United States after regulatory approval

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## Abstract

**INTRODUCTION:** Three treatments for Alzheimer's disease have been approved in the United States. Data are lacking on the characteristics of the initial treatment recipients.

**METHODS:** We identified treatment recipients in the full Medicare fee-for-service data for 2021 to 2023. We compared their age, sex, race/ethnicity, dual eligibility, comorbidities, and median household income and educational attainment in their residence's ZIP Code Tabulation Area (ZCTA) to those of the overall Medicare population aged 65+.

**RESULTS:** Treated patients were more likely to be non-Hispanic White (89% vs 82%) and less likely to be dually eligible (1% vs 8.8%). Average median household income ($97,136 vs $84,449) and proportion of residents with at least a bachelor's degree (41% vs 31%) were higher in treated patients' ZCTAs.

**DISCUSSION:** The first patients receiving amyloid-targeting treatment represent a more privileged subset. While needing to be confirmed with more data, these results point to the need for efforts to make access more equitable.

KEYWORDS
access to care, Alzheimer's disease, amyloid-targeting treatment, disparities, dually eligible, Medicare

## Highlights

- Little is known about the initial 924 patients receiving amyloid-targeting treatments in the United States from 2021 to 2023.
- They were more likely to be White and less likely to be dually eligible than the Medicare population.
- They resided in wealthier and more highly educated areas.
- Comorbidity burden was similar to that observed in clinical trials.
- Those initial results point to the need to improve equitable access to treatment.

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## 1 | INTRODUCTION

Three monoclonal antibodies that target amyloid deposits in early-stage Alzheimer's disease (AD) have been approved in the United States: aducanumab (June 7, 2021) through accelerated approval based on its ability to remove those amyloid deposits and lecanemab (July 6, 2023) and donanemab (July 2, 2024) through traditional approval, as their phase 3 trials also demonstrated a reduced rate of disease progression. In spite of the transformational nature of being the first treatments that target AD's underlying biology, their uptake has been reportedly slow: While the exact number of treated patients is unknown, a press release suggested that only around 5000 people have started treatment with lecanemab[1] in the first year of market availability in the United States. Multiple reasons might have contributed to the slow uptake, such as lack of health system preparedness,[2] uncertainty[3] about reimbursement for diagnostic tests and the treatment itself, and drawn-out decision processes of large, integrated delivery systems about formula inclusion.

In addition, there are concerns about equitable access,[4] as the experience with the introduction of, for example, treatments for HIV[5,6] and hepatitis C[7,8] demonstrated that early adopters tended to be of higher socioeconomic status. Against this background, we analyzed the characteristics of the initial patients, who started these treatments in real-world practice after FDA approval. We used Medicare data for the full fee-for-service population to describe their demographic and clinical characteristics.

### RESEARCH IN CONTEXT

1. **Systematic review**: We reviewed the peer reviewed and "gray" literature (eg, conference abstracts and trade reports). We could only identify one analysis from a memory clinic, which is cited, on the composition of the initial patients, who received amyloid-targeting treatments for AD.
2. **Interpretation**: Our findings from this analysis of Medicare data shows that the initially treated patients represent a more privileged cohort even though disease burden is higher in disadvantaged populations. Compared to the overall Medicare population, treatment recipients were more likely to be White and less likely to be dually eligible for Medicaid and Medicare and resided in wealthier and more highly educated areas.
3. **Future directions**: While the findings will need to be confirmed with additional data as treatments become more routinely used, our results point to the need to improve equitable access to treatment.

## 2 | METHODS

We used the data for the full Medicare fee-for-service population, the component of the Medicare program in which Medicare pays for services directly, spanning January 1, 2021, through December 31, 2023 (the most recent year available), and restricted to beneficiaries aged 65+ with nearly continuous coverage. Data for the Medicare Advantage population (51% of beneficiaries in 2023) were not yet available at the time of the analysis. In the Medicare Advantage program, Medicare pays for the beneficiaries' policies administered by a private health insurer. Treatment initiation was identified based on the Healthcare Common Procedure Coding System (HCPCS) billing codes for aducanumab (J0172) and lecanemab (J0174). Donanemab (J0175) was only approved in 2024 and thus not captured in the data.

