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7 July 2026

Medical Services Advisory Committee
Department of Health, Disability and Ageing
MDP 960
GPO Box 9848
CANBERRA ACT 2601

Dear Medical Services Advisory Committee,

MSAC Application 1738.1 – MBS funding for investigations to support the use of PBS-subsidised lecanemab in people with mild cognitive impairment and mild dementia due to Alzheimer's disease

I am writing on behalf of Dementia Australia to provide additional input on MSAC Application 1738.1, concerning investigations to support the use of PBS-subsidised lecanemab in people with mild cognitive impairment and mild dementia due to Alzheimer's disease.

Dementia Australia is the national peak body for people impacted by dementia in Australia. We represent the estimated 446,500 Australians living with dementia[1] and the 1.7 million people involved in their care. Dementia is now Australia's leading cause of death.[2] Alzheimer's disease is the most common form of dementia, accounting for up to 70 per cent of all cases. Without significant intervention, the number of Australians living with dementia is expected to exceed 1 million by 2065.[3]

AIHW estimates that $4.7 billion in aged care, health care and dementia support program expenditure in 2022–23 was spent directly on dementia, including nearly $3.2 billion in aged care and almost $1.5 billion in health care.[4] NATSEM estimates that without a significant medical breakthrough, dementia would cost Australia more than $1 trillion over the 40 years from 2016 to 2056.[5]

Dementia Australia previously provided input on MSAC Application 1738, encouraging the Committee to consider MBS funding for PET and CSF biomarker testing to detect amyloid beta pathology in people with early-stage Alzheimer's disease. We continue to consider reliable, clinically appropriate and publicly funded diagnostic testing important for appropriate treatment including to confirm eligibility for emerging disease-modifying therapies where indicated.

Since our previous submission, lecanemab has received registration from the Therapeutic Goods Administration for use in a defined group of people with early Alzheimer's disease, and the current application is broader than the original application. It seeks MBS funding for prerequisite investigations to establish the lecanemab treatment population, including amyloid pathology testing through amyloid PET, CSF biomarker testing and plasma pTau217; ApoE ε4 genotype testing; and new MBS items for MRI scans of the brain associated with baseline assessment and monitoring for amyloid-related imaging abnormalities during treatment. It should be noted that the use of the pTau217 biomarker should relieve pressure on amyloid PET and other diagnostic interventions resulting in earlier accurate diagnosis. This is important as Australians can face delays of approximately 3 years on average between initial symptom presentation and a formal diagnosis of dementia or mild cognitive impairment. This increases to an average of 7 years for some young onset dementias, such as frontotemporal dementia. Evidence shows that much can be done through a range of clinical and psychosocial supports to promote brain health, support independence and maximise quality of life. The sooner these supports are initiated, the more likely that progression of the condition may be slowed.

If lecanemab progresses through the PBS assessment pathway, the associated diagnostic and monitoring pathway should be publicly funded and implemented equitably, so access is not determined by cost, geography, or capacity to navigate complex care.

There is currently no single test that confirms Alzheimer's disease in routine practice, and people may experience long delays before receiving a diagnosis. This can be especially difficult for people with young onset dementia, Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse communities, and people living in rural and remote areas who may already experience barriers to timely specialist assessment.

Dementia Australia encourages MSAC to consider the equity implications of the current private-pay environment. At the present time, only people who can afford both private specialist consultations and the diagnostic tests required to determine clinical eligibility, may be able to access anti-amyloid therapies, while others cannot. Following this, a person must also be able to afford the specialist care for continued investigations and monitoring. This is both an issue of medicine subsidy and equitable access to the testing that determines whether a person is eligible, and whether treatment can continue safely.

New therapies for Alzheimer's disease are not a cure and will not be appropriate for everyone. However, for people who may be clinically eligible and who make an informed decision to pursue treatment, access to the associated investigations is important and would represent an important step towards ensuring that informed decisions about lecanemab can be made safely, in a timely fashion and equitably.

We note that the current application includes Apoε4 genotype testing to determine whether a person is a non-carrier or heterozygote, consistent with the proposed treatment population. Dementia Australia considers that genetic testing and biomarker testing must be accompanied by accessible information, supported decision-making, and appropriate pre-test and post-test counselling or equivalent supports. Genetic and biomarker information can have significant implications for how people understand their risk, their diagnosis, their treatment options and, in some cases, potential implications for family members.

This is critical as blood-based biomarkers become more available. The current application includes plasma pTau217 testing, noting that commercial availability of pTau217 plasma assays is expected in the second half of 2026. Dementia Australia supports continued development of blood-based biomarkers as part of an evidence-based diagnostic pathway and recommends that these should be implemented alongside clear clinical governance, confirmatory testing pathways, counselling, and appropriate follow-up support.

Dementia predominantly affects older people and cost-effectiveness approaches that place the greatest weight on life-years gained may undervalue interventions where the main benefit is maintaining quality of life, autonomy and function in later life. Dementia Australia therefore encourages MSAC to clearly explain how personal outcomes, carer impacts, equity considerations and downstream health and aged care impacts have been considered, including where these impacts are uncertain or not included in the economic modelling.

Dementia Australia considers that MBS-funded access to the proposed investigations would be an important step towards a safer and more equitable pathway for people who may be clinically eligible for lecanemab. The eligibility pathway should also be accompanied by:

- clear clinical pathways for amyloid pathology testing, ApoE ε4 genotype testing and MRI monitoring, including guidance on test interpretation, confirmation and follow-up;
- accessible pre-test and post-test information, supported decision-making, and genetic counselling or equivalent supports, particularly in relation to ApoE ε4 and amyloid biomarker results; and
- implementation planning to address rural, remote, Aboriginal and Torres Strait Islander, culturally and linguistically diverse, and young onset dementia access barriers.
- transparent consideration of broader value, including personal outcomes for people living with dementia, carer impacts, equity considerations, and downstream health, disability and aged care impacts.

We encourage the Committee to recognise the importance of any opportunity to make progress in the management of Alzheimer's disease in Australia by considering MBS funding for the proposed diagnostic tests.

Dementia Australia appreciates the opportunity to provide further input to MSAC Application 1738.1. We would be pleased to discuss any of the issues raised in this letter in more detail.

Yours sincerely

Prof Tanya Buchanan
Chief Executive Officer

References

1. Dementia Australia, *Commissioned AIHW Dementia Prevalence Data 2024-2054*. 2023, Dementia Australia.
2. Australian Bureau of Statistics, *Causes of Death Australia, 2024*. 2025, Australian Bureau of Statistics.
3. Australian Institute of Health and Welfare, *Dementia in Australia*. 2025, Australian Government.
4. Australian Institute of Health and Welfare. *Dementia in Australia: Spending on dementia*. 2025 2 July 2026]; Available from: **https://www.aihw.gov.au/reports/dementia/dementia-in-aus/contents/spending-on-dementia**.
5. National Centre for Social and Economic Modelling, *Economic Cost of Dementia in Australia: 2016-2056*. 2017, Institute for Governance and Policy Analysis: Canberra.