Updated Cost-Effectiveness of Lecanemab for the Treatment of Patients with Early Alzheimer's Disease (AD): A Canadian Societal Perspective

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BACKGROUND

- Early Alzheimer's disease (AD), defined as mild cognitive impairment (MCI) due to AD or mild AD dementia with confirmed amyloid pathology, is characterized by progressive cognitive and functional decline.[1-2]
- The burden of AD extends beyond direct healthcare costs, with caregivers often experiencing reduced quality of life (QoL) and increased healthcare utilization.[3]
- Lecanemab is an anti-amyloid monoclonal antibody that slows early AD progression through 2 complementary mechanisms: clearing insoluble amyloid plaque and targeting soluble amyloid-β protofibrils.[4]
- A Canadian societal cost-effectiveness model (CEM) was previously presented while lecanemab was under Canadian regulatory and HTA review to evaluate the anticipated population at the time (i.e., adult patients with early Alzheimer's disease [those in the mild cognitive impairment (MCI) or mild dementia stage] with documented presence of amyloid beta pathology).
- Since then, lecanemab received a Health Canada indication for: ***The treatment of adult patients with a clinical diagnosis of mild cognitive impairment or mild dementia due to Alzheimer's disease (early Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) noncarriers or heterozygotes and who have confirmed amyloid pathology.***
- An updated CEM was required to evaluate cost-effectiveness in the indicated population using 2026 Canadian costs and refinements to the model addressing key limitations identified during CDA's review.
- **Objective:** To evaluate the cost-effectiveness of lecanemab plus SoC versus SoC alone in adults with early AD who are ApoE ε4 noncarriers or heterozygotes and have confirmed amyloid pathology, incorporating updated Canadian inputs and HTA-informed model refinements.

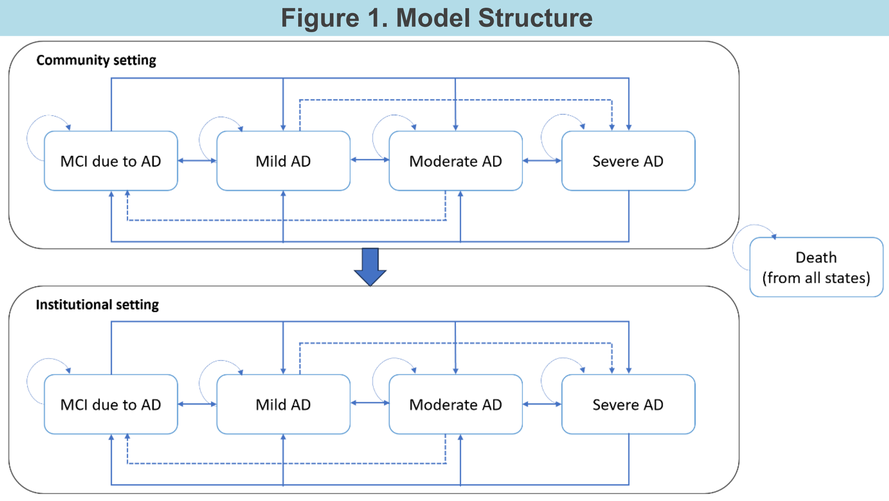
METHODS

Population	Adults with MCI due to AD or mild AD dementia; ApoE ε4 noncarrier or heterozygote; confirmed amyloid pathology
Intervention	Lecanemab 10 mg/kg every 2 weeks + SoC
Comparator	SoC alone (symptomatic treatment [i.e., the cholinesterase inhibitors donepezil, rivastigmine, galantamine])
Perspective	Canadian societal
Horizon / cycle	Lifetime (30 years) / monthly
Discounting	1.5% for costs and outcomes
Outcomes	Life years, quality-adjusted life years (QALYs), and costs

KEY MODEL UPDATES

1. **Modelling of the Indicated Population**
   Analysis aligned with the Health Canada indication (ie, ApoE ε4 noncarriers or heterozygotes with confirmed amyloid pathology).
2. **Incorporation of the Increment Approach for Caregiver Utilities**
   An increment approach was used to estimate caregiver utility impacts and address limitations of additive and decrement methods.[5-7]
3. **Incorporation of Treatment-Effect Waning**
   Treatment effect was assumed to wane linearly after institutionalization-related or other-cause discontinuation.
4. **Incorporation of Longer-Term Evidence**
   Use of 36- and 48-month Clarity AD open-label extension (OLE) data to inform time-to-worsening HR, discontinuation rate, and compliance in scenario analyses.[8]

Figure 1. Model Structure



Model Structure

- A Markov cohort-state transition model **(Figure 1)** was used to conduct a cost-utility analysis for lecanemab plus SoC compared with SoC only. Patients enter the model in either the 'MCI due to AD' or 'Mild AD' health state, using the distribution across these states from the pivotal phase III Clarity AD trial of lecanemab.

