

ECONOMIC, HEALTH, AND QUALITY-OF-LIFE BURDEN ON CAREGIVERS AND STUDY PARTNERS OF LECANEMAB-TREATED INDIVIDUALS WITH ALZHEIMER’S DISEASE

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Introduction

- The burden of caregivers/study partners (CGSP) in Alzheimer’s disease (AD) begins years before formal diagnosis, yet high-quality, prospectively collected CGSP data remain limited¹
- Understanding CGSP experience during the earliest symptomatic stages is critical to capture the broader societal impact of AD²
- Lecanemab, an anti-amyloid protofibril antibody, demonstrated consistent slowing of clinical decline (global, cognitive, functional, and quality of life) and reduction in brain amyloid in early AD³⁻⁵
- This analysis quantifies the economic, health, and quality of life (QoL) burden in US sites experienced by CGSPs of individuals with clinically confirmed early AD using validated burden and QoL instruments from the CGSP Survey, implemented as part of an optional substudy within the lecanemab trials (Study 201 and Clarity AD)

Methods

- This non-interventional, longitudinal cohort substudy linked CGSPs of biomarker-confirmed participants with mild cognitive impairment (MCI) due to AD and mild AD to standardized measures of burden and QoL
- The primary objective was to estimate the non-medical, indirect economic costs associated with caregiving (including opportunity costs)
- The 61-item survey (incorporating validated instruments and customized items) was administered by mail with telephone follow-up to CGSPs who consented to this optional substudy to lecanemab Study 201 and Clarity AD
- Clinical data on subjects’ baseline diagnosis (MCI or mild AD), progression information, and randomization date were used for subgroup analyses

Results

- A total of 69 CGSPs for 34 patients with MCI and 35 patients with mild AD completed the survey (**Table 1**)

Table 1. Demographic Characteristics*

	MCI N=34	Mild AD N=35	All N=69
Age, years			
Mean (SD)	72.6 (7.1)	72.7 (8.9)	72.7 (8.0)
Age Category, n(%)			
75 or above	14 (41.2%)	15 (42.9%)	29 (42.0%)
Sex, n (%)			
Man	14 (41.2%)	15 (45.5%)	29 (43.3%)
Woman	20 (58.8%)	18 (54.5%)	38 (56.7%)
Education, n (%)			
<4-year college graduate	<11 (<32.4%)	≥11 (≥31.4%)	25 (36.2%)
4 college graduate or more	>23 (>67.6%)	<25 (<71.4%)	44 (63.8%)
Total Household Income, 2023, n (%)			
\$90,000 or less	15 (42.4%)	17 (51.5%)	31 (47.0%)
More than \$90,000	19 (57.6%)	16 (48.5%)	35 (53.0%)
Health Insurance Type^a, n (%)			
Medicare	28 (84.8%)	26 (74.3%)	54 (79.4%)
Private insurance	<11 (<33.3%)	≥11 (≥31.4%)	27 (39.7%)
Other	<11 (<33.3%)	<11 (<31.4%)	13 (19.1%)
Resides in...^b, n (%)			
Rural area	<11 (< 32.4%)	<11 (<31.4%)	<11 (<15.9%)
Urban area	>23 (>67.6%)	>24 (>68.6%)	>58 (>84.1%)
Resides in US region^b, n (%)			
Northeast or Midwest	14 (41.2%)	13 (38.2%)	27 (39.7%)
South or West	20 (58.8%)	21 (61.8%)	41 (60.3%)

- a: Percentages may not sum to 100% because respondents were allowed to select more than one response. b: Derived from caregiver’s mailing address.
- *Because survey completion occurred at different timepoints following subject randomization (ie, randomized enrollment into a lecanemab clinical trial), time-since-randomization was later incorporated as a predictor in the models to account for variation in caregiving exposure duration. As the CMS cell size suppression policy stipulates that no cell values of 1 to 10 can be reported directly or derived from other reported cells, cells have been collapsed, and data have been coarsened when necessary. This is why values are reported as < 11 (the actual # cannot be disclosed). Due to the small number of respondents with subjects’ baseline mild AD diagnosis, results were stratified by subjects’ latest diagnosis rather than baseline diagnosis as originally planned. The latest diagnosis considers the baseline diagnosis and progression (if subject progressed prior to survey administration) for each subject.
- Most CGSP survey respondents were spouses or partners of the subject (> 69.6%) and reported providing informal subject care only (> 84.1%), with more than 84% of survey respondents reported living with the subject full-time (**Table 2**)

