

MSAC application 1783.1

Investigations to support the use of PBS subsidised lecanemab in people with mild cognitive impairment and mild dementia due to Alzheimer's disease.

Application for MBS eligible service or health technology

HPP Application number:

HPP200415

Application title:

Investigations supporting use of PBS subsidised lecanemab in people with mild cognitive impairment and mild dementia due to Alzheimer's disease

Submitting organisation:

Eisai Australia Pty Ltd

Submitting organisation ABN:

73117970993

Application description

Succinct description of the medical condition/s:

People with mild cognitive impairment and mild dementia due to Alzheimer's pathology show a slow, progressive decline in memory, executive function, and complex daily tasks. Early changes often include difficulty learning new information, subtle word-finding issues, and reduced efficiency in planning or multitasking. Day-to-day independence is mostly maintained, though people increasingly rely on reminders or support for daily activities such as managing finances or medications. Over time, cognitive deficits broaden and functional performance becomes less reliable as neurodegeneration advances. Without disease-modifying treatment, most people gradually transition to moderate dementia, with clearer functional loss and reduced autonomy.

Succinct description of the service or health technology:

People must be assessed as being eligible for lecanemab prior to initiating treatment. This requires the use of amyloid pathology testing and ApoE ε4 genotype testing. Only people assessed as having positive amyloid pathology test and ApoE ε4 non-carrier or heterozygous are able to receive lecanemab treatment. After a person initiates lecanemab they are monitored for amyloid-related imaging abnormalities (ARIA). These are temporary changes seen on MRI scans in some people receiving lecanemab. People should undergo MRI scans to look for ARIA prior to 3rd, 5th, 7th and 14th infusion of lecanemab (Months 1, 2, 3 and 6).

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Applicant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

Eisai Australia Pty Ltd

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

Yes

Which list/schedule will the other health technologies be listed on?

Pharmaceutical Benefits Scheme

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Other

This application seeks that funding of prerequisite tests establishing the lecanemab treatment population be funded through the MBS, specifically:

- A β pathology testing using any of the following methodologies: amyloid Positron Emission Tomography (amyloid PET) of the brain; Immunoassay assessment of t-tau/A β [1-42] in cerebrospinal fluid (CSF); Immunoassay assessment of pTau217 in plasma
- ApoE ϵ 4 genotype testing by assessment of DNA isolated from plasma

The application also request the creation of new MBS items supporting MRI scans of the brain associated with lecanemab treatment.

PICO sets

Application PICO sets:

PICO set name
Investigations supporting use of PBS subsidised lecanemab in people with mild cognitive impairment and mild dementia due to Alzheimer's disease

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

People with mild cognitive impairment and mild dementia due to Alzheimer's disease

Select the most applicable Medical condition terminology (SNOMED CT):

Alzheimer's disease

Intervention

Name of the proposed health technology:

A β pathology testing using any of the following methodologies: amyloid Positron Emission Tomography (amyloid PET) of the brain; Immunoassay assessment of t-tau/A β [1-42] in cerebrospinal fluid (CSF); Immunoassay assessment of pTau217 in plasma. ApoE ϵ 4 genotype testing by assessment of DNA isolated from plasma. MRI scans of the brain

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

ApoE ϵ 4 genotype testing: No testing and standard medical management

Amyloid PET: No amyloid PET and standard medical management

t-tau/A β [1-42] in CSF testing: Amyloid PET

pTau217 in plasma testing: Amyloid PET

MRI scan of the brain: MRI scanning performed through existing MBS items

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

A change in management is expected to occur as a result of the information provided by ApoE ϵ 4 genotyping and A β pathology testing. Specifically, a change in management to consider initiating lecanemab is expected in people reported as having evidence of A β pathology and ApoE ϵ 4 non-carriers or heterozygous.

Proposed MBS items

Proposed item: AAAAA

MBS item number (where used as a template for the proposed item):

NA

Category number:

PATHOLOGY SERVICES

Category description:

GENETICS

Proposed item descriptor:

Genetic testing to determine apolipoprotein E ϵ 4 (APOE ϵ 4) genotype as requested by a specialist or consultant physician for patients with a clinical diagnosis of Mild

Cognitive Impairment (MCI) due to Alzheimer disease or Mild Alzheimer dementia to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme.