AD Progression

- Transitions during months 0-18 were informed by Clarity AD; longer-term natural-history transitions beyond 18 months used established literature sources from Potashman et al. (2021).[9]

Base-Case Clinical Inputs

- **Treatment effects:** In the base case analysis, separate time-to-worsening CDR-SB HRs derived from the 18-month Clarity AD results were applied beyond 18 months to progressive transitions from MCI due to AD:
  - MCI due to AD: HR 0.701 (95% CI 0.564 - 0.871; p=0.00137)
  - Mild AD: HR 0.584 (95% CI 0.306 - 1.115; p=0.10304)[10]
- **Longer-term treatment-effect scenarios:** The 36- and 48-month Clarity AD OLE analyses compared lecanemab with an ApoE ε4-matched ADNI natural-history cohort. Combined time-to-worsening CDR-SB HRs of 0.73 and 0.70, respectively, were applied to progressive transitions from MCI due to AD and mild AD, along with the corresponding discontinuation and compliance inputs.[8]
- **Treatment discontinuation and effect waning:** Lecanemab was discontinued upon progression to moderate or severe AD, institutionalization, or other causes. After institutionalization-related or other-cause discontinuation, progression remained based on the patient's current AD stage, while the corresponding treatment-effect HR waned linearly to 1.0 over 7.84 years. The duration reflected projected amyloid reaccumulation to 50 CL, a threshold below which limited clinical progression has been observed.[11]
- **Mortality and institutionalization:** Mortality was informed by 2024 Statistics Canada life tables and AD-specific excess mortality.[12-13] As institutionalization data were unavailable from Clarity AD, health-state-specific probabilities from Knapp et al. were converted to monthly transition probabilities and applied to patients in community care; institutionalization was not modelled from MCI due to AD, and institutionalized patients did not return to community care.[14]

Patient and Caregiver Quality of Life

- Patient and caregiver utilities by AD severity were informed by Landeiro et al. (2020) and Lopez-Bastida et al. (2006); institutional-care decrements were informed by Farina et al. (2020).[15-17]
- Caregiver utility increments were calculated relative to the living health state associated with the greatest caregiver burden and added to patient utilities, capturing caregiver benefits from delayed disease progression without adding the caregiver's full utility (the additive approach was evaluated in a scenario analysis).
- Utility decrements for patients incurring AEs (infusion-related reactions, ARIA-E, and ARIA-H events) were included.

Costs included

- Drug acquisition and administration, disease management, diagnostics, adverse events, patient and caregiver direct medical and non-medical costs, institutionalization, and caregiver productivity losses.
- Relevant cost inputs were updated to 2026 Canadian dollars through inflation adjustments and the latest available Ontario Schedule of Benefits and Canadian labour-market and productivity data.[18-19]

