PHARMACY POLICY STATEMENT
Ohio Medicaid

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

Leqembi is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment 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. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. Leqembi reduces amyloid beta plaques, with high selectivity for the soluble aggregated species. Alzheimer's disease, the most common cause of dementia, is a progressive, irreversible neurodegenerative disease associated with cognitive, functional, and behavioral impairments.
Leqembi has a black box warning for amyloid related imaging abnormalities (ARIA). ApoE ε4 homozygotes have a higher incidence of ARIA.

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

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 early Alzheimer's disease with mild cognitive impairment due to Alzheimer's disease OR mild Alzheimer's disease–related dementia (on the basis of National Institute on Aging–Alzheimer's Association criteria (NIA-AA)[2,3]); AND
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 to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA); AND
8. Member's ApoE ε4 status has been or will be determined before starting treatment (must provide documentation of results or pending order for testing); AND
9. Member does NOT have any of the following:
   a) Transient ischemic attacks (TIA), stroke, or seizures within the last 12 months
   b) Contraindication to MRI
   c) Inadequately controlled bleeding disorder

d)