**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**

|  |
| --- |
| **Criteria for Indications & Use**  |

|  |
| --- |
| **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:** |
|  |
| **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:** |