Data on age, sex, race/ethnicity, and dual eligibility status, as well as ZIP Code Tabulation Area (ZCTA) of residence for all patients starting treatment, were obtained from the Medicare enrollment data. We derived whether patients had chronic conditions that were risk factors for cognitive impairment – as recognized by the Lancet Commission[9] – from claims data using the published algorithms of Chronic Condition Warehouse. Conditions include chronic kidney disease (as a proxy for poorly controlled diabetes); chronic obstructive pulmonary disease (as a proxy for smoking history); depression, bipolar, or other depressive mood disorders; diabetes; hearing loss, heart failure and non-ischemic heart disease; hyperlipidemia; hypertension; ischemic heart disease and acute myocardial infarction, peripheral vascular disease, and stroke/transient ischemic attack.

Via zip code of residence, patient-level data were linked to the socioeconomic composition of their ZCTA based on the 5-year estimates of the American Community Survey (ACS) for 2018 to 2022: median yearly household income in 2021 inflation-adjusted dollars[10] and educational attainment of residents aged 65 years and older. Demographic characteristics of patients on the amyloid-targeting treatments were described and compared to those of the broader Medicare fee-for-service population aged 65 years and older ($n$ = 24,905,222). Summary statistics of the chronic conditions among the treated patients were also calculated but not compared to the Medicare population because of the known higher comorbidity burden of AD patients.[11]

## 3 | RESULTS

We identified 924 patients, who started treatment in 2022 and 2023, 377 (41%) on aducanumab, including 18 who switched to lecanemab, and 547 (59%) on lecanemab only. Of those, 57% ($n$ = 522) had diagnosis codes for both mild cognitive impairment (MCI) and dementia, 39% ($n$ = 356) for dementia only, and 5% ($n$ = 41) for MCI only, while five patients had neither diagnosis recorded in their claims data. No patients in our data started treatment in 2021.

One of the 924 patients did not have a valid zip code and was excluded from the subsequent analyses. Table 1 shows the demographic characteristics of the 923 included patients compared with the overall Medicare fee-for-service population aged 65+. Just over

**TABLE 1** Demographic and coverage characteristics of treated group and Medicare population.

| Variable | Treatment recipients (%) (*N* = 923) | Medicare population (%) (*N* = 24,905,222) |
|---|---|---|
| Sex | | |
| Female | 53.41 | 55.65 |
| Race/ethnicity | | |
| Unknown | 4.55 | 2.50 |
| Non-Hispanic White | 88.62 | 82.32 |
| African American | 1.52 | 5.86 |
| Hispanic | 2.38 | 5.03 |
| Other | 2.93 | 4.29 |
| Age group (years) | | |
| 65 to 69 | 12.57 | 23.04 |
| 70 to 74 | 29.25 | 27.05 |
| 75 to 79 | 32.39 | 21.41 |
| 80 to 84 | 19.72 | 14.02 |
| 85+ | 6.07 | 14.48 |
| Dually eligible for Medicare and Medicaid | | |
| Has dual coverage | 1.19 | 8.80 |

**TABLE 2** Comorbidity burden of early treatment recipients.

| Comorbidity | Chronic disease prevalence (%) (*N* = 923) |
|---|---|
| Congestive heart failure | 7 |
| Chronic obstructive pulmonary disease | 7 |
| Peripheral vascular disease | 13 |
| Hearing loss | 15 |
| Chronic kidney disease | 16 |
| Stroke | 18 |
| Diabetes | 21 |
| Coronary heart disease | 26 |
| Depression | 34 |
| Hypertension | 65 |
| Hyperlipidemia | 80 |

half of the treated (53%) patients and the overall population (56%) were female. Treated patients had an average age similar to that of the overall population (75.9 for both). They were more likely to be non-Hispanic White (89% vs 82%) and less likely to be dually eligible for Medicare and Medicaid, an indicator of poverty (1.2% vs 8.8%) in the fee-for-service population of age 65+. On average, the median yearly household income in the ZTCAs in which the treated patients resided was higher, with $97,136, compared with $84,449 in the overall Medicare population, as was the percentage of residents who had completed at least college, with 42% versus 31%.

