Letters

RESEARCH LETTER

Estimated Annual Spending on Lecanemab and Its Ancillary Costs in the US Medicare Program

Lecanemab, an antidementia medication with modest clinical benefit, received accelerated US Food and Drug Administration (FDA) approval. Traditional FDA approval of lecanemab could occur in 2023, prompting Medicare to reconsider coverage restrictions and potentially enabling widespread use. Lecanemab's $26 500 proposed annual acquisition cost and ancillary spending (eg, imaging) could increase Medicare spending, possibly leading to beneficiary premium increases. To estimate annual Medicare spending on lecanemab, we performed a cost analysis using nationally representative survey data from the 2018 Health and Retirement Study (HRS).

Method In this cross-sectional study, we included traditional Medicare and Medicare Advantage beneficiaries aged 65 years or older and used validated cognitive measures to estimate mild cognitive impairment (MCI) or mild dementia prevalence (Figure; eMethods in Supplement 1).[1] We also examined all traditional Medicare and Medicare Advantage 2019 claims data (n = 51.6 million beneficiaries). Due to undercoding and underascertainment, coded prevalence of MCI was low (1.7%); we therefore relied on HRS-estimated MCI and mild dementia prevalence. Given the medication's risks, we assumed patients would undergo screening and diagnostic confirmation de novo. Cognitive screening is also undercoded; we assumed a lower bound informal cognitive screening rate of 27%[2] and an upper bound screening rate of 29.7% (10% anticipated increase). We assumed the lower bound informal screening positivity rate would match HRS-

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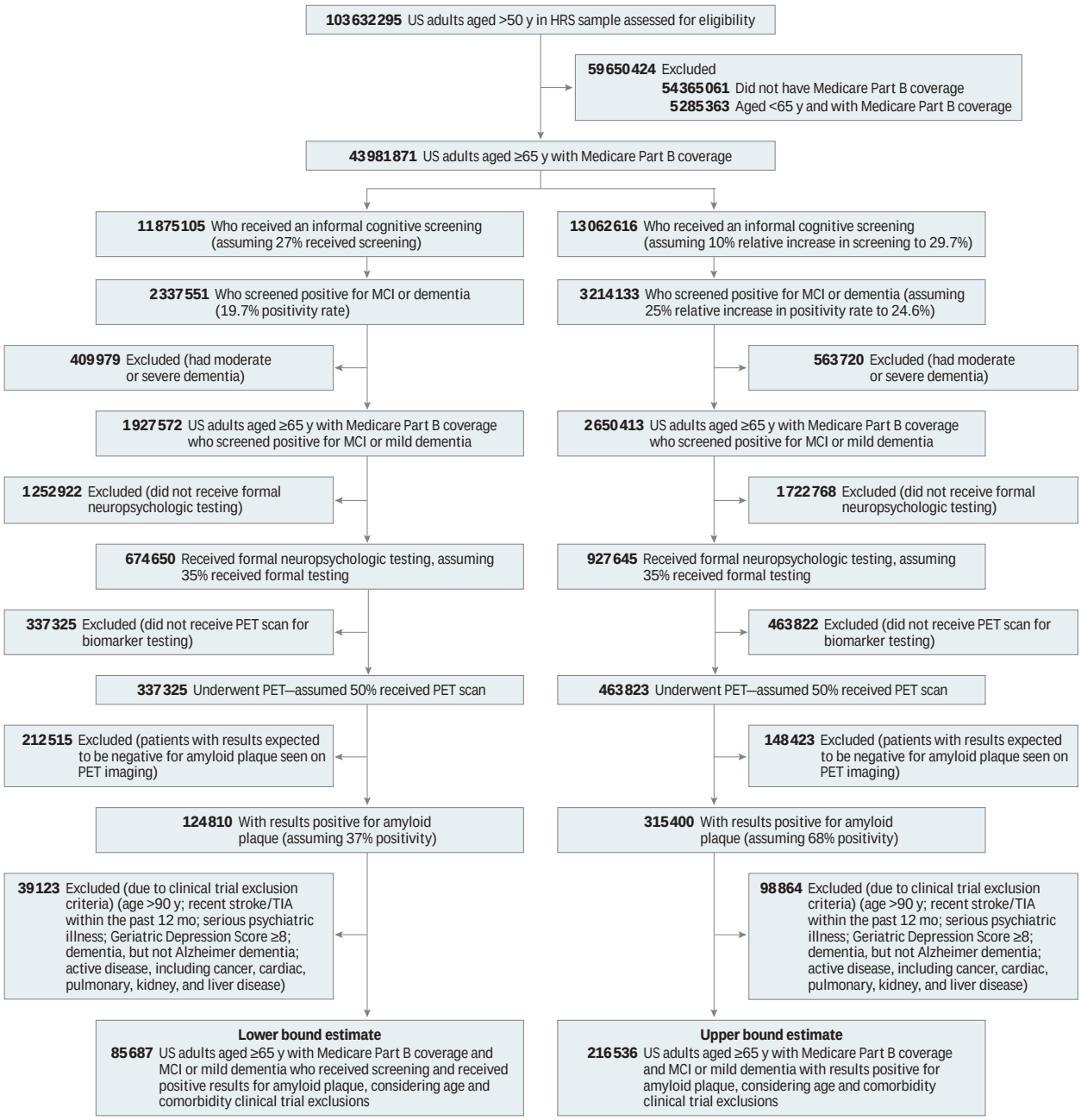
Fig re. Flo Diagram of E ima ed Range of Older US Ad L Wi h Mild Cogni ae Impairmen (MCI) and Demen ia in he 2018 Heal h and Re iremen S d (HRS) Core Sample Po en iall Eligible for Trea men Wi h Lecanemab



