XX Sept 2025

Lecanemab, LEQEMBI 100 mg/mL concentrate for solution for infusion – Update to magnetic resonance imaging (MRI) schedule to include an MRI scan prior to the third infusion of LEQEMBI

Dear Healthcare Professional,

Eisai GmbH in agreement with the European Medicines Agency would like to inform you of the following:

Summary

- The initial SmPC for LEQEMBI recommended that MRI scans be carried out before starting treatment and before the 5th, 7th, and 14th infusions. The MRI schedule for LEQEMBI has now been updated to **add an MRI scan before the 3rd infusion**.
- The additional scan has been introduced to help detect cases of asymptomatic amyloid-related imaging abnormalities (ARIA) earlier and to prevent serious and fatal ARIA-E. Cases of ARIA early during treatment with LEQEMBI treatment have been observed in the post-marketing setting outside the EU.
- The SmPC now specifies that, in general, the MRI should be performed within approximately one week before the scheduled infusion of LEQEMBI and reviewed prior to proceeding with the infusion.

Background on the Safety Concern

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 heterozygotes with confirmed amyloid pathology.

LEQEMBI can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposits (ARIA-H). ARIA can also occur spontaneously in patients with Alzheimer's disease. ARIA usually occurs early in treatment and is usually asymptomatic; however, serious and life-threatening events can occur and it can be fatal. Enhanced clinical vigilance for ARIA is therefore recommended during the first 14 weeks of treatment with LEQEMBI. The initial LEQEMBI SmPC recommends MRI scans before starting treatment and before the 5th, 7th, and 14th infusions.

An assessment of post-marketing data from outside the EU shows that serious and fatal ARIA-E events can occur early in the treatment course. Some events were reported before the 5th infusion of LEQEMBI. Therefore, an additional monitoring MRI scan prior to the 3rd infusion of LEQEMBI is recommended to identify ARIA-E at an early stage. In line with the current SmPC recommendations to mitigate serious and, in a few cases, fatal events,

healthcare professionals may decide to suspend or discontinue LEQEMBI treatment in patients found to have ARIA-E.

The SmPC, patient information leaflet and Eisai educational materials (healthcare professional (HCP) guide and patient card) [will be/have been] updated to reflect this change.

There are additional risk minimization measures associated with the LEQEMBI marketing authorisation, including 1) a controlled access program 2) an HCP guide, and 3) a patient card.

The Controlled Access Program will ensure that LEQEMBI is prescribed to the indicated population. The HCP guide reiterates the required MRI schedule.

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

Company contact point

If you have any questions please contact the Eisai Medical Information department on +44 (0)208 600 1400 or EUMedinfo@eisai.net.

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	LEQEMBI 100 mg/mL concentrate for solution for infusion / lecanemab
Marketing authorisation holder(s)	Eisai GmbH
Safety concern and purpose of the communication	Update to magnetic resonance imaging (MRI) schedule to include an MRI prior to the 3rd infusion of LEQEMBI
DHPC recipients	Distribution to all Healthcare Professionals (HCP) registered in the controlled access program (CAP)
Member States where the DHPC will be distributed	Germany and Austria (and other EU countries after launch until 28 Feb 2026)

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	18 Sept 2025
Submission of translated DHPCs to the national competent authorities for review	22 Sept 2025
Agreement of translations by national competent authorities	24 Sept 2025
Dissemination of DHPC	From 26 September 2025 in Austria and Germany and other EU countries after launch.