**Leqembi™ Indications Checklist**

This document is intended to help practitioners determine appropriateness of LEQEMBI therapy, document clinical decision-making, and support medical necessity. **This guide is not intended to supersede guidance from the FDA, state/local licensing agencies, or other regulatory bodies. For complete information, refer to www.leqembi.com**

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| **Criteria for Indications & Use** |

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| --- | --- | --- | --- | --- | --- |
| **➀ Diagnosis:** | | | | | |
| □ G30.0 Alzheimer’s disease, early onset  □ G30.1 Alzheimer’s disease, late onset | | □ G30.8 Other Alzheimer’s disease  □ G30.9 Alzheimer’s disease, unspecified | | | |
| □ G31.84 Mild cognitive impairment, so stated | | | | | |
| **➁ Confirmation of Beta-Amyloid (Aβ) Pathology:** | | | | | |
| * [**Beta-amyloid PET scan**](https://www.alz.org/media/Documents/health-care-pros-faqs-beta-amyloid-imaging.pdf)   **Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Result:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | OR | * **CSF analysis**   **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Result:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (t-tau, p-tau, or p-tau:Aβ ratio) | |
| **➂** **Confirmation of Cognitive Impairment** (typically completed prior to diagnosis): | | | | | |
| **Assessment Performed**: **Assessment** **Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  □ General Practitioner Assessment of Cognition (GPCOG) □ Mini-Mental Status Exam (MMSE)  □ Memory Impairment Screen (MIS) □ Mini-Cog™ □ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Result/Notes:** | | | | | |
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| **➃** **Genetic Testing for ApoE ε4 Homozygotes:**  **Testing Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** □ Noncarrier; □ Heterozygotes; **OR**  □ Homozygotes; discussed the increased risk of developing serious and symptomatic ARIA with the patient.  □ Patient declined genetic testing; discussed benefits and risks of genotype testing and patient understands that without ApoE ε4 genotype, higher risk for ARIA cannot be identified.  **Notes:** | | | | | |
| **➄ Monitoring for Amyloid Related Imaging Abnormalities (ARIA)**   * **Recent brain MRI obtained prior to initiating therapy Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_   **Result:** (within one year) | | | | | |
| localized superficial siderosis | □ negative | | | | * positive; see notes below |
| 10+ brain microhemorrhages | □ negative | | | | * positive; see notes below |
| brain hemorrhage >1 cm | □ negative | | | | * positive; see notes below |
| **NOTES:** | | | | | |