

# ANTI AMYLOID CLINIC (AAT CLINIC) DONANEMAB 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.

## Who is suitable for treatment with Donanemab?

Donanemab 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 (APOE4/4) cannot receive Donanemab as these individuals are at greater risk of side effects.

## What is Donanemab?

Donanemab 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, Donanemab (Eli Lilly product Kisunla) is a monoclonal antibody that removes amyloid plaques. It was fully approved by the US Food and Drug administration (FDA) in July 2024 for the treatment of Alzheimer's disease.

After reviewing the data and evidence in May 2025 the Australian Therapeutic Goods Administration (TGA) concluded that Donanemab 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.

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

Donanemab received U.S (FDA) full approval on the 2nd of July 2024 after review of positive results from the TRAILBLAZER-ALZ-2 study, a phase three randomised control clinical trial. 76% of people receiving Donanemab had amyloid successfully cleared from their brains by the end of treatment. All participants continued to experience cognitive decline but the group with mild symptoms treated with Donanemab had a reliably slower decline on cognitive tests and questionnaires such as the Integrated Alzheimer's Disease Rating Scale (iADRS) and Clinical Dementia Rating Scale (CDR). This was approximately a 37% reduced risk of progressing to the next stage of disease or corresponding to less progression by 0.67 points on an 18-point scale. These scores monitor progression in activities such as completing daily tasks, doing activities independently, problem solving, remembering, and staying active. The results showed slowing of decline by approximately 5 months over the 18 months of the trial.

Extrapolated data shows that for patients treated earlier, slower functional progression may continue for up to 37.3 months before loss of independence.

In the TRAILBLAZER-ALZ-2 trial Donanemab slowed the progression of memory and thinking decline by more than 20%. After one year nearly half of the people receiving Donanemab had no functional decline in memory and thinking skills. Individuals had a 40% reduction in their decline to carry out a carry out daily activities, such as managing finances, driving and carrying out hobbies.

However, from the trial, some groups did not show statistical benefit including patients with Apolipoprotein Genotype E4 homozygosity (APOE 4/4) and if less than 65 years of age. Also 91.5% of participants were from a white background so we need more data and diversity in clinical trials.

## 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 Donanemab are infusion reactions seen in about 9% 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 14%) 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 33% of patients overall (ARIA-E 24%) but only 5.8% 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 Donanemab 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 Donanemab 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. For other medications that are similar, Lecanemab, 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?

Donanemab is administered at the Day Surgical Unit at Robina Private Hospital as an intravenous infusion every four weeks. The duration of treatment may be up to 18 months.

Each infusion takes around 30 minutes to administer with an additional 30 minutes of observation, and the total period of admission time allocation should be approximately 2 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 2nd, 3rd, 4th and 7th treatments plus additional MRIs, if required, to monitor for side effects.

## What is the cost?

Donanemab costs approximately \$77,220.00 for 18 months. If there is evidence of amyloid clearance on amyloid pet scans, infusions and treatment can be ceased at six or 12 months. 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.

We are happy to answer your questions at any time.

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