Leqembi® (lecanemab-irmb) Medication Precertification Request

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

Aetna Precertification Notification
Phone: 1-866-752-7021 (TTY: 711)
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:		DOB:	
Address:	City:		State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	E-mail:	
Current Weight: ____ lbs or ____ kgs Height: ____ inches or ____ cms		Allergies:		

B. INSURANCE INFORMATION

Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #:

Medicaid: ☐ Yes ☐ No If yes, provide ID #:

C. PRESCRIBER INFORMATION

First Name:		Last Name: *(Check one):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.			
Address:		City:		State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:		Office Contact Name:		Phone:	

Specialty *(Check one):* ☐ **Geriatrician** ☐ **Neurologist** ☐ **Psychiatrist** ☐ **Neuropsychiatrist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *(Patient selected choice)*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ FAX: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: Leqembi (lecanemab-irmb) Dose: _____ **Frequency:** _____

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 patient's ability to tolerate a large volume or load or predispose the patient 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 or provider currently participating in a provider-enrolled patient registry that collects information on treatments for Alzheimer's disease (e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET))?

Please indicate name of provider-enrolled patient registry: _____

☐ 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 concurrently using antithrombotic medications (e.g., aspirin, other antiplatelets or anticoagulants), prophylaxis dose or less (no more than 325 mg daily)?

☐ Yes ☐ No Has the patient been on a stable dose of antithrombotic medications for at least 4 weeks prior to initiation of the requested medication?

☐ 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 geriatrician, 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
- ☐ All 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 Status Examination (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 at least one of the following detected in cerebrospinal fluid (CSF) as determined by lab assay?

→ Please select:

- ☐ Presence of elevated phosphorylated tau (P-tau) protein and/or elevated total tau (T-tau) protein and reduced beta amyloid-42 (AB42)
- ☐ Low AB42/AB40 ratio
- ☐ Elevated P-Tau/AB42 ratio
- ☐ Elevated T-Tau/AB42 ratio

☐ 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)?

☐ Yes ☐ No Has genotype testing for apolipoprotein ε4 (ApoE ε4) status been performed prior to initiation of treatment to inform member of the risk of developing ARIA?

→ ☐ Yes ☐ No If genotype testing has not been performed, has the prescriber informed the patient that it cannot be determined if they are apolipoprotein ε4 (ApoE ε4) homozygous and may be at higher risk for ARIA?

Please indicate the patient's genotype: ☐ Homozygous ☐ Heterozygous ☐ Non-carrier ☐ Unknown

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

☐ Yes ☐ No Does the patient or provider continue to participate in a provider-enrolled patient registry that collects information on treatments for Alzheimer's disease (e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET))?

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

Please enter the start date of therapy: ____/____/____

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

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 5th dose ?

☐ Yes ☐ No Has the patient been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior to the 7th dose?

☐ Yes ☐ No Has the patient been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior to the 14th dose?

☐ 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 18 months of therapy or more only:

☐ Yes ☐ No Has the patient had a positive clinical response as evidenced by stabilization or slowing of disease progression as documented by 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 Status Examination (MMSE)
What is the patient's decline on the 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.