Figure 1 shows the histograms of the ZTCA-level socioeconomic characteristics across the groups. Panel A compares the median household income and Panel B the percentage of residents with at least a college degree. The distributions for both variables are shifted to the right for the treatment recipients, indicating a trend toward higher socioeconomic status.

Table 2 describes the comorbidity burden of the recipients of amyloid-targeting treatment. The most common comorbidities were hyperlipidemia (80%), hypertension (65%), depression (34%), ischemic heart disease (26%), diabetes (21%), stroke (18%), chronic kidney disease (16%), and hearing loss (15%).

## 4 | DISCUSSION

This report is, to our knowledge, the first national study to describe the characteristics of the initial patients, who started amyloid-targeting treatments for AD in the United States outside of clinical trials. The age and sex distributions of these patients were similar to those in the phase 3 trials of lecanemab[12] and donanemab.[13] The comorbidity burden in treated patients was substantial and in line with previously reported estimates for individuals with AD.[11]

However, the socioeconomic composition of the treated patients differed substantially from that of the overall Medicare population. Only 1.2% of patients were dually eligible for Medicare and Medicaid compared to 8.8% in the fee-for-service Medicare population, and patients tended to reside in wealthier and more highly educated locations. This finding is concerning, as AD prevalence tends to be higher in socioeconomically disadvantaged groups because of their higher comorbidity burden.[14] Similarly, patients were disproportionately non-Hispanic White, mirroring enrollment in the recent trials of amyloid-targeting treatments, with around 95% and 77% of non-Hispanic White patients in the phase 3 trials of donanemab[13] and lecanemab,[12] respectively. This is another concerning result, as the prevalence of cognitive impairment is higher in non-Hispanic Black and Hispanic populations.[15]

The demographic and clinical compositions of our sample resemble those of a recently published study on the first 71 patients undergoing treatment with lecanemab in a single memory clinic, which encompassed 96% non-Hispanic White individuals and 28% individuals with a post-college degree.[16] As mentioned previously, similar disparity patterns have been observed for early uptake of treatments for HIV[5,6] and hepatitis C,[7,8] and our study contributes to the body of evidence that more than regulatory and coverage considerations are needed to make new treatments available to vulnerable populations.

### 4.1 | Limitations

This study is not without limitations. We were only able to look at the fee-for-service population, as data for Medicare Advantage Plans are currently only available up to 2021. We also did not include individuals