We used data from the 2018 HRS, a nationally representative longitudinal survey of community-dwelling adults age >50. This biennial household-level survey uses multistage national area-clustered probability sampling. We identified 7588 HRS participants representing 43 981 871 Medicare beneficiaries with age ▫ 65 in 2018. This estimate includes both Medicare fee-for-service and Medicare Advantage beneficiaries. We used the HRS' 27-point cognitive assessment score to identify eligible patients with MCI or mild dementia. This assessment includes items such as serial 7 subtraction and immediate and delayed 10-noun free recall.[1] Participants with scores of 0-6 were classified as having dementia, and participants with scores of 7-11 were classified as having MCI. If the participant was unable to complete the cognitive assessment, they could be represented by a designated health care proxy. For health care proxy responses, an 11-point scoring scale classified scores of 6-11 as having dementia and scores of 3-5 as having MCI. We subclassified the cognitive assessment scales to identify dementia severity with 27-point and 11-point scales: (1) mild dementia, 5 to 6 and 6; (2) moderate dementia, 3 to 4 and 7; and (3) severe dementia, 0 to 2 and 8 to 11. This classification system for dementia severity demonstrated strong validity.[1-3] We performed a sensitivity analysis, in which these dementia staging thresholds corresponded with the presence of an informal caregiver (frequently used as a proxy for declining functional status) (eMethods in Supplement 1). PET indicates positron emission tomography; TIA, transient ischemic attack.

Table. Estimated Annual Spending on Lecanemab Among Older US Adults With Mild Cognitive Impairment or Mild Dementia in the 2018 HRS Core Sample[a]

Service type	No. of events per patient-year	$					
		Estimated per-patient unit costs	Annualized Medicare cost per patient (80% of cost)	Annualized coinsurance cost to beneficiaries, private supplemental plans, MA, and/or state Medicaid plans (20% of cost)	Anticipated annualized per-patient out-of-pocket cost ranges	Annual Medicare cost estimate (millions)	
						Lower bound (n = 85 687 [95% CI, 78 097-93 278])	Upper bound (n = 216 536 [95% CI, 197 368-244 469])
Lecanemab	24	1045.74	20 680.55	5170.14	0-5170.14	1 772 054 651.16	4 478 084 492.91
PET scan	1	1564.88	1251.90	312.98	0-312.98	107 271 898.05	271 082 284.54
Intravenous infusion	24	133.67	2566.46	641.62	0-641.62	219 912 600.77	555 731 848.70
Neurology or geriatrics visit	4	155.75	498.40	124.60	0-124.60	42 706 400.80	107 921 542.40
Routine MRI scan of brain	3	445.01	1068.02	267.01	0-267.01	91 515 772.49	231 265 644.86
Apo E serum testing	1	99.00	79.20	19.80	0-19.80	6 786 410.40	17 149 651.20
ARIA-related additional MRI scans	0.172	445.01	61.25	15.31	0-15.31	5 248 157.38	13 262 396.93
ARIA-related additional neurology visits	0.172	155.75	21.41	5.35	0-5.35	1 834 387.30	4 635 602.69
Hospitalization for severe AE	0.027	14 700.00	317.52	79.38	0-79.38	27 207 336.24	68 754 510.72
Subtotal costs	NA	NA	26 544.72	6636.18	0-6636.18	NA	NA
Total costs accounting for attrition (95% CI)	NA	NA	NA	NA	NA	2 015 163 231.64 (1 836 663 705.13-2 193 686 275.87)	5 092 433 922.60 (4 641 646 185.56-5 749 354 512.07)

Abbreviations: AE, adverse event; Apo E, apolipoprotein E; ARIA, amyloid-related imaging abnormality; HRS, Health and Retirement Study; MA, Medicare Advantage; MRI, magnetic resonance imaging; NA, not applicable; PET, positron emission tomography; TM, Traditional Medicare.

[a] We used data from the 2018 HRS, a nationally representative longitudinal survey of community-dwelling adults with age >50. We identified 7588 HRS participants representing 43 981 871 Medicare beneficiaries with age ▫ 65 in 2018. We used HRS patient weights to calculate drug costs, along with twice-monthly infusion at 10 mg/kg. Lecanemab comes in 2 vial sizes: a 200 mg vial ($254.81) and a 500 mg vial ($637.02). These announced vial prices represent a wholesale acquisition cost; therefore, we added a 3% markup to approximate an actual acquisition cost more closely per Medicare payment rules. We used the most efficient dosing approach to calculate costs. Incorporation of nationally representative patient body weights and the 3% markup yielded an annual weighted patient drug cost of $25 850.69, 80% ($20 680.55) of which would be paid by Medicare, according to TM cost-sharing rules. Ancillary costs attributed to lecanemab were calculated by multiplying the

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