

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the MHLW.

Attachment 2
June 5, 2026

【Therapeutic category】 Other agents affecting central nervous system

【Non-proprietary name】 Lecanemab (genetical recombination)

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p>ARIA more frequently occurs within the first 14 weeks of treatment with the drug. Patients should be especially closely monitored during this period. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning <u>if indicated</u>.</p> <p>Even if a patient has no symptoms suggestive of ARIA, MRI scanning should be performed prior to the 5th dose (up to approximately 2 months after the treatment start), prior to the 7th dose (up to approximately 3 months after the treatment start), prior to the 14th dose (up to</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p>ARIA more frequently occurs within the first 14 weeks of treatment with the drug. Patients should be especially closely monitored during this period. <u>Patients and their families/caregivers should be instructed to seek immediate medical attention</u> if a patient experiences symptoms suggestive of ARIA (<u>headache, confusion, dizziness, visual disturbance, feeling queasy, gait disturbance, convulsion, language disorder, muscular weakness, etc.</u>) <u>irrespective of the relevant period. In this case, clinical evaluation should be promptly performed, including MRI scanning if ARIA is suspected.</u></p> <p>Even if a patient has no symptoms suggestive of ARIA, MRI scanning should be performed prior to the 5th dose (up to approximately 2 months after the treatment start), prior to the 7th dose (up to approximately 3 months after the treatment start), prior to the 14th dose (up to</p>

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

approximately 6 months after the treatment start), and periodically thereafter to check whether ARIA occurs or not.

When ARIA is detected on imaging, attention should be paid to the occurrence of symptoms under close observation, and additional MRI scanning should be performed as necessary with reference to the table in the 7.1 section.

approximately 6 months after the treatment start), and periodically thereafter to check whether ARIA occurs or not. It is advisable to perform MRI scanning prior to the 3rd dose of this drug (up to approximately 1 month after the treatment start) as well. Especially for patients with pretreatment cerebral microhaemorrhage, patients with hypertension, and other patients who need to be carefully monitored for occurrence of ARIA, performing MRI scanning prior to the 3rd dose should be considered.

When ARIA is detected on imaging, attention should be paid to the occurrence of symptoms under close observation, and additional MRI scanning should be performed as necessary with reference to the table in the 7.1 section.