Proposed MBS fee:

\$154.00

Indicate the overall cost per patient of providing the proposed health technology:

\$154.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No additional costs to patients are anticipated if funded through the MBS at the proposed fee

Proposed item: BBBBB

MBS item number (where used as a template for the proposed item):

NA

Category number:

PATHOLOGY SERVICES

Category description:

CHEMICAL

Proposed item descriptor:

Analysis of amyloid and tau proteins in cerebrospinal fluid, requested by a specialist or consultant physician, from a patient with a clinical diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer disease or Mild Alzheimer dementia, to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme

Proposed MBS fee:

\$400.00

Indicate the overall cost per patient of providing the proposed health technology:

\$400.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No additional costs to patients are anticipated if funded through the MBS at the proposed fee

Proposed item: CCCCC

MBS item number (where used as a template for the proposed item):

NA

Category number:

PATHOLOGY SERVICES

Category description:

CHEMICAL

Proposed item descriptor:

Quantitation of phosphorylated at threonine 217 (pTau217) in blood, requested by a specialist or consultant physician, from a patient with a clinical diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer disease or Mild Alzheimer dementia, to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme

Proposed MBS fee:

\$0.00

Indicate the overall cost per patient of providing the proposed health technology:

\$0.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

Consultation with laboratories specialising in pathology testing of Alzheimer's Disease biomarkers revealed that commercial availability of pTau217 in plasma assays is expected in the H2 of 2026. An MBS fee will be proposed once the pricing of pTau217 becomes available.

Proposed item: DDDDD

MBS item number (where used as a template for the proposed item):

NA

Category number:

DIAGNOSTIC IMAGING SERVICES

Category description:

NUCLEAR MEDICINE IMAGING

Proposed item descriptor:

Beta-amyloid positron emission tomography (PET) study of the brain, requested by a specialist or consultant physician, for the evaluation of patients with a clinical diagnosis of Mild Cognitive Impairment (MCI) due to Alzheimer disease or Mild Alzheimer dementia, to determine eligibility for treatment with an anti-amyloid monoclonal antibody agent to treat Alzheimer disease under the Pharmaceutical Benefits Scheme, if:

- the patient considered for this service also meets specific PBS eligibility criteria; and
- the patient has not previously been treated and is not currently undergoing treatment with the pharmaceutical.

Proposed MBS fee:

\$1,800.00

Indicate the overall cost per patient of providing the proposed health technology:

\$1,800.00

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No additional costs to patients are anticipated if funded through the MBS at the proposed fee

Proposed item: EEEEE

MBS item number (where used as a template for the proposed item):

NA

Category number:

DIAGNOSTIC IMAGING SERVICES

Category description:

MAGNETIC RESONANCE IMAGING

Proposed item descriptor:

Magnetic resonance imaging (MRI) scan of the head (including MRA, if performed) for the baseline assessment of patients who will be treated with an anti-amyloid monoclonal antibody agent intended to treat Alzheimer disease under the Pharmaceutical Benefits Scheme (PBS), to ensure the patient does not have pathology which would preclude treatment with this agent.

One scan per patient

Proposed MBS fee:

\$425.05

Indicate the overall cost per patient of providing the proposed health technology:

\$425.05

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No additional costs to patients are anticipated if funded through the MBS at the proposed fee

Proposed item: FFFFF

MBS item number (where used as a template for the proposed item):

NA

Category number:

DIAGNOSTIC IMAGING SERVICES

Category description:

MAGNETIC RESONANCE IMAGING

Proposed item descriptor:

Magnetic resonance imaging (MRI) scan of the head (including MRA, if performed) for the evaluation of patients currently receiving treatment with an anti-amyloid monoclonal antibody agent intended to treat Alzheimer disease under the Pharmaceutical Benefits Scheme (PBS) to ensure the patient does not have pathology which would preclude further treatment with this agent.