RESULTS

PROBABILISTIC BASE CASE RESULTS

Figure 2. Cost-Effectiveness Plane

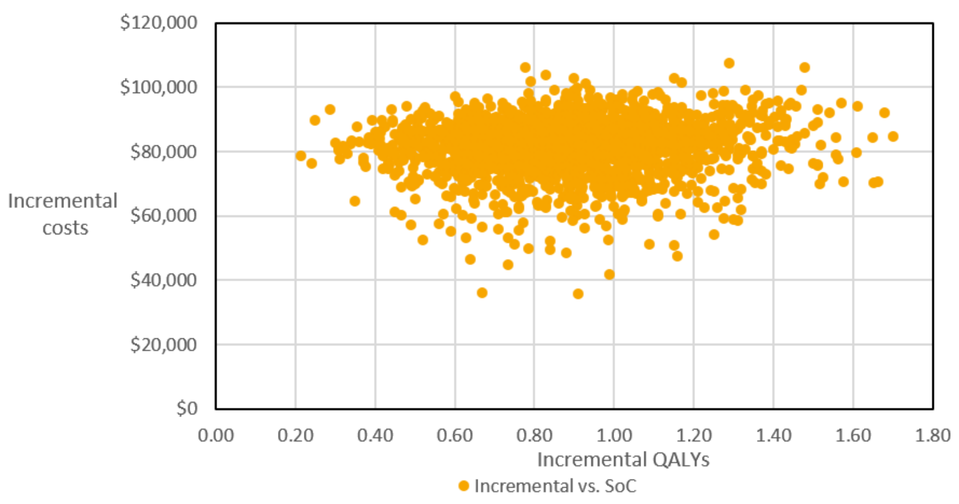
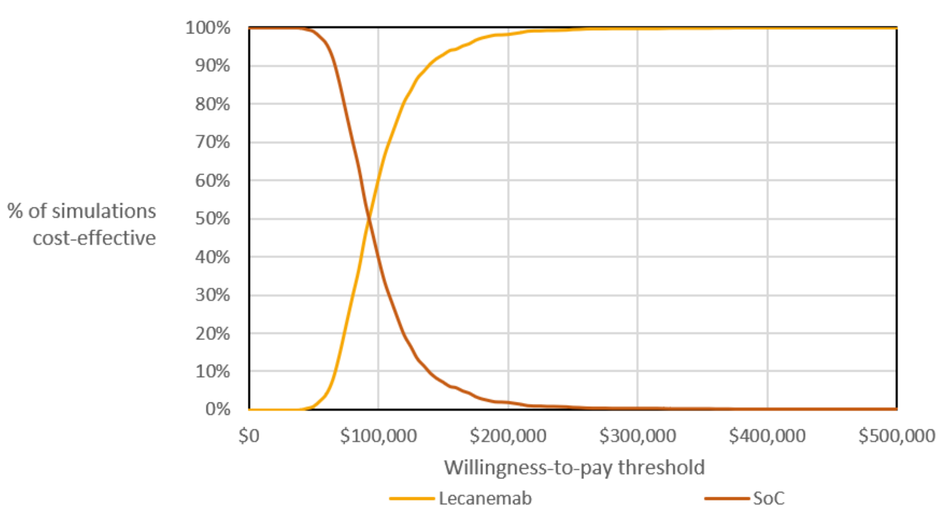


Figure 3. Cost-Effectiveness Acceptability Curve



Cost-effectiveness Results	
Incremental Costs vs SoC	$81,332
Incremental QALYs vs SOC	0.89
ICUR: $91,754 per QALY	

Results by Disease Severity	
Incremental time in MCI due to AD	+0.90 years
Incremental time in mild AD	+0.30 years
Incremental time in moderate AD	-0.14 years
Incremental time in Severe AD	-0.38 years
Median time to dementia	+1.07 years

Results by Care Setting	
Incremental time in community	+0.83 years
Delay in median time to institutionalization	0.80 years

DETERMINISTIC RESULTS AND KEY SCENARIOS

Deterministic Base Case ICUR ($/QALY)
$90,572

Key Scenarios			
Additive Approach for Caregivers	$58,622	48-Month Time-to-Worsening HR	$105,713
Maintenance dose of lecanemab every 4 weeks after 18 months	$60,557	Healthcare Payer Perspective	$124,900
Amyloid Reaccumulating to 76 CL (11.67 Years)	$84,333	10-Year Time Horizon	$127,354

- Across all tested scenarios, lecanemab continued to provide gains in QALYs and delays in dementia and institutionalization.
- ICURs ranged from $58,622 to $127,354/QALY, with results most sensitive to maintenance dosing, time horizon, and perspective.

CONCLUSIONS

- In adults with early AD who are ApoE ε4 noncarriers or heterozygotes, lecanemab plus SoC increased QALYs, prolonged time in earlier disease stages, and delayed dementia onset and institutionalization compared with SoC alone.
- The updated Canadian societal analysis estimated 0.89 incremental QALYs, $81,332 in incremental costs, and an ICUR of $91,754/QALY.
- By delaying disease progression and institutionalization, lecanemab may reduce patient and caregiver burden, including caregiver productivity losses. As patient productivity was not modelled, societal benefits may be underestimated.
- These findings provide decision-makers with an updated assessment of lecanemab in the Health Canada-indicated population, incorporating contemporary Canadian inputs and HTA-informed methodological refinements.

REFERENCES

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ABBREVIATIONS

AD, Alzheimer's disease; ADNI, Alzheimer's Disease Neuroimaging Initiative; ApoE ε4, apolipoprotein E ε4; CDA, Canada's Drug Agency; CDR-SB, Clinical Dementia Rating–Sum of Boxes; CEM, cost-effectiveness model; CI, confidence interval; HR, hazard ratio; HTA, health technology assessment; ICUR, incremental cost-utility ratio; MCI, mild cognitive impairment; OLE, open-label extension; QALY, quality-adjusted life-year; SoC, standard of care.

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