



# Leqembi™ (lecanemab-irmb) Medication Precertification Request

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(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification

Phone: 1-866-752-7021

FAX: 1-888-267-3277

For Medicare Advantage Part B:

Please Use Medicare Request Form

Please indicate:  Start of treatment, start date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  Continuation of therapy, date of last treatment: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Precertification Requested By: \_\_\_\_\_ Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

### A. PATIENT INFORMATION

First Name:		Last Name:			
Address:			City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	DOB:	E-mail:	
Current Weight: ____ lbs or ____ kgs		Height: ____ inches or ____ cms		Allergies:	

### B. INSURANCE INFORMATION

Member ID #: _____	Does patient have other coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No
Group #: _____	If yes, provide ID#: _____ Carrier Name: _____
Insured: _____	Insured: _____
Medicare: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____	Medicaid: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide ID #: _____

### C. PRESCRIBER INFORMATION

First Name:		Last Name: _____ (Check one): <input type="checkbox"/> M.D. <input type="checkbox"/> D.O. <input type="checkbox"/> N.P. <input type="checkbox"/> P.A.			
Address:			City:	State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:		Office Contact Name:		Phone:	

Specialty (Check one):  Gerontologist  Neurologist  Psychiatrist  Neuropsychiatrist  Other: \_\_\_\_\_

### D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

<b>Place of Administration:</b> <input type="checkbox"/> Self-administered <input type="checkbox"/> Physician's Office <input type="checkbox"/> Outpatient Infusion Center Phone: _____ Center Name: _____ <input type="checkbox"/> Home Infusion Center Phone: _____ Agency Name: _____ <input type="checkbox"/> Administration code(s) (CPT): _____ Address: _____	<b>Dispensing Provider/Pharmacy: (Patient selected choice)</b> <input type="checkbox"/> Physician's Office <input type="checkbox"/> Retail Pharmacy <input type="checkbox"/> Specialty Pharmacy <input type="checkbox"/> Other: _____ Name: _____ Address: _____ Phone: _____ FAX: _____ TIN: _____ PIN: _____
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### E. PRODUCT INFORMATION

Request is for: Leqembi (lecanemab-irmb) Dose: \_\_\_\_\_ Directions for Use: \_\_\_\_\_

### F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other any other where applicable (\*).

Primary ICD Code: \_\_\_\_\_  Other ICD Code: \_\_\_\_\_

### G. CLINICAL INFORMATION - Required clinical information must be completed for ALL precertification requests.

#### For All Requests (clinical documentation required for all requests):

Yes  No Is this infusion request in an outpatient hospital setting?

Yes  No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?

Yes  No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?

Yes  No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?  
 Please provide a description of the behavioral issue or impairment: \_\_\_\_\_

Yes  No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?  
 Please provide a description of the condition:  Cardiopulmonary: \_\_\_\_\_  
 Respiratory: \_\_\_\_\_  
 Renal: \_\_\_\_\_  
 Other: \_\_\_\_\_

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

**For Initiation New Start Requests (clinical documentation required for all requests):**

**Alzheimer's Disease**

- Yes  No Is the patient currently enrolled in a randomized controlled trial conducted under an investigational new drug (IND) application or National Institutes of Health (NIH)-supported trial?
- Yes  No Have other forms of suspected neurodegenerative etiology other than Alzheimer's disease been ruled out, including but not limited to frontotemporal lobar degeneration (FTLD) or Lewy body disease (i.e., meeting consensus criteria for possible or probable dementia Lewy bodies)?
- Yes  No Is the patient receiving therapeutic anticoagulation therapy (e.g., anticoagulants, antiplatelets), except for aspirin at the prophylaxis dose or less (no more than 325 mg daily)?
- Yes  No Does the patient have a history of transient ischemic attacks (TIA), stroke, or seizures within the past 12 months?
- Yes  No Does the patient have a bleeding disorder that is not under adequate control (including a platelet count <50,000 or international normalized ratio [INR] > 1.5)?
- Yes  No Will the requested drug be used in combination with any other amyloid beta-directed antibodies (e.g., aducanumab)?
- Yes  No Is the requested medication being prescribed by or in consultation with a gerontologist, neurologist, psychiatrist, or neuropsychiatrist?
- Yes  No Has genetic testing been completed to confirm the patient has a genetic mutation in the amyloid precursor protein (APP), presenilin-1 (PSEN1), or presenilin-2 (PSEN2)?
  - Yes  No Is there clinical documentation to support the patient has early onset Alzheimer's disease?
- Yes  No Does the patient have mild cognitive impairment due to Alzheimer's disease (AD) or mild Alzheimer's disease (AD)?
- Yes  No Does the patient have objective evidence of cognitive impairment at baseline?
  - Based on clinical and cognitive evaluation of the patient, which of the following characteristics does the patient exhibit as objective evidence of mild cognitive impairment at baseline? (Select all that apply)
    - Cognitive concern reflecting a change in cognition reported by patient or information or clinician (i.e., historical or observed evidence of decline over time)
    - Objective evidence of impairment in one or more cognitive domains, typically including memory (i.e., formal or bedside testing to establish level of cognitive function in multiple domains)
    - Preservation of independence in functional abilities
    - The patient is not demented
    - None of the above