The assessment will be performed to determine the continuing safety of treatment. Applicable not more than four times in a 12-month period

Proposed MBS fee:

\$425.05

Indicate the overall cost per patient of providing the proposed health technology:

\$425.05

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

No additional costs to patients are anticipated if funded through the MBS at the proposed fee

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Since obtaining TGA approval lecanemab treatment and the investigations supporting its use are being self-funded.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

It is claimed that amyloid pathology and ApoE ε4 genotype testing, followed by lecanemab treatment in people assessed as having as being ApoE ε4 non-carriers or heterozygous with evidence of amyloid pathology, is superior to no testing plus standard medical management in terms of effectiveness and inferior in terms of safety.

Evidence from the primary analysis CLARITY AD trial and the associated open label extension study provide the rationale for the overall clinical claim. Results from the assessment of the primary efficacy outcome (CDR-SB) from the CLARITY AD program assessed at 18 months (primary analysis of core study) and 48 months (open label extension) demonstrate that people treated with lecanemab derive a clinical benefit from lecanemab. Specifically, the claim of superior effectiveness is based on the increasing adjusted mean difference in CDR-SB reported for lecanemab vs standard medical management over time.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

In 2026 the estimated size of the prevalent population of people with mild cognitive impairment or dementia due to Alzheimer's that meet the cognitive clinical criteria for lecanemab treatment is 401,285.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

REDACTED

Year 2 estimated uptake (%):

REDACTED

Year 3 estimated uptake (%):

REDACTED

Year 4 estimated uptake (%):

REDACTED

Estimate the number of patients who will utilise the proposed technology for the first full year:

REDACTED

Optionally, provide details:

People being investigated for eligibility to access lecanemab through the PBS are anticipated to be managed in a specialist memory clinical. Due to health system capacity constraints, not all people in the prevalent population will be able to be managed in a specialist memory clinic. This is the reason why the estimate of the number of people that will utilise the proposed technology in the first full year is less than the estimated prevalent population.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

1 year

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

1-2 biomarker; 1-5 MRI

Optionally, provide details:

Biomarker test frequency: In most circumstances amyloid pathology and ApoE ε4 genotype testing would only be required once per person. Some people undergoing amyloid pathology testing by CSF or plasma testing may return an equivocal result and undergo repeat testing with amyloid PET.

MRI scans of the brain: Up to 5 MRI scans of the brain would be required, 1 prior to initiating lecanemab plus a further 4 to monitor for ARIA during the early stages of treatment.

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service:

The Australasian Association of Nuclear Medicine Specialists (AANMS)

Australian and New Zealand Society of Nuclear Medicine (ANZSNM)

The Royal College of Pathologists of Australasia (RCPA)

The Royal Australian and New Zealand College of Radiologists (RANZCR)

Entities who request the health technology/service:

Australian and New Zealand Association of Neurologists (ANZAN)

Australian and New Zealand Society for Geriatric Medicine (ANZSGM)

The Royal Australian and New Zealand College of Psychiatrists (RANZCP)

Entity who may be impacted by the health technology/service:

Australian and New Zealand Association of Neurologists (ANZAN)

Australian and New Zealand Society for Geriatric Medicine (ANZSGM)

The Royal Australian and New Zealand College of Psychiatrists (RANZCP)

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

Dementia Australia

Entity who produces similar products:

Eli Lilly and Company

Roche Diagnostics Australia

Cyclotek

Qiagen

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
200275	Clinical chemistry - Clinical chemistry-specific protein IVDs
409060	LEQEMBI lecanemab 200 mg/2 mL concentrated injection vial
409061	LEQEMBI lecanemab 500 mg/5 mL concentrated injection vial
461285	Human genetics-related IVDs

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No

Codependent details

Will a submission be made to the Pharmaceutical Benefits Advisory Committee (PBAC)?

Yes

Please provide a rationale for the codependency and indicate how the proposed PBS restriction would reference the intervention(s) proposed for MSAC consideration:

The foreshadowed PBS restriction includes criteria specifying that a person must be APOE ε4 non-carrier or heterozygote and positive for brain amyloid pathology as indicated by a validated test. These results of testing for these biomarkers also plays a role in establishing a person as being eligible for lecanemab through the therapeutic indication approved by the TGA. MBS funding for testing of these biomarkers is requested in this application.