



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
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2026003369

Date 13 February 2026
Re: Advice lock procedure medicinal product lecanemab (Leqembi®) for Alzheimer's disease

National Health Care Institute

Research, Development and Medicinal Products
Medicinal Products Team

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Contact

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Our reference

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Dear Mr Bruijn,

The National Health Care Institute advises you on the assessment of lecanemab (Leqembi®) for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to Alzheimer's disease. This advice was prompted by the placement of lecanemab in the package lock for expensive medicinal products.

The National Health Care Institute advises you not to include lecanemab in the basic health care package for this indication.

In Alzheimer's disease, the brain is no longer able to process information properly. This is called a cognitive disorder. How this works varies from patient to patient. Forgetfulness, confusion about current time and place, and difficulty with language and speech are common. Alzheimer's is a progressive disease and cannot be cured. Alzheimer's disease usually develops gradually and progresses in different stages. One in five people get dementia. The prevalence of dementia in the Netherlands is currently 310,000 persons. Approximately 70% of these patients have Alzheimer's disease (217,000). At the present time, there are some 80,000 patients with early Alzheimer's disease. The exact cause of Alzheimer's disease is not yet known. The accumulation of certain proteins in so-called amyloid plaques in the brain may lead to the development and progression of Alzheimer's disease. These plaques in the brain are characteristic of Alzheimer's disease but can also occur in the brain in people without dementia. Lecanemab reduces these plaques in the brain and aims to treat patients in the early stages of Alzheimer's disease. A very limited number of patients are potentially eligible for lecanemab.

In addition to being older, an important risk factor for developing Alzheimer's disease is having a certain genetic variation (the ApoE-ε4 allele). People who are carriers have a higher risk of Alzheimer's disease. There is currently no cure available for Alzheimer's disease. However, there are medicinal products that are used to fight the symptoms of the disease, depending on the stage of the disease. Together with a treatment and support plan, this is best supportive care.

Registered indication

Lecanemab (Leqembi®) is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment and mild dementia due to

Alzheimer's disease (early Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4) non-carriers or heterozygous with confirmed amyloid pathology.

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Claim by the marketing authorisation holder

Lecanemab (Leqembi®) has an added value compared to best supportive care for the registered indication.

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Reimbursement advice

The National Health Care Institute advises you not to include lecanemab in the basic health care package for the registered indication. The National Health Care Institute has established that lecanemab does not meet the legal criterion of 'established medical science and medical practice' for this indication. We explain the preparation of this reimbursement advice below.

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General

At your request, the National Health Care Institute assesses whether care should be part of the basic health care package from the perspective of the basic health care package paid from joint premiums.

The National Health Care Institute assesses on the basis of the four reimbursement criteria¹: effectiveness², cost-effectiveness³, necessity⁴ and feasibility⁵. The Scientific Advisory Board (WAR) advises the National Health Care Institute on the (scientific) support and the conclusion of the assessment. Stakeholders are consulted during the process.

Since lecanemab does not meet the legal criterion of 'established medical science and medical practice' for the aforementioned indication, an integral weighting of the four reimbursement criteria and advice by the Package Advisory Commission (ACP) is not required.

Substantive assessment

Effectiveness

Established medical science and medical practice

The randomised study (RCT) CLARITY AD compared lecanemab with placebo in patients with early Alzheimer's disease who had amyloid plaques in the brain. All patients in the study received best supportive care. A total of 1795 patients were enrolled in the study. Patients were treated with lecanemab or placebo for 18 months, followed by a single-arm extension phase of 18 months, with all patients treated with lecanemab. The subgroup analysis on which the registered indication and claim are based is 84.7% (n=1,466) of the total study population.

¹ Real-world package management 4 (2023). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

² Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via www.zorginstituutnederland.nl.

³ Healthcare cost-effectiveness report (2024) National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

⁴ Necessity is related to both the medical need due to the severity of a disease for the patient (burden of disease) and the need to insure something. See the report on real-world package management 4 (2023).

⁵ The reimbursement criterion of feasibility deals with whether it is feasible or sustainable to include a specific type of care in the basic health insurance package. It is therefore mainly a test of a number of implementation aspects, such as the healthcare organisation, the support base, ethical and legal aspects, budget impact, etc. See the report on real-world package management 4 (2023).

The study investigated the effectiveness of lecanemab using questionnaires that measure cognitive function, functioning in daily life and quality of life. The National Health Care Institute assesses whether an effect of a medicinal product is clinically relevant based on clinical relevance limits. These are drawn up on the basis of literature, (Dutch) guidelines and input from physicians' associations. With respect to cognitive function and functioning in daily life, the studies measured a small statistically significant effect in favour of lecanemab, but this effect is not clinically relevant. The single-arm extension has been compared to a historical cohort to determine the long-term effectiveness of lecanemab. In this indirect comparison, no clinically relevant effect was observed, even after 36 months. There is insufficient evidence to make a statement about the effect of lecanemab on the quality of life. The quality of life data of the subgroup had not been published at the time of the assessment.

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In the study, clearance of the amyloid plaques, which are characteristic of Alzheimer's disease, was poorly correlated with improvement in clinical outcomes such as cognitive function. This means that the removal of the amyloid plaques did not necessarily result in improvement of, for example, cognitive function. It remains unclear to what extent the clearance of amyloid plaques is related to the improvement of daily functioning.

Treatment with lecanemab may lead to more severe adverse effects. There is uncertainty about the severe adverse effects for the subgroup under assessment due to the fact that only severe adverse effects have been published for the entire study population. Treatment with lecanemab leads to more amyloid-related imaging abnormalities (ARIA) compared to placebo. ARIA refers to a spectrum of abnormalities seen on MRI scans of the brain. It is more commonly seen in people being treated with medicines aimed at reducing amyloid proteins in the brain, but it can also spontaneously occur.

Most ARIA were asymptomatic. Symptomatic ARIA are characterized by headache, confusion, change in the ability of the eye to distinguish details, dizziness, nausea, gait disorders and seizures. However, ARIA can be severe and lethal in rare cases.

The National Health Care Institute concludes that lecanemab added to best supportive care has not been shown to result in a clinically relevant delay in progression compared to best supportive care alone, on cognitive functioning or functioning in daily life in adult patients with early Alzheimer's disease according to the registered indication. There is insufficient evidence to make a statement about the effect of lecanemab on the quality of life in this population. In addition, lecanemab puts patients at greater risk of severe adverse effects, such as symptomatic ARIA, compared to best supportive care.

The National Health Care Institute, advised by the Scientific Advisory Board (WAR), concluded that lecanemab for the indication mentioned does not meet the established medical science and medical practice.

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

Annexes:
-Pharmacotherapeutic report

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