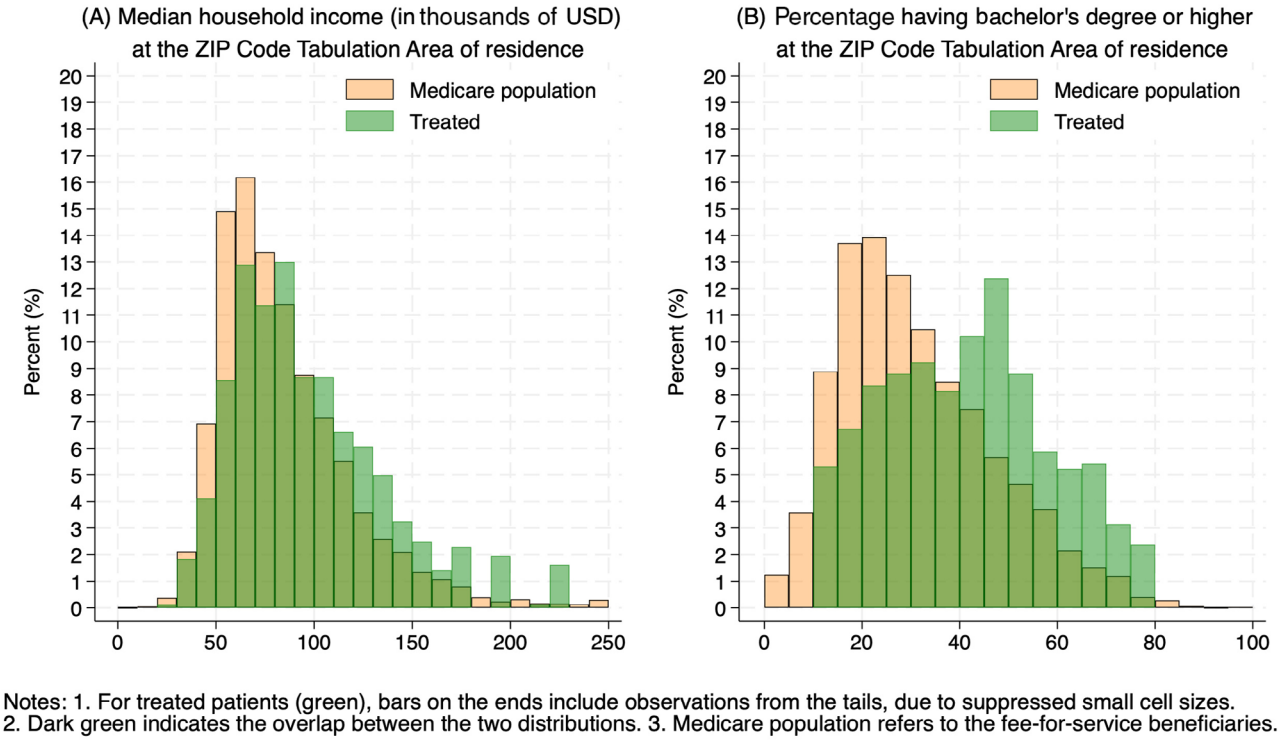


**FIGURE 1** Geographical and socioeconomic composition of the first recipients of disease-modifying treatments of Alzheimer's disease, compared to those of the general fee-for-service Medicare population.

receiving treatment outside of Medicare coverage. The comparison of demographic characteristics between treatment recipients and the Medicare population has limited validity, and comparing to patients who are eligible but did not receive treatments would have been more accurate. However, the limited information available in claims data does not allow identification of treatment eligibility, because MCI remains vastly underdiagnosed and diagnosis codes for dementia do not document disease stage.

## 5 | CONCLUSION

Our findings suggest that the first patients receiving amyloid-targeting treatments represent a more privileged subset, even though disease burden is higher in disadvantaged populations. While these results need to be confirmed with additional data, they point to the need for efforts to make access more equitable. Future research should also investigate at which points of the patient journey obstacles to access arise for disadvantaged populations.

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The study was approved by the Institutional Review Board of USC (UPS 14-00148) under expedited review and with waivers for informed consent and Health Insurance Portability and Accountability Act authorization. All procedures were in accordance with the principles expressed in the Declaration of Helsinki.

### CONFLICT OF INTEREST STATEMENT

Outside of the submitted work, USC has research agreements, on which Dr. Mattke is the principal investigator, with Biogen, C2N, Eli Lilly, Eisai, and Roche/Genentech. Dr. Mattke serves on the board of directors of Senscio Systems and the scientific advisory boards of ALZpath and Boston Millennia Partners. He has received consulting and/or speaker fees from Biogen, C2N Diagnostics, Eisai, Eli Lilly, Novartis, Novo Nordisk, and Genentech/Roche. Selena Yue is a contract employee of Pfizer. The other authors report no conflicts. Author disclosures are available in the supporting information.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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