

ANTI AMYLOID CLINIC (AAT CLINIC) LECANEMAB INFORMATION FOR PATIENTS

Patient and caregiver/support person education for Alzheimer's Disease Anti-amyloid therapy.

Alzheimer's Disease is a progressive neurological disorder that primarily effects cognitive functions. It is likely that you would have attended our Robina Private Hospital Memory Clinic for a comprehensive assessment and diagnosis and cared for by one of our specialists. Alzheimer's Disease is the most common form of dementia. There is no cure but there are treatments available to help manage the symptoms and improve the quality of life.

Within the brain, several changes occur over several decades prior to symptoms emerging. Amyloid protein builds up prior to significant symptoms and is thought to be important for both triggering and perpetuating symptoms. Tau protein, inflammation and vascular changes also are part of the disease process. Emerging treatments focus on removal of Amyloid from the brain.

What is Lecanemab?

Lecanemab is a disease modifying drug that removes amyloid fibrils and plaques from the brain. Developed to tackle the cause of Alzheimer's disease rather than only relieving the symptoms, such as medications like Donepezil, Rivastigmine, Galantamine and Memantine, Lecanemab (Esai product Leqembi) is a monoclonal antibody that removes amyloid plaques. It was fully approved by the US Food and Drug administration (FDA) in June 2023 for the treatment of Alzheimer's disease. After reviewing the data and evidence in September 2025 the Australian Therapeutic Goods Administration (TGA) concluded that Lecanemab is safe and beneficial for people with early Alzheimer's disease and approved it for use in Australia.

This medication is aimed to delay cognitive decline due to Alzheimer's disease. 18-month clinical trials were conducted with the results suggesting that this treatment can slow the rate of cognitive decline. Though, this is not expected to improve cognition or memory. This is not reversing existing disease and not stopping progression but slowing it.

Who is suitable for treatment with Lecanemab?

Lecanemab is for people with early-stage Alzheimer's disease before symptoms require much daily support. It is for patients with mild cognitive impairment or mild dementia. It is not for people with moderate or late-stage disease, or for those with other types of dementia such as dementia with Lewy bodies, vascular dementia or frontotemporal dementia.

In addition, people who carry 2 copies of the apolipoprotein E4 gene (APOE4/) cannot receive Lecanemab as these individuals are at greater risk of side effects. If you have allergies this may raise your risk of allergies to the medication.

You cannot receive Lecanemab if you are taking anticoagulants.

Your MMSE needs to be greater than 22/30.

What clinical effect does Lecanemab have and is it meaningful to me?

The main measure of improvement in studies was the Clinical Dementia Rating Scale (CDR) showed the Lecanemab treatment groups had 27% less decline. Both treatment and non-treatment groups progressed but the treatment group showed delay by 6 months over the 18 month period observed.

70% of people in the study showed PET amyloid clearance at 18 months.

What does treatment involve?

It is likely that you will have been seen through our Memory Clinic and your doctor has performed many baseline assessments. As a service we need to ensure assessments have occurred to determine whether the benefits are likely to outweigh risks before prescribing any treatment. Such assessments can include physical, cognitive and neurological exams, blood tests, APOE Genotyping, magnetic resonance imaging of the brain and positron imaging amyloid scans.

It is important to monitor whether this treatment is beneficial in the real world beyond research trials and so our service collaborates with The Australian Dementia Network Registry Programme (ADNet). Patient information will be confidentially collected and registered with this data base. The data collected about patient outcomes and safety will be of critical importance to make future decisions about treatment options.

What are the potential side effects?

The most common side effects of Lecanemab are infusion reactions seen in about 25% of people. These can include allergic reactions, headache, fever, flu-like symptoms, nausea and vomiting. These are usually mild and treatable.

