

Japan approves LEQEMBI Pen for at-home treatment of early Alzheimer's disease

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The once-weekly subcutaneous autoinjector formulation of lecanemab allows patients or care partners to administer treatment at home instead of relying solely on biweekly hospital infusions.



Eisai and Biogen have received approval in Japan for LEQEMBI Pen, a subcutaneous autoinjector formulation of lecanemab for the treatment of early Alzheimer's disease.

The approval introduces a new route of administration for the anti-amyloid beta protofibril antibody.

LEQEMBI Pen enables patients or care partners to administer treatment at home.

The approved regimen consists of two injections, providing a total dose of 500 mg, once weekly.

Until now, LEQEMBI treatment in Japan has been delivered through intravenous administration every two weeks in a hospital setting.

The new formulation offers an additional option that could reduce the time and healthcare-resource requirements associated with regular infusions.

Each subcutaneous injection takes approximately 15 seconds to administer.

The once-weekly subcutaneous formulation demonstrated exposure similar to the established intravenous regimen.

Eisai and Biogen said this supports the expectation of comparable efficacy between the two administration routes.

The overall safety profile of subcutaneous administration was generally similar to intravenous administration.

Systemic injection- or infusion-related reactions were reported less frequently with subcutaneous administration.

LEQEMBI targets soluble amyloid-beta protofibrils, which are considered among the toxic forms of amyloid involved in Alzheimer's disease.

The treatment is indicated for patients with early Alzheimer's disease, including mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's dementia.

The Japanese approval represents a significant development in efforts to shift some administration of disease-modifying Alzheimer's therapies from hospitals into the home.

For patients and healthcare systems, at-home administration could reduce travel requirements and infusion-centre demand while allowing long-term treatment to be incorporated more easily into daily life.

Eisai and Biogen will continue expanding access to lecanemab while evaluating additional administration approaches and indications.