

PHARMACY POLICY STATEMENT

North Carolina Marketplace

DRUG NAME	Leqembi (lecanemab)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Leqembi is an amyloid beta-directed antibody indicated for the treatment of \$O]KHLPHU¶V GLVHDVF should be initiated in patients with mild cognitive impairment or mild dementia stage of disease (stage 3 or 4), the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages.

Leqembi was granted accelerated approval by the FDA in January 2023 based on reduction in amyloid beta plaques observed in patients treated with Leqembi in a phase 2 clinical trial. Upon reviewing data from the phase 3 CLARITY AD trial that confirmed a clinical benefit, the FDA converted the accelerated approval to a traditional approval in July 2023.

Leqembi is a monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. 7 K H DFFXPXODWLRQ RIDP\ORLG EHWD SODTXHV LQ WKH EUDLQ LV disease. Leqembi reduces amyloid beta plaques, with high selectivity for the soluble aggregated species. \$O]KHLPHU¶V GLVHDVH W&dfldene Milw is a progressive Filter with cognitive, functional, and behavioral impairments.

Leqembi has a black box warning for amyloid related imaging abnormalities (ARIA). \$ S R (0 K R P R] \ J R have a higher incidence of ARIA.

Leqembi (lecanemab) will be considered for coverage when the following criteria are met:

\$O]KHLPHU¶V 'LVHDVH

For initial authorization:

- 1. Member is at least 50 years of age; AND
- 2. Medication must be prescribed by or in consultation with a neurologist or geriatrician; AND
- 3. Member has a diagnosis of HDUO\\$O]KHLPHU¶nWd coolgun Witi+he Dom/phairm Zelut Woule to \$O]KHLPHU¶OVR CPILVOHGD \$VCH]KHLPHarelated dendevited (Down the basis of National Institute on Aging ±\$O]KHLPHU¶V \$VVR(NILLADAW) 43)R, AQNDFULWHULD
- 4. Presence of amyloid beta pathology has been confirmed by one of the following:
 - a) Positron-emission tomography (PET) scan imaging
 - b) Cerebrospinal fluid (CSF) lumbar puncture; AND
- 5. Documentation of Mini mental state examination (MMSE) score of 22 to 30; AND
- 6. Documentation of global Clinical Dementia Rating (CDR) global score of 0.5 or 1.0 and CDR Memory Box score of 0.5 or greater: AND
- 7. Member has had a brain MRI in the past 12 months