Which of the following assessment tools have been completed at baseline? (Select all that apply):

- Clinical Dementia Rating Global Score (CDR-GS)
  - What is the patient's Clinical Dementia Rating Global Score (CDR-GS)? \_\_\_\_\_  Score unknown
- Mini-Mental Examination Status (MMSE)
  - What is the patient's Mini-Mental Status Examination (MMSE) Score? \_\_\_\_\_  Score unknown
- Montreal Cognitive Assessment (MoCA)
  - What is the patient's Montreal Cognitive Assessment Score? \_\_\_\_\_  Score unknown
- None of the above

- Yes  No Has the patient had a positron emission tomography (PET) scan confirming the presence of amyloid pathology?
  - Yes  No Has a lumbar puncture been completed to confirm the presence of elevated phosphorylated tau (P-tau) protein and/or elevated total tau (T-tau) protein and reduced beta amyloid-42 (AB42) OR a low AB42/AB40 ratio as determined by the lab assay in cerebrospinal fluid (CSF)?
- Yes  No Has the patient had a recent brain magnetic resonance imaging (MRI) within one year, prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA)?

**For ALL Continuation Requests (clinical documentation required for all requests):**

- Yes  No Does the patient currently enrolled in a randomized controlled trial conducted under an investigational new drug (IND) application or National Institutes of Health (NIH)-supported trial?

How many months of therapy on the requested medication has the patient completed? \_\_\_\_\_

Please enter the start date of therapy: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**For first reauthorization requests (after initial 6-month approval period) only:**

- Yes  No Has the patient been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior to the 5<sup>th</sup> dose ?
- Yes  No Has the patient been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior to the 7<sup>th</sup> dose?
- Yes  No Has the patient been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior to the 14<sup>th</sup> dose?

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**G. CLINICAL INFORMATION (continued)** – Required clinical information must be completed in its entirety for all precertification requests.

- Yes  No Does the patient have evidence of ARIA?
- For radiographic evidence of ARIA E, which of the following describes the radiographic evidence: (Select all that apply)
- The patient had mild ARIA-E on MRI and is asymptomatic or has mild clinical symptoms
  - The patient has mild ARIA-E on MRI and has moderate or severe clinical symptoms
  - The patient has moderate ARIA-E on MRI and is asymptomatic or has, mild, moderate, or severe clinical symptoms
  - The patient has severe ARIA-E on MRI and is asymptomatic or has, mild, moderate, or severe clinical symptoms
- For radiographic evidence of ARIA H, which of the following describes the radiographic evidence: (Select all that apply)
- The patient had mild ARIA-H on MRI and is asymptomatic
  - The patient had mild ARIA-H on MRI and is symptomatic
  - The patient had moderate ARIA-H on MRI and is asymptomatic or symptomatic
  - The patient had severe ARIA-H on MRI and is asymptomatic or symptomatic

**For continuation requests after the patient has completed 17 months of therapy or more only:**

- Yes  No Has the patient had a positive clinical response as evidenced by stabilization in any of the following measures? (Select all that apply)
- Clinical Dementia Rating Global Score (CDR-GS)  
 What is the patient's Clinical Dementia Rating Global Score (CDR-GS)? \_\_\_\_\_  Score unknown
- Mini-Mental Examination Status (MMSE)  
 What is the patient's Mini-Mental Status Examination (MMSE) Score? \_\_\_\_\_  Score unknown
- Montreal Cognitive Assessment (MoCA)  
 What is the patient's Montreal Cognitive Assessment Score? \_\_\_\_\_  Score unknown
- None of the above

**H. ACKNOWLEDGEMENT**

**Request Completed By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.