Table 2. Caregiver/Study Partners’ Voluntary Caregiving Role

	MCI N=34	Mild AD N=35	All Respondents N=69
Relationship to Subject, n (%)			
Spouse or partner	>23 (>67.6%)	>14 (>40.0%)	>48 (>69.6%)
Parent or parent-in-law	<11 (<32.4%)	<11 (<31.4%)	<11 (<15.9%)
Friend, acquaintance, or neighbor	0 (0.0%)	<11 (<31.4%)	<11 (<15.9%)
Length of Time Providing Voluntary or Informal Care for Subject, n (%)			
Less than a month	0 (0.0%)	0 (0.0%)	0 (0.0%)
Less than a year	0 (0.0%)	0 (0.0%)	0 (0.0%)
A year or more	34 (100.0%)	33 (100.0%)	67 (100.0%)
Total, mean (SD)	5.3 (2.3)	5.3 (2.4)	5.3 (2.3)
Living Arrangement with Subject, n (%)			
Full time	>23 (>67.6%)	>24 (>68.6%)	>58 (>84.1%)
Some of the time	0 (0.0%)	0 (0.0%)	0 (0.0%)
Does not live with subject	<11 (<32.4%)	<11 (<31.4%)	<11 (<15.9%)
Provide Voluntary or Informal Care for Others, n (%)			
No	>23 (>67.6%)	>24 (>68.6%)	>58 (>84.1%)
Yes	<11 (<32.4%)	<11 (<31.4%)	<11 (<15.9%)

- Overall, 64.7% of CGSPs of subjects with MCI reported excellent or very good mental health, compared to only 45.7% of CGSPs of subjects with mild AD (**Table 3**)
- CGSPs of subjects with Mild AD reported more unhealthy days, on average, in the past 30 days than CGSPs of subjects with MCI (a mean of 6.6 ± 8.7 days compared to 4.8 ± 6.8 days; **Table 3**)
- CGSPs of subjects with Mild AD reported more days, on average, in the past 30 days when their health status prevented usual activities, than CGSPs of subjects with MCI (a mean of 3.9 ± 8.5 days compared to 2.2 ± 5.7 days; **Table 3**)

Table 3. Caregivers/Study Partners’ Health

	MCI N=34	Mild AD N=35	All Respondents N=69
Physical health is..., n (%)			
Excellent/ Very good	17 (50.0%)	15 (42.9%)	32 (46.4%)
Good/ Fair/ Poor	17 (50.0%)	20 (57.1%)	37 (53.6%)
Mental health is..., n (%)			
Excellent/ Very good	22 (64.7%)	16 (45.7%)	38 (55.1%)
Good/ Fair/ Poor	12 (35.3%)	19 (54.3%)	31 (44.9%)
Total number of unhealthy days in past 30 days, mean (SD)^a	4.8 (6.8)	6.6 (8.7)	5.7 (7.8)
Total days in past 30 days when health status prevented usual activities, mean (SD)^a	2.2 (5.7)	3.9 (8.5)	3.1 (7.2)

a: From Healthy Days core questions (CDC HRQL– 4).⁶

- Indirect costs (including hours spent on caregiving activities) were higher among CGSP of participants with mild AD compared to those caring for individuals with MCI, and higher among those whose care recipients showed disease progression (**Table 4, Table 5**)
- For CGSPs of subjects with mild AD, more hours providing care for the subject was strongly associated with unhealthier days (P<0.001; **Table 4**)

Results (continued)

Table 4. Predictors of Intangible Cost (Unhealthy Days)

