NC Medicaid **Medicaid**
Outpatient Pharmacy **Effective Date: 01/01/2024**
Prior Approval Criteria
Leqembi Injection

Therapeutic Class Code: H1H

Therapeutic Class Description: Amyloid Directed Monoclonal Antibody

Medication
Leqembi Injection™

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT does not apply to NCHC beneficiaries.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in

the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Criteria for Coverage:

Initial approval:

1. Patient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia as evidenced by all of the following:
   − Clinical Dementia Rating (CDR)-Global score of 0.5 to 1; **AND**
   − Memory Box score ≥ 0.5; **AND**
   − Montreal Cognitive Assessment (MoCA) score 18 to 25 (inclusive) OR equivalent tool indicating MCI or mild dementia (NOTE: range of scores may be adjusted based on educational status of patient); **AND**
   − Objective evidence of cognitive impairment at screening; **AND**
   − Positron emission tomography (PET) scan or cerebrospinal fluid (CSF) assessment of amyloid beta (1-42) is positive for amyloid beta plaque;
   AND
2. Beneficiary is age 18 or older
   AND
3. Prescriber attests other conditions causing similar symptoms have been ruled out (e.g., vascular dementia, dementia with Lewy bodies, frontotemporal dementia, normal pressure hydrocephalus);
   AND
4. Beneficiary does not have risk factors for intracerebral hemorrhage (e.g., prior cerebral hemorrhage > 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel or white matter disease);
   AND
5. Beneficiary has not had a stroke, transient ischemia attack (TIA), or seizure in the last 12 months;
   AND
6. Beneficiary has not demonstrated clinically significant and unstable psychiatric illness in the last 6 months;
   AND
7. Beneficiary is not currently receiving anti-platelet agents (with the exception of prophylactic aspirin or clopidogrel), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin);
   AND
8. Beneficiary has had a recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment;
   AND

9. Baseline disease severity has been assessed using an objective measure/tool (e.g., MoCA, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]);
   AND
10. Leqembi is being prescribed by or in consultation with a neurologist or geriatrician or geriatric psychiatrist.

Renewal Criteria

- Beneficiary must continue to meet the above criteria; **AND**
- Scoring on an objective measure/tool (e.g., ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB) demonstrates improvement, stability, or slowing of decline in cognitive and/or functional impairment; **AND**
- Beneficiary has not progressed to moderate or severe AD; **AND**
- Beneficiary has not experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions); **AND**
- Beneficiary has undergone MRI prior to the 5th, 7th, and 14th infusions to monitor for ARIA with edema (ARIA-E) or ARIA with hemosiderin deposition (ARIA-H); **AND**
- Leqembi administration will be suspended and not resumed until MRI demonstrates radiographic resolution and stabilization of symptoms in the event of any of the following:
  - ARIA-E that is asymptomatic or mildly symptomatic with moderate to severe radiographic severity
  - ARIA-E with moderate to severe symptoms and any degree of radiographic severity
  - ARIA-H that is asymptomatic with moderate radiographic severity
  - ARIA-H with moderate to severe symptoms and any degree of radiographic severity
  - ARIA-H with severe radiographic severity

Procedures:
Initial & renewal approval for up to 6 months

References

1. Leqembi [package insert]. Nutley, NJ; Eisai; January 2023.

Criteria Change Log

01/01/2024	Criteria effective date