Amyloid related imaging abnormalities (ARIA) is another possible side effect known to occur. ARIA seem related to inflammation in the walls of small cerebral cortical blood vessels where the antibodies interact with amyloid in those vessel walls. In trials ARIA also occurred in the placebo treated group (ARIA E 2%, ARIA H 7.8%) so it is part of the natural amyloid clearing processes of Alzheimer's disease. It consists of swelling (ARIA- E) and small haemorrhages (ARIA- H) which can be in the cortex of the brain (microhemorrhage) or on the surface of the brain (siderosis). ARIA is usually asymptomatic and detected only by monitoring MRI scans. In the phase three trial ARIA occurred in 29% of patients overall (ARIA-E 12.6%) but only 2.8% had symptoms (ARIA-H 17.3%) but only 0.7% had symptoms. It seems to be a higher risk of these side effects in APOE 4/4 genotypes (up to 40%).

The Australian TGA approved a modified dose escalation regime of Lecanemab for those with symptomatic ARIA. This is a modified titration that achieves a comparable amyloid reduction after 52 weeks. Most ARIA is without symptoms. Symptoms can be mild temporary reactions including headache, confusion, dizziness, vision changes, difficulty walking and nausea. Management depends on the severity in the presence of symptoms and can include continuing, postponing or stopping infusions, monthly additional MRI monitoring until it resolves and sometimes medication such as steroids to reduce brain swelling. Rarely, ARIA can cause seizures or large areas of inflammation and or bleeding in the brain. ARIA usually occurs in the first three to six months and typically resolves within two to four months.

It is important to note that these are potential side effects based on clinical trials, and not everyone will experience them. Patients will be provided with an alert card and a bracelet explaining that they are taking the Lecanemab in case they need emergency evaluation and treatment.

Has anyone died?

Yes. Unfortunately, there were three deaths in the trial related to the treatment thought to be due to the drug causing ARIA and one further death in a participant who was on placebo. It is worth noting that there was one death of a treated patient who suffered a stroke and was given clot breaking therapy (TPA) leading to massive intra cerebral haemorrhage.

Where and how long is treatment for?

Lecanemab is administered at the day surgical unit at Robina Private Hospital as an intravenous infusion every two weeks. The duration of treatment may be up to 18 months or ongoing maintenance, it is not clear when treatment ends. Each infusion takes around 1 hour but observation is for 3 hours decreasing to 2 hours minimum provided you don't get an allergic reaction.

Please allocate approximately 3 hours. You will need to attend with a support person. A Nurse Navigator will help you through the process to ensure you have had your scans at the appropriate times, side effects are monitored, your doctor's appointments are booked, and the medication is ordered. We ask that you don't drive on the day. A nurse will cannulate you and a medical officer will be in attendance if there are any problems to support the process.

Amyloid PET scans are recommended 6 monthly and treatment can be completed and ceased as early as 6 or 12 months if there is evidence of amyloid clearance.

MRI brain scans are completed prior to the 3rd, 5th, 7th and 14th treatments plus additional MRIs, if required, to monitor for side effects.

What is the cost?

Lecanemab costs approximately \$505 per vial at a dose of 10mg /kg, each vial 200mg/ml, for 18 months. If there is evidence of amyloid clearance on amyloid pet scans, infusions can be considered for cessation or maintenance. Amyloid PET scans currently cost around \$2000. MRIs for this indication are covered by Medicare.

The exact total cost is not yet known and will vary by different health and insurance coverage plans. There is currently no Medicare coverage, and the medication is not yet covered by the Pharmaceutical Benefits Scheme (PBS). Patients may also be responsible for out-of-pocket costs beyond health fund coverage costs associated with infusions, MRI and PET scans, health care provider appointments and other aspects of treatment.

Currently Esai has a cost share programme which supports patients after they contribute the first \$40,000 per annum the company will pay for the remainder of the cost of the medication only for the rest of the 12 months and resets every 12 months.

We are happy to answer your questions at any time.

E: robina.admissions@aurorahealth.com.au

P: 07 5665 5100

A: 1 Bayberry Lane, Robina QLD 4226

Aurora
Robina
Private Hospital