	MCI N = 30	Mild AD N = 29	All Respondents N = 59
Receives respite care (compared to never), std reg coef (P value)	-0.18 (0.36)	-0.43 (<0.001)	-0.27 (0.02)
Subject’s ability to be left alone (compared to not at all), std reg coef (P value)	-0.48 (0.03)	0.20 (0.10)	0.01 (0.91)
Hours spent on caring for subject, std reg coef (P value)	0.12 (0.54)	0.68 (<0.001)	0.63 (<0.001)
Subject’s Independence with Instrumental Activities of Daily Living (IADL), std reg coef (P value)	0.12 (0.53)	0.14 (0.26)	0.09 (0.50)
Subject’s length of time in the study (in years)^a, std reg coef (P value)	-0.10 (0.60)	0.25 (0.03)	0.08 (0.45)
Progressed from baseline diagnosis (compared to did not progress), std reg coef (P value)	n/a ^b	-0.03 (0.83)	-0.03 (0.82)

a: Length of time in the study (in years) is the interval between randomization date and the date the completed mail survey was received or the telephone interview completed.

b: Subjects with latest diagnosis of MCI did not progress from baseline MCI diagnosis; therefore, progression status cannot be a predictor of unhealthy days for CGSPs of subjects with MCI.

- Across all respondents, the most common purchases were food (71.2%), over-the-counter drugs and personal care items (69.7%), prescription drugs (66.7%), out-of-pocket medical expenditures (59.1%), and household expenses for the care recipient (56.1%) (**Table 5**)
- Median informal caregiving costs were substantially higher among CGSPs of subjects who progressed from baseline MCI to mild AD than among those who did not progress, suggesting that progression was more consistently reflected in unpaid caregiving time⁷

Table 5. Subject-Related Goods and Services Purchased as Reported by Caregivers/Study Partners by Subject’s Diagnosis

	MCI N=34	Mild AD N=35	All Respondents N=69
Goods and services caregiver buys for subject^a, n (%)			
Transportation	13 (40.6%)	21 (61.8%)	34 (51.5%)
Changes to the house to accommodate subject’s condition	<11 (<34.4%)	≥11 (≥32.4%)	21 (31.8%)
Out-of-pocket medical expenditures	17 (53.1%)	22 (64.7%)	39 (59.1%)
Prescription drugs	20 (59.4%)	25 (73.5%)	44 (66.7%)
Food	20 (62.5%)	27 (79.4%)	47 (71.2%)
Over-the-counter drugs and personal care items	21 (65.6%)	25 (73.5%)	46 (69.7%)
Household expenses for care recipient	16 (50.0%)	21 (61.8%)	37 (56.1%)
Other	<11 (<34.4%)	<11 (<32.4%)	<11 (<16.7%)
None of these	<11 (<34.4%)	<11 (<32.4%)	<11 (<16.7%)
Source of payment for goods and services bought for subject^a, n (%)			
CGSP’s money	<11 (<40.7%)	<11 (<40.7%)	11 (19.3%)
CGSP’s money, but partially or fully reimbursed	<11 (<40.7%)	<11 (<40.7%)	<11 (<19.3%)
Money the CGSP shares with the subject	24 (88.9%)	24 (80.0%)	48 (84.2%)

a: Percentages may not sum to 100% because respondents were allowed to select more than one response.

*Each cell contains the number of respondents and percentage of respondents, n (%). Missing data are not included in the percentages reported for each survey item. As the CMS cell size suppression policy stipulates that no cell values of 1 to 10 can be reported directly or derived from other reported cells, cells have been collapsed, and data have been coarsened when necessary. These items reflect goods and services purchased for the subject and reported by caregivers/study partners. Because annual dollar amounts were not collected for these categories and many expenditures were paid from funds shared with the subject, these items should be interpreted as subject-related household expenditures rather than caregiver-attributable direct costs.

Conclusions

- Findings indicate a greater economic burden for CGSPs of subjects with Mild AD than for caregivers of subjects with MCI
- Interventions that delay disease progression and reduce caregiving time may potentially reduce economic strain on CGSPs and positively impact their QoL
- Study limitations include a relatively small sample size; this restricts the statistical power for stratified modelling and increases uncertainty in subgroup estimates

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References: 1. El-Hayek YH, et al. J Alzheimers Dis. 2019;70:323-341. 2. Robinson et al. 2019 [need full reference]. 3. Söderberg L, et al. Sci Rep. 2024;14:10868. 4. van Dyck CH, et al. Alzheimers Dement. 2025;21:e70905. 5. van Dyck CH, et al. N Engl J Med. 2023;388:9-21. 6. Andresen EM, et al. Journal of Epidemiology and Community Health. 2003;57:339–343. 7. Data on file. Eisai Inc.